Abstracts of EuroPCR & AsiaPCR/SingLIVE 2013

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Introduction to the scientific abstract presentations at EuroPCR 2013

Jean Fajadet and William Wijns, *EuroPCR Course Directors*

First and above all, we wish to thank all our peers from the interventional community worldwide for demonstrating continued interest in responding to the call for clinical cases and abstracts at EuroPCR. We have indeed received again an increasing number of submissions, both in abstract and clinical case format. In doing so, you are sending a strong message to EAPCI leadership, EuroPCR Course Directors and Programme Committee members. What colleagues from all over the world seem to enjoy the most at PCR events is the opportunity for sharing experiences, exchanging practices, discuss viewpoints, meaning to become an active participant in the collective learning process. Undoubtfully, your personal contribution is greatly valued by your peers, and it is our duty to provide you with an enabling environment that will maximize exchange and mutual enrichment, for the sake of better patient outcomes.

As previously, we are carefully monitoring the relative contributions of the four main chapters of EuroPCR's 2013 programme: Coronary Interventions, Interventions for Structural Heart Disease, Peripheral Endovascular Interventions and Interventions for Hypertension and Heart Failure. Detailed figures are provided in the **Table 1** for your interest. By and large, we are witnessing a growing interest in all non-coronary interventions, indicating that interventional medicine is truly coming of age. These submission statistics also represent important information that helps us shaping the overall programme content. Understandably, sharp experts from the Programme Committee who focus all their energy on the advancement of very specific tools or techniques tend to forget the global picture. The submissions from the community are bringing us all back to reality. These figures are telling us which interventional topics are of interest to you, both for Innovation and Education sessions, and shall weigh heavily on the content of next year's Course.

Table 1.

Cases	Sessions	Cases	Interactive case corner	
Hypertension and heart failure	1	6	1	
Peripheral	12	62	19	
Structural heart disease	18	86	9	
Coronary interventions	85	392	61	
Grand total	116	546	90	
Abstracts	**Sessions**	**Abstracts**	**Posters**	**Moderated posters**
Hypertension and heart failure	4	22	5	5
Peripheral	10	56	24	1
Structural heart disease	15	94	64	9
Coronary interventions	38	226	179	27
Grand total	67	398	272	42

To account for increasing submissions, we have expanded the number of call-for based sessions including abstract presentations, poster displays, case discussion forums, and interactive case corner exchange sessions. New this year, we are introducing the case discussion sessions prepared by the National Working Groups and Interventional Societies. We were pleased with their enthusiastic response and look forward to yet another vehicle that increases the engagement of national EAPCI constituents. As to abstract submissions, we have selected some of the best posters (with highest grades) for additional discussion during moderated sessions that will take place from 16:45-18:15 on Tuesday, Wednesday and Thursday and from 12:00-14:00 on Wednesday and Thursday.

More submissions translate in even more work for graders. We are indebted to all graders who managed to review all submissions with dedication and fairness, in spite of tremendous time pressure. Their names are listed in this abstract book as another token of appreciation. The best contributions have been selected for presentation and discussion. In addition, you will find these abstracts published in this book, for referencing. Contents are also available on our PCRonline website.

Lastly, we wish to express once again our utmost appreciation to all abstract and clinical case submitters as well as to all reviewers for investing invaluable time and effort in taking an active role in designing a superb 2013 vintage of EuroPCR.

Enjoy the meeting!

Introduction to the scientific abstract presentations at AsiaPCR/SingLIVE 2013

Eric Eeckhout & Tian-Hai Koh, *AsiaPCR/SingLIVE Course Directors*

In January 2013, we concluded another successful edition of AsiaPCR/SingLIVE after two and a half days of intense didactic and interactive live sessions. We had a record number of attendees this year, with 2017 participants, including industry partners and many esteemed international faculties. AsiaPCR/SingLIVE has evolved from a regional to an international scientific meeting providing an important platform for the interventional community to learn, interact and collaborate. The aim is to achieve best outcomes for cardiac patients.

Beside attending the meeting, participants also contributed tremendously to AsiaPCR/SIngLIVE by submitting abstracts and sharing their research, experience and new advances in various subspecialties of interventional cardiology. We are certain that attendees have benefited from the many high quality oral or poster presentations. We hope that through this interactivitiy, it will inspire many more abstracts to be submitted to our next edition of AsiaPCR/SingLIVE.

We had four abstracts sessions this year: structural heart, PCI and stents, imaging and physiology, PCI and ACS. A total of 73 authors from 32 countries submitted 121 abstracts, a sharp increase of 36% from 2012. Of these, 24 were allocated oral presentation sessions and 58 posters were presented in the posters gallery. Most of the abstracts originated from Japan, India, South Korea and Russian Federation.

The diversity of abstracts has also broadened. Coronary interventions abstracts formed 82% of the submissions while peripheral interventions and interventions for structural heart disease made up 8% and 10% of the submissions respectively.

The three winning best abstracts in AsiaPCR/SingLIVE 2013 were:

1st place – "Reverse remodelling in patients with severe mitral regurgitation and reduced ejection fraction one year after interventional edge-to-edge mitral valve repair"

2nd place – "Multicenter, prospective, randomised, single blind, consecutive enrollment evaluation of the Elixir DESyne™ Novolimus-eluting coronary stent system with durable polymer compared to the Endeavor Zotarolimus-eluting coronary stent system: 3-year clinical results and 9-months angiographic and IVUS results: the EXCELLA II study'

3rd place – "Five-year clinical outcome of biodegradable Polymer Biolimus-eluting stents versus durable Polymer Sirolimus-eluting stents in patients with and without diabetes mellitus: a Leaders substudy, final report"

At the awards ceremony, the three best abstract presenters were presented with their awards, which were kindly sponsored by the Chien Foundation. Similar to last year, the Chien Foundation also supported the "Best Clinical case award" and "the Chien lectureship award".

Finally, we would like to thank all the contributors of abstract sessions, including abstract submitters, reviewers and graders, for their concerted effort in showcasing the high quality of the abstract sessions at AsiaPCR/SIngLIVE.

Coronary interventions – *Tuesday May 21st*
A decade of experience with DES: insights from large registries and randomised clinical trials

A decade of experience with DES in the real world clinical practice: 10-year follow-up of the DESIRE registry

Costa Jr J.D.R.[1], Sousa A.[1], Moreira A.[2], Costa Jr R.[1], Cano M.[2], Maldonado G.[2], Siqueira D.[1], Campos C.[2], Damiani L.[2], Romano E.[2], Egito E.[2], Sousa J.E.[1]

1. Dante Pazzanese / HCor, São Paulo, Brazil; 2. HCor, São Paulo, Brazil

Aims: Despite the extensive knowledge accrued on DES in the past years, there is still lack of consistent data on the very late outcomes of these devices, especially after 5 years of their implantation. We sought to provide the longest clinical follow-up data on outcomes of unselected patients treated solely with DES

Methods and results: The DESIRE registry is a prospective, single-centre registry encompassing all consecutive patients treated solely with DES since May 2002. The primary goal is the very long-term occurrence of MACE and stent thrombosis (ST). Patients were clinically followed at 1, 6 and 12 months and then annually. A multivariate model was built to determine independent predictors of MACE, TLR and ST. A total of 4,500 patients were included. The mean age was 64±11 years. DM was detected in 29.7% and 44.8% presented with acute coronary syndrome. SVG lesions and STEMI represented 6% and 12% of the cohort, respectively. Follow-up was obtained in 98.5% of the patients (median 5.6 years). Currently, 79.6% of the population is free of any MACE. TVR was performed in 5.3% of the patients. Q-wave MI rate was only 1.7% while total ST rate was 1.9%. The majority of definite ST cases occurred between the 1st and 3rd years. Independent predictors of MACE were treatment of SVG (HR 1,63; 95% CI, 1.22 to 2.18, p=0.001), multivessel disease (HR 1.39; 95% CI, 1.03 to 1.87, p<0.001), residual stenosis (HR 1.3; 95% CI, 1.1 to 1.5, p=0.034), DM (HR 1.6; 95% CI, 1.1 to 2.2, p=0.006) and renal insufficiency (HR 1.5; 95% CI, 1.34 to 1.81, p=0.004). Independent predictors of ST were PCI for STEMI (HR 3.5; 95% CI, 1.3 to 9.4, p=0.013), stent length (HR 1.8; 95% CI, 1.09 to 3.02, p=0.023), moderate/severe calcification at lesion site (HR 2.38; 95% CI, 1.34 to 4.23, p=0.003), and in-stent residual stenosis (HR 1.04; 95% CI, 1.01 to 1.06, p=0.003).

Conclusions: The DESIRE registry probably represents the longest FU of a real world cohort treated solely with DES. In our single-centre experience, the use of DES was associated with very long-term safety and effectiveness with acceptable low rates of adverse clinical events, including ST. Also, there was no steady annual increment in the occurrence of ST, with a marked decrease of this complication after the 3rd year of FU.

Coronary interventions – *Tuesday May 21st*
A decade of experience with DES: insights from large registries and randomised clinical trials

Long-term safety and effectiveness of everolimus-eluting coronary stent system in complex, real-world patients

Krucoff M.W.[1], Rutledge D.R.[2], Gruberg L.[3], Wang J.[2], Simonton C.A.[2], Naidu S.[4], Hermiller J.B.[5]

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Aims: The safety and effectiveness of XIENCE V® Everolimus Eluting Coronary Stent System (XIENCE V) have been demonstrated with consistently low rates of stent thrombosis and major adverse cardiac events from the XIENCE V USA clinical trial through three years. The objective of this analysis is to evaluate whether the long term safety and effectiveness of XIENCE V are sustained through four years in this large pool of complex, real-world patient population. In particular, a novel analysis will be performed to assess the impact of early dual antiplatelet therapy (DAPT) discontinuation on short and long term clinical outcomes, including stent thrombosis as well as the other major adverse cardiac events.

Methods and results: XIENCE V USA is a large, prospective, multicentre, single-arm study designed to examine the performance of XIENCE V in a real-world, all-comer population. A total of 5020 patients (1871 [37%] standard risk, and 3149 [63%] extended risk) were included in the long term follow-up cohort of the study. Clinical endpoints including cardiac death and myocardial infarction, stent thrombosis, as well as target lesion revascularisation will be analysed through four years. DAPT was not mandatory in the XIENCE V USA study, thus providing an ideal opportunity to assess DAPT non-compliance in a real-world setting and its impact on clinical outcomes. This will be the first report to evaluate both safety and effectiveness of XIENCE V following early DAPT interruption with the long term clinical data through four years.

Conclusions: These four-year outcomes from the XIENCE V USA real-world study will be the most robust evaluation of long term outcomes in the largest real world population ever reported and will provide important insights into the long term safety and effectiveness of the XIENCE V everolimus-eluting stent system. In particular, the long term clinical outcomes of XIENCE V with short term DAPT could help to address important clinical questions regarding the safety of early DAPT discontinuation in real-world clinical practice.

The impact of the new resolute integrity stent platform on deliverability, acute outcomes and resource utilisation in a regional population from India and Bangladesh: results from the DELIVER study

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Aims: The Resolute Integrity™ zotarolimus-eluting stent utilises novel continuous sinusoid technology. A single cobalt alloy wire is formed into a repeating sinusoidal pattern, wrapped helically and fused to improve conformability, provide greater flexibility and ease of delivery without compromising other important stent design characteristics. The objective of the DELIVER study is to evaluate delivery success, resource utilisation and in-hospital outcomes following use of the Resolute Integrity stent in a large, real world patient population including 2122 patients from India and Bangladesh.

Methods and results: DELIVER is prospective, multicentre, single arm, open-label, observational study. Patients with coronary artery disease and a lesion of reference vessel diameter of 2.25 to 4.0 mm were eligible for inclusion. Group 1 received the Resolute Integrity stent as the first choice of stent treatment and Group 2 were treated following delivery failure of another stent type. The primary endpoint for the study is delivery success defined as complete passage of the stent across the target lesion with full expansion to the desired diameter at the desired location. Other endpoints are in-hospital clinical outcomes and resource utilisation including volume of contrast dye, guide wires and dilation balloons used. Resource utilisation between patients treated transradially and patients treated transfemorally will be compared. Furthermore, risk factors for in-hospital events including stent thrombosis will be analysed.

Conclusions: We will present deliverability, acute outcomes and resource utilisation data for the Resolute Integrity stent in a large population of patients from India and Bangladesh.

Coronary interventions – *Tuesday May 21st*
A decade of experience with DES: insights from large registries and randomised clinical trials

Off-label use of second generation DES in a broad and heterogeneous patient population: insights from 2-year clinical outcome of the TWENTE trial

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Aims: We therefore assessed 2-year outcome data of the randomised TWENTE trial, which compares the second-generation zotarolimus-eluting Resolute and everolimus-eluting Xience V stents in 1387 patients. While in routine clinical practice DES are mainly implanted in patients with at least one "off-label" indication for DES use, there is only limited knowledge about potential differences in safety and long-term outcome between patients with off-label indications for DES use and patients with on-label indications only.

Methods and results: Off-label indications included renal insufficiency, ejection fraction <30%, occurrence of acute myocardial infarction (MI) within the previous 72 hours, more than 1 lesion/vessel, more than two vessels treated, lesion length >27 mm, bifurcation, graft lesion, in-stent restenosis, unprotected left main lesion, and lesion with thrombus or total occlusion. We assessed various safety and efficacy-related endpoints, such as cardiac death, MI, target-vessel revascularisation, and stent thrombosis rates. MI was defined according to the Academic Research Consortium as 2x the upper reference-limit of creatine kinase with elevated confirmatory markers, and peri-procedural MI as MI within ≤48 hours after PCI. A total of 1033 (74.5%) patients were treated with DES for at least one off-label indication, and 354 (25.5%) were treated for on-label indications only. Patients with off-label DES use (n=1033; 74.5%) had more diabetes (22.9% vs. 17.5%; p=0.032), previous MI (35.9% vs. 22.3%; p<0.001), complex lesions (76.1% vs. 60.7%; p<0.001), and acute coronary syndromes (57.8% vs. 33.3%; p<0.001). Nevetheless, between both groups there was no significant difference in clinical endpoints, with the only exception being a higher incidence of target vessel-related MI (6.4% vs. 2.8%; p=0.01), resulting from a higher periprocedural MI rate in patients with off-label DES use (5.0% vs. 1.4%; p=0.003). As a consequence, the composite endpoint target vessel failure rate (cardiac death, target-vessel related MI, or target-vessel revascularisation) was higher in patients with off-label DES use (p=0.039). However, logistic regression analysis, correcting for predictors of target vessel failure, demonstrated that off-label DES use showed no association with the target vessel failure rate (adjusted HR 0.95, 0.95%CI: 0.61-1.48, p=0.83). In addition, in patients with off-label DES use, clinical outcome did not differ between the Resolute ZES and XIENCE V EES study arms.

Conclusions: Despite significant differences in baseline characteristics, patients with off-label and on-label use of second-generation DES did not differ in 2-year clinical outcome, except for more periprocedural MI in patients with off-label DES.

Coronary interventions – *Tuesday May 21st*
A decade of experience with DES: insights from large registries and randomised clinical trials

Three-year outcomes of patients with multiple vessels treated by DES with biodegradable polymer: insights from NOBORI 2 study

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Aims: Despite favourable clinical outcomes reported with use of drug eluting stents (DES), treatment of multivessel disease still remains controversial as some long term data favour bypass surgery. Our aim was to assess long term results of Nobori, DES with biodegradable polymer, when used in this complex clinical setting.

Methods and results: In a large multinational registry (NOBORI 2) that enrolled 3,067 patients, 677 and 2390 patients respectively had multiple (MV) or single vessel (SV) treated with the Nobori® DES. Patient's data are entered electronically; continuously monitored on-line and on-site, and all adverse events are adjudicated by an independent clinical event committee. No differences have been found in baseline characteristics between MV and SV patients except in previous myocardial infarction (MI; 37.6% vs. 31.9%; p<0.01) and diabetes (33.8% vs. 28.2%; p<0.01) more frequent in MV patients, and previous PCI (27.9% vs. 33.4%; p<0.01) more frequent in SV patients. Procedural findings revealed significant difference in several QCA parameters such as pre-procedure (2.58±0.60 vs. 2.63±0.57; p=0.01) and post-procedure reference vessel diameter (2.85±0.52 vs. 2.90±0.49; p<0.001), acute gain in stent and in segment, all being lower in MV. Pre-procedural minimal luminal diameter (0.88±0.50 vs. 0.81±0.50; p<0.01) was higher in MV patients. At 3-years there was no significant difference in cardiac death (CD; 2.8% vs. 2.1%; p=NS), and MI (4.3% vs. 2.8%; p=NS), while revascularisations in target lesion (TLR; 4.9% vs. 3.0%; p=0.02) and target vessel (TVR; 7.5% vs. 4.7%; p<0.01), were higher in MV. The composite endpoints of MACE (11.5% vs. 7.9%; p<0.01) and target lesion failure (TLF; 9.0% vs. 5.8%; p<0.01) were higher in MV patients. Stent thrombosis (ST) rate was very low and without difference between two groups (1.3% vs. 0.8%; p=NS). When adjusted for baseline characteristics, at 3-year, there were no differences in CD, MI, TLR and TVR while difference in MACE and TLF were less significant.

Conclusions: As expected clinical outcomes in MV patients were less favourable, however relatively low adverse events rate suggest that Nobori DES is safe an efficient for those patients when PCI is selected treatment option.

Coronary interventions – *Tuesday May 21st*
A decade of experience with DES: insights from large registries and randomised clinical trials

New generation DES for STEMI: a new paradigm for safety

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Aims: Early generation drug-eluting stents (DES) for ST-elevation myocardial infarction (STEMI) have an increased frequency of very late stent thrombosis compared to bare metal stents (BMS), leading to concerns about their safety. New generation DES compared to early generation DES have lower rates of stent thrombosis (ST) but there are limited data with STEMI patients. The purpose of this study is to compare the long-term safety of new generation DES with early generation DES and BMS when used for STEMI.

Methods and results: Our study population consists of 3,464 consecutive patients with STEMI treated with successful stenting using BMS (n=1187), early generation DES (n=1525) or new generation DES (n=752) at the Minneapolis Heart Institute (MHI) and Cone Heart and Vascular Centre from 2003 through 2011. Patients with STEMI due to ST were excluded. Early generation DES included 1,094 paclitaxel-eluting stents (PES) and 431 sirolimus-eluting stents (SES), and new generation DES included 73 zotarolimus-eluting stents (ZES) and 679 everolimus-eluting stents (EES). New generation DES became available in 2008. ST was defined as definite ST by Academic Research Consortium (ARC) criteria. Clinical follow-up was complete to one year in 90.0% of patients. Mean follow-up time was 2.6 years with BMS, 3.5 years with early generation DES, and 1.3 years with new generation DES. At 30 days, compared to BMS, patients with new generation DES had lower mortality (2.2% vs. 7.7%, p<0.001), similar reinfarction (1.5% vs. 2.1%, p=0.33), and similar ST (1.0% vs. 1.7%, p=0.20). Compared to early generation DES, patients with new generation DES has similar mortality (2.2% vs. 2.4%, p=0.75), similar reinfarction (1.5% vs. 1.7%, p=0.60), and similar ST (1.0% vs. 1.1%, p=0.69). At 2 years, compared to BMS, patients with new generation DES had lower mortality (3.9% vs. 11.9%, p<0.001), similar reinfarction (4.6% vs. 5.2%, p=0.36), and less ST (1.3% vs. 3.8%, p=0.024). Compared to early generation DES, new generation DES has similar mortality (3.9% vs. 5.8%, p=0.21), similar reinfarction (4.6% vs. 5.4%, p=0.56), and trends for less ST (1.3% vs. 3.3%, p=0.13). After adjusting for differences in baseline variables, new generation DES had significantly less ST compared to BMS (HR [95% CI]=2.10 [1.07-4.12], p=0.031) and trends for less ST compared to early generation DES (HR [95% CI]=1.70 [0.88-3.30], p=0.12).

Conclusions: Our study shows that the use of new generation DES in STEMI patients is associated with reduced rates of ST compared to BMS and shows trends for reduced rates of ST compared to early generation DES.

One-year outcomes in 1010 unselected patients treated with a new-generation everolimus-eluting stent: the multicentre PROMUS element european post-approval surveillance study

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Aims: The PROMUS Element platinum chromium everolimus-eluting stent has demonstrated comparable outcomes to the predicate XIENCE V everolimus-eluting stent. The PROMUS Element European Post-Approval Surveillance Study (PE-Prove) is a prospective, open-label, multicentre observational study designed to assess outcomes following PROMUS Element implantation in an unselected patient population.

Methods and results: All consented patients who were candidates for coronary artery stenting were eligible to enrol. The primary endpoint was target vessel failure (TVF; defined as death related to the target vessel, myocardial infarction [MI] related to the target vessel, and target vessel reintervention) at 12 months post-implantation. All patients were required to have cardiac enzyme testing 12-24 hours post-procedure or prior to discharge, whichever came first. An independent clinical events committee adjudicated all reported deaths, major adverse cardiac events, and stent thromboses. Patients will be followed annually for 5 years. A total of 1010 patients were enrolled at 40 clinical sites in Europe. Patients were 75.4% male and 24.9% had medically treated diabetes at enrollment. AHA/ACC Type B2/C lesions were present in 50.0% of patients and 6.9% presented with chronic total occlusion. A total of 17.8% of patients presented with an MI within 24 hours prior to the index procedure and 20.1% of patients presented with unstable angina. The target lesion was the culprit lesion for ST-segment elevation MI in 7.3%. Overlapping stents were implanted in 14.5% and bailout stenting was required in 2.9%. At 1 year post-procedure, 79.6% of patients were adhering to dual antiplatelet therapy. The 1-year per-patient TVF rate was 6.2% (60/975), 33 of which were related to the PROMUS Element stent (3.4%). Rates of cardiac death, MI, and Academic Research Consortium definite/probable stent thrombosis were 1.7%, 3.5%, and 0.6%, respectively. The target vessel revascularisation rate was 3.2% (31/975), 20 of which were related to the PROMUS Element stent (2.1%). Additional results in high-risk subgroups (e.g., diabetes, small vessels, long lesions) will also be presented.

Conclusions: In a large and relatively complex group of real-world patients, coronary artery revascularisation with the PROMUS Element everolimus-eluting stents provides favourable results with low event rates consistent with those reported for other contemporary drug-eluting stents.

Coronary interventions – *Tuesday May 21st*
A decade of experience with DES: insights from large registries and randomised clinical trials

Cardiac adverse events, stent thrombosis, bleeding and dual antiplatelet therapy: first report of the primary endpoint of the e-BioMatrix registry

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Aims: The e-BioMatrix registry, composed of two arms (PMS and PMR) for regulatory purposes, was designed to evaluate the one year clinical outcome of patients treated with one or more Biomatrix or Biomatrix Flex drug-eluting stent, and verify whether the results of the LEADERS randomised trial could be reproduced in routine clinical practice.

Methods and results: The design of the registry uses the same all-comers principle as that applied in the prospective randomised LEADERS trial. Investigators were encouraged to enroll all consecutive patients treated at their centre. Only inability to obtain informed consent, or use of either non-study stents or stand-alone alternative revascularisation techniques were exclusion criteria. Planned staged procedures within 90 days were considered part of the index procedure. The primary endpoint was defined as the rate of Major Adverse Cardiac Events (MACE), a composite of cardiac death, myocardial infarction (Q-wave and non Q-wave), or clinically-driven target vessel revascularisation at 12 months. Dual antiplatelet therapy (DAPT) was recommended for 6-12 months after the procedure. 5559 patients at 63 European interventional cardiology centres were included. Their mean age was 63±11 years; 24.1% of patients were diabetics, 23.7% had prior PCI and 7.2% prior CABG. 50% presented with stable disease, and 50% with ACS (34.7% of them with STEMI). 19% of patient population had a multi-vessel procedure and 31.8% of the population had a multi-lesion procedure. 3.3% of lesions were situated in the left main stem and 1.7% in a saphenous bypass graft. A single stent was implanted in 57% of patients, 2 stents in 26% and 3 or more in 17%. The mean total stent length implanted per procedure was 32.7+21.6 mm. Clinical follow-up was obtained for 95.48% of patients at 1 year. Compliance with DAPT was 99.2% at discharge, 98.5% at 30 days, 95.7% at 6 months and 75% at 12 months. Overall mortality at 12 months was 1.6% (0.9% cardiac and 0.7% non-cardiac). All other MACEs, stent thrombosis and bleedings are in the process of being adjudicated by an independent clinical events committee and will be reported at the time of presentation. Specific attention will be given to the incidence of ST and MB, their associated mortality and their relationship to DAPT. The results will be compared to those of the LEADERS randomised trial.

Conclusions: These preliminary results show that both overall and cardiovascular mortality as well as compliance with the recommended DAPT regimen are comparable to those observed in the randomised LEADERS trial. Full 12 month follow-up data will be presented at the time of meeting.

Coronary interventions – *Tuesday May 21st*
Outcome in contemporary coronary intervention

Thrombotic events and plaque progression in HIV-infected patients with ACS: insights from an international contemporary registry

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Aims: HIV patients are at high risk of subsequent cardiac events after an ACS, while remain unclear if this vulnerability depends from enhanced thrombosis or progression of plaque.

Methods and results: All consecutive patients with HIV infection receiving standard (highly active antiretroviral therapy) HAART therapy presenting with ACS in our centres from January 2001 to September 2012 were studied, recording clinical data regarding the cardiac history and HIV treatment, as well details about the coronary intervention procedures. Cardiac death, new myocardial infarction or revascularisations and in-stent thrombosis were recorded as co-primary end points. We enrolled 201 patients, 179 (89%) male with a median age of 53 (47-62) years, 96 (48%) presenting STEMI. After a median of 701 (284-1237) days, 30 (15%) of patients died, 12 (6%) for cardiac reason, 20 (10%) suffered a myocardial infarction, 29 (15%) a subsequent revascularisation and 7 (3.8%) a stent thrombosis with an overall incidence of 44 (21.6%) MACE (major adverse cardiac events). Patients that experience MACE did not differ for cardiovascular risk factor or treatment of choice while showed a higher rate of chronic renal failure (9, 20.5% vs. 8, 5.4% p=0.002) and multivessel/left main disease at presentation (30, 68.2% vs. 70, 47.6% p=0.017). At the multivariable adjustement, the only independent predictor of MACE was the multivessel/left main disease (HR 1.16-5.58; p=0.02) whereas CD4 count <200 cells/mm^3 (HR 1.13-11.8; p=0.031) and not being treated with nucleoside-reverse transcriptase inhibitors (HR 2.59-49.72.; p=0.001) were independent predictor of new myocardial infarction and cardiac death, respectively. No predictors of repeated revascularisation were identified.

Conclusions: CD4 count and HAART therapy are clinical predictors of subsequent thrombotic events but do not seem to influence the progression of plaque that is represented by repeated revascularisation.

Coronary interventions – *Tuesday May 21st*
Outcome in contemporary coronary intervention

Cardiac Troponin I elevations after elective PCI: applying the new universal definition of myocardial infarction

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Aims: Contemporary cardiac troponin (cTn) assays may improve the detection of myocardial damage after percutaneous coronary intervention (PCI) and the prediction of subsequent adverse events. The recently released 3rd Universal Definition of Myocardial Infarction (MI) has set the cTn levels for diagnosing type 4a MI at 5 x the upper reference limit (URL). The aim of our study was to evaluate the prognostic value of cTnI measured with an available sensitive assay after successful uncomplicated PCI.

Methods and results: In our institution 930 consecutive patients with normal baseline cTnI levels underwent elective and angiographically successful PCI. In this population we investigated the correlation between cTnI levels 24 hours after PCI and major adverse events at a median follow-up time of 3.0 years. Postprocedural cTnI levels above the URL were common (68.9% of the study population) and were >5 fold the URL in 46.2% of patients. Abnormal cTnI levels were associated with more severe coronary atherosclerosis and more complex interventions, but failed to predict subsequent cardiac mortality or MI. However, when the cut-off of 5 fold suggested by Universal Definition was applied (>5 times the URL), the occurrence of type 4a MI appeared to be associated with an increased risk of overall death (HR 1.88, 95% CI 1.07-3.30; P=0.03) and cardiac death (HR 2.46, 95% CI 1.26-4.80; P=0.009). After adjustment for clinical and angiographic findings, this remained an independent predictor of cardiac death.

Conclusions: In a large single-centre population of elective PCI patients, cTnI elevations were common and associated with more complex disease and more complex interventions. However, only cTnI levels meeting criteria for type 4a MI advocated by the 3rd Universal Definition (5 x URL) predicted long term cardiac mortality.

Time-related changes of the infarct related coronary segment severity before acute myocardial infarction: insights from a retrospective angiographic study

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Aims: The working hypothesis that coronary artery occlusion occurs in segments with mild stenosis severity is based on older angiographic studies, but challenged by recent reports. In order to assess a possible time related relationship of the infarct related coronary segment (IRCS) severity, we retrospectively analysed the angiographic data of PCI procedures for acute myocardial infarction (AMI) and for which a previous angiography had been performed within the last 6 years in our centre.

Methods and results: The inclusion criteria were: AMI treated within 1 month by PCI during the period 2000-2011. Exclusion criteria were: repeat PCI, stent thrombosis, PCI on grafts, immediate transfer to the referring hospital. Among 2807 consecutive procedures, 124 patients (4.4%) had a previous angiography within 6 y. At the presentation of AMI, mean age was 65.7 y, NSTEMI was present in 54%. PCI was performed within 24 h in 44%, within 1 week in 43% and within 1 month in 13%. The mean interval between the first angiography and the PCI for AMI was 2.8 y. The mean diameter stenosis (DS) (assessed by visual estimation) of the IRCS was 28%±28% at the time of the first angiography and 89±10% at the time of AMI, suggesting that coronary occlusion occurs in mildly stenosed segments. The cases were analysed according to the time interval between the AMI and the previous angiography.

Conclusions: A long delay between previous angiography and the angiography at the time of AMI is associated with the finding of a very mild DS of the IRCS at the initial angiogram. The observed changes of DS severity of the IRCS were dependent on the time interval between the initial angiography and AMI. There seems to be an acceleration of DS severity progression of the IRCS within the last 2 years before AMI. Therefore, sudden occlusion in mildly stenosed segments seems unlikely.

Tako-tsubo cardiomyopathy and coronary artery disease: a possible coexistence

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Aims: In the medical literature several cases of Tako-tsubo cardiomyopathy with coronary artery disease have been reported, and in the clinical practice several typical Tako-tsubo cardiomyopathy cases show relevant stenosis of the coronary arteries that cannot be related to the dysfunctional myocardium. This study sought to evaluate the prevalence, clinical characteristics and outcome of patients with Tako-tsubo cardiomyopathy and relevant coronary artery disease in a large multicentre database.

Methods and results: In 26 centres, 450 patients admitted with the diagnosis of Tako-tsubo cardiomyopathy underwent coronary angiography within 48 hours of hospital admission and were prospectively included in the Tako-tsubo Italian Network Registry. Overall, 43 (9.6%) patients had at least 1 relevant coronary stenosis (≥50%) not supplying the dysfunctional myocardium, while 407 (90.4%) had irrelevant stenosis or truly normal coronary arteries. Tako-tsubo cardiomyopathy patients with relevant coronary artery disease were more likely to have advanced age, diabetes, familial history of coronary artery disease, and acute functional mitral regurgitation as compared with those without. At 6-month follow-up, the incidence of death, Tako-tsubo cardiomyopathy recurrence and rehospitalisation rates were similar between patients with relevant coronary artery disease and patients with normal coronary arteries. At multivariable Cox analysis, independent predictor of death was Charlson comorbidity index, while the presence of coronary artery disease did not significantly influence mid-term outcome.

Conclusions: The presence of coronary artery disease is a possible finding in a nontrivial proportion of patients with Tako-tsubo cardiomyopathy. Thus, when the stenotic artery does not supply the dysfunctional myocardium or when the extent of dysfunctional myocardium is wider than the territory of distribution supplied by a single stenotic coronary artery, the presence of angiographically relevant coronary artery disease should not be considered an exclusion criteria for Tako-tsubo cardiomyopathy.

Coronary interventions – *Tuesday May 21st*
Outcome in contemporary coronary intervention

Serum parathyroid hormone is an independent predictor of adverse cardiovascular events in patients with coronary artery disease after PCI

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Aims: It was reported that high serum intact parathyroid hormone (iPTH) levels were associated with increased cardiovascular events in patients with heart failure, but it remains unclear whether higher iPTH levels have any impact on patients with coronary artery disease after PCI. The purpose of the present study was to investigate the relationship between serum iPTH levels and adverse cardiovascular events after PCI.

Methods and results: Between July 2009 and May 2012, we consecutively enrolled 295 patients (229 male, mean age 69.2±11.3 years old) who received PCI. Patients with end-stage renal disease (eGFR <10 mL/min/1.73 m^2) including haemodialysis patients were excluded from this study and serum iPTH levels were evaluated before PCI. In this study, 131 patients (44%) had an acute coronary syndrome (ACS) and 164 (56%) patients had stable angina pectoris, and 144 patients (ACS, n=31; stable angina pectoris, n=113) were implanted DES (48%), and the other 151 patients (ACS, n=100; stable angina pectoris, n=51) underwent BMS implantation (51%). All patients were administered aspirin (100-200 mg/day) and clopidogrel (75 mg/day) at least for 6 months after PCI. Study endpoint was adverse cardiovascular events, defined as myocardial infarction (MI) and cardiovascular death. During median follow-up time of 513 days (range 289-775 days), 20 adverse cardiovascular events (5 MI and 15 cardiovascular deaths) were observed. Cardiovascular death consisted of 6 deaths due to MI, 6 worsening heart failure and 3 were from other causes. There were no differences in baseline clinical characteristics (age, sex, current smoking, body mass index, hypertension, dyslipidaemia, diabetes mellitus, history of prior myocardial infarction, percentage of ACS and medication) between patients with and without adverse ardiovascular events. In patients with adverse cardiovascular event, estimated glomerular filtration rate and haemoglobin were significantly lower. Brain natriuretic peptide was higher in patients with versus without cardiovascular event. Serum level of iPTH was also significantly higher in patients with cardiovascular adverse events (95.1±83.9 pg/ml) compared with those without (49.3±31.7 pg/ml, P<0.01). Receiver operating characteristic analysis determined that optimal cut-off value of iPTH to predict adverse cardiovascular event was 80 pg/ml (45.0% sensitivity and 89.1% specificity, AUC 0.741). The multivariate logistic regression analysis showed that high iPTH (>80 pg/ml) was an independent predictor of adverse cardiovascular events (odds ratio 4.14, 95% confidence interval 1.09 to 15.36, P=0.037). Kaplan-Meier analysis showed that patients with low iPTH (<80 pg/ml) were more likely to be free of adverse cardiovascular events than those with high iPTH (>80 pg/ml) (p<0.001 followed by log-rank test).

Conclusions: Our study showed that elevated iPTH was associated with a greater incidence of adverse cardiovascular events. Serum iPTH level could be a useful biomarker to stratify high risk coronary artery disease patients after PCI.

Coronary interventions – *Tuesday May 21st*
Outcome in contemporary coronary intervention

ST elevation ≥1 mV in V4R means reversible ischaemia of the right ventricle, which has nothing to do with necrosis of right ventricular wall in magnetic resonance imaging

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Aims: ST elevation in the right precordial leads is one of the most reliable methods for detecting acute right ventricular ischaemia, which before the era of primary angioplasty was synonymous with necrosis seen in the autopsy. Late Enchancement Magnetic Resonance (LE CMR) allows the assessment of the presence of right ventricular wall infarction (RVMI).

Methods and results: 114 Patients (79 males, 35 females) with acute inferior myocardial infarction was included. In all cases on admission electrocardiogram (ECG) for ST – segment elevation in the V4R right precordial lead was performed, with subsequent emergency angiography and primary percutaneous coronary intervention of the right coronary artery (RCA). Each patient underwent CMR in 3-5 day after admission. ST elevation ≥1 mV in V4R on admission was present in 83(73%) cases, LE CMR revealed RVMI in 48 (42%) cases. 10 of those with ST≥1 mV in V4R had a LE CMR study positive for RVMI, 45 (39%) with positive ECG for RVI had no signs of RVMI in LE CMR (kappa=0,1; p=0,19).

Conclusions: ST elevation ≥1 mV in V4R on admission is only a sign of reversible ischaemia inconsistent with LE CMR findings in 3-5 days after procedure.

Contemporary PCI practices across three continents: Europe, Asia and South-America

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Aims: Our aim was to evaluate the current PCI practice in a large population of the patients from a daily clinical practice in Europe, Asia and Latin-America (LAM).

Methods and results: e-NOBORI is a prospective, multinational, single-arm, multicentre, observational registry. A total of 7344 patients have been enrolled in Europe, 1214 in Asia and 949 in Latin-America. The primary endpoint of the study is target lesion failure (TLF) a composite of cardiac death (CD), target vessel myocardial infarction (MI) and target lesion revascularisation (TLR) at 1-year. Patients in Europe were the oldest (~63 years), with the lowest rate of diabetes (31%) and multivessel (MV) treatment (21%) and with highest rate of previous stroke (6%), history of PCI (31%), peripheral vascular disease (10%), ACS at admission (42%), number of lesions treated (2.04±1.62); and multiple stenting in a lesion (15%). Ratio of primary PCI was highest in Europe (11%), while pain to balloon time at <3h was the most frequently recorded in LAM (43%) and the least frequently in Asia (24%). Median door to balloon time was shortest the Europe (45 min), followed by Latin-America (70 min) and Asia (91 min). Femoral access site was preferred in Asia (78%) and radial in Europe (57%). The most complex lesions were detected in Asia (Type C; 35%), with the highest rate of *de novo* (93%), ostial (14%), and chronically occluded lesions (6%). In Europe lesions were more often thrombotic (11%) and calcified (33%), while in LAM there was highest rate of true bifurcation (7%) and restenotic lesions (9%). Direct stenting was most frequent in Europe (39%) while in Asia both pre- and post-dilatation were most often practiced (82% and 33% respectively). The procedure success was ~99% in all 3 continents. At 1-month the rate of CD was 0.2%, 0.3% and 0.9%, MI 0.5%, 0% and 1.1% and TLR 0.2%, 0% and 0.1% and at 1 year the rate of CD was 0.5%, 1.3% and 1.2%, MI 0.7%, 0.2% and 1.9% and TLR 0.8%, 0.6% and 0.2% for Europe, Asia and Latin-America, respectively. The TLF at 1 month was 0.6%, 0.3% and 1.6% and at 1 year 1.5%, 2.0% and 3.0%, respectvely. Stent thrombosis frequency at 1 year was the same on the 3 continents: 0.3%. Clinical follow-up of the patients is still ongoing and final 1 year results will be presented first time at PCR.

Conclusions: Interesting findings were observed related to regional differences in procedure characteristics and complexity of the patients and lesions. Despite these differences the procedural success was equally high for all three regions and the preliminary clinical outcomes showed similarly low TLF rate in this complex, all comer's population, treated with Nobori DES, in three continents.

The coronary sinus reducer a device based therapy for refractory angina: efficacy and safety results from the ongoing open label registry

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Aims: An increasing number of patients with advanced coronary artery disease have refractory angina pectoris with poor quality of life despite optimal medical therapy. The Coronary Sinus (CS) Reducer is an emerging new option to treat patients with refractory angina. The Reducer is currently being investigated in two parallel clinical trials: The COSIRA (Coronary Sinus Reducer for Treatment of Refractory Angina) is a prospective, multicentre, randomised, double-blind, sham-controlled clinical trial, and its accompanying REDUCE-1 registry, both are presently enrolling patients. We present here the current results of the registry, which is recruiting patients with severe refractory angina with limited or no option for revascularisation.

Methods and results: Baseline and 6 months follow-up evaluations consist of clinical assessment, CCS (Canadian Cardiovascular Society) score, and objective evaluation of ischaemia by stress test (exercise duration, time to chest pain and time to ST depression), dobutamine echocardiography (calculated wall motion score index, LV ejection fraction), and stress thallium scan (summed rest score and summed stress score). 16 patients have thus far been enrolled in the registry, of which 8 have reached the 6 months follow-up. Median CCS diminished from 3.0 at baseline to 1.0 at 6 months, exercise duration was improved in all (mean 2:41±1:30 minutes at baseline to 4:48±1:19 minutes at 6 months), summed rest score and mean summed stress score by SPECT were reduced (7.5±3.3 to 3±1.7 and 19±8.8 to 9.5±2.6 respectively). Among the 16 patients enrolled, no serious adverse effects attributed to the Reducer were recorded.

Conclusions: These initial safety and efficacy results with the CS Reducer are very encouraging. The complete 6 months efficacy and safety data for the 16 patients will be presented at the EuroPCR 2013 meeting.

Coronary interventions – *Tuesday May 21st*
Impact of IVUS in a real world practice

Mechanisms of in-stent restenosis after drug-eluting or bare-metal stent implantation. The Nordic Intravascular Ultrasound Study (NIVUS)

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Aims: The aim of this study was to evaluate, by intravascular ultrasound (IVUS), the minimum lumen area site and the extent and distribution of intima hyperplasia in patients presenting with in-stent restenosis after DES or BMS implantation.

Methods and results: The "Nordic Intravascular Ultrasound Study – (NIVUS)" study was conducted in Nordic and Baltic countries as a prospective multicentre registry, where in-stent restenoses were examined by IVUS, between August 2007 and November 2009. 208 patients (DES n=120 (58.1%) and BMS n=88 (41.9%)) had IVUS performed before treatment for an in-stent restenosis, DES median 608 days [interquartile range (IQR) 243-1181] vs. BMS median 269 days [IQR 150-977] (p=0.005) after the index PCI. Stents implanted at the index procedure time were longer in the DES group compared to the BMS group 25.0±12.3 mm vs. 19.9±9.2 mm, p=0.001, whereas stent size was significantly lower in the DES group (3.1±0.5 mm vs. 3.3±0.4 mm, p=0.005). At the minimum lumen area site in the stented segment, the stent area (5.8±2.2 mm^2 vs. 7.6±2.4 mm^2, p<0.001) and IH area (2.6±2.0 mm^2 vs. 5.0±2.2 mm^2, p<0.001) were significantly lower in patients treated with DES compared to BMS. The minimum stent area (MSA) within the entire stented segment was significantly lower in patients treated with DES compared to BMS (4.7±1.8 mm^2 vs. 6.3±2.1 mm^2, p<0.001). The percentage of stents with a MSA of ≤5.0 mm (stent under expansion) was higher in DES (58.7% vs. 37.7%, p=0.008) compared to BMS treated patients. The cross sectional area of IH at the MSA site was significantly lower in DES compared to BMS (0.7±1.2 mm^2 vs. 2.7±2.2 mm^2, p<0.001). Focal in-stent restenosis was more often seen in DES treated patients compared to BMS treated patients (DES n=84 (59.9%) vs. BMS n=15 (17.0%)), p<0.001. Among different types of DES, focal in-stent restenosis was more common in Cypher (n=31 (73.8%)) stents than in Taxus (n=24 (58.5%)) or Endeavor (n=7 (36.8%)) stents, p=0.022. Occurrence of stent fractures was similar for DES (n=4 (4.2%)) and BMS (n=2 (2.2%)), p=0.416.

Conclusions: In patients with in-stent restenosis, stent under expansion, was more often seen in DES than BMS restenosis. Compared to BMS, DES more often had focal in-stent restenosis with less intimal hyperplasia.

Coronary interventions – *Tuesday May 21st*
Impact of IVUS in a real world practice

Clinical impact of IVUS-guided left main PCI. Propensity score analysis from the multicentre ESTROFA-LM study

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Aims: Whether the use of IVUS during drug-eluting stent implantation in the left main adds a clinical benefit remains unclear. There is only one single study that supports this statement. Therefore we sought to investigate the clinical impact of the use of IVUS in this setting.

Methods and results: From a retrospective multicentre study that compared different drug-eluting stents in the setting of left main we have analysed the clinical impact of the use of IVUS. Consecutive patients from 21 different hospitals with left main lesions treated with DES were included. A propensity score matching method was used to obtain matched pairs of patients with and without IVUS guidance during DES implantation in LMCA. A total of 770 patients were included in the registry. IVUS was used in 233 cases (30.2%) and not used in 537 patients. After a three-year follow-up period the use of two stents, age, diabetes and acute coronary syndrome were found independent predictors of events in the global group after a Cox analysis. In the subgroup of 409 (53.1%) patients with distal left main lesions the independent predictors were the use of two stents, age, diabetes and the use of IVUS, being the latest a protective predictor (HR 0.5, IC 95% 0.23-0.99; p=0.04). After propensity score matching 200 matched pairs of patients treated with DES in LMCA with and without IVUS were included in the analysis. Among these, 80 and 85 patients in each group respectively were treated in distal LM lesions. Survival free of cardiac death, MI and TLR at 3 years was 90.2% with IVUS and 86.7% without IVUS (p=0.7). In distal lesion subgroups, survival free of cardiac death, MI and TLR at 3 years was 94.4% with IVUS and 82% without IVUS (p=0.08)

Conclusions: The results of this multicentre registry suggest a potential clinical benefit derived from IVUS-guided PCI with DES in distal left main lesions.

The impact of IVUS guided PCI for complex lesion on long-term clinical outcomes in a real-world practice

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Aims: Intravascular ultrasound (IVUS) provides useful information of vessel anatomy and can result optimal stenting. Recent studies reported that suboptimal stent expansion and residual segment restenosis are related with adverse outcome. Complex lesions (i.e American College of Cardiology/ American Heart Association class type C) are associated with lower procedural success and poorer late outcomes. Thus we investigated long term clinical outcomes of IVUS guided percutaneous coronary intervention (PCI) in type C lesion with drug eluting stents compared with angiography guided PCI in a real-world practice.

Methods and results: Total 966 patients who underwent PCI for type C lesion were enrolled from June 2003 to December 2010 at our institution. Mean follow-up duration is 33.1 months. 342 patients were treated with IVUS guided PCI and 624 patients treated with angiography guided PCI. The clinical end point was major adverse cardiovascular event (MACE) composite of cardiac death, myocardial infarction (MI), target lesion revascularisation (TLR) and definite or possible stent thrombosis. Baseline clinical characteristics were similar in both patient groups. IVUS guided PCI group had higher frequency of ostial and proximal lesion. IVUS guided PCI group showed the longer stent length and larger maximal stent diameter and greater number of implanted stents. There was no significant difference in total MACE between IVUS guided PCI and angiography guided PCI groups (14.8% vs. 18.8% p=0.12). However, IVUS guidance reduced the development of stent thrombosis (1.0% vs. 2.8% p=0.05) and ISR (11.0% vs.15.8% p=0.04) compared with angiography guided PCI group. In multivariate-adjusted Cox regression analysis, maximal stent diameter was the only independent predictor of MACE.

Conclusions: Though MACE was not different between two groups, IVUS guided PCI for complex lesion is associated with lower risk of ISR and stent thrombosis. Thus, IVUS- guided PCI may be considered selectively as an effective strategy for complex coronary lesions aimed at reducing the stent thrombosis in high risk patients.

Peri-medial high-echoic band, a novel IVUS finding, predicts chronic vessel enlargement

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Aims: Coronary arterial segments distal to the severely stenotic lesion may shrink as a result of decreased coronary flow. Pathological studies have demonstrated that vessel shrinkage is accompanied with folding of the internal elastic membrane. Peri-medical high echoic band (PHB) by IVUS may indicate the folding of the internal elastic membrane and thus may detect chronically shrunken vessels which have potential to enlarge after revascularisation. The aim of this study was to investigate if PHB observed at the distal segment to the culprit lesion predicts vessel enlargement after successful revascularisation of the culprit lesion.

Methods and results: Twenty seven lesions from 27 patients with ischaemic heart disease who underwent coronary intervention were enrolled and studied. Distal part of the culprit lesion was imaged by IVUS immediately after revascularisation. PHB was defined as a high-echoic band observed at the luminal side of the media (Figure). Coronary angiography was repeated at 9 months follow-up and serial changes in lumen diameter (LD) of the distal segments were compared between those with (PHB group) and without PHB (no PHB group). During follow-up, LD increased significantly in PHB group (1.2±0.3 to 1.7±0.5 mm, P=0.001), whereas LD did not change overtime in non-PHB group (2.0±0.7 to 2.1±0.7 mm, P=NS).

Conclusions: Presence of PHB by IVUS may be suggestive of chronic vessel shrinkage that has potential to enlarge late after revascularisation of the proximal culprit lesion.

Coronary interventions – *Tuesday May 21st*
DES: updated evidence from randomised clinical trials

Direct implantation of rapamycin-eluting stents with bioerodible drug carrier technology utilising a next generation DES coronary integrated delivery system: the DIRECT II study

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Aims: The Svelte Drug-Eluting Stent (DES) combines the anti-proliferative drug sirolimus with a novel, amino acid-based, fully bioabsorbable drug carrier. The device is specifically designed for direct stenting and offers the potential to shorten and simplify coronary interventional procedures, minimise contrast use and reduce overall procedure costs. The DIRECT II study is a prospective, randomised, active-control, multicentre study comparing the safety and efficacy of the Svelte Drug-Eluting Coronary Stent Integrated Delivery System (IDS) to that of the commercially available Resolute Integrity™ Drug-Eluting Stent.

Methods and results: One hundred fifty-nine (159) patients (2:1 randomisation Svelte IDS: Resolute Integrity™ to establish non-inferiority in the primary efficacy endpoint of in-stent late lumen loss) will be treated in up to 20 centres in Europe and Brazil, with clinical and angiographic follow-up at 6-months to assess the primary endpoints of angiographic Target Vessel Failure (TVF) and Late Lumen Loss (LL), as well as secondary safety and efficacy endpoints. Patients with symptomatic ischaemic heart disease due to a single, *de novo* stenotic lesion contained within a native coronary artery with a Reference Vessel Diameter (RVD) between 2.5 mm and 3.5 mm and lesion length ≤20 mm amenable to revascularisation with percutaneous coronary intervention (PCI) and stent deployment are included. Stent evaluation post-procedure and at 6-month follow-up in thirty (30) patients treated with the Svelte Drug-Eluting Coronary Stent Integrated Delivery System (IDS) will also be performed at pre-determined sites with OCT capability. Additional clinical follow-up will take place at 1-month and annually through 5-years on all patients. The study commenced January 2013, with enrolment expected to be complete by June 2013. Procedural and 30-day data on all available patients, along with illustrative case examples with OCT image analysis, will be available for presentation in May 2013. Comparative data for time and cost savings, including overall procedural time, adjunctive product use, contrast use and radiation exposure, will also be reported.

Conclusions: A review of the Svelte Drug-Eluting Coronary Stent Integrated Delivery System (IDS) and available procedural and 30-day results from the study will be provided. These data will provide insights into the potential procedural and clinical benefits, as well as time and cost savings, of this unique drug-eluting stent and integrated delivery system.

Coronary interventions – *Tuesday May 21st*
DES: updated evidence from randomised clinical trials

BIOFLOW-III: an "All Comers" registry with a sirolimus eluting stent, presentation of one year target lesion failure rata

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Aims: The aim of this registry is to evaluate the clinical performance of a new generation Sirolimus eluting stent system (Orsiro) in a large patient population in standard clinical care.

Methods and results: Between August 2011 and March 2012, 1,359 subjects presenting with *de novo* and restenotic coronary artery lesions were enrolled consecutively in this international, multicentre BIOFLOW-III registry using the Orsiro Sirolimus eluting stent. The Orsiro is a unique hybrid solution that combines passive and active components. PROBIO passive coating encapsulates the stent and minimises interaction between the metal stent and surrounding tissue. BIOlute active coating contains a highly biocompatible and biodegradable polymer. Primary endpoint is Target Lesion Failure rate (TLF) at twelve months follow-up. Pre-specified subgroups were diabetes, small vessels, chronic total occlusion and acute myocardial infarction. Nine hundred seventy three men (72%) and three hundred eighty six women were enrolled at 43 sites in 12 countries. The mean age was 66.1±10.7, ranging from 29 - 91 years. Based on our preliminary data, the majority of subjects presented with hypertension 76%, hypercholesteremia 60%, smoker 54%, and diabetes 29%. 38% of all stented vessels had a diameter ≤2.75 mm, 4% presented with chronic total occlusion. Eleven percent of the subjects experienced unstable angina, 47% stable angina. Acute MI was seen in 32% of the subjects (NSTEMI 22%, STEMI 11%). The portion of elderly subjects (>75 years) is represented by 25%. A challenging patient population was seen in the registry with more than 50% type B2/C lesions. Moderate and severe calcification was observed in 33%. Preliminary follow-up compliance is 97% (1'313/1'359) at 6-month.

Conclusions: Preliminary data in this complex population demonstrates a low TLF rate comparable to other state of the art DESat 6-month. Six-and 12-month data will be available upon presentation.

Improved safety and reduction in stent thrombosis associated with biodegradable polymer based biolimus-eluting stents vs. durable polymer based sirolimus-eluting stents in patients with coronary artery disease: final 5-year report of the limus eluted from a durable vs. erodabale stent coating (LEADERS) randomised, non-inferiority trial

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Aims: The LEADERS Trial is the first randomised study to evaluate biodegradable polymer-based drug-eluting stents (DES) against durable polymer DES. This landmark study has concluded its final five-year follow-up.

Methods and results: The LEADERS Trial was a ten-centre, assessor-blind, non-inferiority, 'all-comers' trial (n=1707), with minimal exclusion criteria. All patients were centrally randomised to treatment with either biodegradable polymer biolimus-eluting stents (BES, n=857) or durable polymer sirolimus-eluting stents (SES, n=850). Baseline SYNTAX Scores were assessed by an independent central core laboratory. The Primary Endpoint was a composite of cardiac death, myocardial infarction (MI), or clinically indicated target vessel revascularisation (TVR) within 9 months. Secondary endpoints included extending the Primary Endpoint to 5 years and definite stent thrombosis (ST). Analysis was by intention to treat. At 5 years, the BES was non-inferior to SES for the Primary Endpoint (186 [22.3%] vs. 216 [26.1%], rate ratio [RR] 0·83 [95% CI 0·68-1·02], p for non-inferiority <0·0001, p for superiority=0·071). The BES was associated with a significant reduction in the more comprehensive patient orientated composite endpoint of all-cause Death, any MI and all-cause revascularisation (297 [35.1%] vs. 339 [40.4%], RR 0·84 [95% CI 0·71-0.98], p for superiority=0·023). A significant reduction in very late definite ST from 1-5 years was evident with the BES (n=5 [0.7%] vs. n=19 [2.5%], RR 0.26 [95% CI 0·10-0.68], p=0.003, pinteraction=0·022), corresponding to a significant reduction in ST associated clinical events (Primary Endpoint) over the same time period (n=3/749 vs. n=14/738, RR 0.20 [95% CI 0·06-0.71], p=0.005, pinteraction=0·035). Secondary analyses associated the BES with a significant reduction in definite ST in higher (≥12) SYNTAX Scores (n=9 [2.5%] vs. n=22 [6.6%], RR 0.38 [95% CI 0·18-0.83], p=0.011), but not lower (<12) SYNTAX Scores (n=8 [2.4%] vs. n=6 [1.9%], RR 1.37 [95% CI 0·47-3.95], p=0.56) (pinteraction=0·051).

Conclusions: The safety benefit of the biodegradable polymer BES, compared to the durable polymer SES, was related to a significant reduction in very late ST (>1 year) occurring in more complex coronary disease, and a reduction in associated composite clinical outcomes.

Comparison of biodegradable polymer and durable polymer drug-eluting stents in an all-comers patient population (BIO-RESORT): rationale and study design of a randomised multicentre trial in an all-comers population

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Aims: To evaluate the safety and efficacy of each of two novel drug-eluting stents (DES) with biodegradable polymer-based coatings vs. a reference DES with durable polymer-based coating that is used as gold standard.

Methods and results: BIO-RESORT is an investigator-initiated, prospective, single-blinded, randomised multicentre trial in a Dutch all-comers population. Patients with various clinical syndromes, requiring percutaneous coronary interventions (PCI) with DES implantation, are eligible for enrollment, with only few exclusion criteria. In these patients, the type of DES implanted is randomised (stratified for the presence of diabetes mellitus) in a 1:1:1 ratio between the ORSIRO sirolimus-eluting stent with circumferential biodegradable polymer coating vs. the SYNERGY everolimus-eluting stent with abluminal biodegradable polymer coating vs. the RESOLUTE INTEGRITY zotarolimus-eluting stent with durable polymer coating. The primary endpoint is the incidence of target vessel failure at one-year follow-up, a composite endpoint consisting of cardiac death, target vessel-related myocardial infarction, or clinically driven target vessel revascularisation. A total of 3540 patients will be enrolled based on a power calculation that assumes a target vessel failure rate of 8.5% at one year follow-up with a 3.5% non-inferiority margin, giving the study a power of 85% with an alpha level of 0.025 and allowing for up to 3% loss to follow-up. Among the secondary endpoints, the impact of diabetes mellitus on post-PCI outcome will be evaluated. In addition, the BIO-RESORT SILENT DIABETES sub-study will investigate the prevalence of so far undetected diabetes and its potential relevance for clinical outcome. The first patient was enrolled on December 21, 2012.

Conclusions: BIO-RESORT is a large, prospective, randomised, multicentre trial with 3 arms, comparing head-to-head two DES with biodegradable polymer coatings vs. a reference DES with durable polymer coating. The trial will provide novel insights into clinical outcome of modern DES in a clinically relevant all-comers population. In addition, the BIO-RESORT trial and the BIO-RESORT SILENT DIABETES study address the impact of known and so far undetected diabetes mellitus on post-PCI outcome.

Coronary interventions – *Tuesday May 21st*
DES: updated evidence from randomised clinical trials

BIOTRONIK: safety and clinical performance of the DES orsiro in the treatment of subjects with single *de novo* coronary artery lesions II (BIOFLOW-II): a quantitative analysis by IVUS and OCT

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Aims: The present BIOFLOW-II sub study aimed to assess the results of subjects randomised to receive either the BIOTRONIK Orsiro Sirolimus Eluting Stent (SES) or the Abbott Xience Prime™ Everolimus Eluting Stent (EES) with respect to neointimal hyperplasia, stent apposition and stent strut coverage at 9 months after procedure using both IVUS and OCT imaging techniques.

Methods and results: We performed a randomised, non-inferiority trial in subjects (N=458, 63.4±10.0 yrs, ranging from 36-80 yrs) with symptomatic coronary artery disease due to de novo stenotic lesions in native coronary arteries with a reference vessel diameter ≥2.25 mm and ≤4.0 mm and a lesion length ≤26 mm registered at trials.gov (NCT01356888). Subjects were randomly assigned (2:1) to receive the Orsiro SES or the Xience Prime™ EES. A cohort of the enrolled subjects were invited to participate in either the IVUS (N=66) or the OCT (N=65) substudy. No subjects were included in both substudies. The IVUS substudy endpoints were neointimal hyperplasia and stent apposition at 9 months after procedure. The OCT sub study endpoints were neointimal hyperplasia, stent apposition and stent strut coverage at 9 months after procedure. All subjects in the substudies were enrolled between July 5, 2011-Jan 10, 2012. Substudy images from baseline and the 9 month follow-up are analysed by independent and blinded core laboratories; IVUS by Medstar, Washington DC, USA and OCT by Cardialysis, Rotterdam, The Netherlands.

Conclusions: The BIOFLOW-II IVUS and OCT sub studies compares the efficacy of the thin-strut, silicon-carbide coated Orsiro SES with biodegradable polymer with the Xience Prime™ EES. The IVUS and OCT 9-month follow-up data is currently being analysed. Results will be presented for the first time during the meeting.

Coronary interventions – *Tuesday May 21st*
Procedural factors determining outcome in high-risk patients

Assessment of short-term outcome after PCI in the setting of cardiogenic shock: impact of transfer policies after the procedure. A report from the Belgian registry of PCI

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Aims: To assess the impact of transfer policies on the assessment of 30-day inhospital mortality.

Methods and results: During the 5-year period (01.01.2006 - 31.12.2010), 2390 PCI procedures were performed in Belgium in the setting of cardiogenic shock (representing 1.9% of all PCI procedures). Subsequently 459 patients (19.2%) were transferred alive to referring/revalidation centres (ranges: 6-35%). Mean age: 68.2±12.7 y; female gender: 30%; renal failure: 7%; active/former smoker: 28%/18%; CRR prior to PCI: 48.5%, haemodynamic support: 61%; 1 vessel disease: 31%, 0 VD: 30%; 3 VD: 37%; left main PCI: 8%; PCI on saphenous grafts: 2%. Inhospital complications: stroke: 1.5%; emergency CABG: 3.2%; mortality: 41.2%. In the BWGIC database, survival status at 30 days were known for 1189 patients (930 deaths+259 still in hospital), 459 patients were transferred and 1742 were discharged alive at home. The 30-day inhospital mortality was 39% by the cumulative event rate ("Crude"mortality) and 51% by the Kaplan-Meier method. The lack of survival status (in 51% of the cases) at 30 days has a major impact on the outcome assessment. The discordance between the 2 methods started at day 4 after the PCI and increased progressively to the absolute difference of 12% at 30 days. These differences were found in all centres ranging from 4-23%. We found a significant relationship between the transfer rate and the difference between 30-day "crude" mortality - KM mortality (spearman r: 0.579). Multivariate analysis revealed male gender (OR: 0.78) and smoking (OR: 0.91) predicting better prognosis, whereas age, renal failure, CPR, extent of CAD, left main PCI were marker of poorer prognosis.

Conclusions: In this large Belgian multicentre registry on PCI procedures in the setting of cardiogenic shock, the "Crude" 30-day hospital mortality underestimates Kaplan-Meier event rates by approximally 30%. The available inhospital data seem of limited value to perform quality control or benchmarking. These observations emphasise the need for 30-day survival status in all cases after invasive procedures, ideally by automate feedback from the national institute for statistics.

Urgent invasive strategy for out-of-hospital cardiac arrest survivors is associated with better survival

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Aims: Out of hospital cardiac arrest (OHCA) is a leading cause of adult death in industrialised world. Hospital survival rates ranging from 21% to 40% and have not improved in recent years. Acute coronary occlusion is the leading cause of cardiac arrest, however, because of limited data, the indications and timing of coronary coronary angiography (CA) and angioplasty (PCI) in this setting are controversial except for ST-elevation in 12-lead electrocardiogram (EKG). The aim of our study is to understand etiology and survival of patients admitted to our hospital with return of spontaneous circulation (ROSC) after OCHA and whether a strategy that leads to an urgent CA and PCI, if required, can improve the outcome.

Methods and results: Observational retrospective study. Between January 2006 and December 2009, 70 patients with ROSC after OHCA were referred to our hospital. Mean age was 69,5±13,9; 63% male gender; 11% previous coronary artery disease (CAD), first rhythm was ventricular tachycardia/ventricular fibrillation (VT/VF) in 62%; in 41% diagnosis was acute coronary syndrome (ACS) based upon EKG and enzyme. Hospital survival rates was 48,5%. One year survival rates was 76% of dismissed. Postresuscitation neurologic injury (PNI): 32,8%. According to the presence of ACS: patient with ACS are mostly male, without differences in age or previous CAD vs. patients without ACS. VT/VF is the most frequent presentation rhythm in ACS patients (89% vs. 40%; p<0,01). Only in 34% of ACS patients the first EKG showed sign of myocardial infarction/ischaemia. VT/VF is the first rhythm equally in both STEMI and nonSTEMI. Early sign of PNI generally are associated with underuse of CA and PCI and worst prognosis. Successfull urgent CA and PCI are associated with improved hospital survival in patient with ACS (equally in STEMI 83% vs. 51% p=0,003 and NSTEMI 81% vs. 55% p=0,004); and in FV/TV as first rhythm (90% vs. 38% p>0,001).

Conclusions: In patients survived from OHCA successful urgent PCI is associated with improved in hospital survival for STEMI, NSTEMI and VT/VF as first rhythm.

Coronary interventions – *Tuesday May 21st*
Procedural factors determining outcome in high-risk patients

Mortality differences for out-of-hours emergency admissions in the National Health Service (NHS): lessons from the english primary angioplasty model of care

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Aims: We examined the influence of out-of-hours admission on survival following Primary Angioplasty (PPCI) for ST-elevation myocardial infarction (STEMI) in our centre – a clinical service that is delivered entirely by senior physicians.

Methods and results: Baseline patient and procedural characteristics were collected on 1120 consecutive patients undergoing PPCI for STEMI over a 39 month period. Out-of-Hours admission was categorised according to: 1) The day of admission: Weekday (Monday 8am to Saturday 8am) vs. Weekend (Saturday 8am to Monday 8am) 2. The time of admission: Work-Hour (Monday to Friday 8am to 5pm) vs. Non Work-Hour (Monday to Friday 5pm to 8am the following day, weekends and national public holidays) As a marker of outcome, 30-day survival was tracked from the United Kingdom Office of National Statistics for all patients. Categorised according to Weekday [775 (67.4%) patients] vs. Weekend [365 (32.6%) patients] presentation, there was no difference in 30-day mortality between the two groups [number of deaths - Weekday: 40 (5.3%), Weekend: 22 (6.0%); p=0.61]. Analysis of survival using a multivariate Cox model did not identify day of admission as an independent determinant of mortality [HR: 1.16 (95% CI: 0.69 to 1.95); p=0.58]. Similarly, analysis on the basis of presentation during Work-Hour [386 (34.5%) patients] vs. Non Work-Hour [734 (65.5%) patients] did not show a difference in mortality between the groups [number of deaths - Work-Hour: 22 (5.7%), Non Work-Hour: 40 (5.4%); p=0.86]. Multivariate analysis of survival once again did not identify time of admission as an independent determinant of mortality [HR: 0.74 (95% CI: 0.43 to 1.26); p=0.27].

Conclusions: Our findings are at odds with the international and national indicators of outcome for emergency admissions where there is a clear disparity in survival between patients admitted during a weekday and a weekend. Although the model of care presented is not representative of all emergency care, our results provide direct evidence that the input of senior clinicians can positively influence survival of emergency out-of-hours admissions.

Coronary interventions – *Tuesday May 21st*
Procedural factors determining outcome in high-risk patients

In-hospital outcomes of biventricular assist devices for high-risk PCI

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Aims: Revascularisation by coronary artery bypass grafting (CABG) is eligible in severe multivessel disease patients (SYNTAX score >22). Percutaneous coronary intervention (PCI) in this patient group also carries the risk of adverse outcomes in case of low left ventricular ejection fraction (EF), a technically difficult procedure, or when a large area of viable myocardium is supplied by target vessels. Currently, evidence for intraaortic balloon pump (IABP) application in PCI is still pending due to the lack of adequate circulatory support and the need for a certain level of left ventricular function. Perhaps, biventricular assist devices supported by extracorporeal membrane oxygenation (ECMO) can provide effective haemodynamic support for high-risk PCI patients with multivessel disease who have contraindications for CABG.

Methods and results: Eight patients with multivessel disease ineligible for CABG were included in the study. The average age was 62.8±6.1 years, EuroScore 10.6±2.4 and EF 41.6±13.2. Half of the patients (n=4) had severe comorbidities, 66% had acute coronary syndrome with ST-segment elevation myocardial infarction (NSTEMI). All patients underwent the high-risk PCI facilitated by ECMO. Six patients had unprotected left main stenosis of more than 70%, all of them presented multivessel lesion of coronary bed (SYNTAX score 32.4±5.4). The haemodynamic support in all patients was provided with venoarterial biventricular assist devices with perfusion index of 2.4-2.7 L/(min.m^2). Primary end-point of the study was death, myocardial infarction (MI), stroke, target vessel revascularisation (TVR), bleeding and stent thrombosis. On average, the procedure took 224±25 min with endovascular stage of 82.5±34 min. The average number of implanted stents per patents was 3:1. The average implanted stent length was 54.8±16.2 mm. Seven patients underwent bifurcation stenting (87.5%), two patients underwent chronic total occlusion revascularisation (25%) and six subjects - unprotected left main intervention (75%). Angiographic success without associated in-hospital major clinical complications (e.g., death, MI, stroke, repeat TVR, bleeding, and stent thrombosis) was achieved in all cases. Complete revascularisation was performed in 75% (n=6) of all the patients.

Conclusions: Biventricular assist devices for the high-risk PCI facilitated by ECMO ensure to perform successful myocardial revascularisation in patients ineligible for CABG.

Coronary interventions – *Tuesday May 21st*
Procedural factors determining outcome in high-risk patients

Midterm outcomes of iatrogenic coronary artery dissection

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Aims: Iatrogenic coronary artery dissection during coronary angiography (CAG) and percutaneous coronary intervention (PCI) is a rare but feared complication. We evaluated the midterm angiographical and clinical outcomes of iatogenic coronary artery dissection.

Methods and results: From June 2000 to July 2012, CAG and PCI were performed on 62249 patients in our hospital (CAG, 44847; PCI, 17402). Iatrogenic coronary artery dissection occurred in 0.13% (80/62249). Bailout stent implantation with bare metal stent (BMS) or drug-eluting stent (DES) was performed on 72 patients (BMS, 43; DES, 29). Follow-up CAG at 3 to 8 months after stent implantation was performed on 58 patients (BMS, 34; DES, 24), we compared the midterm clinical and angiographical outcomes of iatogenic coronary artery dissection between BMS and DES implantations. Clinical outcomes were evaluated by target lesion revascularisation (TLR) and major adverse cardiac events (MACE), including a composite of death, myocardial infarction, and TLR. There was no MACE except TLR in each group, and the TLR rate showed no significant difference between BMS and DES implantation (8.8% vs. 4.2%, p=0.64). However, coronary artery dissection reappeared in 6 cases after DES implantation, the rate of reappearing coronary artery dissection was significantly higher after DES implantation than after BMS implantation (BMS, 0.0%; DES, 25.0%; p<0.01).

Conclusions: Midterm outcomes after stent implantation for iatrogenic coronary artery dissection with BMS or DES are acceptable. After DES implantation, however, coronary artery dissection could reappear, and we should follow-up carefully.

The J-CTO score vs. the SYNTAX score focused attention on the evaluation of chronic total occlusion: comparison as the predictor of successful revascularisation for coronary total occulusion

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Aims: Chronic total occlusion (CTO) intervention is still challenging because of the limited procedural success rate. The SYNTAX score is a unique tool to score complexity of coronary artery disease involving CTO lesion. The SYNTAX score is helpful to anticipate procedural difficulties in a complex involving CTO lesion, Left Main and/or three vessel diseases. and possibly predict clinical outcome. However, as we know, the SYNTAX score is not localised tool for CTO lesions. Whereas, the J-CTO score was reported as having difficulty in grading of PCI for CTOs. We evaluated whether the SYNTAX score focused attention on the evaluation of CTO lesion (the Sys-CTO score) could predict successful revascularisation for CTO-PCI or not, compared with the J-CTO score.

Methods and results: We investigated the Sys-CTO score and the J-CTO score in consecutive 206 patients (219 lesions) treated with coronary angioplasty for CTOs, in a single-centre. The Sys-CTO score was availed focused on each CTO lesion by extracting from the SYNTAX Calculator 2.11. The J-CTO score was determined by assigning one point for each independent parameter (Blunt shape of entry (BL), angiographic evident calcification within CTO segment (CA), bending >45 degrees within CTO route (BE), occlusion length ≤20 mm (LO), re-try (previously attempted but failed) (RE) and summing all points accrued. Successful revascularisation rate were 84.0% (184/219), and average the Sys-CTO score and average the J-CTO score were 12.3±6.3, 1.85±1.33, respectively. We divided all CTO lesions into two groups; the successful revascularisation lesions (n=184; SG): the failed revascularisation lesions (n=35; FG). Relationship between the value of the J-CTO score and successful revascularisation rate (%) were shown as follows; (0):100, (1):93.4, (2):82.1, (3):67.6, (4):69.6, (5):66.7, respectively. As for the J-CTO score, there were statistic difference between the two groups;SG: 1.7±1/3, FG:2.8±1.1(P<0.05). Whereas, as to the Sys-CTO score, there were no balanced between the two groups; SG: 12.1±6.3, FG: 13.4±5.8 (p=n.s). In the detailed evaluation of the Sys-CTO score, these distinctive six parameters seemed to be predictive factors inhibiting successful revascularisation (P<0.05); Beyond the segment visualised contrast ≥1 segment (FG:37.1%; SG:27.1%), Blunt stump (FG:62.9%; SG:47.3%), Bridging (FG:31.4%; SG12.0%), Severe tortuosity (FG:20.0%; SG:10.3%), Heavy calcification (FG:54.3%; SG22.8%), Diffuse diseased and narrowd segment (FG:48.6%; SG33.2%). The breakdown analysis of each J-CTO score parameter within FG were as follows; RE 15;42.9%, LO 16;45.7%, BE 18;51.4%, BL 22;62.9%, CA 27;77.1%.

Conclusions: The Sys-CTO score could not be predictive factor by itself. However, these distinctive six parameters could be a useful predictor of a successful revascularisation for CTO-PCI as well as the J-CTO score.

The impact of high residual platelet reactivity after clopidogrel loading on cardiac mortality in patients treated by PCI for chronic total occlusion

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Aims: There is evidence that clopidogrel nonresponsiveness is a strong marker of poor outcome in patients with coronary artery disease treated invasively. No data exist about the impact of high residual platelet reactivity after 600 mg clopidogrel loading on long-term clinical outcome in patients undergoing drug-eluting stent (DES) implantation for coronary chronic total occlusion.

Methods and results: The Florence chronic total occlusion-PCI registry include consecutive patients treated for at least 1 chronic total occlusionby DES supported percutaneous coronary intervention (PCI). Patients had prospective platelet reactivity assessment by light transmittance aggregometry after a loading dose of 600 mg of clopidogrel and using adenosine 5'-diphosphate as agonist. High residual platelet reactivity was defined as aggregation by 10 µmol/L adenosine 5'-diphosphate ≥70. Clopidogrel therapy 75 mg daily was recommended for at least 1 year. The end point of the study was long-term cardiac mortality. Cardiac survival was assessed by Kaplan-Meier estimation and independent predictors of cardiac mortality were evaluated by forward stepwise Cox regression analysis. From 2005 to 2010, 713 consecutive patients underwent chronic total occlusion PCI and had "*in vitro*" platelet reactivity assessment. A successful PCI was achieved in 569 patients (80%). The incidence of high residual platelet reactivity after clopidogrel loading was 18%. There were no significant differences in baseline characteristics between patients with high residual platelet reactivity and patients with low residual platelet reactivity. Successful chronic total occlusion-PCI rates were similar between groups (76% vs. 81%). The 2-year cardiac survival rate was 98±1% in the low residual platelet reactivity group and 79±7% in the high residual platelet reactivity group (p<0.001). By multivariable analysis, high residual platelet reactivity resulted as a independent predictor of cardiac death (HR 3.0; p=0.007); the others variables related to cardiac death were age (HR 1.1; p=0.001), left ventricular ejection fraction <0.40 (HR 6.8; p=0.001) and diabetes (HR 2.4; p=0.033).

Conclusions: High residual platelet reactivity after clopidogrel loading is a strong prognostic marker of increased risk of cardiac death in patients undergoing PCI for chronic total occlusion.

Coronary interventions – *Tuesday May 21st*
Coronary chronic total occlusion: from procedural success to long term outcome

Macrophage migration inhibitory factor is associated with higher collateralisation grade in patients with coronary chronic total occlusions

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Aims: Chronically total occluded coronary artery (CTO) is often associated with collateral circulation that is only partially supplying to the lack of antegrade blood flow. Therefore, variable degree of residual myocardial ischaemia might still be present. The macrophage migration inhibitory factor (MIF), secreted by endothelial cells, has been showed to promote *in vitro* the recruitment of the endothelial progenitor cells to the ischaemic tissues. It is still unknown whether MIF is involved in collateral formation of patients with CTO.

Methods and results: Blood collection for MIF evaluation was performed in 32 consecutive patients (n=32) undergoing to percutaneous coronary intervention (PCI) of CTO at three different sites: a) Femoral arterial sheath (ART); 2) Tip of the guiding catheter proximal to CTO (PROX); 3) Tip of the microcatheter distal to CTO (DIST) after the occlusion was crossed, but not yet dilated. MIF was also assessed at ART and PROX level in 10 patients with normal coronary arteries, who served as controls (CTRL). Degree of collateralisation was assessed by Rentrop classification (0 to 3). Rentrop class ≤2 identified patients with Low Collateralisation Grade (LCG; n=19), Rentrop class 3 identified patients with High Collateralisation Grade (HCG; n=13). MIF was analysed with a commercially available ELISA kit. Within CTO patients, a significant MIF increase was found across the 3 sampling sites (ART: 20.9±7.4 vs. PROX: 28.0±18.8 vs. DIST 39.4±20.6 ng/ml, p<0.01). MIF was significantly higher at DIST level in HCG as compared with LCG patients (45.2±23.9 vs. 35.5±17.6 ng/ml, p=0.05), while no difference was found at PROX (26.5±9.1 vs. 28.9±21.7 ng/ml, p=0.41) or ART level (18.7±5.2 vs. 22.3±8.4 ng/ml, p=0.42). Within CTRL patients, MIF was not significantly increased at the 2 sampling sites (ART: 18.7±7.4 vs. PROX: 15.6±5.3, p=0.10). Compared with CTRL patients, MIF was found significantly elevated in CTO patients at PROX (p=0.05), but not at ART (p<0.55) level.

Conclusions: Higher MIF levels are found downstream to the arterial occlusion. This along with lower levels found proximal to the occlusion and at peripheral level suggest a loco-regional MIF production. In addition, the higher the MIF levels the higher the collateralisation grade.

Coronary interventions – *Tuesday May 21st*
Coronary chronic total occlusion: from procedural success to long term outcome

SYNTAX score based assessment for effect of PCI among patients with chronic total occlusion

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Aims: Assessment of patients with CTO by SYNTAX score may help to identify the appropriate candidate and strategy of CTO-PCI.

Methods and results: We investigated consecutive 245 patients who underwent CTO-PCI adjunctive to medical therapy. All those patients were assessed by SYNTAX score based on their initial angiogram. We compared them according to results of CTO-PCI, and investigated their long-term outcomes among three groups divided by SYNTAX score (low score (<20), medium score (20-32), and high score (>32). Primary end point of this study was major adverse cardiac event (MACE) comprise to all cause death, non-fatal myocardial infarction, additional revascularisation including bypass surgery during subsequent follow-up period. Mean age(y) was 65.0±11, 65.7±10, and 69.3±10 (P=0.04). Ejection fraction (%) was 57.5±15, 55.8±15, and 51.5±16 (P=0.04). According to SYNTAX score assessment, mean SYNTAX score of each groups was 14.2±5, 25.4±4, and 44.1±10 (P<0.001), specific score at CTO site was 10.2±3, 15.2±7, and 15.4±7 (P<0.001). Procedural success rate among those groups was 85.7%, 90.8% and 80.0% (P=0.16) and their residual SYNTAX score after the PCI was 3.5±6, 4.3±7, and 13.6±16 (P<0.0001). According to survival analysis, success of CTO-PCI was effective compared to the failure cases among patients with high and intermediate SYNTAX score, in contrast to the low SYNTAX score group (median 769 days, success vs. failure (%); 12.4 vs. 0: P=0.967, 18.5 vs. 61.9: P=0.008, and 22.9 vs. 53.8: P=0.004). By multivariate analysis, residual SYNTAX score was only independent predictor of occurrence of MACE (hazard ratio: 1.05, 95% confidence interval: 1.02-1.08, P=0.002).

Conclusions: Role of PCI among pre-procedural low SYNTAX score subset needs further investigation. The residual SYNTAX score after PCI was an independent predictor of long-term outcomes. We should pay attention not only to the success of CTO-PCI but also the selection of appropriate candidates and optimal revascularisation based on SYNTAX score.

Coronary interventions – *Tuesday May 21st*
Coronary chronic total occlusion: from procedural success to long term outcome

Usefulness of the Werner classification to predict successful retrograde guidewire placement when using a western-style surfing technique in chronic total occlusion PCI

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Aims: The Werner classification has been shown to predict successful placement of the retrograde guidewire and overall procedural success when chronic total occlusion (CTO) percutanous coronary interventions (PCI) are performed by Japanese operators. Its usefulness for the prediction of successful placement of the wire at the distal CTO cap when using a "surfing" trial and error technique is not known.

Methods and results: We reviewed angiographic data, and procedural reports of consecutive retrograde CTO PCI performed between 01/2010 and 12/2012 at the Quebec Heart and Lung Institute by one high-volume operator (S.R.). The Werner class of the final collateral channel (CC) (CC0 without connection between donor and recipient artery; CC1 with continuous, thread-like connection and CC2 as small side branch-like size of the CC) actually crossed or attempted was evaluated. Distal guidewire successful placement was defined as positioning of the wire tip at the distal cap. We also calculated the time required to perform such step, starting from positioning of the microcatheter in the donor artery up to distal cap placement of the wire. Trend tests were performed. Out of a total of 240 cases performed during the period, 204 were done at the QHLI, in which 52% involved a retrograde component. Septal CCs were used in 73%, whereas epicardial CC were used in 20%. Otherwise, grafts were used. When using an epicardial CC, successful placement was achieved in 91%, whereas it was 79% when using septal CCs (Fisher's exact test p=0.24). Successful placement at the distal cap was a very strong predictor of procedural success (p<0.0001). Overall, including in failed cases, 19.6 min were required to perform such step. When restricting to septal CCs, the proportion of crossed CCs are: p: NS; CC0(n=34), Successful retrograde wiring: 85%; CC1(n=50), Successful retrograde wiring: 76%; CC2(n=12), Successful retrograde wiring 83%.

Conclusions: Successful crossing of small CCs (CC1) or even invisible CC0 remains high with the surfing technique. Therefore, small or invisible septal CCs should not discourage a retrograde attempt in appropriate cases.

Coronary interventions – *Tuesday May 21st*
Unsettled issues with oral anti-platelet therapy: which one? How much? How long?

Prevalence and predictors of dual antiplatelet therapy non-compliance after DES placement: one-year results from the XIENCE V USA study

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Aims: The safety of the XIENCE V®Everolimus Eluting Coronary Stent System (XIENCE V) has been demonstrated with consistently low rates of adverse cardiac events. This novel analysis evaluates the adherence of dual antiplatelet therapy (DAPT) in contemporary clinical practice following XIENCE V implantation. The hypothesis is that socioeconomic factors (SEF) along with risk of major bleeding would predict non-compliance.

Methods and results: XIENCE V USA is a large, prospective, single-arm study examining the real-world performance of XIENCE V. DAPT was recommended for at least 1 year in patients who were not at high risk of bleeding. 6,886 patients were included in this analysis. Non-compliance was defined as discontinuation of either aspirin or thienopyridine for at least 1 day. A unique multivariable logistic regression analysis was performed to assess the independent predictors of DAPT non-compliance. 1,240 patients (18%) were DAPT non-compliant. Predictors are as follows: major bleeding by TIMI within 1 year (odds ratio [OR]=6.34, P<0.0001), discharged on coumadin (OR=2.48, P<0.0001), anemia (OR=1.46, P=0.0082), age (OR=1.31, P=0.0007), gender (OR=1.21, P=0.0200), thienopyridine loading dose use (OR=1.18, P=0.0453), prior PCI (OR=0.83, P=0.0410), and prior MI (OR=0.74, P=0.0016). A new and innovative analysis examining the impact of referral patterns on DAPT compliance will also be presented.

Conclusions: Demographic, clinical and procedural variables were identified as independent predictors of DAPT non-compliance. Patients with major bleeding during the first year and those who were discharged on Coumadin were associated with highest risks of DAPT non-compliance. Prior MI or PCI were associated with reduced risk of DAPT non-compliance. SEFs were not predictive of DAPT non-compliance.

Coronary interventions – *Tuesday May 21st*
Unsettled issues with oral anti-platelet therapy: which one? How much? How long?

Effect of shorter dual antiplatelet therapy on one year clinical outcomes after implantation of DES

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Aims: Extended use of dual anti-platelet therapy (DAPT) after implantation of DES remains controversial despite clear guidelines. Our aim was to compare adverse events in patients who were under DAPT for a minimum of 12 months with those who stopped DAPT earlier. All patients were treated with Nobori, DES with biodegradable polymer.

Methods and results: Information from 2 large prospective, multicentre, multinational, single-arm, observational NOBORI registries about duration of DAPT was available for 6845 patients. DAPT was continued up to 1 year for 5006 patients (DAPT cohort), while 1845 had stopped it earlier on different time intervals, the most frequently between 3 and 6 months (non-DAPT cohort). The adverse events are adjudicated by an independent clinical event committee. We analysed impact of DAPT duration on stent thrombosis, target lesion failure (TLF) a composite of cardiac death (CD), target vessel myocardial infarction (TV-MI) and target lesion revascularisation (TLR) and MACE (composite of cardiac death, any MI and TVR) at one year. In the DAPT cohort there was more male patients (78% vs. 75%, p=0.02), higher frequency of acute coronary syndrome (45% vs. 41%, p=0.01) and multivessels treatment (25% vs. 20%, p<0.001). Non-DAPT patients were older (65±11 vs. 63±12, p<0.001), had more often hypertension (76% vs. 70%, p<0.001), renal failure (7% vs. 5%, p=0.001) and previous stroke (7% vs. 4%, p<0.001). Patients in DAPT cohort had more lesions treated (2.1±1.6 vs. 2.0±1.3; p<0.001) and more lesions at bifurcations (12% vs. 10%, p=0.009) and CTOs (3% vs. 2%, p=0.02) but less frequently with thrombus (9% vs. 11%, p=0.001). Access site in DAPT cohort was more often femoral (57% vs. 51%; p<0.001). TLF rate at 1 year was 2.1% for patients in DAPT cohort (CD: 0.1%, TV-MI: 0.9% and TLR: 1.4%) and 1.6% for the non-DAPT patients (CD: 0.27%, TV-MI: 0.60% and TLR: 1.08%). Target vessel failure rate was significantly higher in DAPT cohort of patients (2.88% vs. 2.01%; p=0.04), mainly because of higher rate of target vessel revascularisation (2.14% vs. 1.30%; p=0.024). Stent thrombosis rate was not different, with 0.30% in DAPT cohort vs. 0.33% in NDAPT. The rate of bleeding was low and similar in both groups.

Conclusions: Our results indicate that shorter duration of DAPT did not have negative impact on the one year clinical outcomes and that such practice is feasible treatment option for patients who have received new generation DES. Whether biodegradable polymer, as applied on Nobori DES, might have some effects on those findings remains to be seen when results of dedicated randomised study become available.

Coronary interventions – *Tuesday May 21st*
Unsettled issues with oral anti-platelet therapy: which one? How much? How long?

Clinical outcomes with 6 months dual antiplatelet therapy after implantation of Biolimus-A9 drug eluting coronary stents

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Aims: Optimal duration of dual antiplatelet therapy (DAPT) following drug eluting stent (DES) implantation remains poorly defined. Current guidelines suggest a minimum of 12 months DAPT. However, endothelialisation of biodegradable polymer biolimus-eluting stents occurs early, and 6 months DAPT may be adequate for these patients. We evaluated long term outcome in patients treated with biolimus-eluting stents who were treated with 6 months DAPT, with particular emphasis on cardiac death and non-fatal stent thrombosis occurring 6 to 12 months after stent implantation.

Methods and results: Between March 2008 and November 2011 patients treated with biolimus-eluting stents at the Sussex Cardiac Centre received six months DAPT. Vital status was tracked through the Medical Research Information Service (MRIS). Possible episodes of non-fatal stent thrombosis, according to the definition of the Academic Research Consortium (ARC), between months 6 and 12 were tracked via systematic searches of databases in all 5 centres undertaking percutaneous coronary intervention in Sussex. 692 patients (77.2% male), aged 65.6±12.5 years received biolimus-eluting DES. Presentations included acute coronary syndrome (47.2%) and stable coronary disease (52.8%). Vessels treated included left main stem (6.8%), left anterior descending (37.4%), circumflex (19.1%), right coronary artery (34.5%) and saphenous vein graft (2.1%) respectively. High-risk subsets included diabetes (15.6%); AHA type C lesions (35.1%) and chronic total occlusions (12.8%). During a median follow-up of 700 days there were 42 cardiac deaths (6.1%); 4.2% at 0-6 months, 1.0% at 6-12 months and 0.9% at >12 months. 19 of the 23 deaths within the first 30 days related to primary PCI for acute myocardial infarction complicating out of hospital cardiac arrest. Of the 7 deaths between 6-12 months, one death was adjudicated as possible stent thrombosis (ARC definition). There were no cases of non-fatal known stent thrombosis. Cardiac death accrued with smooth decremental incidence. Statistical examination showed no evidence of event clustering between 6 and 12 months.

Conclusions: After implantation of biodegradable polymer biolimus-eluting coronary stents, 6 months of dual antiplatelet therapy appears to be adequate, safe and effective.

Clinical outcomes associated with dual antiplatelet therapy interruption following implantation of the resolute zotarolimus-eluting stent

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Aims: Dual antiplatelet therapy (DAPT) comprising daily aspirin and a thienopyridine, is prescribed following DES implantation to reduce the risk for stent thrombosis (ST) and related clinical events. Current guidelines recommending DAPT continuation for 12 months after stent placementwere based on observations of increased risk for late (>30 days) and very late (>1 year) ST following use of first generation DES. Interruptions in DAPT therapy can occur for a variety of reasons including patient nonadherence, bleeding episodes, or the need for invasive medical or dental procedures that present an increased risk for bleeding. Furthermore, the optimal duration of DAPT therapy following placement of newer DES such as the Resolute™ Zotarolimus-eluting stent (R-ZES) is unclear.

Methods and results: Patient-level data was pooled from 4,896 patients treated with a R-ZES in the global RESOLUTE clinical program to analyse the impact of DAPT interruption of ≥14 days duration or discontinuation on risk for ST and related cardiac death/ target vessel myocardial infarction (CD/TVMI). The rationale for the 14 duration assessment is based on literature demonstrating that it takes 14 days after thienopyridine discontinuation for platelet function to recover. Clinical events were assessed based on the timing of first DAPT interruption (0-1, >1-12). Reasons for any DAPT interruption included medical/dental /surgical procedures (42%), clinical indications (13%), patient nonadherence (24%), and 21% were listed as other. The mean patient age was 63.9 years; 30.1% were diabetic and 45.0% presented with an acute coronary syndrome. A total of 874 (17.9%) patients discontinued or interrupted DAPT ≥14 days during the first year after R-ZES implantation. Among these patients, 122 were interrupted between 0 and 1 months and 6 ST events occurred in this group. However, among the 752 patients with a first interruption >14 days beyond 1 month, there were no ST events at 1 year. The rates of CD/TVMI were lower for the subjects with any DAPT interruption prior to the event between 1 and 12 months (8/772, 1.17%) compared with rates of CD/TVMI in subjects with early DAPT interruption (8/159, 5.03% for 0-1 month interruption).

Conclusions: Permanent or prolonged DAPT interruption during the first year after R-ZES implantation was common and was often for clinical reasons or medically necessary procedures. DAPT interruptions after 1 month were not associated with an increase in ST or CD/TVMI. Further analysis of a larger patient cohort is in progress and will be presented.

Comparison of clinical efficacy and safety of clopidogrel resinate with clopidogrel bisulfate in patients undergoing PCI

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Aims: While clopidogrel bisulfate (Plavix®) is very susceptible to degradation or chiral inversion by moisture including acidic or alkaline conditions as well as dry heat, clopidogrel resinate (Pregrel®), a new salt form of clopidogrel, is very stable in the physicochemical stability and the gastrointestinal stability tests as well as was highly safe in toxicity studies compared to conventional clopidogrel bisulfate. In 2007, clopidogrel resinate was approved for marketing by the Korean Food and Drug Administration based on a Phase I bioequivalence study. However, no data are available on the comparison of impact of the two drugs on adverse clinical outcomes.

Methods and results: Plavix was used exclusively from January 2004 through April 2010 and then Pregrel was used exclusively from May 2010 through September 2011. We dichotomised the overall population (n=10,487) into two groups according to prescribed type of clopidogrel: Pregrel (n=1,360) and Plavix (n=9,127) group. To reduce the impact of treatment selection bias and potential confounding in an observational study, we performed rigorous adjustment for differences in baseline characteristics of patients by use of the weighted Cox proportional-hazards regression models with the inverse probability-of-treatment weighting (IPTW) and the propensity score method was used to identify 1:1 matched cohort (n=2,470). We compared adverse outcomes during 6 months after PCI in the overall cohort and the propensity score matched cohort. In the overall cohort, there was no significant difference between Pregrel and Plavix groups in the 6-month cumulative rates of composite of major adverse cardiac and cerebrovascular events (including any death, non-fatal myocardial infarction and stroke) (4.1% vs. 4.8%; adjusted HR, 0.93; 95% CI, 0.73-1.19, p=0.38), stent thrombosis (0.3% vs. 0.4%; adjusted HR, 0.58; 95% CI, 0.24-1.41 p=0.31), or combined TIMI major and minor bleeding (0.1% vs. 0.5%; unadjusted HR, 0.29; 95% CI, 0.04-2.08, p=0.22). In the propensity score matched cohort, overall findings were consistent.

Conclusions: In conclusion, clopidogrel resinate, a new salt form of clopidogrel, was as efficacious and as safe as conventional clopidogrel resinate to prevent adverse clinical outcomes after PCI.

Coronary interventions – *Tuesday May 21st*
Unsettled issues with oral anti-platelet therapy: which one? How much? How long?

Switching from clopidogrel to prasugrel in patients having coronary stent implantation

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Aims: There are no clinical data concerning the safety of switching from clopidogrel to prasugrel in patients undergoing coronary stenting. However, in the daily activity, clinicians face the decision of switching patients at high-risk of thrombotic events from clopidogrel to prasugrel. Thus, we sought to evaluate clinical events in high-risk patients undergoing coronary stent implantation and prasugrel therapy with (SWITCH group) or without (NAÏVE group) prior clopidogrel therapy.

Methods and results: From March 2010 to December 2011 a total of 454 high-risk patients, aged 70±10 years, underwent non-emergent stent implantation and received prasugrel therapy. Of these, 315 (69%) patients received clopidogrel before switching to prasugrel therapy. In 239 patients with high residual platelet reactivity on clopidogrel, prasugrel decreased platelet aggregation from 72±11% to 43±16% (p<0.001). There was no difference in in-hospital major or minor TIMI bleeding (2.8% vs. 4.3%; p=0.411) between the SWITCH and NAÏVE groups as well as in mortality, acute stent thrombosis, reinfarction and stroke rates. At multivariable analysis, independent predictors of bleeding were female gender (OR 5.56 [1.41-19.88], p=0.014) and chronic renal failure (OR 6.27 [1.59-21.65], p=0.009), but switching therapy did not. This result was confirmed after switching propensity score adjustment (c-statistic 0.81; Hosmer-Lemeshow test p=860).

Conclusions: In conclusion, switching from clopidogrel to prasugrel in high-risk patients undergoing coronary stent implantation seems not to be associated with any major concern regarding prasugrel safety and efficacy.

Coronary interventions – *Tuesday May 21st*
Unsettled issues with oral anti-platelet therapy: which one? How much? How long?

Prasugrel vs. clopidogrel in medically managed unstable angina/NSTEMI: insights from the TRILOGY ACS platelet substudy in angiographically triaged patients

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Aims: We sought to compare the effect of prasugrel vs. clopidogrel on platelet reactivity as measured in P2Y12 reaction units (PRU) and the rate of the primary composite endpoint (cardiovascular death, myocardial infarction, or stroke) in relation to number of diseased vessels at prerandomisation angiography.

Methods and results: TRILOGY ACS compared prasugrel+aspirin vs. clopidogrel+aspirin in a primary cohort of 7243 ACS patients <75 years with ≥1 high-risk criterion who were medically managed without revascularisation; median follow-up was 17 months. Of 3085 patients (43%) undergoing prerandomisation angiography, platelet function testing was available in 669 (22%). Platelet reactivity was lower for patients receiving prasugrel vs. clopidogrel across all TRILOGY patients (p<0.001for PRU at 30 days). Among all patients who underwent angiography, median platelet reactivity for those receiving prasugrel (n=334) was 70 PRU (interquartile range [IQR]: 36-132) vs. 199 PRU (137-257) for those receiving clopidogrel (n=335) at 30 days; p<0.001. In patients who underwent angiography, prasugrel was associated with lower platelet reactivity regardless of dose: among patients <60 kg who received 5-mg prasugrel (n=28), median platelet reactivity was 140 PRU (IQR: 93-128) vs. those receiving clopidogrel (n=31), who had a median of 209 PRU (168-258); patients ≥60 kg who received 10-mg prasugrel (n=306) had a median of 64 PRU (34-128) vs. those receiving clopidogrel (n=304), who had a median of 198 PRU (132-256). The rate of the primary endpoint was significantly lower among patients randomised to prasugrel vs. clopidogrel: hazard ratio (HR) 0.77; 95% confidence interval (95% CI) 0.61-0.98; p=0.031. Treatment effect was consistent among patients with minor coronary disease, including 0 (30%-50% maximal visual stenosis, any vessel) or 1 (>50% stenosis, 1 vessel) and 2-3 vessel disease on angiography: HR 0.76 (95% CI: 0.52-1.10) and HR 0.82 (95% CI: 0.60-1.11), respectively (interaction p=0.75). Among 617 patients with 3-vessel disease, the treatment effect was not apparent, but with a wide CI (HR 0.99 [95% CI: 0.67-1.46]). Crossover to treatment with PCI or CABG was infrequent at 7.4% and occurred at a median of 189 days (52-406).

Conclusions: As in the overall study, the TRILOGY angiographic substudy showed a consistently greater antiplatelet effect with prasugrel vs. clopidogrel, and the lower rate of the primary endpoint among patients who underwent angiography during the index ACS event is likely explained by the confirmed presence of coronary disease.

Coronary interventions – *Tuesday May 21st*
Unsettled issues with oral anti-platelet therapy: which one? How much? How long?

Comparison of clopidogrel and prasugrel in patients with unprotected left main disease treated with everolimus-eluting stents: insight from the Florence left main-PCI registry

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Aims: Randomised trials and registries have shown that everolimus-eluting stent performs better than first generation drug-eluting stent (DES). Prasugrel as compared to clopidogrel in acute coronary syndromes treated invasively is associated with improved clinical outcome and decreased risk of stent thrombosis. No data exist about prasugrel as compared to clopidogrel in patients with unprotected left main disease treated with everolimus-eluting stent. The aim of the study was to compare clinical outcome in patients receiving Clopidogrel or Prasugrel who underwent unprotected left main disease -PCI with everolimus-eluting stent.

Methods and results: From the prospective Florence left main PCI registry, consecutive patients receiving everolimus-eluting stent were included in the analysis. Antiplatelet treatment included clopidogrel until March 2010, while prasugrel was routinely used from April 2010. The end points of the study were cardiac mortality and stent thrombosis at 1 year of follow-up. Definite, probable and possible stent thromboses were defined according to the Academic Research Consortium criteria. From January 2004 to 2011, 192 patients underwent everolimus-eluting stent implantation for unprotected left main disease. Out of these 94 patients received clopidogrel and 98 received prasugrel. Patients on prasugrel therapy had a worse baseline risk profile than patients on clopidogrel, but these differences did not reach statistical significance: mean age 70±10 vs. 71±11 yrs, male 78% vs. 75%, diabetes 28% vs. 21%, acute myocardial infarction 15% vs. 8%, left ventricular ejection fraction <0.40 40% vs. 32%, renal insufficiency (creatinine >1.5 mg/dL) 15% vs. 8%, 3-vessel disease vs. 35% vs. 30%, EuroSCORE ≥13 31% vs. 21%. Procedural characteristics were similar in prasugrel group and clopidogrel group: left main stenting of both branches 30% vs. 28%, respectively, mean stent length (mm) 24±12 vs. 21±10, IVUS guidance 58% vs. 56%. One-year clinical outcome was significantly better in the prasugrel group as compared to clopidogrel group: cardiac mortality rate 2.0% and 8.5%, respectively (p=0.044), stent thrombosis rate 0 vs. 4.3% (p=0.039).

Conclusions: As compared with clopidogrel, prasugrel improves clinical outcome in all comers patients with unprotected left main disease receiving everolimus-eluting stent.

Coronary interventions – *Wednesday May 22nd*
Left main PCI for left main disease intervention: outcome in 2013

Long-term results of multivessel and left main coronary artery stenting in comparison with surgical revascularisation in patients with NSTE-ACS: the MILESTONE registry

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Aims: The optimal revascularisation strategy in patients with multivessel coronary artery disease (MVD) and unprotected left main coronary artery stenosis (ULMCA) presenting with non-ST acute coronary syndrome (NSTE-ACS) is unspecified. Therefore, we aimed to compare long-term outcomes after percutaneous (PCI) and surgical (CABG) intervention in this cohort

Methods and results: In this multicentre prospective registry, 4856 patients with non-ST elevation myocardial infarction (NSTEMI), unstable angina and MVD with or without ULMCA stenosis were included. Following cardiac team consensus 3033 patients underwent PCI with stent implantation (including 10.3% drug eluting stents) whereas 1338 were assigned for CABG. The follow-up on mortality was obtained at 3 years from all patients. In the overall population, patients assigned for PCI were younger (64.4±10 vs. 65.2±9 y.o., p=0.03), more frequently presented with NSTEMI (32.0 vs. 14.5% p=0.01), cardiogenic shock (1.5 vs. 0.7% p<0.01) history of prior PCI (13.1 vs. 5.5%; p<0.01) and CABG (10.6 vs. 4.6%, p<0.01). The Euroscore and TIMI risk score were slightly higher in PCI patients (5.36±2.3vs. 5.16±2.0 and 3.87±1.0 vs. 3.79±0.9 respectively, p<0.01). Patients consigned to CABG more often presented with triple and left main disease (82.2 vs. 33.8% and 13.7 vs. 2.4%; p<0.01). Otherwise, proximal LAD was more often revascularised with stenting (21.5 vs. 11.1%; p<0.01). After adjustment for differences in baseline risk factors (stand. diff. <5% in all variables, C-Statistic=0.82), 929 matched pairs were selected. Thirty day mortality was lower after PCI prior to matching (2.1 vs. 3.1%; p<0.01), whereas after balancing, the difference was not significant (2.5 vs. 2.8%; p=0.62). Three year survival was in favour of PCI when compared to surgery prior (87.5 vs. 82.8%, HR:1.44, 95%CI: 1.2-1.7, p<0.01) and after matching (86.4 vs. 82.3%, HR 1.33, 95%CI:1.05 - 1.7, p<0.01). Stenting was associated with significantly better outcome in the following subgroups: age>65, female gender, unstable angina, euroscore>5, TIMI risk score>4, DES and two vessel disease.

Conclusions: Basing on this large, propensity matched registry data, in patients with NSTE - ACS and MVD with or without ULMCA stenosis, stenting was associated with lower risk of mortality at long term follow-up. The subgroup analysis highlighted improved outcomes with PCI in high clinical risk cohorts.

Coronary interventions – *Wednesday May 22nd*
Left main PCI for left main disease intervention: outcome in 2013

Unprotected left main coronary artery intervention: in hospital and long-term outcome in a single large tertiary centre

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Aims: Percutaneous coronary intervention (PCI) is increasingly utilised for revascularisation in unprotected left main coronary artery (ULMCA) disease. Data of in-hospital and long-term mortality in this subset of patients remain sparse. We present our experience of ULMCA PCI, in a large tertiary cardiac centre.

Methods and results: This is a retrospective dataset, evaluating all ULMCA PCI performed in our centre between September 2003 and December 2011. In total there were 483 procedures performed with long-term mortality data available over a median duration of 21 months (IQR 10 months to 43 months). The patient cohort consisted of 58% with the diagnosis of non ST elevation acute coronary syndrome (NSTE-ACS), 17% with STEMI and 25% with stable angina. In-hospital and long-term mortality were 7% and 22% respectively. In-hospital mortality in the group of patients with STEMI, NSTEACS and stable angina were 23%, 6% and 1.6% respectively. Long-term mortality was highest in the subset of patients presenting with STEMI (31%), followed by NSET-ACS (26%) and stable angina (10%). The use of drug eluting stents (DES) [adjusted RR 0.40 (95% CI, 0.23-0.69)] and Intravascular ultrasound (IVUS) [adjusted RR 0.17 (95% CI 0.04-0.72)] were independently associated with improved long-term survival.

Conclusions: ULMCA PCI in a high volume PCI centre is associated with favourable long-term survival. The use of DES and IVUS guided PCI appear to have favourable effect to improve long-term outcome and should be considered in the routine management of this patient population. The results of ongoing randomised trials in LMS will help confirm the role of PCI in this group of patients.

Coronary interventions – *Wednesday May 22nd*
Left main PCI for left main disease intervention: outcome in 2013

The role of female sex in the contemporary treatment of the left main coronary artery: insights from the W- DELTA (Women- DES for left main coronary artery disease) Registry

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Aims: The aim of this study was to evaluate long-term clinical outcomes in a cohort of women treated with percutaneous coronary intervention (PCI) utilising drug-eluting stents (DES) vs. coronary artery bypass grafting (CABG).

Methods and results: All consecutive women from the Drug Eluting stent for LefT main coronary Artery disease (DELTA) Registry with ULMCA disease treated by PCI with DES or CABG were analysed. A propensity matching was performed to adjust for baseline differences between the 2 treatment groups. In total, 817 women were included: 489 (59.8%) underwent treatment with PCI with DES vs. 328 (40.2%) with CABG. Propensity score matching identified 175 matched pairs of patients, with no differences in all-cause (Odds Ratio [OR] 1.385; 95% Confidence Interval [CI] 0.684-2.802; p=0.365) or cardiovascular mortality (OR 0.909; 95% CI 0.376-2.199; p=0.832), myocardial infarction (MI) (OR 2.762; 95% CI 0.721-10.590; p=0.138) or cerebrovascular accident (CVA) (OR 0.833; 95% CI 0.250-2.783; p=0.767) resulting in no difference in the primary study objective of death, MI or CVA (OR 1.406; 95% CI 0.765-2.585; p=0.273), However, there was an advantage of CABG over PCI in major adverse cardiovascular and cerebrovascular events (MACCE) (OR 2.333; 95% CI 1.383-3.935; p=0.001), driven exclusively by target vessel revascularisation (TVR) (OR 5.403; 95% CI 2.315-12.610; p<0.001).

Conclusions: In women with significant ULMCA disease, no difference was observed in death, MI and stroke at long term follow-up. However, repeat revascularisation remained higher in the PCI cohort.

Safety in a very long term follow-up (>5 years) of a cut-off value of 6 mm² for the minimal lumen area of intermediate left main coronary artery lesions

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Aims: Clinical significance of intermediate left main (LM) coronary artery lesions remains nowadays an open issue. The LITRO study prospectively validated after a two-year follow-up period the value of 6 mm² for minimal lumen area (MLA) as a safety criterion to defer revascularisation. The aim of this study is to asses the safety of this cut off value in a very long term follow-up.

Methods and results: We included from 2000 to 2005 all patients with intermediate stenosis (30-60% stenosis) in unprotected LM where revascularisation was deferred due to a MLA greater than 6 mm². During that period 78 patients underwent IVUS examination and among those 47 (60%) showed an MLA >6 mm² and were not revascularised. The mean age was 62.5±10 years, 23.4% were diabetics, 63.8% had acute coronary syndromes and 76.6% of patients had lesions in other vessels. During a mean follow-up period of 8±3 years there were 5 cardiac deaths (10.6%), two sudden and three due to myocardial infarction (MI). The sudden deaths took place in a 64 years old male and a 65 years old male 2 years and 7 years after LM assessment respectively. The first one had multivessel disease with multiple drug-eluting stents implanted. Regarding the MI-related deaths, two of them occurred in octogenarian patients with non left main related MI and the remaining corresponded to a 68 years old male with stent thrombosis in other vessel and subsequent complications. Only 2 patients (4.2%) required LM revascularisation with surgery and PCI each, after two and six years from initial assessment respectively. Survival free of LM revascularisation at 5 years was 97.6%.

Conclusions: The MLA cut off value of 6 mm² in LM in order to decide whether to treat intermediate LM lesions seems to be a safe criterion in 5-year follow-up.

Coronary interventions – *Wednesday May 22nd*
Left main PCI for left main disease intervention: outcome in 2013

Primary PCI of unprotected left main: a single-centre experience

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Aims: Primary PCI of unprotected left main (LM) disease remains a challenge for interventional cardiologist with worst clinical outcome when compared to non-LM disease. Limited data are available on these patients. This study sought to evaluate in-hospital and long term clinical outcome of patients undergoing emergency percutaneous coronary intervention (PCI) for acute myocardial infarction due to a culprit lesion in unprotected left main coronary artery.

Methods and results: In this retrospective, single-centre, observational study, a total of 1259 patients were admitted between 2006 and 2011 with acute myocardial infarction and treated with primary PCI. Of these, 44 patients (3,5%) underwent emergency PCI to an unprotected left main coronary artery. Our population consist of 19 male and 15 female with a mean age was 71.6±15.1 years. Radial approach was used in 18 patients (40,9%). 68% of patients presented cardiogenic shock and twenty-three patients required IABP insertion. Regarding lesion subset 11 patients had ostium lesion and 33 patient presented a bifurcation lesion. Single stent strategy with provisional technique was performed in 20 patient and double stent strategy (crush in 7 patients and T-stenting in 6 patients) was necessary in 15 patients with DES implanted in 28 patients, BMS in 15 patients and one patient treated with POBA due to a stent restenosis. Periprocedural death occurred in 4 patients (9%) and overall in-hospital mortality was 29,5%. Survival rate at mean follow-up of 18.3±16.1 months was 50% (22 patients) and 10% experienced 6 months instent restenosis at angiographic follow-up.

Conclusions: Patients with acute myocardial infarction and unprotected left main stenosis are a high-risk subgroup with a substantial mortality, particularly if they present in advanced Killip Class. Our study demonstrate that in these patients, PCI is a feasible treatment option associated with reasonably good outcomes.

Coronary interventions – *Wednesday May 22nd*
MSCT: emerging indication in interventional cardiology

Coronary CT-guided invasive treatment strategy in patients with recent acute chest pain results from the CATCH trial

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Aims: We report results from the randomised, controlled trial CArdiac cT in the treatment of acute CHest pain (the CATCH trial). The aim was to test if a coronary CT angiography (CCTA) guided approach in addition to standard care in patients admitted on suspicion of acute coronary syndrome, but with normal electrocardiogram and biomarkers, could improve the positive predictive value (PPV) of standard diagnostic testing. Secondarily we aimed to assess clinical safety of CCTA in terms of intermediate term clinical events.

Methods and results: Of 612 patients assessed for eligibility, 446 patients (73%) were randomly assigned to a CCTA-guided strategy (223 patients) or standard care (223 patients), including a functional test. A luminal coronary stenosis >70% in any larger vessel or >50% in the left main, whereas for patients with CCTA stenoses between 50-70%, the stress test in combination with a clinical judgement was used. In the CCTA-guided group 42 patients (20%) were referred for invasive coronary angiography vs. 25 patients (12%) in the standard care group (p=0.02). Significant coronary artery stenoses were confirmed on ICA in 31 patients (15%) vs. 9 patients (4%) (p=0.0002), and 25 patients (12%) vs. 9 patients (4%) were subsequently revascularised in the two groups (p=0.004). PPV was 74% vs. 36% (p=0.002). Clinical events (cardiac death, myocardial infarction, unstable angina pectoris, revascularisation and readmission for chest pain), during 120 days of follow-up, were noted in six patients (2.8%) in the CCTA-guided group vs. 15 patients (6.9%) in the standard care group (p=0.05).

Conclusions: In patients with recent acute-onset chest pain, CCTA guided treatment strategy on top of standard care results in more appropriate coronary revascularisations and a low 120 days event rate, compared to standard care alone.

Coronary interventions – *Wednesday May 22nd*
MSCT: emerging indication in interventional cardiology

Geographic miss with aorto-ostial coronary stent implantation: insights from coronary computed tomography angiography

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Aims: Accurate positioning of aorto-ostial coronary stents is challenging using conventional 2D coronary angiography. Coronary CT angiography allows detailed anatomic imaging of implanted stents. We assessed the accuracy of aorto-ostial stent deployment using CT angiography.

Methods and results: 256-row CT angiography scans of patients who had undergone aorto-ostial stenting were analysed. We assessed the location of the proximal stent edge within an aorto-ostial landing-zone defined as within 1 mm of the aorto-ostial plane and compared the findings with angiographic review (2 experienced operators). Twenty-three stents (23 patients) were studied. On conventional angiography, complete lesion coverage was present in 95% of cases and optimal location of the proximal stent edge within the aorto-ostial landing-zone in 76%. However, CT angiography showed variation in the distance between the aorto-ostial plane and different aspects of the proximal stent edge (mean 2.0±1.3, range 0.3-5.0 mm). All aspects of the proximal stent edge were located within the aorto-ostial landing-zone in only 3 (13%) cases, with geographic miss in the remaining 87%.

Conclusions: Geographic-miss was common in aorto-ostial stenting and was underestimated by conventional 2D angiography. CT angiography is a useful tool which provides new insights into the assessment and follow-up of patients undergoing aorto-ostial stent implantation.

Longitudinal deformation of coronary stents: evaluation with multislice computed tomography

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Aims: Recent publications on longitudinal deformation of coronary stents have raised concerns about the safety of platinum chromium drug-eluting stents (PtCr-DES). This study sought to evaluate the longitudinal deformation of PtCr-DES compared with cobalt chromium drug-eluting stents (CoCr-DES) and stainless steel DES using 64-slice computed tomography as the primary image modality.

Methods and results: This study included stents that could have been potentially compressed by mechanical actions such as guiding catheter impingement, post-dilation, kissing balloon and/or IVUS after implantation. Exclusion criteria were: patients with contraindication to multislice computed tomography (impaired renal function, contrast media allergy), cases in which the stent length evaluation could be biased (atrial fibrillation, overlapped stents) and patients that did not consent. Finally, 45 stents (15 PtCr-DES, 15 CoCr-DES, 15 stainless steel DES) were evaluated 295±116 days after implantation by 2 experienced cardiologists. The primary endpoint (relative change in stent length) was compared with ANCOVA analysis with Bonferroni correction for multiple comparisons. Baseline characteristics did not differ between groups. One stent length measurement in the CoCr-DES group was not conclusive due to movement of the patient during the image acquisition. The relative length change was 4.0%±4.0% for stainless steel DES, 5.9%±6.9% for CoCr-DES and 6.6%±6.0% for PtCr-DES ($p>0.2$). Deformation >10% of nominal length was observed in 2 (13%) stainless steel DES, 3 (21%) CoCr-DES and 4 (26%) PtCr-DES (all $p>0.2$). After adjustment for nominal stent length, no differences were found ($p>0.2$). Moreover, no stent fracture was found.

Conclusions: Our study shows that longitudinal stent deformation in potentially compressed coronary stents is a relatively common phenomenon in all the studied platforms, rather than specifically associated to PtCr-DES.

Coronary interventions – *Wednesday May 22nd*
MSCT: emerging indication in interventional cardiology

Value of preprocedural multidetector computed tomography angiography in prediction of successful percutaneous intervention upon patients with chronic totally occluded coronary arteries

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Aims: Multislice Computed Tomography has demonstrated an increasing role in planning for the difficult procedure of percutaneous coronary intervention (PCI) upon coronary chronic total occlusions. Our study aimed to detect Multislice Computed Tomography findings that can predict outcome of PCI upon coronary chronic total occlusions.

Methods and results: 46 patients having chronic total occlusion (certain or likely) underwent multislice computed tomography before undergoing PCI. multislice computed tomography data regarding artery before chronic total occlusion, chronic total occlusion segment and artery after chronic total occlusion were all analysed in relation to procedure outcome and to approach outcome (ante or retrograde). Also the capability of multislice computed tomography to visualise side branches at chronic total occlusion site, proximal stump and artery distal to chronic total occlusion was compared to the capability of invasive coronary angiography to visualise these details. PCI succeeded in 31 (67.4%) patients and failed in 15 (32.6%) patients. Ostial location of chronic total occlusion (P=0.03) and smaller size of the artery distal to chronic total occlusion (P=0.02) were significantly associated with increased failure of procedure. Ostial location of chronic total occlusion (P=0.05), distal cap calcification (P=0.05) and smaller size of the artery distal to chronic total occlusion (P=0.05) were significantly associated with increased failure of antegrade approach. multislice computed tomography showed to be less sensitive than coronary angiography in visualisation of side branches at site of chronic total occlusion (sensitivity 88%) and chronic total occlusion proximal stump (sensitivity 85.7%) but it is efficient as coronary angiography in visualisation of the artery distal to chronic total occlusion (sensitivity 100%).

Conclusions: Ostial location of chronic total occlusion and smaller size of artery distal to chronic total occlusion increase total failures and antegrade failures. Distal cap calcification increase antegrade failure. Multislice computed tomography is less sensitive than coronary angiography in visualising side branches and proximal stump, while having same accuracy in visualising the artery distal to chronic total occlusion.

Coronary interventions – *Wednesday May 22nd*
MSCT: emerging indication in interventional cardiology

The characteristics of plaque in target lesion on cardiac computed tomography before PCI may be helpful to predict in-stent restenosis

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Aims: This study aimed to access relation between the characteristics of plaque in target lesion on cardiac computed tomography (CCT) and in-stent restenosis (ISR).

Methods and results: The study population comprised 217 patients (male 105, 48.7%, mean age 63.3 years) who performed the CCT before PCI. The patients were successfully treated with PCI with DES and performed follow-up angiography after above 6 months (mean follow-up duration: 338 days). We defined ISR as minimal lesion diameter (MLD)/ reference diameter (RD) <0.5. Of 217 patients treated with DES stent, 29 patients (13.3%) presented with a definite ISR. In clinical characteristics of the overall patients including 188 patients without ISR and 29 patients with ISR, the incidence of the ACS (44.8% vs. 22.6%, p=0.045) and prior MI (37.5% vs. 17.1%, p=0.023) are significantly higher ISR group than no-ISR group. There was no difference of angiographic characteristics including lesion location, chronic total occlusion, bifurcation, RD, MLD, degree of stenosis (DS), lesion length between ISR group and no-ISR group. Also, there was no difference of PCI characteristics including stent diameter, stent length, MLD and DS after PCI. The incidence of plaque in target lesion on CCT is 71.9% (no plaque: 28.1%, non-calcified plaque: 31.3%, mixed plaque: 32.3%, calcified plaque: 8.3%). The incidence of the mixed plaque on CCT is significantly higher ISR group than no-ISR group (69.0% vs. 26.6%, OR: 6.1, 95%CI: 2.6-14.4, p<0.001). However, there was no difference in non-calcified (27.6% vs. 34.0%, p=0.408) and calcified plaque (3.4% vs. 9.0%, p=0.479) on CCT. In multivariate logistic regression analysis, the mixed plaque on CCT was the independent predictor for ISR after adjustment for cardiovascular risk factors including age, sex, diabetes, hypertension, smoking, ACS, prior MI and left ventricular function estimated ejection fraction. (OR 7.7, 95%CI: 1.9-30.5, p=0.004)

Conclusions: The mixed plaque in target lesion on CCT before PCI may be helpful to predict ISR.

Coronary interventions – *Wednesday May 22nd*
From bench to cath lab: clinical implication of stent design

Point compression and stent longitudinal deformation: a novel clinically-relevant bench test comparing 6 contemporary stent designs

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Aims: Stent longitudinal deformation, an uncommon event most often occurring at the stent proximal end may lead to adverse clinical events. A previously published longitudinal deformation bench test applied force to the circumference of the proximal stent hoop, and measured the distance compressed. Different designs had different susceptibility to deformation. Those with fewer connectors between hoops were more susceptible to deformation, with the Element 2-connector design being the most susceptible, in keeping with clinical reports. This led to recommending the addition of further connectors to the Element platform. While this deformation test did provide novel insights, its major limitation was that clinically the force causing deformation is localised to part of the proximal hoop, rather than applied to the full circumference. We designed a new bench test that enables force to be applied to a point on the proximal hoop and used this test to compare 6 contemporary stent designs.

Methods and results: Each 3.0 mm diameter stent was deployed so that its distal end was fixed in the apparatus and its proximal 5 mm lay malapposed in a 3.5 mm tube. A narrow rod contacted a point on the proximal hoop for application of force. This rod was connected to an Instron universal testing machine so that force and compression distance could be measured. The 6 stent designs (5 examples of each) tested were the Vision (Abbott Vascular, Santa Clara, CA), MultiLink 8 (Abbott), Biomatrix Flex (Biosensors, Singapore), Integrity (Medtronic Santa Rosa, CA) Omega or Element (Boston Scientific, Natick, MA) and the new NG (Next Generation) Promus (Boston Scientific) that is the Element design with additional connectors between proximal hoops. With force applied to one point on the circumference of the proximal hoop, all hoops were pushed closer together with this effect most pronounced below the point of force application. In addition to this compression, those portions of hoops on the maximally compressed side may overlap, become malapposed and obstruct the lumen. The proximal end of the stent tilts so that struts on the opposite side to the compression point also become malapposed and obstruct the stentlumen. The Element design required the least force to be compressed 4 mm (0.38±0.06N) and the Biomatrix Flex the most (0.88±0.11N). The Integrity, Multi-Link 8, Vision and Promus NG required similar forces for compression especially up to 3 mm and these were less than for Biomatrix Flex and more than for Element. When a 0.5N force was applied, the Biomatrix Flex was compressed the least (1.30±0.15 mm) and the Element the most (4.28 mm) with the other 4 compressing a similar distance which was more than the Biomatrix Flex and less than Element.

Conclusions: Localised application of force to the proximal end of a stent caused least distortion to the Biomatrix Flex and most to the Element design. The redesigned Element with additional connectors between proximal hoops (NG Promus) has improved longitudinal strength compared with the Element design.

Stent apposition may be more important than stent type in preventing longitudinal stent deformation

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Aims: Longitudinal deformation of stents is a rare but potentially catastrophic complication with published studies of unconstrained stents showing intrinsic differences exist between stent designs. Stent apposition is thought to reduce the incidence of stent "catch" but may also have significant mechanical protective effects with embedding and friction forces improving stent longitudinal stability and this study attempts to quantitate the relative importance of stent apposition vs. stent type.

Methods and results: Five common stents (Multilink Vision, Multilink 8, Promus Element, Driver and Integrity) were examined. Stent size was 3/18 mm or closest length. As distinct from previous studies, stents were deployed within silicone tubes. Twelve of each stent type was tested such that 60 individual stents were used. Purposefully malapposed stents (3 mm stent in 4 mm tube) were compared to well deployed stents (3 mm stent post dilated to 3.5 mm in a 3 mm tube). Stents were compressed by applying a single point force to mimic clinical scenarios. A MACH 1 Micromechanical Testing Machine with a load cell was configured such that it would move at a constant velocity of 0.1 mm/s. Serial photographs of the stent were taken with a macro lens and the images analysed and combined with the time/load data from the load cell. Stent compression was expressed as a percentage of its original length. After testing the compliance of various tubes using IVUS measurements, a 3 mm lumen diameter with 1 mm wall thickness silicone tube with a compliance of 5.3%/100 mmHg (GeckoOptical) was selected to represent typical coronary arterial compliance. A similar 4 mm lumen diameter tube was used for the malapposed testing. Significant compression was seen in all malapposed stents. At lower forces, all stents compressed similarly other than Element, which was more vulnerable. Compression at 50 gm. was 46.7±8.8% (Element) vs. 18.6±2.8% (other 4 stents, p=0.003) and at 100 gm. was 74.6±1.4% vs. 34.8±6.8% (p=0.032). At 150 gm., however, the differences between the stents were considerably reduced. Stent apposition had a profound protective effect. At 50 gm, all stents compressed by <4%, which represented an approximate tenfold improvement for Element and a fivefold improvement for other stents. Similar results were seen at all forces and even at 150 gm., maximum compression for any stent was less than 10%. At all forces, there were no statistical differences between any stents including Element.

Conclusions: All stents are vulnerable to significant deformation at low forces when malapposed, with Element being twice as susceptible. Stent apposition has a profound protective effect and can reduce longitudinal deformation by as much as tenfold depending on the stent type. In this study, stent apposition was the predominant determinant of vulnerability to longitudinal deformation.

Improved arterial healing in response to a novel polyphosphazene surface-modified stent in swine

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Aims: The relative risk of thrombosis attributed to current generation drug-eluting stents although rare, is burdened by high mortality rates while restenosis remains the major limitation of bare metal stents. Polyzene®-F (PzF) (CeloNova BioSciences, San Antonio, Texas, USA) is an attractive candidate for improving stent patency as it represents a biocompatible and durable stent surface modification intended to resist thrombosis, improve endothelialisation, and minimise inflammation. The following study was designed to evaluate the safety profile of the COBRA PzF-surface modified coronary stent system compared to standard bare metal Multi-Link Vision in the swine model.

Methods and results: COBRA PzF surface-modified stents (n=33) were deployed in healthy pig coronary arteries in single and overlapping configurations with equal numbers of Multi-link Vision stents, which served as controls. Devices were harvested at 5, 28, and 90-days after whole heart perfusion-fixation at physiologic pressure and then processed in methylmethacrylate (MMA) resin before microtomy and staining. Histologic end-points included, vessel injury, neointimal growth, and arterial stent healing, specifically inflammation. Histomorphometric parameters at 5-days were comparable between test and control devices although the percentage of giant cells in COBRA PzF was significantly lower relative to Vision (19.52±6.00% vs. 29.45±9.18%, P=0.034). For 28-day single stents injury scores for COBRA PzF group were significantly lower than Vision (0.064±0.041 vs. 0.63±0.61, P=0.010). Neointimal area in COBRA PzF was also significantly less than Vision (1.49±0.29 mm^2 vs. 3.17±1.61 mm^2, P=0.031). Notably, none of the COBRA PzF stents showed granulomatous reactions unlike the 37.44±40.43% of struts observed for Vision. Overlapping 28-day COBRA PzF demonstrated similar reduction in neointimal growth (1.45±0.33 mm^2 vs. 2.85±0.65 mm^2, P=0.0008) and injury score (0.039±0.095 vs. 0.42±0.36, P=0.0495). Granulomatous reactions were again absent in COBRA PzF relative to 14.84±15.99% struts in Vision stents. Long-term 90-day results will be available at the time of presentation.

Conclusions: COBRA PzF surface-modified coronary stents deployed in single and overlapping configurations demonstrated significantly lower neointimal growth and inflammatory responses as compared to Multi-link Vision stents. Our results suggest that the PzF represent a promising new surface modification and when applied to the COBRA stent platform exhibits an improved safety profile.

Coronary interventions – *Wednesday May 22nd*
From bench to cath lab: clinical implication of stent design

Microstructure modifications of stent surfaces influence endothelial cell migration and substrate thrombogenicity

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Aims: Atherosclerosis and resulting cardiovascular disease are currently the most common cause of death and illness in the world. Dilatation of stenosed arteries combined with stent implantation is currently one of the most performed cardiovascular interventions, but requires a long-term therapy with anti-platelet agents to prevent stent thrombosis. Stents with microstructured surfaces should improve stent vascularisation, reduce thrombotic events and consequentially shorten the length of anti-thrombotic therapy.

Methods and results: Differently designed, 2-5 µm high elevations or hollows were lithographically etched on silicon plates, subsequently coated with silicon carbide. As controls, smooth silicon plates, bare metal substrates, and cell culture plastic were used. The migration of human umbilical vein endothelial cell (HUVECs) was assessed in a modified barrier assay using cell culture inserts (n=10). 8h/24h after cell seeding, inserts were removed and cell migration was monitored for 2, 20, 30, 40, 60, and 72 hours. Actin cytoskeleton was visualised with green phalloidin. Platelet concentrate or whole blood were incubated on the different surfaces in static and flow conditions to investigate surface thrombogenicity (n=10). For cell counting, P-selectin antibody conjugated with fluorescein was used. Images were taken with an incident light fluorescent microscope used for studies of non-transparent objects. Comparing different types of structured surfaces, improved endothelial cell migration over 72h was observed for 4-5 µm pillow-likestructures, whereas smaller spiky structures (2 µm), hollows, and smooth surfaces(i.e. smooth silicon plates, bare metal substrates)had a negative effect on endothelial migration. Moreover, substrate specific interactions between the tested endothelial cells and the structure relief could be detected. The thrombogenicity assays under static and flow conditions performed using whole blood and platelet concentrate showed that the platelet adhesion was reduced on larger structures as compared to smaller sharp-edged structures, hollows, or the smooth surfaces.

Conclusions: Different microstructured surfaces have strong influence on endothelial cell migration and platelet adhesion. These results open new possibilities to design stent surfaces which improve adherence and migration of endothelial cells, and inhibit thrombogenic processes.

Coronary interventions – *Wednesday May 22nd*
FFR in the real world

Clinical outcome of patients treated with angio-guided vs. FFR-guided CABG surgery

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Aims: Revascularisation is indicated with documented ischaemia or fractional flow reserve (FFR) ≤0.80 in case of angiographic intermediate stenoses. While FFR is well established for patients undergoing percutaneous coronary intervention, little is known for candidates to coronary artery bypass graft surgery (CABG). We aimed at investigating the long-term clinical outcome of patients undergoing Angio-guided vs. FFR-guided CABG.

Methods and results: Between 2006 and 2010, 627 consecutive patients treated with elective CABG were retrospectively included in this registry in the presence of at least one angiographically intermediate stenosis (50-70%). Patients were excluded if requiring concomitant valve surgery. Patients were divided into: a) Angio-guided (n=429) CABG group, in case no FFR was measured at the time of the pre-operative diagnostic angiogram; b) FFR-guided CABG group (n=198), in case at least one intermediate stenosis was measured by FFR, and grafted with FFR≤0.80 or deferred with FFR>0.80. Clinical endpoint was major adverse cardiovascular events (MACE) at 2 years, defined as the composite of overall death, myocardial infarction and target vessel revascularisation. There were no significant clinical differences between the groups. Rate of angiographic multivessel disease was comparable: Angio-guided group, n=404 (94%) vs. FFR-guided group, 186 (95%), p=0.722. In the FFR-guided group, rate of multivessel disease was significantly down-graded after FFR measurement to 86% (p<0.05 vs. before FFR); this was associated with lower number of grafts implanted (2.6±1.2 vs. 3.2±1.2, p<0.001) and lower rate of on-pump surgery (49% vs. 69%, p<0.001), compared to Angio-guided group. At 2 years, MACE was not significantly different between Angio-guided and FFR-guided group (16% vs. 12%, HR: 1.161, 95% CI. 0.741-1.821, p=0.984). Yet, compared with the Angio-guided group, the FFR-guided group presented significantly lower rate of angina CCS II-IV at the latest follow-up (47% vs. 31%, respectively; RR=1.50, p<0.001).

Conclusions: Measuring FFR in intermediate coronary stenoses prior to CABG is associated with a reduced number of grafts and improved symptoms without increasing the risk of MACE at 2 years.

Possible improvement of the SYNTAX score by individualised coronary angiographic area at risk assessment

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Aims: In the SYNTAX score the Leaman weighing factor is used for the evaluation of the left ventricular areas affected by the lesion. Taking the two main coronary circulation systems the scoring system orders predefined points to the segments of the coronary artery. Our aim was to create a more detailed analysis of the coronary types in order to find the area at risk precisely.

Methods and results: The coronary angiograms were analysed retrospectively from the data of 19 patients deceased from ST-elevation myocardial infarction. The Leaman factor and the result of an individualised coronary angiographic area at risk assessment called Holistic Coronary Care (HCC) software were compared with the extent of infarction found by the autopsy. With the consideration of the complementary distribution of the left anterior descending artery and posterior descendent branch as well as the right and the left coronary artery there were 3x4=12 circulation types registered in the HCC. The size of the supplied area by the software (standard 17-segment model) was compared to the size of the involved area according to the Leaman weighing factor. With regards to the individual circulation types in the HCC 0-64.7% of the left ventricle was ordered to the right coronary artery, 5.9-64.7% to the circumflex artery and 29.4-64.7% to the left anterior descending artery. Using the Leaman factor these values were 0 or 8.3%, 25 or 41.7% and 58.3%, respectively. Multivariate regression analysis showed significant correlation between the extension of the infarction detected by autopsy and the HCC segment number (r=0.78, p=0.0002), while there was no significant correlation with the Leaman factor (r=0.46, p=0.08).

Conclusions: With defining the individual circulation types with the HCC software it is possible to determine the left ventricular segments related to the lesion with better correlation than by Leaman weighing score. This area at risk determination can form a basis of the modification of the (functional) SYNTAX score.

Comparison of coronary anatomical stenosis and fractional flow reserve in ostial lesions

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Aims: Ostial lesion is difficult to evaluate stenotic significance by coronary angiography. Intravascular ultrasound (IVUS) and fractional flow reserve (FFR) may be helpful to assess whether the ostial stenosis is significant (FFR <0.80).

Methods and results: In 74 patients with angina who has ostial lesions with intermediate stenosis (30-70%) by coronary angiography, seventy-seven lesions were enrolled. The lesions were divided into large (50 lesions; reference diameter ≥3.0 mm) and small (27 lesions; reference diameter <3.0 mm) ostial lesions. In large ostial lesions, there were moderate correlations between FFR and minimum lumen area (MLA) (r=0.434, p=0.002), % plaque burden (r=−0.486, p<0.001) or % area stenosis (r=−0.462, p=0.001). And there was mild correlation between FFR and angiographic % diameter stenosis (%DS) (r=−0.287, p=0.043). Whereas in small ostial lesions, there was no correlation between FFR and MLA, % plaque burden or % area stenosis. There was a moderate correlation between FFR and %DS (r=−0.513, p=0.006). The best cutoff values for functional significance to discriminate between FFR <0.8 from ≥0.8 in large ostial lesions were %DS of 44% (Area under curve [AUC], 0.721; 95% confidence interval [CI], 0.573-0.871), % plaque burden of 67.4% (AUC, 0.798; 95% CI, 0.668-0.928) and % area stenosis of 50.5% (AUC 0.718; 95% CI, 0.663-0.981). In small ostial lesions, the best cutoff value was%DS of 54.5% (AUC, 0.771; 95% CI, 0.583-0.960). The cutoff value of the other measurements could not be found.

Conclusions: There were much more direct correlations between FFR and IVUS measurements in large ostial lesions than there were in small ostial lesions. Inevitably, the severity of small ostial lesions assessed by angiography can be overestimated in comparison with cutoff value of %DS in large ostial lesions.

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FFR in the real world

Relationship between IVUS parameters and post-DES FFR

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Aims: Intravascular ultrasonography (IVUS) determinants of post-stent fractional flow reserve (FFR) are not well recognised. This study aimed to assess the relationship between IVUS parameters and FFR after percutaneous coronary intervention (PCI).

Methods and results: IVUS and FFR measurements were performed in 101 lesions after successful PCI. Functionally suboptimal PCI was defined as ≤0.90 of post-stent FFR. Mean post-stent FFR was 0.91±0.06. Post-stent FFR ≤0.90 was observed in46 (45.5%) lesions. The 55 lesions with post-stent FFR >0.9 (54.5%) had larger proximal (9.2±2.9 mm^2 vs. 7.4±2.3 mm^2, p=0.001) and distal reference lumen CSA (7.4±2.7 mm^2 vs. 6.3±2.1 mm^2, p=0.017), and intra-stent lumen CSA (7.4±2.5 mm^2 vs. 6.1±1.7 mm^2, p=0.004) and lower proximal reference plaque burden (45±8.2% vs. 50±11%, p=0.017) than those with post-stent FFR ≤0.90. Post-stent FFR had weak correlation with proximal reference lumen cross sectional area (CSA) (r=0.388, p<0.001) and distal reference lumen CSA (r=0.204, p=0.041), proximal reference plaque burden (r=-0.255, p=0.010), and intra-stent lumen CSA (r=0.330, p=0.001). Meanwhile, post-stent FFR had no correlation with stent length (r=-0.178, p=0.075). On multiple logistic analyses, proximal reference plaque burden ≥50% was an independent predictor for functionally suboptimal PCI (odds ratio, 3.498; 95% confidence interval, 1.509 to 8.106).

Conclusions: Reference lumen CSA, intra-stent lumen CSA, and proximal reference plaque burden are associated with post-stent FFR. Insufficient FFR measured after PCI may reflect presence of residual disease in the proximal segment.

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FFR in the real world

Impact of the supply area on the FFR value in stable coronary artery disease

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Aims: The aim of this study is to assess the impact of the supply area on the fractional flow reserve (FFR) value.

Methods and results: A total of 296 lesions in 236 patients were assessed by quantitative coronary angiography and FFR. The supply area as percentage of left ventricle was estimated angiographically using a modified version of the Alberta Provivncia Project for Outcome Assessment in Coronary Heart Disease (APPROACH) score (3.25 to 47.75%). FFR <0.75 was seen in 93 (31.4%) of the overall 296 lesions. There was a positive correlation between minimal lumen diameter (MLD) and FFR (R=0.584, P<0.001), and negative correlation between lesion length and FFR (R= –0.306, P<0.001), and between supply area (modified APPROACH score) and FFR (R=-0.408, P<0.001). The independent determinants of functionally significant stenosis based on FFR were MLD (odds ratio [OR] 0.022; confidential interval [CI] 0.007-0.062; P<0.001), lesion length (OR 1.049; CI 1.020-1.079; P=0.001), and the supply area (OR 1.102; CI 1.068-1.137; P<0.001).

Conclusions: Not only the anatomical parameters of epicardial coronary stenosis but also its supply area affects the functional significance of coronary artery stenosis. Functional significance of coronary stenosis depends on the balance of the lesion severity and its supply area.

Effect of body mass index on angiographic outcomes in diabetic patients undergoing PCI using different DES

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Aims: Previous studies have suggested that obese patients might have better outcomes after percutaneous coronary intervention (PCI) than patients with a normal or low body mass index (BMI). The purpose of this study was to assess the effect of BMI on angiographic outcomes in diabetic patients undergoing PCI using different drug-eluting stents.

Methods and results: From November 2002 to March 2011, 8567 consecutive *de novo* coronary lesions were treated using drug-eluting stents (everolimus-eluting stent (EES); n=1934, paclitaxel-eluting stent (PES); n=1215, sirolimus-eluting stent (SES); n=5418). Angiographic follow-up was routinely performed 8 months after a successful procedure (follow-up rate was 81%). Patients were divided according to BMI into the normal BMI category (BMI of <25) and the higher BMI category (BMI of <25). Angiographic outcomes were compared among patients with the implanted stent types. In non-DM group, no significant difference between the BMI categories was observed with different drug-eluting stents. In DM group, the risk for restenosis in SES (HR 0.62, 95% CI 0.46-0.84) and PES (HR 0.55, 95% CI 0.32-0.92) were lower with higher BMI category than normal BMI category. In contrast, the risk for restenosis in EES (HR 1.36, 95% CI 0.73-2.58) was similar between the BMI categories.

Conclusions: BMI affects angiographic outcomes in diabetic patients treated with SES and PES but not in those with EES.

Coronary interventions – *Wednesday May 22nd*
Diabetes and coronary artery disease: a bad association!

Impact of the prevalence of diabetes mellitus on coronary plaque vulnerability assessed by integrated backscatter intravascular ultrasound in the Japanese population

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Aims: Diabetes mellitus (DM) is a well-established risk factor for coronary artery disease (CAD). However, little is known about relationship the prevalence of DM and coronary plaque vulnerability assessed by integrated backscatter intravascular ultrasound (IB-IVUS) in the Japanese population. We assessed the relations among DM and coronary plaque instability using IB-IVUS.

Methods and results: One hundred sixteen consecutive patients with stable CAD who underwent percutaneous coronary intervention were enrolled. Nonculprit coronary lesions with mild to moderate stenosis were measured by IB-IVUS. A total of 20 IB-IVUS images were recorded at an interval of 0.5 mm for 10 mm length in each plaque. Patients were divided into two groups: the DM groupand the non-DM group. Plaque volume (PV) and percentage of PV (%PV, 100×PV/Vessel Volume) in the DM group were significantly higher than those in the non-DM group (66.0±22.7 mm^3 vs. 56.8±21.2 mm^3, P=0.0278 and 42.5±9.7% vs. 39.0±8.8%, P=0.0453, respectively). Lipid volume (LV) and percentage of LV (%LV, 100×LV/PV) in the DM group were significantly higher than those in the non-DM group (28.9±15.5 mm^3 vs. 22.2±13.0 mm^3, P=0.0130 and 42.1±12.4% vs. 37.3±12.2%, P=0.0409, respectively). Furthermore, multiple regression analysis revealed that the prevalence of DM was independently associated with PV (p=0.0351), LV (p=0.0164) and %LV (p=0.0304) among IVUS parameters in addition to other metabolic factors.

Conclusions: Nonculprit coronary lesions in patients with DM are associated with more lipid-rich plaque content and a greater PV, suggesting that DM patients increased plaque vulnerability in the Japanese population.

Coronary interventions – *Wednesday May 22nd*
Diabetes and coronary artery disease: a bad association!

Angiographic comparison of biolimus-eluting vs. sirolimus-eluting coronary stents in patients with diabetes mellitus: the diabetes and DES V randomised angiography trial

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Aims: We aimed to compare angiographic and clinical outcomes after the implantation of biolimus-eluting (BES) and sirolimus-eluting (SES) stents in patients with diabetes.

Methods and results: We randomised 151 patients with diabetes and coronary artery disease to BES (n=78) or SES (n=73) implantation. Angiographic and clinical follow-up were assessed after 10 and 12 months, respectively. The primary endpoint was angiographic in-stent late luminal loss. Secondary endpoints included angiographic restenosis rate, the need for target lesion revascularisation (TLR) and major adverse cardiac events (MACE) defined as cardiac death, myocardial infarction, definite stent thrombosis, or TLR at 9-month follow-up. The 10-month quantitative coronary analysis have been performed and the statistical analyses are currently being performed. At 12-month clinical follow-up, MACE had occurred in 8 (10.5%) patients in the BES group and 9 (12.3%) patients in SES group (p=0.7233), and TLR was performed in 7 (9.0%) and 3 (4.1%) patients in the two groups (p=0.2434). Definite stent thrombosis occurred in 1 patient, and definite/probable stent thrombosis in 2 patients; both patients were treated with a BES.

Conclusions: In patients with diabetes, BES and SES had similar 12-month clinical outcomes. The results of the 10-month quantitative coronary analysis will be presented at the meeting.

Coronary interventions – *Wednesday May 22nd*
Diabetes and coronary artery disease: a bad association!

Effect of diabetes mellitus in new-generation DES including permanent and biodegradable polymer in real-world practice: 1-year clinical outcomes

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Aims: Diabetes mellitus (DM) is one of the major risk factors related to clinical adverse outcomes. The second-generation drug-eluting stents (DES) with permanent polymer have been shown the superiority in the safety and efficacy compared with the first-generation DES. Recently, new-generation biolimus-eluting stent (BES) with biodegradable polymer also have demonstrated promising results. But, there is lack of evidence of these DESs in diabetic patients. We aimed to evaluate 1-year clinical outcomes of new-generation DES according to the presence of DM in all-comer patients.

Methods and results: Consecutive 1940 patients were treated with everolimus-eluting stent (EES), zotarolimus-eluting stent resolute (ZES-R) or BES from Jan 2008 to Dec 2011. They were divided into 2 groups with or without DM. Primary endpoint was the device-oriented composite endpoint (DOCE), defined as a composite of cardiac death, target-vessel related myocardial infarction (MI) and clinically indicated target lesion revascularisation (CI-TLR). BES, EES and ZES-R were implanted in 357 (18.4%), 860 (44.3%), and 723 (37.3%) patients, respectively. In DM group, there was a high proportion of female, hypertension, chronic kidney disease, multivessel disease and SYNTAX score. Total number, diameter and length of stents were higher in DM group. DOCE was not different between 2 groups (8.6% vs. 6.2%, p=0.074). But, the occurrence of CI-TLR was significantly higher in DM group (2.9% vs. 1.0%, p=0.004).

Conclusions: One year clinical outcome of new-generation DES showed no difference of DOCE in patients with or without DM. But, the incidence of CI-TLR was still higher in diabetic patients.

Coronary interventions – *Wednesday May 22nd*
Diabetes and coronary artery disease: a bad association!

Biological efficacy of twice daily aspirin in type 2 diabetic patients with coronary artery disease

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Aims: Diabetes mellitus is associated with a high rate of events after ACS and PCI despite aspirin treatment. Once daily aspirin might not provide 24h stable biological efficacy in patients with diabetes. We compared the biological efficacy of the same daily dose of aspirin given either once or divided twice per day in a population of diabetic patients with previous coronary artery disease.

Methods and results: 92 consecutive diabetic patients with at least one criteria of time-dependent aspirin efficacy; elevated hs-CRP, fibrinogen, platelet count or active smoking, were prospectively included. Consecutive patients were randomly treated with 150mg aspirin daily given either once per day (150 mg morning) or twice per day (75 mg morning and 75 mg evening) in a crossover study. The main outcome was platelet reactivity measured by light transmission aggregometry triggered by arachidonic acid (0.5 mg/mL) at trough level, before morning aspirin intake. Platelet function analyser-100 was also performed to evaluate global reactivity on collagen membrane of platelet sensitised with epinephrine. Mean age was 64±10 years old, 85% of patients were male, 43% were treated by insulin. Time from diagnosis of diabetes mellitus was 12±3.6 years. Fifty two percent of patients were receiving both aspirin and clopidogrel and 47% were treated by proton pump inhibitors. Of the criteria qualifying patients as being at high risk of time-dependent aspirin efficacy, 27% of patients were current smokers, 46% had an hs-CRP >4 mg/L, 38% had fibrinogen >4 g/L and 36% had a platelet count >270 103/mm3. Thirty percent had two of these criteria, 15% had three and 7% four. There was no change in other treatment regimen between the two periods except aspirin regimen. The mean interval between change of aspirin treatment regimen and blood sampling was 10±2days. Patients had similar biological parameters at the time of the two blood samples. Mean maximal aggregation intensity measured by light transmission aggregometrytriggered by arachidonic acid was 19.7±15.4% on aspirin once per day and 11.9±10.4% on aspirin twice per day ($p<0.0001$). Biological resistance (maximal aggregation intensity ≥20%) was observed in 42% of patients on aspirin once per day and 17% on aspirin twice per day ($p<0.001$). Of the 39 patients with biological resistance on aspirin once per day, 24 (62%) overcame resistance on aspirin twice per day. Of the 16 resistant on aspirin twice per day, only one (6%) patient overcame resistance on aspirin once per day. Results were concordant with global evaluation of platelet reactivity by platelet function analyser-100. Mean closure time using platelet function analyser-100 with epinephrine was 225±83s on aspirin once per day compared to 241±77s on aspirin twice per day ($p=0.05$). We found 41% of patients with globally normal platelet reaction (closure time ≤193 s) on aspirin once per day and 29% on aspirin twice per day ($p=0.12$). A better twice per day aspirin efficacy was independent of clopidogrel co-treatment.

Conclusions: In a population of diabetic patients with coronary artery disease with either smoking or elevated inflammatory markers, the same daily dose of aspirin divided twice per day can significantly decrease the rate of biological resistance at trough level.

Coronary interventions – *Wednesday May 22nd*
Revascularisation strategies for multi-vessel disease patients: stents, bypasses or both?

Quantification of incomplete revascularisation and its association with five-year mortality in the synergy between PCI with taxus and cardiac surgery trial: validation of the residual SYNTAX score

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Aims: The recently developed residual SYNTAX Score is an objective measure of the degree and complexity of residual stenosis after percutaneous coronary intervention (PCI). We report the validation of the residual SYNTAX Score in the randomised SYNTAX Trial at 5 years.

Methods and results: In a *post hoc* analysis, the residual SYNTAX Score was assessed by calculating the SYNTAX Score immediately after the index PCI procedure (890/903, 98.6%). In the PCI arm, the mean baseline SYNTAX Score was 28.4±11.5. The mean reduction in the SYNTAX Score after PCI was 23.8±10.9. Post procedurally, the mean residual SYNTAX Score was 4.5±6.9. Following PCI, the residual SYNTAX Score was distributed as follows, 0 (n=386, 42.7%) i.e. CR, >0 to 4 (n=184, 20.4%), >4 to 8 (n=167, 18.5%), >8 (n=143, 15.8%). A residual SYNTAX Score >8 appeared to be a surrogate marker of increasing clinical co-morbidity (age, diabetes, peripheral vascular disease, poorer ejection fraction) and anatomical complexity (baseline SYNTAX score, total occlusions, bifurcations, diffuse or small vessel disease, heavy calcification and long lesions). A residual SYNTAX Score 10.0 was associated with a doubling of the hazard ratio (2) for 5 year all-cause death; corresponding residual SYNTAX Scores were 10.7 for all-cause death/myocardial infarction (MI)/cerebrovascular accident (CVA), and 11.3 for 5 year major adverse cardiac and cerebro-vascular events (MACCE). Five year clinical outcomes – including all-cause death, death/MI/CVA, MACCE and definite/probable stent thrombosis – were substantially increased in patients in the highest tertile of the residual SYNTAX Score (>8), with a more pronounced effect with a residual SYNTAX Score >12. Multivariate analyses indicated that the residual SYNTAX Score to be a strong indicator of long term mortality. Stratified analyses in the diabetic and left main subgroups will be presented.

Conclusions: The residual SYNTAX Score appears to be a powerful indicator of long term prognosis after PCI with DES in patients with left main or three vessel disease. The residual SYNTAX Score may aid determining a 'reasonable' level of revascularisation.

Coronary interventions – *Wednesday May 22nd*
Revascularisation strategies for multi-vessel disease patients: stents, bypasses or both?

Impact of complete revascularisation on long-term outcomes of percutaneous DES implantation for multivessel coronary artery disease according to left ventricular systolic function

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Aims: The importance of complete revascularisation in patients with multivessel coronary artery disease (MVD) remains unclear and contradictory. We sought to compare the impact of complete revascularisation (CR) with drug eluting stents (DES) on long-term outcomes in MVD patients according to left ventricular ejection fraction (LVEF).

Methods and results: A total of 1,593 patients who have undergone percutaneous coronary intervention (PCI) with DES and echocardiography between March 2003 and December 2010 were enrolled using a single-centre registry. CR was defined as the absence of diameter stenosis ≥70% in major epicardial coronary arteries or their branches with a diameter ≥2.0 mm after successful PCI. They were divided into 2 categories: LVEF ≥50% (n=1,330) and LVEF <50% (n=263). Primary outcome was all-cause death or MI. The secondary outcome was major adverse cardiac and cerebrovascular events (MACCE), including all-cause death, MI, any revascularisation, and cerebrovascular accidents. The median follow-up duration was 44 (interquartile range: 27 to 66) months. CR was achieved in 997 patients (62.6%), 63.7% of those with LVEF ≥50% and 57.0% of those with LVEF <50% (p=0.042). Patients with CR had lower rates of all-cause death or MI and MACCE (adjusted hazard ratio [HR] 0.73, 95% confidence interval [CI] 0.54-0.99, p=0.042 and adjusted HR 0.76, 95% CI 0.62-0.92, p=0.006). Among the patients with LVEF <50%, the long-term cumulative rate of all-cause death or MI was significantly lower in the CR group (CR vs. incomplete revascularisation, 19.3% vs. 32.7%, adjusted HR 0.52, 95% CI 0.30 to 0.93, p=0.028). However, the benefit of CR for the primary outcome was not observed in patients with LVEF ≥50%.

Conclusions: In patients with decreased LVEF, the achievement of complete revascularisation with DES reduces long-term mortality or MI.

Coronary interventions – *Wednesday May 22nd*
Revascularisation strategies for multi-vessel disease patients: stents, bypasses or both?

Acute and long-term impact of stent thrombosis and graft occlusion on clinical outcomes and mortality in the synergy between PCI with taxus and cardiac surgery trial: the SYNTAX trial at 5 years

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Aims: The acute and long term impact of stent thrombosis (ST) and graft occlusion (GO) on clinical outcomes and mortality has not been reported in the SYNTAX Trial.

Methods and results: The incidence of 5-year ST and GO, and their association with clinical outcomes, were analysed with Kaplan-Meier estimates, log-rank comparisons, and Cox regression in the PCI (n=903) and CABG (n=897) arms. ST and GO were defined using the study protocol definitions, Academic Research Consortium (ARC) definition for ST, and the newly devised 'ARC like' definition for GO (i.e. definite, probable or possible GO). On a lesion level basis, protocol defined ST (n=47, 72 lesions) more frequently occurred in the left main (14/72, 19.4%) and proximal coronary vessels (37/72, 51.4%). Protocol defined GO (n=32, 41 lesions) most frequently was reported with grafts anastomosed to the distal right coronary artery (17/41, 41.5%) and mid left anterior descending artery (LAD) (9/41, 22.0%). On a patient level basis, 5-year definite (or protocol defined) ST and GO did not significantly differ (definite ST: 6.8% [n=48/903], definite GO: 5.5% [n=32/897], p=0.34). Landmark analyses indicated significantly more definite ST within 30 days (definite ST: 2.7% [n=19/48, 40%], definite GO: 1.0% [n=6/32, 19%], p=0.033), but not >30 days - 5 years (p=0.78). The clinical events committee adjudicated definite ST (n=48) to be directly linked to 4 deaths (4/48, 8.3%), 11 MI (11/48, 22.9%), 23 all cause revascularisation (23/48, 47.9%), and 10 no clinical events (10/48, 20.8%). 17/48 definite ST (35.4%) were associated with 5-year mortality (median time to cardiac death 0 days, interquartile range 0-16 days, maximum 321 days). Definite GO (n=32) was directly linked to no deaths, 7 MI (7/32, 21.9%), 21 all-cause revascularisation (21/32, 65.6%), and no clinical event (4/32, 12.5%). Definite GO was not associated with 5 year cardiac mortality. Independent predictors of definite/probable ST <30 days included lack of post-procedural antiplatelet therapy, peripheral vascular disease and heavy calcification; and >30 days, any angiographically observed thrombus or trifurcation lesion. Independent predictors of definite GO included lack of left internal mammary artery graft to LAD, number of bypass grafts and lack of pre-procedural aspirin.

Conclusions: Although ST and GO had similar incidences at 5 years, the clinical impact of ST appeared greater, with a negative impact on short to longer term mortality. Newer generation DES, with proven reductions in ST, may have an impact in reducing mortality.

Comparison of conventional CABG vs. robotically enhanced minimally invasive hybrid revascularisation in patients with two vessel disease

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Aims: Latest guidelines suggest that surgical revascularisation may be preferable in case of significant disease of the left anterior descending- (LAD) plus one other coronary artery. Robotically enhanced minimally invasive bypass surgery (RE-MIDCAB) opened new frontier, especially for the revascularisation of the LAD. The aim of our study was to compare short- and long-term outcome after conventional CABG vs. hybrid-procedure consisting in RE-MIDCAB, combined with percutaneous coronary intervention (PCI) for the treatment of two-vessel-disease.

Methods and results: We investigated 246 patients with stable- or unstable angina, who had two-vessel-disease, including LAD and were candidates for CABG. Indication and strategy of revascularisation was defined by the heart team. Patients were divided into two groups, namely CABG vs. Hybrid group, regarding the chosen strategy. CABG group consisted of patients (n=166) where conventional surgery was performed with arterial grafting of the LAD and grafting of one other vessel with any kind of conduit. Hybrid group consisted of patients (n=80) where RE-MIDCAB was performed with arterial grafting of the LAD and additionally PCI of one other vessel was done. There were no significant clinical differences between the two groups, the median follow-up was 24 (21-24) months. Comparing the CABG group with the Hybrid group, during postprocedural hospital stay there was no difference in the combination of death and clinical myocardial infarction (MI) (n=5, 3% vs. n=3, 4%, respectively; RR: 0.80, p=ns), or in the composite of non-death/non-MI complications (n=68, 41% vs. n=28, 35%, respectively; RR: 1.17, p=ns). In the CABG group significantly lower postprocedural haemoglobin (Hb) levels (g/dL) were observed (10, 9-10 vs. 11, 10-12, respectively; p<0.001) result in higher relative loss of Hb (29%, 23-37 vs. 22%, 17-27, respectively; p<0.001). Postprocedural Troponin T (µg/mL) rise was significantly higher in the CABG group (0.19, 0.08-0.40 vs. 0.03, 0.01-0.07, respectively; p<0.001), suggesting higher operative myocardial damage. At 24-month follow-up there was no significant difference between CABG vs. Hybrid in major adverse cardiac events, defined as the composit of overall death, MI and target vessel revascularisation (n=18, 11% vs. n=10, 13%, respectively; HR: 0.615, 95% CI. 0.264-1.432, p=ns).

Conclusions: In patients with two-vessel-disease including LAD a less invasive, hybrid revascularisation (consisting in RE-MIDCAB plus PCI) can be proposed. This method is associated with a similar clinical outcome as conventional CABG, while avoiding sternotomy and also reducing periprocedural blood loss and myocardial damage.

The feasibility of transulnar approach for coronary intervention

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Aims: These days access for coronary angiography and intervention isincreasingly achieved via the radial artery in majority of centres to avoid the vascularcomplications of femoral access. This study was performed to evaluate the feasibility of transulnar approach for coronary interventions as an alternative to transradial approach.

Methods and results: A total number of 125 TUA procedures were performed if the patients have positive reverse Allen's test. All patients with negative reverse Allen's test and absent radial pulse were excluded from the study. The procedure was performed with small French sheaths and catheters in most cases under local anaesthsia. The sheaths were removed after the procedure and patients were discharged the same day in case of diagnostic procedure and the next day after PCI. The procedure site was inspected before discharge. We performed 125 coronary interventions by the TUA. There were 85 males (68%), aged 52±11 years. The success rate for the TUA was 83.2% (104/125 cases). The commonest reason for the failure of procedure was inability to insert the wire or spasm. Out of successful 104 cases, fifty-three procedures (51%) were diagnostic and 51 (49%) were therapeutic angioplasty procedures. Mostly small-sheath diameters were usually employed. For coronary angiography, most catheters (40/53, 75%) were 5 Fr or smaller. In terms of angioplasty procedures, 19% were performed with 5 Fr catheters and 81% with 6 Fr catheters. The left anterior descending artery was the target vessel in most of the cases (38%). A total of 69% of the treated patients received glycoprotein IIb/IIIa inhibitors. Local complications were noted in only 7 (6.7%) patients. There was no ulnar pulse loss. All the patients were asymptomatic at discharge.

Conclusions: The transulnar approach is suitable vascular route for both diagnostic and therapeutic coronary interventions and can be used as an alternative to transradial approach.

Coronary interventions – *Wednesday May 22nd*
Radial access: anything new?

Additional protection equalises operator radiation dose by using left radial to standard femoral approach during coronary angiography

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Aims: The radial approach has many advantages in comparison to the femoral one, the disadvantage is a higher radiation level. The aim is the comparison of a radiation dose by using a left radial approach (LRA), LRA with an additional protection (LRA-P) and a femoral approach (FA).

Methods and results: We randomly evaluated 444 patients undergoing coronary angiography by 3 experienced operators (each operator performing more than 300 LRA coronary angiography per year). All procedures were performed in the same angiographic room with a flat-panel angiographic detector Philips Allura Xper FD 10. LRA according to our experience is effective with a very low need for conversion to FA (around 1%). In comparison to the right radial approach (RRA) by LRA the access to coronary vessel is more similar to FA and tortuosity in central part is less frequent and at the same time the LRA and RRA radiation dose is not different. The studied group was divided into 3 subgroups – LRA (n=145), LRA-P (n=149) and FA (n=150). An operator radiation dose was measured by an electronic radiation dosimetr Canberra Dosicard/E attached to the outside breast pocket of the lead apron. In all cases standard shielding was applied it means a lead apron (or a lead vest and a skirt), a thyroid lead collar, lead glasses, an upper lead acrylic shield with flexible radiation protective flaps, low leaded flaps and a table mounted lower body side shield with a pivot arm. Except from the standard shielding an additional lead drape over a patient´s abdomen and legs in part of patients by LRA was used (LRA-P). LRA, LRA-P and FA radiation dose by each procedure was compared. There were no differences in gender (male in LRA 68%, LRA-P 67% and FA 61%), body-mass index (LRA 29.3±4.8 kg/m2, LRA-P 28.4±4.2 kg/m2 and FA 29.4±5.4 kg/m2), patients with FA were older (LRA 66.1±10.0 vs. FA 70.3±10.7 y, p=0.001 and LRA-P 66.8±9.9 vs. FA 70.3±10.7 y, p=0.011). Despite the same fluoroscopy time, the radiation dose was higher by LRA comparing to FA (LRA vs. FA fluoroscopy time 4.0±4.8 vs. 4.3±5.0 min, p=0.598, dose equivalent 9.6±10.4 vs. 3.9±4.8 µSv, p<0.0001). By catheterisation with an additional protection the radiation dose by LRA significantly decreased (LRA vs. LRA-P fluoroscopy time 4.0±4.8 vs. 3.8±3.6 min, p=0.127, dose equivalent 9.6±10.4 vs. 3.9±3.8 µSv, p<0.0001). With additional protection LRA radiation dose equalised FA (LRA-P vs. FA fluoroscopy time 3.8±3.6 vs. 4.3±5.0 min, p=0.599, dose equivalent 3.9±3.8 vs. 3.9±4.8 µSv, p=0.364).

Conclusions: Despite the same radiation time the operator radiation dose during coronary angiography by LRA is much higher in comparison to standard FA. By using the additional protection with lead drape the radiation dose by LRA is diminished to the same level as by FA.

Coronary interventions – *Wednesday May 22nd*
Radial access: anything new?

Universal guiding catheter during radial primary PCI for STEMI improves efficacy and reperfusion time

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Aims: Radial primary percutaneous coronary intervention (Rppci) improves safety through bleeding reduction but is technically more demanding and may be more time consuming. The use of a single universal guiding catheter could shorten the procedure and decrease reperfusion time. To investigate the efficacy of an universal guiding catheter during Rppci.

Methods and results: Retrospective, single-centre analysis of 610 STEMI patients who had Rppci via the right radial artery using a universal guiding catheter [Ikari 3.5-4/ Terumo (77 patients)] for both diagnosis and intervention. These patients were compared to 533 STEMI patients who had conventional catheterisation using separate diagnostic and interventional guiding catheters. Demographic, clinical, angiographic and therapeutics variables were studied. End points were: Door to device time, angiographic success rate, TIMI grade III flow, fluoroscopy time and volume of dye. Both groups were similar in terms of age (58±12 vs. 57±12), male gender (83% vs. 82%), risk factors, admission blood pressure (120±16 vs. 117±20 mmHg) as well angiographic aspects and therapeutics aspects including use of direct stenting (68% vs. 59%, p=0.08) and aspiration devices (40% vs. 46%, p=ns). The universal guiding catheter cohort demonstrated shorter door to device time (85±40 vs. 101±60 min, p=0.01), shorter fluoroscopy time (9.7±6 vs. 12.8 min, p=0.02) and smaller volume of contrast (116±57 vs. 139±60 cc., p<0.01). Angiographic success rate (96% vs. 92%) and rate or TIMI flow III (93% vs. 93%) was similar in both groups.

Conclusions: The implementation of an strategy of unique, universal guiding catheter for diagnosis and therapy during radial primary PCI could improve the efficacy of this approach. Prospective evaluation of this approach is needed.

Is the radial artery suitable for recatheterisation? Results from a prospective registry

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Aims: Transradial approach (TRA) has become increasingly common for coronary angiography and intervention (CA/PCI) and a wealth of knowledge exists about its feasibility. Nevertheless radial injury and occlusion do occur and little is known about the success rate with its repeated use. Evidence of a long lasting use of the TRA might encourage a shift toward this access route. We aimed to evaluate the feasibility of a second TRA its predictors of failure.

Methods and results: In a dual centre prospective registry from January 2009 to October 2012, 6392 patients (median age 66, interquartile range 16; 67% male; 37% due to ACS) who underwent a first procedure (36% PCI) by right TRA were identified; the crossover rate to another access was 5.8%. During the study period, a second TRA was performed in 686 of these patients in whom the interventionalist's clinical assessment wasfavourable; the crossover rate to another access was 6.9% and similar to the first TRA (Chi-square p=0.267). Three independent predictors of failure in the latter group were identified by binary logistic regression, with the following adjusted odds-ratio (95% confidence interval): female sex 3.67 (1.98-6.8), use of 10 cm (vs. 25 cm) introducer sheath 3.52 (1.73-7.16) and previous valvular surgery 3.02 (1.06-8.61). No differences with statistical significance were observed regarding advanced age, low body surface area, need for intervention or smaller sheath diameter.

Conclusions: A second transradial approach is as feasible as the first. The use of shorter sheaths, female sex and previous valvular surgery patients reduce success in subsequent radial access.

Coronary interventions – *Wednesday May 22nd*
Radial access: anything new?

Safety of early discharge after transradial stenting of coronary arteries

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Aims: Access for coronary angiography and intervention is increasingly performed via the radial artery in majority of centres to avoid the vascular complications of femoral access. This study was performed to evaluate the feasibility of same day early discharge after transradial percutaneous coronary intervention.

Methods and results: Non-probabilty purposive sampling was used and total number of 400 patients were enrolled. They underwent transradial intervention who had non-ischaemic Allen's test. Patients with negative reverse Allen's test and absent radial pulse were excluded from the study. The procedure was performed with small French sheaths and catheters in most cases under local anaesthsia. The sheaths were removed after the procedure and patients were discharged the same day after PCI. The procedure site was inspected before discharge. The patients were followed after 6 months for major adverse cardiac events. Out of 400 enrolled patients, ninety percent patients underwent single vessel PCI and 10% had multivessel PCI. Four hundred and forty vessels (1.1 per patient) were treated using 440 stents (1.1 per patient) with mean (SD) size of 3.0±0.5 mm. Twenty three patients (5.75%) underwent balloon inflation alone; 5 for in-stent restenosis and six optimal results with balloon only in small vessels (<2.5 mm). Most of the patients underwent PCI through right radial artery approach and 6 French system was most commonly used. Periprocedural myocardial infarction (on ECG criteria) occurred in four patients, all admitted to hospital (1%). No readmissions, deaths, need for emergency CABG or haemorrhage requiring transfusion occurred in the 12 hours following PCI. Same day discharge occurred in 342 patients (85.5%). Reasons for non-discharge included a suboptimal result requiring prolonged in hospital monitoring (n=9, 2.25%), use of abciximab (n=29, 7.25%), and puncture site haematoma (n=20, 5%). The response rate to the follow-up was 360/400 (90%). At a mean of six months, the reported overall MACE rate was 8.5%: repeat PCI 5%; CABG 2%; myocardial infarction 1%; death 0.5% (two patients; which developed severe chest pain at home and were received dead in emergency).

Conclusions: Same day discharge after transradial PCI is as safe and feasible strategy as transradial approach, reduces access site complications and allows early mobilisation thereby decreasing burden on hospital resources.

Coronary interventions – *Wednesday May 22nd*
Coronary intervention in the elderly population

Efficacy of prasugrel in elderly patients undergoing PCI

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Aims: It has been documented that prasugrel is able to provide net clinical ischaemic benefit in acute coronary syndrome patient undergoing percutaneous coronary intervention. However, in patients older than 75 years prasugrel have shown less clinical efficacy and higher risk of bleeding than in the overall cohort. In patients older than 75 years, prasugrel is generally not recommended, but a dose of 5 mg should be used if treatment is deemed necessary. There are only few data about residual platelet reactivity with prasugrel in elderly patients. The aim of this study was to compare, in patients undergoing percutaneous coronary intervention, the platelet reactivity during prasugrel therapy in elderly and non elderly patients.

Methods and results: Consecutive patients undergoing percutaneous coronary intervention treated with prasugrel (manteinance dose of 5 mg for elderly and 10 mg for non-elderly patients) were included in the study. Platelet reactivity was evaluated by light transmission aggregometry using adenosine diphosphate 10 mmoL as agonist. High on treatment platelet reactivity was defined as test result ≥70%. Of 718 screened patients, 228 (32%) had ≥75 years and 490 (68%) had <75 years. Elderly patients were more frequently of female gender (32% vs. 16%, p=0.0001), hypertensive (76% vs. 63%, p=0.0001) and with chronic kidney insufficiency (19% vs. 7%, p=0.0001) as compared with non elderly; while smoking habits (6% vs. 66%, p=0.0001) was more frequent in non elderly group. Residual platelet reactivity was 47±18% and 36±16% in the elderly and non elderly group, respectively (p=0.001). High residual platelet reactivity was found in 10.5% and 1.9% patients (p=0.0001); while extremely low residual platelet reactivity (<40%) was found in 39% and 61% patients (p=0.0001) elderly and non elderly group, respectively. There was no difference in in-hospital mortality, acute stent thrombosis, reinfarction and major bleeding between the two groups but a higher rate of minor TIMI bleeding (5% vs. 1%; p=0.0001) in elderly as compared with younger group. Age resulted the stronger predictor of high platelet reactivity (HR 1.117 [1.061-1.176]; p<0.0001) and at the same time independently associated with bleeding events (HR 1.061 [1.001-1.124]; p<0.045) at multivariable analysis.

Conclusions: Elderly patients are more likely to experience high residual platelet reactivity during prasugrel therapy than younger patients. Despite the use of a reduced prasugrel mantenance dose and higher level of residual platelet reactivity by functional test, elderly patients show increased risk of bleeding during prasugrel therapy as compared to younger patients. Thus, in elderly patients bleeding risk is not entirely attributable to platelet function.

Coronary interventions – *Wednesday May 22nd*
Coronary intervention in the elderly population

A comparative analysis of cardiovascular and frailty prognostic risk scores in patients with ACS. The STORM study

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Aims: Nowadays prognostic scores (GRACE, ACEF) are widely used and validated to stratify acute coronary syndrome (ACS) patients' risk, but they cannot guarantee an optimal prognostic assessment because of their cardiovascular selectivity and the uncertainty concerning their applicability in patients with an heavy burden of frailty (e.g. advanced heart failure, cancer). It has been decided, therefore, to integrate this evaluation with the "Gold Standards Framework" (GSF) score that best characterises the patients at issue, and with the "World Health Organization Quality Of Life (WHOQOL-BREF) score, for an additional analysis of the quality of life. STORM (acS in paTients end Of life and Risk assessment study) objective is to clarify the GSF and WHOQOL predictive properties related to frail, elderly and end of life patients.

Methods and results: All consecutive unselected ACS patients admitted between May and July 2012 in the Emergency Department at S. Giovanni Battista's hospital (Molinette) have been initially screened in this observational perspective study. The primary endpoint has been defined as the composite of cardiac death (defined as arrhythmic or due to heart failure or ACS) and re-hospitalisation for ACS at 1 and 6 months from discharge. The individual components of the primary endpoint, death from all causes, discharge at home or at nursing home, being at home or in nursing home at 6 months, have been the secondary endpoints. 156 patients have been included with a median age of 71±11.78 years, 63.5% being male. During the 30 days follow-up 10 patients died. Another 10 were re-hospitalised for ACS or heart failure. Prognostic risk scores assessment has highlighted that the majority of deceased patients both for cardiac causes (30% vs. 0.7%; p<0.0001) and for all causes (60% vs. 2.8%; p<0.0001) had a positive GSF score. Dead patients happened to have a lower WHOQOL score however this difference is not statistically significant (88.3±12.7 in the living group vs. 79.25±10.5; p=0.09) moreover 10.2% of non cardiac death had a score <89 (median of all the scores) vs. 1.9% >89 but with a p=0.074. Multivariate analysis has showed that positive GSF score is significantly predictive with an Odd Ratio of 12.97 (IC 2.97-51.67; p=0.011) and with a AUC in the ROC analysis of 0.78 (0.71-0.85) for all the events.

Conclusions: The present study showed that GSF risk score is a useful tool to integrate prognostic evaluation in elderly ACS patient with frailty and comorbidities in order to better address them to an invasive or a conservative treatment pathway. The relatively small number of patients and the short follow-up require further investigations to effectively validate these promising results.

Everolimus-eluting vs. bare metal stent in octogenarians: the XIMA trial. Results at one-year follow-up

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Aims: There is scarce data on interventional outcomes with drug-eluting stents (DES) in octogenarians. The coronary substrate for revascularisation is more likely to be complex, suggesting that DES should be advantageous, but bleeding risk is increased in prolonged course of dual antiplatelet therapy.
Methods and results: We designed a multicentre international randomised comparison of everolimus-eluting stent (EES) and bare-metal stent (BMS) in octogenarian patients with complex coronary disease. Patients with STEMI were excluded. Primary outcome was the combined of death, infarction, TVR, stroke and major bleeding (TIMI) at one year. 800 patients were recruited in 22 centres across the UK and Spain. The patients were well matched between the 2 groups. A 68% of patients were treated after and ACS. Recommended dual antiplatelet therapy period was 1 month after BMS and 12 months after EES. There was no significant difference in the primary endpoint at 1 year, 18.7% in the BMS group and 14.5% in the EES group (p=0.09). Death rate was equivalent (7.2% in BMS vs. 8.5% in EES; p=0.5), however the rate of MI and TVR were lower in the EES group, MI 4.3% vs. 8.7% (p=0.01) and TVR 2.0% vs. 7.0% (p=0.009). The major bleeding rate was comparable 1.7% in BMS and 2.3% in EES group (p=0.6). In subgroup analysis EES was more beneficial in males, 85-90 yrs, stable angina, 2-vessel disease and radial access.
Conclusions: This trial has shown at 1 year no difference in mortality between groups, similar rates of major haemorrhage in both groups and significantly lower rates of target vessel revascularisation and myocardial infarction among DES-treated patients.

Coronary interventions – *Wednesday May 22nd*
Coronary intervention in the elderly population

Radial vs. femoral accesses for PCI in octogerians with ACS

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Aims: The purpose of this observational study was to evaluate the prognostic effects of radial artery access (RA) vs. femoral artery access (FA) in octogenarians undergoing percutaneous coronary intervention (PCI) due to acute coronary syndrome, i.e. ST-elevation myocardial infarction (STEMI) and unstable angina/non-STEMI (UA/NSTEMI).
Methods and results: Data were obtained from the SCAAR registry (Swedish Coronary Angiography and Angioplasty Registry) for PCI procedures performed in Västra Götaland region in Sweden between 2005-2011. We evaluated combined endpoint consisting of 30-days mortality and in-hospital complications (stroke, bleeding, infarction, renal insufficiency, urgent revascularisation, ventricular arrhythmias) in 1447 patients ≥80 years of age. PCI was performed through RA in 540 patients and FA in 907 patients. Adjustments for differences in baseline characteristics were made with propensity score. The following variables were included in the calculation of the propensity score: age, gender, indication for PCI, smoking habits, hypertension, diabetes, hyperlipidaemia, severity of coronary artery disease, previous infarction, previous PCI, previous coronary artery by-pass surgery (CABG), anticoagulation therapy with glycoprotein IIb/IIIa receptor antagonists (GP IIb/IIIa), bivalirudin, clopidogrel, unfractionated heparin/low-molecular weight heparin (UH/LMWH), year, hospital. There were 595 patients (41.1%) with STEMI and 852 (58.9%) with UA/NSTEMI. The combined end point occurred in 212 patients of which 114 (54%) were deaths. The mean age was 83.4±3.2 and 83.5±3.1 in the RA and FA group respectively (p=0.51). The two groups were balanced regarding gender, diabetes, smoking habits, hypertension and hyperlipidaemia and in use of UH/LMWHand drug-eluting stents. RA patients were more likely to be pre-treated with aspirin, clopidogrel and to receive bivalirudin. FA patients were more likely to had previous myocardial infarction, previous PCI, previous coronary CABG and to receive GP IIb/IIIa. More patients with STEMI underwent PCI through FA. Unadjusted combined endpoint was lower in the RA group (OR=0.68; 95% CI 0.53 - 0.87; p=0.02). However, no difference was found between the groups after adjustment with propensity score (OR 0.96; 95% CI 0.67-1.37; p=0.81).
Conclusions: In this study, PCI through radial artery access was not associated with reduced combined endpoint at 30-days in octogerians with acute coronary syndromes. Properly designed randomised clinical trials are needed to test whether radial artery is superior to femoral artery access in octogenarians with acute coronary syndromes in regard to major adverse cardiovascular events.

EuroPCR | **Coronary interventions** – *Wednesday May 22nd*
Coronary intervention in the elderly population

Clinical course after PCI for ACS in elderly patients in Japan

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Aims: Japan is the most aging society in the world. We verify the effectiveness and safety of PCI for ACS of elderly people compared to non-elderly people in Japan.

Methods and results: We analysed all 569 ACS patients coming to our hospital from 2005 till 2010. 169 patients (29.7%) were above 75 years old (79.9±3.9 [SD] years old). According to ARC definition, MACCE composite endpoint was defined (death of any cause, cerebrovascular disease, recurrent myocardial infarction and revascularisation). In ACS setting, the percentage of AMI was low in elderly patients (elderly vs. non-elderly=37.9 vs. 49.5%, p=0.011). As clinical background, comorbidity of hypertension was high (87.6 vs. 78.3%, p<0.010) and that of dyslipidaemia was low (59.2 vs. 77.8%, p<0.010). Elderly patients tended to be anemic (haemoglobin=11.7±1.8 vs. 13.6±2.1 g/dL, p<0.010) and had worse renal function (glomerular filtration rate=55.3±24.7 vs. 72.2±30.8 mL/min/1.73 m^2, p<0.01). DES usage was more frequent in elderly patients (elderly vs. non-elderly=65.3 vs. 53.6%, p=0.015) with smaller stent diameter (3.05±0.66 vs. 3.22±0.67 mm, p=0.010). Total stent length was not significantly different (24.0±18.7 vs. 23.1±14.3 mm, p=0.53). In 554±504 days of observation, 207 events were counted as MACCE in all ACS patients. In Kaplan-Meier analysis, MACCE-free rate of both groups did not have the statistical difference (mean survival time: elderly vs. non-elderly=1278.4 vs. 1244.6 days, log-rank test: p=0.60). When Kaplan-Meier analyses were performed for each item in MACCE, still there was not a significant difference for all items including death of any cause. Complications related to PCI happened only in two non-elderly patients (cerebral infarction and coronary artery perforation by guide wire).

Conclusions: As far as we analysed our hospital data, clinical course after PCI for ACS in elderly patients was not worse than non-elderly patients, so age seems not to be a reason to defer PCI for ACS.

EuroPCR | **Coronary interventions** – *Wednesday May 22nd*
FFR are we working with the best threshold

Deferred lesion intervention of coronary lesions deferred for borderline vs. non-borderline FFR values

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Aims: Current evidence supports deferral of percutaneous coronary intervention (PCI) for intermediate severity coronary lesions with fractional flow reserve (FFR) values >0.80. The real world natural history following deferral of PCI of intermediate lesions with borderline FFR values (0.81 to 0.85) is unknown. We evaluated the incidence of deferred lesion intervention during long-term follow-up of patients following FFR-guided deferral of intermediate lesions with FFR values of borderline vs. non-borderline significance.

Methods and results: We retrospectively identified 674 patients at our centre with 816 intermediate severity coronary lesions that underwent FFR assessment from 10/2002 to 7/2010 and had deferral of PCI based on FFR. Patients were divided into those with borderline (0.81 to 0.85) vs. non-borderline (>0.86) FFR values. Any subsequent PCI or coronary artery bypass grafting (CABG) of a deferred lesion during long term follow-up was classified as a deferred lesion intervention. Patient/lesion characteristics and rates of deferred lesion intervention were compared between lesions with borderline vs. non-borderline FFR values using univariate and Cox-proportional hazards analyses. Clinical diagnoses for patients undergoing lesion assessment included: unstable angina (40%), stable angina (37%), acute myocardial infarction (10.6%), and other clinical indications (13%). The mean FFR value for deferred lesions was significantly lower for lesions with borderline (n=275) vs. non- borderline (n=541) FFR values (0.83±0.01 vs. 0.91±0.03; p<0.001). There were no significant differences in discharge medications following FFR assessment between patients with borderline vs. non-borderline FFR lesions. During a mean follow-up of 4.6±2.1 years, 144 deferred lesions (17.6%) underwent deferred lesion intervention by PCI (n=107) or CABG (n=37). Intervention of a deferred lesion was performed significantly more frequently for lesions with borderline FFR values compared with non-borderline FFR values (24.0% vs. 14.4%; p=0.004). Lesions with a borderline FFR were associated with a higher risk of deferred lesion intervention compared with lesions without borderline FFR values (HR 1.72, 95% CI 1.24-2.39; p=0.001).

Conclusions: In patients with intermediate severity coronary lesions where PCI is deferred due to negative FFR assessment, lesions with a borderline FFR (0.81 to 0.85) were associated with a higher risk of deferred lesion intervention compared with lesions with a non-borderline FFR (>0.86). Further study is needed to refine the management of coronary lesions with a borderline FFR value.

Physiological lesion severity assessment: the effect of cut-off value definition for the classification of intermediate coronary lesions

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Aims: We sought to determine the effect of using a clinical (equivalent to a 0.80 FFR cut-off value), compared with an ischaemia-derived cut-off value for the identification of lesion-specific myocardial ischaemia.

Methods and results: A total of 232 patients with stable coronary artery disease were included. All patients underwent myocardial perfusion scintigraphy prior to coronary angiography according to a two-day stress-rest protocol, which was considered positive when a reversible perfusion defect was allocated to the perfusion territory of the coronary artery of interest. During coronary angiography, intracoronary pressure and flow velocity were measured distal to 299 lesions by means of separate sensor-equipped guide wires. Hyperaemia was induced by an intracoronary bolus of adenosine (20-40 μg). The stenosis resistance index was defined as the ratio of stenosis pressure gradient to distal flow velocity, and was determined during basal (basal stenosis resistance index (BSR)), as well as hyperaemic (hyperaemic stenosis resistance index (HSR)) conditions. FFR was defined as the ratio of distal coronary pressure to aortic pressure during hyperaemia. HSR>0.80 mmHg · cm^{-1} · sec was considered positive. Lesion-specific myocardial ischaemia was defined as the combination of a positive myocardial perfusion scan, and a positive HSR. Receiver operating characteristics (ROC) curves were used to determine the optimal ischaemia-derived cut-off values for BSR and FFR as the cut-off values with the highest sum of sensitivity and specificity for myocardial ischaemia identified by the reference standard. The optimal 'clinical' cut-off value for BSR was defined as the cut-off value with the highest sum of sensitivity and specificity for FFR ≤0.80. Dichotomous classification agreement with the reference standard was determined according to the respective ischaemic and clinical cut-off values. The optimal ischaemic cut-off value was 0.66 mmHg·cm^{-1}·sec for BSR, and 0.75 for FFR. The optimal 'clinical' cut-off value for BSR, e.g. the optimal cut-off value for FFR 0.80 in the present dataset, was 0.47 mmHg·cm^{-1}·sec. For both BSR and FFR, changing the cut-off from ischaemic to clinical yielded an increase in the number of false-positive test outcomes (6.3% increase for BSR, 11% increase for FFR), while it did not lead to a relevant decrease in false-negative test outcomes (1.0% decrease in for BSR, 0.7% decrease for FFR), overall resulting in an increase in inaccurately classified lesions (5.4% increase for BSR, and 10.4% increase for FFR). When focussed on FFR, the effect of moving from the ischaemic FFR cut-point of 0.75 to the clinical cut-point of 0.80 resulted in an increase in the false positive rate from 9.4% (28 out of 299 lesions) to 20.4% (61 out of 299 lesions), an 11% increase (33 out of 299). The 33 lesions were all non-ischaemic by the reference standard, with a mean HSR of 0.53 mmHg · cm^{-1} · sec. In contrast, only 0.7% (2 out of 299 lesions) were inaccurately identified as non-ischaemic at the ischaemic 0.75 FFR cut-point, and were accurately classified as ischaemic by the clinical 0.80 cut-point.

Conclusions: The use of clinical cut-off values leads to a substantial increase in inaccurate classifications compared with ischaemic cut-off values, regardless of the physiological index used.

Coronary interventions – *Wednesday May 22nd*
FFR are we working with the best threshold

Should we use a fixed FFR cut-off to guide coronary revascularisation? Implications of FFR biological variability on clinical decisions

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Aims: Current appropriateness guidelines recommend the utilisation of fractional flow reserve (FFR) to guide coronary revascularisation based on a fixed cut-off of 0.8. However, this does not take into account the intrinsic measurement variability of a single FFR result. We quantify the effects of FFR measurement variability on FFR-guided treatment decisions.

Methods and results: FFR reproducibility data from DEFER was analysed (two repeated FFR measurements in the same lesion, 10 minutes apart) and the standard deviation of the difference (SDD) between repeated measurements was calculated. The measurement certainty (probability that the FFR-guided revascularisation strategy will not change if the test is repeated 10min later) was subsequently established across the whole range of FFR values, from 0.2 to 1. Outside the [0.75-0.85] FFR range, measurement certainty of a single FFR result is >95%, giving clinicians confidence on a treatment strategy. However, closer to its cut-off, certainty falls to less than 80% within [0.77-0.83], reaching a nadir of 50% around 0.8. In clinical practice, that means that each time a single FFR value falls between 0.75 and 0.85, there is a chance that the FFR-derived revascularisation recommendation will change if the measurement is repeated 10min later, with this chance increasing the closer the FFR result is to 0.8.

Conclusions: A measurement FFR gray-zone is found between [0.75-0.85]. Therefore, clinicians should make revascularisation decisions based on broadened clinical judgement when FFR falls within this measurement gray-zone, particularly between [0.77-0.83], when measurement certainty falls to less than 80%.

Coronary interventions – *Wednesday May 22nd*
FFR are we working with the best threshold

Long-term clinical outcomes in deferred coronary lesions according to degree of lesion severity by FFR

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Aims: Although the future risk for cardiac events is related to coronary stenosis severity, there is little evidence about the future risk according to coronary stenosis severities which are functionally nonsignificant.

Methods and results: Six hundred twenty eight patients (731 lesions) who were deferred revascularisation by fractional flow reserve (FFR) ≥0.80 were enrolled. All lesions were divided into 4 group(G)s; as by distribution quartile of FFR, 0.80≤G1<0.85, 0.85≤G2<0.89, 0.89≤G3<0.94, 0.94≤G4≤1.00. Major adverse cardiac events (MACEs; composite of cardiac death, myocardial infarction and any revascularisation) were compared between groups. Mean follow-up duration was 23.7 months. MACEs rate was 4.4% (32/731 lesions). Revascularisation rate of deferred lesions was 3.7% (27/731 lesions). Anatomical characteristics were significantly different according to FFR value (% diameter stenosis: G1 52.2±14.5%, G2 47.9±13.2%, G3 47.7±12.7%, G4 45.1±12.3%, minimal lumen diameter: 1.35±0.43 mm, 1.53±0.45 mm, 1.55±0.44 mm, 1.77±0.56 mm, lesion length: 19.5±10.8 mm, 15.9±9.4 mm, 14.4±8.3 mm, 12.8±7.0 mm, all p value<0.001). However, there were no differences of MACEs between groups (G1 4.3%, G2 4.4%, G3 5.9%, and G4 2.4% respectively, p=0.448).

Conclusions: Overall clinical outcome of deferred coronary lesions by FFR was excellent. Although there were definite different anatomical characteristics between groups according to degree of lesion severity (FFR), clinical outcomes were not different between groups by FFR.

Coronary interventions – *Wednesday May 22nd*
FFR are we working with the best threshold

Baseline FFR predicts hyperemic FFR according to the sites of lesions

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Aims: Previous studies demonstrated that there is a little correlation between baseline FFR (fractional flow reserve) and hyperemic FFR. However, there are little studies about the usefulness of baseline FFR for predicting functional significance according to the sites of lesions which are related with myocardial burden. The present study was designed to evaluate the relationship between baseline FFR and hyperemic FFR according to the sites of lesions.

Methods and results: We enrolled 170 patients, 170 intermediate coronary lesions (proximal LAD (Left Anterior Descending coronary artery): 80 lesions, mid to distal LAD: 90 lesions), and measured FFR with intracoronary pressure wire. Resting pressure ratio (baseline FFR) through the coronary lesion was measured and FFR was measured after inducing maximal hyperemia (intracoronary continuous adenosine infusion, 300-360 microg/min). Functional significance of stenosis was defined as FFR ≤0.80 or ≤0.75. There was a linear correlation between baseline FFR and hyperemic FFR (r=0.667, p<0.001). There was no significant difference in baseline FFR (proximal LAD: 0.94±0.03, mid to distal LAD: 0.93±0.04, p=0.23), hyperemic FFR (proximal LAD: 0.78±0.07, mid to distal LAD: 0.80±0.07, p=0.08), Ejection fraction (%) (proximal LAD: 66.24±6.57, mid to distal LAD: 66.44±6.45, p=0.84), percent stenosis (%) (57.49±14.82, 56.84±16.14, p=0.78), and lesion length (mm) (19.51±9.51, 20.10±10.75, p=0.71) between proximal LAD and mid to distal LAD. The difference between baseline FFR and hyperemic FFR was significant according to the sites of lesions (0.15±0.06 at proximal LAD, and 0.13±0.05 at mid to distal LAD, p=0.001). Using a receiver operating characteristic curve analysis, the best cutoff values of baseline FFR for predicting hyperemic FFR ≤0.80 were 0.95 (sensitivity 90.2%, specificity 58.6%, AUC: 0.788, p<0.0001, 95% CI: 0.682-0.871) at proximal LAD, whereas 0.94 (sensitivity 90.9%, specificity 78.3%, AUC: 0.910, p<0.0001, 95% CI: 0.830-0.960) at mid to distal LAD. The best cutoff values of baseline FFR for predicting hyperemic FFR ≤0.75 were 0.94 (sensitivity 85.7%, specificity 59.6%, AUC: 0.796, p<0.0001, 95% CI: 0.691-0.878) at proximal LAD, whereas 0.92 (sensitivity 90.0%, specificity 81.4%, AUC: 0.897, p<0.0001, 95% CI: 0.816-0.951) at mid to distal LAD.

Conclusions: Although the baseline FFR can predict functionally significant stenosis of coronary artery, the best cutoff values of baseline FFR for predicting significant ischaemia are different according to the sites of lesions. We should consider the sites of the lesions when interpreting baseline FFR.

Contrast induced nephropathy: a new predictive model based on pre-procedural glycemia and glomerular filtration rate

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Aims: The risk of contrast induced nephropathy (CIN) is predicted by the already proposed formula of the ratio of contrast volume to glomerular filtration rate (GFR). Recent data from literature underscore that the incidence of CIN is significantly influenced by admission glycemia. Therefore, our aim was to identify a predictive model of CIN based on the quantity of contrast used during primary PCI (pPCI), known independent predictors of CIN, and pre procedural glycemia.

Methods and results: 679 STEMI patients treated with pPCI were enrolled in our prospective study. CIN was defined as an absolute serum creatinine increase ≥0.3 mg/dl after procedure. Admission hyperglycemia was defined as glucose levels >198 mg/dl. Medium volume of contrast (CV) we used ranged from 30 to 700 ml. We observed a significant increase in the incidence of CIN with the increase of the CV/GFR ratio which was in turn influenced by admission hyperglycemia. We therefore created a model of CIN prediction based on CV, GFR and admission glycemia. This model results from the product of admission glycemia and CV/GFR×100. We then confronted our model with previously proposed models for prediction of CIN in pPCI patients (model 1: CV/GFR >3.7; model 2: CV/{[5×weigth (Kg)]/ serum creatinin (mg/dl)} >1) obtaining better AUC with ROC analysis (AUC 0.72 vs. 0.63, p<0.001 with model 1, AUC 0.72 vs. 0,59, p<0.001 with model 2). At multivariate analysis a value of 4.2 was the best indipendent predictor of CIN.

Conclusions: Our CIN risk model based on CV and admission glycemia was more accurate than the existing models. This model can be useful before pPCI to identify the safe quantity of contrast to use, and after pPCI to identify the subgroup of patients at higher risk of CIN.

Effect of transient contrast-induced nephropathy on mortality in patients undergoing PCI

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Aims: It is well known that contrast-induced nephropathy (CIN) is associated with increased long-term mortality, although CIN ranges from a transient elevation of the serum creatinine (SCr) concentration to permanent renal failure necessitating dialysis. The aim of this study was to identify whether transient CIN independently affected mortality in patients undergoing percutaneous coronary intervention (PCI) or not.

Methods and results: CREDO-Kyoto cohort-2 is multicentre registry of consecutive patients undergoing first PCI or coronary artery bypass surgery among 26 centres between January 2005 and December 2007. Transient CIN was defined as an elevation in SCr ≥0.5 mg/dL or 25% from baseline within 5 days, but returned to baseline level at one year (276-455 days) after PCI. Of 13087 patients enrolled in the PCI arm of the registry, we excluded patients who were on dialysis before PCI, without laboratory data, died within 12 months after PCI, and who were lost to follow. Among 4576 patients in our study cohort, 113 patients (2.5%) died from 13 to 24 months after PCI. Elderly, multi-vessel disease, congestive heart failure, atrial fibrillation, malignancy, diabetes, anemia, usage of statin, chronic kidney disease were associated with mortality by univariate analyses. Transient CIN occurred in 482 patients (10.5%) and independently affected mortality [odds ratio: 2.09, 95% confidence interval: 1.26-3.35] even after adjustment for above 9 factors.

Conclusions: Transient CIN after PCI occurred in one to 10 patients and was shown to be an independent risk factor for mid-term mortality.

Coronary interventions – *Wednesday May 22nd*
Renal function and clinical outcome after PCI

Female gender and contrast-induced nephropathy in primary percutaneous intervention for STEMI

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Aims: Patients undergoing primary primary percutaneous intervention are at high risk for contrast-induced nephropathy, a complication that has been demonstrated to negatively affect outcomes. Compared with males, female patients are exposed to higher risk of contrast-induced nephropathy and higher mortality after primary percutaneous intervention. The role of female gender, however, remains ill-defined given its complex interplay with several co-morbidities and clinical variables. The aim of the preset study was to investigate the relationship of patients' variables, including gender, with contrast-induced nephropathy and mortality after primary percutaneous coronary intervention.

Methods and results: We conducted a prospective, single-centre study in 323 consecutive patients undergoing primary percutaneous intervention. We assessed development of contrast-induced nephropathy and mortality during a 18-month median follow-up period. Contrast-induced nephrophaty was defined as an increase in serum creatinine (≥25% or ≥0.5 mg/dl) from baseline occurring at any time during the first 3 post-procedural days. Contrast-induced nephrophathy occurred in 23 femaleand 26 male patients (25.0% vs. 11.2%, p=0.003), while cumulative mortality was 10.6%. Reduced (<40%) left ventricular ejection fraction (OR: 7.32, 95% CI: 2.60 to 21; p<0.001) and female gender (OR: 2.49, 95% CI: 1.22 to 5.07; p=0.01) independently predicted contrast-induced nephropathy, whereas the occurrence of contrast-induced nephrophathy (HR: 3.65, 95% CI: 1.55 to 8.59; p=0.003) and the Mehran risk score (HR: 1.76, 95% CI: 1.13 to 2.74; p=0.01) independently predicted long-term mortality.

Conclusions: After primary percutaneous coronary intervention, female gender and reduced left ventricular function are associated with increased risk of contrast-induced nephropathy, whereas Mehran risk score and development of contrast-induced nephropathy predict long-term mortality.

Coronary interventions – *Wednesday May 22nd*
Renal function and clinical outcome after PCI

Long-term survival in patients undergoing DES PCI of the unprotected left main coronary artery according to renal function: Milan and New-Tokyo (MITO) registry

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Aims: There is little available data regarding the long term follow-up of patients treated with drug-eluting stent (DES) on the Unprotected Left Main (ULM) according to estimated GFR (e-GFR).

Methods and results: All 1052 consecutive patients treated with DES implantation for ULM stenosis between April 2005 and August 2011 were retrospectively assessed for impact of renal function. The patients were classified into severe (e-GFR<15), moderate (15<30), mild (30<60) and normal renal function (60<) groups (59, 41, 366 and 586 patients respectively). All death and cardiac death at 5-years was as follows; 67.1%, 50.3%, 20.3% and 9.3% and 44.9%, 22.0%, 9.7% and 3.4%, respectively (Figure). An estimated GFR was strongly associated with all death (adjusted HR 0.981; 95%CI 0.971-0.991, p=0.01) and cardiac-death (adjusted HR 0.973; 95% CI 0.959-0.986, p=0.01).

Conclusions: Estimated GFR seem to predict the outcome in patients undergoing PCI with DES for ULM disease.

Two years clinical prognosis of everolimus eluting vs. sirolimus eluting stents in patients with chronic kidney disease

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Aims: Assess two-year clinical outcomes of Everolimus-eluting versus Sirolimus-eluting stenst in patients with chronic kidney disease.

Methods and results: 2051 patients (4412 lesions) who underwent elective percutaneous coronary intervention with EES or SES were collected. The eGFR was calculated according to the MDRD formula. CKD was defined in which eGFR was under 60ml/min. A total of 876 CKD patients (EES: 216 patients 409 lesions, SES: 660 patients 1346 lesions) were studied. The incidence of MACCE (Death, Target lesion revascularisation, Stent thrombosis, Cerebrovascular disorder) up to 2 years was evaluated. In addition angiographic lumen loss between EES and SES were evaluated. Survival analyses revealed higher free rate from MACCE of EES recipients compared with SES (94.9% vs. 87.1%, P=0.01). Survival free rate from ischaemic driven TLR was higher in EES group too (98.1% vs. 89.9%, P<0.001). Although stent thrombosis was occurred 4 patients in SES, there was no incidence of stent thrombosis in EES group. 8 month late lumen loss was equal between EES and SES (0.36±0.69 mm vs. 0.35±0.66 mm, P=0.89). Late lumen loss after 2 years was larger in EES than SES (0.58±0.65 mm vs. 0.42±0.62 mm, P=0.02).

Conclusions: At mid-term follow-up, EES performance was superior to SES in renal dysfunction patients.

Long-term follow-up of 14,439 chronic total coronary occlusion angioplasty cases from the United Kingdom central cardiac audit database

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Aims: We aimed to analyse a large registry of 14,439 chronic total occlusion PCI procedures to examine rates of successful intervention and assess the effect on patient survival. We also aimed to assess the impact of the location of the chronic total occlusion and the completeness of revascularisation on patient survival.

Methods and results: We analysed the UK Central Cardiac Audit Database for all chronic total occlusion PCI cases carried out in England and Wales between 1st January 2005 and 31st December 2009. Vital status as of September 2010 was obtained from the Medical Research Information Service. 4.4% out of 326,398 PCI procedures were for elective treatment of a chronic total occlusion. Patients (n=14,439) had a mean age of 63.5±10.5 years; 78.1% were male. Chronic total occlusion PCI was successful in 10,199 cases (71.2%). During a median follow-up of 2.7 years (inter-quartile range 1.56 - 3.81), successful PCI of at least one chronic total occlusion was associated with improved survival (hazard ratio 0.71, 95% CI 0.62 to 0.82; p<0.001). Complete revascularisation was associated with improved survival compared to partial revascularisation (where a chronic total occlusion was successfully opened but with residual obstruction in one or more other vessels) (hazard ratio 0.71, 95% confidence interval 0.57 to 0.88; p=0.002) or failed revascularisation (where revascularisation of the chronic total occlusion failed) (hazard ratio 0.61, 95% confidence interval 0.51 to 0.73; p<0.001). Failure to successfully open any of the major target vessels was associated with increased mortality after multivariable analysis {Left anterior descending artery (hazard ratio 1.83; confidence interval 1.21-2.79, p<0.001), circumflex artery (hazard ratio 2.06; confidence interval 1.23-3.45, p=0.02), right coronary artery (hazard ratio 1.63; confidence interval 1.18-2.25, p=0.03)}. Survival outcomes were not influenced by the vessel treated.

Conclusions: Successful intervention of at least one chronic total occlusion lesion is associated with improved long-term survival. The reduction is greatest in patients where complete revascularisation is achieved. Location of the occluded vessel did not influence outcome.

Coronary interventions – *Wednesday May 22nd*
Percutaneous revascularisation from CTO's : results from registries

Prognostic implication of left anterior descending artery chronic total occlusion in patients with a complete coronary revascularisation achieved by PCI

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Aims: No data exist about the prognostic impact of successful PCI of left anterior descending artery chronic total occlusion in patients with a complete coronary revascularisation achieved by PCI.

Methods and results: The Florence coronary chronic total occlusion-PCI registry started in 2004 and includes consecutive patients with at least 1 coronary chronic total occlusion attempted PCI. The study is based on the cohort of patients with a complete revascularisation. The prognostic impact of left anterior descending artery chronic total occlusion on cardiac mortality was assessed by Kaplan-Meier estimation and by forward stepwise Cox regression multivariable analysis. Patients treated with drug-eluting stent, since 2004 to 2010, 644 patients with at least 1 coronary chronic total occlusion successful PCI for coronary chronic total occlusion (>3 months) with a complete coronary revascularisation within one month. From January 2004 to December 2010 a complete coronary revascularisation was achieved in 194 patients with left anterior descending artery-coronary chronic total occlusionand in 450 patients with non left anterior descending artery-coronary chronic total occlusion. Baseline characteristics of patients with left anterior descending artery-coronary chronic total occlusion and non left anterior descending artery chronic total occlusion were similar: mean age 68±11 vs. 67±11 yrs, male 83% vs. 86%, diabetes 22% vs. 23%, previous myocardial infarction 51% vs. 48%, acute coronary syndrome at admission 34% vs. 29%, 3-vessel coronary disease 43% vs. 48%, left ventricular ejection fraction 44%±13 vs. 45%±12, stent length >40 mm inleft anterior descending artery -coronary chronic total occlusion51% vs. 57% in non-left anterior descending artery chronic total occlusion. A multivessel PCI was performed in 70% of both groups. The clinical follow-up rate was 100% (median 1 year). The cardiac survival rate was higher in the non-left anterior descending artery chronic total occlusion group as compared to left anterior descending artery chronic total occlusion group (96%±2% vs. 89%±3%; p=0.004). At multivariable analysis the independent predictors of cardiac mortality were left anterior descending artery chronic total occlusion (HR 2.9; p=0.025), age (HR 1.1; p=0.002) and left ventricular ejection fraction <0.40 (HR 14; p<0.001).

Conclusions: The successful treatment of non-left anterior descending artery chronic total occlusion with a complete revascularisation is associated with a very high survival rate. Left anterior descending artery chronic total occlusion is a predictor of cardiac mortality despite the completeness of coronary revascularisation.

Coronary interventions – *Wednesday May 22nd*
Percutaneous revascularisation from CTO's : results from registries

Transradial intervention for chronic total occlusion

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Aims: Transradial Intervention (TRI) is currently applied to more complex lesions in PCI. However, the efficacy and feasibility of TRI for chronic total occlusion (CTO) is not established.

Methods and results: PCI for a total of 221 CTO lesions were performed in our hospital between January 2008 and December 2011. TRI was used in 158 lesions (71.5%). We retrospectively evaluated the medical record of the TRI cases. Average age was 65.1±11.6 years old and male was 77.5%. Coronary risk factors were smoking history (50.5%), diabetes mellitus (41.0%), dyslipidaemia (68.6%), hypertension (78.1%), family history (12.4%), old myocardial infarction (39.0%) and chronic kidney disease (5.7%). CTO lesions were located in the left anterior descending artery (31.3%), left circumflex artery (23.5%), right coronary artery (43.5%) and left main trunk (1.7%). Antegrade approach was performed in 84.2% and antegrade plus retrograde tracking including at least one TRI was in 15.8% (n=25 lesions). Size of the guiding catheter in TRI was 6 Fr or less in 95%. During undergoing PCI for CTO, The median time of fluoroscopy was 51.2±30.5 minutes and contrast medium was 251±115 ml. Success rate of the antegrade approach was 88.0% and that of antegrade plus retrograde approach was 64.0%. Total success rate for CTO was 84.2%. Major complications within 30 days were as follows; death 0%, myocardial infarction 0% and emergency bypass surgery 0%. No bleeding complication was observed but 3 coronary perforations were successfully treated by fat embolisations or negative pressure method.

Conclusions: TRI for CTO lesions with current approach seemed to be acceptable. Further investigation is necessary.

Complications with PCI by retrograde approach: Data analysis from Retrograde Summit in Japan

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Aims: We aimed to investigate the occurrence of procedural complication which is relevant to the retrograde approach in PCI for chronic total occlusions since it is one of concern in this technique.

Methods and results: Japanese Retrograde Summit has retrospectively collected 1,166 of retrograde procedural data performed between 2009 and 2011 in 28 of participant hospitals. We analysed the cases with procedural complications or any minor events that are especially relevant to the retrograde approach – such as channel injury or trouble in donor artery – in order to understand occurrence rate and its clinical impact. Retrograde approach relevant complications/events were observed in 133 cases and 112 cases of them were channel injury by guide wires or catheters. However, only 25 cases of them required treatment. The rest were left under observation, receiving no additional treatment as they were minor injuries. Notably, significant channel injury which caused cardiac tamponade due to severe channel perforation was observed in 5 cases of all injuries. Donor artery trouble such as dissection and spasm occurred in 10 cases. No thrombus formation was reported in this registry cases. Major adverse cardiac and cerebrovascular event occurred in 18 cases (1.5%) and other procedural complications were 57 cases (4.9%).

Conclusions: In the retrograde approach, specific procedure-related complications are a point of concern. However, our registry data indicates major complications were not often reported. Other complications including major adverse cardiac and cerebrovascular event rate were deemed acceptable. We need to understand coronary anatomy or lesion morphology before we start the procedure to avoid any inadvertent complications.

Coronary interventions – *Wednesday May 22nd*
Percutaneous revascularisation from CTO's : results from registries

DES with bioresorbable polymer for chronic total occlusion: short and long-term clinical outcomes

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Aims: Data on the performance of DES with bioresorbable polymer in chronic total occlusion (CTO) recanalisation setting are limited and therefore the NOBORI-CTO study was conducted as part of 2 large worldwide registries.

Methods and results: In two large, prospective, single-arm, multicentre registries, 12444 patients were treated with Nobori DES, out of which 454 had at least one CTO lesion revascularised. The primary endpoint was Target Lesion Failure (TLF), a composite of cardiac death (CD), target vessel related myocardial infarction (MI) and target lesion revascularisation (TLR). CTO patients were 60±11y old, 84% males, with a cardiovascular history of prior MI, prior PCI and previous cardiac surgery in 46.4%, 27.8% and 6.0% of patients, respectively. Lesions were mostly located in the LAD (38.4%), followed by RCA (36.9%) and LCX (23.3%). Multiple vessels were treated in 36.3% of patients (2.18±1.38 lesions per patient) with an average of 1.49±0.77 stents per lesion. Lesions were complex (82.6% B2/C type), ostial (15.6%), calcified (42.8%), containing thrombus (2.8%) and 9.9% required bifurcation treatment. Pre- and post-dilatation were performed in 87.0% and 36.1% of lesions, respectively. Antegrade approach was chosen in the majority of procedures (89.7%), and a high frequency of single wire technique (77.3%) as compared to parallel wire (15.5%) and seesaw wire (2.3%) techniques. Several other techniques were used for CTO treatment including CTO dedicated wires (41.4%), OTW balloon (9.5%), microcatheter (29.0%), rotational atherectomy (1.7%) and cutting balloon (2.8%). IVUS guidance was performed in 7.5% of patients. The average contrast volume and fluoro times were 279.6±138.4mL and 38.2±39.8 minutes, respectively. Mean diameter stenosis before procedure was 91±16% and TIMI 0 and 1 were recorded in 59% of the lesions. After procedure mean diameter stenosis was 7±17% and TIMI 0 and 1 were observed in 3% of the lesions. In hospital and up to 1-month, there were no deaths nor TLR and there were 5 MIs (1.0%). Two cardiac deaths (0.6%) and three TLRs (1.2%) were reported up to one year follow-up bringing the total TLF rate to 2.6%. In the cohort of patients followed at 3-year, 3 patients suffered a cardiac death (3.1%), 1 had an MI (1.0%), 3 underwent TLR (3.1%) and TLF rate was 6.2%. A total of 87% of the patients were angina free. No definite or probable stent thrombosis occurred up to 3 years.

Conclusions: Treatment of CTO with Nobori DES showed excellent outcomes. Particularly appealing is the absence of stent thrombosis despite the multiple overlapping stents. The low rate of procedural complications and adverse events up to 3 years suggests that this stent is a valuable treatment option for patients with CTO who are considered candidates for PCI.

Coronary interventions – *Wednesday May 22nd*
Individualised antiplatelet therapy based on testing or genotyping: idea from the past or solution for the future

Individualising dual antiplatelet therapy after PCI: the IDEAL-PCI registry

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Aims: To evaluate the impact of tailoring dual antiplatelet therapy with multiple electrode aggregometry on clinical outcome in an all-comers PCI population, including STEMI patients, as high on-treatment platelet reactivity to ADP is associated with adverse ischaemic events after PCI.

Methods and results: Prospective, single-centre cohort observation of 1008 consecutive PCI patients with stent implantation or drug eluting balloon dilatation. STEMI patients without contraindication received 60 mg prasugrel, all others 600 mg clopidogrel loading. On-treatment platelet reactivity was measured by the Multiplate Analyser, a new generation impedance aggregometer, latest at the time of PCI (but not earlier than 12 hours after loading). In case of PCI within 6 hours after loading and/or significant thrombus burden, a glycoprotein IIbIIIa inhibitor was added and serial measurements until discharge were performed. In case of non-response (>49 U ADP-induced aggregation), antiplatelet therapy was individualised according to the protocol with either prasugrel loading (since June 2009), ticagrelor loading (since March 2011), or clopidogrel reloadings (until June 2009). The primary efficacy end point was definite stent thrombosis, the secondary endpoints probable stent thrombosis and cardiovascular death at 30 days. The safety endpoint was bleeding according to TIMI criteria. Demographics: 53% of the 1008 consecutive patients presented with ACS (9% STEMI, 44% NSTEMI; 5% in cardiogenic shock). 30% females, 32% diabetics, mean age 65±12, (range 29-90). 73% complex lesions (b2/c), 11% LM and 58% LAD interventions. 99% stentimplantation (94% 2nd gen. DES, 5% BMS); 2.2 stents/patient (range 1-12; total stent length 8-241 mm). 21% glycoprotein inhibitor usage in ACS. Platelet reactivity: 94,8% received clopidogrel, 5% prasugrel and 0.2% ticagrelor loading (known clopidogrel allergy). Clopidogrel non-response occurred in 30% (73±19 U vs. 28±11 U, p<0.0001) and was treated in 70% with prasugrel, 27% with clopidogrel and 3% ticagrelor reloading to reach sufficient levels (22±12 U; p<0.0001 vs. initial response). Prasugrel non-response occurred in 2,4% (88±22 U vs. 20±12 U, p<0.0001) and was successfully treated with ticagrelor reloading (30±13 U; p<0.006 vs. initial response). Clinical endpoints: No acute stent thrombosis (0%) occurred in the total patient cohort. In the ACS cohort one fatal subacute definite stent thrombosis (0,099%; a patient with gram-negative sepsis and diarrhea), two probable stent thrombosis (0,2%; sudden death after discharge without autopsy) and 15 additional cardiovascular deaths (1,5%; 67% due to cardiogenic shock) occurred. In stable patients no stent thrombosis or cardiovascular death occurred (0%). No increase in bleeding complications (TIMI major and minor) could be detected in the individualised (2,7%) vs. the standard group (2,5%; p=0.6)

Conclusions: A strict protocol of individualising antiplatelet therapy with the Multiplate Analyser is able to minimise early thrombotic events in an all-comers PCI population including STEMI patients to a so far unsurpassed degree, without increasing bleeding complications. Based on these findings we strongly recommend the incorporation of Multiplate guidance of dual antiplatelet therapy after PCI in routine clinical practice.

Coronary interventions – *Wednesday May 22nd*
Individualised antiplatelet therapy based on testing or genotyping: idea from the past or solution for the future

Dual antiplatelet therapy monitoring in patients with unprotected left main stenting

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Aims: Persistent platelet reactivity (PPR) under aspirin and/or thienopyridines is associated with acute events after angioplasty. We aimed to determine the rate and potential clinical impact of PPR in patients treated by angioplasty for left main stenosis.

Methods and results: We prospectively included 125 patients referred for angioplasty for ULMD in a single-centre registry. For the first 64 patients (ALMA-1), angioplasty was performed under aspirin and clopidogrel treatment without previous platelet reactivity assessment. For the last 61 patients (ALMA-2), platelet reactivity was assessed (light transmission aggregometry triggered by arachidonic acid and ADP and VASP index) systematically before angioplasty: patients found to have aspirin-related PPR were administered aspirin twice daily and those with clopidogrel-related PPR had their daily clopidogrel dose doubled or replaced by prasugrel. Overall, patients mean age was 69±13years, 37% were diabetic, 37% had NSTEMI and 62% had multivessel disease. The left main lesion was ostial in 23%, medial in 8% and distal or both in 69%. Mean SYNTAX score was 22.8±9.2. More than 30% of the patients have an additive EuroSCORE≥6. Procedural characteristics were similar in both studies. Follow-up was successful at 1 yearin all patients. In ALMA-2, concerning aspirin pathway, mean maximal aggregation intensity measured by light transmission aggregometry triggered by arachidonic acid was 15.4±17.0%. The proportion of patients with persistent platelet reactivity for aspirin (maximal aggregation intensity ≥20%) was 28% and aspirin was given twice a day in all these patients. Concerning thienopyridines pathway, mean maximal aggregation intensity measured by light transmission aggregometry triggered by ADP 20 µmol was 53.6±18.5%. Mean VASP index was 46±19%. Finally, considering light transmission aggregometry triggered by ADP and VASP together, 26% of patients (n=16) had persistent platelet reactivity under thienopyridines. After platelet reactivity assessment, taking account these results, 31% of patients (n=19) received prasugrel and 26% (n=16) were treated by high-dose clopidogrel. Finally, 8% of patients (n=5) have persistent platelet reactivity under both, aspirin and thienopyridine treatment. Dual antiplatelet therapy at 1 year was continued in 86% of patients in ALMA-1 and 92% of patients in ALMA-2 (p=NS). The rate of 1-year major cardiovascular events was decreased in ALMA-2 vs. ALMA-1 (8.2%vs.20.8%; p=0.04) as a composite endpointof cardiovascular death and stent thrombosis (0.0%vs.8.3%; p=0.02).

Conclusions: In this real-life study, PPR for aspirin or clopidogrel was found to be frequent in patients referred for ULMD angioplasty. Monitoring DAPT could play a major role in determining ischaemic events after PCI since the optimisation of the treatment we propose in our study appears to significantly decrease the rate of acute events such as cardiovascular death and ST. Further studies are needed to define which patients would require PPR assessment and the optimal therapeutic adaptation.

Impact of high platelet reactivity on clopidogrel after coronary stenting to the late lumen loss at long-term follow-up

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Aims: Previous studies had reported that high platelet reactivity (HPR) is associated with recurrent ischaemic events after PCI. We assessed the platelet reactivity on clopidogrel and aspirin after coronary stenting, and evaluated the participation in clinical outcomes and QCA findings. Previous studies had reported that high platelet reactivity (HPR) is associated with recurrent ischaemic events after PCI. We assessed the platelet reactivity on clopidogrel and aspirin after coronary stenting, and evaluated the participation in clinical outcomes and QCA findings.

Methods and results: PRU (P2Y12 reaction units) and ARU (Aspirin reaction units) were measured by VerifyNow P2Y12 and Aspirin assays in 171 patients (56: acute coronary syndrome [ACS] and 115: stable angina [SA]) underwent coronary stenting. All patients received 300mg clopidogrel loading immediately after PCI followed by 50 to 75 mg and aspirin daily 200 mg. Blood samples were obtained 12 to 24 hours (PRU1, ARU) and 2 to 4 weeks (PRU2) after PCI. HPR on clopidgrel was defined as 235 or more in PRU1 (HCPR1) and PRU2 (HCPR2) and HPR on aspirin as 550 or more in ARU (HAPR). We assessed the prevalences of HPR and compared MACE (cardiac death, MI, stent thrombosis, urgent revascularisation) and QCA at 6 months follow-up between patients with and without HCPR2. ACS patients had significantly higher valuesin ARU and PRU1 than SA patients (ARU: 470 vs. 433, p=0.003 and PRU1: 282 vs. 240, p=0.002), but PRU2 were similar in both (224 vs. 223, p=NS). The rate of HAPR was 9.9% (23.2% in ACS vs. 5% in SA, p=0.0006), however the rate of HCPR1 was 60.8% (76.8% in ACS vs. 53% in SA, p=0.003) and the rate of HCPR2 remained 48.5% (47.2% in ACS vs. 49.1% in SA; p=NS). Baseline characteristics were similar between the HRPR2 and non-HCPR2 groups except that the HCPR2 group had more haemodialysis patients than the non-HCPR2 group (10% vs. 2%; p=0.04). Only two patients with HCPR2 had urgent revascularisation (one patient had an MI), however, no other MACE had occurred. In QCA at 6-months after PCI, late lumen loss was significantly larger in HCPR2 group compared to non-HCPR2 group (0.38 mm vs. 0.18 mm; p=0.029).

Conclusions: In the majority of ACS patients, platelet reactivity had been activated 12to 24 hours after loading dose of clopidogrel. Adequate inhibition of platelet reactivity on clopidogrel 2 to 4 weeks after coronary stenting could reduce late lumen loss at follow-up.

Coronary interventions – *Wednesday May 22nd*
Individualised antiplatelet therapy based on testing or genotyping: idea from the past or solution for the future

How long does it take for clopidogrel to inhibit platelets in patients undergoing primary PCI for STEMI: the time course of platelet reactivity in the acute phase of STEMI as measured with various platelet function tests (TOPS) study

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Aims: The objective of this sub analysis of the TOPS study is to describe the course and extent of platelet reactivity in STEMI patients undergoing primary PCI after a loading dose of clopidogrel in the ambulance.

Methods and results: The TOPS study is a non-randomised, open-label and single-centre study. Patients were eligible if three criteria were met: STEMI diagnosis (<6 hours after onset of symptoms), performance of primary PCI with stent implementation and administration of a loading dose of dual antiplatelet therapy in the ambulance (600 mg clopidogrel and 500 mg Aspegic iv), followed by a daily maintenance dose of clopidogrel 75 mg and acetylsalicylic acid 80 mg, both once daily. Platelet reactivity was measured directly before PCI and 6, 24 and 48 hours, 1, 2 and 4 weeks after drug intake, using the VerifyNow P2Y12 assay and Light Transmittance Aggregometry (LTA 20 µmol/L ADP). HPR was defined as ≥236 Platelet Reactivity Units (PRU) for VerifyNow and ≥64.5% Maximum Platelet Aggregation (MPA) for LTA. We analysed the time until platelet reactivity dropped below the HPR cut off level as an interpolated point on a straight line between the measurements. Eight patients participated in the study. All patients showed HPR at the start of the PCI (320±45 PRU, 83.0±5.1% MPA). Platelet reactivity dropped below the HPR cut off level after 6.4 hours for LTA and 8.6 hours for VerifyNow, on average. After 24 hours (LTA) to 57 hours (VerifyNow) the lowest level of platelet reactivity was measured (119±52 PRU, 47.8±10.6% MPA), after which platelet reactivity slowly increased. Eight days after PCI, platelet reactivity was 167.5±51 PRU and 64.0±7.8% MPA, with no patients exhibiting HPR according to the VerifyNow cut off level, but 4 patients exhibiting HPR according to LTA cut off level. The pattern of fast decrease, followed by a slow increase of platelet reactivity was best seen in the VerifyNow measurements. In the LTA measurements this pattern was less explicit.

Conclusions: In many STEMI patients undergoing primary PCI, platelets are not inhibited adequately during the first (6-9) hours, despite a loading dose of clopidogrel. This finding indicates the possible need for additional antiplatelet therapy in the acute setting of STEMI.

Coronary interventions – *Wednesday May 22nd*
Individualised antiplatelet therapy based on testing or genotyping: idea from the past or solution for the future

Optimising P2Y12, receptor inhibition in ACS patients based on platelet function testing: impact of prasugrel vs. high-dose clopidogrel

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Aims: We aimed to determine the clinical impact of intensifying P2Y12-receptor inhibition in ACS patients with high on-clopidogrel platelet reactivity (HPR), while keeping others on low-dose clopidogrel treatment.
Methods and results: Between September 2011 and May 2012, consecutive ACS patients undergoing PCI who were pretreated with clopidogrel 600 mg were enrolled into this single-centre prospective registry. Platelet reactivity to ADP was assessed with the Multiplate device 6-24 hours after clopidogrel loading dose, or 24 hours after tirofiban cessation. Patients with HPR (ADP test>46 U) were either switched to prasugrel (60 mg loading plus 10 mg maintenance dose) or given high-dose clopidogrel (repeated 600 mg loading plus 75/150 mg maintenance dose). Outcome measures included definite/probable stent thrombosis (ST), vascular mortality and TIMI major bleeding. During 9 months, 563 patients were enrolled into the registry. Mean follow-up time was 200 days. Based on Multiplate assessments, 141 patients (25%) had HPR; prasugrel was used in 54%, while high-dose clopidogrel in 46% of the cases. Despite the treatment adjustment, patients with HPR tended to have higher risk for vascular mortality or ST compared to those without HPR (7.1%, vs. 3.8%, p=0.11). Compared to patients treated with high-dose clopidogrel, patients with HPR switched to prasugrel had a significantly lower risk for mortality or ST (10.8% vs. 4.0%, p=0.02). Similarly, ST was significantly higher with high-dose clopidogrel compared to prasugrel in patients with HPR (4.7% vs. 1.3%, p=0.03). Patients without HPR had low rates of ST on standard-dose clopidogrel (1.1%). TIMI major bleeding events did not differ significantly between groups.
Conclusions: In consecutive, high-risk ACS patients with HPR undergoing PCI, prasugrel is significantly more effective to reduce vascular mortality or ST compared to high-dose clopidogrel. However, ACS patients without HPR might remain on low-dose clopidogrel, since they have low rates of thrombotic events.

Coronary interventions – *Wednesday May 22nd*
Impact of thrombus aspiration device on the results of primary PCI

Manual thrombectomy with platelet glycoprotein IIb/IIIa blockade is associated with lower mortality in patients treated with primary PCI (9266 patients from the London Heart Attack Group)

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Aims: We aimed to assess the impact of manual thrombectomy and glycoprotein IIb/IIIa use on mortality in patients presenting with STEMI across all PPCI centres in London over a 5 year period from 2007 until 2012.
Methods and results: This was an observational cohort study of 9,266 consecutive patients with STEMI treated with PPCI between 2007 and 2012 at 8 tertiary cardiac centres across London, UK. The primary end-point was all-cause mortality at a median follow-up of 3.0 years (IQR range: 1.2-4.6 years). Patients were split into three groups: those who underwent PCI using mechanical thrombectomy and GPIIb/IIIa inhibitors, those receiving either GP IIb/IIIa inhibitor or mechanical thrombectomy, and those receiving neither. Of the 9266 consecutive STEMI patients presenting for PPCI, 2334 (25.2%) had both mechanical thrombectomy and adjunctive glycoprotein IIb/IIIa blockade, 5132 (55.4%) had either mechanical thrombectomy or glycoprotein IIb/IIIa blockade, 1800 (19.4%) had neither therapy. Patients who had both manual thrombectomy and GPIIb/IIIa blockade were significantly younger, more likely to be male, and had lower rates of diabetes, previous MI, previous PCI, renal failure and previous CVA. Patients receiving both therapies were also less likely to have been in cardiogenic shock, were more likely to receive a drug-eluting stent, have undergone the procedure via the radial access route and have a successful procedure (defined as TIMI 3 flow at the end of procedure). Kaplan-Meier estimates of mortality showed the lowest rates of events for those patients receiving both therapies, followed by those receiving a single therapy, with the highest rates of adverse outcome in those receiving neither therapy (13.1% [95% CI 10.1-14.0] vs. 16.6% [95% CI 12.6-18.7] vs. 24.7% [95% CI 20.1-29.4], p<0.0001). However, after multivariable adjustment, thrombectomy use with adjunctive GPIIb/IIIa was still associated with significantly decreased mortality rates when compared with those that had neither therapy (hazard ratio: 0.77,95% confidence interval: 0.62-0.96, p=0.02). Other independent predictors of mortality were age, cardiogenic shock, diabetes mellitus and procedural success.
Conclusions: Manual thrombectomy with adjunctive GPIIb/IIIa blockade appears to be offered to a lower risk cohort of patients than those receiving neither. After multivariate adjustment however, manual thrombectomy use with adjunctive GPIIb/IIIa blockade is still associated with improved outcome, in the form of decreased mortality, in this large observational cohort.

Comparison between two catheters for coronary thrombus aspiration in patients with STEMI submitted to primary angioplasty: preliminary results of the COCOTH study

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Aims: Thrombus aspiration devices during primary angioplasty are known to improve myocardial reperfusion by protecting microcirculation against distal embolisation. Aim of this study was to compare the effects of two different thrombus aspiration devices, the manual catheter Export® and the more complex and expensive mechanical device Angiojet®, on several indices of acute myocardial reperfusion and necrosis entity.

Methods and results: 100 ST Elevation Myocardial Infarction patients were enrolled in the COCOTH study and randomised to treatment with Export® (n=55) or Angiojet® (n=45). The primary endpoint was the estimate of ST elevation reduction in the electrocardiogram 90 minutes after primary angioplasty. Secondary endpoint was the comparison between the two groups of patients of some angiographic parameters, among which Thrombus Score, TIMI Flow and TIMI Frame Count both before and after primary angioplasty, as well as Infarct Size and Severity measured at myocardial scintigraphy. A significant reduction in ST elevation was observed in both groups 90 minutes after primary angioplasty vs. before the procedure ($p<0.001$ in both groups) without any significant difference in their respective values between the two groups of patients. No significant difference was observed between the two groups in Thrombus Score as well as TIMI Flow and TIMI Frame Count either before and after primary angioplasty. Moreover, no significant difference between the two groups of patients was observed in relation to Infarct Size and Severity.

Conclusions: Primary angioplasty with thrombus aspiration devices was effective in both groups of patients treated with Angiojet® or Export® catheter, without any significant difference in some indices of myocardial reperfusion and necrosis entity. These results could have important implications with particular regard to cost-effectiveness; in fact, if confirmed, they could lead to design a protocol recommending the routinary use of manual devices during primary angioplasty, reserving the more expensive mechanical devices for particular cases, such as failure of manual thrombus aspiration systems and persistent or massive intracoronary thrombosis.

Coronary interventions – *Wednesday May 22nd*
Impact of thrombus aspiration device on the results of primary PCI

The randomised myocardial perfusion assessment after thrombus aspiration in patients with STEMI trial

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Aims: Routine thrombus aspiration (TA) is superior to conventional primary PCI in terms of improved myocardial perfusion in patients with STEMI. However, myocardial perfusion after thrombus aspiration has not been evaluated by a quantitative index of microcirculatory resistance (IMR). The aim of this study was to quantitatively assess myocardial perfusion after TA in patients with STEMI.

Methods and results: We performed a randomised, controlled clinical trial to evaluate impact of manual thrombus aspiration (the Eliminate aspiration catheter, Terumo Medical Supply, Japan) on microcirculatory resistance after primary PCI in 128 patients with the first STEMI randomly assigned to thrombus aspiration or conventional primary PCI group before coronary angiography. The primary endpoint was defined as a significant reduction of IMR in thrombus aspiration compared to conventional PCI group. Myocardial perfusion grade and resolution of ST-segment elevation were also assessed. Infarct size and left ventricle remodeling were assessed by echocardiographic indices. Manual thrombus aspiration, as compared with conventional PCI, resulted in significantly lower IMR (31.9±21.3 U vs. 47.0±35.8 U, P=0.0082). Treatment with thrombus aspiration, as compared with conventional PCI, resulted in similar rates of myocardial perfusion grade 0 or 1 (20.8% vs. 29.4%; relative risk, 0.71; 95% CI, 0.38 to 1.30; P=0.26) and complete resolution of ST-segment elevation (59.7% vs. 47.1%; relative risk, 1.27; 95% CI, 0.90 to 1.79, P=0.17). In a multiple regression model with the log-transformed IMR as dependent variable, after adjusting for clinical, angiographic and procedural variables, thrombus aspiration remained a strong independent predictor of lower IMR (27.14 U; 95% CI, 23.79 to 30.95 U, vs. 36.11 U; 95% CI, 30.74 to 42.41 U, P=0.0076). Histopathological examination confirmed successful thrombus aspiration in 89.6% of patients. The results of echocardiographic analysis will be available at the time of the presentation.

Conclusions: Manual thrombus aspiration reduces microcirculatory resistance indicating better myocardial perfusion compared to conventional PCI in patients with STEMI.

Coronary interventions – *Wednesday May 22nd*
Impact of thrombus aspiration device on the results of primary PCI

Impact of thrombus aspiration during primary PCI in acute myocardial infarction complicated by cardiogenic shock

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Aims: Primary percutaneous coronary interventions (PPCI) for ST-segment elevation myocardial infarction (STEMI) can be complicated by spontaneous or angioplasty-induced embolisation of atherothrombotic material. Some studies found that thrombus aspiration (TA) during PPCI resulted in improved myocardial reperfusion and survival, but whether these benefits are extended in cardiogenic shock (CS) complicating STEMI is unknown. In this retrospective study we evaluated the feasibility and the impact on survival of TA in this high risk population.

Methods and results: From September 2001 to May 2010 we collected data of consecutive patients within 12 h of STEMI complicated by CS underwent PPCI. TA was allowed during PCI per operator discretion. Clinical and procedural characteristics as well as in-hospital and long-term mortality were analysed according to TA. PPCI was performed in 155 patients with STEMI complicated by CS (12.4% of all PPCI) including 70 patients (45.2%) who underwent TA and 85 patients (54.8%) who underwent conventional PCI. Patients in TA group were more likely to present with right ventricular infarction (24.3% vs. 5.9%, p=0.002), higher mean left ventricular ejection fraction (40±9% vs. 35±7%, p<0.0001), lower mean door-to-balloon time (54±47 vs. 77±60 min, p=0.01), higher rate of infarct related artery (IRA) occlusion (94.3% vs. 73%, p=0.001), larger mean diameter of IRA (3.3±0.6 vs. 3.1±0.4 mm, p=0.003) and less likely to have left main coronary artery as IRA (2.8% vs. 21.2%, p=0.002). Furthermore, in the TA group there was a broader use of glycoprotein IIb-IIIa inhibitors (87.1% vs. 70.6%, p=0,01) and of intra aortic balloon pump (87.1% vs. 69.4%, p=0.015). TA was associated with an higher rate of ST-segment resolution >50% (67% vs. 39.4%, p=0.038) and of in-hospital mortality (31.4% vs. 48.2%, p=0.05). At a mean follow-up of 6.1±2.1 years, TA was still associated with a lower rate of overall mortality (42.8% vs. 64.7%, p=0.01). At multivariate analysis the only independent predictors were the success of the PCI for in-hospital and the ST-segment resolution for long-term survival. TA showed a trend towards the significance as independent predictor of long-term survival.

Conclusions: In this retrospective study TA was performed in almost 50% of patients undergoing PPCI for STEMI complicated by CS, who represented a population at lower clinical and angiographic risk. Furthermore, TA was not an independent predictor of survival. However, TA was significantly associated with ST-segment resolution that, in turn, was an independent predictor of long-term survival. Evidence-based data coming from larger studies would be necessary in order to confirm these findings.

Coronary interventions – *Wednesday May 22nd*
Impact of thrombus aspiration device on the results of primary PCI

Optimisation in implantation of second-generation everolimus-eluting stents by manual thrombus aspiration in primary PCI: findings from the EXAMINATION trial

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Aims: Manual thrombus aspiration reduces the thrombus burden during primary PCI in STEMI. The EXAMINATION trial demonstrated the safety and efficacy of everolimus-eluting stent implantation in the setting of STEMI. So the aim of this study is to assess the impact of manual thrombus aspiration during primary PCI in the EXAMINATION trial population.

Methods and results: The 1498 patients of the EXAMINATION trial were classified according to the use of manual thrombus aspiration into two groups. Angiographic results, stent implantation characteristics, primary patient-oriented endpoint (combination of all-cause death, myocardial infarction and any revascularisation) and secondary device-oriented endpoint (combination of cardiac death, target vessel myocardial infarction and clinically-driven target lesion revascularisation), definitive or probable stent thrombosis and major or minor bleeding at two years were evaluated. 976 (65.2%) patients were classified into thrombus aspiration group, and 522 (34.8%) patients into non-thrombus aspiration group. Patients in thrombus aspiration group were younger (60.57±12.17vs. 62.37±12.71, p=0.007) and with less prevalence of female gender (15.4% vs. 19.9%, p=0.025), previous MI (4.5% vs. 6.9%, p=0.049) and multivessel disease (10.9% vs. 15.7%, p=0.007) as compared to non-thrombus aspiration group. Thrombus aspiration was more often used in patients with low initial TIMI flow (0.58±1.04vs. 1.62±1.28, p<0.001), achieving a similar final TIMI flow (2.90±0.44 vs. 2.88±0.51, p=0.549). Thrombus aspirationgroup received fewer stents (1.35±0.62 vs. 1.45±0.71, p=0.005) and bigger stents (3.25±0.44 mm vs. 3.11±0.46 mm, p<0.001) as compared to the other group. A higher rate of direct stenting (69.2% vs. 43.3%, p<0.001) and a lower rate of post-dilatation (13.0% vs. 18.0%, p<0.009) was also present in thrombus aspirationgroup in comparison with non-thrombus aspiration group. The clinical follow-up at two years did not show any difference in the primary end point between thrombus aspiration group and non-thrombus aspiration group (14.8% vs. 17.8%; Hazard ratio, 95% confidence interval (CI): 1.231 (0.949-1.598), p=0.122). The lack of difference persisted after multivariate adjustment (Adjusted hazard ratio, 95% CI: 1.096 (0.822-1.460), p=0.534). No differences in other clinical endpoints were found between groups.

Conclusions: Manual thrombus aspiration in the setting of STEMI is associated with optimisation in angiographic results and stent implantation, with bigger and fewer stents, higher rate of direct stenting and lower rate of post-dilatation as compared to conventional primary PCI. Manual thrombus aspiration was not associated with clinical impact at two years.

Does direct stenting reduce mortality during primary PCI for STEMI independent of thrombectomy?

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Aims: Randomised trial data suggest that direct stenting (DS) during primary percutaneous coronary intervention (PPCI) for STEMI is associated with improved markers of reperfusion, such as ST segment resolution, myocardial blush grade and TIMI flow. However, there are few data as to whether these angiographic surrogates translate into a mortality benefit.

Methods and results: Consecutive patients attending two high-volume centres undergoing PPCI for STEMI between September 2008 and December 2010 were included in the analysis. All patients received aspirin 300mg and clopidogrel 600mg at point of STEMI diagnosis in the community. Use of predilatation (PD), manual thrombus aspiration (TA) and glycoprotein inhibitors (GPI) were at operator discretion. Demographic data and clinical outcomes were obtained by interrogation of local and national databases. A total of 1664 patients (mean age 65.3±12.5 years, 74.7% male) underwent PPCI during the study period. We excluded 77 who were not stented from the final analysis. Overall in hospital mortality was 3.0% (47/1587), with 30-day and 1-year mortality of 4.2% (66/1587) and 7.2% (114/1587) respectively. There was a significant 1-year survival advantage in patients who underwent DS (30.2%) compared with those who were stented after PD (3.16% vs. 8.63%; p<0.001). GPI use was similar in both groups (57.7% DS vs. 60.7% PD; p=0.29) whereas TA was higher in those who underwent DS (73.5% DS vs. 61.1% PD; p<0.0001). However, in those patients who underwent DS, there was a trend towards greater mortality with TA (3.64% TA vs. 1.83% no TA; p=0.35) suggesting that it is not the reason for mortality benefit in the DS group.

Conclusions: In an unselected real-world population undergoing PPCI for STEMI, DS is associated with a significant reduction in 1-year mortality. This effect appears to be independent of both GPI and TA use.

Manual thrombectomy fails to improve the index of microvascular resistance measured invasively during primary PCI: results of a randomised trial

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Aims: Manual thrombectomy (MT) at time of primary percutaneous coronary intervention (PPCI) may limit microvascular obstruction and subsequent infarct size, by reducing distal embolisation of thrombus. We assessed if MT use during PPCI would improve the index of microvascular resistance (IMR), compared to balloon angioplasty (BA).

Methods and results: Thirty patients presenting to the PPCI service with an occluded coronary artery that had at least TIMI 1 flow restored by the guide-wire were randomised 1:1 to receive either MT or BA prior to stenting. Coronary transit time (Tmn) by thermodilution and distal (Pd) and aortic (Pa) pressures were measured with/without intravenous adenosine induced hyperemia (140 mcg/kg/min). Measurements were taken after the lesion was wired (baseline), after MT or BA and finally after stent deployment. Coronary wedge pressure (Pw) was measured during stent balloon occlusion and central venous pressure (Pv) was assumed to be 5 mmHg. IMRc was calculated as ((Pa-Pv)*Tmn)*((Pd-Pw)/(Pa-Pw)) (corrected for collaterals). Cardiac troponin I (TnI) was measured at baseline and 12 hours. Mean hyperemic IMRc was not significantly different between groups at baseline (MT 30.9 vs. BA 46.1, p=0.25), prior to stenting (MT 42.2 vs. BA 40.4, p=0.98), nor after final stent deployment (MT 46.1 vs. BA 44.0, p=0.87). However hyperemic ΔIMRc from baseline was increased after MT (+40.6%; p=0.23) and this trend continued after stent deployment (+46.0%; p=0.09). This effect was not observed in those receiving BA. Again non-hyperemic ΔIMRc rose after MT (+50.4%; p=0.03) and after stenting (+83.5%; p=0.03). The ΔTnI was similar between groups.

Conclusions: In this randomised study, MT failed to demonstrate a superior reduction in IMRc or ΔTnI compared to BA. Serial invasive measurements suggest that MT may actually cause a detrimental increase in IMRc. These results question the proposed beneficial mechanism and effect of MT on microvascular function.

Coronary interventions – *Wednesday May 22nd*
Impact of thrombus aspiration device on the results of primary PCI

Efficacy of embolic protection stent as a function of thrombus size in STEMI patients: a MASTER trial substudy

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Aims: The aim of this report is to evaluate the impact of thrombus area in patients with acute STEMI undergoing PCI, and treated with MGuard Embolic Protection Stent vs. a control stent. The MGuard is a novel thin-strut metallic embolic protection stent with a PET micronet covering designed to trap and exclude thrombus and friable atheromatous debris and prevent distal embolisation.

Methods and results: A total of 433 patients with STEMI undergoing PCI were randomised in the MASTER Trial to either the MGuard stent or a control (BMS or DES) stent. Post-procedure complete ST segment resolution (>70% compared to baseline, STR) and TIMI 3 were significantly improved in patients randomised to the MGuard stent compared to control (57.8% vs. 44.7%, P=0.008; 91.7% vs. 82.9%, p=0.006, respectively). A visible thrombus was present in 88.5% of all patients, and its mean area was 34.58±18.24 mm2. When grouping both arms together, thrombus area was less or more than 30 mm2 in 193 and 190 patients, respectively. Aspiration was performed more frequently when a larger thrombus was present (80.8% vs. 65.8%, p=0.0009); Stent length (22.0 mm vs. 18.5 mm, p<0.0001) and diameter (3.5 mm vs. 3.0 mm, p<0.0001) were significantly different between the groups. In patients with small thrombus area vs. large thrombus area, TIMI3, MBG3 and cTFC were all superior, and clinical outcomes were all numerically lower. Interestingly, thrombus area did not affect STR. When comparing stent type, MGuard resulted in superior rates of complete STR (62.2% vs. 44.9%, p=0.02) and TIMI 3 (87.9% vs. 74.5%, p=0.02) only in the <30 mm2 thrombus area group.

Conclusions: Among patients with STEMI undergoing emergent PCI, superior rates of TIMI3, MBG3 and cTFC were achieved when a smaller than 30 mm^2 thrombus area was present. The MGuard Embolic Protection Stent compared to conventional metallic stents resulted in superior rates of complete STR and TIMI 3, with a distinct advantage in patients with thrombus area <30 mm^2.

Coronary interventions – *Wednesday May 22nd*
Use of DES in specific subsets of patients/ lesions

Stenting strategy after coronary rota-ablation in calcific and complex lesions. Long-term follow-up of the prospective ROTALINK study

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Aims: Coronary rotational atherectomy is a valuable strategy in case of complex and calcific coronary lesions. However, there's lack of long term data regarding the safety and efficacy of subsequent drug eluting stent (DES) implantation. We here report the final follow-up of a multicentre prospective study, whose aim was to evaluate the long term clinical outcome of patients treated with RA followed by any strategy (DES, bare metal stent (BMS) implantation or plain balloon angioplasty).

Methods and results: Six italian centres with high experience in rotational atherectomy participated at the ROTALINK study. Primary study endpoint was the incidence of major adverse cardiovascular events (death, myocardial infarction and target lesion revascularisation) after DES, BMS or balloon angioplasty at the longest available follow-up. Onethousand-threehundred-and-ninetyseven patients with 1602 lesions treated with rotational atherectomy and with an average follow-up of 30 months were enrolled into the study. There were no significant differences regarding main baseline clinical and angiographic characteristics among study groups, if we exclude an higher incidence of diabetes in the DES group (29.4 vs. 20.8 in the BMS group, p=0.001). In-hospital major adverse cardiovascular events were significantly higher in the DES group (7.6% vs. 2.6% vs. 2.0%, p=0.0001 for both comparisons), mainly due to an higher incidence of periprocedural myocardial infarction defined as CK-MB increase >3 times the upper limit of normal (6.4% vs. 1.2% vs. 2.1%, p=0.0001 for both). Thirty-month major adverse cardiovascular events were significantly lower in the DES group (15.1% vs. 24.2% vs. 20.8%, p=0.0001 between DES and BMS); this reduction was driven by a significantly lower incidence of target lesion revascularisation (8% vs. 14.6% vs. 13.9%, p=0.001 between DES and BMS). We did not observe any significant difference regarding death, myocardial infarction and stent thrombosis between the three study groups. At multivariate regression analysis the determinants of long term major adverse cardiovascular events were age, creatinine clearance <40 ml/min, BMS implantation and balloon angioplasty at index procedure.

Conclusions: After rotational atherectomy, DES implantation seems an optimal strategy because warrants lower long term major adverse cardiovascular events, although this strategy is associated with an inexplicable higher incidence of periprocedural myocardial infarctions. BMS or balloon angioplasty strategies seem equivalent.

Clinical outcomes of long-length (>28 mm) DES vs. long-length (>28 mm) bare metal stents in primary PCI for STEMI

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Aims: Primary percutaneous coronary intervention (PPCI) is the preferred reperfusion therapy for ST-elevation myocardial infarction (STEMI). Bare metal stents (BMS) is considered as the standard stent for STEMI although this may no longer hold true with recent studies showing favourable outcomes with newer generation drug-eluting stents (DES). For patients with *de novo* long coronary artery disease, outcomes remain relatively unfavourable for stent-based coronary intervention. The long term outcomes of DES implantation in long coronary lesions in the setting of PPCI for STEMI are unclear.

Methods and results: We evaluated the clinical outcomes of 175 STEMI patients (153 male, mean age 58.8±11.3 years) with *de novo* long coronary lesions (>28 mm) which were treated with BMS (89 patients) and DES (86 patients) during PPCI from June 2010 to November 2011. The primary end-point was major adverse cardiac event (MACE) ie a composite of cardiovascular death, re-infarction and target lesion revascularisation (TLR) within 1 year of follow-up. Secondary endpoints included individual components of MACE and rate of stent thrombosis. Both groups had similar baseline clinical characteristics at presentation. The mean number of stents, stent diameter and total stent length were also similar for both groups(BMS group: 1.22±0.5, 3.1±0.42 mm, 34.7±8.6 mm vs. 1.23±0.45, 3.0±0.43 mm, 36.1±10.1 mm, p=NS). The in-hospital mortality was similar for both groups (BMS group: 7.9% vs. 2.3% in DES group, p=0.16). The 1-year MACE rate was significantly lower in the DES group (0%) when compared to the BMS group (6.7%, p=0.01). There was no significant difference in the rate of cardiovascular mortality and re-infarction between both groups. However, there was a trend towards a much lower rate of TLR at 1 year for the DES group (0% vs. 4.9% in the BMS group, p=0.06). There were 3 cases of stent thrombosis in the BMS group (3.4%) with none observed for the DES group (0%, p=0.11).

Conclusions: Our registry findings showed that the use of DES for *de novo* long coronary lesions (>28 mm) in the setting of PPCI for STEMI appears to be safe and more effective than BMS. The MACE rate at 1 year was significantly lower in the DES group. Further studies in a larger patient population with longer clinical follow-up are necessary to confirm our preliminary findings.

Coronary interventions – *Wednesday May 22nd*
Use of DES in specific subsets of patients/ lesions

Impact of stent longth on long-term clinical outcome following newer-generation DES implantation

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Aims: The aim of this study was to compare the impact of stent length on long-term clinical outcome between first- and newer-generation drug-eluting stents (DES).

Methods and results: The effects of stent length (≥32 mm vs. <32 mm) were evaluated on clinical outcome in 8,126 patients who underwent PCI using either first-generation DES (Sirolimus- and Paclitaxel-eluting stent, n=6239) or newer-generation DES (Everolimus- and Zotarolimus-eluting stent, n=1887) between January 2004 and December 2009. The primary clinical outcome was major adverse clinical event (MACE) comprising all-cause death, non-fatal myocardial infarction, ischaemic-driven target vessel revascularisation and ST during 3 years of follow-up. While stent length of ≥32 mm was significantly associated with higher cumulative rates of MACE in patients treated with first-generation DES (log rank, p=0.001), it was not associated with primary outcome in those with newer-generation DES (log rank, p=0.481). Multivariate analysis also demonstrated that stent length of ≥32 mm was not associated with MACE in patients receiving newer-generation DES (adjusted HR, 1.101; 95% CI, 0.775-1.565; p=0.591), whereas being as an independent predictor of MACE in those implanted with first-generation DES (adjusted HR, 1.208; 95% CI, 1.055-1.383; p=0.006).

Conclusions: In newer-generation DES, stent length may not be associated with long-term clinical outcome in contradiction to first-generation DES era.

Coronary interventions – *Wednesday May 22nd*
Use of DES in specific subsets of patients/ lesions

One-year follow-up of patients treated with new-generation polymer-based 38 mm everolimus-eluting stent: the P38 study

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Aims: To assess the clinical outcome at one year follow-up of real-world patients with long coronary lesions treated with the 38 mm Xience Prime (Abbott Vascular, Santa Clara, CA, USA) everolimus-eluting stent. Long lesions account for approximately 20% of contemporary percutaneous coronary interventions (PCI) and represent special challenges to the interventional cardiologists, including increased risk of restenosis, periprocedural injury, geographical miss, and stent deliverability. Accordingly, results of drug-eluting stent (DES) in the treatment of simpler lesions are of limited applicability to long lesions and data on their performance in such a lesion subset are quite limited.

Methods and results: Two hundred and three consecutive patients (152 men, 68±9 years) presenting at five Italian centres between January 2010 and December 2011 with a long coronary lesion (≥35 mm) treated by PCI with at least one implanted 38 mm Xience Prime were enrolled in the P38 study. Dual antiplatelet therapy was prescribed for 12 months. Their clinical data were prospectively registered: 35% were diabetics, 41% had unstable presentation, and 71% had multivessel coronary disease. The target vessel was left anterior descending/diagonal branch in 91 patients, right coronary artery in 62 patients, left circumflex artery/obtuse marginal branch in 46 patients, and venous graft in 4 patients. In 69 patients, more than one stent was implanted in overlap and the mean stented segment was 47±16 mm. Angiographic success, defined as residual stenosis <20% in the target vessel with TIMI 3 flow, and procedural success, defined as angiographic success without the occurrence of major adverse cardiac events during the hospital stay, were achieved in 99% of patients. At one-year follow-up, 5 patients had died from cardiac causes, 7 had a non-fatal myocardial infarction and 8 underwent target vessel revascularisation, yielding a rate of major adverse cardiac events of 9.9%. One (0.5%) definite and one (0.5%) probable stent thrombosis were reported.

Conclusions: The use of a new-generation polymer-based 38 mm everolimus-eluting stent in a complex real-world population with unselected long lesions is associated with excellent angiographic and procedural results and with good clinical outcomes at one-year follow-up.

Coronary interventions – *Wednesday May 22nd*
Use of DES in specific subsets of patients/ lesions

PCI of left anterior descending coronary artery is safe when using latest generation DES

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Aims: Given the large amount of myocardium potentially at risk, the disease of left anterior descending (LAD) coronary artery and particularly of the proximal segment, has long been a focus of concern and subject of debate. Therefore our aim was to assess efficacy and long term (3 years) symptomatic improvement and survival of patients treated by one type of drug eluting stent (Nobori) in every day percutaneous coronary intervention (PCI) practice.

Methods and results: Out of 3067 patients treated with Nobori DES and enrolled in NOBORI 2 study, 834 had lesion at proximal LAD. The data were collected electronically and monitored on-line and on-site. All adverse events were adjudicated by an independent clinical event committee. The main outcome measures of the study were target lesions failure (TLF) and its individual components – cardiac death, myocardial infarction (MI) and target lesion revascularisation (TLR) and stent thrombosis (ST). Patients with treated proximal LAD (P-LAD) had similar age and gender as non-P-LAD patients, but had significantly less often history of PCI, CABG, or MI. On the other hand they more frequently presented in the course of STEMI, had higher number of vessels treated, more lesions detected and treated and more stents implanted. The lesions were more frequently ostial and at bifurcation, but less often tortuous. The reference vessels diameter was significantly higher in P-LAD lesions and they required more often post-dilatation. At the index hospitalisation both groups showed similar (<1%) rate of adverse events and hospitalisation time was similar. At 3-year, TLF was recorded in 6.9% of patients in P-LAD and in 6.4% in non-P-LAD (p=NS). The rate of cardiac death was 2.2% and 2.3% (p=NS), MI was 3.2% and 3.1% and TLR was 3.7% and 3.4% (P=NS), while 89% and 88% of the patients were free from angina in P-LAD and non-P-LAD group, respectively. Stent thrombosis was rare in both groups with 0.7% in P-LAD and 1.0% in the non-P-LAD.

Conclusions: Clinical outcomes showed favourable results when using the latest generation DES, Nobori for the treatment of proximal LAD demonstrating its long term safety and efficacy.

Comparison of biolimus A9-eluting stents and everolimus-eluting stents in diabetic patients with coronary artery disease

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Aims: Comparison of DES in diabetic patients has not been sufficiently evaluated. The purpose of this study was to compare Nobori biolimus A9-eluting stents and everolimus-eluting stents in diabetic patients.

Methods and results: We performed coronary stent implantation using biolimus A9-eluting stents (BES) in 108 diabetic patients with 170 lesions and everolimus-eluting stents (EES) in 148 diabetic patients with 213 lesions. Follow-up coronary angiography was performed 9 months after stent implantation. There were no significant differences in baseline clinical characteristics between the two groups. There were also no significant differences in vessel diameter (2.69±0.48 mm in BES group vs. 2.60±0.66 mm in EES group, p=0.26) and lesion length (16.9±7.8 mm in BES group vs. 16.0±5.9 mm in EES group, p=0.46). In-stent late loss was similar in both groups (0.35±0.43 mm in BES group vs. 0.33±0.43 mm in EES group, p=0.69). And angiographic restenosis rate was similar (5.8% in BES group vs. 5.2% in EES group, p=0.85). Major adverse cardiac events at 9 months were 6.2% in BES group and 6.2% in EES group (p=0.75).

Conclusions: Biolimus A9-eluting stents were non-inferior to everolimus-eluting stents in reducing in-segment late loss and reduced angiographic restenosis and major adverse cardiac events at 9 months in patients with diabetes mellitus and coronary artery disease.

Comparable low 1-year cardiac mortality among diabetic and non-diabetic patients undergoing coronary stenting with biolimus-A9-elution and biodegradable polymer

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Aims: Patients with diabetes mellitus (DM) undergoing percutaneous cardiovascular intervention (PCI) remain a challenging population with higher risk of adverse events compared to non-diabetic patients. Little is known on the outcomes of Biolimus A9™-eluting stents with biodegradable polymer in diabetic patients.

Methods and results: The electronic databases of two prospective registries (e-BioMatrix PMR and PMS) with similar structure addressing safety and efficacy of Biolimus A9-eluting stents with biodegradable polymer in clinical practice were pooled and the outcomes at one year were analysed. The diabetic (DM) population consisted of 1341 patients while 4213 patients were non-diabetics (non-DM). DM mean age was 64.6±10.2 and mean Charleson comorbidity index was 2.11±1.56. The corresponding values for non-DM were 62.8±11.1, 0.76±1.03. In DM, prior myocardial revascularisation, myocardial infarction, congestive heart failure, and renal failure were observed in 34%, 28%, 10%, and 7%, respectively. The corresponding findings for non-DM were 26%, 24%, 3%, and 2%. A total of 47% of DM presented with acute coronary syndromes (ACS) (approximately ¼ STEMI, ½ NSTEMI and ¼ unstable angina) while the corresponding figure for non-DM was 51%. With respect to procedural characteristics, 1, 2, and 3 or more stents were implanted in 57%, 25%, and 18% of DM, respectively; similar findings were observed in non-DM. In DM, LAD stenting was performed in 49% of cases and multivessel intervention was performed in 22% of patients while the corresponding figures for non-DM were 55% and 18%. 1-year cardiac mortality was 1.3% in DM and 0.8% in non-DM (P=0.09). Additional data on myocardial infarction, repeat revascularisation and stent thrombosis will be available for the meeting.

Conclusions: In a sizable DM population with high proportion of ACS, the Biolimus A9-eluting stent with biodegradable polymer conveys a low 1-year mortality which is comparable to the one of non-DM patients despite higher baseline risk.

Coronary interventions – *Wednesday May 22nd*
Use of DES in specific subsets of patients/ lesions

Comorbidities determine prognosis in patients undergoing coronary stenting: Results from two large registries evaluating biolimus-A9-eluting from biodegradable polymer stents

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Aims: We assessed in two large prospective registries (e-Biomatrix PMR and PMS) the efficacy and safety of biolimus-A9-eluting stents with biodegradable polymer, and whether comorbidities influence prognosis in patients undergoing coronary revascularisation.

Methods and results: We used the Charlson comorbidity index (CCI), a scoring system involving weighting factors on the basis of disease severity, including cardiovascular diseases, diabetes, renal failure, chronic infections and malignant tumors. Of the 5,559 patients, 3,516 (=63.3%) had at least one comorbidity, of which the most common comorbidities were prior myocardial infarction (38.3% of the population), diabetes mellitus (23.2%), peripheral vascular disease (6,5%), heart failure (5,7%), chronic obstructive pulmonary disease (5,1%) cerebral vascular disease (5,1%) and renal failure (2,7%). Patients were categorised into four groups: CCI-0 (no comorbidity; n=2041), CCI-1 (one comorbiditiy; n=2162), CCI-2 (two comorbidities; n=776), CCI ≥3 (three or more comorbidities; n=578). With increasing CCI patients were older, had higher rates of hypertension, hypercholesterolemia, and obesity, but were less often current smokers. They had undergone increasingly often a prior PCI or CABG and had more often decreased LV ejection fraction. LV EF <40%: CCI-0: 3,8%, CCI-1: 7,4%, CCI-2: 13,2%, CCI ≥3: 26,2%; p<0.01. Compared to the other groups, patients with CCI ≥3 underwent PCI less often for STEMI (CCI-0: 36,8%, CCI-1: 37,9%, CCI-2: 32,3%, CCI ≥3: 16,3%). Intervention characteristics including number of vessels treated and stent diameter and length were similar among the groups. CCI was associated with an increased overall one year mortalitiy (CCI-0: 0,9%, CCI-1: 1,3%, CCI-2: 2,3%, CCI≥3: 4,3%; p<0.01) and cardiac mortality (CCI-0: 0,7%, CCI-1: 0,6%, CCI-2: 1,2%, CC I≥3: 2,4%; p<0,01).

Conclusions: Comorbidities seem not to impact on intervention characteristics in patients undergoing coronary revascularisation. However, prior myocardial infarction, diabetes, vascular disease, pulmonary disease and renal insufficiency have a major impact on one year mortality.

Coronary interventions – *Wednesday May 22nd*
Radial access: a gold standard worldwide?

Radial vs. femoral accesses for PCI in patients with ACS

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Aims: The purpose of this observational study was to evaluate the effects of radial artery access (RA) vs. femoral artery access (FA) in patients undergoing percutaneous coronary intervention (PCI) due to acute coronary syndrome i.e. ST-elevation myocardial infarction (STEMI) and unstable angina/non-STEMI (UA/NSTEMI).

Methods and results: Data were obtained from the SCAAR registry (Swedish Coronary Angiography and Angioplasty Registry) for PCI procedures performed in Västra Götaland region in Sweden between 2005-2011. We evaluated 30-days mortality in 10007 patients, N=4386 in RA and N=5621 in FA. The two groups were compared using Cox proportional hazards regression with "shared frailty" to account for hierarchical database. Adjustments for differences in baseline characteristics were made with propensity score. The following variables were included in the calculation of the propensity score: age, gender, indication for PCI, smoking habits, hypertension, diabetes, hyperlipidaemia, severity of coronary artery disease, previous infarction, previous PCI, previous coronary artery by-pass surgery (CABG), anticoagulation therapy with glycoprotein IIb/IIIa receptor antagonists (GP IIb/IIIa), bivalirudin, clopidogrel, unfractionated heparin/low-molecular weight heparins (UH/LMWH), year, hospital. The two groups were balanced regarding age, gender, diabetes, smoking habits, hypertension and hyperlipidaemia. RA patients were more likely to be pre-treated with aspirin, clopidogrel and to receive bivalirudin and drug-eluting stents during the procedure. FA patients were more likely to had previous myocardial infarction, previous PCI, previous CABG and to receive GP IIb/IIIaand UH/LMWHduring the procedure. There were 3761 patients (37.6%) with STEMI and 6246 (62.4%) with UA/NSTEMI. More patients with STEMI underwent PCI through FA. RA was associated with 38% reduction in 30-days mortality (1.5% vs. 2.8%; HR 0.62; 95% CI 0.44-0.87; p=0.005).

Conclusions: In patients with acute coronary syndromes, PCI through radial artery access is associated with reduced 30-days mortality. A properly designed randomised clinical trial is urgently needed to test the hypothesis that radial artery access decreases mortality in patients with acute coronary syndromes.

The impact of radial access on in-hospital mortality of patients undergoing primary PCI. Data from the Portuguese interventional cardiology registry

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Aims: The aims of this study are to compare in-hospital mortality in patients undergoing primary PCI via radial access or femoral access, based on the Portuguese Interventional Cardiology Registry (PICR), and evaluate the interaction with the use of glycoprotein IIbIIIa (GP IIbIIIa) inhibitors.

Methods and results: 6559 consecutive patients with STEMI undergoing primary PCI prospectively included in the PICR from Jan/2007 to Dec/2012. Radial access was used in 1384 patients (21%) and femoral access in 5175 (81.9%). We compared demographic and clinical variables between the 2 groups. Independent predictors of in-hospital mortality were identified by multivariate analysis. The interaction with the use of GP IIbIIIa inhibitors was also evaluated. In-hospital mortality occurred in 3.3% of patients undergoing primary PCI via femoral access and in 0.8% of patients undergoing primary PCI via radial access (p<0.01). After multivariate analysis, radial access was an independent predictor of in-hospital mortality (OR 0,3; IC 0,125-0,699, p=0,006). Other predictors identified in the model were age >65 years (OR 3.1, IC 1.940-4.816, p<0.001), history of heart failure (OR 3.0, IC 1.144-7.910, p=0.026), history of peripheral artery disease (OR 8.5, IC 4.693-15.472, p<0.001), history of smoking (OR 0.5, IC 0.332-0.862, p=0.010), haemodynamic support (OR 8.9, IC 5.622-14.194, p<0.001), left main PCI (OR 4.7, IC 2.246-9.834, p<0.001), right coronary artery PCI (OR 1.7, IC 1.182-2.559, p=0.005). The benefit of choosing radial access over femoral access was independent from Gp IIbIIIa inhibitors use (p for interaction NS).

Conclusions: In this population of STEMI patients undergoing primary PCI, radial access was associated to a lower in-hospital mortality regardless the use of Gp IIbIIIa inhibitors.

Outcomes of femoral vs. radial access for cardiac catheterisation

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Aims: The best approach for access with cardiac catheterisation procedures is currently being debated. Safety outcomes for various access sites have not been examined on a large scale in the clinical setting.

Methods and results: This is a real-world, large scale descriptive study utilising ACC data from multiple clinical sites that were entered prospectively on consecutive patients from over 20 hospitals participating in this cardiovascular registry. All patients undergoing a cardiac catheterisations procedure are included in the database of approximately 60,000 patients for the time period between January 1, 2010 and December 31, 2011. Endpoints included complications of bleeding, myocardial infarction, shock, transfusion, and death. Composite scores were calculated for combined bleeding events and for major clinical events. Outcomes were compared between access location (femoral vs. radial) for each closure approach (device vs. compression). Chi square analysis and odds ratio parameters were used to determine statistical equivalence at p<0.05. A total of 59,530 patients were included (61.5% male, 38.5% female, 91.5% Caucasian, 8.5% minority). PCI was performed on 33,381 (66.0%). A device method was used in 39.5% of procedures. There were 57274 femoral (96%), 1855 radial (3%), 305 brachial (0.5%), and 57 other (0.1) access approaches used. The overall early bleeding (within 72 hr) rate was 1.6%, post access site bleed rate was 0.3%, transfusion rate was 2.6%, and mortality rate was 1.1%. Among patients for whom device closure was used, there was no advantage to the radial/brachial approach in terms of major or bleeding complication rates. Post MI (femoral 0.7% vs. radial/brachial 0.6%, p=0.89), bleeding within 72 hr (femoral 1.2% vs. radial/brachial 1.0%, p=0.41), composite major event rate (femoral 3.0% vs. radial/brachial 3.2%, p=0.46), and composite bleed rate (femoral 4.3% vs. radial/brachial 3.5%, p=0.06). There was a significant disadvantage in bleeding complications to the femoral approach when manual compression was used (femoral 7.3% vs. radial/brachial 3.5%, p<0.01). However, there was a highly significant difference in mortality for radial/brachial (4.0%) than femoral (1.1%) [p=0.001].

Conclusions: These findings demonstrate, for the first time in a large clinical registry, that outcomes associated with various access approaches are similar in terms of major complications. Results suggest that an advantage to radial is eliminated when femoral closure is accompanied by device closure and bivalirudin use.

Coronary interventions – *Wednesday May 22nd*
Radial access: a gold standard worldwide?

Predictors of conversion from radial to femoral access in cardiac catheterisation

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Aims: To study the prevalence of conversion from radial access to femoral access in cardiac catheterisation and identify its clinical and demographic predictors.

Methods and results: Prospective multicentre registry, including 7664 consecutive patients undergoing catheterisation via radial access between Jan/2009 and Oct/2012 (66±11 years, 32% female). A total of 2982 procedures (38.9%) were PCIs and the most used route was the right radial access (97.6%). We evaluated the incidence of conversion to femoral access and its predictors by logistic regression analysis. Radial access failure rate was 6.2%, with conversion to femoral access in most cases (93.9%). The need for conversion was more frequent in older patients (mean age 69±12 yrs vs. 65±11 yrs, p<0.001), women (8.6% vs. 4.5%, p<0.001) and in patients with a smaller body surface area (mean BSA 1.82±0.18 vs. 1.87±0.20, p<0.001). Smoking was associated with lower radial access failure (4.2% vs. 7.0%, p<0.001). Conversion rate to femoral access was more frequent in PCIs (7.4%) than in diagnostic catheterisations (4.8%), p<0.001. Conversion rate was also higher when shorter introducer were used compared to the longer ones (8.0% vs. 3.6%, p<0.001), but less with 6F caliber introducer compared to 4F or 5F introducers (5.5% vs. 7.6%, p=0.009). Independent predictors of conversion from radial access to femoral access were the use of short introducers (OR 3.401, IC 2.375-3.895, p<0001), angioplasty (OR 1.727, IC 1.374-2.171, p<0001), female gender (OR 1.568, IC 1.233-1.994, p<0.001), multivessel disease (OR 1.458, IC 1.168-1.819, p=0.001), BSA£1.938 (OR 1.452, IC 1.124-1.877, p=0.004), age>66 years (OR 1.356, IC 1.090-1.688, p=0.006).

Conclusions: Transradial approach for cardiac catheterisation was associated witha high success rate. The need for conversion to femoral access was very low, especially when long introducers were used. Some demographic predictors of conversion were identified (female gender, older age and smaller BSA), which could be taken in consideration when choosing the vascular access.

Coronary interventions – *Wednesday May 22nd*
Radial access: a gold standard worldwide?

Right vs. left access for transradial coronary angiography in elderly patients. The impact of the brachiocephalic trunk

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Aims: To compare the right radial and left radial artery approaches for a diagnostic coronary angiography performed in elderly patients by experienced operators.

Methods and results: Patients aged 70 years or older who underwent a coronary angiography were prospectively randomised to a transradial right or left approach. Time used for the catheterisation, radiation exposure, material used (catheters, wires) and whether or not a difficulty was found by the interventionalist were all registered in each exam. All procedures were performed by an experienced radial interventionalist (>200 radial procedures / year) and using the same technique (5F Judkins catheters, starting with the right coronary artery and using a long wire to exchange the catheters). Only the diagnostic procedure was considered, therefore if a coronary angioplasty was deemed necesary after the coronary angiography, the time spent as well as the radiation exposure during the coronary intervention were not considered for analysis purposes. STEMI patients, those who had haemodynamic instability and those with previous CABG were excluded from this study. Accordingly, one hundred and two patients were included: 52 through the right and 50 through the left radial artery. Patiens were 76,7 years old in both groups and 57% and 45% were female, respectively (p=0.1). The total number of projections (8.0 vs. 7.5, p=0.3) as well as contrast media used (108 ml vs. 106 ml, p=0.4) were comparable among groups. Average time spent to gain radial access (puncture and sheath insertion) was 117 sec (SD 115) for the right radial and 92 sec (SD 83) for the left radial artery (p=0.1). For the right radial access, a mean of 206 sec (SD 92) was needed to engage the right coronary artery and record the first projection. This time was significantly lower for the left radial route (169 sec (SD 80), p=0.01). Total procedure time was 782 sec (SD 285) for right and 695 sec (SD 296) for the left radial approach (p=0.06). Regarding radiation exposure, there was a slight, albeit not significant difference in radioscopy time favouring the left radial access (286 sec (SD 161) vs. 256 sec (SD 192), p=0.1); no difference in absorbed radiation (dose area product) was found between groups. An extra wire (usually hydrophillic) was more frequently used in the right radial procedures in comparison to the left radial ones (33% vs. 5%, respectively, p<0.01). Finally, the interventionalist found some degree of difficulty in 57% of the procedures performed through the right radial artery and in 27% when the left radial artery was accessed (p<0.01). This difference was mainly due to brachiocephalic trunk tortuosity, found in 24%, exclusively for the right radial approach.

Conclusions: When catheterisation for patients 70 years of age or older is performed by experienced hands, the left radial access is associated with lesser extra material use and fewer difficult procedures than the right radial approach. In addition, less time is needed to navigate to the ascending Aorta and engage the right coronary artery. Nevertheless, this is neither related to shorter procedures nor to less radiation exposure. The brachiocephalic trunk tortuosity might account at least in part for these findings.

The transradial approach for primary PCI in octagenarians: its safety, feasibility and limitations

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Aims: We aim to report the safety, efficacy and limitations of performing primary PCI in octogenarians via the TR at the CK Hui Heart Centre which has been carrying out PCI via the transradial route (TR) route since 2001. All operators performed >300 PCI procedures annually via the radial route.

Methods and results: Data on patient characteristics, procedure detail and outcomes were collected from the local hospital and the provincial APPROACH (Alberta Provincial Project for Outcomes Assessment in Coronary Heart disease) databases from January 2007 till April 2012. 169 patients (Male 53.8%, mean 84.9 years) underwent primary PCI where most procedures were done by the TR (141 cases vs. 28 cases). There was no difference in patient characteristics in terms of age, body mass index, prevalence of hypertension, diabetes, treated hyperlipidaemia, current smoking history, and previous history of STEMI, PCI or CABG in either cohort. Female patients (65.5% vs. 41.9%, p=0.025), cardiogenic shock (25.0% vs. 2.1%, p<0.001), intra aortic balloon pump support (10.7% vs. 0.7%, p=0.015) and renal impairment/creatinine clearance <30 ml/minute (21.4% vs. 7.1%, p=0.029) were more prevalent in the TF group. There was no difference in contrast volume (TF 237 ml vs. TR 227 ml, p=ns), catheter lab to first balloon inflation (TF 35.1 minutes vs. TR 32.9 minutes, p=ns) and fluoroscopy times (TF 16.3 minutes vs. TR 20.4 minutes, p=ns) or number of diagnostic/guide catheters used per procedure (TF 4.1 vs. TR 4.3, p=ns) between both groups. 9.9% of the TR group crossed over to TF to successfully complete the procedure. The TF cohort had a significantly higher incidence of access site bleeding (10.7% vs. 1.4%, p=0.034) and blood transfusion requirements (28.6% vs. 4.9%, p<0.001). Post procedure haemoglobin drop was higher in the TF cohort (1.3 g/dl vs. 0.5 g/dl, p<0.001). Peak creatinine kinase levels post primary PCI were higher in the TF group (2422 IU/L vs. 1558 IU/L, p=0.006). 24 hour, 30 day and 1 year mortality were higher in the TF cohort (10.7% vs. 1.4%, p=0.033; 23.2% vs. 3.6%, log rank p<0.001 and 33.3% vs. 11.8%, logrank p=0.0002) respectively. Cardiogenic shock was found to be an independent predictor of mortality over time (HR 0.14, 0.03-0.62 [95% CI], p=0.009).

Conclusions: While the TR approach for primary PCI is safe and feasible in stable octogenarians with overall low cross over rates and associated with fewer bleeding complications, the TF approach remains the preferred access of choice in high risk patients presenting with haemodynamic instability. This preference in access does not however translate into any favourable short and long term outcomes. Primary PCI via the TR approach amongst octogenarians should be the preferred strategy in high volume TR PCI centres.

How to choose the best antispastic agent to prevent radial artery spasm during PCI? The SPASM3 study

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Aims: Following a recent verapamil stock-out, a switch to diltiazem or isosorbide dinitrate was proposed as a substitution for the prevention of radial artery spasm in patients undergoing transradial coronary interventions. The aim of our study was to compare the efficacy and safety of these three vasodilators in this setting and to find independent predictors of RAS.

Methods and results: A total of 731 patients were consecutively randomised to receive diltiazem, verapamil, or isosorbide dinitrate through the arterial sheath. The primary endpoint was the occurrence of a radial artery spasm defined as a limitation of the catheter movement and/or a significant pain perceived by the patient during catheter mobilisation. Secondary endpoints included the occurrence of a severe radial artery spasm, a severe pain in the arm, the need for morphine chlorydrate or midazolam injection, the crossover to the contralateral radial or femoral artery and the safety events. Radial artery spasm occurred in 147 patients (20.1%) and was significantly more frequent among patients receiving diltiazem [n=67 (26.6%)] compared to verapamil [n=38 (16.2%)] and isosorbide dinitrate [n=42 (17.2%)] (p<0.006). The same trend was found for severe radial artery spasm (p=0.13). No significant difference was found between the three groups in terms of severe pain, crossover and safety events. Morphine chlorydrate was used in 2.7% of the procedures and significantly more often in the isosorbide dinitrate group (4.9%) than in the other groups (p=0.03). Midazolam was used in 11.6% of the procedures and significantly more often in the diltiazem group (15.5%) than in the other groups (p=0.03). Four factors were found to be independently associated with the occurrence of radial artery spasm: female gender, failure at first attempt to radial artery access, emergency procedure and use of diltiazem.

Conclusions: Verapamil and isosorbide dinitrate are more effective that diltiazem to prevent radial artery spasm. Verapamil and isosorbide dinitrate have a similar efficacy, but the former is associated with a better tolerance (ie less morphine chlorydrate injections).

Coronary interventions – *Wednesday May 22nd*
Radial access: a gold standard worldwide?

Transradial approach does not increase the risk of stroke or transient ischaemic attack in patients undergoing diagnostic and therapeutic cardiac catheterisation: analysis of 16,710 cases of a large volume single-centre registry

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Aims: Concerns have been raised about the potential risks of increased Stroke/Transient Ischaemic Attack rates [stroke/TIA] with radial access. We aim to assess the association between the risk of stroke and radial artery vascular access site in current practice of both diagnostic and interventional cardiac procedures.

Methods and results: We retrospectively analysed the data from of 16,710 diagnostic and interventional procedures, in which there was manipulation of the aortic arch, included in a large volume single-centre prospective registry between Jan/2006 and Nov/2012. Radial artery was used as the primary vascular access site in 4,195 cases and 36 patients converted from femoral to radial: the radial-to-femoral conversion rate was 7%. Target cases were identified by cross-matching patients who underwent both cardiac catheterisation and cranial-CT during the same admission episode (n=67), using the institution's official codification database. Procedure related events were adjudicated according to a definite diagnosis established by a neurologist, as those occurring within 48 hours after the procedure. For patients discharged before that, subsequent reporting was used. In order to reduce bias, radial procedures were considered as those in which transradial assess was used either primarily of after conversion. Transradial approach increased from 0.7% in 2006 to 75% in 2012, with a sharp change between 2009 and 2010 (5.5% to 36%). Total incidence of stroke/TIA was 0.16% (n=27) and did not change significantly over the study period, despite the increase in radial procedures (p=0.26 for the comparison between years). Overall, we could not demonstrate a significant difference in stroke/TIA rates between patients undergoing cardiac catheterisation via radial vs. femoral artery (0.14% vs. 0.16%; p=0.81). Results were consistent in 4 pre-specified sub-groups according to sex, age (≥65 y.o. vs. younger), interventional vs. diagnostic and ACS vs. stable. After correction for important differences in baseline characteristics (using a logistic regression model) radial assess site was not a predictor of stroke/TIA (OR 0.86; 95% CI 0.27-2.7; p=0.80).

Conclusions: Stroke/TIA rates were within range of international reports. Our observational study suggests that widening the use of the transradial approach for cardiac catheterisation, is not associated with an increased risk of clinically relevant procedure-related neurologic complications.

Coronary interventions – *Thursday May 23rd*
PCI of bifurcation lesions: results from registries and new dedicated stents

Impact of bifurcation technique on long-term clinical outcomes in 976 patients with distal unprotected left main coronary artery stenosis treated with DES: Milan and New-Tokyo registry

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Aims: Unprotected distal left main (UDLM) bifurcation intervention still remains technically challenging despite improvement in device technology.

Methods and results: Between April 2005 and August 2011, 976 consecutive patients with UDLM following PCI with DESimplantation were evaluated: 633 were treated with 1 stent (1-S) and 343 with 2 stents (2-S). The end point of the study was the incidence of cardiac mortality, target lesion revascularisation (TLR) and TLR for main-branch (TLR-MB) including ULM itself and proximal left anterior descending artery. More complex lesions were observed in the 2-S group (3 vessel disease, 53.3% vs. 43.9%, p=0.01, true-bifurcation, 85.5% vs.49.8%, p<0.001, calcification; 61.0% vs.49.1%, p<0.001) despite similar comorbidities. Peri-procedural MI occurred more frequently in the 2-S group as compared to the 1-S (12.0% vs.6.1%, p=0.01). During follow-up period (median 36.9 months), survival free from cardiac mortality was similar between the 2 groups (cardiac mortality at 3-years; 5.1% in 1-S vs.2.9% in 2-S, HR 0.56, CI 0.28-1.14, p=0.11) despite higher occurrence of TLR and TLR-MB at 3-years (TLR; 11.7% vs. 23.5%, HR 2.19 CI 1.60-3.00, p<0.001 and TLR-MB; 5.1% vs. 9.9%, HR1.60 CI 0.94-2.75, p=0.09). When we assess the impact of 2-S, mini-crush (109 patients), culotte technique (69) and TAP (41) were similar clinical result at long term while old crush technique (54) was worse as compared to these new techniques. (cardiac mortality at 3-years; 7.4% in crush, 0.9% in mini-crush, 2.4% in TAP vs. 2.9% in culotte, TLR at 3-years; 31.5%, 21.1%, 24.4% vs. 23.2% and TLR-MB; 14.8%, 4.6%, 7.3% vs.11.6%, respectively).

Conclusions: Compared with the 2-stent technique, the 1-stent technique is associated with a better TLR-free survival. However, our registry demonstrated that new 2-stent technique such as mini-crush, culotte and TAP technique seems to be feasible except higher incidence of revascularisation.

Long-term clinical outcomes following treatment of bifurcation lesions with the zotarolimus-eluting stent

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Aims: Percutaneous coronary intervention (PCI) of bifurcation lesions is technically challenging. The Resolute Integrity™ zotarolimus-eluting stent has been designed to provide greater flexibility, mechanical properties and efficacy for bifurcation PCI. We aim to explore the 3-year clinical outcomes following treatment with R-ZES in bifurcation lesions.

Methods and results: There were 703 patients (1147 lesions) with at least 1 bifurcation lesion treated with the R-ZES from the RESOLUTE All Comers randomised clinical trial (n=190 patients, 296 lesions); and RESOLUTE International trial (n=512 patients, 791 lesions) from the RESOLUTE Clinical Program. An independent Clinical Events Committee adjudicated all adverse events. Baseline patient characteristics include a mean age of 69.3±11.1 years, 20.6% female, 27.0% with diabetes, 28.9% with a prior PCI, 24% current smokers, and 31.3% presented with a myocardial infarction (MI) as the reason for revascularisation. Almost 2/3 of bifurcation lesions were located in the left anterior descending artery (64.9%) and 73.2% were lesion class B2/C. There were 1.6±0.8 lesions treated per patient, and 2.0±1.2 stents with a total stent length of 37.5±24.8 mm per patient. Sidebranch stenting occurred in 19.1% of treated lesions. Bifurcation techniques included 38.8% T stenting, 25.9% mini-crush or crush stenting, 9.5% V stenting, 7.5% simultaneous kissing stents, 5.4% culotte stenting, and 12.9% other. In-hospital event rates were 0.7% cardiac death, 4.3% target vessel MI and 5.3% target lesion failure (TLF). At 3-year follow-up, the rate of cardiac death was 2.9%, target-vessel MI was 6.6%, target lesion revascularisation was 6.7%, target vessel revascularisation was 9.3%, and TLF was 13.4%. Overall ARC-defined definite and probable stent thrombosis (ST) was 2.5%, with 2.0% early (≤30 days) ST and 0.4% very late (>1 year) ST. Among 2772 patients in these 2 trials with non-bifurcated lesions the overall rate of ST was 1.2% with 0.3% very late ST.

Conclusions: Treatment of bifurcation lesions with the R-ZES in an all comers population resulted in excellent safety and effectiveness outcomes through 3 years of follow-up with a low rate of very late ST.

Coronary interventions – *Thursday May 23rd*
PCI of bifurcation lesions: results from registries and new dedicated stents

DES for treatment of bifurcation lesions: short and long-term clinical outcomes

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Aims: Clinical outcomes of coronary bifurcations treatment are in general inferior when compared to non-bifurcation lesions. The use of drug-eluting stents for the treatment of bifurcation lesions lowers the rate of restenosis and subsequently provides improved clinical outcomes. Therefore, our aim was to study the performance and short and long-term safety of the Noboridrug-eluting stent in this lesion subset.

Methods and results: A total of 12444 patients were enrolled in 2 large prospective, single-arm multicentre NOBORI registries. The primary endpoint was Target Lesion Failure (TLF) defined as cardiac death (CD), target vessel related myocardial infarction (TV-MI) and target lesion revascularisation (TLR). At least 1 bifurcation lesion (BFL) was treated in 1411 of the enrolled patients. We report short and long term results of patients with BFL compared to patients without BL treated (NBFL). Patients in both groups were of similar age (63.5±11.1 vs. 62.9±11.8; p=NS) with more males (81.3% vs. 76.4%; p<0.01) and unstable angina (26.5% vs. 17.8%; p<0.01) in BFL group and higher incidence of diabetes in NBFL group (26.9% vs. 32.9%; p<0.01). In the BFL group number of treated lesions was higher (2.3±1.4 vs. 2.0±1.4; p<0.01), lesions were more complex (B2/C: 78.4% vs. 56.3%; p<0.01), more frequently calcified (32.1% vs. 28.0%; p<0.01), ostial (19.4% vs. 10.2%; p<0.01), located in the LAD (51.7% vs. 42.5%; p<0.01) and LM (3.9% vs. 1.5%; p<0.01) than in NBFL group. For the treatment of bifurcation lesions more than 60% of the lesions were treated by single stent strategy. T-stenting was used in 19.9%, while crush (5.8%) and Culotte (6.8%) were used less frequently. The final balloon kissing was performed in 59% of lesions. TV-MI and TLF rates at 1 month follow-up were higher in the BFL group (1.3% vs. 0.3%; p<0.01 and 1.4% vs. 0.5%; p<0.01), remaining higher at 1 year follow-up (2.2% vs. 1.0%; p<0.01 and 4.2% vs. 2.7%; p<0.01). In the cohort followed up to 3-year the rate of TV-MI (3.2% vs. 2.1%) and TLR (4.4% vs. 3.1%) were similar between the groups, while cardiac death rate was significantly lower in BFL group (0.8% vs. 2.7%, p<0.001). TLF was comparable at 3-year (6.7% vs. 6.4% p=NS), with a very low frequency of definite and probable stent thrombosis in both subgroups (0.7% vs. 0.9%).

Conclusions: Nobori DES, with its specific open cell design and biodegradable polymer showed favourable short and long-term clinical outcomes with low rates of TLF and stent thrombosis proving to be safe and efficient in the treatment of challenging bifurcation lesions.

Coronary interventions – *Thursday May 23rd*
PCI of bifurcation lesions: results from registries and new dedicated stents

Clinical outcomes after final kissing balloon inflation compared with no final kissing balloon inflation in bifurcation lesions treated with a dedicated coronary bifurcation stent

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Aims: Although being a two-stent technique, it could be hypothesised that Tryton Side Branch Stent™ offers some advantages over conventional stents perhaps eliminating the absolute necessity of final kissing balloon inflation (FKBI). Therefore we compared clinical outcomes between FKBI and no FKBI in patients with bifurcation lesions treated with Tryton.

Methods and results: We included 759 patients of whom information on FKBI was available. Clinical outcomes were defined as target vessel failure (TVF; composite of cardiac death, any myocardial infarction (MI), and clinically indicated target vessel revascularisation (TVR)), cardiac death, MI, clinically indicated TVR, and ST (subdivided into definite and probable). FKBI was performed in 626 patients (83%). The average age was 67 years in the FKBI group and 65 in the no FKBI group, with 75% and 77% male patients, respectively. There were some differences in baseline clinical and procedural characteristics between patients with and without FKBI performed. In the FKBI group, less patients had diabetes mellitus, renal dysfunction and previous MI, and more patients had hypercholesterolemia, bifurcations with a medium (≥30º≤80º) angle, larger reference vessel diameters (RVD) of the MB and the SB, and longer MB lesion length. Differences in procedural characteristics were more successful Tryton placements, larger main branch stents, and different stent platform design in the FKBI group. Follow-up data was available in 731 (96%) patients with a median follow-up of 190 days [IQR: 175-364]. In the FKBI group cardiac death occurred less often compared with the no FKBI group (1.7% vs. 4.2%, respectively, p=0.005). There were no differences in MI rates (5.3% vs. 4.1%, p=0.98), TVR rates (4.9% vs. 3.5%, p=0.39), TVF rates (9.5% vs. 9.2%, p=0.47), and ST rates (definite ST 0.2% vs. 0.8%, p=0.20 and probable ST 0.2% vs. 0%, p=0.66).

Conclusions: No clinical differences except cardiac death could be detected between patients with and without FKBI after Tryton placement. These differences in cardiac death rates could be explained by the differences in baseline characteristics and angiographic characteristics (more diabetics, patients with renal dysfunction, previous MI and smaller main branch stents in the no FKBI group).

Coronary interventions – *Thursday May 23rd*
PCI of bifurcation lesions: results from registries and new dedicated stents

First-in-man study of dedicated bifurcation sirolimus-eluting stent - complete 6-month clinical results

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Aims: The aim of this first-in-man study is to assess effectiveness and safety of dedicated bifurcation sirolimus-eluting stent BiOSS LIM (Balton, Poland) in patients with stable coronary artery disease (CAD) or NSTE-ACS.

Methods and results: BiOSS LIM is a coronary dedicated bifurcation sirolimus-eluting balloon expandable stent made of 316L stainless steel. It is coated with a biodegradable polymer comprised of lactic and glycolic acids. The polymer releases sirolimus in a time-controlled manner lasting ca 8 weeks. The stent consists of two parts with different diameters connected with two struts of 1.5 mm length. BiOSS LIM is mounted on a dedicated bifurcation balloon (Bottle, Balton, Poland) with three markers. The third marker localised at the mid part shows proximal end of its smaller distal part. The stent delivery is a rapid exchange system. Patients with a final diagnosis of stable CAD or NSTE-ACS who signed informed consent between October 2011 and October 2012 were included into the study. The enrollment was performed in three invasive cardiology centres (Warsaw, Poland; Sofia, Bulgaria and Marbella, Spain). Patients with STEMI or Medina type 001 bifurcation lesions were excluded from the registry. Provisional T-stenting was obligatory strategy. Double antiplatelet therapy was planned for 12 months. An angiographic control was planned at 9-12 months in all patients. The primary end-point of the study is the rate of death, myocardial infarction, in-stent thrombosis and target lesion revascularisation after 12 months. Here are presented complete results of 3-month follow-up. However at the time of EuroPCR 2013 complete clinical 6-month follow-up will be available as well as angiographic controls will be performed in more than 50% of enrolled patients. 60 patients with stable CAD or NST-ACS (78.3% vs. 21.7%, respectively) were included into this prospective, feasibility and safety assessment registry. The average age of enrolled patients (71.7% males) was 66.4±11.3 years. There were 46 (76.7%) patients with hypertension, 23 (38.3%) with diabetes and 17 (28.3%) with prior MI. Additionally, 28 patients (46.7%) underwent prior PCI, while 6 (10%) patients had previous CABG. In 50% of cases the lesion was localised in LMS, followed by 41.7% in LAD, 6.7% in LCx and 1.7% in RCA. According to Medina classification true bifurcations were present in 80%. All BiOSS stents were implanted successfully (avg. pressure 14 atm). The mean nominal stent parameters were as followed: 3.67±0.40 mm×2.98±0.39 mm× 17.13±2.06 mm. In 8 (13.3%) cases the second stent was implanted within the side branch. There were 78.7% of cases performed from radial access and 21.3% from femoral access. In 5 cases (8.3%) asymptomatic increase in TnI level was observed. At one and three months all patients were uneventful (out-of hospital MACE rate 0%).

Conclusions: Dedicated bifurcation sirolimus-eluting stent BiOSS LIM is a feasible device with promising safety profile and short-term clinical effectiveness. Long-term data are pending.

Real-world experience of the self-expanding AXXESS DES in bifurcation

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Aims: The AXXESS (Biosensor, Switzerland) is a dedicated bifurcation drug-eluting stent, comprised of a self-expanding conical-shaped stent platform and bioabsorbable polymer coating that releases Biolimus. We aim to report procedural and in-patient outcomes of this stent in patients undergoing treatment to bifurcation coronary lesions in a real-world setting.

Methods and results: We analysed 52 patients (mean age 61.1 years) who received AXXESS stents in 55 bifurcation lesions. 3 (5.8%) patients received 2 AXXESS stents for 2 bifurcation lesions each. 40.4% of patients presented with acute coronary syndrome including 5 patients (9.6%) with STEMI and 1 with cardiogenic shock. 65.5% of lesions treated were true bifurcations (MEDINA classification 1,0,1 or 1,1,1 or 0,1,1), 3 (5.5%) were chronic total occlusions and 1 (1.8%) in-stent restenotic lesion. In total, 121 stents were implanted. AXXESS stents alone were implanted in 10 (18.2%) lesions. Additional drug-eluting stents (Biomatrix, Biosensor, Switzerland) were implanted proximal to the AXXESS stent in 17 (30.9%), distal main branch in 31 (56.4%) and side-branch in 28 (50.9%) lesions. Final kissing angioplasty was performed in 54.5% lesions. All lesions were successfully treated and all devices were successfully deployed. All side branches were easily re-crossed with workhorse guidewire without need of micro catheter or balloon support. We defined optimal AXXESS position as landing the distal stent edge at or distal to the bifurcation carina and without obstructing side-branch ostium or distal main branch. Based on this criteria, 33 (60.0%) AXXESS stents were optimally placed. There was no side-branch ostium or distal main branch obstruction. 6 (11%), 9 (16%) and 7 (12.7%) AXXESS stents were placed <1 mm, 1-2 mm and ≥2 mm proximal to the bifurcation carina. There were no in-hospital major adverse cardiac events.

Conclusions: The AXXESS stent can be used to treat complex 'real world' bifurcation lesions without the limitations associated with conventional bifurcation techniques including jailing the side-branch ostium and inability to fully scaffold the side branch ostium. Precise deployment of the self-expanding stent can be more difficult than traditional balloon-expandable stents.

Coronary interventions – *Thursday May 23rd*
PCI of bifurcation lesions: results from registries and new dedicated stents

Bifurcation stenting: clinical outcomes of true and non-true bifurcations treated with DES

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Aims: Our aim was to compare clinical outcomes of the patients with true and non-true coronary artery bifurcation lesions treated with one type of stent, Nobori® DES.

Methods and results: Within the large, prospective, single-arm, multicentre, eNOBORI registry, 737 patients (1272 lesions) had at least one bifurcation treated. Bifurcation lesions (BL) were divided into true (TBL, 420 patients; 766 lesions) andnon-true bifurcation lesions (NTBL, 317 patients; 506 lesions). All adverse events (including stent thrombosis) are adjudicated by an independent clinical event committee. Primary endpoint of the study is target lesion failure (TLF) defined as composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and target lesion revascularisation (TLR). Patients in both groups had similar baseline characteristics and risk factors. Average number of lesions treated per patient and stents implanted per lesion was higher in TBL than in NTBL (2.50±1.53 vs. 2.18±1.50; p<0.01 and 1.28±0.56 vs. 1.18±0.46; p<0.01, respectively). According to the Medina classification, the most frequent lesion type in TBL was [1.1.1] (66.7%), whereas in NTBL, [1.1.0] type was most abundant (41.1%). Lesion characteristics were comparable between the two groups, except for a higher percentage of ostial lesions (24.4% vs. 16.4%; p<0.001) and left main protection (38.2% vs. 12.5%; p=0.03) but lower frequency of thrombus presence (8.4%vs 13.9%; p<0.01) in TBL vs. NTBL. Complex techniques were more often used in TBL than in NTBL: T-stenting (22.4% vs. 19.0%), Crush (9.6% vs. 3.6%) and Culotte (6.8% vs. 0.6%). Final balloon kissing was was performed in 66.9% and 46.8% of lesions in TBL and NTRL, respectively. Direct stenting was more frequent in NTBL (36.8% vs. 24.0%; p<0.01) and procedural success was similar in TBL and NTBL groups (98.3% vs. 99.4%). In-hospital event rates were similar in both groups with 4 and 1 periprocedural MIs in TBL and NTBL, respectively. Between hospital discharge and 1 month there were two additional TV-MIs and two TLRs in TBL group with no events in NTBL. From 1 month to 1 year 2 patients died and 2 patients underwent TLR in TBL group with no additional events in NTBL. Preliminary TLF rate at 1 year (calculated on 334 patients that were followed up) was significantly higher in TBL group: 11/207 (5.3%) vs. 1/127 (0.8%) in NTBL group (p=0.03). No stent thrombosis were observed in the NTBL whereas 2 definite, subacute ST (0.48%) occurred in TBL patients (p=NS).

Conclusions: As expected, clinical outcomes after treatment of true bifurcation lesions were less favourable compared to the non-true bifurcation lesions however, the results of both cohorts are very good up to one year. The low rates of TLF and stent thrombosis add further evidence to support use of Nobori®DES in this challenging lesion subset.

Coronary interventions – *Thursday May 23rd*
PCI of bifurcation lesions: results from registries and new dedicated stents

Final clinical outcomes of patients with coronary bifurcation lesions treated with a Biolimus A9 eluting dedicated stent: 5-year results from the prospective, multicentre DIVERGE trial (DES intervention for treating side branches effectively)

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Aims: The aim of DIVERGE trial is to evaluate the safety and efficacy of the Axxess™ stent (self-expanding bifurcation Biolimus A9 eluting stent with abluminal biodegradable polymer coating) for the treatment of *de novo* bifurcation lesions in native coronary arteries. We present the final 5-year clinical data.

Methods and results: A total number of 302 patients with single *de novo* coronary bifurcation lesions (including 77% "true" bifurcations lesions) were treated with the Axxess™ stent in the prospective, single-arm, multicentre DIVERGE trial. At 9 months, 99.7% of patient underwent clinical follow-up. The cumulative MACE rate was 7.7%, id-TLR 4.3%, definite stent thrombosis 1.3% per protocol and 1.0% according to academic research consortium (ARC). Furthermore, 94% completed angiographic follow-up. Quantitative coronary angiography (QCA) analysis demonstrated a 6.4% in-segment bifurcation restenosis rate and an in-stent restenosis rate within the Axxess stent of 0.7%. The combined Axxess and Cypher stenting strategy resulted in very high success rates: device success was 100%, lesion success was 99.3% and procedure success (angiographic success without in-hospital MACE) was 96.7%. At 4 years, 292 patients (96.7%) completed clinical follow-up. The rates of death, MI, id-TLR and overall MACE at four-year follow-up were 5.1%, 7.9%, 10.6%, and 18.5%, respectively. Furthermore, the rates of cardiac death and ischaemia-driven target vessel revascularisation (id-TVR) were 3.8% and 13.4%, respectively. Despite frequent use of multiple and side branch stenting, the very late definite/probable stent thrombosis (1 year-4years) occurred only in 5 cases and was 1.7% per protocol. Among these incidents of ST, only one definite VLST was attributed to the Axxess™ stent, whereas all events were present in the Cypher stent. At 5 year, 286 patients (94.7%) completed clinical follow-up. Site-reported events between 4 and 5 year follow-up were 6 MACEs: 1 revascularisation procedure, 2 deaths, 1 MI, and 1 CABG. There was also one additional case of very late ST (VLST). 5 year follow-up events are currently under adjudication and the final data will be reported at the time of the presentation.

Conclusions: The dedicated Axxess bifurcation stent has demonstrated sustained efficacy and safety in patients with complex coronary bifurcation lesions during a long-term follow-up out to 5 years. The complete and final 5-year clinical outcomes will be presented at the meeting.

Coronary interventions – *Thursday May 23rd*
Determinants of outcome in STEMI patients

Impact of angina prior to acute STEMI on short-term outcomes after primary PCI: results from MonastiR Acute Myocardial Infarction (MIRAMI)

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Aims: The clinical significance of ischaemic chest pain before acute ST-elevation myocardial infarction (STEMI) remains an interesting issue of investigation particularly in the era of percutaneous coronary intervention (PCI). This study aimed to assess the impact of angina prior to STEMI on short-term clinical outcomes in patients with acute STEMI undergoing primary PCI.

Methods and results: Among a total of 346 consecutive patients with STEMI undergoing primary PCI, 131(37.9%) had episodes of angina within 24 hours of STEMI (Prior Angina group) and the remaining 215 were free of anginal symptoms (non-Prior Angina group). Clinical characteristics, angiographic and procedural features, and in-hospital and 30-day outcomes were compared between the two groups. Patients with angina prior to STEMI had fewer totally or nearly totally occluded infarct-related artery (TIMI flow grade 0-1) at initial angiography (78.0% vs. 86.7%, p=0.01), and achieved more TIMI flow grade 3 after primary PCI (90.3% vs. 84.9%, p=0.04). These were associated with higher rates of overall procedural success (95.9% vs. 91.8%, P=0.02) and of complete ST-segment resolution at 90 minutes after the procedure (51.7% vs. 40.3%, p=0.001). During a 30-day clinical follow-up, the left ventricular ejection fraction was significantly improved (54.0±8.6% vs. 49.1±9.7%, p=0.002) and the primary endpoint of major adverse cardiac events was reduced butnot significantlyin the Prior Angina group (7.2% vs. 12.7%, P=0.01).

Conclusions: Presence of angina prior to acute STEMI is associated with better outcome at a 30-day clinical follow-up in patients undergoing primary PCI.

Obstructive sleep apnea syndrome and STEMI, an ischaemic preconditioning mechanism?

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Aims: There is increasing evidence that nocturnal cycles of hypoxemia-reoxygenation in obstructive sleep apnea syndrome (OSAS) may lead to an ischaemic preconditioning. OSAS might contribute to increase coronary collateral vessel (CCV) development in patients with acute coronary occlusion. We tested the hypothesis that patients with OSAS and acute myocardial infarction will exhibit more CCV by assessing the relationship between Apnea -Hypopnea Index (AHI) and Rentrope grade.

Methods and results: The present study prospectively included 71 patients with a first inaugural STEMI who underwent coronary angiography within 24 h from onset. All patients underwent overnight polygraphy before discharge to diagnose OSA and classified according to the apnea-hypopnea index (AHI) (OSAS: AHI >10/h; non-OSAS: AHI <10/h). CCV were scored by visual analysis and were analysed according to the Cohen and Rentrop grading system. Patients with TIMI 3 flow were excluded. Eighty-three percent of the patients were men with mean age of 58.3±11years. 31 patients had a history of diabetes, hypertension was present in 30 patients, smoking in 53, and the mean BMI was 26.49±4.18. All patients had a complete or subtotal occlusion of the infarct-related artery. The left anterior descending artery (LAD) was the culprit artery in 37 patients (52%), the left circumflex (LCX) in 14%, the right coronary artery (RCA) in 34% and the mean left ventricular ejection fraction was 50±9%. No visible collateral filling was found in 35 Patients, Rentrope grade 1 was showed in 14, grade 2 in 12 and grade 3 in 10 patients. Polygraphy identified OSAS in 52% and 8 patients had severe OSAS (AHI>30). Patients with developped CCV (Rentrope 1, 2 or 3)showed significantly higher AHI compared with those without CCV (Rentrope 0) (17.74±13.2 vs. 12.24±10.9, P=0.025).

Conclusions: These findings suggest that coronary collateral development is augmented in patients with STEMI and OSAS.

Coronary interventions – *Thursday May 23rd*
Determinants of outcome in STEMI patients

MI Sxscore for risk stratification in patients undergoing PCI for acute STEMI: a substudy of the COMFORTABLE AMI randomised controlled trial

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Aims: We aimed to investigate the performance of the MI Sxscore and its incremental value in risk stratification in a contemporary prospective multicentre randomised primary PCI trial.

Methods and results: The MI Sxscore was determined for all patients in the COMFORTABLE AMI trial which randomly assigned 1,161 patients to treatment with bare-metal stents (BMS) or biolimus-eluting stents (BES). Patient- (death, recurrent myocardial infarction (MI) and any revascularisation) and device-oriented (cardiac death, recurrent target-vessel MI and target lesion revascularisation) major adverse cardiac events (MACE) were compared across tertiles of the MI Sxscore and according to stent type. The change of the c-statistic by addition of the MI SXscore to a model including the TIMI risk score for the assessment of patient- and device-oriented MACE was determined. The median MI SXscore was14 (IQR: 9-21). Patients were divided into tertiles of Sxscorelow (≤10), Sxscoreintermediate (11-18) and Sxscorehigh (≥19). At 1 year, patient-oriented MACE occurred in 15% of the Sxscorehigh, 9% of the Sxscoreintermediate and 5% of the Sxscorelow tertiles (p<0.001) and device- oriented MACE occurred in 8% of the Sxscorehigh, 6% of the Sxscoreintermediate and 4% of the Sxscorelow tertiles (p=0.03). Addition of the MI Sxscore to the TIMI risk score improved prediction for patient (c-statistic value increase from 0.63 to 0.69) and device-oriented MACE (c-statistic value increase from 0.65 to 0.70). Differences in the risk for device-oriented MACE between BMS and DES were more pronounced among Sxscorehigh than Sxscorelow tertiles (12% vs. 18% (diff. 6%) than in Sxscorelow: 6% vs. 4% (diff. 2%)).

Conclusions: The MI Sxscore allows for accurate risk stratification of patient- and device oriented MACE among patients undergoing primary PCI and the addition of the MI Sxscore to the TIMI risk score is of incremental prognostic value.

Coronary interventions – *Thursday May 23rd*
Determinants of outcome in STEMI patients

Deferred stent implantation in patients with STEMI: a pilot study

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Aims: The purpose of this work was to describe the short-term clinical outcomes after an alternative coronary stent implantation strategy in patients with ST-segment elevation myocardial infarction (STEMI).

Methods and results: In order to minimise the risk of acute embolisation of thrombus and plaque material from the culprit lesion, we sought to establish a stable blood flow of the IRA during primary percutaneous coronary intervention (PCI) without acute stent implantation in patients with STEMI. Bivalirudin or a glycoprotein 2b/3a antagonist was continued for 4 to 18 hours, and deferred stent implantation was scheduled 24 to 72 hours later. Major adverse cardiac events were recorded during follow for a median of 6 months. Cardiac magnetic resonance imaging was performed in a subset of patients to evaluate myocardial salvage and left ventricular ejection fraction. The epicardial flow of the infarct-related artery was normal at admission in 40% of 124 patients. In 11 patients (9%) immediate stent implantation was judged necessary, one 15 minutes after the primary procedure due to secondary closure of the infarct-related vessel. Thus, stent implantation could be deferred in a total of 113 patients (91%). In 38% of the patients stent implantation was declined at the second examination, and all stents were patent when re-examined 3 months later. Blood transfusion was necessary in one patient because of bleeding at the access site. Major adverse cardiac events occurred in 2 patients (1 cardiac death, 1 case of reinfarction who had target lesion revascularisation) during 8 months follow-up. In 5 patients (4%) no PCI was performed. Myocardial salvage determined by cardiac magnetic resonance in 32 patients was relatively high, and left ventricular ejection fraction normalised in most patients.

Conclusions: Deferred stent implantation seems safe in patients with STEMI. Although the concept has to be evaluated in a randomised comparison with conventional treatment, the strategy seems promising and may prove beneficial for patients referred for primary PCI in whom a stable epicardial blood flow is obtained after thrombectomy/balloon dilatation.

Coronary interventions – *Thursday May 23rd*
Determinants of outcome in STEMI patients

Long-term clinical follow-up in survivors undergoing successful PCI in the patients with acute myocardial infarction complicated by cardiogenic shock

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Aims: We aimed to investigate the predictors of major adverse cardiac events (MACEs) among surviviors undergoing successful percutaneous coronary intervention (PCI) in the patients with acute myocardial infarction (AMI) complicated by cardiogenic shock (CS).

Methods and results: Between May 2007 and January 2012, 1,754 AMI patients (69.1±12.4 years, 1,229 males) who complicated by CS, undergoing successful PCI were enrolled. 1,544 of them were discharged to home (Survivor group, 66.3±12.4 years, 350 males) and 210 with in-hospital death (In-hospital death group, 72.0±11.7 years, 279 males). We analysed clinical outcomes in Survivor group during 1 year. Primary endpoint was composite of MACEs at 1 year. Patients in Survivor group were more likely to be younger, male gender (71.0% vs. 46.7%, p<0.0001), and higher body mass index. Survivor group had less history of diabetes mellitus and more smoking history. They had less STEMI, higher left ventricular ejection fraction, and lower regional wall motion score (RWMS), lower serum glucose, creatinine, cardiac enzymes, N-terminal prohormone of brain natriuretic peptide (NT-proBNP), and higher total cholesterol, triglyceride, and low density lipoprotein cholesterol. In coronary angiographic findings, total occlusion and multivessel disease were less frequent in Survivor group. And left main (2.1% vs. 9.6%, p<0.0001) and left anterior descending (30.5% vs. 39.7%, p=0.007) were less likely, but right coronary artery (54.9% vs. 41.1%, p<0.0001) was more likely to be infarct-related artery in Survivor group. In univariate analysis, cardiopulmonary resuscitation (CPR) before arrival, history of ischaemic heart disease, tachycardia, high serum creatinine, NT-proBNP or BNP, and low RWMS at addmission were the predictors for 12 months MACEs in survivors undergoing successful PCI in the patients with AMI complicated by CS. In multivariate logistic regression analysis, CPR before arrival (OR=3.85, 95% CI=1.10-13.54, p<0.035), high NT-proBNP or BNP (OR=2.31, 95% CI=1.03-5.18, p=0.043), short door to balloon time (OR=4.92, 95% CI=1.32-18.31, p=017) were independent predictors for 12 months MACEs in surviviors undergoing successful PCI in the patients with AMI complicated by CS.

Conclusions: CPR before arrival, High NT-proBNP or BNP at admission, short door to balloon time were independent predictors of 12 months MACEs in survivors undergoing successful PCI in the patients with AMI complicated by CS.

In-hospital mortality in women with acute myocardial infarction treated by primary angioplasty: data from the Portuguese Interventional Cardiology registry

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Aims: Previous studies have shown that mortality in women after myocardial infarction is superior than man. Thus, one of the objectives of Stent for Life Initiative is improving the performance of the treatment of ST elevation MI (STEMI) in this risk group. Our aim was to evaluate how sex influences the short term prognosis in patients undergoing primary angioplasty (P-PCI) based on the Portuguese Interventional Cardiology Registry (PICR).

Methods and results: Of 60,158 patients prospectively included in a large registry of contemporary PCI, from 2002 to 2012, we included in this analysis 7544 consecutive patients with STEMI treated by P-PCI, of which 1856 (25%) were female. The primary end-point was in-hospital mortality. The effect of gender on the outcome was assessed using a propensity score-adjusted regression model. Women were older (68±14 vs. 61±13, p<0.001) and had higher prevalence of diabetes (30% vs. 21%, p<0.001) and hypertension (69% vs. 55%, p<0.001). Men were revascularised earlier (within 6 hours of onset of symptoms) than females (71% vs. 63%, p<0.001). Evolution in cardiogenic shock was more frequent in women (7.1% vs. 5.7%, p=0.032). Female gender was associated with a worse short term prognosis, with 1.7 times higher risk of in-hospital death (4.3% in women and 2.5% in men, 95%CI 1.30 to 2.27, p<0.001). After computed propensity score matching based on baseline clinical characteristics, in-hospital mortality was similar between women and men (OR 1.00, 95%CI 0.68 to 1.48, p=1.00).

Conclusions: The poorer short term prognosis of women undergoing primary angioplasty could be related to its higher risk-factor burden and with later access to treatment. After correction for baseline clinical differences, sex has no positive impact on prognosis. This population is one of the primary targets of the Stent for Life initiative.

Coronary interventions – *Thursday May 23rd*
Determinants of outcome in STEMI patients

Mid and long-term clinical outcomes of patients with STEMI treated with DES

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Aims: We aim to assess mid- and long-term outcomes in STEMI patients treated with Nobori, DES with biodegradable polymer.

Methods and results: In two large, prospective, single-arm, multicentre registries, 12444 patients were treated with the Nobori DES, out of which 1082 patients were treated in the course of an acute ST-segment elevation myocardial infarction. Mid-term outcomes (up to one year) are available for 590 patients, whereas long-term outcomes up to 3 years are available for 248 patients. All adverse events were adjudicated by an independent clinical event committee. The primary endpoint was Target Lesion Failure (TLF) defined as a composite of cardiac death (CD), target vessel related myocardial infarction (MI) and target lesion revascularisation (TLR). STEMI patients were 60±12y old, 79% males, 17% with prior MI and 10% with prior coronary revascularisations. The pain-to-balloon time was <3 hours in 37.7%; >3 <6 hours in 22.3%; >6 <12 hours in 11.9% and >12 hours in 20.4% of the patients. The median door-to-balloon time was 51 minutes. Multiple vessels were treated in 20% of patients. The lesions were complex (62.7% B2/C type) ostial (8.4%), calcified (25.7%), containing thrombus (46.5%) and 6.4% required bifurcation treatment. Low perfusion (TIMI flow 0/1) was observed in 43.7% of lesions before procedure, while TIMI 3 after procedure was achieved in 97%. Most of the STEMIs had anterior or inferior locations (49% and 39% respectively) and 82% of patients had Killip class 1. Culprit arteries were LAD (47%), RCA (34%) and LCX (17%). Almost half of all STEMI patients (43.5%) received adjunctive treatment: either haemodynamic support (9.4%), intravenous thrombolysis (17.1%), pre-procedural GP IIB/IIIa inhibitor (10.6%) or other specific treatment (13.4%). In 26% of patients, thrombus aspiration was performed. Radial access was used in 53% of the procedures. At 1-month 5 patients had re-infarction (0.5%), and 5 had TLR (0.5%). At 1 year 590 patients were available for follow-up, out of which 4 patients died because of cardiac reasons (0.7%), 4 more patients suffered re-infarctions (total 9 - 1.5%) and 9 more patients underwent TLR (total 14-2.3%). The TLF rate was 3.2%. There were 6 definite or probable stent thromboses, of which 5 subacute and one late ST (1%). In the cohort of patients followed at 3-year, 2 patients died from cardiac causes (0.8%), 10 had re-infarction (4.0%) with a TLF rate of 6.1%. A total of 96% of the patients were angina free. No patient suffered very late stent thrombosis between 1- and 3-year follow-up.

Conclusions: Use of Nobori, DES with biodegradable polymer, in the treatment of patients with STEMI was associated with favourable mid- and long-term outcomes and low rate of stent thrombosis. Those data, obtained on one of the largest population of STEMI patients, confirm both efficacy and particularly safety of DES with biodegradable polymer in this complex patient's subset.

Coronary interventions – *Thursday May 23rd*
New methods for physiological assessment of coronary stenosis?

The instant wave-free ratio is calculated at a time when pressure is naturally proportional to flow obviating the need for adenosine administration

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Aims: Pressure derived indices of coronary stenosis severity improve outcomes when used to guide revascularisation. But adoption is limited due to the need for vasodilator administration. These are required to induce stable microvascular resistance, when the trans-stenotic pressure gradient is proportional to flow; under such conditions pressure can be used as a surrogate for flow. The instant wave-free ratio (iFR) is a vasodilator-free pressure-only index of coronary stenosis severity calculated during the diastolic wave-free period. We aim to characterise the haemodynamics of the wave-free period and determine if the trans-stenotic pressure gradient is proportional to flow during this period at rest.

Methods and results: Pressure and flow velocity was measured in 56 vessels distal to a coronary stenosis at rest. Mean flow velocity, resistance, trans-stenotic pressure gradient and distal to proximal pressure ratio was calculated over the complete cardiac cycle, and 50 intervals within diastole. Instantaneous diastolic pressure gradient-flow velocity curves were constructed. The diastolic wave-free period was the only period in the cardiac cycle where the pressure loss due to the stenosis had a proportional relationship with underlying flow velocity. This varied according to stenosis severity (mean pressure gradient: 4.4±4.2 mmHg mild (FFR 0.81-1.0) vs. 13.3±12.2 mmHg moderate (FFR 0.6-0.8) and 55.7±11.1 severe (FFR <0.60) stenoses, p<0.001).

Conclusions: The diastolic wave-free period is the only period within the cardiac cycle when the trans-stenotic pressure gradient is proportional to flow. The instant wave-free ratio, calculated during the diastolic wave-free period, can therefore be used to make assumptions about underlying intra-coronary flow conditions without the need for vasodilators; potentially improving the adoption of physiologic guided revascularisation.

Coronary interventions – *Thursday May 23rd*
New methods for physiological assessment of coronary stenosis?

Disturbed coronary haemodynamics in vessels with intermediate stenoses evaluated with FFR

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Aims: In chronic ischaemic heart disease (IHD), focal stenosis, diffuse atherosclerotic narrowings (DAN) and microcirculatory dysfunction (MCD) contribute to limit myocardial flow. The prevalence of these IHD levels in fractional flow reserve (FFR) interrogated vessels remains largely unknown.

Methods and results: Using intracoronary measurements, a total of 91 coronaries (78 patients) with intermediate stenoses were classified in four FFR and coronary flow reserve (CFR) agreement groups using FFR>0.80 and CFR <2 as cutoffs. Microcirculatory resistance and angiographic atherosclerotic burden were also assessed using the index of microcirculatory resistance (IMR) and the Gensini score, respectively. MCD was assumed when IMR ≥29.1 (75th IMR percentile). Only 20 (37%) vessels with normal FFR (n=54, 59.3%) presented both normal CFR and IMR, while most (63%) presented disturbed haemodynamics: abnormal CFR in 28 (52%) and MCD in 18 (33%). Vessels with FFR >0.80 presented higher IMR [median 24.9 (IQR 17.0-36.3)] than those with FFR ≤0.80 [13.9 (8.9-20.4), p<0.001]. In vessels with FFR >0.80 and CFR <2, (n=28, 39%), atherosclerotic burden was inversely associated with CFR (r= –0.207, p=0.055), and IMR had a wide dispersion (7-72.7 U), suggesting a combination of DAN and MCD. Vessels with FFR<0.80 and normal CFR presented the lowest IMR, suggesting a preserved microcirculatory function.

Conclusions: A substantial number of stenosed coronaries with normal FFR present abnormal haemodynamics. Integration of FFR, CFR and IMR supports the existence of differentiated patterns of IHD that combine focal and DAN with variable degrees of MCD.

Contrast-induced hyperemia in the functional evaluation of coronary lesions with a pressure wire

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Aims: Our purpose was to evaluate the "FFR" obtained after a conventional intracoronary contrast medium injection (FFRcont) and after adenosine-induced maximal hyperemia (FFRad) and to determine in which cases contrast medium could obviate the need of pharmacological hyperemia.

Methods and results: 58 coronary lesions (34 patients, mean age 63.2±9.6 years) were prospectively evaluated, using pressure-wire (St. Jude Medical). FFRcont was calculated after a conventional intracoronary injection of contrast medium. FFRad was calculated after maximal hyperemia with intravenous adenosine. FFRad was <0.80 (functionally severe) in 23 (39.7%) lesions. FFRcont was <0.80 in 18 (31.0%) lesions. FFRcont values were strongly correlated with FFRad values (Spearman's rho=0,994, p<0,0001). FFRcont<0.80 showed a sensibility of 100%, specificity 87.5%, positive predictive value 78.3% and negative predictive value 100% for the identification of lesions with FFRad <0.80. All lesions with a FFRcont >0.84 (n=24, 41.1%) showed a FFRad ≥0.80 (i.e., functionally not severe). All together, the functional severity of lesions was correctly identified by FFRcont in 72.4% of cases.

Conclusions: Contrast-induced hyperemia is strongly correlated with adenosine-induced maximal hyperemia. FFR values after contrast-induced hyperemia accurately identify functional severe lesions in a significant proportion of cases; particularly, when lower than 0.80, FFR values after contrast-induced hyperemia always identify severe lesions, obviating the need of adenosine-induced maximal hyperemia. These results should be confirmed in a larger population.

The instant wave-free ratio, a vasodilator free index, provides lower microvascular resistance than that during adenosine mediated FFR in a significant proportion of patients

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Aims: It is assumed that adenosine administration consistently provides lower microvascular resistance than that possible at rest. Phasic analysis of the cardiac cycle has permitted the derivation of a new pressure only adenosine free stenosis index – the instant wave-free ratio (iFR). In this study we compare microvascular resistance during the resting diastolic wave-free period, a period in the cardiac cycle with intrinsically low microvascular resistance during which iFR is calculated, to that during the whole cardiac cycle during adenosine administration, when FFR is calculated.

Methods and results: In 51 vessels intra-coronary pressure and flow velocity was measured distal to the stenosis at rest and during adenosine mediated hyperaemia. iFR, FFR, baseline and hyperaemic microvascular resistance were calculated using automated algorithms. In 39% of stenoses (20 stenoses), over both physiologically unobstructed and obstructed vessels (FFR range 0.35-0.99), microvascular resistance was lower during the resting wave-free period compared to that during FFR (median iFR resistance 210 mmHg/cm.s (inter-quartile range 268.3 mmHg/cm.s) vs. median FFR resistance 308.8 mmHg/cm.s (inter-quartile range 291.1 mmHg/cm.s, p<0.001). This phenomenon of lower microvascular resistance with iFR compared to FFR occurred in 34.4% (11 stenoses) in the 0.6-0.9 FFR range.

Conclusions: The phasic analysis of the cardiac cycle isolates a period within diastole, the wave-free period, during which microvascular resistance is lower than that achieved during adenosine mediated FFR in almost 40% of patients. Furthermore, this phenomenon occurs in one third of patients in the clinically important 0.6-0.9 FFR range. These finding challenge the a priori assumption that adenosine consistently reduces microvascular resistance from the resting state.

Coronary interventions – *Thursday May 23rd*
New methods for physiological assessment of coronary stenosis?

Adverse plaque characteristics by coronary CT-angiography are associated with ischaemia-causing lesions by FFR: a prospective multicentre study

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Aims: Fractional flow reserve (FFR) at the time of invasive coronary angiography (ICA) is the gold standard for determining lesion-specific ischaemia. While adverse plaque characteristics (APC) by coronary CT angiography (CT) – including positive remodeling (PR), low attenuation plaque (LAP) and spotty intraplaque calcification (SC)– are associated with future acute coronary syndromes, their relationship to lesion-specific ischaemia is unclear. We assessed whether APCs are associated with ischaemia-causing lesions by FFR.

Methods and results: 252 patients from 17 centres in 5 countries were prospectively enrolled [DeFACTO (Diagnostic Accuracy of Fractional Flow Reserve From Anatomic CT Angiography) study]. Patients underwent CT and ICA, with clinically-indicated FFR performed for 407 coronary lesions. Stenosis severity by CT (visual estimation; 0%, 1-29%, 30-49%, 50-69%, and 70-100%) and QCA (quantitative coronary angiography) of each lesion was evaluated by an independent core laboratory, with >50% and <50% stenosis by CT considered obstructive and non-obstructive, respectively. Presence of APCs within coronary lesions by CT was defined as: (1) PR, maximal lesion diameter/reference diameter >1.10; (2) LAP, any voxel <30 HU; and (3) SC, nodular calcified plaque <3 mm. Lesion-specific ischaemia was defined by an FFR <0.8. By FFR, ischaemia was identified in 151/407 lesions (37.1%), with QCA stenosis severity higher in ischaemic vs. non-ischaemic lesions (58.6 vs. 40.1%, p<0.001). APC was detected in 207/407 lesions (50.9%); PR was found in 191 lesions (46.9%), LAP in 90 lesions (22.1%), and SC in 67 lesions (16.5%). APCs were strongly associated with ischaemia, with a 3-4 higher prevalence than in non-ischaemic lesions for PR (79.5% vs. 27.7%, p<0.001), LAP (43.7% vs. 9.4%, p<0.001) and SC (27.2% vs. 10.2%, p<0.001). In multivariate analysis adjusting for CT stenosis severity, a dose-response relationship was observed between number of APCs and ischaemia, with risk of ischaemia increasing for 1 [Odds ratio (OR) 4.0, 95% confidence interval (CI) 2.5-7.4, p<0.001)], 2 (OR 10.5, 95% CI 5.3-20.5, p<0.001) and 3 (OR 10.4, 95% CI: 4.0-27.0, p<0.001) APCs. Amongst APCs, PR (OR 6.8, 95% CI: 4.1-11.3, p<0.001) was associated with the greatest risk of ischaemia over LAP (OR 4.5, 95% CI: 2.6-8.0, p<0.001) or SC (OR 2.5, 95% CI: 1.4-4.6, p<0.001) in multivariate analysis adjusting for CT stenosis severity respectively. The presence of PR was strongly associated with ischaemia for both obstructive (OR 4.1, 95% CI: 2.1-8.2, p<0.001) and non-obstructive (OR 7.4, 95% CI: 2.7-19.9, p<0.001) stenoses.

Conclusions: Incremental to stenosis severity, APCs by CT are associated with increasing risk of ischaemia by FFR. This anatomic data may serve as a useful adjunct to physiologic methods for identification and exclusion of coronary lesions that cause ischaemia.

Coronary interventions – *Thursday May 23rd*
GPIIbIII inhibitors : still useful in 2013?

The effect of glycoprotein IIb/IIIa inhibitors on mortality following PCI for NSTE-ACS

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Aims: The use of glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors have been shown to improve both short and long-term outcome in patients undergoing percutaneous coronary intervention (PCI) for Non-ST segment Elevation Acute Coronary Syndrome (NSTE-ACS). However, many of the older trials were performed in the absence of clopidogrel or newer P2Y12 inhibitors. We set out to investigate whether the use of GP IIb/IIIa inhibitor in NSTE-ACS patients was associated with improved outcomes.

Methods and results: This was an observational study of 5227 patients with NSTE-ACS who underwent PCI from October 2003 to July 2011 at an interventional cardiology centre. All patients received dual antiplatelet therapy (DAPT) which consisted of clopidogrel (loading dose 600 mg followed by 75 mg daily) and aspirin (loading dose 300 mg followed by 75 mg daily). Outcome was assessed by all-cause mortality (this information was provided by the Office of National Statistics via the British Cardiovascular Intervention Society - Central Cardiac Audit Database (BCIS-CCAD). 43.6% (2280/5227) of patients were treated with GP IIb/IIIa inhibitors. Baseline characteristics show that patients treated with GP IIb/IIIa inhibitors were younger (GP IIb/IIIa 62.0 years vs. non-GP IIb/IIIa 65.1 years, p<0.001), more likely to be male (GP IIb/IIIa 74.7% vs. non-GP IIb/IIIa 71.2%, p=0.004), and have fewer co-morbidities including previous myocardial infarction (GP IIb/IIIa 26.7% vs. non-GP IIb/IIIa 33.7%, p<0.001), renal disease (GP IIb/IIIa 1.84% vs. non-GP IIb/IIIa 4.65%, p<0.001) and peripheral vascular disease (GP IIb/IIIa 2.15% vs. non-GP IIb/IIIa 3.77%, p=0.007). They had lower rates of multi-vessel disease (GP IIb/IIIa 4.25% vs. non-GP IIb/IIIa 6.01%, p=0.008) and were more likely to have a successful angiographic result (GP IIb/IIIa 98.8% vs. non-GP IIb/IIIa 96.6%, p<0.001). Kaplan-Meier estimates of all-cause mortality showed significantly improved survival in patients treated with GP IIb/IIIa inhibitors ([GPIIb/IIIa 11.4%; 95% CI 8.1-13.8%] vs. [non GPIIb/IIIa 18.2%; 95% CI 14.0-22.2%], p<0.001. This was maintained in age-adjusted Cox regression analysis (hazard ratio 0.8; 95% CI 0.683-0.938; p=0.006). However, on multivariate analysis this benefit was lost (hazard ratio 0.933; 95% CI 0.762-1.142; p=0.501).

Conclusions: In the era of routine DAPT use, GP IIb/IIIa inhibitors do not appear to confer any long-term survival benefit in NSTE-ACS patients undergoing PCI.

Similar anti-inflammatory effects of intracoronary and intravenous abciximab administration during primary PCI: a single-centre open label randomised study

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Aims: Intracoronary abciximab administration during primary percutaneous coronary intervention (PCI) could offer clinical advantages over the intravenous route. Besides antiplatelet effects, abciximab can modulate inflammation via cross-reactivity with GPIIb/IIIa, avb3, and aMb2 receptors. The aim of our study was to assess whether abciximab administration route could influence its anti-inflammatory effects.

Methods and results: 89 consecutive STEMI patients candidate to primary PCI were randomised to receive intracoronary (Group A, 47 patients) or intravenous (Group B, 42 patients) abciximab bolus. The primary endpoint was the extent of inflammation, measured by C-reactive protein (CRP), VCAM-1 and ICAM-1 levels. Data are expressed in medians [interquartiles]. In group A and B troponin levels were similar (baseline: 0.12 [0.03-0.94] vs. 0.27 [0.07-1.24] ng/mL, P=0.73; postprocedural: 22.00 [14.75-69.43] vs. 31.96 [8.23-7.20] ng/mL, P=0.83). Both groups also showed similar baseline (0.31 [0.14-0.69] vs. 0.22 [0.09-0.59] mg/mL, P=0.80) and postprocedural CRP levels (2.28 [1.37-4.23] vs. 2.16 [1.15-3.22] mg/dL, P=0.69), similar baseline (272.5 [224.7-340.8] vs. 262.2 [221.2-306.4] ng/mL, P=0.33) and postprocedural sICAM-1 levels (281.5 [244.6-337.4] vs. 287.2 [226.9-359.2] ng/mL P=0.71) and similar baseline (771.6 [620.9-971.0] vs. 748.6 [592.2-838.8] ng/mL, P=0.30) and postprocedural sVCAM-1 levels (785.2 [671.6-947.1] vs. 745.9 [641.1-841.9] ng/mL, P=0.17). In-hospital and 6 months event rates were similar in the 2 groups.

Conclusions: Our study suggests that abciximab have similar effects over inflammation after primary PCI, despite the administration route. It is unlikely that clinical benefits of intracoronary abciximab demonstrated by previous studies can be due to modulation of integrin receptors.

Coronary interventions – *Thursday May 23rd*
GPIIbIII inhibitors : still useful in 2013?

Intracoronary bivalirudin alone vs. abciximab plus heparin regimen in primary PCI

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Aims: In comparison to an abciximab plus heparin regimen, intravenous bivalirudin alone was demonstrated to reduce overall mortality and bleeding after primary PCI. However bivalirudin use was also associated to slower postprocedural coronary blood flow (CBF) and more frequent thrombotic complications. Intracoronary administration has the theoretical advantage to supply a very high concentration of bivalirudin directly in the coronary thrombus without increasing the bleeding risk, as the overall dose of the drug given to the patient remains unchanged. Thus we evaluated in primary PCI patients the effects over postprocedural CBF of a bivalirudin alone regimen with the loading bolus administered directly in the PCI vessel and we compared it with the standard abciximab plus heparin regimen.

Methods and results: In 117 consecutive primary PCI patients (BIVA Group) bivalirudin was given as IC bolus (0.75 mg/kg) via an OTW catheter, followed by a continuous IV infusion of 1.75 mg/kg/hr. This cohort was compared with a propensity score matched control group of 117 consecutive STEMI patients (ABCX Group) treated with primary PCI and a combined regimen of abciximab (IC bolus 0.25 mg/kg followed by IV infusion of 0.125 mcg/kg/min for 12 h) plus heparin. All patients received preprocedural Clopidogrel 600 mg loading dose. For each patient we evaluated TIMI flow, TIMI frame count (cTFC) in the infarct-related artery, myocardial blush grade, occurrence of no-reflow and distal embolisation, ST elevation resolution, troponin I (TnI) release after PCI. As safety issue, TIMI major bleeding rates during hospitalisation were considered. Clinical and angiographic features of the 2 groups were well balanced. In BIVA group TIMI flow (2.8±0.5 vs. 2.7±0.6, P=0.10), myocardial blush grade (2.6±0.7 vs. 2.5±0.4, P=0.52) and cTFC (15.9±8.1 vs. 17.9±10.4 frames, P=0.26) were similar to ABCX group. However in BIVA Group a nonsignificant trend for lower no-reflow rates (5.1% vs. 10.9%, P=0.08) with lower distal embolisation rates (3.4% vs. 10.2%, P=0.03) were observed. Moreover in BIVA Group significantly better ST resolution after PCI was observed (ST reduction from baseline: –76.1±25.4% vs. –54.5±35.8%, P<0.001; >70% ST-elevation reduction 90 min after PCI: 65.5 vs. 38.7%, p<0.001) with significantly lower postrocedural TnI release (median 50.6, quartiles 21.9-129.1 vs. median 80.8, quartiles 28.1-194.3, P=0.01). Finally in BIVA Group a lower TIMI major bleeding rate was observed (5.2% vs. 16.8%, P=0.01).

Conclusions: Our study demonstrated that, in patients treated with primary PCI, intracoronary bivalirudin administration was non-inferior to an abciximab plus heparin regimen in terms of angiographic coronary flow indexes. Moreover our results strongly suggest that intracoronary bivalirudin could improve myocardial reperfusion and reduce infarct size with a favourable effect on bleeding complications, in comparison with abciximab. Future randomised comparisons to assess the potential advantages of intracoronary bivalirudin administration are warranted.

Coronary interventions – *Thursday May 23rd*
GPIIbIII inhibitors : still useful in 2013?

High bolus dose tirofiban compared with abciximab in primary PCI: a propensity score matched outcome study

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Aims: The optimal adjunctive pharmacotherapy during PPCI is not well defined, particularly in patients treated via the radial route. High bolus dose (HBD) Tirofiban is used in some centres though this is currently an off-label indication. We aimed to analyse the outcomes of patients treated with HBD Tirofiban compared with Abciximab at the time of primary PCI (PPCI) for ST-elevation myocardial infarction (STEMI).

Methods and results: Data of routine practice from two large UK tertiary centres, with differing protocols for glycoprotein 2b3a inhibitor use during PPCI, were pooled. Patients were included in the original study population if they were treated with either HBD Tirofiban or Abciximab as an adjunctive pharmacotherapy during PPCI for STEMI. To allow meaningful analysis of outcomes, propensity scores for treatment assignment to either HBD Tirofiban or Abciximab were calculated using logistic regression based on 23 co-variates thought to be relevant to clinical outcome. HBD Tirofiban patients were matched to Abciximab-treated controls on a 1-to-1 nearest neighbour basis. Follow-up data on survival was available for all patients. Mortality was compared using Kaplan-Meier estimates calculated at time intervals from 30 days to 3 years. Using logistic regression, propensity scores were calculated for 1,473 HBD Tirofiban treated patients and 2,641 Abciximab-treated controls. Propensity score matching was successful in generating balanced groups with no statistically significant differences and resulted in 942 pairs (1,884 patients). The c-statistic for the propensity score model was 0.82 (0.80-0.83) indicating excellent discrimination and the Hosmer-Lemeshow test was non-significant (p=0.295). PPCI was performed through the radial route in 1,693 patients (89.9%) and DES were used in 1024 patients (54.4%). Prior MI was recorded in 220 patients (11.7%) and diabetes mellitus in 224 (11.9%). Multi-vessel disease was present in around one-third of patients (658, 34.9%), although multi-vessel and LMS procedures were less common (114, 5.7%). Median follow-up was 704 days (IQR 336-997 days) and was not different between groups (Wilcoxon test p=0.846). There were 148 events during follow-up (74 deaths in each group). Survival analysis demonstrated no significant difference in mortality at 30 days between HBD Tirofiban and Abciximab in the matched cohort (HBD Tirofiban 3.7% vs. Abciximab 3.2% HR 1.01 (95% CI 0.92-1.10), p=0.96. No difference was noted during follow-up with mortality at 3 years: 9.4% for the HBD Tirofiban group and 9.3% for the Abciximab group; HR 1.15 (95% CI 0.79-1.67), p=0.45.

Conclusions: In this observational study of adjunctive glycoprotein 2b3a inhibitor treatment in PPCI, we found no difference in survival between HBD Tirofiban treated patients compared with propensity-score matched Abciximab controls. These findings were in a cohort of patients treated predominantly via the radial artery, and were consistent to 3-year follow-up.

Coronary interventions – *Thursday May 23rd*
GPIIbIII inhibitors : still useful in 2013?

Eptifibatide and abciximab are associated with similar outcomes when used during primary PCI for STEMI

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Aims: Glycoprotein IIb/IIIa inhibitors are recommended by guidelines in patients with ST-segment elevation myocardial infarction (STEMI) treated with primary percutaneous coronary intervention (PPCI). There are few studies directly comparing these 2 agents. The aim of this study was to compare the effectiveness of eptifibatide relative to abciximab in patients with STEMI treated with Primary PCI.

Methods and results: This was an observational cohort study of 2083 patients who received a GPIIb/IIIa inhibitor whilst undergoing primary percutaneous coronary intervention (PPCI) from 2006 to 2012. Patients who did not receive a GPIIb/IIIa inhibitor were excluded. The primary end-point was the first major adverse cardiac event (MACE) defined as death, non-fatal myocardial infarction, stroke or target vessel revascularisation. 1522 patients received abciximab with 561 receiving eptifibatide. Patients who received eptifibatide had higher rates of previous PCI and hypercholesterolaemia and were more likely to undergo a procedure from the radial route than those that received abciximab. Unadjusted Kaplan-Meier analysis revealed no significant difference in the 1-year event rates between patients given eptifibatide vs. abciximab. Age-adjusted Cox analysis demonstrated no difference in 1 year outcome between abciximab and eptifibatide (Hazard Ratio 1.01 [95% Confidence Interval 0.73-1.39]), which persisted after multivariate adjustment (Hazard Ratio 1.37 [95% Confidence Interval 0.93-1.96]). In addition, after regression adjustment incorporating a propensity score (age, gender, ethnicity, previous MI, PCI or coronary artery bypass grafting (CABG), diabetes, hypertension, hypercholesterolaemia, smoking status, presence or absence of shock, and ejection fraction) into the hazards model as a covariate, no difference in outcome emerged (Hazard Ratio 1.21 [95% Confidence Interval 0.83-1.54]).

Conclusions: This observational data suggests that eptifibatide is associated with similar outcomes to abciximab in patients with STEMI undergoing primary PCI.

Radial access site not associated with higher radiation exposure during coronary angiography and PCI: a regional substudy from the SCAAR database

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Aims: We aim to study clinical and procedural characteristics associated with higher radiation exposure to patients undergoing percutaneous coronary interventions (PCI) and coronary angiograms (CAG).

Methods and results: Our present study included all CAG and PCI procedures in 5 PCI centres in the eastern part of Sweden between 1st January 2008 and 19th January 2012. The radiation exposure and clinical data were prospectively collected in these 5 PCI centres in Sweden as part of the SCAAR registry. A prediction model was made for the radiation exposure (DAP) expressed in Gy·cm^2. A total of 20,669 procedures were included in the present study, consisting of 9,850 PCI and 10,819 CAG procedures. In multivariate analyses, body mass index (kg/m^2) (B=0.04, SE=0.001, p<0.001), history of coronary artery bypass graft (B=0.28, SE=0.01, p<0.001), 2, 3 or 4 treated lesions (B=0.67, SE=0.03, p<0.001, B=0.85, SE=0.04, p<0.001 and B=1.04, SE=0.06, p<0.001) and chronic total lesions (B=0.33, SE=0.03, p<0.001) were associated with the highest radiation exposure. With increased operator experience, radiation exposure decreased (B=-0.25, SE=0.01, p<0.001). After correcting the complexity of the procedures, radial access route was not associated with increased radiation exposure (B=0.004, SE=0.01, p=0.67).

Conclusions: In the thus far largest study population to assess radiation exposure, we found that high body mass index (kg/m^2), history of coronary artery bypass graft, number of treated lesions and chronic total occlusions were associated with the highest patient radiation exposure. Radial access site was not associated with higher radiation exposure when compared with femoral approach.

Automated image enhancement significantly reduces radiation dosage in coronary angiographt with preserved image quality

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Aims: Radiation exposure is related with adverse events on population level. For healthcare workers the work related radiation dose allowed is limited by governing agencies for health purposes. Although the dosage patients receive is relatively limited, the as low as reasonable achievable (ALARA) principle remains applicable. ClarityIQ is developed to reduce the radiation exposure without loss of image quality.

Methods and results: Diagnostic coronary angiography images of the left coronary artery (LCA) were acquired in LAO 45 with 20 cranial angulation with hand injected contrast dye. Quality of ClarityIQ (50% radiation reduction) was compared with standard image acquisition (100% radiation exposure) and scored as better, good, fair and poor by the operator. Our preliminary data show that 47 patients (mean age 62.8±11.1) were enrolled. The mean BMI was 26.6 kg/m^2±3.7. All had normal kidney function (MDRD >60) and no known previous myocardial infarction of the LCA. The image quality of the ClarityIQ images was of adequate diagnostic quality in all patients. ClarityIQ was not considered of better quality, in 29 cases the image quality was good and in 17 fair. In one case the operator judged the images poor based on a blurred aspect of the coronary tree, but still useful for diagnostic coronary angiography. The mean Air Kerma was 31.3 J/kg for ClarityIQ and 72.9 J/kg for the standard image acquisition (p<0.05).

Conclusions: This study demonstrates that with a novel acquisition technique that enhances the coronary tree based on a computer algorithm adequate images can be acquired with a reduction of 43% of radiation dose. Thus resulting in less stochastic effects of radiation for the cath-lab personnel and also less deterministic effects for the patient. Further research is needed to assess whether ClarityIQ is also suitable for large patients and different angulations.

Coronary interventions – *Thursday May 23rd*
Radiation safety during PCI

Obesity as a factor in increasing dose-area product in patients undergoing primary PCI

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Aims: There is enough evidence to consider that obesity is a major determinant of radiation dose in patients undergoing fluoroscopy-guided interventional procedures. Our purpose is to study the correlation between body mass index (BMI) and dose-area product (DAP) in patients undergoing primary PCI.

Methods and results: We prospectively studied 111 consecutive patients with STEMI who underwent primary PCI between July and December 2012. We calculated the DAP, the fluoroscopy time, the DAP per minute of fluoroscopy (DAP/min) and the overall duration of procedures to analyse the correlation between these variables and BMI. Mean age was 62.41±14.1 years, and 74.8% of the patients were male. Mean BMI was 28.3±4.4 kg/m^2 (31.5% of patients were obese and 45% overweight). Median DAP was 71 Gyxcm^2 (12-981) for procedures with a median duration of 50 minutes (7-180) with a median fluoroscopy time of 9.75 minutes (2-90.6). Median DAP/min was 6.8 Gyxcm^2 (1-130.48). There was a moderate positive linear correlation between BMI and the DAP (r=0.274, p=0.013) and the DAP/min (r=0.454, p<0.0001) and a weak negative linear correlation between BMI and the fluoroscopy time (r=-0.188, p=0.05), and the overall duration of the procedure (r=-0.211, p=0.028). There was a positive linear correlation between DAP and fluoroscopy time (r=0.235; p=0.038) and the overall duration of the procedure (r=0,308; 0=0.005). The obese patients had a higher DAP (277.6 vs. 118.5 Gyxcm^2; p=0.03) and a higher DAP/min (31.91 vs. 12.3 Gyxcm^2; p=0.03) than non-obese patients.

Conclusions: Albeit the primary PCIs of patients with higher BMI have a lower duration and fluoroscopy time, these patients receive more radiation. Obese patients receive more than twice the effective dose of radiation than non-obese patients during these procedures. It is also remarkable that there is a higher correlation between DAP or DAP/min and BMI than with fluoroscopy time.

Coronary interventions – *Thursday May 23rd*
Radiation safety during PCI

Reference levels of radiation exposure in primary PCI. A single-centre experience

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Aims: European regulations recommend to assess reference levels of radiation exposure in interventional cardiology. There are few published data about the reference levels of radiation exposure in percutaneous coronary interventions. The purpose of this study is to establish reference levels from the experience of a tertiary university hospital.

Methods and results: We prospectively studied 111 consecutive patients with STEMI who underwent primary PCI between July and December 2012 in the interventional cardiology unit of a university hospital. We analysed the dose-area product (DAP), the fluoroscopy time, the DAP per minute of fluoroscopy (DAP/min) and the overall duration of procedures to assess the radiation exposure. We consider the third quartile as our reference level of radiation exposure in these procedures. Mean age was 62.41±14.1 years, and 74.8% of patients were male. Mean BMI was 28.3±4.4 kg/m^2. Median DAP was 71 Gyxcm^2 (12-981) for procedures with a median duration of 50 minutes (7-180) with a median fluoroscopy time of 9.75 minutes (2-90.6). Median DAP/min was 6.8 Gyxcm^2 (1-130.48). The third quartile of DAP, DAP/min, fluoroscopy time and duration of the procedure was 111 Gyxcm^2, 11.8 Gyxcm^2, 15.1 minutes and 60 minutes respectively.

Conclusions: In our experience, reference levels of radiation exposure in primary PCIs should be 111 Gyxcm^2 of DAP and 11.8 Gyxcm^2 of DAP/min. Reference parameters of fluoroscopy time and overall duration of the procedure should be 15.1 minutes and 1 hour respectively. Because of the lack of published data and recommendations on this subject, multicentre studies are needed to define reference levels of exposure to ionising radiation in these procedures.

Effectiveness of lead cap in radiation protection of head in the cardiac catheterisation laboratory

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Aims: Occupational head exposure of radiation was suggested to be associated with brain tumors in interventional cardiologists. The brain is of particular interest, because it is one of the least protected organs during interventional procedures. Our aim was to investigate the efficacy of the lead cap in radiation protection of the head and compare it with that of a ceiling mounted lead glass screen in a real life setting. Our secondary goal was to test the comfort and convenience of the lead cap when worn on a regular daily basis.

Methods and results: Radiation dose to the operator was recorded by the three dosimeters placed outside the lead cap, inside the cap and outside the apron at the level of trunk for a total of 18 months. Only the lead cap (Burkhart Roentgen International, St Petersburg, Florida, USA) but not the ceiling suspended protective glass screen was used during the first three months of measurement of radiation dose to the head. Later concomitant use of both protection devices was analysed. The dosimeter outside the cap recorded a dose of 2.77 mSv radiation when the ceiling mounted screen was not used during the first 3 months. The doses were 2.4 to 12.5 times higher in comparison to the measurements that were recorded when the ceiling suspended screen was used. However, a remarkable dose of radiation (ranged between 1.16-0.22 mSv) was received by the operators head despite the use of ceiling mounted screen. Yet, even without the protection of the ceiling mounted screen, the dose recorded by the dosimeter inside the lead cap during the first period was <0.1 mSv. As expected, the doses to the head recorded by the dosimeter inside the cap during the next 15 months period were also less than 0.1 mSv with the use of the ceiling mounted screen. Therefore, a cap with only 0.5 mm lead equivalence reduced the dose to the head to ignorable levels regardless of the use of the screen.

Conclusions: A cap with only 0.5 mm lead equivalence was much more protective than the mounted screen and reduced the dose to the head to ignorable levels regardless the use of the mounted screen. Although being a subjective conclusion, the operator regularly wearing the lead cap reported that the lead cap is reasonably comfortable and offers an acceptable wearing comfort when used on daily practice.

Glycosilated haemoglobin levels and the risk of contrast induced nephropathy in non-diabetic patients undergoing coronary angiography or PCI

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Aims: Few data have been reported regarding the association between glycemic levels in non-diabetics patients and the risk of Contrast Induced Nephropathy (CIN). Therefore, the aim of our study was to evaluate the association between glycosilated haemoglobin and the risk of CIN among non diabetic patients undergoing coronary angiography and /or angioplasty.

Methods and results: Our population is represented by 521 non diabetic patients, with impaired renal function (Creatinine clearance <60) undergoing elective or urgent coronary angiography and/or angioplasty at Eastern Piedmont University, Novara. Patients were divided according to tertiles of baseline glycosilated-haemoglobin (Group 1, <5.6%, n=153; Group 2, 5.6-5.8%, n=154; Group 3, >5.9%, n=214). CIN was defined as an absolute ≥0,5 mg/dl or a relative ≥25% increase in the serum creatinine level at 24 or 48h after the procedure. Patients with elevated glycosilated-haemoglobin levels had less often a previous stroke (p=0.036), had higher levels of white blood cells (p=0.006), higher tryglicerides (p=0.022), elevated basal glycemia (p=0.01), lower creatinine clearance (44,2±12.1 - p=0.04) and higher levels of basal creatinine (p<0.001). In addition, they were more often on therapy with diuretics (p=0.003) and Ca2 antagonist (p=0.029) at admission. CIN occurred in 62 patients (11,9%) with a significant linear association with glycosilated haemoglobin (7.8% in Group 1 vs. 10.4% in Group 2 and 15.9% in Group 3; p=0.017). The association between glycosilated haemoglobin and the occurrence of CIN was confirmed by multivariate analysis after correction for baseline confounding factors (Adjusted OR [95% CI]=1.52 [1.05-2.19], p=0.026).

Conclusions: This is the first study so far conduced showing that among non-diabetics patients with impaired renal function, glycosilated-haemoglobin at the admission is linearly related with the risk of CIN after coronary angiography or percutaneous interventions.

Coronary interventions – *Thursday May 23rd*
Updates on contrast induced nephropathy

Admission hyperglycemia and contrast induced nephropathy

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Aims: Admission hyperglycemia is a frequent condition in ST elevation myocardial infarction (STEMI) associated with an increased risk of contrast induced nephropathy (CIN) after primary percutaneous coronary intervention (pPCI). We evaluate the possible different role of acute and chronic hyperglycemia on CIN and the impact of its early spontaneous or pharmacologic normalisation.

Methods and results: 679 STEMI patients treated with pPCI were enrolled in our prospective study. CIN was defined as an absolute serum creatinine increase ≥0.3 mg/dl after procedure. Admission hyperglycemia was defined as glucose levels >198 mg/dl: acute or chronic increase was identified respectivelyin patients with a glycated haemoglobin A1c ≤7% and >7%. In hyperglicemic patients, a decrease of fasting glucose levels <140 mg/dl in second day was considered for early normalisation. Admission hyperglycemia (17%) was an independent predictor for CIN incidence, but at subgroup analysis its prognostic impact emerged only in non diabetic patients. Similarly, only in this subgroup its rapid normalisation was associated to a lower incidence of CIN and to a better outcome. Actually, CIN incidence was significantly higher in patients with acute hyperglycemia than in those with chronic hyperglycemia (34.5% vs. 16.9%, p=0.03), irrespective of diabetes mellitus.

Conclusions: Admission hyperglycemia relates to an increase risk of CIN, especially when it occurs acutely. A condition of glycemic levels ≥198 mg/dl and glycated haemoglobin A1c ≤7%, identifies patients at higher risk, in whom a rapid glycemic control could become a further strategy of CIN prevention.

Coronary interventions – *Thursday May 23rd*
Updates on contrast induced nephropathy

Haemodialysis for removal of contrast medium from the coronary sinus could reduce proximal tubular damage

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Aims: Previously we reported the haemodialysis with suction from the coronary sinus during coronary angiography (CS-dialysis) can remove more amount of contrast medium than the conventional haemodialysis (SVC-dialysis). Therefore, in a chronic kidney disease model, we evaluated the kidney injury after contrast medium infusion with CS-dialysis.

Methods and results: We subjected 14 swine (39.6, SD: 2.0 kg), and their renal arteries were embolised by percutaneous catheter technique. After two weeks, the serum creatinine concentrations increased from 1.01 (SD: 0.21) to 2.29 (0.40) (mg/dl). The vascular access catheter was inserted into the coronary sinus for suction and the other one was placed into the femoral vein for return blood (CS-dialysis group; n=4), and a double-lumen vascular access catheter was inserted into the superior vena cava (SVC-dialysis group; n=5). The CS-dialysis and SVC-dialysis groups underwent haemodialysis during the contrast medium infusion, and the control group (n=5) did not. Contrast medium (180 ml; iopamidol-370) was infused into the left coronary artery in all groups at the rate of 180 ml/hr. The kidneys were removed and subjected to micro-CT three days after contrast medium infusion. Before the contrast medium infusion, the serum creatinine levels were 2.36 (0.23), 2.24 (0.44), and 2.28 (0.51) (mg/dl) in CS-dialysis, SVC-dialysis, and control group, respectively. After the contrast medium infusion, the peak serum creatinine levels were 2.59 (0.59), 2.76 (0.71), and 2.57 (0.47) (mg/dl), respectively. There was no significant difference between each groups or time courses. A day after contrast medium infusion, urine albumin levels were 116 (90), 483 (530), and 998 (790) (mg/g·creatinine), respectively. The CS-dialysis group exhibited significantly lower urine albumin level than the control group ($p<0.05$). The CT numbers of the renal cortex were −46.9 (11.4), 4.6 (37.2), and 81.3 (49.6) (HU), respectively. The CT numbers of the CS-dialysis group were significantly lower than the control group ($p<0.05$). The low CT number means less contrast medium retention in the tissue.

Conclusions: The CS-dialysis significantly reduced proximal tubular damage and contrast medium retention in the renal cortex. The contrast medium retention in the renal cortex may induce some damages at proximal tubules. The coronary angiography with CS-dialysis was found to be more effective in removing contrast medium, indicating that it could prevent contrast-induced kidney injury.

High dose atorvastatin pretreatment for preventing contrast-induced nephropathy in patients receiving primary PCI: prespecified substudy of a prospective randomised clinical trial

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Aims: Controversies persist whether statin pre-treatment can prevent contrast-induced nephropathy (CIN). We evaluate the efficacy of high dose atorvastatin on CIN occurrence.

Methods and results: We studied whether atorvastatin 80mg loading and subsequent use for 5days (high dose group[HD]) could prevent CIN as compared to those received atorvastatin 10mg (regular dose group[RD]) in patients with ST-elevation myocardial infarction undergoing primary angioplasty. Primary endpoint was incidence of CIN, defined as a ≥25% or ≥0.5 mg/dL increase in baseline serum creatinine within 5 days after contrast administration. Secondary endpoint was 1- and 6-month renal function change and composite of all cause mortality, renal failure, heart failure and target vessel revascularisation. One hundred and tenpatients were allocated to HD and 108 to RD from August 2007 to February 2009. CIN incidence was 5.5% (6/110) in HD and 10.2% (11/108) in RD, a nonsignificant difference (p=0.193). CIN occurred significantly less in HD than RD, 0% vs. 16.7% (p=0.024) respectively in subgroups of renal insufficiency (creatinine clearance [CrCl] ≤60 mL/min) and 4% (1/25) and 23.1% (6/26) (p=0.048) in old patients ≥70. Composite of clinical outcomes at 6-month was comparable in HD and RD groups (7.9% and 13.1%, p=0.26). Serum creatinine tended to decrease in HD and increased in RD, but the change was not statistically different (p=0.093).

Conclusions: High dose atorvastatin treatment does not prevent CIN in patients receiving primary angioplasty. However it demonstrated potential of lowering CIN in patients with renal insufficiency and elderly.

Urinary liver-type fatty acid-binding protein (L-FABP) predict contrast-induced nephropathy and persistent renal damage after PCI

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Aims: Contrast-induced nephropathy (CIN) has been generally considered to be transient and associated with unfavourable clinical outcomes. The temporal evolution of renal function in patients with acute kidney injury after contrast medium is not well known. Urinary liver-type fatty acid-binding protein (L-FABP) is a proximal tubular injury candidate biomarker for early detection of acute kidney injury, with variable performance characteristics depending on clinical settings. The aim of this study was to investigate the predictive effects of L-FABP in CIN with persistent renal dysfunction in patients undergoing percutaneous coronary intervention (PCI).

Methods and results: 1286 patients underwent coronary angiography at our institution; 289 of 1286 had an estimated glomerular filtration rate (eGFR) of <60 mL/min and were enrolled. CIN was defined as an absolute increase ≥0.5 mg/dL over baseline serum creatinine within 3 days after the administration of contrast medium. In patients who developed CIN, persistent renal dysfunction was defined as a relative decrease of eGFR ≥25% over baseline at 3 months. Urinary L-FABP measured at baseline and 24 hr after procedure. The overall incidence of CIN was 12.1% (n=35), and persistent renal dysfunction occurred in 28.6%(n=10) of CIN patients. There were no differences in general coronary risk factors, baseline eGFR, contrast media/kg volume, percentage change of creatinine level and cardiac function between transient and persistent renal dysfunction. Patients with transient renal dysfunction showed a lower urinary L-FABP level at baseline and 24hr after procedure compared with those with persistent renal dysfunction (1.43 vs. 3.41 ng/g.Cr, median at baseline, p<0.01: 6.12 vs. 16.7 ng/g.Cre, median at 24hr after procedure, p<0.01). At Cox regression analysis, the increase rate of L-FABP between baseline and 24 hrs after procedure were found to be the most forced significant risk factor for persistent renal dysfunction.

Conclusions: We conclude that the measurement of urinary L-FABP may aid in the CIN for patients undergoing PCI. It may also be a useful biomarker for predicting the occurrence of the persistent renal damage.

Coronary interventions – *Thursday May 23rd*
Updates on contrast induced nephropathy

Impact of chronic kidney disease on long-term clinical outcomes of diabetic patients undergoing PCI: in DES era

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Aims: Diabetes mellitus is the most important predictor of chronic kidney disease and both diabetes mellitus and chronic kidney disease are associated with adverse cardiovascular outcomes. However, impact of chronic kidney disease on clinical outcomes in diabetic patients with coronary artery disease has been not fully elucidated in the DES era. Therefore, we investigated the impact of chronic kidney disease on long term clinical outcomes in diabetic patients who undergoing PCI with DES.

Methods and results: Using a retrospective, single-centre registry in Korea between March 2003 and December 2010, we analysed 2187 consecutive diabetic patients who treated PCI with DES. Chronic kidney disease was defined estimated glomerular filtration rate <60mL/min per 1.73 m^2 based on Modified of Diet in Renal Disease formula. The primary outcome was cardiac death or myocardial infarction. The secondary outcomes included all cause mortality, stent thrombosis, and major adverse cardiac and cerebrovascular event, including all-cause death, myocardial infarction, stent thrombosis, cerebrovascular accident, and any revascularisation. The median follow-up duration was 48 months (interquartile range 27 to 70). The rate of cardiac death or myocardial infarction was higher in the diabetic nephropathy group (diabetes mellitus vs. diabetic nephropathy, 4.9% vs. 18.1%, adjusted hazard ratio 2.95, 95% confidence interval 2.14 to 4.07, p<0.001). Similarly, the incidences of all cause mortality (6.9% vs. 28%, adjusted hazard ratio 3.03, 95% confidence interval 2.32 to 3.95, p<0.001), stent thrombosis (1.4% vs. 4.1% adjusted hazard ratio 1.88, 95% confidence interval 1.001 to 3.54, p=0.05), and major adverse cardiac and cerebrovascular event (22.7% vs. 36.6%, adjusted hazard ratio 1.70, 95% confidence interval 1.42 to 2.03, p<0.001) was significantly higher in the diabetic nephropathy group than diabetes mellitus group.

Conclusions: Among diabetic patients who treated PCI with DES, chronic kidney disease has been associated with increased adverse cardiovascular events.

Coronary interventions – *Thursday May 23rd*
Updates on contrast induced nephropathy

Which DES is useful in PCI for patients with renal insufficiency?

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Aims: In percutaneous coronary intervention (PCI), patients with chronic kidney disease (CKD) have high rate of cardiovascular events. Our aim was to compare the clinical outcomes of CKD patients after PCI with second generation drug-eluting stent (DES).

Methods and results: 866 consecutive patients (1192 lesions) with CKD (eGFR<60[ml/min 1.73 m^2]: calculated by the simplfied Modification of Diet in Renal Disease equation) were treated with zotarolimus-eluting stent (Z group: 274 lesions), everolimus-eluting stent (E group: 720 lesions) or biolimus-eluting stent (B group: 198 lesions) implantation between May 2009 and April 2012, and were follow-up to 8 months. The primary endpoints were angiographic outcomes and MACE (death, AMI, CABG, target lesion revascularisation: TLR). No significant difference was detected in the baseline demographic, angiographic and lesion characteristics. Angiographic follow-up was performed in 921 lesions (77.3%). In 8 months follow-up, the mean values of late lumen loss in Z group was the largest in those groups (Z group: 0.5±0.7 mm, E group: 0.2±0.6 mm, B group: 0.2±0.7 mm; p<0.0001). Binary restenosis in Z group was the highest in those groups (Z group: 10.1%, E group: 4.8%, B group: 6.2%; p=0.03). TLR in Z group was the highest too (Z group: 4.4%, E group: 1.4%, B group: 2.0%; p=0.02). However no significant difference was detected in MACE (Z group: 6.2%, E group: 3.2%, B group: 2.5%; n.s.). In patients with diabetes mellitus (364 patients, 507 lesions, 42.5%), TLR in Z group was the highest too (Z group: 6.6%, E group: 1.9%, B group: 1.6%; p=0.03). However no significant difference was detected in patients without diabetes mellitus (Z group: 2.6%, E group: 1.0%, B group: 2.2%; n.s.).

Conclusions: In second generation drug-eluting stent era, EES and BES implantation improved the TLR with CKD due to diabetic nephropathy.

Clinical outcomes following PCI with DES vs. bare metal stents in patients on chronic haemodialysis

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Aims: Patients on chronic haemodialysis (HD) are recognised as a high-risk group for adverse events after percutaneous coronary intervention and whether DES are associated with improved outcomes over bare metal stents is still uncertain. The purpose of this study was to assess the efficacy of DES compared with bare metal stents at short and long term follow-up in an unselected sample of haemodialysis patients.

Methods and results: All patients on chronic (at least 6 months) haemodyalisis treated with PCI and stent implantation (bare metal stent or DES) between 2005 and 2010 in 3 tertiary care centres were retrospectively selected and analysed. No patient was excluded from the analysis. A total of 169 patients were selected, 77 treated exclusively with bare metal stents and 92 exclusively with DES. Baseline clinical characteristics were similar in the two groups as well as the number of treated vessel, treated lesions and the stent per patient ratio. As far as the whole population is concerned, in-hospital cardiac death occurred in 3.6% of patients, MI in 1.2%, re-PCI in 0.6%, and CABG was performed in 1.2%. No cerebrovascular accidents were recorded. Incidence of MACCE (hierarchically reported) was 5.3%. Major bleedings and definite/probable stent thrombosis occurred in 1.8% and 0.6% of cases, respectively. No difference between groups was found in terms of any of the specified clinical events. At long-term follow-up (mean±SD: 790±593 days), cardiac death in the whole population was 17.2%, non cardiac death was 21.9% (overall death 39.1%), MI was 5.9%, CVA occurred in 0.6%, TLR and TVR were 12.4% and 13%, PCI performed on non target vessel 9.5% and CABG was performed in 0.6%. The incidence of MACCE (hierarchically reported) in the whole population was 32%. Major bleedings and definite/probable stent thrombosis occurred in 1.2% and 3.6% of cases, respectively. When bare metal stents and DES groups were considered, no major differences were found with the exception of the incidence of MI, that was significantly higher in the DES group (1.3% vs. 9.8% p=0.02). At the multivariate analysis, cereborvascular accident was found to be an independent predictor of cardiac death, cardiac death+MI+cereborvascular accident and MACCE; previous PCI and diabetes were independent predictors of cardiac death and cardiac death+MI+cereborvascular accident while years on haemodyalisis was an independent predictor of repeat revascularisation. Survival free from cardiac death did not differ between the bare metal stents and DES groups over time (67.9% vs. 74.2%, p 0.29) as well as survival free from death+MI+cereborvascular accident and from any revascularisation: 66.7% vs. 62.2% p 0.74 and 77.6% vs. 66.2% p 0.07. MACCE-free survival in the bare metal stent and DES group was 57.6% vs. 50.9% (p 0.11) respectively.

Conclusions: PCI in patients on chronic HD treatment is associated with an high incidence of adverse events at follow-up, mainly represented by death. In our study, the use of DES was not associated with a reduction of target lesion and target vessel revascularisation but was significantly associated with an higher incidence of MIs.

Coronary interventions – *Thursday May 23rd*
Updates on contrast induced nephropathy

How haemodialysis duration influences the clinical outcomes of patients after implantation of DES

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Aims: In percutaneous coronary intervention (PCI), haemodialysis (HD) patients are high risk of cardiovascular events. But it's not known whether HD duration is associated with clinical outcomes. The aim of this study was to evaluate the impact of HD duration on clinical outcomes in patients with drug-eluting stents (DES) implantation.

Methods and results: Between April 2007 and September 2011, 147 patients (335 *de novo* lesions) on dialysis were treated with DES. We investigated the correlation between HD duration and late loss at 8 months follow-up. In multiple logistic regression analysis, we evaluated whether HD duration was independent predictor of major adverse cardiovascular events (MACE). At 8 months follow-up, positive correlation was not found between HD duration and late loss (r=0.16, P=0.18). Meanwhile, multiple logistic regression analysis revealed that HD duration was one of the independent predictors of MACE (OR 1.02, P=0.02).

Conclusions: In haemodialysis patients, HD duration was not associated with restenosis at the follow-up point. But the longer HD duration affected poor outcomes of patients after implantation of DES.

Coronary interventions – *Thursday May 23rd*
The role of drug eluting balloons in contemporary coronary intervention

Coronary endothelial dysfunction following drug-eluting balloon only treatment of *de novo* lesions in human

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Aims: To evaluate the effects of drug-eluting balloon only (i.e. without stent implantation) treatment on the vascular function of coronary arteries in human. Unlike drug-eluting stents, drug-eluting balloon technology allows for one-shot transfer of an antiproliferative drug to the vessel wall with no persisting material or sustained drug delivery, thus theoretically preventing any delayed response to treatment.

Methods and results: Twenty patients (16 men, age 65±8 years) treated by drug-eluting ballooon for focal stenosis involving native arteries underwent coronary vascular function testing at six months follow-up. The cold pressor test and intracoronary nitroglycerine administration were implemented to assess endothelium-dependent and endothelium-independent vasomotion, respectively. Percent change of mean lumen diameter was assessed by quantitative coronary angiography at three sites: the treated segment (as identified by anatomical landmarks) and two other angiographically normal segments – one proximal and one distal – being distant 10 mm from the treated one. Moreover, another segment of similar diameter in a normal coronary branch served as reference. Paclitaxel-based drug-eluting balloons implementing two different technologies were used, namely the In.Pact Falcon (Medtronic Invatec, Roncadelle, Italy) in 10 patient and the second-generation DIOR (Eurocor, Bonn, Germany) in another 10 patients. Cold pressor test increased the rate pressure product by 31±6%, which induced a significant vasodilation in the reference coronary segment (8.9±3.0%) but not in the treated segment (–1.4±5.1%) or in the proximal (–1.3±2.9%) and distal (–1.8±3.3%) angiographically normal arterial segments (p=0.012). In contrast, after intracoronary nitroglycerine administration, all coronary segments dilated similarly (reference segment by 17.3±7.3%, treated segment by 15.6±8.7%, proximal normal segment by 13.7±7.4% and distal normal segment by 17.9±7.9%, p=0.34). Moreover, no significant differences were observed between patients treated with In.Pact Falcon or second-generation DIOR drug-eluting balloons.

Conclusions: Treatment of *de novo* coronary artery disease by paclitaxel-based drug-eluting balloon is associated at six months follow-up with impaired vascular function after cold pressor test but not nitroglycerine administration. These findings suggest a long lasting effect of the antiproliferative agent on the endothelial function despite a rapid transfer of the drug to the vessel wall and appear independent on the drug-eluting balloon technology.

Coronary interventions – *Thursday May 23rd*
The role of drug eluting balloons in contemporary coronary intervention

Late lumen enlargement: a potential new paradigm in vascular therapy

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Aims: Local drug delivery to human coronary arteries by application of a balloon coated with iopromide or urea as carrier and paclitaxel as pharmacologic agent (DCB) has been shown to reduce in-stent restenosis (ISR) and late lumen loss in *de novo* lesions of small coronary arteries in comparison to other forms of PCI. While inherent healing processes after plane PTCA have led to a high rate of restenosis mainly due to recoil and intimal proliferation, we observed an unanticipated in residual stenosis while following patients after application of DCBs. It was the aim of this study to systematically study and quantify this phenomenon.

Methods and results: We evaluated 58 native coronary artery lesions mainly of small vessels (12 RCA, 21 LAD and 25 CX) in 56 consecutive patients (10 females, 46 males, mean age 67.4±10.3 yrs) directly after DCB intervention and 4±2 months thereafter by quantitative coronary angiography. Treatment of ISR and left main lesions was excluded from this analysis. Mean vessel reference diameter was 2.59±0.45 mm and initial stenosis grade was 69.1±14.0%. To exclude a vasomotor tone effect a non-target vessel was evaluated as to the diameter change within the observation period and from identical cine frames (n=43). All PCIs were technically performed according to the recommendations of the German Consensus Group (Eurointervention 2011). Minimal and mean lumina of the lesion and the treated segment increased highly significantly. 69% of patients showed this positive remodeling, while 29% had minor luminal renarrowing. Only 5% of patients showed late lumen loss of more than 0.2 mm, while 33% showed late lumen gain over 0.2 mm. No reintervention occurred in any of these patients, and MACE rate was 1.8%. There was only 1 binary restenosis. The late lumen increase of the target lesion within the observation period was 0.16 mm (1.75±0.58 vs. 1.91±0.55 mm p<0.001) and the diameter stenosis was further reduced from 33.8±12.3to 26.9±13.8% (p<0.001) while there were no changes in the vessel diameter of the non target reference vessel (2.33±0.60 vs. 2.34±0.61 mm p=n.s.).

Conclusions: Local application of paclitaxel by drug coated balloons to native coronary arteries leads to late lumen increase in contrary to all other forms of PCI, which all lead to LLL.

Angiographic and clinical outcome in the treatment of restenosis of DES with drug coated balloons in diabetics

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Aims: The PEPCAD-DES Study showed a significantly lower late loss with the use of a drug coated balloon in comparison (SeQuent Please balloon catheter (B.Braun Melsungen AG, Germany) in comparison to balloon angioplasty alone in the treatment of instent-restenosis of drug-eluting stents (DES). In the presence of diabetes there are higher rates of ISR reported in comparison to a healthy population. Purpose of this study was to investigate the impact of diabetes mellitus on late lumen loss and angiographic restenosis in patients, who were treated with a drug-coated balloon (DCB) in comparison to balloon angioplasty alone (POBA) for instent-restenosis (ISR) of drug-eluting stents (DES).

Methods and results: 110 patients with an ISR of either Cypher-, Taxus- or XienceV-stent in a native coronary artery with indication for percutaneous coronary intervention with a reference diameter ranging from 2.5 mm to 3.5 mm and lesion lengths less or equal to 22 mm were included in six centres in Germany. Exclusion criteria were: acute myocardial infarction, chronic total occlusion, lesion in grafts, bifurcation lesion, left main lesion, restenosis and in-stent restenosis, contraindication for acetylsalicylic acid or clopidogrel. The length of the paclitaxel eluting balloon was chosen to overlap the treated instent-lesion for at least 1 mm at the proximal and distal margin. All patients were scheduled for control angiography at 6 months. 38 patients were randomised to POBA and 72 patients to DCB. Of these 26 (36.1%) patients. of the DCB-group and 13 (34.2%) were diabetics. DCB as compared with POBA significantly reduced late loss in diabetics and non-diabetics, respectively. At angiographic 6 month follow-up late lumen loss (LLL) in patients treated with a DCB (n=22) was 0.51±0.72 mm in diabetics, and 0.39±0.54 mm in non-diabetics (n=42). In patients treated with POBA LLL was 1.45±0.85 mm in the diabetic subgroup and 0.91±0.71 mm in non-diabetics (n=24). Rates of target lesion revascularisation (TLR) rates were significantly lower with DCB vs. POBA for non-diabetics (15.2% vs. 36.0%; p=0.045), but not for diabetics (15.4% vs. 38.5%; p=0.107) Overall rates of major adverse cardiac events (MACE) were significantly reduced in non-diabetics (17.4% vs. 44.0%; p=0.016) and in diabetics (15.4% vs. 61.5%; p=0.003), respectively.

Conclusions: Paclitaxel coated balloon angioplasty was superior to POBA for treatment of DES-ISR and reduced significantly MACE-rates in diabetics and non-diabetics. DCB effect on late loss was more effective in patients without diabetes.

Clinical efficacy and safety of paclitaxel-eluting balloon in a real-world single-centre registry of south-east asian patients

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Aims: Drug eluting balloon (DEB) is a new therapeutic option for treatment of obstructive coronary lesions in percutaneous coronary intervention (PCI). We evaluated the clinical efficacy and safety of SeQuent Please paclitaxel-eluting balloon in our cohort of South-East Asian patients in real world clinical practice and report on the clinical outcomes.

Methods and results: Between January 2010 to October 2012, 310 patients (76% male, mean age 61.4±11 years) with a total of 324 coronary lesions were treated with SeQuent Please DEB. The primary endpoint was major adverse cardiac events (MACE) at 9 months follow-up ie a composite of cardiovascular death, target vessel related myocardial infarction (MI) and target lesion revascularisation (TLR). Secondary endpoints included individual components of MACE. The majority of patients presented with acute coronary syndrome (75%). 48% of patients were diabetics. The mean left ventricular ejection fraction was 45±13%. The most common indication for the use of DEB was small vessel disease (54%) followed by instent restenosis (ISR) (22%), bifurcation lesions (6%) and others (18%). Of the 71 ISR, DEB intervention was performed for 56% bare metal ISR and 44% drug-eluting ISR. The most common target vessel for DEB was left anterior descending artery (38%) followed by right coronary artery (18.2%), left circumflex (16.4%) and others (27.5%). DEB-only PCI was the predominant approach (81% of patients) whereas DEB followed by bare metal stenting was performed for the remaining 19% of patients. An average of 1.24+0.5 DEB were used per patient, with mean DEB diameter of 2.6±0.6 mm and average length of 24.4±11.7 mm. At 9 months follow-up, 4.7% of patients developed MACE. There was no reported death. MACE was mainly driven by TLR (4.1%) followed by target vessel related MI (2.4%). For patients who had stent implantation, there was no incidence of stent thrombosis.

Conclusions: SeQuent Please DEB is a safe and effective treatment modality for coronary artery lesions especially small vessel disease, ISR and bifurcation lesions. The intermediate term clinical outcomes in our cohort of South-East Asian patients are good with low incidence of MACE.

Coronary interventions – *Thursday May 23rd*
The role of drug eluting balloons in contemporary coronary intervention

Randomised comparison a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels 12 month results of the BELLO study

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Aims: Limited data are available regarding the efficacy of drug-eluting balloons (DEB) in *de novo* disease. Aim of this study is to compare the 12-month clinical outcomes of DEB to paclitaxel-eluting stent (PES) implantation in small vessels.

Methods and results: BELLO is a prospective, multicentre trial that randomised 182 patients with lesions located in small vessels (reference diameter <2.8 mm) to treatment with a paclitaxel DEB and provisional bare-metal stenting (n=90) or PES implantation (n=92). Baseline characteristics were well matched, except for a smaller vessel size in the DEB group (2.15±0.27 vs. 2.25±0.24 mm; P=0.003). Majority (89%) of lesions involved vessels with a diameter <2.5 mm. Bailout stenting was required in 20% of lesions in the DEB group. At 6-months, DEB met the primary endpoint of noninferiority for angiographic in-stent (in-balloon) late loss as compared to PES (0.08±0.38 mm vs. 0.29±0.44 mm; difference –0.21 [95% CI –0.34 to –0.09]; Pnoninferiority<0.001). Also at 6-months, DEB and PES were associated with similar rates target lesion revascularisation (TLR: 4.4% vs. 7.6%; P=0.37) and MACE (7.8% vs. 13.2%; P=0.77). During the 6 to 12-month follow-up period, there were 2 further TLR, both in the PES group. Thus, the clinical event rates at 12-months in DEB and PES were as follows: MACE: 10% vs. 18.5%, P=0.31; MI: 1.1% vs. 5.5%, P=0.1; TLR: 4.4% vs. 9.8%, P=0.25.

Conclusions: In the BELLO trial, DEB and PES were associated with similar late loss and angiographic restenosis rates at 6-months for the treatment of small vessel disease. The efficacy of a paclitaxel DEB appears to maintained at 12-months after the procedure with similar revascularisation rates as a paclitaxel-eluting stent.

Coronary interventions – *Thursday May 23rd*
The role of drug eluting balloons in contemporary coronary intervention

Treatment ostial bifurcated lesions (001 of Medina classification) with a second generation of placlitaxel eluting balloon: 6 months outcomes of the Spanish multicentre registry

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Aims: In the DES era, the best strategy to treat ostial lesions (001 Medina Classification) remains debatable and all suggested methodologies have specific limitations. We sought to assess the efficacy and safety of a placlitaxel-coated, drug-eluting balloon (PEB) in patients with 001 bifurcated lesions placed in secondary branches.

Methods and results: 42 patients with 001 bifurcated lesion treated by using the second generation Dior (EurocorGm), PEB (3.0 μg/m² balloon surface area), were included in this prospective multicentre (9 Spanish centre) registry. After optimal dilatation, a PEB was inflated for a minimum of 45 seconds. Repeat angiography was planned at 6-8 months in all patients. Dual antiplatelet therapy was recommended at standard doses for at least 4 weeks. Left main bifurcated lesions, severe calcification and cardiogenic shock, were the only exclusion criteria. Patients were 62±11 years old, 45% diabetic, 48% ACS as clinical presentation, 83% had LVEF >50%, and 19% had 3-vessel disease. The most frequent lesion treated was first diagonal (45%). In 35% of patients a stent was implanted outside the target lesion. Pre-dilatation was done in all the cases, with cutting balloon in 61%. Angiographic success was 88% (in 12% of lesions a BMS was implanted because of significant acute recoil or coronary dissection more that type B). At 1 month (follow-up completed in all the patients) there was no adverse event (MACE). At 6 months (follow-up completed in 65% of patients) there was 11.5% cumulative and non-hierarchical MACE (3 MI, 0 cardiac deaths, 3 TLR). There was no subacute thrombosis or occlusion. At 6 months, angiographic follow-up was completed in 10 patients; reference diameter was 2.18±0.3 mm with a late loss of 0.31 mm.

Conclusions: We report the largest series of patients with 001 bifurcated lesions treated with PEB. In this complex setting, the optimal treatment is unknown. PEB is a safe strategy (0% acute occlusion/thombosis) and it seems effective at 6 months follow-up with a 11.5% TLR. Angiographic follow-up will be available at the time of the meeting.

The role of drug-eluting balloon in the treatment of diffuse *de novo* coronary artery disease

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Aims: To report our experience with drug-eluting balloon (DEB) alone or in combination with drug-eluting stent (DES) implantation in the treatment of diffuse *de novo* coronary artery disease (CAD) (>25 mm).

Methods and results: We retrospectively evaluated all patients who were treated with DEB for diffuse *de novo* CAD between June-2005 and October-2012. Endpoints analysed at were major adverse cardiac events (MACE) defined as composite of all-cause death, myocardial infarction (MI) and target vessel revascularisation (TVR), TVR and target lesion revascularisation (TLR). Quantitative coronary analysis QCA analysis was performed in lesions treated with DEB alone±predilatation. Lesions that received bail-out DES were included in the analysis. During the study period, 262 patients were treated with DEB, 69 of which for diffuse *de novo* CAD >25 mm. A high proportion of patients were diabetic (n=32, 46.4%) Mean EuroSCORE was 3.24±2.28. Multivessel disease was present in the majority of the patients (n=49, 71.0%) with mean SYNTAX score 23.7±10.3. Bail-out stenting for dissection or residual stenosis >50% was used in 7 lesions (7.4%). A hybrid approach, utilising a combination of DES and DEB, for treating very long disease (67.7 mm±13.4 mm) was used in 34 lesions (36.6%). In these cases the overall ratio of DEB/DES use was 1.24 suggesting that greater lesion length was treated by DEB rather than DES.52 lesions were treated only with DEB with mean lesion length of 35.4 mm±5.7 mm. Outcome rates at 2-year follow-up for MACE and TVR were 20.8% and 14.8%, respectively. The TLR rate per patient was 9.6% and per lesion was 8.0%. There were no cases of definite or probable stent thrombosis (ST).

Conclusions: Our study suggests that DEB use can be an alternative approach to DES for the treatment of diffuse coronary disease either alone in the smaller coronary vessels or in combination with DES in very long lesions. This can reduce overall stent length and stent use in small vessels, both of which are predictors of worse clinical outcomes.

Coronary interventions – *Thursday May 23rd*
The role of drug eluting balloons in contemporary coronary intervention

The paclitaxel-coated balloon catheter presents a therapeutic alternative in select coronary indications results of an analysis of the raw data of 7 prospective studies

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Aims: The paclitaxel-coated balloon catheter (DCB) based on the PACCOCATH® technology hasyielded angiographic and clinical results superior to drug-eluting stents in situations like bare-metal in-stent restenosis and a trend towards better outcome in small coronary vessels and side branches of coronary bifurcations. The sample size of each individual study, however, was relatively small.

Methods and results: To strengthen the evidence, the raw data of all 401 patients (63.3±10.5 years, 74.3% men) with 446 stenoses that were treated with SeQuent™ Please DCB or its predecessor in the PACCOCATH ISR I/II, PEPCAD I, II, IV, V and INDICOR were analysed. Main outcome parameters encompassed the 6-9 month angiographic and 1-year MACE data. The patients were categorised into the following groups: de novo lesions in native vessels treated with DCBonly (82Px./106 stenoses), stenoses in native vessels treated with DCB and several types of bare-metal stents (BMS) (DCB+BMS: 202Px. /223 stenoses) and bare-metal in-stent restenosis treated with DCB only (BMS-ISR; 117Px./117 stenoses). DCBonly compared to BMS-ISR did not show statistically different results for late lumen loss (LLL) (0.19±0.59 mm vs. 0.23±0.53 mm), LLLIndex (0.15±0.31 vs. 0.16±0.56), target lesion revascularisation (TLR) (4/82 (4.9%) vs. 6/117(5.1%)), lesion related myocardial infarction major and target lesion thrombosis (both parameters in both groups 0), cardiac death (0/82 (0%) vs. 1/117(0.9%)), and major adverse cardiac events (MACE) (4/82(4.9%) vs. 6/117(5.1%)). In DCB combined with BMS, TLR (16/202(7.9%)), lesion related myocardial infarction (7/202(3.5%)), target lesion related thrombosis (5/202(2.5%)), and cardiac death (3/202(1.5%)) were statistically not different compared ro DCB only in de novo lesions while in DCB+BMS the LLL (0.55±0.65 mm) was significantly ($p<0.001$) greater as were LLLIndex (0.34±0.41, $p<0.001$) and MACE 25/202 (12.4%) ($p=0.08$). The 1-year MACE rates were independent from gender, and the cardiovascular risk factors smoking, hyperlipidaemia, obesity, hypertension, and diabetes.

Conclusions: Angiographically, DCBonly was superior to its combination with bare metal stents while MACE data trended superior. Neither did lesion characteristics nor cardiovascular risk factors impact the outcome of the treatment options.

Coronary interventions – *Thursday May 23rd*
Bioresorbable scaffolds: clinical results

Two-year clinical data and multi-modality imaging results up to 1-year follow-up of the BIOSOLVE-I study with the paclitaxel-eluting bioabsorbable magnesium scaffold (DREAMS)

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Aims: In order to assess the intermediate term safety, clinical performance and the bioabsorption process of the Paclitaxel-Eluting Bioabsorbable Magnesium Scaffold (DREAMS) 2-year clinical data and multi-modality imaging outcomes up to 1 year follow-up are reported.

Methods and results: Forty-six subjects were enrolled in the first-in-men BIOSOLVE-I study, and assigned to two different cohorts with different invasive follow-up schedules. Clinical follow-up for both cohorts is scheduled at 1, 6, 12, 24 and 36 months, angiographic and IVUS follow-up for cohort 1 at 6 months and for cohort 2 at 12 months. A subgroup of patients underwent OCT and vasomotion testing. The primary endpoint is Target Lesion Failure (TLF), defined as the composite of cardiac death, target vessel myocardial infarction and clinically driven target lesion failure, at 6 months for cohort 1 and at 12 month for cohort 2. For some patients also 18-month imaging data are available. Clinical: TLF rate at 24-month was 6.8% including two clinically driven target lesion revascularisations and one peri-procedural target vessel myocardial infarction occurring during 12-month follow-up angiography. No cardiac death or scaffold thrombosis was observed. Angiographic: In-scaffold late lumen loss was 0.52±0.39 mm at 12 months. Vasoconstriction after acetylcholine was documented by quantitative coronary angiography (D=-10.04%; p=0.0008 vs. baseline) followed by vasodilatation after nitroglycerine (D=8.69%; p<0.0001 vs. baseline) which demonstrates the uncaging aspect of the absorption process already at 6-month follow-up with no further change at the 12-month follow-up. IVUS: Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (p=0.0015) which remains stable until 12-month follow-up. This decrease of dense calcium is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material. Scaffold absorption is also supported by echogenicity evaluation, where the decrease of the intensity of the ultrasound signal is used to quantify the change in strut structure. Preliminary echogenicity data demonstrate that in the first 6-month a relatively large decrease of hyperechogenicity (28.5%) is observed, followed by lower decrease (18.4%) in the 6 months thereafter, with indications that the hyperechogenicity at 18-month returns to the values seen pre-implantation.

Conclusions: DREAMS shows excellent safety and efficacy data with no death and no scaffold thrombosis up to 2 years in the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

Coronary interventions – *Thursday May 23rd*
Bioresorbable scaffolds: clinical results

Prospective, multicentre evaluation of the DESolve Nx novolimus-eluting bioresorbable coronary scaffold: first report of principal clinical and imaging endpoints

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Aims: The DESolve NX study is a prospective, multicentre evaluation of the safety and efficacy of the DESolve™ Nx Novolimus-Eluting Bioresorbable Coronary Scaffold (BCSS) in patients with single *de novo* native coronary artery lesions through clinical endpoints and multiple imaging modalities

Methods and results: 126 patients with single, *de novo* coronary artery lesions were enrolled in this prospective, multicentre, single-arm study. Those patients receiving the study device are being analysed for multiple clinical endpoints including: Device and Procedure Success; Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularisation (CI-TLR); Clinically-indicated Target Lesion and Target Vessel Revascularisation, (CI-TVR) and Stent Thrombosis assessed at 1, 6 and 12 months and annually to 5 years. All patients underwent angiographic assessment at 6 months and a subset of patients underwent IVUS and OCT assessment at 6 months. Additional imaging analyses will be conducted in the subset of patients at 12 months using MSCT and at 24 months using Angiography, IVUS and OCT to assess the long-term scaffold, lesion and vessel characteristics. Device Success and Procedure Success were 95.2% and 100% respectively demonstrating the feasibility and initial safety of this novel device.

Conclusions: The DESolve™ Nx Novolimus-Eluting BCSS demonstrated initial safety and efficacy in this study. A first report of the principal clinical and imaging outcomes through 6 months will be presented.

Absorb extend: an interim report on the 12-months clinical outcomes of approximately 400 patients enrolled

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Aims: ABSORB EXTEND was initiated as an international continued access study (outside of the US) to expand experience with the Absorb BVS. Additionally, patients were treated for longer coronary lesions than those in the ABSORB trial using either longer scaffold lengths or planned overlap of the Absorb BVS.

Methods and results: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that is planning to enroll up to 1,000 subjects at up to 100 sites. Included are patients with lesions ≤28 mm in length and reference vessel diameter of 2.0-3.8 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two *de novo* native coronary artery lesions, each in a different epicardial vessel, is permitted. Interim 12-month data for approximately 400 patients enrolled in ABSORB EXTEND will be available for the first time in May 2013 and will provide additional data on the safety and performance of the Absorb BVS in a larger population of patients, including those with longer lesions and dual vessel treatment. Clinical composites and component end points will be presented out to 12 months.

Conclusions: Clinical and angiographic outcomes from the First-in-Man ABSORB trial have demonstrated the safety and efficacy of the Absorb BVS in lesions ≤14 mm. Interim outcomes in 400 patients at 12 months, (the largest patient cohort reported at this time point to date) from ABSORB EXTEND will provide further insight into the longer-term safety and efficacy of the ABSORB BVS in patients with longer lesions across multiple geographies.

Coronary interventions – *Thursday May 23rd*
Bioresorbable scaffolds: clinical results

Implantation of ABSORB everolimus-eluting bioresorbable vascular scaffolds in the setting of ACS patients

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Aims: Everolimus-eluting bioresorbable vascular scaffold systems have recently been introduced in the market for the treatment of coronary artery stenoses. Experience on the use of these devices is limited to type A lesions in elective settings. Treatment of ruptured plaques with bioresorbable scaffold systems might have the advantage to promote the formation of new fibrotic tissue (plaque sealing) without the disadvantages of permanent metal stent implantation.

Methods and results: 64 culprit lesions in 63 patients (age 57±15) were treated with the Absorb everolimus-eluting bioresorbable scaffold system. 40 patients were classified as NSTEMI or unstable angina, 23 had STEMI, 9 were diabetics, 31 were smokers or previous smokers, 39 had hypertension and 15 dyslipidaemia, 19 were females. None had a history of previous myocardial infarction. The lesion was in the left anterior descending coronary in 27 cases, in the circumflex coronary in 10 and the right coronary in 27. Angiographic evidence of intravascular thrombosis was present in all lesions treated. 64 scaffold systems (mean diameter 3.1±0.3 mm, mean length 18.9±4.2 mm) were successfully implanted (100% device success rate). Mean fluoroscopic time was 8.4±5.8 and mean use of angiographic contrast was 153±57 ml. Mean peak troponin I and creatinin-phosphokinase were 40±64 ng/ml and 1275±1730 micrgr/lt (range <0.02 - 165 ng/ml and 64-4611 micrgr/lt). Mean hospital stay was 3±1 days. At one-month clinical follow-up, there was no death, target lesion revascularisation procedures. Seven patients underwent repeat percutaneous intervention in non-target lesions (5 of them were planned interventions).

Conclusions: Our data provide evidence that the use of bioresorbable scaffold systems is feasible and safe also in the setting of acute coronary syndromes.

Coronary interventions – *Thursday May 23rd*
Bioresorbable scaffolds: clinical results

Incidence and short-term clinical outcomes of small side branch occlusion after implantation of an everolimus-eluting bioresorbable vascular scaffold: an interim report of 435 patients in the ABSORB-EXTEND single-arm trial in comparison with an everolimus-eluting metallic stent in the SPIRIT first and II trials

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Aims: The thicker strut of metallic stents potentially contributes to a higher incidence of side branch occlusion (SBO). The aim of this study was to investigate the incidence and clinical sequelae of small side branch occlusion after Absorb bioresorbable vascular scaffold (BVS) implantation.

Methods and results: We performed a post-hoc angiographic assessment of 1209 side branches in 435 patients enrolled in the ABSORB-EXTEND single-arm trial, in comparison with 682 side branches in 237 patients treated with the everolimus-eluting metallic stent (EES) in the SPIRIT first and II trials. Any visible side branches originating within the device implantation site or the 5-mm proximal and distal margins were included in the angiographic assessment. SBO was defined as a reduction in thrombolysis in myocardial infarction flow to grade 0 or 1. Post-procedural SBO was observed in 73 side branches (6.0%) in BVS group and 28 side branches (4.1%) in EES group (p=0.09). Patients with post-procedural SBO were significantly associated with an increased incidence of in-hospital myocardial infarction (6.5% in SBO group vs. 0.5% in non-SBO group, p<0.01). Multivariable analysis revealed that BVS was an independent predictor of post-procedural SBO (OR, 2.09; 95% CI, 1.18-3.68). However, there were no significant differences in the incidence of post-procedural CK-MB elevation and in the peak level of post-procedural cardiac troponin between the two treatment groups. By stratified analysis, BVS demonstrated a higher incidence of post-procedural SBO compared to EES only in small side branches with a reference vessel diameter (RVD) ≤0.5 mm (10.5% vs. 3.9%, p=0.03 between the groups, p for interaction=0.08).

Conclusions: BVS was associated with a higher incidence of post-procedural SBO compared to EES. This effect was mostly limited to small side branches with a RVD ≤0.5 mm.

Coronary interventions – *Thursday May 23rd*
You cannot miss the great session on Rotablator!

Rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: two-year clinical outcome of the randomised ROTAXUS trial

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Aims: In the randomised ROTAXUS trial, routine lesion preparation of complex calcified coronary lesions using rotational atherectomy (RA) prior to paclitaxel-eluting stent (PES) implantation did not reduce late lumen loss at 9 months compared to stenting without RA. Clinical outcomes at 9 months were comparable. So far, no long-term data of prospective head-to-head comparisons between both treatment strategies have been reported.

Methods and results: ROTAXUS randomly assigned 240 patients with complex calcified native coronary lesions to RA followed by stenting (n=120) or stenting without RA (n=120, standard therapy group). Stenting was performed using a polymer-based slow-release PES. The primary endpoint was in-stent late lumen loss at 9-month follow-up angiography. A clinical follow-up at 2 years was performed for 224 patients (93.3%, 112 patients in each group) and is reported on an intention-to-treat basis. The mean age of the study population was 71.1±7.7 years, 75.8% were males and 27.1% were diabetics. Patients most frequently presented with stable angina (86.2%) and had a preserved left ventricular ejection fraction (54.3±11.1%). All patients were treated for moderate or severely calcified coronary lesions, 89.7% were type B2/C lesions, and 73.3% of patients had multivessel disease. Initial angiographic success was high and identical in both groups (96.7%), but significantly more patients in the standard therapy group were crossed-over (12.5% vs. 4.2%, p=0.02). At 2 years, 10 patients in the RA group (8.9%) and 9 patients in the standard therapy group (8.0%) had died (p=0.81). The rates of myocardial infarction (8.0% vs. 6.3%, p=0.60) and target vessel revascularisation (19.6% vs. 23.2%, p=0.51) were similar in both groups. Cumulative major adverse cardiac events, defined as a composite of death, myocardial infarction and target vessel revascularisation, occurred in 34 patients (30.4%) in the RA group and 40 patients (35.4%) in the standard therapy group (p=0.39).

Conclusions: ROTAXUS comprised the oldest patient cohort with the most severe lesions ever studied in a randomised controlled PCI trial. Despite high rates of initial angiographic success, nearly one third of the patients had a major adverse cardiac event within a 2-year follow-up period, with no differences between patients treated with or without RA. Coronary calcification remains a challenge for current interventional therapies and new therapeutic approaches are needed.

PCI in calcified vessels: an insight into the impact of rotational atherectomy by OCT

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Aims: We aimed to characterise the appearances of coronary vessels immediately following rotational atherectomy (RA) and after stent deployment by the use of optical coherence tomography (OCT), and to determine predictors of strut malapposition.

Methods and results: We retrospectively analysed the OCT images of 17 consecutive patients who had undergone RA-facilitated PCI. OCT images taken immediately after RA (and before any balloon dilatation) were available in 13 patients and were used to characterise the appearances of the vessel, particularly the presence of dissection and thrombus. In all patients, the stented segments were examined every 5 frames (1 mm) for the presence of stent strut malapposition, defined as when the distance from the endoluminal surface of the strut to the vessel was higher than the sum of the metal and polymer thickness. The depth and circumference of calcium was also quantified by OCT. The mean [SD] age was 71.8 [8.7] years and 76.5% were men. The mean lesion length was 44.5 [17.1] mm, with a median distal reference diameter 3.1 mm (IQR 2.3-3.5) and proximal reference diameter 3.4 mm (IQR 3.0-4.2). The mean calcium depth and calcium arc was 750.0 [167.3] µm and 309.9 [68.6] degrees respectively and the burr:distal vessel ratio was 0.53. Despite the use of unfractionated heparin and dual antiplatelet therapy during the procedure, visible but limited platelet thrombus was identified in 92% of cases and coronary dissection was present in 77% of cases. A total of 6987 stent struts were analysed and 603 (8.6%) were malapposed, most commonly in the proximal stented segment (54.7% proximal, 30.0% mid, 15.3% distal). Post dilation was performed in all cases where stent malapposition was identified by OCT. The median distance of malapposition from the endoluminal wall was 110.8 µm (IQR 85.6-143.9) and reference vessel size correlated positively with the degree of strut malapposition (distal reference diameter: r=0.686, p=0.002, proximal reference diameter: r=0.654, p=0.004). At a medium follow-up 13.0 months (IQR 6.5-17.0), there were no adverse clinical events.

Conclusions: High resolution OCT allows detailed analysis of vessel architecture following RA and demonstrates significant vessel wall trauma, with a high incidence of visible platelet thrombus and coronary dissection not identified on angiography. Despite extensive circumferential calcium in this study, rates of stent malapposition were low following RA and correlated with vessel size.

Coronary interventions – *Thursday May 23rd*
You cannot miss the great session on Rotablator!

Plaque modification vs. debulking strategy in calcified coronary lesions. Long-term clinical outcome and technical determinants of the rotational atherectomy: the Rotablator Udine registry

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Aims: Percutaneous coronary intervention (PCI) of heavily calcified lesions is a challenge for the interventional cardiologist. The aim of this study was to investigate the immediate and long-term outcome of patients treated with rotational atherectomy (RA).

Methods and results: All consecutive patients treated by PCI with RA at our centre between 09/1998-12/2011 entered in a database and were analysed retrospectively. Clinical indication were Acute Coronary Syndrome in 148 patients (52%). Data of early and late (mean follow-up 69±52 months) major adverse cardiac events (MACE) included cardiac death, stroke, acute myocardial infarction (AMI) and target lesion failure (TLF). A total of 283 patients (306 lesions) were included. Mean age was 70±10, 80% were male, 33% diabetic and 42% had chronic renal failure (CRF). 234 patients (83%) had multivessel disease. According to ACC/AHA classification, 79% were type C. Mean vessel diameter was 3.3±0.4 mm. After RA, cutting-balloon (CB) was used in 35% of cases. Drug eluting stents (DES) were implanted in 42% of patients, bare metal (BMS) in 45%. Patients were divided in two groups, according to Burr/Artery Ratio (BAR): group 1 (BAR≤0.5 plus cutting-balloon use, 64%) and group 2 (BAR>0.5 with or without cutting-balloon, 31%). Procedural success was 96.6%, early mortality 1.4%, stroke or TIA 1.4%, acute renal injury 5.3%. CK-MB rise >5x Upper Limit value occurred in 2.8% of patients and vessel perforation in 1.4%. CRF (95% CI,1.2-1.7, p=0.03), Peripheral Artery Disease (CI 95%1.6-6.6, p=0.006), no use of cutting-balloon in lesion treated with BAR≤0.5 (CI 95% 1.2-42.3, p=0.0001) and transient/persistent slow-no flow (CI 95% 1.5-9.8, p=0.01) were independent predictor of MACEs. Persistent no-slow flow was significantly less represented in group 1 (0.5% vs. 1.9%, p=0.01), like as coronary perforation (0.5% vs. 3.9%, p=0.001) and acute stent thrombosis (2.4 vs. 0%, p=0.01). The incidence of MACE was significantly lower in group 1 at 6 months (5.4% vs. 9.8%, p=0.03), 1 year (7.1% and 12.2%, p=0.001) and 5 years (17.7% vs. 31.3%, p=0.001).

Conclusions: Rotational Atherectomy may be a safe technique in the treatment of complex lesions, with high success rate. A "minimalistic approach" using small BAR and the CB (Rota-Cut technique) followed by DES implantation, seems promising in reducing complications and improving outcome. Further studies are necessary in order to support these registry data.

Coronary interventions – *Thursday May 23rd*
You cannot miss the great session on Rotablator!

Can rotablation be performed safely as a radial procedure?

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Aims: The aim of this study was to compare in-hospital outcomes for patients undergoing rotablation via the radial and femoral route.

Methods and results: From September 2008 to December 2012, 125 consecutive patients (75 femoral, 50 radial) who underwent rotablation in our centre were enrolled in this study. A retrospective comparison of in-hospital outcomes has been performed. For radial approach, the sheathless guiding catheter (GC) (Sheathless Eaucath, Asahi Intecc®, Japan) has been used, which has a 1-2 French smaller diameter compared with the corresponding introducer sheath and a hydrophilic coating along its entire length. This system can be used to insert the GC into the radial artery without the use of an introducer sheath. The outer diameter of the 7.5 Fr. sheathless GC (2.49 mm) is also less than that of a 6 Fr. introducer sheath (2.62 mm). Patient radiation exposure (7171±4609 cGy cm^2 vs. 4317±2487 cGy cm^2, p=0,001) and in-hospital stay (2.2±3.1 vs. 1.2±0.8 days, p=0.001) was nearly double in femoral than in radial respectively. Burrs (1.65±0.2 mm vs. 1.7±0.2 mm, P=0.9), screening time (18±9.9 min vs. 21±9.7 min, P=0.79) and major access site bleeding complications (0.0% vs. 1.3%) were similar in radial and femoral groups respectively. Procedural success (91% vs. 100%) was lower in the femoral than in the radial group, whereas the incidence of in-hospital death was zero in both groups.

Conclusions: This study shows that radial artery access is a feasible, safe and effective approach for rotablation using the 7.5 Fr sheathless GC.

Coronary interventions – *Thursday May 23rd*
You cannot miss the great session on Rotablator!

Contemporary clinical outcomes of patients treated with or without rotational coronary atherectomy' an analysis of the UK central cardiac audit database

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Aims: Coronary calcification is an independent predictor of mortality, and is anatomically associated with incomplete balloon expansion and failure of stent insertion. Rotational atherectomy (RA) is a useful tool for treating coronary calcification, allowing plaque modification by de-bulking.

Methods and results: We assessed procedural outcome and medium-term survival among patients undergoing percutaneous coronary intervention (PCI) with or without RA from the UK Central Cardiac Audit Database (CCAD) between September 2007 and March 2011. Vital status was established via the Medical Research Information Service as of March 2012. Data from 221,669 percutaneous coronary intervention (PCI) procedures were analysed; 2152 patients (0.97%) underwent adjunctive RA (RA+); the remainder underwent conventional PCI (RA–). RA+patients were older (71.7±9.6 vs. 64.1±12.8 yrs; p<0.001), and had a higher incidence of diabetes (26.4% vs. 18.0%; p<0.001), hypertension (61.9% vs. 49.4%; p<0.001), peripheral vascular disease (9.9% vs. 4.2%, p<0.001), cerebrovascular disease (5.5% vs. 3.4%, p<0.001), renal impairment (3.4% vs. 1.5%, p<0.001), poor left ventricular function (11.4% vs. 4.3%, p<0.001) and concomitant valvular heart disease (2.4% vs. 0.7%, p<0.001). Procedural success was lower among RA+patients (90.3% vs. 94.6%; p<0.001) and procedural complications were more frequent (9.7% vs. 5.4%; p<000.1). After a mean follow-up of 2.4±1.2 years, unadjusted Cox proportional hazard modeling demonstrated poorer survival for RA+patients (HR 2.21, 95%CI 1.97-2.49; p<0.0001). This disadvantage remained after adjustment for adverse variables (HR 1.26, 95% CI: 1.11-1.44; p=0.0004) and following propensity analysis. There was evidence however of improved survival for RA+patients with left main stem disease (HR 0.52, 95% CI 0.35-0.75, p<0.0001), and peripheral vascular disease (HR 0.65, 95% CI 0.43-0.98, p<0.0005).

Conclusions: Rotational atherectomy was undertaken in patients with higher pre-procedural risk. Medium term survival was worse among patients undergoing rotational atherectomy, and this survival disadvantage remained after correction for available adverse factors. However this disadvantage appears to be linked predominantly to the premorbid risk of the patient population rather than the technique itself. Rotational atherectomy, however remains a technique of value for patients with heavily calcified coronary lesions.

Stent thrombosis with zotarolimus-eluting resolute stents compared with everolimus-eluting stents: an updated meta-analysis of randomised clinical trials

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Aims: New generation drug-eluting stents (DES) improve safety and efficacy compared with early generation DES. However, it is still debated whether new generation zotarolimus-eluting Resolute stents (R-ZES) differ from everolimus-eluting stents (EES) in terms of safety, particularly as it relates to the propensity for stent thrombosis (ST).

Methods and results: PubMed and conference proceedings were searched for reports of randomised clinical trials comparing R-ZES and EES until December 2012. Three trials were identified: RESOLUTE All Comers, TWENTE, and ISAR-LM 2. Clinical outcomes were extracted independently by 2 investigators. Random-effects meta-analyses were performed comparing clinical outcomes in R-ZES treated patients and EES treated patients up to maximum available follow-up. The pre-specified primary safety endpoint was definite or probable ST according to the ARC criteria. No evidence of heterogeneity was observed across trials for the analysed endpoints (I-squared=0% for all analysed endpoints). The use of R-ZES was associated with a similar risk of definite or probable ST compared with EES (RR 1.35, 95% CI 0.81-2.25). Similarly, the risk of the composite of cardiac death and myocardial infarction did not show differences between R-ZES and EES (RR 1.13, 95% CI 0.91-1-41). According to a landmark analysis at 1 year, the use of R-ZES was associated with a trend towards a higher risk of ST compared with EES during the first year (RR 1.91, 95% CI 0.95-3.87), whereas no difference was observed between R-ZES and EES in the risk of very late ST occurring beyond 1 year after stent implantation (RR 1.01, 95% CI 0.38-2.68). With respect to effectiveness, R-ZES had a similar risk of repeat revascularisation as EES (RR 1.13, 95% CI 0.89-1-42).

Conclusions: R-ZES has a similar safety and effectiveness profile compared with EES, with no apparent difference in the risk of ST, cardiac death and myocardial infarction during long-term follow-up. However, a higher propensity of ST with R-ZES compared with EES during the first year after stent implantation cannot be excluded.

Coronary interventions – *Thursday May 23rd*
Stent thrombosis: new evidence from clinical trials and registries

Three-year stent thrombosis rates and major clinical events for zotarolimus-eluting vs. sirolimus-eluting stent for multivessel coronary stenting: an analysis from the PROTECT randomised trial

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Aims: The PROTECT randomised trial compared the long-term safety of two DES with different antiproliferative properties: the Endeavor zotarolimus-eluting stent (E-ZES; Medtronic, Inc) and the Cypher sirolimus-eluting stent (C-SES; Cordis, Johnson & Johnson). The primary outcome was definite or probable stent thrombosis at 3 years. Within PROTECT, we examined primary and secondary outcomes among patients undergoing multivessel stenting and whether there was an interaction between multivessel or single vessel stenting and randomised assignment to E-ZES or C-SES.

Methods and results: PROTECT was the largest randomised clinical trial comparing DES, enrolling 8709 patients from 36 countries in 2007, including 1644 patients undergoing multivessel stenting (of 4055 lesions) whom 802 were allocated to the E-ZES group and 842 patients to the C- SES group. The test of interaction between multivessel stenting and treatment assignment was pre-specified. Among the 1644 patients who underwent multivessel stenting, age, major risk factors, history of MI, of CABG and of prior PCI were similar between groups. Procedures were staged in 22.2 vs. 19.6% of E-ZES vs. C-SES patients (p=0.203). The average number of stents and stent length did not differ between groups. Device success was more frequent in the E-ZES group (96.2 vs. 94.2%, p=0.004). Use of DAPT at 36 months was similar in both groups (32.5% vs. 30.6%, p=0.47). Among patients with multivessel stenting, the primary endpoint, definite or probable stent thrombosis at 3 years, was reduced in the E-ZES group compared to the C-SES group (1.3% for E-ZES vs. 3.0% for C-SES; p=0.024, p value for interaction=0.0513). The rate of definite stent thrombosis was 0.5% for E-ZES and 2.2%% for C-SES; p=0.004. The rate of death and large MI was 5.9% vs. 8.5% for E-ZES and C-SES respectively, p=0.052. Death rates did not differ between groups, but rates of large MI were 1.8% vs. 3.6% for E-ZES vs. C-SES respectively, p=0.031. Rates of any MI (ARC definition) were also lower with E-ZES (19.2 vs. 26.5%, p<0.001). Conversely, among patients undergoing single vessel stenting, outcomes were similar in the two trial arms.

Conclusions: In the PROTECT trial, among patients undergoing multivessel stenting, E-ZES was superior to C-SES in reducing the primary endpoint of definite or probable stent thrombosis at 3-years, and the rates of large MI. These results suggest that E-ZES may be preferred to C-SES when multivessel stenting is considered.

Coronary interventions – *Thursday May 23rd*
Stent thrombosis: new evidence from clinical trials and registries

Impact of diabetes on stent thrombosis and major clinical events at 3 years after zotarolimus-eluting vs. sirolimus-eluting coronary stent implantation: an analysis from the PROTECT randomised trial

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Aims: The PROTECT randomised trial compared the long-term safety of two DES with different antiproliferative properties: the Endeavor zotarolimus-eluting stent (E-ZES; Medtronic, Inc) and the Cypher sirolimus-eluting stent (C-SES; Cordis, Johnson & Johnson). The primary outcome was definite or probable stent thrombosis at 3 years. Within PROTECT, we analysed outcomes in diabetic vs. non diabetic patients and examined whether there was an interaction between diabetes and randomised treatment on clinical outcomes.

Methods and results: PROTECT was the largest randomised clinical trial comparing DES, enrolling 8709 patients from 36 countries in 2007, including 2410 diabetics of whom 1174 were allocated to the E-ZES group and 1236 patients to the C-SES group. The test of interaction between diabetes and treatment assignment was prespecified. At 3 years, the primary endpoint, definite or probable stent thrombosis, was higher among diabetics than non diabetics (2.5% vs. 1.3%, p<0.001). The rate of total death and large, non-fatal MI (9.5% vs. 4.3%, p<0.001) did also differ. Use of DAPT was higher in the diabetic subgroup (38.4% vs. 25.1%, p<0.001) Among diabetics, the primary endpoint did not differ between groups (2.4% for E-ZES vs. 2.6% for C-SES; p=0.79). No significant interaction was noted between stent type and diabetes (p=0.58). The rate of definite stent thrombosis was 1.0% for E-ZES and 1.9%% for C-SES; p=0.081. The rate of death and large, non-fatal MI was also similar between groups (8.9% and 10.0% for E-ZES and C-SES respectively, p=0.393) as were rates of individual components of the main secondary endpoints under similar DAPT coverage (40.4% vs. 36.5%, p=0.07).

Conclusions: In this large, contemporary, international trial, 3-year stent thrombosis rates and death / large non-fatal MI rates were much higher among diabetics than non diabetics, but there was no interaction between diabetes and the comparison of S-SES vs. Z-SES. Both devices appear to provide similar stent thrombosis rates and major clinical outcomes in diabetics up to 3 years under a fairly high prevalence of DAPT coverage.

Coronary interventions – *Thursday May 23rd*
Stent thrombosis: new evidence from clinical trials and registries

IVUS assessment of stent fracture in stent thrombosis after drug-eluting or bare-metal stent implantation the NIVUS study

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Aims: Angiographic and intravascular ultrasound studies have demonstrated stent strut fracture to be a cause of stent failure in drug-eluting stents. We used intravascular ultrasound (IVUS) to compare stent fractures in patients presenting with a stent thrombosis after drug-eluting stent (DES) or bare-metal stent (BMS) implantation.

Methods and results: The "Nordic Intravascular Ultrasound Study – (NIVUS)" study was conducted in Nordic and Baltic countries as a prospective multicentre registry where IVUS was used in patients with stent thrombosis between October 2007 and January 2010. Overall 25 stent fractures were diagnosed in 124 patients presenting with definite stent thrombosis (20.1%). Stent fractures occurred in 1 of 7 (14.3%) acute stent thromboses, 5 of 26 (19.2%) subacute stent thromboses, 0 (0.0%) late stent thromboses and 19 of 82 (23.2%) very late stent thromboses (p=0.366). Ten of 39 (25.6%) stent fractures occurred in BMS and 15 of 86 (17.4%) occurred in DES, p=0.676: (7 (19.7%) in sirolimus-eluting stents, 6 (15.8%) in paclitaxel-eluting stents, 2 (16.7%) in other DES). IVUS analysis showed that 19 (76%) of the stent fractures were complete and 6 (24%) partiel. The frequency of total stent fracture was similar in DES and BMS (n=12 of 15 (80.0%) vs. n=7 of 10 (70.0%), p=0.566). Partiel stent fracture was seen in paclitaxel-eluting stents and BMS, but not in sirolimus-eluting stents, where all stent fractures were complete. As compared to BMS, stent lengths were longer in DES [median (interquartile range): 24.0 mm (23.0-28.0 mm) vs. 26.0 mm (15.0-25.75 mm), p=0.031] and stent fracture lengths similar [1.2 mm (0.5-1.9 mm) vs. 1.2 mm (0.6-2.4 mm), p=0.77]. Malalignment of proximal and distal stent fragments occurred more frequently in DES compared to BMS (n=8 (53.3%) vs. 2 (20.0%), p=0.096). The occurrence of fracture adjacent to stent overlap or in a calcific lesion was lower in DES compared to BMS (n=5 (33.3%) vs. 7 (70.0%), p=0.072. External elastic membrane area was similar in DES and BMS [19.4 mm^2 (16.5-22.9 mm) vs. 19.1 mm^2 (15.7-25.8 mm), p=0.807].

Conclusions: Stent fracture was a frequent finding in patients with stent thrombosis. The occurrence of stent fracture and IVUS characteristics were similar in DES and BMS, although malalignment of stent fragments tended to occur more often in DES.

Stent susceptibility to fracture. An independent bench comparison of 6 contemporary stent designs using a repetitive bend test

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Aims: The aim of this study was to compare in a standardised way on the bench the susceptibility to fracture of 6 different contemporary stent designs using a repetitive bend test.

Methods and results: Tested were 90 stents each 3.0 mm in diameter. Fifteen examples of each of 6 different stent designs namely Vision and MultiLink 8 (Abbott Vascular), Biomatrix Flex (Biosensors International), Element and NG Promus (Boston Scientific) and Integrity (Medtronic). The Vision and MultiLink 8 are constructed from cobalt chromium with strut thickness of 81µ and 3 connectors between hoops. The Biomatrix Flex is constructed from stainless steel with strut thickness 120µ and 2 connectors between hoops. The Element is constructed from platinum chromium, strut thickness 81µ and 2 connectors between hoops. The NG Promus is the same as the Element but with additional connectors between the proximal 3 hoops. The Integrity is constructed from nickel chromium with strut thickness 91µ and 2 and 3 connectors between hoops. To perform the accelerated fatigue test, one end of each stent was mounted on a fixed mandrel and the other end on a mandrel that moved from side to side. The 5 mm of stent between mandrels was exposed to repetitive bending of±3.5 mm at a frequency of 6 Hz. Each stent was inspected for fractures 13 times during the 10 million cycles test. The first Biomatrix Flex fracture was observed at 17783 cycles and all Biomatrix stents had fractured by 56234 cycles. The first Vision fracture was seen a 56234 cycles and the last by at 10 times more cycles at 562341 cycles. The first MultiLink 8 fracture was seen at 100000 cycles and the last at 1 million cycles. The fractures were found at (mean±SD) of 39000±13000 cycles for Biomatrix Flex, 288000±193000 for Vision and 314000±240000 for MultiLink8. None of the Element, NG Promus or Integrity stents had fractured by 10 million cycles.

Conclusions: The stent design most susceptible to fracture was the Biomatrix Flex and the next most were the Vision and MultiLink 8 designs. The Element, NG Promus and Integrity designs were the least susceptible to fracture with no fractures observed by 10 million cycles. Factors predisposing to stent fracture include stent design and construction material.

Stent thrombosis overtime in patients undergoing DES implantation in routine practice

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Aims: Stent thrombosis (ST) has been described as a rare event in current drug-eluting stent (DES) era; however, its occurrence has been associated with relatively high morbimortality. Our aim was to investigate the incidence and predictors of ST in the very late FU in a large cohort of patients from real-world clinical practice treated with DES as default percutaneous coronary intervention (PCI) strategy.

Methods and results: A total of 4,229 patients with 6,518 coronary lesions undergoing routine or emergency PCI were prospectively (and consecutively) enrolled in the DESIRE (Drug-Eluting Stent In the REal World) registry at single institution between May/2002 and May/2012 (enrollment ongoing). By protocol, clinical follow-up was performed at 1 and 6 months, and yearly up to 10 years post-index procedure (98%). Stent thrombosis (ST) was defined according to the propositions of the Academic Research Consortium. Mean age was 64 years, 31% had diabetes, 30% were current smokers, 23% had previous myocardial infarction (MI), 50% had prior revascularisation, and 9% had renal insufficiency. As for clinical presentation, around 16% had recent MI (<30 days) and 25% had unstable angina. Overall, patients were treated with 7,000 DES and angiographic success was high (>99%) despite relatively high complexity in the majority of lesions (64% type B2/C). Up to 10 years (median time 4.9 years) FU, cumulative incidence of ST was 2.3%, given that 95.9% of patients were ST-free at 10 years (Kaplan-Meier survival curve). Of the 97 ST reported, only 1% occurred <24 hours postprocedure (acute ST). In addition, subacute (1-30 days) events were found in 12%, late (1-12 months) in 27%, and very late (>12 monhts) in 59%. In regard to the ST type, 52% of events had angiographic documentation of stent occlusion (definite ST); 2% were classified as probable ST, and 46% were possible ST.

Conclusions: In this large, prospective real-world registry, unselected patients with complex coronary lesions undergoing DES implantation had relatively low cumulative incidence of ST (2.3%), given that around 96% of patients were ST-free up to 10 years FU (according to the ARC definition). Overall, the majority of ST occurred >1 year, and 52% had angiographic documentation of the stent occlusion (definite ST).

Coronary interventions – *Thursday May 23rd*
Stent thrombosis: new evidence from clinical trials and registries

Incidence and predictors of stent thrombosis after PCI in acute myocardial infarction

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Aims: Stent thrombosis has been unsolved and catastrophic problem in patients underwent percutaneous coronary intervention (PCI). However, there is a paucity of data about the incidence, predictors and prognosis of stent thrombosis in acute myocardial infarction after PCI.

Methods and results: We consecutively enrolled 4754 acute myocardial infarction patients who underwent PCI in the COREA-AMI (COnvergent REgistry of cAtholic and chonnAm university for AMI) from January 2004 to December 2009. We analysed the incidence, predictors and prognosis of definite or probable stent thrombosis by Academic Research Consortium. Median follow-up duration was 41 months (interquatile range 27-58). Bare-metal stents and drug-eluting stent (DES) were implanted in 450 and 4304 patients, respectively. Definite or probable stent thrombosis during follow-up occurred in 119 patients (2.5%), including 2 acute (0.04%), 20 subacute (0.4%), 38 late (0.8%), 59 very late (1.2%). And annual incidence of stent thrombosis after 1 year from index PCI was from 0.42% to 0.52%. There was no difference of the rate of stent thrombosis between bare-metal stent and DES (3.8% and 2.4%, p=0.07). The independent predictors of ST were decreased left ventricular ejection fraction (hazard ratio 0.97, 95% confidence interval 0.96 - 0.99) and no reflow phenomenon (HR 2.0, 95% CI 1.08-3.72). The mortality rate was 22.7% (27 patients) in patients with stent thrombosis.

Conclusions: Stent thrombosis is not uncommon in patients with acute myocardial infarction who underwent PCI irrespective of stent type. And decreased left ventricular ejection fraction and no reflow were independent predictors of stent thrombosis.

Coronary interventions – *Thursday May 23rd*
Stent thrombosis: new evidence from clinical trials and registries

Cardiogenic shock is the strongest predictor of stent thrombosis in real-world, all-comer patients undergoing coronary artery stenting

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Aims: Stent thrombosis (ST) is an infrequent but potentially fatal complication of PCI. The reported incidence of ST varies from 0-5%, due to differences in definition of ST, inclusion/exclusion criteria, and the type of stent and dual anti-platelet therapy used. We aimed to examine the incidence of ST and associated risk factors in this 'real-world, all-comers' study.

Methods and results: All patients undergoing PCI at South Yorkshire Cardiothoracic Centre (UK) between 2007 and 2010 were included, with no exclusion criteria. To calculate the incidence of ST, we used all ARC-defined categories including definite ST, probable ST, and possible ST. We also identified ST according to ARC-defined time scales as early (within 30 days), late (30-365 days), and very late (after 365 days). To identify risk factors associated with ST, we used definite and probable ST only. The outcome data were collected using national mortality database, hospital electronic database, and patient records. Univariate predictors were identified by Student t-test and Chi-square test, and entered into a Cox proportional hazards model to identify factors independently associated with ST. During the study period 5,833 patients underwent PCI with stent implantation. The mean age was 63±11 years; 72% of the patients were males, 13% were diabetics, 39% had PCI for stable angina and 61% for acute coronary syndromes. 2.1% patients had cardiogenic shock at the time of index PCI. Median follow-up length was 700 days (interquartile range 341-1122 days). The incidence of ST was 3.5% (n=204) consisting of 1.2% (n=70) definite ST, 0.7% (n=39) probable ST and 1.6% (n=95) possible ST. Of all ST, 39% occurred early, 53% late and 8% very late. At multivariate analysis, cardiogenic shock (HR 8.3, 95% CI 5.0-14.0, p<0.001), stent length (HR 5.0, 95% CI 3.4-7.3, p<0.001), STEMI (HR 3.8, 95% CI 2.5-5.7, p<0.001), lack of DAPT (HR 2.4, 95% CI 1.5-3.9, p<0.001), stent diameter (HR 2.3, 95% CI 1.5-3.4, p<0.001), diabetes mellitus (HR 2.1, 95% CI 1.3-3.3, p=0.002, use of 1st generation DES (HR 1.7, 95% CI 1.1-2.7, p=0.01) and 3-vessel PCI (HR 2.1, 95% CI 1.1-4.0, p=0.02) were independently associated with definite and probable ST. All these factors, except 3-vessel PCI, were also independently associated with definite ST alone. Analysis of definite and probable ST together revealed that cardiogenic shock, stent size (small diameter and long length), STEMI, diabetes mellitus, and 3-vessel PCI were associated with early (acute and sub-acute) ST. Lack of DAPT was associated with late ST. Stent length, STEMI, and use of 1st generation DES were independently associated with delayed (late and very late) ST.

Conclusions: The incidence of definite, probable, or possible ST in this 'real-world' registry is 3.5%. Cardiogenic shock, often excluded in clinical trials, is the strongest independent predictor of ST.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

Multicentre, prospective, randomised, single blind, consecutive enrollment evaluation of the Elixir DESyne™ novolimus-eluting coronary stent system with durable polymer compared to the endeavor zotarolimus-eluting coronary stent system: long-term 3 year results from

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Aims: To evaluate the long term safety and efficacy of the Elixir DESyne™ Novolimus-Eluting Coronary Stent System (CSS) compared to the Endeavor Zotarolimus-Eluting CSS through assessment of clinical, angiographic, and IVUS endpoints through 3 years.

Methods and results: 210 patients were randomised 2:1 either to the DESyne CSS loaded with 5 mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a durable methacrylate polymer, or to the Endeavor CSS loaded with 10 mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analysed for the primary endpoint of late lumen loss (LLL) assessed by QCA at 9 months. All patients also underwent evaluation for secondary endpoints which included a Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularisation (TLR); clinically-indicated Target Vessel Revascularisation (TVR); and stent thrombosis all evaluated at 1, 6, 9, and 12 months and annually through 5 years. Stents were also assessed for angiographic endpoints at 9 months including: in-stent and in-segment LLL. A subset of patients underwent IVUS evaluation including percent neointimal obstruction at 9 months. The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control. Table 1 summarises 9-month angiographic and IVUS results and clinical results through 2 years which trend lower for the DESyne stent.

Conclusions: The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control (Endeavor). Long term clinical results through 3 years and a review of angiographic and IVUS results will be presented.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

Two-year clinical outcomes in the EVOLVE FHU trial: a randomised evaluation of a novel bioabsorbable polymer-coated, everolimus-eluting stent

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Aims: The aim of the EVOLVE FHU study was to compare the performance of 2 dose formulations of SYNERGY, a novel bioabsorbable polymer everolimus-eluting stent (EES), vs. the durable polymer PROMUS Element EES.

Methods and results: The EVOLVE FHU trial enrolled 291 patients with a *de novo* lesion ≤28 mm in length in a coronary artery of ≥2.25 to ≤3.5 mm diameter. The SYNERGY stent (Boston Scientific Corporation, Natick, MA, USA) releases everolimus from an ultra-thin abluminal bioabsorbable poly (DL-lactide-co-glycolide) polymer on a thin-strut, platinum chromium stent platform. The bioabsorbable polymer is absorbed shortly after drug elution is complete at three months. Three patient groups were compared: patients implanted with PROMUS Element vs. patients receiving SYNERGY stents releasing everolimus at an equivalent dose to PROMUS Element ('SYNERGY' group) and at half that dose ('SYNERGY ½ Dose' group). The primary clinical endpoint of target lesion failure (defined as cardiac death or myocardial infarction related to the target vessel, or target lesion revascularisation) at 30 days was 0%, 1.1%, and 3.1% in the PROMUS Element, SYNERGY, and SYNERGY ½ Dose groups, respectively (PROMUS Element: vs. SYNERGYP=0.49; vs. SYNERGY ½ Dose P=0.25). The primary angiographic endpoint of in-stent late loss at 6-months was noninferior between the control and SYNERGY groups (0.15±0.34 mm for PROMUS Element, 0.10±0.25 mm for SYNERGY, and 0.13±0.26 mm for SYNERGY ½ Dose; PROMUS Element: vs. SYNERGY P=0.19; vs. SYNERGY ½ Dose P=0.56). At 6 months, resolved, persistent, and late-acquired incomplete stent apposition by IVUS were, respectively, 4.4%, 0%, and 2.9% for PROMUS Element, 0%, 0%, and 3.2% for SYNERGY, and 0%, 1.6% and 1.6% for SYNERGY ½ Dose. No significant differences were found between PROMUS Element and either SYNERGY formulation for these or other measured IVUS parameters including net volume obstruction. At 12 months, target lesion failure was also similar between groups (PROMUS Element 5.1%, SYNERGY 4.4% and SYNERGY ½ Dose 4.2%; PROMUS Element: vs. SYNERGY P=1.0; vs. SYNERGY ½ Dose, P=1.0). Other clinical event rates including death, MI and revascularisation were low and similar between groups. No stent thromboses were found in any group within 12 months.

Conclusions: Over 12 months, everolimus delivered from an ultra-thin bioabsorbable abluminal polymer resulted in similar clinical, angiographic and IVUS-related outcomes compared with PROMUS Element. This will be the first presentation of the 2-year clinical results.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

Randomised all-comer comparison of zotarolimus-eluting and sirolimus-eluting coronary stents: five-year follow-up in the SORT OUT III trial

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Aims: The SORT OUT III trial is a randomised clinical trial comparing the zotarolimus-eluting Endeavor™ stent (Endeavor-ZES, Medtronic, Santa Rosa, CA) vs. the sirolimus-eluting Cypher™ stent (SES, Cordis, Johnson & Johnson, Warren, NJ) in patients with coronary artery disease receiving routine clinical care. Previous shorter-term follow-up of this study showed that the Endeavor-ZES was inferior to the SES with regard to both safety and efficacy endpoints at 1-year follow-up. However, there was a trend towards better outcomes with the Endeavor-ZES between 1- and 3-year follow-up. The current study aims to report the 5-year results.

Methods and results: Under the auspices of the Danish Organisation for Randomised Trials with Clinical Outcome (SORT OUT), we randomised 2,332 patients to Endeavor-ZES (n=1,162) or SES (n=1,170) treatment. Endpoints were a composite of cardiac death, myocardial infarction, or target vessel revascularisation (MACE), and these endpoints and definite stent thrombosis individually. Five-year follow-up data has now been obtained, the events are currently being adjudicated, and the statistical analysis will be performed in February 2013. This trial is registered with ClinicalTrials.gov, number NCT00660478.

Conclusions: Five-year results will be presented at EuroPCR 2013.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

BIOTRONIK: safety and slinical performance of the DES Orsiro in the treatment of subjects with single *de novo* coronary artery lesions-II (BIOFLOW-II)

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Aims: The purpose of the BIOFLOW II trial is to compare the Orsiro Sirolimus Eluting Stent (SES) with the Xience Prime™ Everolimus Eluting Stent (EES).

Methods and results: We performed a randomised, non-inferiority trial in subjects (N=458, 63.4±10.0 years, ranging from 36-80 yrs) with symptomatic coronary artery disease due to de novo stenotic lesions in native coronary arteries with a reference vessel diameter ≥2.25 mm and ≤4.0 mm and a lesion length ≤26 mm registered at trials.gov (NCT01356888). Subjects were randomly assigned (2:1) to receive the Orsiro SES or the Xience Prime™ EES. The primary endpoint of the study is in-stent late lumen loss (LL) assessed at 9 months, analysed according to the intention-to-treat principle. All subjects were enrolled between July 5, 2011-March 23, 2012 and were invited to undergo repeat angiography at 9 months. Clinical follow-up visits are performed at 1, 6, 12 months and annually for up to 5 years after the procedure. Quantitative coronary angiography at baseline and follow-up is analysed by an independent and blinded core laboratory (Medstar, Washington DC, USA).

Conclusions: The BIOFLOW-II trial compares the angiographic efficacy of the thin-strut, silicon-carbide coated Orsiro SES with biodegradable polymer with the Xience Prime™ EES. The clinical and angiographic 9-month follow-up data is currently being analysed. Results will be presented for the first time during the meeting.

Long-term (final) results of the XAMI trial, a multicentre randomised trial to compare first generation sirolimus-eluting stents with second generation everolimus-eluting stents in acute myocardial infarction

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Aims: The XAMI trial (XienceV stent vs. Cypher stent in primary PCI for Acute Myocardial Infarction) is the first randomised trial presenting three year follow-up data of the second generation drug eluting stents in STEMI patients.
Methods and results: 625 Patients treated with primary PCI for STEMI were randomised 2:1 to everolimus-eluting stents (EES) or sirolimus-eluting stents (SES). At one year, criteria of non-inferiority of the primary endpoint of major adverse cardiac events (MACE: cardiac death, nonfatal myocardial infarction or any target vessel revascularisation (TVR)) were clearly met: 4,0% for EES vs. 7.7% for SES (p=0.048), suggesting superiority of the EES. The incidence of definite and/or probable stent thrombosis was low, especially in the EES, 1,2% vs. 2,7% for SES (p=0.21). Three year final results of the trial will be available for presentation, focussing on the incidence of very late stent thrombosis and possible superiority of the EES as suggested at one year.
Conclusions: The final three year results will elucidate whether EES still shows significant lower MACE than first generation SES and whether very late stent thrombosis rates will further favour the use of EES in STEMI.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

Four-year outcomes from the randomised comparison of a zotarolimus-eluting and an everolimus-eluting stent in the RESOLUTE All Comers trial

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Aims: RESOLUTE All Comers compares the Resolute™ zotarolimus-eluting stent and XIENCE V™ everolimus-eluting stent in an all-comers population. Safety and efficacy outcomes were similar between the Resolute zotarolimus-eluting stent and the everolimus-eluting stent through 3 years. We evaluated 4-year outcomes in order to determine whether these stent devices continued to be clinically equivalent.
Methods and results: RESOLUTE All Comers is a randomised, noninferiority, single-blind, multicentre trial that enrolled patients with minimal exclusion criteria. The primary endpoint was 1-year target lesion failure, a composite of cardiac death, target vessel myocardial infarction, or clinically-driven target lesion revascularisation. Secondary endpoints were clinical outcomes at yearly increments. There were 1140 patients randomised to the Resolute stent and 1152 randomised to the Xience V stent, of whom 1120 (98.2%) and 1130 (98.1%) were enrolled at 3 years. The groups were well-balanced, with a high proportion of complex patients (67%) including 48% with ACS at presentation, 59% multivessel disease and 17% bifurcated lesions. Target lesion failure at 3 years was similar between the Resolute stent (13.1%) and Xience V (12.4%; hazard ratio, 1.05; 95% confidence interval, 0.84 to 1.33; p=0.65) groups. The similarity between the Resolute and Xience V stents persisted in each of the individual components of target lesion failure: cardiac death (3.9% vs. 3.3%; p=0.43), target vessel myocardial infarction (5.2% vs. 4.9%; p=0.77), and clinically-driven TLR (6.0% vs. 5.8%; p=0.86). Dual antiplatelet therapy adherence at 3 years was similarly low between groups (Resolute, 13.8% vs. Xience 13.4%; p=0.85). The 4-year outcomes from the RESOLUTE All Comers Trial will be available for presentation at the EuroPCR annual meeting in May 2013.
Conclusions: The RESOLUTE All Comers Trial demonstrated that the Resolute stent was safe, effective, and clinically equivalent to the Xience V stent through 3 years of follow-up. Longer-term follow-up may add to the safety and efficacy profile of these new generation DES in an all-comers population.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

Treatment of small vessels (<2.75 mm) with two new generation DES. One year clinical outcomes from the COMPARE II study

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Aims: We performed a pre-specified substudy on outcome in patients with small vessel treatment (reference diameter <2.75 mm) within the all-comer COMPARE II trial.

Methods and results: COMPARE II is a multicentre prospective randomised (2:1) trial, of Nobori, Biolimus eluting stent with biodegradable polymer (BES) and Xience/Promus, everolimus eluting stent (EES) in 2707 patients (1795 BES arm: 912 EES arm) with limited in- and exclusion criteria. Within COMPARE II study, a total of 766 patients with at least 1 small vessel (<2.75 mm) were treated, of which 513 were randomised to the Nobori BES and 253 to the Xience/Promus EES. The primary endpoint was the composite of safety (cardiac death, non fatal myocardial infarction) and efficacy (target vessel revascularisation) at 12 months. Data were entered electronically and continuously monitored. All adverse events were adjudicated by an independent clinical event committee. In the small vessel subpopulation, baseline patient and lesion characteristics showed no differences between the two study arms, except for the average lesion length 16.35±9.45 vs. 17.44±9.91, respectively BES vs. EES (p=0.02). The mean reference vessel diameter was 2.67±0.41 (948 lesions) vs. 2.66±0.45 (500 lesions), respectively in the BES and EES arm (p=0.60). Lesions were complex (B2/C: 60.6% in BES vs. 62.2% in EES arm) and often moderately to severely calcified (35.0% in BES vs. 32.8% in EES arm). No differences in lesion location were observed between the two study arms. At 12 months follow-up, the primary endpoint was 7.0% in the BES arm vs. 7.9% in the EES arm (p=0.66). In the BES and EES arm, 1.6% vs. 1.6% patients suffered cardiac death (p=1.0), 3.3% vs. 3.6% MI (p=0.83), 4.3% vs. 4.4% TVR (p=1.0), and 2.5% vs. 2.0 TLR (p=0.80), respectively. Definite and probable stent thrombosis rate was 0.8% in BES and 1.6% in EES (p=0.45), despite similar DAPT regimens.

Conclusions: In an all-comer population, treatment of small vessels with the biodegradable polymer Nobori DES showed similar outcomes compared to the everolimus eluting Xience/Promus stent.

Coronary interventions – *Thursday May 23rd*
New generation DES: comparision with older DES

New generation DES in treatment of patients with multivessel coronary artery disease. Comparison of one year clinical outcomes of biolimus-eluting (Nobori) and everolimus-eluting (Xience/Promus) stents in COMPARE II study

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Aims: In the COMPARE II, all comers population, similar results were obtained at one year in Biolimus-eluting Nobori stent (BES) and Everolimus-eluting Xience/Promus stent (EES) study arms. We aim to compare safety and efficacy outcomes in patients with multivessel CAD (a pre-specified study subset) treated with both new generation DES in COMPARE II trial.

Methods and results: COMPARE II trial is a large randomised, multicentre, non-inferiority trial with total of 2707 patients enrolled at 12 sites across Europe, randomised in 2:1 ratio to the treatment with BES and EES with similar 12 months dual antiplatelet therapy. A total of 683 patients with multivessel CAD have been treated within the COMPARE II trial, 453 of which in BES and 230 in EES arm. Primary endpoint was the composite of cardiac death (CD), non-fatal myocardial infarction (MI) and target vessel revascularisation (TVR). There were no significant differences between both study arms for baseline characteristics such as age (64.3 vs. 63.7; p=0.4) and male gender (78.2% vs. 78.7%; p=0.9), nor for risk factors such as presence of diabetes mellitus (23.0% vs. 25.7%; p=0.4) and renal failure (5.1% vs. 8.7%; p=0.09) in BES and EES arms respectively. The lesion length (17.53±10.71 in BES vs. 17.86±10.25 in EES) and reference vessel diameters (2.9±0.5 in both arms) were also similar. At 12 months, rate of CD (1.1% vs. 1.3%; p=1.0), MI (4.4% vs. 5.7%; p=0.5), target lesion revascularisation (4.2% vs. 2.6%; p=0.4), TVR (5.7% vs. 3.9; p=0.4), target lesion failure (6.8% vs. 7.4%; p=0.9) and primary endpoint (8.6% vs. 9.1%; p=0.9) were similar in BES and EES arms, Definite and propable stent thrombosis rate up to 12-months was also comparable (1.1% in BES vs. 1.3% in EES arm; p=1.0).

Conclusions: Although this substudy was not powered to detect differences between the two stents, the BES with biodegradable polymer, was found as safe and effective as the EES even in this challenging patients population. This adds valuable evidence about clinical outcomes with contemporary DES.

Predictor of recurrent in-stent restenosis after DES implantation

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Aims: We evaluated the predictive factors for recurrent in-stent restenosis (repeat restenosis) lesions treated with drug-eluting stents (DES).
Methods and results: A total of 1,118 patients who received 1 year follow-up angiography after DES implantation were analysed. Recurrent PCI was performed in 50 of 1118 patients (4.3%). 18 patients (1.5%) were performed recurrent PCI due to recurrent ISR and 32 patients (2.7%) were due to new lesions. We compared recurrent in-stent restenosis group with no in-stent restenosis group. Post stent minimum lumen diameter at first PCI was smaller in the recurrent ISR group compared with no recurrent ISR group (2.65±0.48 mm vs. 2.37±0.41 mm p=0.01). The rate of post stent diameter stenosis was higher in the recurrent ISR group (15.3% vs. 19.4% p=0.04). Multivariate analysis showed post-procedural minimum lumen diameter at first PCI was single independent predictors of recurrent in-stent restenosis.
Conclusions: Smaller post-procedural minimum lumen diameter at first PCI is single independent predictor of recurrent in-stent restenosis. Our data imply obtaining of bigger post-procedural minimum lumen diameter using adjuvant balloon at first PCI may prevent recurrent in-stent restenosis after DES implantation.

Coronary interventions – *Friday May 24th*
Predictors of instent restenosis and stent thrombosis after DES implantation

Comparison of outcomes after repeat PCI for sirolimus-eluting stent restenosis lesion with or without stent fracture

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Aims: Presence of stent fracture (SF) after sirolimus-eluting stent (SES) implantation has been reported to be associated with an increased risk of in-stent restenosis and target lesion revascularisation (TLR). Incidence of SF and the relevance to cardiovascular events are previously reported. But little is known about the outcomes after repeat DES implantation for SES restenosis lesion with SF. So this study compared the outcomes after repeat PCI for SES restenosis lesion with or without SF.
Methods and results: From April 2007 to August 2011, total 2020 lesions implanted SES during PCI at our hospital. Total 148 lesions, 7.3% had restenosis (defined as% diameter stenosis >50%) in follow-up angiogram and 61 lesions occurred stent fracture which was defined as complete or partial separation of the stent as assessed by plain fluoroscopy. Thirty-three SES restenosis lesions with SF (SF group) and 42 SES restenosis lesions without SF (Non SF group) were retrospectively evaluated for re-restenosis rate during follow-up after repeated implantation of DES. Baseline characteristics were similar. One-year cumulative incidence of re-restenosis after repeat DES implantation for SF group and non SF group were 72% and 41% (P=0.0395), respectively.
Conclusions: Restenosis lesions with SF had significantly high incidence of re-restenosis after repeat DES implantation.

Coronary interventions – *Friday May 24th*
Predictors of instent restenosis and stent thrombosis after DES implantation

Analysis of 158 cases of longitudinal stent deformation: comparison of a multicentre case series cases with cases reported in the MAUDE database

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Aims: We sought to collect a large series of longitudinal stent deformation (LSD) cases from multiple centres, to compare to those reported from the MAUDE database.

Methods and results: Two experienced interventional cardiologists analysed angiographic images and case histories from 50 cases of LSD from 6 high volume European Centres (reviewed case series). These cases were compared to the 108 cases identified from the MAUDE database described in 2 published reports (MAUDE series). Overall, LSD was most commonly associated with the Element stent (128/158, 81%) with few cases associated with other platforms (Integrity, Driver, Xience, Liberte, Cypher, Nobori, Biomatrix all 1-10 cases in total). However, the excess of Element type stents was more common in the MAUDE series (92/107 cases, 86%) than in the reviewed case series (36/50 cases, 72%; p=0.047). In the MAUDE series the mechanism was unclear in 46 cases (43%), whereas the mechanism was determined in all of the reviewed case series. Guide catheter / guide catheter extension induced LSD was less common in the MAUDE series (20/70 cases, 29%) than in the reviewed case series (24/50 cases, 48%; p=0.035). Guide catheter extensions included Heartrail, Guideliner and Proxis catheters. Secondary devices most commonly involved postdilation or stent balloons (56 cases) with IVUS catheters, filter devices and thrombectomy catheters in 20 cases. In the reviewed case series, LSD was treated in 47/50 cases, in whom there were no major complications. However, there was considerable difficulty re-entering the deformed stent in 12 of these cases. Stent thrombosis causing STEMI and cardiogenic shock complicated 1/3 of untreated cases. In the MAUDE analysis stent thrombosis complicated by acute MI occurred in 10 patients; 2 of these patients died. An additional 2 patients required emergency CABG. There was therefore a trend to a lower MACE rate in the reviewed case series (1/50 cases) than in the MAUDE series (12/108 cases, p=0.06).

Conclusions: The Element stent was the platform most commonly associated with LSD. However, the Element stent was over-represented in the MAUDE database either reflecting a higher complication rate associated with LSD of the Element stent or possibly related to increased awareness about this association. Secondary device induced LSD was the most frequent cause of LSD in both series, with guide catheter induced cases under-represented in the MAUDE series, possibly due under-reporting. When treated by re-expansion or restenting, LSD is well tolerated. However, considerable procedural difficulty caused by LSD and major complications were reported in both series.

Coronary interventions – *Friday May 24th*
Predictors of instent restenosis and stent thrombosis after DES implantation

Impact of polymer type and location on stent thrombogenicity and endothelial cell coverage

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Aims: Newer generation drug eluting stents (DES) have evolved towards replacing conformal durable polymers with abluminal biodegradable polymers for modulating drug delivery. Despite this change, the impact of polymer type (durable vs. biodegradable) and location (conformal vs. abluminal) on vascular healing remains unclear. This study compares the effects of conformal durable (CD)-PVDF (Xience polymer), abluminal biodegradable (AB)-PLGA (Synergy polymer) and bare-PtCr stent (uncoated) surfaces on thrombogenicity and human endothelial cell strut coverage (ECSC).

Methods and results: The thrombogenicity of uncoated, CD-PVDF and AB-PLGA stent surfaces was determined by measuring the deposition of platelets, fibrin cell aggregates on stents exposed to flowing human blood.%ECSC using collagen-embedded flat stents was analysed at 21 days. Uncoated stents had significantly less platelet accumulation (~50% reduction), fibrin deposits (~300% reduction) and cell aggregates (~500% reduction) compared to CD-PVDF, and did not significantly differ from AB PLGA stents. At 21 days,% ECSC was 55% in the CD-PVDF group and 91% in the uncoated group (40% reduction, p<0.001). CD-PVDF stents eluting everolimus further reduced%ECSC rates to 39% (30% reduction, p=0.005). Conversely, AB-PLGA stents had comparable%ECSC rates (79%, 11% reduction, p=NS) compared to uncoated stents (89%) and did not differ significantly in the presence of everolimus release (73%, p=NS). For stents eluting everolimus,%ECSC was significantly greater on AB-PLGA coated stents (73%) compared to PVDF coated stents (38%) (p<0.001).

Conclusions: The CD-PVDF polymer displays higher degrees of thrombogenicity and lower%ECSC rates compared to uncoated and AB-PLGA surfaces. While everolimus elution appears to affect%ECSC in PVDF coated stents, ECSC was minimally affected in the AB-PLGA group. The clinical implications of these findings in the genesis of stent thrombosis deserve further investigation in humans.

Incomplete stent apposition and multiple interstrut hollows in in-stent restenosis lesions assessed with OCT

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Aims: It was reported that incomplete stent apposition (ISA) and multiple interstrut hollows (MIH) could be related to abnormal vessel wall reactions after sirolimus-eluting stent (SES) implantation, which might be potential risk factors of stent thrombosis. Still, little is known about the incidences of ISA and MIH in in-stent restenosis (ISR) lesions after various types of stent implantation. Thus, ISR lesions of bare-metal stent (BMS) and 1st-generation drug-eluting stent (DES) were assessed with optical coherence tomography (OCT).

Methods and results: Between May 2008 and May 2012, we performed OCT on 214 ISR lesions after BMS and DES implantations (BMS, 38; sirolimus-eluting stent [SES], 122; paclitaxel-eluting stent [PES], 54), whose findings, ISA and MIH, were compared among the stents. MIH was defined as multiple hollows (the maximum depth >0.5 mm) existing between and outside the well-apposed stent struts. More ISA occurred in SES lesions than in BMS lesions (32.0% vs. 15.8%; p=0.06), and also in PES lesions than in BMS lesions (37.0% vs. 15.8%; p=0.03). More MIH occurred in SES lesions than in BMS lesions (43.4% vs. 15.8%; p<0.0001), and also in PES lesions than in BMS lesions (27.8% vs. 15.8%; p=0.01).

Conclusions: Abnormal vessel wall reactions may be more related to restenosis in 1st generation DES than that in BMS.

Coronary interventions – *Friday May 24th*
Predictors of instent restenosis and stent thrombosis after DES implantation

The duration but not the intensity of an inflammatory response to the implantation of sirolimus-eluting coronary stents may predict restenosis

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Aims: To estimate a relation between the intensity and the duration of the inflammatory reaction after the implantation of sirolimus-eluting coronary stents and the probability of restenosis development.

Methods and results: We enrolled 241 patients with stable angina pectoris who were candidates for coronary stenting. The mean age of the patients was 59,2±8,3 years, 84% of them were men. Each patient underwent an implantation of the sirolimus-eluting stents (SES) (from 1 to 5 per patient). All patients obtained clopidogrel 75 mg/d, aspirin 75 mg/d, liprimar 20 mg/d. To determine the concentration of high-sensitive C-reactive protein (hs CRP) in serum by nephelometry, venous blood samples were obtained from each patient before the stenting; 1, 2, 7 days, 1, 3, 6 and 12 months after the procedure. Coronary angiography was performed 12 months after the stenting in 151 patients. Restenosis (stenosis >50% of stented segment diameter) revealed in 21 patients (13,9% of angiography controls, 8,7% of enrolled patients), those patients formed group I. 130 patients without restenosis proved by angiography formed group II. We did not reveal a significant difference in the concentration of hsCRP between groups throughout the study period. In both groups the concentration of hsCRP was increasing during the first 2 days after the intervention: from 1,4[0,5-2,2] to 3,7[2,1-7,9] g/l in the group I (here and in the following data are presented like median [25th-75th percentiles]) and from 1,6[0,8-2,8] to 4,7[2,1-9,4] g/l in the group II. In the following we revealed a gradual decrease of hsCRP concentration. In the group II it was significantly (p<0,05) lower than the initial since 1 month after the intervention (1,3[0,7-2,4] g/l) and afterwards. In the group I the concentration of hsCRP became significantly (p<0,05) lower than the initial since 6th month after the stenting (1,1[0,4-1,4] g/l). The minimal level of hsCRP was observed 1 year after the stenting: 1,1 [0,8-2,5] g/l in the group I and 0,9 [0,4-1,6] g/l in the group II. To analyse the direction of hsCRP concentration changes, we used a difference between its initial and current concentrations (ΔhsCRP). ΔhsCRP was positive in the most cases during the first 7 days after the stenting. In the group II ΔhsCRP became negative in the most cases (60%) on a 1st month after the stenting. In the group I ΔhsCRP became negative in the most cases (76%) on a 6th month after the stenting. At 3rd month after the stenting ΔhsCRP was negative in 29% of the group I patients whereas in the group II at the same time ΔhsCRP was negative in 64% of cases (p=0,04).

Conclusions: We observed a biphasic response to the implantation of SES. An initial rise of hsCRP serum concentration was subsequently replaced by its fall below the initial level. An inflammatory response to the implantation of SES was more prolonged in those patients who develop restenosis in comparison to patients without restenosis.

Coronary interventions – *Friday May 24th*
Predictors of instent restenosis and stent thrombosis after DES implantation

Higher levels of serum cystatin C are associated with in-stent restenosis after treatment with DES

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Aims: Increased serum levels of cystatin C have been known as an independent risk factor of cardiovascular events. However, the association between cystatin C and in-stent restenosis (ISR) has not been well described in the drug-eluting stent (DES) era.

Methods and results: Of 251 consecutive lesions which underwent elective percutaneous coronary intervention (PCI) in our hospital and treated with a single DES, 126 lesions which could be evaluated by follow-up angiography, were examined. Moreover, we excluded 8 patients with haemodialysis and 11 patients with renal dysfunction (serum creatinine levels >1.5mg/dl). Finally, 107 patients with relatively normal renal function and without complex coronary lesions, were examined for serum levels of cystatin C and other conventional risk factors in fasting state after admission for PCI. The DES was implanted in all cases. 17 lesions were treated with sirolimus-eluting stent, 55 lesions were treated with paclitaxel-eluting stent, 32 lesions were treated with everolimus-eluting stent, and 3 lesions were treated with other DES. After an average follow-up of 9.1 months, angiographical in-stent restenosis was found in 15 lesions (14%). There was no significant difference related to type of DES. Moreover, baseline patient's characteristics, lesion characteristics calculated by quantitative coronary angiography, therapeutic procedures were similar between patients with and without ISR. There were no significant differences in lipid and glucose profiles and other risk factors between patients with and without ISR. However, serum levels of cystatin C were significantly higher in patients with ISR than those without it (1.19±0.28mg/dl vs. 1.02±0.18mg/dl, P=0.04). In multivariate analysis, serum levels of cystatin C were associated with ISR (odds ratio=0.03, 95% confidence interval=0.01-0.44, P=0.01).

Conclusions: Serum levels of cystatin C before PCI, were associated with ISR after an elective PCI using DES. This indicates that cystatin C would be a useful predictor for ISR in the DES era.

Coronary interventions – *Friday May 24th*
Predictors of instent restenosis and stent thrombosis after DES implantation

Minimal progression of late lumen loss and stable clinical long-term results from the DESSOLVE I FIH trial

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Aims: Thirty patients with coronary artery disease were enrolled in the DESSOLVE I FIH clinical trial and were revascularised with the MiStent sirolimus-eluting absorbable polymer stent (Micell Technologies, Durham, NC). The MiStent SES is a thin-strut (64um) cobalt-chromium stent with crystalline sirolimus contained within a fully absorbable polymer coating. The coating is cleared from the stent in 45-60 days concurrent with complete polymer absorption by 90 days. The crystalline sirolimus remains in the tissue for continued elution of sirolimus and long-term suppression of NIH. Patients were enrolled into 3 independent cohorts of 10 patients each to be evaluated at 4, 6 or 8 months with all patients returning for a second evaluation through 18 months consisting of angiography, IVUS and OCT. Clinical follow-up was also conducted on all available patients at 2 years to assess long term clinical safety.

Methods and results: At 18 months, imaging was available for 27 patients and clinical follow-up was available for 28 patients through 2 years. All imaging modalities, angiography, IVUS and OCT, support lack of long term progression of neointimal hyperplasia. The evaluation of late lumen loss over time remained stable at 0.9 mm at 18 months as determined by core lab angiography. There were no occurrences of repeat revascularisation or stent thrombosis (ST). Only a single MACE event (1/30, 3.3%) was reported, a non-Q wave myocardial infarction at 44 days post index procedure related to a non-target vessel during a diagnostic angiogramwas experienced.

Conclusions: The DESSOLVE I FIH results demonstrate low angiographic late lumen loss between 4 and 8 months, with minimal progression at 18 months and no clinical or angiographic restenosis at 2 years. IVUS and OCT confirmed minimal neointimal hyperplasia progression over time. Long-term clinical follow-up remained favourable with no additional clinical events. Full 18-month imaging and 2-year clinical safety data will be presented.

Association of neointimal morphology by OCT with rupture of neoatherosclerotic plaque very late after coronary stent implantation

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Aims: Neoatherosclerosis within a stent has been recently described as a culprit of late stent failure. It is unclear if specific morphological characteristics are associated with neoatherosclerotic plaque instability and in consequence with clinical presentation. We investigated by optical coherence tomography (OCT) the association of neoatherosclerotic plaque morphology with neointimal rupture and clinical presentation in patients late after coronary stent implantation.

Methods and results: From 1/1/2007 to 31/1/2012, 74 patients from two institutions underwent OCT assessment of a coronary stent implanted at least 18 months prior to OCT study. Native atherosclerosis criteria were used for neointimal characterisation. Neointimal rupture was identified as fibrous cap disruption with cavity formation. Neoatherosclerosis was observed in 59.5% of the stents (n=44). Stents with neoatherosclerosis were more often associated with symptoms compared to stents without neoatherosclerosis (59.1% acute coronary syndrome (ACS), 25% stable angina, and 15.9% asymptomatic vs. 43.3% ACS, 6.7% stable angina, 50% asymptomatic, p<0.01). Among neoatherosclerotic lesions (n=44), neointimal rupture was detected in 19 (43.2%) and had higher incidence in ACS (61.5%) than in stable angina (18.2%) and asymptomatic (14.3%) (p<0.05). Thrombus was detected in all 19 cases with neointimal rupture. Fibrous cap thickness was lower in neointimal rupture lesions compared to lesions without neointimal rupture (48±21 μm vs. 104±58 μm, p<0.01). Lipid content tended to be higher in lesions with neointimal rupture (260±103° vs. 203±85°, p=0.051). Lesions with neointimal rupture had more often dense macrophage infiltration than lesions without neointimal rupture (84.2% vs. 44.0%, p<0.05). There were no differences in the rates of neovascularisation or calcifications between lesions with or without neointimal rupture (neovascularisation: 10.5% vs. 8.0%, p=0.99; calcifications: 36.8% vs. 28.0%, p=0.75).

Conclusions: The presence of neoatherosclerosis is frequent and more common among symptomatic patients. Importantly, neointimal rupture is associated with ACS late after stent implantation. Specific morphological characteristics, such as cap thickness and macrophage infiltration are associated with rupture of neoatherosclerotic plaques.

OCT characteristics of in-stent restenosis are different between first and second generation DES

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Aims: Characterisation of neointimal tissue is essential to understand the pathophysiology of in-stent restenosis after drug eluting stent (DES) implantation. Using optical coherence tomography (OCT), we compared the morphologic characteristics of late in-stent restenosis between first generation and second generation DES.

Methods and results: Optical coherence tomography was performed in 65 lesions with DES in-stent restenosis. In stent restenosis was defined as >50% of diameter stenosis within the stent segment. Late ISR was defined as the first ISR observed between 1 and 5 years after stent implantation. Patients with late in-stent restenosis of first generation sirolimus eluting stent (SES) and paclitaxel eluting stent (PES) and second generation zotarolimus eluting stent (ZES) and everolimus eluting stent (EES) were enrolled in this study. Qualitative restenotic tissue analysis included assessment of tissue structure (homogeneous or heterogeneous), presence of microvessels, peri-strut low intensity area, disrupted intima with cavity, and intraluminal material and was performed at every 1-mm slice of the entire stent. The proportion of cross-sections with heterogeneous intima was significantly higher in second generation DES compared to the first generation DES (84.7±30.9 vs. 40.0±37.5%, p<0.0001). Patchy pattern, speckled pattern and intraintimal or peristent microvesselswere significantly more frequent in second generation DES. In contrast, peri-strut low intensity areaswere observed more frequently in the first generation DES.

Conclusions: The morphological characteristics of restenotic tissue in first and second generation DES are different with predominantly intima hyperplasia in first generation and neoatherosclerosis in second generation DES.

Coronary interventions – *Friday May 24th*
Insights from OCT

Short to mid-term endothelisation patterns after implantation of second generation DES in ACS patients

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Aims: Lack of the endothelial strut coverage and incomplete stent apposition have been identifed as pathologic risk factors for late stent thrombosis. We sought to assess the rate of strut endothelialisation and incomplete strut apposition late (>30 days) by optical coherence tomography (OCT) after implantation of second generation drug eluting stents (DES) in acute coronary syndrome (ACS) patients.

Methods and results: The study cohord consisted of 13 ACS patients who were treated with a total of 19 second generation DES implants. The DES types consisted of everolimus eluting stents (Xience V; n=11) in 9 patients, zotarolimus-eluting stents (Endeavor Resolute; n=3) in 2 and Biolimus A9-eluting stents (BioMatrix; n=3 and Nobori n=2) in 2 patients. The average time elapsed from stent implantation to OCT examination was 110 (48-343) days. Struts were graded as covered when overlying tissue thickness was >10 μm or uncovered when overlying tissue thickness was <10 μm. Struts were classified as malapposed/incompletely apposed when they protruded into the lumen at a distance ≥110 μm for the zotarolimus- and everolimus-eluting stents and ≥112 μm for the biolimus A9-eluting stents. A total of 1841 struts were included in the analysis after exclusion of struts overlying side branches (n=45). A total of 1278 struts (69.4%) were covered with neointima whereas 563 struts (30.6%) were uncovered. There were 1755 struts (95.3%) with complete apposition and 86 struts (4.7%) with incomplete apposition. The rates of uncovered struts and incomplete strut apposition according to DES type were as follows: 28.0% (385/1376) and 4.8% (66/1376) for the everolimus-eluting stents, 59.8% (143/239) and 8.4% (20/239) for the biolimus-eluting stents and 14.6% (33/226) and 0% (0/226) for the zotarolimus-eluting stents respectively. Thrombus was present in 1 (7.6%) patient and in 1 (7.6%) patient optical coherence tomography (OCT) evaluation showed low OCT signal-intensity area resembling a “black hole”. There were no events at one year clinical follow-up in all 13 patients.

Conclusions: At a median time of 110 days after implantation of second generation DES in ACS patients, endothelialisation is halted in 1 out of 3 stent struts whereas the rate of incomplete strut apposition is low. Thrombus formation and low OCT signal-intensity areas have been recorded; however these findings were not accompanied by clinical events and their significance needs to be tested in the upcoming trials.

Coronary interventions – *Friday May 24th*
Insights from OCT

Fourier-domain OCT in the evaluation of the left main coronary artery stenosis. Correlation with FFR

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Aims: Fourier-domain optical coherence tomography (FD-OCT) has been used to assess the severity of coronary artery stenosis. However, its value in the evaluation of the left main coronary artery (LMCA) lesions is still unknown. The aim of this study was to assess the safety and diagnostic efficacy of FD-OCT in identifying functional severity of the LMCA stenosis determined by fractional flow reserve (FFR).

Methods and results: Eighteen patients (15 stable and 3 unstable angina) with an isolated LMCA stenosis (40-80% diameter stenosis by angiographic visual estimation) underwent invasive physiological assessment and FD-OCT imaging of the left main lesion before any intervention. FFR at maximum hyperemia was ≤0,80 in 7/18 (38,8%) patients. Three (16.6%) patients showed ischaemic symptoms during OCT image acquisition but none had any major adverse cardiac event. OCT provided optimal visualisation of the entire length of the LMCA in 16/18 (89%) patients. Ostial LMCA stenosis was present in 6/18 (33.3%) patients. OCT minimum lumen diameter (MLD), minimum lumen area (MLA), reference lumen area (RLA), lumen area stenosis and lesion length were: 1.84±0.30 mm, 4.01±1.16 mm2, 12.21±3.29 mm2, 64.8±12.4%, 5.5±2.99 mm, respectively. FFR values were strongly correlated with OCT derived MLA (r=0.67, p<0.01) and lumen area stenosis (r=-0.76, p<0.001). Receiver-operating characteristic curve suggested an OCT measured MLA <4.1 mm (sensitivity 86% and specificity 82%) and lumen area stenosis>67% (sensitivity 86% and specificity 91%) as the best cut-off values for predicting FFR<0.80.

Conclusions: FD-OCT is safe and feasible for the LMCA imaging even in ostial lesions(MLA <4.1 mm and lumen area stenosis >67% measured by FD-OCT strongly predict the physiological significance of an LMCA stenosis.

Three-dimensional OCT assessment of side-branch opening after kissing balloon inflation in bifurcation lesions

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Aims: In bifurcation stenting, incomplete stent apposition and opening of jailed side-branch orifice after final kissing balloon inflation may relate to clinical outcome, i.e. stent thrombosis and restenosis. Based on the bench test, the rewiring position and the configuration of jailing strut have been considered an important factor to avoid stent strut in front of side-branch orifice after side-branch dilation. However, there have been no tools to assess them clearly during PCI. Three-dimensional optical coherence tomography (3D-OCT) is useful to evaluate bifurcation stenting. We investigated the relations between the rewiring position and the side-branch opening after kissing balloon inflation (KBI).

Methods and results: A total of 13 patients who underwent OCT examination before and after KBI in bifurcation stenting was enrolled in this study. After stent deployment in the main branch across the side branch, the coronary guide wire was re-crossed to the side branch through the jailing strut under fluoroscopic guidance. Frequency-domain OCT (SJM ILUMIEN FD-OCT system) images were obtained from the distal portion of main branch at the pullback speed of 10 mm/s. 3D stent images was reconstructed using the in-house software which detected stent strut automatically. The configuration of jailing strut and the re-wiring position were assessed on the 3D-OCT image. Of 13 cases, 5 cases had unfavourable configurations that the connector between the hoops jailing strut in front of side-branch orifice located from the carina. In 10 cases the re-crossing guide wire could pass through the most distal cell, however, in 3 cases the rewiring positions were the proximal cell. Seven cases (54.8%, Group A) complied with both (i) the re-crossing guide wire passes through the most distal cell and (ii) there were no connectors bridging from the carina, the remaining 6 cases (Group B) did not comply with at least either (i) or (ii). After KBI, side-branch orifices were evaluated with 3D-OCT. The percentage of ISA struts (%ISA) were analysed in the consecutive cross-sectional OCT images at the bifurcation segment. The area of side-branch orifice (A1) and the area free of struts (A2) were measured on 3D-OCT. The percentage of area stenosis of side-branch orifice (%SOAS) was calculated as follows: (A1-A2)/A1x100%. %ISA and %SOAS were compared between 2 groups. Both %SOAS and%ISA in Group A were significantly smaller than those in Group B (%SOAS: 5.4±2.8% in Group A vs. 22.9±9.1% in Group B, p=0.0043, %ISA: 0.6±0.9% in Group A vs. 12.2±6.5% in Group B, p=0.0074).

Conclusions: 3D-OCT could evaluate the re-wiring position and the side-branch opening after KBI during PCI. Both the distal re-wiring position and favourable configuration of jailing strut in front of side branch orifice could achieve the better side-branch opening after KBI while only half of cases satisfied them in this study.

The existences of mural thrombi are associated with neointimal coverage failure after DES implantations

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Aims: The purpose of this study was to compare the neointimal coverage, and the existence of thrombi after DES implantation assessed by coronary angioscopy (CAS) with quantitative parameters measured by OCT.

Methods and results: We evaluated consecutive 24 stented lesions in patients with stable angina who had undergone DES implantation at 8 months after implantations. Using both of CAS and OCT, stented segments (4,574 struts) were quantitatively assessed. Namely, presence or absence of thrombi was judged by CAS and neointimal thickness (NIT) and the rate of uncovered struts were measured by OCT. Angioscopic neointimal stent coverage was classified into three grades as follows: 0=uncovered struts without neointima, 1=visible struts through thin neointima, and 2=no visible struts. In addition, the serum concentration of high-sensitivity C-reactive protein (hs-CRP) was measured. Mural thrombi were detected in 6 of 24 stents. The patients with mural thrombus detected by CAS showed significantly thinner NIT (0.096±0.097 mm vs. 0.134±0.107 mm, P<0.001) and higher rate of uncovered struts (18.9% vs. 14.5%, P=0.001) in comparison with those without thrombus. Furthermore, hs-CRP was higher in thrombus positive patients (1.22±1.49 vs. 0.24±0.34, P=0.015). There was an increase in NIT according with the grading of angioscopic neointimal coverage (0.104±0.089 mm vs. 0.119±0.099 mm vs.0.202±0.128 mm, P<0.001), while lower grades of angioscopic neointimal coverage were associated to the rate of uncovered struts (18.5% vs. 14.2% vs. 7.2%, P<0.001).

Conclusions: The present study suggests that angioscopic findings of the presence of mural thrombi after DES implantations correlates with thinner neointima and larger area of uncovered strut which possibly caused by active inflammation.

Coronary interventions – *Friday May 24th*
Insights from OCT

Healing course of tissue prolapse and intra-stent dissection after PCI: a sequential OCT study

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Aims: Vessel injury after stent implantation can be visualised in detail using optical coherence tomography (OCT). Until now, the healing of this injury could not be determined. The objectives of our study were to observe the incidence of tissue prolapse (TP), intra-stent dissection (ISD) and intra-stent cavity (ISC) after DES implantation and to assess healing at mid-term follow-up, comparing sequential OCT pullbacks using a dedicated software allowing for exact spatial comparison of baseline and follow-up images.

Methods and results: In 50 stented segments, OCT was performed immediately after DES implantation and at 9-month follow-up. In the baseline OCT pullback, the presence of tissue prolapse, ISD and ISC was assessed. The healing at these sites was investigated in the corresponding follow-up pullback using a validated registration software, allowing for exact spatial comparison of baseline and follow-up images. One-hundred and ten sites of TP protruding ≥200 µm in the lumen were seen in 41/50 (82%) stents. The median number of TP sites was 2 (IQR 1-3) per stented segment. TP was visible in 13±12% of frames per stent. Mean TP length was 292±94 µm and mean TP area was 0.3±0.17 mm2 at the site of maximal protrusion. A total of 268 ISD extending ≥200 µm in the lumen were visualised in 49/50 (98%) stents. The median number of ISD per stent was 5 (IQR 2-8). ISD were seen in 20±13% of frames per stented segment. The mean length of ISD was 539±293 µm at the site of maximal extension in the vessel lumen. We detected 88 ISC with a cavity depth ≥200 µm in 40/50 (80%) stents. A median number of 1 ISC (IQR 1-3) per stent was seen. In 1.5±1.3% of frames per stent, ISC was visible. The mean depth of ISC was 410±196 µm at the site of maximum extension in the vessel wall. The underlying plaque type at the site of these different types of vessel injury was fibrotic in 36%, fibrocalcific in 5%, lipid-rich in 47% and mixed in 8%. In 4%, the underlying vessel wall was free of atherosclerotic disease. Incomplete healing, visible as a residual flap on follow-up OCT, was seen at 38 sites of vessel injury at 9 months. ISC showed significantly more incomplete healing than ISD. In 19% of ISC, a residual flap was seen, whereas only 8% of ISD were not completely healed ($p<0.0001$). Residual flaps were more frequently observed in mixed plaques. No residual flaps were seen at sites with normal underlying vessel wall. ISCs healing with a residual flap were deeper than completely healed cavities (505±168 µm vs. 387±196 µm; $p=0.004$). ISDs showing residual dissection also tended to be more extensive than flaps healing completely, although the difference was not significant (667±397 µm vs. 528±281 µm; $p=0.17$).

Conclusions: Tissue prolapse, ISD and ISC are common findings after DES implantation. The underlying vessel wall is diseased in the vast majority of these sites of vessel injury. Healing is incomplete in 8% of ISDs and 19% of ISCs at mid-term follow-up. Residual dissection is more frequently observed when the underlying plaque type is mixed. The healing course of these remaining dissection flaps in the long term and the effect of incomplete healing on late and very late outcomes remain to be determined.

Coronary interventions – *Friday May 24th*
Insights from OCT

The comparison of IVUS and optical coherent tomography for the control of the results of the coronary arteries stenting

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Aims: Despite the wide use of intravascular ultrasound (IVUS) and optical coherent tomography (OCT) in scientific researches, the data of the direct comparison of these two methods are limited in practical medicine. The main goal of the research was to compare the informativeness of IVUS and OCT methods during the coronary stenting with the drug eluting stents.

Methods and results: 125 patients were observed under the research and the 6 types of limus-eluting stents were implanted to these patients. The selection of the sizes of the implanted stents was based on the data of the initial IVUS. The control IVUS was performed after the implantation of the stents and the optimal angiography results were achieved. The additional dilatation with balloon was carried out if the result was suboptimal under the IVUS. The intervention was completed by performing OCT procedure. The data of the IVUS at the initial measurements significantly differed than results of the quantitative angiography (the minimum diameter of the lumen, the reference diameter, the length of the lesion, the area of the lumen, $p<0.001$, and percentage area stenosis ($p<0.05$). The average diameter of the used stents is 3.72±0.28 mm, postdilation by balloon of a larger diameter (3.95±1.06 mm) was made for 48.8% patients. Significant differences between IVUS and angiography in such data as the area of a plaque, the area of a lumen and percentage area stenosis, were noticed while comparing the quantitative results of the stenting. The data of OCT and angiography also significantly differed in the estimation of the plaque and the lumen areas. The evaluation of the lumen diameter taking into account the data of all three methods didn't show any significant differences as well as the percentage area stenosis between data obtained by IVUS and OCT. At the same time the differences between IVUS and OCT data were also significant in the estimation of the plaque area and the percentage area stenosis, and of the index of an eccentricity of the lumen. The qualitative analysis of the images concluded that OCT showed the higher rate of residual problems as compared to IVUS. The malapposition was found in 21 patients (16.8%), protrusion of fibers throughout the structure of a stent – in 64 patients (51.2%). In the most cases these changes were not recorded by IVUS. The analysis of the data received from IVUS and OCT images showed that the optimal result of the both methods was recorded in 26% of the observed patients, the optimal IVUS result and suboptimal OCT result – in 38%, also the suboptimal result of both IVUS and OCT researches – in 36%.

Conclusions: IVUS and OCT are not competing, but complementary methods for the research. IVUS is better for estimation of the volume and the character of an occlusive substratum, as well as in a morphological estimation of a lesion significance. On the other hand OCT provides more detailed and authentic information relative to inner imposing, and the condition of a stent and a vessel intima.

OCT assessment of *in vivo* bioresorbable vascular scaffold expansion

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Aims: Suboptimal or incomplete metallic stent expansion is associated with increased rates of restenosis and target vessel revascularisation, and may also predispose to stent thrombosis. Stent manufacturers provide a compliance chart relating implanted stent diameter to nominal stent size and deployment pressure, but these are based on *in vitro* measurements, and have been to shown to be unreliable in predicting final stent dimensions. Whilst early clinical data from bioresorbable vascular scaffolds (BVS) suggests low rates of these complications, concerns remain regarding their mechanical strength and the incidence of recoil; furthermore, there are limited real-world data on *in vivo* BVS expansion rates.

Methods and results: All patients undergoing BVS implantation at a single-centre between August and December 2012 were included. All lesions were predilated before BVS implantation and postdilatation was performed at individual operator discretion as per the manufacturer's recommendations. OCT was performed after intervention to determine BVS expansion and strut apposition. Two experienced and trained operators performed off-line OCT analysis. Within each 1 mm longitudinal interval of the BVS segments, measurements were taken for minimum scaffold diameter (MSD) and scaffold cross-sectional area (CSA). BVS expansion was defined as MSD (or CSA) divided by the manufacturer's compliance chart predicted MSD (or CSA). Central segments were defined as the middle 1/3 of the length of each implanted BVS; peripheral segments were defined as those either distal or proximal to the central segments. A total of 19 BVS were implanted in 17 patients (76.5% male; age 60.8±10.7 years) under OCT guidance. The target lesion was LAD 10, RCA 5, Cx 1 and SVG 1; 16/17 lesions were ACC/AHA type B2/C. The majority of platforms were 3.0 mm (14/19; 3.5 mm 3/19, 2.5 mm 2/19) and all but 2 were deployed at 16atm (maximum recommended deployment pressure). 8 patients (47.1%) underwent postdilatation. In total, 360 frames of scaffolded segment were analysed. Overall, 99% of MSD measured by OCT (1.86-3.73 mm; mean 2.84±0.34 mm) were smaller than those predicted from the compliance charts (2.94-4.01 mm; mean 3.43±0.3 mm). Of the analysed frames, only 24% achieved 90% of the predicted MSD, and 6.9% the predicted CSA. Overall, BVS achieved 82.8%±8.5% of the predicted MSD and 82.5%±12.0% of the predicted CSA. BVS expansion was significantly reduced in the central segments compared with the peripheral segments (MSD 79.9±8.1% vs. 84.4±8.3%, p<0.0001; CSA 78.7±11.0% vs. 84.6±12.0%, p<0.0001), an effect that persisted even in those lesions that were most aggressively predilated with 1:1 balloon:stent sizing (MSD 83.4±5.2% vs. 88.5±6.3%, p<0.0001; CSA 84.2±7.4% vs. 88.6±8.7%, p=0.01).

Conclusions: Similar to metallic stents, BVS compliance charts are unreliable in predicting final *in vivo* scaffold dimensions, which may be dependent on lesion and vessel compliance. Furthermore, BVS expansion is significantly reduced in the region of treated target lesions. Since aggressive post-dilatation is not recommended, our data highlights the importance of optimal predilatation before BVS implantation. Further studies are required to elucidate whether these factors will be relevant to long-term outcomes.

Two- year IVUS assessment of the changes in eccentricity and symmetry indexes in metallic and bioresorbable platform devices: insights from ABSORB Cohort B and SPIRIT II trials

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Aims: The everolimus-eluting poly-l-lactic-acid (PLLA) bioresorbable scaffold (BVS) has previously been investigated in the ABSORB Trials. We report the dynamic changes in geometrical parameters of coronary vessels treated with either the temporary BVS or permanent everolimus-eluting metallic stent (XIENCE V [XV]), to assess if differences appear at a period of up to 2 years, a time point previously shown to indicate complete bioresorption of the BVS device.

Methods and results: Thirty-three patients from the ABSORB Cohort B (BVS) and 48 patients from the SPIRIT II (XV) trials were examined with intravascular ultrasound (IVUS) at baseline (BL) post device implantation, 6 months (6m) and at 2-year (2yr) follow-up. The eccentricity (minimum diameter/maximum diameter) and symmetry indices ([maximum-minimum diameter]/maximum diameter) of lumen, scaffolds/stent and vessel were calculated frame-by-frame and expressed as an average per device. Compared to the XV, the scaffolds/stent of BVS exhibited a significantly lower eccentricity index at baseline (BVS: BL 0.874±0.034, 6m 0.866±0.026, 2yr 0.883±0.024;XV: BL 0.924±0.025, 6m 0.932±0.020, 2y 0.930±0.028; p<0.001) and higher symmetry index (BVS: BL 0.318±0.070, 6m 0.337±0.077, 2yr 0.360±0.075; XV: BL 0.249±0.083,6m 0.222±0.066, 2yr 0.229±0.077, p<0.001) with these differences being maintained at 2 years. The vessel of BVS exhibited a significantly greater symmetric index at 2 years (BVS: 2yr 0.289±0.061, XV: 2yr 0.231±0.070, p=0.003)

Conclusions: The scaffolds of BVS demonstrated significantly different geometrical characteristics compared to XV at implantation, with these differences being maintained at up to 2 years. Contrary to scaffolds/stent, the vessel of BVS demonstrated similar geometrical characteristics at implantation, with greater symmetric index at 2 year compared to XV.

Coronary interventions – *Friday May 24th*
Bioresorbable scaffolds: lessons learned from intracoronary imaging

Bioresorbable vascular scaffold strut malapposition occurs more frequently in areas of fibrocalcific plaque: insights from OCT

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Aims: The bioresorbable vascular scaffold (BVS) has several theoretical advantages over existing metallic stents, including complete resorption and restoration of vasoreactivity. However, the mechanical properties of the BVS do not allow aggressive post-dilatation (PD), with consequent potential for strut malapposition depending on the interaction between the BVS and underlying tissue. Our aim was to assess the incidence of malapposition and whether this was related to plaque characteristics.

Methods and results: All patients undergoing BVS implantation at a single-centre were included. Optical coherence tomography (OCT) was performed both before implantation to optimise sizing and after to ensure adequate deployment. PD was performed at operators' discretion as per manufacturer's recommendation. An operator not involved in implantation adjudicated lesion type and degree of calcification by visual angiographic analysis. Two experienced and trained OCT operators analysed runs at 1 mm longitudinal intervals; where malapposition was seen, analysis was performed at 0.2 mm intervals. Each operator adjudicated and quantified malapposition, defined as a strut with ≤50% contact of abluminal strut surface with the endothelium. Tissue characterisation was defined as the predominant plaque composition in the quadrant of each strut. The degree of malapposition was measured from the adluminal strut edge to the endothelium in a radial direction, with the stent strut width being a standard 0.158 mm as previously published. 17 patients (76.5% male; age 60.8±10.7 years) underwent BVS implantation. The target lesion was LAD 10, RCA 5, Cx 1 and SVG 1; 16/17 lesions were ACC/AHA type B2/C. Calcification was absent (82.4%), mild (5.9%) and moderate (11.8%) on independent review. The median number of stents implanted was 1 with median size of 3.0×18 mm. 8 patients (47.1%) had PD performed. Agreement on OCT-defined strut malapposition between observers was excellent (Kappa 0.847). In total, 604 frames of OCT were analysed (median 33 per patient). 5202 BVS struts were identified with 420 (8.1%) of these being malapposed. Number of malapposed struts varied significantly between individuals, ranging from 0 to 139 (median 11, IQR 2.5-38.25). The predominant tissue characterisation of apposed compared to malapposed struts was fibrous (83.4% vs. 49.0%), fibrocalcific (10.5% vs. 48.1%), lipid (0.3% vs. 0.0%) and normal (5.8% vs. 2.9%) respectively ($p<0.001$). Furthermore malapposed struts in fibrocalcific areas were at a greater distance from the wall than those in other areas (0.166±0.098 mm vs. 0.147±0.077 mm; $p=0.027$).

Conclusions: Our analysis shows that the incidence of strut malapposition using BVS is comparable to existing DES platforms. However, malapposition was more frequent and occurred to a greater degree (ie greater distance from the vessel wall) in fibrocalcific areas. Intracoronary imaging should be considered mandatory prior to implantation of BVS to ensure unrecognised calcification does not lead to unnecessary malapposition.

Coronary interventions – *Friday May 24th*
Bioresorbable scaffolds: lessons learned from intracoronary imaging

Six-month IVUS results from the prospective, multicentre DESolve NX trial with a novel PLLA-based drug-eluting bioresorbable vascular scaffold

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Aims: Percutaneous coronary intervention (PCI) with bioresorbable scaffolds has created interest since the need for mechanical support for the healing artery is temporary, and beyond the first few months there are potential disadvantages of a permanent metallic implant. The DESolve Bioresorbable Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and a potent anti-proliferative sirolimus metabolite, Novolimus. The drug dose is 5 mcg per mm of scaffold length. We aim to present the detailed IVUS findings for the subset of patients enrolled in the DESolve NX trial.

Methods and results: The DESolve NX is a prospective and multicentre trial, which enrolled 126 patients with *de novo* coronary lesions treated with a single scaffold available in three diameters (3.0, 3.25 and 3.5) and two lengths (14 and 18 mm). The first 40 patients enrolled in this trial also consented to an IVUS sub-study, which consisted of a paired analysis of the automatic pullbacks performed at the end of the baseline procedure and at six-month follow-up (an additional 24 month follow-up will also be performed). All analyses are being performed by an independent IVUS corelab. The mean age of the enrolled population was 61.9 years, 68.2% of which were men and 21% had diabetes. Pre procedure reference vessel lesion length and diameter were 11.2±3.8 mm and 3.06±0.31, respectively. All 40 patients in the IVUS substudy had their scaffolds successfully deployed and IVUS performed at the end of the procedure. At baseline, average scaffold diameter and area were 2.72±0.27 mm and 5.86±1.15 mm^2 respectively. No scaffold discontinuity (e.g. fracture) was observed in any of the 40 cases at the post procedure IVUS examination. Six-month IVUS follow-up was adequately obtained for all patients enrolled in the subset. The follow-up analysis is currently being processed and the results will be available at the time of the meeting.

Conclusions: We are entering a new era of vascular restoration therapy with the advent of bioresorbable vascular scaffolds. The concept of a transitory vascular support, which mimics the initial effects of a metallic stent but "disappears" in the subsequent months, seems very attractive and also feasible according to preliminary evaluations. This DESolve NX trial was designed to assess the feasibility of the deployment of the DESolve bioresorbable scaffold in vessels with Type A and B lesions, and at the same time, by means of intravascular imaging, provide some understanding on the versatility of the device in regards to the scaffolding properties as well as the vascular response. An analysis of the IVUS results through 6 months will be presented.

Coronary interventions – *Friday May 24th*
Bioresorbable scaffolds: lessons learned from intracoronary imaging

Evaluation of the novel novolimus-eluting bioresorbable vascular scaffold for treatment of *de novo* coronary artery stenosis: serial OCT analysis of the DESolve NX study

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Aims: The DESolve system is a novel Poly-L-Lactic Acid (PLLA)-based scaffold, designed to provide both temporary vessel support along with neointimal suppression, followed by full bioresorption between one and two years. In the DESolve FIM study, the myolimus-eluting DESolve bioresorbable scaffold demonstrated good vessel support with lack of chronic recoil. Six-month efficacy and safety were demonstrated by the 7.18±3.37% neointimal obstruction calculated by IVUS and the overall high frequency of covered struts (98.68±2.44%) by OCT. In the present report, we aim to present the first serial OCT evaluation of the novel PLLA-based novolimus-eluting DESolve bioresorbable scaffold applied in a larger number of patients included in the DESolve NX study.

Methods and results: The DESolve NX study enrolled 126 patients with single *de novo* native coronary lesions at 13 sites. A serial (baseline and 6-month follow-up) analysis of the first 25-patient subset who underwent OCT investigation will be presented. All OCT images were analysed by an independent core laboratory at 0.6-mm interval. At baseline, lumen, scaffold, plaque prolapse and incomplete scaffold apposition (ISA) areas were determined. At follow-up, serial changes in lumen and scaffold dimensions and degree of NIH formation on top of the struts will be assessed. Frequency of covered struts and NIH thickness on top of each covered strut will also be examined. OCT imaging end-points were scaffold expansion and structural integrity post-procedure and neointimal obstruction and degree of strut coverage at six-month follow-up. At baseline, overall adequate scaffold expansion (93.75±9.21%) was obtained. A mean of 30.44±5.16 cross-sections were analysed per scaffold. Mean lumen and scaffold areas measured 6.80±1.35 mm^2 and 6.95±1.32 mm^2, respectively, with a minimum scaffold area post-procedure of 5.71±1.15 mm^2. In average, plaque prolapse accounted for a very small area of lumen reduction post-procedure (0.03±0.02 mm^2). ISA was detected at baseline in 9 scaffolds and also presented a very small mean area (0.07±0.13 mm^2). A total of 9,871 struts were analysed at baseline. Six month follow-up OCT analysis will be presented at the meeting.

Conclusions: The novel PLLA-based novolimus-eluting bioresorbable scaffold demonstrated an excellent acute performance, tolerating a very good expansion with virtually no structural deformity concerns. Good vessel wall conformability was also demonstrated, resulting in minimal areas of scaffold malapposition. Six-month OCT analysis is being conducted and will be presented at the meeting.

Coronary interventions – *Friday May 24th*
PCI of bifurcation lesions: impact of procedural techniques on clinical outcome

Modified flower petal technique in the treatment of isolated ostial bifurcation lesions

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Aims: For percutaneous treatment ofisolated ostial bifurcation lesions involving the main branch or the side branch, it is important to accurately place a stent to cover the lesion entirely without protruding into the other branch. The optimal strategy for patients with isolated ostial bifurcation lesions has not yet been determined. We proposed a new technique called Modified Flower Petal technique for the treatment of isolated ostial bifurcation lesions.

Methods and results: Between September 2010 and June 2012, we selected 64 patients who had Medina type 0.1.0 or 0.0.1 coronary bifurcation lesions. The procedure starts with wiring of both branches (the first wire in diseased branch and second wire in non-diseased branch). Stent-balloon system is prepared outside of the guiding catheter. First, the plastic stent cover is pulled back slightly to expose the final proximal stent strut and the stent delivery system balloon is inflated to 5-6 atmospheres and deflated. Then, the proximal end of second wire is passed through the final proximal stent strut. The stent cover is removed and another balloon is loaded on the second wire as a braking balloon and centreed on the last proximal stent strut. Then the final proximal strut of the stent is re-crimped by hand. The prepared stent-balloon system is advanced through the guiding catheter to the lesion localisation until the braking balloon stopped the advancement of the stent. In this way, the braking balloon can prevent excessive stent advancement into the diseased vessel and provides complete coverage of lesion by stent struts. Firstly, the stent balloon is inflated and deflated. Secondly, braking balloon is inflated. Thus, the protruding final proximal strut contacts the opposite site of the other vessel wall. The most important characteristics of this new technique are complete coverage of lesion without protruding into the other branch and lower metallic burden at carina region. All patients were followed up to 9 months after the intervention. Quantitative coronary angiography (QCA) analyses were performed for both the main and the side branch at baseline, after stent implantation and at 9-month follow-up. Thirty-four (53.1%) and 30 (46.9%) of the patients had Medina type 0.1.0 and 0.0.1, respectively. The bifurcation angle in all patients was under 700. Procedural success rate was 100%. There was no major adverse cardiac event during hospital stay. Clinical and angiographic follow-up were available in 59 patients (92.2%). There was no death, MI, subacute or late stent thrombosis at 9 months follow-up. In one patient, in-stent restenosis requiring re-intervention was noted.

Conclusions: This new "modified flower petal" technique is safe and highly effective in the management of isolated ostial bifurcation lesions. It has also some advantages such as complete coverage of lesion without protruding into the other branch, lower metallic burden at carina region and excellent immediate and mid-term clinical outcomes.

Coronary interventions – *Friday May 24th*
PCI of bifurcation lesions: impact of procedural techniques on clinical outcome

Single-stent crossover technique from distal unprotected left main coronary artery to the left circumflex artery

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Aims: To report the clinical outcomes following single-stent crossover technique from distal unprotected left main coronary artery (LMCA) to the left circumflex artery (LCx).

Methods and results: Between April 2002 and April 2011, single-stenting with drug-eluting stent for *de novo* distal unprotected LMCA disease was performed in 584 patients. Of these, 31 underwent LMCA-LCx stenting which were compared with the remaining 553 LMCA-left anterior descending artery (LAD) stenting. At 3-year follow-up, there were no significant differences between LMCA-LCx and LMCA-LAD stenting in major adverse cardiac events (24.1% vs. 19.6%, p=0.540), cardiac death and myocardial infarction. There was a trend for higher target lesion revascularisation (TLR) in the LMCA-LCx group, which was significant when the stented-branch was only considered (18.2% vs. 3.0%, p<0.001). In both TLR-subgroups, LCx-ostium was frequently involved (83.3% in LMCA-LCx vs. 66.2% in LMCA-LAD TLR-subgroups, p=0.39). In contrast, LAD-ostium was more frequently involved in LMCA-LCx TLR-subgroup (83.3% vs. 21.0%, p<0.001).

Conclusions: TLR rate at the LCx-ostium is high irrespective of LMCA-LCx or LMCA-LAD stenting. Although LMCA-LCx stenting is the strategy of choice in certain situations, especially in LCx-ostial disease in the absence of LAD disease, this may predispose to LAD-ostium restenosis.

Coronary interventions – *Friday May 24th*
PCI of bifurcation lesions: impact of procedural techniques on clinical outcome

Predictors of side branch occlusion after main vessel stenting in coronary bifurcation lesions: results from the coronary bifurcation stenting II registry

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Aims: Side branch occlusion is one of the serious procedural complications of bifurcation percutaneous coronary intervention (PCI). However, predictors of side branch occlusion are not well established. We sought to investigate predictors of side branch occlusion after main vessel stenting in coronary bifurcation lesions.

Methods and results: Consecutive patients undergoing PCI using drug-eluting stents for bifurcation lesions with side branch ≥2.3 mm were enrolled from 18 centres in Korea between January 2003 and December 2009. We selected patients treated with the provisional strategy and identified those with side branch occlusion (Thrombolysis in Myocardial Infarction flow grade <3) after main vessel stenting. Among 2227 bifurcation lesions, SB occlusion occurred in 187 (8.4%) after main vessel stenting. Preprocedural percent diameter stenosis of the SB ≥50% (OR 2.34; 95% CI 1.59-3.43; p<0.001), lesion length of the side branch (OR 1.03; 95% CI 1.003-1.06; p=0.03), preprocedural percent diameter stenosis of the proximal main vessel ≥50% (OR 2.34; 95% CI 1.57-3.50; p<0.001), and acute coronary syndromes (OR 1.53; 95% CI 1.06-2.19; p=0.02) were independently predictive of side branch occlusion after main vessel stenting. side branch occlusion occurred less frequently in the left main lesions compared with in the non-left main lesions (OR 0.34; 95% CI 0.16-0.72; p=0.005). SB flow was restored spontaneously in 26 (13.9%) and by SB intervention in 103 (55.1%), but not in 58 (31.0%) of 187 occluded SB. Jailed wire in the SB was associated with flow recovery of the occluded SB after MV stenting (OR 2.17; 95% CI 1.14-4.12; p=0.02).

Conclusions: In addition to angiographic findings of the SB, proximal MV stenosis and clinical presentation are associated with occlusion of SB after MV stenting. Jailed wire in the SB may be helpful for flow recovery of the occluded SB.

Impact of stent design on strut apposition and side branch access after provisional bifurcation stenting

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Aims: Final kissing balloon inflation is often performed to improve side branch access and stent strut apposition near the side branch ostium after provisional bifurcation stenting. Selecting a stent with a sufficiently large cell size is important to limit the obstruction towards the side branch. Since most contemporary stent designs have large cells, the importance of stent platform selection for provisional bifurcation stenting is unclear.

Methods and results: Three coronary balloon-expandable '3 mm' stents were included in this study: the Element stent (Boston Scientific), the Integrity stent (Medtronic), and the Multi-Link 8 stent (Abbott Vascular). Advanced finite element computer simulations were used to deploy these stents within three different stenotic bifurcation models. A post-dilatation with a larger balloon (at 14atm) was performed in the proximal main vessel in order to fully appose the stent in that region and to facilitate side branch access (proximal optimisation technique). Final kissing balloon inflation was performed at 12atm, with simultaneous balloon inflation and deflation. Every stent was implanted three times in each bifurcation model, leading to 27 cases. The results were evaluated in terms of strut (mal)apposition and side branch access. Stent struts were considered malapposed when the distance between the strut and the vessel wall exceeded 100 micron. Side branch access was quantified by the percentage of surface area obstruction at the side branch ostium. Data are given as means and standard deviations and were compared using Student's unpaired t test. The percentage of malapposed struts was 8.5±4.1%, 3.4±0.7% and 6.6±2.2% for respectively the Element, the Integrity and the Multi-Link 8 platform. In all bifurcation models, the amount of malapposed struts was significantly lower for the Integrity stent, mainly because of a lower amount of malapposed struts within the proximal main vessel. The percentage of side branch obstruction was 18±13%, 18±11% and 22±8% for respectively the Element, the Integrity and the Multi-Link 8 platform, with no statistically significant differences between the stents.

Conclusions: Final kissing balloon inflation does not guarantee full apposition of the stent struts near the side branch ostium and within the proximal main vessel. Furthermore, the amount of malapposed struts is influenced by the stent design. A similar and important obstruction of the side branch was observed for all platforms.

Long-term clinical outcome of the T-stenting and small protrusion technique for coronary bifurcation lesions

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Aims: To report long-term clinical outcomes in patients treated with the provisional T-stenting and small protrusion (TAP) technique. Several strategies have been proposed for treating bifurcation lesions, each with its own merits and technical challenges. The TAP technique is a relatively new strategy, which is technically less challenging and ensures complete coverage of the side-branch ostium and minimises stent overlap. Although there is reasonable amount of data for other bifurcation strategies, long-term clinical outcomes for the TAP technique are limited.

Methods and results: We retrospectively evaluated all patients who underwent TAP technique with drug-eluting stents between July 2005 and January 2012. The measured endpoints at follow-up were major adverse cardiac events (MACE) defined as composite of cardiac death, myocardial infarction (MI) and target vessel revascularisation (TVR). A total of 95 patients (81.1% male) with a mean age 64.8 years underwent TAP stenting. Procedural success was achieved in 100% of cases. True bifurcation was observed in 75 (78.9%) patients. First-generation drug-eluting stents were used in 55.8% of patients. The outcome rates at 3-year follow-up of MACE, cardiac death/follow-up MI, TVR and TLR were 12.9%, 3.1%, 9.7% and 5.1%, respectively. There were no cases of follow-up MI or stent thrombosis (definite and probable).

Conclusions: These results demonstrate that TAP technique is associated with acceptable clinical outcomes with no episodes of definite and probable stent thrombosis. Further studies should compare TAP technique with other two-stent strategies.

Coronary interventions – *Wednesday May 22nd*
From bench to cath lab: clinical implication of stent design

Influence of microstructure modifications on surface endothelialisation: importance for stent design

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Aims: Coronary artery disease is the leading cause of death in the developed countries. Stent implantation, combined with dilatation of stenosed arteries, is currently one of the most performed interventions in coronary artery disease, but it requires a long-term dual anti-platelet therapy to prevent thrombosis on extrinsic stent material and subsequent vessel occlusion. By accelerating the growth of endothelial cells on the stent surface to provide a barrier between the implant and the circulating blood, the duration of dual anti-platelet therapy could be reduced. We analysed the effects of different microstructured surfaces on stent endothelialisation *in vitro*.

Methods and results: Differently designed, 2-5 µm high elevations or hollows were lithographically etched on silicon plates, subsequently coated with silicon carbide. As controls, smooth silicon plates, bare metal substrates, and cell culture plastic were used. Endothelialisation was assessed using human umbilical vein endothelial cells (HUVECs). The experiments in static conditions were performed using 8-well Ibidi slides (n=17), and cell attachment under arterial flow conditions was analysed using a programmed pump (n=10). To measure cell spreading and growth, actin cytoskeleton was visualised with green phalloidin. For cell counting, nuclei were stained with Hoechst 33258 stain. Images were taken with incident-light fluorescent microscope used for studies of non-transparent objects. Compared to smooth surface, 4-5 µm pillow-like structures improved endothelial cell attachment and growth, whereas smaller, spiky structures (2 µm) influenced endothelialisation negatively. Moreover, cell spreading was induced by larger structures (45 µm), whereas smaller structures (2 µm) and bare metal substrate induced cell rounding. The silicon carbide coating did not affect cell-surface interactions and showed advantages over bare metal substrate. The results obtained with silicon carbide-coated substrates were subsequently confirmed in uncoated substrates with the same structure patterns. Flow experiments were performed to simulate *in vivo* flow in the arteries, which positively verified the results of experiments under static conditions.

Conclusions: Microscale modifications of stent surface which accelerate endothelialisation might prove clinically beneficial by improvement of the safety profile following stent implantation.

Coronary interventions
Abstracts from AsiaPCR/SingLive

Multicentre, prospective, randomised, single blind, consecutive enrollment evaluation of a novolimus-eluting coronary stent system with bioabsorbable polymer compared to a zotarolimus-eluting coronary stent system: 12-month clinical and 6-month angiographic and IVUS results: the Excella BD study

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Aims: To evaluate the safety and effectiveness of the Elixir DESyne™ BD Novolimus Eluting Coronary Stent System (CSS) with a bioabsorbable polymer compared to the Endeavor Zotarolimus Eluting Coronary Stent System through the assessment of clinical, angiographic, and IVUS endpoints.

Methods and results: 149 patients were randomised 3:1, either to the Elixir DESyne BD Novolimus Eluting CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a bioabsorbable polylactide-based polymer, or to the Endeavor Zotarolimus-eluting CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analysed for the primary endpoint of in-stent late lumen loss (LLL) assessed by QCA at 6 months. Moreover, all patients underwent evaluation for the secondary endpoints including the Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularisation; clinically-indicated Target Vessel Revascularization (TVR), and stent thrombosis at 1, 6, 9, and 12 months and annually through 5 years. Lesions were also evaluated for angiographic endpoints at 6 months including: in-segment LLL, percent diameter stenosis, minimal lumen diameter post-procedure and at 6 months, and angiographic binary restenosis (ABR) (≥50%). A subset of patients underwent intravascular ultrasound (IVUS) evaluation including percent (%) neointimal obstruction at 6 months. The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD compared to the control (0.12±0.15 vs. 0.67±0.47, p<0.001), additionally, in-stent ABR was significantly lower for DESyne BD (0% vs. 7.9%, p=0.003). Excellent clinical results at 6 months were demonstrated for both devices. Clinical results through 12 months and additional angiographic and IVUS results will be presented.

Conclusions: Clinical results through 12 months and complete angiographic and IVUS results will be presented.

BEST 2013 ABSTRACT

Multicentre, prospective, randomised, single blind, consecutive enrollment evaluation of the Elixir DESyne™ Novolimus-Eluting Coronary Stent System with durable polymer compared to the Endeavor Zotarolimus-Eluting Coronary stent system: 3-year clinical results and 9-month angiographic and IVUS results: the EXCELLA II Study

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Aims: To evaluate safety and effectiveness of the Elixir DESyne™ Novolimus-Eluting Coronary Stent System (CSS) compared to the Endeavor Zotarolimus-Eluting CSS through assessment of clinical, angiographic, and IVUS endpoints.

Methods and results: 210 patients were randomised 2:1 either to the DESyne CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a durable methacrylate polymer, or to the Endeavor CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analysed for the primary endpoint of late lumen loss (LLL) assessed by QCA at 9 months. All patients also underwent evaluation for secondary endpoints which included a Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularisation (TLR); clinically-indicated Target Vessel Revascularisation (TVR); and stent thrombosis all evaluated at 1, 6, 9, and 12 months and annually through 5 years. Stents were also assessed for angiographic endpoints at 9 months including: in-stent and in-segment LLL. A subset of patients underwent IVUS evaluation including percent neointimal obstruction at 9 months. The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne CSS as compared to control (0.11±0.32 vs. 0.63±0.42, p<0.001). Neointimal volume obstruction by IVUS was significantly lower for the DESyne stent (4.5±5.1 vs. 20.9±11.3, p<0.001). Through 2 years, the rate of clinical events for the DESyne stent has remained stable as compared to the control stent which demonstrated a yearly increase in the number of events. Clinical results through 3 years will be presented.

Conclusions: The study met the non-inferiority endpoint and also demonstrated superiority of the DESyne CSS as compared to control. Clinical results through 3 years and a review of angiographic and IVUS results will be presented.

Long term clinical outcomes of long paclitaxel drug eluting stents' real world experience

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Aims: To evaluate the long term clinical outcomes after implanting long PES in real world patients.

Methods and results: Retrospective analysis of 586 consecutive patients who underwent PCI using Taxus Liberté, paclitaxel drug eluting stent during the period December 2005 to August 2007 was done. 90.1% were followed up for a mean duration of 53 months (12-76 months). Long stents was defined as ≥28 mm length (group A) -178 patients (33.7%) which were compared to relatively short stents ≤27mm length (group B) - 350 patients (66.3%). The study population was a high risk group with 43.3% diabetics in group A, 46.3% diabetics in group B (p-0.524). Baseline characteristics were well matched except for inducible ischaemia on treadmill which were more in group A vs. group B 42.7% vs. 31.9% (p-0.012), Patients in group A required more than one stent 50.6% vs. 37.7% (p –0.004). Mean no of stents implanted per patient was 1.5. MACCE at hospital discharge was 0% in group A vs. 0.7% in group B (p–0.557), at 12 months was 4.4% vs. 4.3% (p-0.984), at 53 months was 11.1% vs. 10.6% (p-0.871). Target lesion revascularisation TLR at discharge was 0% in group A and 0.2% in group B (p-1.0), at 12 months was 3.1% vs. 1.1% (p-0.138), TLR at 53 months was significantly higher in group A 4.9% vs. 1.6% (p-0.025). There is no statistical difference in ST at discharge 0% in group A vs.0.2% group B (p-0.681), at 12 month 0.6% vs. 1.6% (p-0.681), at 53 months was 0.6% vs. 2.1% (p-0.290) respectively. At 53 months Definite ST was 0.6% in group A vs. 0.3% in group B (p-0.513), Probable ST was 0% vs. 0.3% (p-1.0), possible ST was 0.6% vs. 2.7% (p-0.186), still not statistically significant. There was no In hospital mortality in either groups. All cause mortality at 12 months was 0 in group A vs. 1.6% (p-0.185), at 53 months 2.5% vs. 5.3% (p-0.175). The overall event-free survival over a mean period of 53months was similar in both the groups (87.2% vs. 86.4%).

Conclusions: The real world long term MACCE and stent thrombosis of ≥28 mm Taxus Liberté stents in complex intervention group was comparable to ≤ 27mm stents at a mean follow-up of 53 months and showed efficacy and safety similar to that with the limus family of drugs.

Coronary interventions
Abstracts from AsiaPCR/SingLive

Multicentre, first-in-man evaluation of the myolimus-eluting bioresorbable coronary scaffold: 12-month clinical and 6-month imaging results

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Aims: To evaluate the clinical safety and effectiveness of the DESolve™ Myolimus-Eluting Bioresorbable Coronary Scaffold (BCSS) in patients with single *de novo* native coronary artery lesions through clinical endpoints and multiple imaging modalities.

Methods and results: The DESolve BCSS, a novel drug eluting device, combines a PLLA-based scaffold coated with a bioresorbable polylactide-based polymer and the drug Myolimus. Myolimus, a macrocyclic lactone mTOR inhibitor, has demonstrated potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixir's metallic Myolimus-eluting coronary stents. Drug dose is 3 mcg per mm of scaffold length, Sixteen patients with single, *de novo* coronary artery lesions were enrolled in this multicentre, single-arm FIM study. One was deregistered after not receiving a study stent. The 15 remaining patients are being analysed for multiple clinical endpoints: Device and Procedure Success; Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, and clinically-indicated target lesion revascularisation (CI-TLR); clinically-indicated Target Lesion and Target Vessel Revascularisation, (CI-TVR) and stent thrombosis assessed at 1, 6 and 12 months and annually to 5 years. Multiple assessments by angiographic, IVUS and OCT at 6 months were completed. An additional analysis using multislice computed tomography (MSCT) will be completed at 12 and 24 months. At 6 months, the in-scaffold late lumen loss was 0.19±0.19 by QCA, the% volume obstruction was 7.18±3.37 by IVUS, and by OCT 98.68±2.44% of struts were demonstrated as covered. There was one MACE event, a TLR, through 6 months. Clinical results through 12 months and detailed imaging results through 6 months will be presented.

Conclusions: The DESolve™ Myolimus-Eluting BCSS demonstrated both excellent safety and effectiveness in this FIM study, thus warranting further clinical evaluation of the novel technology in larger clinical studies. Clinical results through 12 months and and imaging results through 6 months will be presented.

Coronary interventions
Abstracts from AsiaPCR/SingLive

Pre-dilatation of side branch during provisional t-stenting for true bifurcation

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Aims: Pre-dilatation for side branch(SB) before main vessel (MV) stenting is one of the options to avoid SB occlusion, however the efficacy is controversial among operators. We aimed to evaluate the efficacy of side branch-pre-dilatation before provisional SB stenting for true bifurcation.

Methods and results: 3032 lesions treated with PCI between April 2007 and July 2011, subjects were consecutive 260 *de novo*, non-left-main, true bifurcation (248 patients) treated with provisional T stenting. True bifurcation was defined as Medina class (1,1,1) (1,0,1) and (0,1,1). We divided these bifurcations into two groups according to SB-flow after stenting: SB pre-dilatation group(115 bifurcations) and Non pre-dilatation group (145 bifurcations). There was no difference in patient and lesion characteristics involving Medina classification or ACC/AHA classification between two groups. 40 bifurcation (15%) suffered SB-flow deterioration defined as TIMI grade 0-2. Fluoroscopy-time was longer (44 min vs. 24min: $p<0.01$) and contrast volume was higher (283ml vs. 200ml $p<0.01$) in pre-dilatation group. Technical factors involving stent type, stent/balloon size and inflation pressure did not show significance between two groups. QCA analysis revealed that regarding minimum lumen diameter (MLD), percent diameter stenosis (%DS), and RVD, no difference was seen in these groups.

Conclusions: In SB pre-dilatation before provisional T stenting for true bifurcation, approximately 13.9% of jailed SB-flow deterioration cannot be avoided, and more complex procedure was needed if SB flow damage occurred. Pre-dilatation is not influenced chronic SB TIMI flow. And factor related to SB-flow deterioration in this procedure were SB MLD and MV RD.

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Coronary interventions
Abstracts from AsiaPCR/SingLive

BEST 2013 ABSTRACT

Five-year clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with and without diabetes mellitus: a LEADERS Sub-study, final report

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Aims: Patients with diabetes mellitus (DM) undergoing percutaneous cardiovascular intervention (PCI) represent a challenging population with higher risk of adverse events compared to non-diabetic patients. We investigated the impact of DM on long-term clinical outcomes of biolimus-eluting stents (BES) with biodegradable polymer versus sirolimus-eluting stents (SES) with durable polymer within the randomised multicentre all-comers LEADERS trial through 5 years.

Methods and results: A stratified analysis of clinical outcomes out to 5 years (final report of the study) was performed in 1707 patients randomised to BES and SES within the LEADERS all-comers trial with regards to the presence or absence of diabetes (one of three pre-specified subgroup analyses). Among diabetics, clinical outcomes were further stratified by insulin dependency. 414 patients out of 1707 were diabetics (24.3%) with 223 patients in the BES group and 191 in the SES group. Patients with diabetes were older, more likely to have hypertension, hypercholesterolemia, history of previous PCI or CABG (all p-values <0.01). Of 414 Diabetic patients, 158 (38%) were insulin-dependent (81 patients in the BES and 77 in the SES group). At 1 year, the composite endpoint of MACE (cardiac death (CD), myocardial infarction (MI) or clinically indicated TVR (ci-TVR)) was similar for DM patients in the BES and SES arms (15.7% vs. 14.7%, p=0.75) and for non-DM patients (8.8% vs. 11.2%, p=0.28), with a non-significant interaction. One year outcomes for CD, MI and ci-TVR were similar in patients with and without DM between the two groups. As expected, IDDM patients had higher rates of ci-TVR and MACE compared to NIDDM patients (13.3% vs. 7.0% and 18.4% vs. 13.3%) at 1 year. In the group of NIDDM patients, no difference in clinical outcomes was observed between two stents. Within IDDM patients, the use of BES compared to SES resulted in a lower CD rate (0% vs.6.5%). There was no difference in other clinical endpoints between two stents. The long-term analysis is currently ongoing.

Conclusions: Patients with IDDM continue to be a challenging population. The 5-year follow-up will be reported during this meeting.

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Coronary interventions
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A single-centre initial experience in treating coronary artery disease with everolimus-eluting bioresorbable vascular scaffold (BVS)

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Aims: Everolimus-eluting bioresorbable vascular scaffold (BVS) has been shown to be effective in treating *de novo* coronary artery lesions with a good 2 year outcome. This technology was recently introduced to our centre in Singapore and the aim of this report is to describe our initial experience with the BVS.

Methods and results: Between July 2011 to July 2012, all patients who underwent PCI with intent for BVS use were included in the analysis. The pre-procedural reference vessel diameter (RVD) was assessed by quantitative coronary analysis (QCA), intravascular ultrasound (IVUS) or optical coherence tomography (OCT). A suitable lesion for BVS is a lesion with a RVD of 2.0 to 3.3mm and lesion length <28mm(single or overlapping). 25 patients, mean age 55.6±11yr, 84% (n=21) male, underwent attempted BVS implantation. Indications were stable angina (52%), unstable angina (28%), and NSTEMI (20%). 60% (15) were hypertensive, 20% (5) had diabetes mellitus, 76% (19) dyslipidaemic, and 48% (12) were smokers. 6 Fr access was used in all patient and 80% via a radial approach. Pre-procedure RVD was assessed by QCA in 80% (20), IVUS in 16% (4), and OCT in 4% (1). Overall, 32 BVS were successfully implanted in 23 (91%) patients (1.4 BVS/patient); two patients had circumflex (LCX) stenosis not crossable by the BVS despite aggressive lesion preparation. An equivalent metallic drug eluting stent crossed without difficulty in both cases. Of the 30 lesions intervened, success rate was 100% (12/12) for LAD, 100% (7/7) for RCA and 67% (4/6) for LCX. Pre-procedural RVD was 2.7±0.4 mm, diameter stenosis was 77±1%, and lesion length was 17.5±7.5 mm. Post-procedural RVD was 2.9±0.3mm with residual diameter stenosis of 2.5±2.0%. No adverse events were documented at 30-days post-procedure.

Conclusions: BVS can be successfully deployed in a wide range of clinical presentations with good short-term results. Moderate to severe LCX lesions, however, appeared to have a higher rate stent delivery failure.

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Changes of plaque volume and plaque composition during dual lipid-lowering therapy (atorvastatin+ezetimibe) compared to standard therapy. Study with intravascular ultrasound and virtual hiostology

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Aims: The comparison of plaque volume and plaque composition changes during aggressive dual lipid-lowering therapy compared to standard one in patients with stable angina.

Methods and results: 121 patients were enrolled to the study. Randomised was in ratio 1:1 to the aggressive group A (atorvastatin 80 mg and ezetimibe 10 mg per day) and to the standard group S (dose and type of statin therapy was leaded by general practitioners). Follow-up period was 12 months. Only one artery with diameter stenosis less than 50% according to angiography was chosen for analysis done by intravascular ultrasound and virtual histology. The final analysis was performed in 112 patients (in 89 patients with complete virtual histology analysis due to technical reasons). Mean length of analysed plaque was 44.9 mm. We found decrease of percent atheroma volume (PAV) –0.7% and decrease of indexed total atheroma volume (TAVi, computed as total atheroma volume /plaque length) –0,35±0.7 mm^3/mm in group A, compared to increase PAV +1.23% and TAVi in group S. Both differences were statistically significant with p=0.01 and 0.03 respectively. The total cholesterol, LDL cholesterol and hsCRP levels were significantly lower in group A compared to group S. The LDLc cut off point for starting of atherosclerosis regression was 87 mg/dl (from analysis of all patients together). The vessel volume increased in patients with diabetes (DM) compared to decrease in non-diabetic (NDM) patients (1.6 vs. –2.0%, p=0.027). There was a trend for different change of TAVi in DM compared to NDM patients (0.11 vs. –0.23, p=0.07). The strong positive correlation between changes of plaque and vessel volumes (p<0.0001, r=0.56) was present. We found decrease of fibrous and fibro-fatty tissue and increase of dense calcification and necrotic core in both groups. These differences were not statistically significant between the two groups. However, the increase of dense calcification and necrotic core between baseline and follow-up were significant in group S (both p=0.02).

Conclusions: The aggressive dual lipid-lowering therapy (atorvastatin plus ezetimibe) starts atherosclerosis regression. Standard therapy does not even stop the progression of atherosclerosis. The positive remodeling was more frequent in DM patients probably for increase of the plaque volume. Vessel volume closely correlates with the plaque volume. Despite significant decrease of lipid levels the continuous plaque shift from fibro and fibro-fatty to necrotic with calcification was still present in both groups, however more in patients with standard treatment.

Coronary interventions
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Serum uric acid levels are associated with vulnerable plaque volume assessed by integrated backscatter intravascular ultrasound

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Aims: The purpose of this study was to investigate the relationship between serum uric acid (UA) levels and plaque components assessed by a novel tissue characterisation system, integrated backscatter intravascular ultrasound (IB-IVUS).

Methods and results: Between July 2009 and April 2012, we enrolled the 279 consecutive patients (214 male, mean age 69±11 years old) who underwent primary percutaneous coronary intervention(PCI) using IB-IVUS in the present study. IB-IVUS images were captured at a speed of 0.5 mm/sec using a motorised pull-back system of IB-IVUS imaging system (VISIWAVE, Terumo, Japan) with a 40 MHz mechanically rotating intravascular catheter. Plaque analysis was performed in the range of stenting lesion at 1 mm axial intervals. In the present study, there were 118 patients with acute coronary syndrome (ACS) and 161 patients with stable angina pectoris. All patients checked up serum UA levels before PCI, and baseline serum UA levels were approximately normally distributed, ranging from 0.9 to 11.2 mg/dL with a mean±SD of 5.5±1.4 mg/dL. They were divided into 4 groups according to the serum UA levels (group 1 [n=62] <4.5 mg/dL; group 2 [n=74] 4.5 to 5.4 mg/dL; group 3 [n=83] 5.4 to 6.3 mg/dL; group 4 [n=60] >6.3 mg/dL). There were no significant differences in baseline clinical characteristics among 4 groups; age, smoking, body mass index, hypertension, dyslipidemia, diabetes mellitus and percentage of ACS and medication except for sex. We evaluated tissue characterisation of coronary plaques at culprit lesion using IB-IVUS. Percentages of lipid volume (%LPV) were increased with increasing UA levels (47±1.6% in group 1; 46±1.4% in group 2; 50±1.3% in group 3; 61±1.6% in group 4, p < 0.001). On the other hands, percentages of fibrosis volume (%FV) were decreased with increasing UA levels (43±1.1% in group 1; 44±1.0% in group 2; 41± 1.0% in group 3; 33±1.2% in group 4, p < 0.001). In addition, we investigated relationship between plaque components analysed by IB-IVUS at culprit minimum lumen site (MLS) and UA levels. Percentages of lipid area (%LPA) at MLS were increased with increasing UA levels (49±1.9% in group 1; 47±1.7% in group 2; 52±1.6% in group 3; 61±1.9% in group 4, p < 0.001). On the other hands, percentages of fibrosis area (%FA) at MLS were decreased with increasing UA levels as well (42±1.5% in group 1; 42±1.3% in group 2; 40±1.3% in group 3; 32±1.5% in group 4, p < 0.001). The UA levels significantly correlated with%LPV (r=0.46),%FV (r=-0.42),%LPA at MLS (r=0.31) and %FA at MLS (r=0.29) respectively.

Conclusions: Increased serum UA levels were associated with larger lipid and smaller fibrosis assessed by IB-IVUS, which relate to plaque vulnerability. Our study results suggest that lowering UA levels may be another therapy to stabilise vulnerable plaques.

Analysis of in-stent neoatherosclerosis after drug-eluting stent implantation using a 40 MHz intravascular ultrasound imaging system

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Aims: In-stent neoatherosclerosis is a frequent reporte in drug-eluting stents studies (DES) and occurs earlier than in bare metal stent (BMS). Analyses of neointimal tissue components in follow-up periods have not been fully examined *in vivo*. The aim of this study was to characterise in-stent neoatherosclerosisusing radiofrequency signals from 40 MHz intravascular ultrasound (IVUS), called iMAP-IVUS.

Methods and results: IVUS examinations were performed on 32 consecutive angina patients (32 lesions) underwent repeated PCI for the treatment of DES in-stent restenosis. We assessed neointimal tissue characteristics using iMAP-IVUS. Neointimal plaque volumes were calculated by the difference between stent and lumen volumes and coded tissue as four components; fibrous, lipidic, necrotic, and calcified. The patients were divided into two groups according to the follow-up duration: group A (≤1 year, 18 lesions) and group B (>1 year, 14 lesions). Mean follow-up periods between stent implantation and repeated PCI were 21±20 months (group A: 8±2 months; group B: 37±20 months). Baseline clinical and angiographic characteristics were similar for the two groups. And a 3D volumetric analysis did not demonstrate any significant differences in the IVUS parameters between the two groups. The percentages of fibrotic, lipidic and calcified relative volume were similar in the both group, too. However, the percentages of necrotic relative volume was greater in the group B (>1 year) than in the group A (≤1 year) (11.07% vs. 8.28%, P< 0.05).

Conclusions: Our results revealed that long follow-up patients have significantly larger necrotic plaque volumes than short follow-up patients. These results suggest that in-stent neoatherosclerosis might be important mechanism of failure or very late stent thrombosis of DES.

Coronary interventions
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The role of collateral pressure index assessing collateral function and coronary haemodynamics in patients with total or nearly total occluded coronary lesions

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Aims: The aim of this study was to assess collateral function and coronary haemodynamics of the total or nearly total occluded coronary lesions in acute and chronic coronary lesions by fractional flow reserve (FFR) using pressure wire.

Methods and results: Between March 2011 and March 2012, 56 patients (49 men; mean age=58.0±10.9 year-old) who underwent percutaneous coronary intervention (PCI) for total or nearly total occluded coronary lesions were included in this study. The FFR at maximum hyperemia induced by intravenous adenosine was determined at per- and post-intervention. The pressure-derived collateral pressure index (CPI) was determined as (Pw-Pcvp)/(Pa-Pcvp), where Pw represents coronary wedge pressure, Pcvp central venous pressure, and Pa mean aortic blood pressure. Both were measured during transient coronary occlusion by a balloon inflation of 1 to 3 minutes. Of these patients, chronic stable angina was present in 29 patients and acute coronary syndrome was present in 27 patients. Twenty nine patients had a chronic total occlusion lesion (CTO) and 27 patients had an acute total occlusion (non-CTO). Collateral flow grade by Rentrop classification ≥2 was higher in patients with CTO. Reference vessel diameter was significantly lower in patients with CTO, whereas number of stents was significantly higher in patients with CTO. Amount of contrast and fluoroscopy time was also significantly higher in patients with CTO. The mean pre-intervention FFR in CTO patient was 0.51±0.11, whereas mean pre-intervention FFR in non-CTO patient was 0.62±0.15. Baseline CPI (0.31±0.11 versus 0.25±0.11, p=0.041) and recruitable CPI (0.31±0.08 versus 0.23±0.11, p=0.003) was significantly higher in CTO compared with non-CTO. There was no significant differences between baseline CPI and recruitable CPI in patients with CTO (0.31±0.10 versus 0.31±0.08, p=0.909) and non-CTO (0.24±0.10 versus 0.23±0.11, p=0.877).

Conclusions: Baseline CFI and recruitable CFI were significantly lower in patients with non-CTO compared with CTO patients. Collateral flow changes immediate after PCI was not observed both CTO and non-CTO patients.

Coronary interventions
Abstracts from AsiaPCR/SingLive

Quantitative assessment of microcirculatory resistance in infarct-related and non-infarct-related coronary arteries in patients with ST-segment elevation myocardial infarction tretaed with primary percutaneous coronary intervention

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Aims: The aim of this study was to quantitatively assess microcirculatory resistance in infarct-related and non-infarct-related coronary arteries in patients with ST-segment elevation myocardial infarction (STEMI).

Methods and results: We determined index of microcirculatory resistance (IMR) in infarct-related and non-infarct-related coronary arteries with no critical stenosis (diameter stenosis <70% in non-infarct-related arteries) in 70 patients with the first STEMI treated with primary percutaneous coronary intervention. Coronary wedge pressure was measured in infarct-related artery and used for the calculation of corrected IMR. The IMR in the infarct-related artery was significantly increased as compared with IMR in non-infarct- related arteries: median 32.5 U (range 7.4 to 162.1) vs. 20.3 U (range 7.9 to 49.9; P<0.001) in an adjacent vessel and 32.5 vs. 22.6 U (range 5.9 to 105.1; P=0.0022) in artery giving collateral blood supply to the infarct-related artery. Corrected IMR was also increased compared to IMR in non-infarct-related arteries: 29.9 U (range 10.3 to 112.2) vs. 20.3 U, P<0.001 and 29.9 vs. 22.6 U, P=0.0047. The IMR values in the adjacent vessel and vessel giving collateral blood supply to infarct-related artery were similar (20.3 vs. 22.6 U, P=0.32).

Conclusions: Microcirculatory resistance is elevated in the infarct-related artery as compared with non-infarct-related arteries in patients with STEMI. There is no difference in the microcirculatory resistance between vessel adjacent to infarct-related artery and vessel giving collateral blood supply to infarct-related artery.

Coronary interventions
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Reduction in treatment times through formalized data feedback: results from a prospective multicentre study of ST-elevation myocardial infarction

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Aims: We evaluated the effect of systematic data analysis and standardised feedback on treatment times and outcome in a prospective multicentre multicentre study of ST-elevation myocardial infarction (STEMI).

Methods and results: Over a 15-month period, 1,183 patients presenting with STEMI were enrolled. Six primary PCI hospitals in Germany and 29 associated non-PCI hospitals participated. Data from patient contact to balloon inflation were collected and analysed. Predefined quality indicators including the percentage of patients with preannounced STEMI, direct hand over in the catheterisation laboratory, C2B (contact-to- balloon) <90 min, D2B (door-to-balloon) <60min, and D2B <30 min. were discussed with staff on a quarterly basis.

Median D2B decreased from 71 to 58 min and C2B from 129 to 103 min between the first and the fifth quarter (p<0.05 for both). Contributing were shorter stays in the ER (emergency room), more direct hand-offs from ambulances to the catheterisation laboratory (from 22% to 38%, p<0.05), and a slight increase in the number of patients transported directly to the PCI facility (primary transport). One-year-mortality was reduced in the total group of patients and in the subgroup of patients with primary transport (p<0.05). The sharpest fall in mortality was observed in patients with primary transport and TIMI risk score ≥3 (n=521) with a decrease in 30-day-mortality from 23.1% to 13.3% (p<0.05) and in one-year- mortality from 25.6% to 16.7% (p<0.05).

Conclusions: Formalised data feedback is associated with a reduction in treatment times for STEMI and with an improved prognosis, which is most pronounced in high-risk patients.

The benefit of primary percutaneous coronary intervention in 'early' latecomers with ST-segment elevation acute myocardial infarction

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Aims: A high proportion of patients with ST-segment elevation myocardial infarction (STEMI) visit emergency room more than 12 hours after symptom onset. In this setting, the chance of an existing coronary collateral circulation, the ischaemic preconditioning and the infarct-related artery patency should be taken into consideration for patients with STEMI presenting from 12 to 72 h after symptom onset. These patients are known as 'early' latecomers. The aim of this study is to evaluate the benefit of primary percutaneous coronary intervention (PCI) in "early" latecomers with STEMI in modern PCI era.

Methods and results: Between November 2005 and January 2008, 754 'early' latecomers (499 men; mean age=65.2±12.8 years-old) were analysed from the Korean Acute MI registry. Patients were stratified into three groups based on symptom-to-door (STD) time; STD time of 12-<24 hours (n=369, 62.1%), 24-<48 hours (n=168, 28.3%), and 48-72 hours (n=57, 9.6%). The 12-month MACE was defined as a composite of death, non-fatal MI, and revascularisations. Of these patients, primary PCI was performed in 594 (78.8%) 'early' latecomers. During the follow-up, 126 (16.7%) MACEs occurred. Kaplan-Meier survival curve showed primary PCI significantly reduced 12-month MACEs (21.4% versus 36.5%, log-rank p<0.001) compared with conservative treatment group in overall 'early' latecomers. There were no significant differences in 12-month MACEs (20.6% versus 21.8%, p=0.772) between door-to-balloon (D2B) time of <90 min and D2B time ≥90 minutes in primary PCI group. In Cox proportional hazards model, primary PCI (hazard ratio [HR] 0.604, 95% confidence interval [CI] 0.372 to 0.980, p=0.041) was an independent predictor of 12-month MACEs after adjustment for confounding variables. In subgroup analysis, 12-month MACEs were significantly lower in primary PCI group compared with conservative treatment group in patients with an STD time of 12-<24 hours (20.0% versus 37.0%, p=0.007) and an STD time of 24-<48 hours (19.0% versus 36.1%, p=0.033). However, there were no significant differences in 12-month MACEs between primary PCI and conservative treatment in patients with an STD time of 12-<24 hours (38.9% versus 35.7%, p=0.836).

Conclusions: The 'early' latecomers with STEMI represent a heterogenous group, many of these patients may derive significant benefit from immediate PCI.

Coronary interventions
Abstracts from AsiaPCR/SingLive

The optimal timing of invasive management in patients after successful fibrinolysis for acute myocardial infarction

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Aims: To study the early results of percutaneous coronary interventions (PCI) in patients with ST-elevated myocardial infarction (STEMI) after successful thrombolytic therapy.

Methods and results: A total of 183 patients underwent PCI in the first 2 days after STEMI. All patients were treated with alteplase (within 6 hours after onset of the symptoms) and had complete ST-segment resolution. All patients underwent invasive management if continuous chest pain or signs of recurrent ischaemia, or life-threatening arrhythmias and unstable haemodynamic conditions were present. Patients were grouped according to time interval between onset of the symptoms and PCI: group 1: <12 hours (n=81, 7.9±3.2 hours); group 2: 12-48 hours (n=102, 18.4±4.7 hours). The primary endpoint were major adverse cardiac events (cardiac death, myocardial infarction, recurrent angina, repeated PCI and coronary artery bypass surgery) at 30 days. The secondary endpoints were: the incidence of "no-reflow" or "slow-flow" (TIMI 0-1 or 2) phenomenon during the procedure, subacute stent thrombosis. Cardiac troponin I level was measured after 12 and 72 hours after symptom onset. There were no differences among groups in baseline clinical characteristics and angiographic findings. There were no differences in the incidences of MACE after PCI between groups (14.8% in group 1 vs. 13.7% in group 2). Subacute stent thrombosis occurred in 2 (2.5%) patients in group 1 and in 2 (2%) patients in group 2 (difference is non-significant). The incidence of "no-reflow" or "slow-flow" phenomenon was more common in group 1 (11.1%) compared to group 2 (2.9%), p=0.034. The mean level of cardiac troponin after 12 hours was 531±36.4 ng/ml in group 1 and 539±21.5 hg/ml in group 2 (difference is non-significant). The mean level of cardiac troponin after 72 hours was 232±26.8 ng/ml in group 1 and 139±27.3 ng/ml in group 2, p=0.016.

Conclusions: During 30-days of follow-up the clinical results and the incidence of MACE in patients with STEMI and successful fibrinolysisdid not differ between group with immediate PCI (within 12 hours from symptom onset) and delayed PCI (12-48 hours). However, the delayed PCI was associated with better antegrade flow after procedure and lower troponin I level measured at 72 hours after symptom onset. Larger studies are needed to determine the prognostic value of this findings and further investigate the issue.

Coronary interventions
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Outcomes and Predictors of 1 year all-cause mortality in patients undergoing percutaneous coronary intervention (PCI) in Singapore

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Aims: Ischaemic heart disease (IHD) is one of the leading causes of death in Singapore and PCI is an important aspect of the management of IHD. However local data on outcomes and predictors of all-cause mortality in patients who undergo PCI remain limited. We aim to study the outcomes and predictors of 1-year all-cause mortality among patients undergoing PCI in Singapore.

Methods and results: A retrospective analysis of all patients from 2007 to 2009 who underwent PCI in a large tertiary institution was conducted. Clinical data from the Singapore Cardiac Data Bank and administrative data from National Heart Centre, Singapore of up to 1-year after the index PCI were included. Descriptive analyses of the clinical characteristics, comorbidities such as renal impairment (defined as ongoing dialysis or serum creatinine >200 µmol/L) and 6 month adherence to antiplatelet and statin therapy were collected. Outcome variables evaluated included 1 year all-cause mortality and number of readmissions for repeat PCI over a 1-year period. 2,206 patients were studied. There were 80.1% males (n=1767). There were 70.4% Chinese, 12.7% Malay, 13.1% Indian and 3.7% of other ethnicity. Median age is 59 years old (52, 67) and median left ventricular ejection fraction (LVEF) is 60% (50, 61). 15.7% (n=347) of 2,206 patients had impaired LVEF ≤40%. 18.0% (n=398) of patients underwent PCI for STEMI. The rate of non-adherence to either antiplatelet or statin therapy 6 months post PCI is 20.1% (n=444). 14.3% (n=316) underwent readmissions for repeat PCI. The in hospital, cumulative 6 month and 1 year all- cause mortality were 0.3% (n=6), 0.9% (n=20) and 2.4% (n=52) respectively. Acute myocardial infarction is the most frequent cause of mortality at 1 year at 34.6% (n=18) of deaths. The predictors of 1 year all-cause mortality for patients post PCI by multivariate logistic regression analysis are female gender (OR 3.439 CI 1.761-6.716, p=0.001); renal impairment (OR 3.921 CI 2.028-7.581, p<0.001); prior Coronary Artery Bypass Graft surgery (CABG) (OR 4.577 CI 1.827-11.469, p<0.001); Impaired LVEF <40% (OR 2.751 CI 1.424- 5.319, p=0.003) and non adherence to either antiplatelet or statin medications at 6 months post PCI (OR 8.954 CI 4.598-17.437, p<0.001).

Conclusions: The 1 year all- cause mortality rate of patients undergoing PCI at 1 year is 2.4%. Female gender, renal impairment, history of prior CABG, impaired LVEF <40% and non drug adherence at 6 months to either antiplatelet or statin medications are predictors of 1 year all- cause mortality.

Coronary interventions
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Multicentre Dedicated Bifurcation Stent Registry

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Aims: The use of regular drug-eluting stent (DES) reduced the in-stent restenosis and repeat target lesion revascularisation, but it is always reminded for its off-label use and the disadvantage of using regular DES is the side branch restenosis, the non-turbulence flow created by traversing the stent strut for side branch access. We report our first experience in AXXESS which is the dedicated bifurcation stent with polymer-coated with Biolimus A-9 DES in bifurcation procedure among Thai patients.

Methods and results: This was a prospective registry among Thai hospitals. The lesions involved is any type of 1-X-X lesion of MEDINA classification, with angle of the bifurcation less than 70o , the main branch diameter is between 3.0-3.5 mm and side branch diameter is larger than 2.25 mm. The AXXESS is always implanted at the proximal parent vessel. The requirement of distal parent vessel or side branch vessel was left to the physician's discretion. Procedural result is defined as clinical success without loss of any TIMI flow of parent and side branch vessel. CK-MB is measured at the day after the procedure. The treated lesion is analysed using quantitative coronary analysis "MEDIS-bifurcation software". All patients will be scheduled for 9-12 month controlled coronary arteriography to measure the minimal luminal diameter and per cent binary restenosis of the treated vessel. From 8-April 2012 to 31-Aug-2012, we enrolled 38 patients who has been successfully treated with AXXESS bifurcation. Male gender is predominant (n=26, 68.4%). Diabetes was the frequent risk factor(n=15, 39.5%). There were 41 bifurcation lesions treated. The most frequent type was 1-1-1 bifurcation (n=23, 56.1%). AXXESS were implanted in all 39 lesions. The parent vessels were treated with BioMatrix DES (n=24, 58.5%), the side branch were treated (n=19, 54.3%)of cases. Two patient received two AXXESS for two different proximal parent vessels lesions. There were 2 cases with AXXESS deployment failure, too distal into the distal parent vessel. Failed side branch access was found in two cases. There was no loss of side branch vessels. All side branch vessels achieved TIMI 3 flow. CK-MB was measured in 34 cases. CK-MB >3 XRL was founded in 12 cases (31.6%).

Conclusions: We observed good results in this AXXESS dedicated bifurcation stent treatment with safety and efficacy in providing the initial clinical and angiographic outcomes. The mid-term minimal reference diameter will be further reported.

Adoption of TAVI in Western Europe

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Aims: Transcatheter aortic valve implantation (TAVI) has not been previously described. We sought to examine the adoption kinetics of TAVI in Western Europe.

Methods and results: TAVI adoption patterns were investigated across 11 European nations: Germany, France, Italy, United Kingdom (UK), Spain, The Netherlands, Switzerland, Belgium, Portugal, Denmark and Ireland. Two sources of data were used: (1) lead physicians in each nation provided national registry data; and (2) the European Cardiovascular Monitor system. The penetration of TAVI in each nation was determined as a measure of actual TAVI use relative to potential use. Between January 2007 and December 2011, a total of 34,317 patients underwent TAVI in the 11 study nations. Almost half of all implants were performed in Germany (45.9%), with Italy (14.9%) and France (12.9%) the next most frequent implanters. Ireland accounted for the smallest proportion of implants (0.4%). In 2011, the highest annual increase in procedural volume was observed in France (61%) and Germany (49%), while Ireland (–15%) and Portugal (–3%) were the only nations to experience a decline. The annual number of implants increased 33-fold from 455 in 2007 to 14,946 in 2011. Although the annual procedural volume growth rate has decreased from 429% in 2008 to 40% in 2011, it remained positive. We observed a wide variation in the number of TAVI implants per million of population. Germany (88.7) and Portugal (6.1) accounted for the highest and lowest number of TAVI implants per million of population in 2011, respectively. Among the 11 study nations, the mean number of TAVI implants per million was 32.9±24.9 while the mean number of TAVI implants per million ≥75 years was 398±283. The number of centres performing TAVI increased approximately 9-fold from 37 in 2007 to 342 in 2011. In 2011, Germany (90) and Italy (87) had the highest number of TAVI centres whereas Portugal, Denmark and Ireland (3) had the lowest. Belgium had the highest number of TAVI centres per million of population (2.1) and Portugal (0.3) the lowest. On average, there were 0.9±0.6 TAVI centres per million of population. These numbers led to an average of 41±28 TAVI implants per centre in 2011, with estimates in individual countries ranging from 10 in Ireland to 89 in Germany. In 2011, we estimate that there were 28,400 living TAVI recipients and 158,371 potential TAVI candidates in the 11 study nations.

Conclusions: There is substantial variation in the adoption of TAVI and in the annual number of TAVI implants per centre across nations. TAVI remains greatly underutilised with an estimated weighted penetration rate of 17.9%.

When does baseline left ventricular function influence survival post TAVI? The Australia New Zealand study

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Aims: Left ventricular (LV) function and the aortic gradient generated by it on the long-term outcomes post TAVI.

Methods and results: The CoreValve ANZ Study is currently enrolling patients with severe aortic stenosis at 10 centres in Australia and New Zealand. Baseline characteristics include mean age 84 years, Logistic EuroSCORE 17% and Society of Thoracic Surgeons risk 6% for 476 patients enrolled as of October 2012. Changes in LV ejection fraction (EF) by echo were assessed comparing discharge, 1-, 12- and 24 months follow-up to baseline. An absolute difference of 5% was considered a clinically meaningful change in EF allowing for inter-operator variability. Survival analysis for patients with ≥5% increase in EF between baseline and 1 month was also performed. Patients with true severe aortic stenosis (valve area ≤1.0 cm^2) were divided into 4 Groups; Group A (n=39) low EF (≤50%) with low gradient (≤40 mmHg); Group B (n=56) low EF with normal gradient (>40 mmHg); Group C (n=53) normal EF (>50%) with low gradient and Group D (n=218) normal EF with normal gradient. Group A includes patients with and without LV reserve. We presumed patients in Group B had adequate LV reserve in spite of low EF. Group C includes patients with paradoxical low gradient severe aortic stenosis, for which limited data exists on their natural history post valve replacement. Group D represents patients with well-established positive outcomes following valve replacement for symptomatic aortic stenosis. The primary endpoints for these analyses were all cause and cardiovascular mortality at 2 years. LVEF at baseline was available for 366 patients. Groups A and B experienced the greatest overall improvement in EF at discharge compared with baseline ($p<0.001$). An absolute increase in EF ≥5% at 1 month occurred in 59% of patients in Group A, and 80% of patients in Group B. Only Group B showed improvements in EF post TAVI at each follow-up compared with baseline (all $p<0.01$). All-cause and cardiovascular survival at 2 years in each group were (A) 66%, 66%; (B) 82%, 83%; (C) 72%, 74% and (D) 78%, 86%, respectively. Group D showed significant reduction in all cause (78% vs. 66%, $p=0.02$) and cardiovascular (86% vs. 66%, $p=0.001$) mortality compared with Group A. In Group D late death was driven by non-cardiac causes. Group C showed reduce survival compared to B and D but was not significant. Survival at 2 years in patients with EF≤50% (Groups A+B) who showed at least 5% improvement (predominantly Group B) in EF post TAVI was 89%, compared with 72% in those who did not (predominantly Group A) 72% ($p=0.023$).

Conclusions: Patients with low EF and low aortic gradients have worse outcomes post TAVI especially if LV function fails to improve post procedure. Patients with normal gradient and low EF showed sustained improvement in EF with excellent survival and should proceed to TAVI if indicated. The paradoxical low gradients severe aortic stenosis patients showed reasonable mid-term benefit and should not be denied TAVI.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI results from worldwide registries

One year outcomes in real world patients treated with TAVI: the advance study

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Aims: Transcatheter aortic valve implantation (TAVI) is now considered the standard of care in extreme risk patients with severe aortic stenosis and an alternative to surgery in those considered high risk. The CoreValve ADVANCE study evaluated the clinical benefits of the CoreValve system in a fully monitored, "real world" trial performed in 44 centres in 12 countries in Western Europe, Asia and South America. Previously reported acute and short-term results from the CoreValve ADVANCE study have demonstrated encouraging patient outcomes. This abstract reports for the first time the complete 1-year patient outcomes from the ADVANCE study.

Methods and results: From March 2010 to July 2011, the ADVANCE study enrolled 1015 patients (mean age 81±6 years, 51% female, mean Logistic EuroSCORE 19±12%, New York Heart Association III/IV 80%) who were evaluated by the local Heart Teams. All primary endpoint-related events were fully adjudicated according to the Valve Academic Research Consortium definitions by an independent Clinical Events Committee. At 1-year, 99.3% (818 out of 824 alive) of patients implanted were available to complete a follow-up, representing a 0.7% withdrawal rate. One year freedom from all-cause and cardiovascular mortality were 82.1% and 88.3%, respectively. Freedom from stroke was 95.5% and freedom from myocardial infarction was 99.1% at 1 year. Valve performance was maintained through 1 year as measured by mean gradient (9.5±4.7 mmHg at 6 months and 9.5±5.2 mmHg at 1 year) and effective office area (1.7±0.5 cm^2 at 6 months and 1 year). Additionally, improvement in patient symptoms was achieved in the majority of the patients (New York Heart Association I/II 87%).

Conclusions: The ADVANCE study is one of the largest "real world" TAVI trials performed in multiple experienced centres. Low 1-year mortality and stroke rates, along with maintained valve performance throughout 1-year demonstrate the safety and effectiveness of Medtronic CoreValve implantation in patientswith severe aortic stenosis at high and extreme operative risk.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI results from worldwide registries

TAVI for inoperable patients with severe aortic stenosis treated by medical management: a united kingdom based cost utility analysis on patient level data from the advance study

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Aims: We used individual patient level data from the CoreValve ADVANCE Study and an existing economic model to study the long term cost-effectiveness of the CoreValve system, from a United Kingdom National Health Service perspective.

Methods and results: A 5-year probabilistic version of the published Markov model was developed. The treatment options compared were TAVI (CoreValve system) and medical management. The risks of key clinical events (including mortality), intraoperative conversion to surgical aortic valve replacement, short term rehabilitation and concomitant pacemaker use were derived from the ADVANCE individual patient level data. Long-term survival data were derived by extrapolating observed survival data from PARTNER (medical management, 36 months) and ADVANCE (six months) using independent survival functions. The costs of TAVI and other sources of short and longer-term resource implications were taken from national databases. Medical management included a range of drugs (statins, warfarin, ACE inhibitors, clopidogrel) as well as balloon aortic valvuloplasty. The impact on health related quality of life was assessed via utility decrements applied to age-specific EuroQoL (EQ-5D) population norms to generate outcomes expressed in terms of quality adjusted life years. Extensive probabilistic, sensitivity and threshold analyses were performed to identify key cost-effectiveness drivers and the relationships between key parameters. The model was constructed to comply with the National Institute for Health and Clinical Excellence reference case for cost-effectiveness analyses. The base case incremental cost-effectiveness ratio of TAVI vs. medical management was £12,600 per quality adjusted life years gained (95% interval £9,800 to £15,600). At a cost-effectiveness threshold of £20,000 per quality adjusted life years gained the probability that TAVI is cost-effective was 100%. The result was insensitive to changes in the cost of all drugs, implant procedure, initial hospital stay and follow-up hospitalisations, the probabilities of all adverse events and all utility decrements.

Conclusions: From a United Kingdom reimbursement perspective, despite the procedure costs related to only the TAVI group, the CoreValve system appears to represent a good value for money for the United Kingdom National Health Service. The results are robust to changes in key input values.

Thirty day outcomes from the multicentre European pivotal trial for transapical TAVI with a self-expanding prosthesis

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Aims: The new Engager™ system, a second-generation device for transcatheter aortic valve implantation (TAVI), allows anatomically correct rotational positioning and captures the native leaflets for sealing. These design features are expected to ensure optimal positioning of the valve within the annulus with possible reduction of paravalvular regurgitation. We report the evaluations for safety and clinical performance of the Engager™ transapical system in patients with severe aortic valve stenosis at high risk for surgical aortic valve replacement (AVR).

Methods and results: From September 2011 through December 2012, 125 patients were enrolled to the Engager™ European Pivotal Trial at eight sites in Europe and Israel (five in Germany and one each in Belgium, Switzerland and Israel). Inclusion criteria comprised severe aortic stenosis, NYHA ≥II, logistic EuroSCORE ≥20% or contraindication to surgical AVR. Patient evaluations were completed at 24 to 48 hours post procedure, at hospital discharge, at 30 days and six months. Annual follow-up will be performed through 5 years. The patients had a mean age of 82.0±4.7 years (62.4% female). The valve size distribution was as follows: 25.8% 23 mm, 74.2% 26 mm. Since analysis of the full cohort is ongoing, the outcomes reported in this abstract are from an interim analysis which was performed on the initial 61 patients from four sites in Germany who were enrolled through May 2012: For these patients (mean age 81.9±4.4 years, 62.3% female, 88.5% NYHA III/IV) procedural success was 94.3 according to a modified VARC definition and the rates of all-cause mortality and stroke at 30 days were 9.9% and 1.8%, respectively; at 6 months, these rates were reported as 16.9% and 5.5%, respectively. None of the patients experienced greater than mild paravalvular regurgitation at 30 days or 6 months. At 6 months, the majority of subjects (82.2%) were in NYHA class I/II. Based on echocardiographic findings, valve performance at 6 months continued to show significant reductions in mean aortic gradient and increases in aortic valve area following Engager bioprosthesis implantation.

Conclusions: Early postoperative and intermediate follow-up results with the Engager™ transapical aortic valve replacement system support good valve performance and safety. Analyses for 30 day outcomes of the full cohort are underway and will be provided in the conference presentation.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI results from worldwide registries

TAVI in Switzerland: early periprocedural and 30 day outcomes from the national, multicentre SWISS TAVI registry

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Aims: The SWISS TAVI Registry was established as a national collaboration among the Swiss Working Group of Interventional Cardiology and the Swiss Society of Cardiac Surgery to prospectively assess the safety and efficacy of TAVI in Switzerland.

Methods and results: The SWISS TAVI Registry (NCT01368250) is a national, prospective, multicentre, centrally monitored registry, which provides procedural and clinical outcomes of consecutive patients undergoing TAVI using CE approved devices at Swiss cardiovascular centres. Data are entered in an online database (www.swisstaviregistry), which is maintained and monitored by an independent Clinical Trials Unit. From February 2011 to July 2012, a total of 424 patients were entered into the SWISS TAVI registry and were prospectively followed at 30 days. The majority of patients underwent TAVI as treatment for native aortic valve stenosis (98.1%), while 1.7% and 0.2% received TAVI for degenerative aortic bioprosthesis and severe aortic regurgitation, respectively. Patients were elderly (mean age 82.5±5 years), similarly distributed according to gender (females 51%) and highly symptomatic (75.0% NYHA class III or IV). Patients with severe aortic stenosis (mean transaortic gradient 44.5±17 mmHg, aortic valve area 0.7±0.2 cm^2) either were deemed inoperable or at high risk for conventional surgery (STS Risk Score 8.2±7). Accordingly, comorbidities were commonly encountered: peripheral vascular disease (19.4%), chronic obstructive pulmonary disease (16.1%) and coronary artery disease (57.4%). Patients undergoing TAVI were treated with the Medtronic CoreValve (46.7%), Edwards Sapien (47.6%), JenaValve (4.5%) and Symetis Acurate TA valve (1.2%). The majority of patients received TAVI using the femoral access (78.8%), while 19.8% were treated through the transapical access and in 1.4% alternative access routes were used. All clinical events were reviewed by an independent clinical event committee and adjudicated according to the VARC I endpoint definitions. At 30 days, all cause mortality occurred in 5.2%, cerebrovascular events in 3.3% (major stroke 2.6%), bleeding was as frequent as 20.4% (life threatening bleeding 6.9%), vascular access site complications as 14.7% (major vascular complications 8.1%) and acute kidney injury occurred in 3.5% of patients.

Conclusions: The SWISS TAVI registry is a prospective, national, centrally monitored cohort study recording consecutive TAVI procedures in Switzerland. The first outcome report based on independently adjudicated events shows favourable procedural and clinical outcomes in unselected TAVI patients.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI results from worldwide registries

TAVI in Israel 2008-2013: results from the national Israeli TAVI registry

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Aims: Transcatheter aortic valve implantation (TAVI) is a novel emerging technology for the treatment of severe and symptomatic aortic stenosis patients that are considered to be of high surgical risk. Israel adopted TAVI relatively early with first cases performed at 2008. We report the national extent and characteristics of TAVI use and its outcome at 30 days and 1 year.

Methods and results: I-TAVI is a national ongoing registry, established by the Israeli Workgroup for Interventional Cardiology, which includes all 10 Israeli TAVI centres. During the first four years there were over 1,400 TAVIs in Israel. Mean patients age was 81.9±6 and Logistic Euroscore 20±12%. 85% of the procedures were performed via the transfemoral route and the majority of procedures were performed under concious sedation and local anaesthesia. An updated data will be presented regarding patient characteristics, procedural details and 30 d and 1 year outcome.

Conclusions: TAVI is widely expanding in Israel. The technology appears safe and effective for the treatment of severe aortic stenosis in patients at high-surgical risk.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI results from worldwide registries

TAVI in patients with an annulus dimension suitable for either the Edwards valve or CoreValve

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Aims: This study sought to compare the outcomes following transcatheter aortic valve implantation (TAVI) with the Edwards valve and the CoreValve in patients with an annulus of intermediate size.

Methods and results: From October 2008 to April 2012, in two French centres, a total of 320 patients (age 83.1±7.2years, 45% male) with intermediate-sized aortic annulus (20-25 mm) who had received either an Edwards valve (n=170) or a CoreValve (n=150) via the transfemoral approach were studied. Male gender was more frequent (55.3% vs. 35.9%, p<0.01) in the CoreValve group, whereas annulus size (21.8±1.6 vs. 21.7±1.4 mm, p=0.98) and logistic EuroSCORE (22.9±11.6 vs. 21.3±12.2, p=0.12) were similar. Device success (95.2 vs. 94.0%, p=0.66) and 30-day survival (90.0% vs. 91.8%, p=0.58) were similar. Major vascular complication, annulus rupture and acute coronary occlusion were more frequent in the Edwards group (11.2 vs. 5.3%, p=0.06, 1.8% vs. 0%, p=0.15, 1.8% vs. 0%, p=0.15, respectively) whereas the incidence of post-procedural aortic regurgitation grade ≥2/4 and new pacemaker implantation were more frequent in the CoreValve group (16% vs. 30.1%, p<0.01 and 4.8% vs. 19.3%, p<0.01, respectively). There was a trend towards increased 1-year cumulative survival rate in the Edwards valve compared to the CoreValve (81.8±3.1vs. 76.2±3.8, log-rank p=0.06).

Conclusions: In patients with an annulus of intermediate size, similar device success and short and mid-term outcomes were achieved with either of the valves, irrespective of specific complications related to each individual valve.

Assessment of the aortic annulus with transesophageal echocardiography, CT-scan and magnetic resonance compared to direct surgical sizing: can we rely on imaging measurements?

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Aims: To evaluate aortic annulus sizing performed by transesophageal echocardiography (TEE), cardiac multi-detector computed tomography (MDCT) and magnetic resonance (MR) and compare the results to direct intra-operative sizing.

Methods and results: Forty-five patients, 22 (48.9%) males, age 78.9±3.7, underwent AVR for severe aortic stenosis after TEE, MDCT and MR evaluation. In TEE the annulus was measured at the base of the leaflets insertion in the parasternal long-axis view with X-plane technique. In MDCT and MR aortic annulus was assessed by the "virtual tube", which consists in the average between two different techniques previously described: 1) measurement at the left ventricle outflow tract scrolling in basal direction as soon as the native cusps attachements disappear, indentifying the "basal ring" 2) measurement of a circle joining all the three aortic commissures at the most basal attachement to the aortic wall, identifying the "virtual ring". All assessments were performed double-blinded by two operators for each imaging technique. Intra-operative evaluation was performed introducing millimiter Hegar dilators through the aortic annulus after complete removal of the leaflet and accurate decalcification. Fit of the possible biggest dilator was defined as optimal. Comparison between imaging and surgery was carried out with two-tails Student and variance tests, chi-square test, regression line, Pearson's linear correlation coefficient and Bland-Altman plots. There was no intra-observer variability. The inter-observer variability has been checked with the variance test before averaging them in a mean value typical of each technique. We obtained p=0.96 for MDCT, p=0.64 for MR and p=0.17 for TEE, all non statistically different. All three imaging techniques agree each other and with the standard reference. Particularly MDCT and TEE suffer from a slight overestimation for smaller diameters and a slight underestimation for larger ones, whereas MR was consistently overestimating across all diameter ranges. The Bland-Altman analysis for TEE, MDCT and MR showed the best agreement with the standard reference: mean difference for TEE 0.5±1.9 mm (limits of agreement –3.3 and+4.3 mm); mean difference fot MDCT 0.2±1.5 mm (limits of agreement –2.7 and +3.1 mm); mean difference for MR 1.3±1.7 mm (limits of agreement –2.0 and+4.6 mm). Given a±2 mm allowance around the Hegar sizing, the percentages of right measurements were surprisingly low: 71% (32/45) for TEE; 76% (34/45) for MR; 80% (36/45) for MDCT. These percentages where not statistically different each other (p=0.62).

Conclusions: Available imaging techniques are reproducible, but not totally reliable. MDCT and TEE suffer from overestimation for smaller diameters and underestimation for larger ones, leading to challenging measurements and unpredictabilty. MR instead constantly overestimates, and for this reason seems safer for the choice of the size of TAVI prosthesis.

Aortic annulus dimensions measured using different modalities in patients considered for TAVI

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Aims: An accurate measurement of aortic annulus diameter is crucial for correct bioprosthesis sizing and a successful transcatheter aortic valve implantation (TAVI). Although transesophageal echocardiography (TEE) is considered the gold standard method for measurement of aortic annulus dimensions in TAVI, other diagnostic modalities may be able to assess the aortic annulus dimensions more accurately. The present study evaluates differences in aortic annulus measurements with intracardiac echocardiography (ICE), multislice computed tomography (MSCT) and two-dimensional TEE (2DTEE). Furthermore we sought to assess the impact of bioprosthesis sizing on post-procedural aortic regurgitation (AR).

Methods and results: Bioprosthesis sizing in our centre is mainly based on the aortic annulus diameter measured with ICE or 2DTEE, the latter when ICE is not available. Starting from September 2012 we prospectively measured the aortic annulus diameters with ICE, MSCT and 2DTEE in 22 patients scheduled for TAVI. We compared the quantitative aortic annulus dimensions obtained by these different modalities. Immediate post-procedural AR was measured using aortography and echocardiography. The mean aortic annulus diameter measured by different modalities were as follow: 24,8 mm (±2,2 mm) with ICE, 25,1 mm (±2,4 mm) with MSCT, and 22,5 mm (±2,1 mm) with 2DTEE. No important difference was found between the annulus diameters measured using MSCT and ICE (p=0,44), whereas they both differed significantly from the annulus diameters measured using 2DTEE (p=0,002 and p=0,002, respectively). Although the average aortic annulus diameters measured by ICE and MSCT were found to be similar, the differences between the two measurements for individual patients were large enough (1,3±1,0 mm) to have modified the choice of valve prosthesis size in 10 of 22 patients (45%). Three out of 10 patients with potentially modified prosthesis size yielded post-procedural at least moderate AR, which may have been avoided by implantation of a larger prosthesis, as suggested by MSCT measures. On the other hand 2DTEE measured annulus diameters would have led to smaller prosthesis sizes in 47% of patients, however probably without any clinical consequence.

Conclusions: This study highlights the usefulness of software-assisted pre-procedural assessment of the aortic annulus in patients considered for TAVI. Aortic annulus diameters were significantly larger by MSCT and ICE than by 2DTEE and furthermore MSCT based valve sizing may have prevented moderate or higher degree of AR after TAVI.

Interventions for structural heart disease – *Tuesday May 21st*
Various imaging techniques for TAVI procedures

Rotational angiography provides accurate positioning of the valve prosthesis during TAVI

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Aims: Optimal positioning of the transcatheter aortic prosthesis is paramount to procedural success of transcatheter aortic valve implantation (TAVI). Contemporary angiography systems allow intraoperative rotational angiography enabling three-dimensional reconstruction of the aortic root: the Dyna-CT technique. Unlike the use of preoperatively obtained multislice computed tomographic (MSCT) data, no registration process is necessary to overlay the resulting intraoperative three-dimensional reconstructions with the life images because the patient will not change position. The present study aims to investigate the value of the DynaCT technique for determination of the optimal C-arm angles for valve implantation during TAVI.

Methods and results: Starting from July 2012, Dyna-CT technique is used in our centre for intraoperative determination of optimal C-arm angles during TAVI. Twenty nine patients who underwent transcatheter implantation of the Edwards SAPIEN XT™ bioprosthesis with the use of the DynaCT technique were compared to most recent 29 patients who underwent TAVI before July 2012, in whom the optimal C-arm angles were determined preoperatively using MSCT. Dyna-CT imaging allowed for optimal positioning of the aortic valve bioprosthesis in 26 out of 29 patients (90%). As opposed to the Dyna-CT group, in the MSCT group at least small correction of a few degrees was always needed to find the optimal C-arm angles during the procedure. The use of Dyna-CT was associated with 44% decrease in amount of radiation and 24% increase in the amount of contrast (p=0.002 and p=0.008, respectively) as compared to the MSCT group. The latter was as expected, since for Dyna-CT on average 40ml more contrast is needed. However this extra amount of contrast is diluted (20 mL in 60 mL) and was not associated with a higher incidence of contrast nephropathy in our patients.

Conclusions: Dyna-CT technique allows for easy image integration of a three-dimensional model of the aortic root with life fluoroscopy during TAVI. This technique increases the overall accuracy of specialised imaging during TAVI and diminishes the amount of radiation needed for these procedures.

Interventions for structural heart disease – *Tuesday May 21st*
Various imaging techniques for TAVI procedures

Novel use of aortic valve IVUS to guide TAVI

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Aims: To evaluate the feasibility of using large field aortic valve ultrasound (IVUS) to guide valve sizing in Transcatheter Aortic Valve Implantation (TAVI).

Methods and results: TAVI has developed as a therapeutic option for patients with severe aortic stenosis who are inoperable or at high risk for conventional surgical aortic valve replacement. Accurate imaging of the aortic valve and annulus is important as poor valve sizing may adversely affect patient outcomes. This feasibility study describes the novel use of a new intravascular ultrasound (IVUS) catheter (Visions®PV0.35, Volcano corporation, San Diego, CA) for guiding prosthesis sizing in TAVI by performing aortic valve IVUS. The catheter has a maximum imaging diameter of 60 mm (as compared to <20 mm for coronary IVUS) and uses 10MHz frequency ultrasound. The catheter is 8.5F sheath compatible and advanced in an over-the-wire technique over a 0.35" wire. We performed aortic valve IVUS on 7 consecutive patients (mean age 81.6±3.0 years, mean EuroSCORE II 11.3±6.1%, mean STS score 4.6±1.6%) for planned transfemoral TAVI with the CoreValve (Medtronic, Minneapolis, MA). IVUS imaging was performed pre-TAVI after balloon valvuloplasty over a stiff 0.35" wire in the left ventricle. The aortic annulus was examined by measuring annulus area, as well as minimum and maximum aortic annulus diameters. Annulus perimeter was not measured by IVUS due to limitations of the imaging console. All 7 patients also had intra-procedure Trans-Oesophageal Echocardiography (TOE) and 5 of the 7 patients had pre-TAVI Multi-Detector Computed Tomography (MDCT) to guide valve sizing. All patients had successful IVUS imaging with measurements of minimum and maximum annulus diameters and annulus area. Of the 5 patients who had MDCT and IVUS, the annulus measurements were compared. The mean annulus area was 460.4 mm^2 by IVUS and 455.7 mm^2 by MDCT. There was a positive correlation between the IVUS and MDCT annulus area measurements (r=0.84, p=0.23) which was not statistically significant. The mean ellipticity index (EI) was greater when measured with IVUS (1.28) than when measured with MDCT (p=0.03). Also of interest was IVUS imaging post TAVI which demonstrated valve leaflet function and may potentially be of benefit in evaluating the degree and cause of post procedural aortic regurgitation. There were no complications associated with the use of this technique and all patients are still alive with no stroke, myocardial infarction, vascular complications or acute kidney injury according to Valve Academic Research Consortium (VARC) definitions at 30 days.

Conclusions: Using IVUS to guide TAVI is feasible and warrants further evaluation and comparison with other multi-modality imaging. The technique is fast, safe and intuitive to operators with experience in coronary IVUS. Further studies are ongoing comparing IVUS with MDCT and TOE which may justify its continued use as an adjunctive imaging modality in TAVI.

The extent and distribution of aortic annulus calcification is a predictor of postprocedual paravalvular regurgitation in patients who undergo TAVI - A cardiac computed tomography angiography study

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Aims: To investigate if the extent and distribution of aortic valve calcification is associated with postprocedural prosthesis eccentricity and paravalvular regurgitation in patients undergoing transcatheter aortic valve implantation (TAVI). TAVI is increasingly applied in patients with symptomatic severe aortic stenosis who are considered at high risk for cardiac surgery. Currently, 2 kinds of valves are available, including 1) the self-expanding Medtronic CoreValve™ and 2) the balloon-expandable Edwards-SAPIEN valve. To date, little is known about the way these 2 different valves accommodate to the anatomy of the aortic annulus during TAVI and if postprocedural prosthesis eccentricity is related to paravalvular regurgitation.

Methods and results: 40 patients (27 women (67.5%), 13 men (32.5%); mean age of 81.1±5.25 years) underwent CoreValve (n=27) or Edwards-SAPIEN (n=13) prosthesis implantation between May 2009 and March 2011. All patients underwent both pre- and postprocedural (after 6.3±0.7 months) ECG-triggered 256-slice cardiac computed tomography angiography (cardiac CTA). Following parameters were systematically analysed: 1) the surface, perimeter, long and short axis diameter of the aortic annulus in pre- and postprocedural cardiac CTA and 2) the extent and distribution of aortic annulus calcification in preprocedural cardiac CTA. The presence of a postprocedural paravalvular insufficiency was evaluated semiquantitatively by transthoracic echocardiography. Significant greater eccentricity was observed in CoreValve compared with the Edwards-SAPIEN prosthesis (mean EccentricityCoreValve=1.21 vs. mean EccentricityEdwards=1.05, p=0.0001). Hereby, area reduction of the ideal prosthesis surface of 67.8±6.7% was observed for the CoreValve vs. 80.0±9.3% for the Edwards-SAPIEN prosthesis p<0.0001. A significant association was observed between the total extent of the native valve calcification as well as between the distribution of the calcification with postprocedural prosthesis eccentricity (r=0.54, p=0.01 and r=0.46, p=0.03, respectively). Furthermore, a significant association was observed between postprocedural valve eccentricity and paravalvular regurgitation (r=0.5; p=0.009). Both associations were observed for CoreValve but not for the Edwards-SAPIEN prosthesis. Using multivariable analysis, the extent and in particular the distribution of calcification in the native valve were significant predictors for postprocedural regurgitation independent of the perimeter of the aortic annulus and of the size of the implanted CoreValve prosthesis (r=0.45, p<0.05 and r=0.60, p=0.02, respectively). In case of the Edwards prostheses no such associations were observed.

Conclusions: The extent as well as the distribution of native aortic annulus calcification is predictive for postprocedural prosthesis eccentricity and paravalvular regurgitation, which is an important marker for long-term mortality in patients undergoing TAVI. This observation applies for the Medtronic CoreValve but not for the Edwards-SAPIEN valve.

Mitral valve assessment through multidetector: computed tomography in patients undergoing transfemoral aortic self-expandable valve implantation with simultaneous mitral regurgitation

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Aims: Indication of percutaneous aortic valve implantation (TAVI) when simultaneous presence of moderate-to-severe mitral regurgitation (MR) occurs is subject of debate. Albeit CT is routinely performed to TAVI candidates in many centres, the potential usefulness of this tool to decide which patients with double valvulopathy may benefit from isolated TAVI is unknown.

Methods and results: We analysed 64 patients treated with transfemoral self-expandable aortic prosthesis according to the baseline degree of their MR. All clinical and procedural variables were prospectively recorded. An off-line analysis of echocardiografic and multidetector non-gated CT images, including separate annulus and leaflets semi-quantitative analysis of calcium degree ranging from 0=none to 3=severe, was performed in order to determine predictors of its improvement. Mean age was 82±6 years, STS-score 7.42±5.3%, and logEuroSCORE 14.73±8.59%. Patients with moderate-to-severe mitral regurgitation (20 patients, 31.25%) presented a worse baseline profile (STS-score 10.3±6.7% vs. 6.2±4.1, p=0.013), and worse left ventricule ejection fraction (46.8±15.1 vs. 60.1±22.5, p=0.001). Baseline NYHA functional class was ≥3 in 70% vs. 59% (p=0.470). Median systolic pressure of pulmonary artery was 54 (IQR: 41-59) vs. 37 (IQR: 23-50) mmHg, p<0.001. They neither exhibite significant diferences concerning in-hospital mortality (15% vs. 4.5%, p=0.170), nor at long-term. In 10 patients (50%) MR degree improved to mild or none. The predictors of MR improvement were: median STS-score (10.3% [IQR:6.4-16-5] vs. 5.05% [IQR:3.8-7.1], p=0.009), body mass index (22.7±3.5 vs. 26.4±3.9, p=0.046), absence of left bundle brunch block (80% vs. 20%, p=0.007), median AVA at baseline (0.63 (IQR:0.5-0,7) vs. (0.75 (IQR:0.7-0.8), p=0.004), degree of leaflets calcification (by CT), and mitral annuls size (by echo and CT). A 10% of the patients with improvement in the MR degree had moderate-severe leaflets calcification by CT, as compared to 60% of those remaining at high MR degree (p=0.05). Annulus size as measured in four-chamber view was also larger (40.0±4.17 mm) than in those who experienced MR improvement with 34.1±3.0 mm, p=0.002. Receiver operator characteristics curve analysis offered 35.85 mm as the best sensibility (90%) and specificity (90%) cut-off value to determine improvement in the MR degree, 95% CI 0.91 (0.78-1.00), p=0.002.

Conclusions: Patients with severe aortic stenosis treated with self-expandable TAVI who suffer from simultanous moderate-to-severe MR had a worse baseline profile but not higher mortality. Half of them had a significant reduction in the degree of MR which was related to lower mitral leaftlets calcification and lower annulus size as measured by CT.

Interventions for structural heart disease – *Tuesday May 21st*
Various imaging techniques for TAVI procedures

Impact of automated 3-dimensional aortic annular assessment by multidetecter computed tomography in TAVI

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Aims: This study was sought to evaluate the accuracy, reproducibility and predictive value for post-procedural aortic regurgitation (AR) of a novel automated multidetector row computed tomography (MDCT) post-processing imaging software, 3mensio Valves (version 5.1.sp1, Medical Imaging BV, Bilthoven, The Netherlands), in the assessment of patients undergoing transcatheter aortic valve implantation (TAVI).

Methods and results: One hundred five patients who underwent screening MDCT before TAVI were evaluated. Aortic annular measurement and the discrimination value for post-procedural AR were compared between automated 3mensio Valves software and manual data post-processing software dedicated workstation (EBW; Philips Medical). For aortic annular measurement, the automated 3mensio Valves software required less image postprocessing time and showed good agreements with manual MDCT measurements as demonstrated by Bland-Altman analysis. The automated software had better inter- and intra-observer reproducibility especially for the measurement of aortic annulus area compared to manual measurement (intra-observer intraclass correlation coefficients 0.98 vs. 0.97, inter-observer 0.96 vs. 0.95). In 44 patients after implantation of self-expanding valve, Valve diameter/ the CT-measured geometric mean annulus diameter by automated 3mensio Valves software showed moderate and better discrimination ability in predicting post-procedural AR compared with manual measurement (area under the curve 0.77, 95% confidence interval 0.63 to 0.91, $p<0.01$, area under the curve 0.68, 95% confidence interval 0.50 to 0.86, $p=0.06$, respectively).

Conclusions: The automated 3mensio Valves software demonstrated reliable, reproducible aortic annulus measurement and better predictive value for post-procedural AR suggesting important clinical implications for preoperative assessments of patients undergoing TAVI.

Interventions for structural heart disease – *Tuesday May 21st*
Various imaging techniques for TAVI procedures

Feasibility and safety of computed tomography angiography-fluoroscopy fusion imaging for guidance of structural heart disease interventions within the catheterisation laboratory

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Aims: The integration of computed tomographic angiography imaging with fluoroscopy in the catheterisation laboratory, also known as computed tomographic angiography-fluoroscopy fusion imaging, now provides an alternative to traditional fluoroscopically-guided interventions for structural heart disease. The objective of this study is to assess the feasibility and safety of computed tomographic angiograph-fluoroscopy fusion imaging for structural heart intervention guidance.

Methods and results: We prospectively enrolled patients from August 2010 to December 2012 who had a pre-procedural helical computed tomographic angiography with multi-phase acquisition and retrospective ECG-gating and a structural heart disease intervention utilising computed tomographic angiography-fluoroscopy fusion imaging (HeartNavigator software, Philips, Best Netherlands) for procedural guidance. A total of 90 patients were evaluated who underwent the following fusion-guided access/interventions during a total of 104 procedures: transapical access (n=46), transseptal access (n=33), transfemoral access (n=29), transaortic access (n=5), paravalvular leak closure (n=55), TAVI (n=25), valve-in-valve implantation (n=14), pseudoaneurysm closure (n=5), ventricular septal defect closure (n=3), alcohol septal ablation (n=2), coarctation stenting (n=1), patent ductus arteriosus closure (n=1), and pulmonary artery stenting (n=1). Successful segmentation, registration, and overlay were performed in all cases. 15.4% of cases required contrast angiography for registration with the remainder registered to internal markers such as valve prosthesis, calcification, pacemaker/sternal wires, and bones. Technical procedural success was achieved for access and intervention in 99% and 95.8% respectively. No procedural complications related to fusion imaging were identified. Mean additional contrast and radiation exposure (computed tomographic dose index and dose-length product) of pre-procedural computed tomographic angiography was 80±24 cc, 37.1±16 mGy, and 1382.9±934 mGy*cm.

Conclusions: Computed tomographic angiography-fluoroscopy fusion imaging for guidance is feasible and safe with limited additional contrast and radiation exposure for a multitude of complex structural heart disease interventions. Further study on the validation of fusion imaging technology for structural heart interventions is required.

One year outcomes following TAVI for severe aortic stenosis in elderly patients with low left ventricular ejection fraction

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Aims: Low ejection fraction (EF) is a predictor of morbidity and mortality after surgical aortic valve replacement but little is known about its effect on clinical outcomes after transcatheter aortic valve implantation (TAVI). We sought to assess risks and benefits of TAVI with the SAPIEN XT valve (Edwards Lifesciences LLC) in elderly patients with aortic stenosis and low EF

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post-approval study, which enrolled >2,600 consecutive patients at 94 sites in 17 countries. A total of 157 patients (mean age 81.3±5.4 years), were identified with low EF≤30% (LowEF group), and 2,142 patients (mean age 81.7±5.8 years) with EF>30% (EF>30 group) served as controls. Endpoints are defined per VARC. One-year clinical and echocardiographic data are being collected and will be adjudicated and analysed by PCR. Compared to EF>30 group, LowEF patients were more likely to be male (42.9% vs. 68.8%, p<0.0001), had more severe symptoms (NYHA III/IV; 77.0% vs. 90.4, p<0.0001) and a greater STS score (8.4±7.0 vs. 9.5±6.1, p=0.042). Low EF patients had significantly higher incidence of congestive heart failure, previous myocardial infarction (MI) or insulin-dependent diabetes. Effective orifice area was similar for the two groups (0.7±0.2 vs. 0.7±0.2 cm^2, p=0.41); however, mean gradient was significantly lower (34.1±12.4 mmHg vs. 47.5±16.3 mmHg, p<0.0001) and pulmonary pressure was significantly higher (51.2±13.1 mmHg vs. 44.7±14.9 mmHg, p<0.0001) in the LowEF group compared to the EF>30 group. At 30-day follow-up, overall mortality (10.2% vs. 6.1%, p=0.044), cardiac death (5.3% vs. 2.1%, p=0.017), and stroke (4.6% vs. 2.0%, p=0.036) were significantly higher in the LowEF group as compared to the EF>30 group. There were no significant differences between the two groups in terms of MI (1.3% vs. 0.6%, p=0.27), major vascular complications (1.9% vs. 1.7%, p=0.79), major bleeding events (9.0% vs. 7.3%, p=0.42) or newly onset atrial fibrillation (6.7% vs. 5.1%, p=0.42). NYHA functional class improved significantly at 30-day with majority of patients being in NYHA I/II (92.7% for LowEF group and 89.6% for EF>30 group, p=0.36). One-year data, including multivariate predictions of mortality, will be available by the time of PCR.

Conclusions: Low EF in patients undergoing TAVI was associated with significant co-morbidity at baseline and increased mortality and stroke at 30-day follow-up; however, functional NYHA class improvement and periprocedural complications were similar to patients with EF>30%. One-year data will help to further understand the risk of low EF in patients undergoing TAVI and identify factors needed to optimise the outcomes.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI: predictors of clinical outcomes

One year outcomes after TAVI in patients with severe aortic stenosis and moderate or severe mitral regurgitation

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Aims: Moderate and severe mitral regurgitation (MR) is associated with higher mortality in patients with congestive heart failure (CHF) but little is known about its impact on outcomes in patients with severe aortic stenosis undergoing TAVI. Isolated surgical aortic valve replacement generally has a positive impact on functional MR but the effect of TAVI is not well understood. We sought to assess the effect of MR on clinical outcomes after the implantation of a transcatheter SAPIEN XT valve (Edwards Lifesciences, LLC), and analyse the impact of TAVI on MR.

Methods and results: The SOURCE XT is a multicentre, prospective, post approval study, which enrolled more than 2,600 consecutive patients at 94 sites in 17 countries. A total of 968 patients (36.8%) did not have any MR at baseline; 1,144 patients (43.5%) had mild MR, 461 patients (17.5%) had moderate MR, and 56 patients (2.1%) had severe MR. Patients with moderate or severe MR were included in the MR group (MR, n=517) and those with none or mild MR were included in the control group (Controls, n=2,112). Compared to the Controls, patients in the MR group were slightly older (82.3±5.4 vs. 81.6±5.9, p=0.0148), more likely to be female (63.1% vs. 56.5%, p=0.0073), had more severe symptoms (NYHA class III/IV; 81.4 vs. 75.9%, p=0.0073) and a higher STS score (10±8.3 vs. 8.1±6.6, p<0.0001). MR patients had significantly higher incidence of CHF, atrial fibrillation or renal insufficiency. Mean gradient was similar for the two groups (47.5±17.0 vs. 47.3±20.1 mmHg, p=0.81); however EF was significantly lower (50.1±12.0% vs. 53.0±11.2%, p<0.0001) and pulmonary pressure was significantly higher (50.5±16.0 mmHg vs. 43.3±14.1 mmHg, p<0.0001) in the MR group vs. Controls. At 30-day follow-up, there were no significant differences between the two groups in terms of overall mortality (7.2% vs. 5.9%, p=0.28), cardiac death (2.5% vs. 2.2%, p=0.64) or stroke (1.2% vs. 2.6%, p=0.0627). One month after TAVI, MR had improved by at least 1 degree in 30.4% of patients with any MR at baseline and in 66% of patients with moderate or severe MR. Functional NYHA class improvement was similar for the two groups. One year data will be available by the time of PCR including multivariate predictions of mortality and changes in MR

Conclusions: Patients undergoing TAVI with concomitant moderate or severe MR had a worse risk profile than patients with no significant MR but similar 30-day mortality. MR improved in 2/3 of patients early after the procedure. One year data will help to further understand the benefit of TAVI for patients with significant pre-procedural MR.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI: predictors of clinical outcomes

The new treatment strategy of transcatheter aortic valve implantation for patients with small body surface area

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Aims: Transcatheter aortic valve implantation (TAVI) is a hot topic in cardiovascular field. However, western anatomical criteria of TAVI is golden standard but we need to elucidate the new treatment strategy of TAVI for the patients with small body surface area (BSA) like Asian. In this study, we verified anatomical indications of TAVI in our institute retrospectively.

Methods and results: Between 2009 and 2012, we performed TAVI using Edwards-SAPIEN valve in our institute in 52 consecutive patients with severe aortic stenosis (age, 83.0±5.4 years; male, 42.3%; STS score, 10.1±7.0%). Aortic valve area and mean PG were 0.62±0.20 cm^2 and 59.4±18.5 mmHg, respectively. BSA was remarkably small (1.44±0.14 cm^2: 1.08-1.73 cm^2). We have measured aortic root constructions including annular diameter using electrocardiogram-gated multi-slice computed tomography and aortic root constructions were significantly smaller than previous reports (valsalva height, 18.8±2.0 mm; cusp length, 12.7±2.0 mm; distance between the annulus and coronary orifice, 12.7±1.3 mm). Furthermore, mean diameter of femoral artery was 6.06 mm. Therefore, we established strict CT sizing guidelines, including valve selection and balloon regulation, based on the results from our series (i.e., when the aortic annular diameter derived from CT is 24.0 mm, a 26-mm valve is selected with the balloon volume reduced by 1 mL). Device success and several complications including vascular access site and access-related complications were evaluated by the Valve Academic Research Consortium-2 (VARC-2) criteria. We performed TAVI via trans-femoral approach (TF) in 19 patients, trans-iliac approach (TI) in 12 patients, and trans-apical approach (TA) in 21 patients according to the femoral and iliac diameter. 23-mm Edwards-SAPIEN was implanted in 39 patients (75.0%). Device success rate was 98.1%. Periprocedural myocardial infarction occurred in two patients (3.8%) via TA approach. Both cases, which were caused by disproportionate relationship between small valsalva and relatively large cusps (left coronary valsalva height of 14.4 mm and left coronary cusp of 14.1 mm in one case), required additional percutaneous coronary intervention. Non-disabling stroke occurred in only one patient (1.9%) via TF approach. Vascular access site and access-related complications occurred in five patients (9.6%; additional intervention for bleeding of the femoral, iliac, and apical access site needed in 1 patient, 2 patients, and 1 patient, respectively. One needed additional intervention for dissection of the iliac access site). After TAVI, EOAI improved to 1.20±0.24 cm^2/m^2, and PPM was never found. Regarding mid-term results, all-cause mortality rate at 30-days and one-year with Kaplan-Meier analysis were 2.0% and 14.9%, respectively. Furthermore, cardiovascular mortality rate at 30-days and one-year with Kaplan-Meier analysis were 2.0% and 4.3%, respectively.

Conclusions: We achieved satisfactory procedural, early, and mid-term results of TAVI by using our strict and advanced indications of devices and balloon volume selection. To prevent the complications including vascular complication and coronary obstruction which tend to occur especially in small BSA patients, we need additional high volume and detailed study to decide the new treatment strategy of TAVI for patients with small vascular and cardiac anatomy like Asian.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI: predictors of clinical outcomes

Aortic regurgitation after TAVI with balloon-expandable and self-expandable prostheses: a pooled analysis from a two-centre experience

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Aims: Aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI) has been associated with poor survival. Limited data exist comparing trans-femoral TAVI with the self-expandable Medtronic CoreValve (MCV) vs. balloon-expandable Edwards SAPIEN XT (ESV) valve.

Methods and results: We pooled the prospective TAVI databases of two centres in Germany to compare the incidence of AR between MCV vs. ESV. The primary endpoint was more-than-mild post-TAVI AR as assessed by echocardiography. We also assessed device success and survival within one year. Endpoints were adjudicated according to the Valve Academic Research Consortium criteria and analysed by unadjusted and propensity-score-adjusted models. A total of 394 patients were included, 276 patients were treated with the MCV and 118 patients with the ESV. The occurrence of more-than-mild AR after TAVI was significantly higher in the MCV group than in the ESV group (12.7% vs. 2.6%, p=0.002). This difference remained significant after propensity adjustment (adjusted odds ratio 4.59, 95% confidence interval 1.03-20.44). The occurrence of any degree of AR was also higher in the MCV group (71.6% vs. 56.9%, p=0.004). Device success was mainly influenced by the occurrence of post-TAVI AR and was consequently higher with ESV compared to MCV (95.8% vs. 86.6%, p=0.007). At one year, survival was not significantly different between both valve types (83.8% MCV vs. 88.2% ESV, p=0.42), but was significantly worse in patients with more-than-mild vs. no/mild post-TAVI AR (69.8% vs. 87.4%, p=0.004) and in those with device failure (65.6% vs. 87.4%, p<0.001).

Conclusions: In this two-centre experience, more-than-mild AR after TAVI was more frequent with MCV compared to ESV. Consequently, device success was more frequent with ESV. Both more-than-mild AR after TAVI and device failure were associated with higher mortality at one year.

Predictors of late mortality in 201 patients with more-than-mild aortic regurgitation after TAVI: an analysis from the multicentre German TAVI registry

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Aims: More-than-mild aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI) has been associated with increased mortality. Nevertheless, a considerable proportion of these patients survive and appear to tolerate AR. Identification of patients at higher risk of death may assist in tailoring therapy, but predictors of mortality in this subset of patients are largely unknown.

Methods and results: A total of 1432 patients treated with TAVI at 27 hospitals were included in the German TAVI registry. One year follow-up data were available for 1318 patients (92%). Of the latter, 201 patients (15.2%) had significant (more-than-mild) AR after TAVI as evaluated by post-procedural supra-aortic angiography. Among these patients, baseline demographic, clinical, echocardiographic and angiographic characteristics were compared among survivors and non-survivors to identify factors associated with mortality at one year. The study population's mean age was 81.2±6.6 years and men represented 55%. The mean logistic EuroSCORE was 22±15%. Overall, 92% of patients received the Medtronic CoreValve system and 8% received the Edwards Sapien valve. At one year, 61 patients (31%) with significant post-TAVI AR had died. Compared to patients who survived, patients who died had more commonly significant coronary artery disease (73% vs. 55%, p<0.05), peripheral arterial disease (34% vs. 17%, p<0.01) and chronic renal impairment (69% vs. 50%, p<0.05). Patients who died had a lower baseline left ventricular ejection fraction (44±18% vs. 52±16%, p<0.01), higher prevalence of more-than-mild (≥2+) mitral regurgitation (44% vs. 27%, p<0.05), and a higher systolic pulmonary artery pressure (51±18 vs. 44±19 mmHg, p<0.01), but the severity of aortic stenosis was similar, and the prevalence and severity of pre-TAVI AR was comparable (any AR in 88% vs. 83%, respectively, p=0.29). The baseline logistic EuroSCORE was higher in non-survivors (29±17 vs. 20±13%, p<0.001). Using Cox regression analysis, only baseline mitral regurgitation ≥2+ (hazard ratio [HR] 1.75, 95% confidence interval [CI] 1.04.-2.93, p=0.03) and systolic pulmonary artery pressure (HR 1.01, 95% CI 1.00-1.03, p=0.03) were independently associated with one-year mortality, while female gender tended to be protective (HR 0.58, 95% CI 0.33-1.03, p=0.06).

Conclusions: In patients with more-than-mild AR after TAVI, pre-existing AR is not protective, whereas more-than-mild pre-procedural mitral regurgitation and an elevated pulmonary artery pressure are independently associated with one-year mortality.

Impact of pulmonary hypertension on outcome after TAVI

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Aims: Pulmonary Hypertension (PH) is a significant risk factor in patients with severe aortic stenosis (AS) undergoing surgical aortic valve replacement. However, the prognostic implication of PH is unclear in high-risk patients with AS undergoing Transcatheter Aortic Valve Implantation (TAVI). Therefore, we sought to assess the impact of preoperative PH on outcome after TAVI based on data of the German Aortic Valve Interventions Registry.

Methods and results: Between January 2009 and June 2010, a total of 1285 patients undergoing TAVI were included in this registry (mean age 81.7±6.1, 41.9% males). Patients were grouped according to systolic pulmonary artery pressure (PASP): group I, 277 patients, (21.6%) with PASP<30 mmHg, group II, 598 patients (46.5%) with PASP 30-50 mmHg and group III, 410 patients (31.9%) with PASP>50 mmHg. Patients in group III had a significantly higher Euroscore (26±16 mmHG vs. group I 18±11 mmHg vs. group II 18±11 mmHg; p<0.0001) and were more symptomatic with significantly more patients presenting in NYHA class IV (28.5% vs. group I 13.6% vs. group II 8.3%; p<0.0001). In all subgroups the majority of TAVI-procedures was performed transfemorally with a high procedural success rate. The rate of TAVI-associated complications was comparable in all groups (cerebrovascular accident: group I 3.3% vs. group II 3.9% vs. group III 2.0%, p=0.25; permanent pacemaker: group I 33.8% vs. group II 38.1% vs. group III 35.2%, p=0.24). Functional NYHA class and survival at 30 days demonstrated excellent outcome in all groups irrespective of PA pressure (30-day survival group I: 91.2% vs. group II 93.0% vs. group III 91.9%; p=0.59). All subgroups experienced a significant improvement of self-assessed quality-of-life (according to EuroQol5d-visual analogue scale) with the largest gain in group III (0.112±0.35 vs. group I 0.055±0.32 vs. group II 0.04±0.32; p=0.15).

Conclusions: In conclusion, non-surgical patients with severe AS have a high prevalence of PH. However, based on the registry data this condition does not increase complication rate and early mortality after TAVI. Patients with PH benefit from the procedure with functional improvement and significantly improved postoperative quality-of-life.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI: predictors of clinical outcomes

Impact of diabetes on early and mid-term Valvular academic research consortium outcomes in TAVI patients: insights from a multicentre registry

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Aims: Several factors have been identified as predictors of early and midterm events after TAVI, but the impact of diabetes on outcomes, especially if insulin dependent, showed contrasting results. The aims of this study are to evaluate the clinical characteristics and the early and mid-term VARC outcomes of diabetic patients undergoing TAVI.

Methods and results: All consecutive patients undergoing TAVI at our institutions were enrolled, and divided according to diabetes status. All cause mortality at 30 days and at follow-up was the primary end point, while periprocedural complications, rate of cardiovascular mortality, myocardial infarction, stroke, re-intervention at follow-up were secondary outcomes. All end points were adjudicated according to VARC. 511 patients were enrolled; 78 with orally treated/diet controlled diabetes, 72 with insulin treated diabetes and 361 without diabetes. Patients with orally treated diabetes were more frequently female and patients with insulin treated diabetes were younger. 30 days mortality was not significantly higher in patients with orally treated diabetes (6.4%) and insulin treated diabetes (9.7%) compared with not diabetic patients (4.7%, p=0.73 and 0.1 respectively). Bleedings, vascular complications, post procedural acute kidney injury and peri-procedural stroke were not significantly different in the three groups. At a median follow-up of 400 days (IQR 178-715) patients with insulin treated diabetes had a significantly higher all cause morality rate (33.3% vs. 18.6%, p=0.008), and higher myocardial infarction incidence (8.3% vs. 1.4%, p=0.004) when compared with patients without diabetes. Stroke, cardiovascular mortality and re-interventions at follow-up were similar in the three groups. After multivariable adjustment insulin treated diabetes was independently correlated with death (HR 1.75, 95% CI 1.1-2.8) and myocardial infarction (HR 5.6, 95% CI 1.5-20.5).

Conclusions: Diabetes doesn't significantly affect rates of complications in TAVI patients. Insulin treated diabetes, but not orally treated diabetes, is independently associated with deaths and myocardial infarction at mid term follow-up.

Interventions for structural heart disease – *Tuesday May 21st*
TAVI: predictors of clinical outcomes

Prevalence, invasive haemodynamic characteristics and clinical outcomes of patients with 'paradoxical' low flow, low gradient severe aortic stenosis with preserved ejection fraction undergoing TAVI

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Aims: We aimed to assess the prevalence, invasive haemodynamic characteristics and clinical outcomes of patients with "paradoxical" low flow, low gradient severe aortic stenosis (AS) with preserved ejection fraction (EF) undergoing TAVI.

Methods and results: Out of 533 consecutive patients with severe native valve AS (indexed aortic valve area ≤0.6 $cm^2.m^{-2}$) undergoing TAVI at our institution between August 2007 and August 2012, we studied 263 symptomatic patients with a normal EF (≥50%) who had a right and left heart catheterisation with aortic valve crossing prior to TAVI (53% treated with CoreValve, 46% with Edwards SAPIEN and 1% with Symetis ACCURATE valve). Patients were stratified by flow and gradient into the following 4 groups (low flow defined as a stroke volume index [SVI] ≤35 $ml.m^{-2}$ and low gradient as a mean gradient ≤40 mmHg): group 1, normal flow and high gradient (NFHG; n=36 [13.7%]), group 2, normal flow, low gradient (NFLG; n=19 [7.2%]), group 3, low flow, high gradient (LFHG; n=123 [46.8%]) and group 4, "paradoxical" low flow, low gradient (LFLG; n=85 [32.3%]). The primary endpoint was cardiovascular death at 30-days and 1 year and the secondary endpoint was the change in New York Heart Association (NYHA) functional status at 1 year follow-up compared with baseline. As compared with NFHG, patients with "paradoxical" LFLG were more frequently female (33.3% vs. 55.3%, p=0.04) had a higher afterload (systemic vascular resistance=1395.91±421.99 vs. 2006.65±586.92 $dyne.s.cm^{-5}$, systemic arterial compliance=0.61±0.22 vs. 0.39±0.13 $mL.mmHg^{-1}.m^2$, valvulo-arterial impedance=5.06±0.94 vs. 6.94±1.88 mm $Hg.mL^{-1}.m^{-2}$, p<0.001 for all), a lower left ventricular EF (63.08±6.05 vs. 60.25±6.53%, p=0.03), a lower cardiac output (5.05±0.86 vs. 3.72±0.74 $L.min^{-1}$, p<0.001) and a similar indexed aortic valve area (0.35 vs. 0.34, p=0.57). In addition, patients with paradoxical LFLG were at borderline significant higher surgical risk (Society for Thoracic Surgeons Score: 5.2±2.93 vs. 6.49±3.4, p=0.051). No significant differences in cardiovascular mortality were observed at 30 days (NFHG: 5.7% vs. NFLG: 5.3% vs. LFHG: 7.7% vs. LFLG: 4.9%, p=0.97) or at 1 year (NFHG: 11% vs. NFLG: 5.3% vs. LFHG: 9.9% vs. LFLG: 4.9%, p=0.94). Based on the NYHA functional classification system, 70.6%, 42.9%, 65.3% and 71.7% in NFHG, NFLG, LFHG and "paradoxical"LFLG groups, respectively, improved by at least one NYHA level at one year follow-up compared with baseline.

Conclusions: "Paradoxical" LFLG AS was observed in one third of patients with preserved EF undergoing TAVI and was associated with high afterload. These patients derived similar symptomatic benefit to patients with high gradient aortic stenosis after TAVI, despite being at a more advanced stage of their disease. Symptomatic eligible patients with "paradoxical" LFLG severe AS should be considered for TAVI despite a low transvalvular mean gradient.

MitraClip therapy in patients with functional or degenerative mitral regurgitation: a single-centre clinical experience

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Aims: The MitraClip device (Abbott Vascular, Menlo Park, CA) is an emerging percutaneous procedure to treat both functional and degenerative mitral regurgitation (FMR & DMR). This procedure is generally indicated for patients who are not eligible for surgical treatment, because of a high surgical risk. Nevertheless, MitraClip procedure is largely safe, well-tolerated and effective. We report mid-term outcomes of MitraClip implantation in inoperable or high-risk surgical candidates with both FMR & DMR.

Methods and results: From October 2008 to October 2012, 136 patients were treated in our institution (mean age 71.5±10.8 years, male gender 77.2%). All patients were periodically followed-up: mean follow-up time was 15.3±12.4 months, median 11.5 months, interquartile range (IQR) 5-23.6 months, minimum 0.1 month maximum 48.3 months. In 98 patients (72%) the mechanism of MR was functional (FMR), where in 75.5% was attributable to ischaemic reason and 24.5% was idiopathic, while it was degenerative (DMR) in 38 (28%). The following mean surgical risk scores were calculated: LogEuroSCORE (21.3±15%), STS Mortality (10.9±9.7%) and STS Morbidity and Mortality (45.6±23.6%). At admission, 77.2% of patients were in NYHA class III or IV. Median proBNP value was 1895 pg/ml (IQR 1064.1-3531) and was higher in FMR patients (2508 pg/ml, p-value <0.001). Main comorbidities were: chronic renal failure (48.5%), chronic obstructive lung disease (29.4%), peripheral vascular disease (19.1%), cerebrovascular disease (10.3%). All patients underwent standardised assessment of mitral valve anatomy by 3D-transoesophageal echocardiogram. EVEREST clinical and anatomical criteria were fulfilled in 47.1%, mean EF value was 36.6±17.3, LVEDD 65.7±9.5, VLESD 49.5±11,9, PAPs 48.1±15,2. Procedural success (MR ≤2+) was achieved in 92.6%. Mean procedural time was 100.6±47,02 minutes. It was 117.3±52.1in the first 50 treated patients and 88.2±45.5 in the last 50. Most patients (87, 64.0%) received two clips, while one clip was used in 44 cases (32.3%) and three clips in 5 (3.7%). Median length of stay was 4.8 days (IQR 3.8-7 day). 30-day mortality was 2.2% (3 pt); post-procedural adverse events included: renal failure (19.8%), IABP (11.4%), blood transfusion (11.4%), infections (3.7%). Notably, there were no cerebrovascular events (0%) or AMI (0%). At discharge, MR was ≤2+in 88.2% of patients (with no difference between FMR and DMR p-value=0,43). Actuarial survival at 12 months was 89±2.9% in the overall population, not significantly different in two groups (DMR 89.5±5%, FMR 87,4±4%; p-value=0.25). At 12 months follow-up, EF was 41.9±14.4% (significantly increased compared with pre-procedure value; p-value=0.03), freedom from MR>2+ was 74.4±3.9% (DMR 76.2±7.9, FMR 79.2±4.6; p-value=0.7). At latest follow-up, 87.7% of patients were in NYHA class I and II. Overall MR reduction (pre-procedure vs. latest follow-up) was: 0 in 2.4%, 1+ in 17.1%, 2+ in 37.8%, 3+ in 36.6% and 4+ in 6.1%.

Conclusions: MitraClip is a safe and effective procedure in high risk patients with FMR and DMR. Improvement of functional status is stable overtime and MR reduction is durable in most patients.

Thirty-day and 1 year safety and efficacy outcomes of patients undergoing edge-to-edge percutaneous mitral valve repair (from the GRASP registry)

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Aims: The aim of this study was to report the 30-day and 1-year outcomes of percutaneous mitral valve repair with the Mitraclip technique in patients with grade ≥3+mitral regurgitation (MR) enrolled in the prospective GRASP (Getting Reduction of mitrAl inSufficiency by Percutaneous clip implantation) registry

Methods and results: Acute device success was defined as residual MR ≤2+after clip implantation. The primary safety endpoint was the rate of major adverse events (MAEs) at 30 days. The primary efficacy endpoint was freedom from death, surgery for mitral-valve dysfunction, or grade ≥3+ MR at 30-days and 1 year. A total of 117 patients were treated. Eighty-nine patients (76%) presented with functional MR and 28 patients (24%) with organic MR. Acute device success was observed in all patients. Device implantation time significantly diminished with experience and varied significantly between cases with one vs. ≥2 clips. No procedural mortality was recorded. MAEs occurred in four patients at 30 days (4.3%). Deterioration to MR ≥3+ was recorded in 25% of degenerative MR and 7% of functional MR at 1 year. No surgery for mitral-valve dysfunction occurred within 1 year. Freedom from death, surgery for mitral-valve dysfunction, or grade ≥3+ mitral regurgitation was 96.4% and 75.8% at 30 days and 1 year, respectively. No significant differences were noted in the primary efficacy endpoint between patients with degenerative MR and those with functional MR.

Conclusions: Percutaneous mitral valve repair with the Mitraclip technique was shown to be safe and reasonably effective in 117 patients from a real-world setting.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous mitral valve repair with the MitralClip system: determinants of outcome

Echocardiographic analysis of left cardiac chambers reverse remodeling after MitraClip implantation in functional mitral regurgitation

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Aims: Percutaneous mitral valve repair for mitral regurgitation (MR) can be performed with the MitraClip System. This procedure has been demonstrated to be feasible and safe in high-surgical-risk patients, leading to reduction in MR severity and improvement in clinical status and quality of life. Our aim was to analyse the echocardiographic results in terms of left cardiac chambers reverse remodeling in patients with functional MR.

Methods and results: Between November 2009 and December 2012, mitral repair with the MitraClip device was successfully performed in high-surgical-risk patients with severe functional mitral regurgitation. All patientsunderwent clinical and echocardiographic follow-up at discharge (t1), 1 (t2) and 6 months (t3). Changes in echocardiographic parameters from baseline to follow-up were analysed with repeated measures ANOVA. Reverse remodeling was defined as decrease of 10% in the LV end-diastolic volume. The study population included 43 patients with functional mitral regurgitation. Acute device success was achieved in 40 patients (93%). Three patients experienced partial detachment of a single clip before discharge, with restoration of the initial grade 3 MR, and only 1 of them underwent percutaneous re-implantation. The 34 patients reaching the 6-month follow-up were evaluated in the present analysis. Patients with MR grade ≥3+were 6.2%, 11.8% and 13.6% at discharge, 1 and 6 months, respectively ($p<0.0001$) vs. 100% at baseline (t0), with a significant reduction in mitral regurgitation fraction (from 66.5±13.9%, to 43.7±15.3%, 54.3±20.9% and 38±8.7% respectively; $p=0.001$). Improvements in LV size and function were also observed. At t0, t1, t2 and t3, respectively, the LV end-diastolic diameter was 66.4±10.6 mm, 63.9±10.5 mm, 63.1±10.7 mm and 62.6±11.1 mm ($p<0.0001$), the LV end-systolic diameter was 52±12.4 mm, 49.3±12.2 mm, 49.1±12 mm and 46.5±12.2 mm ($p=0.03$), the LV end-diastolic volume 195.3±69.8 ml, 177.9±69.4 ml,174.3±74.3 ml and168.1±74.7 ml ($p<0.0001$), the LV end-systolic volume 125.6±60 ml, 114.2±54.9 ml,110.7±58.1 ml and100.6±62.8 ml ($p<0.0001$), the LV ejection fraction 36.5±11.6%, 38.8±9.4%,38.1±9.6%, and41.7±10.4% ($p=0.008$). During follow-up, a significant reduction in the LV sphericity index was observed from the baseline value of 0.74±0.11 to 0.72±0.11 and 0.71±0.12 at 1 and 6 months respectively($p=0.02$). Minor differences in LV eccentricity index were obtained with improvement between discharge and 1-month follow-up (from 0.65±0.11 to 0.68±0.12; $p=0.04$). Moreover, we observed left atrial reverse remodeling with significant decrease in atrial volume: from 115.1±56.1 ml, to 92.9±25.7 ml, 104.3±47 ml and 101.6±36 ml at t0, t1, t2 and t3, respectively ($p<0.0001$). Reverse remodeling was observed in 65.6% and 54.5% of patients at the 1- and 6-month follow-up. Furthermore, the systolic pulmonary artery pressure decreased significantly from baseline to follow-up (from 50.2±6.9 mmHg (t0), to 39.7±6.8 mmHg (t1),40.0±10.7 mmHg (t2), and 37.1±6.9 mmHg (t3); $p<0.0001$) and a marked clinical benefit was observed. with 88.9% and 86.4% of patients in NYHA class ≤2 at 1 and 6 months. respectively. vs. 26.3% at baseline ($P<0.0001$).

Conclusions: The present analysis reports significant left cardiac chambers reverse remodeling associated with improvements in functional parameters and clinical status in high risk patients with functional MR after mitral valve repair with the MitraClip System.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous mitral valve repair with the MitralClip system: determinants of outcome

Haemodynamic impact of residual interatrial communication after transcatheter treatment of mitral regurgitation

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Aims: The Mitraclip® (Abbott, USA) procedure needs trans-septal access of left atrium for placing the 22F guiding catheter. Because of the large diameter of the catheter there is often a residual interatrial communication of variable diameter with left to right shunt. Little is known about the haemodynamic impact of this shunt in the peculiar setting of severe left ventricular dysfunction.

Methods and results: 26 consecutive patients with severe mitral regurgitation at high risk for cardiac surgery underwent Mitraclip procedure. Mean age 77±6 years, Logistic Euroscore25±5%, all had severe mitral regurgitation, 20 were functional, 6 were degenerative, mean left ventricular ejection fraction was 25±7%has to be clarified, all procedures were performed under general anaesthesia except 4 who were treated under conscious sedation. After the guiding catheter removal the diameter of residual interatrial communication was measured in two orthogonal plane with trans-esofageal echocardiography, and a complete right and left heart catheterisation was performed. The follow-up consisted in echocardiographic assessment at 24 hours, 15 and 30 days. Twelve patients received two mitraclips, procedural success was 100%, the mean device time was 45±28 min, without complications or intraprocedural deaths. The mean diameter of the residual interatrial communication was 5 (rang 3 to 10 mm), the mean Qp/Qs was 1.2 (range 1.1 to 1.4), one patient developed right heart failure and underwent transcatheter closure 15 days with an Amplatzer Septal Occluder (St. Jude U.S.A), all the other patients showed a spontaneous reduction of the hole diameter.

Conclusions: The residual interatrial communication after trans-septal access with the Mitraclip Guiding Catheter is variable in diameters and entity of left to right shunt. The majority tend to reduce spontaneously, but the haemodynamic impact of left to right shunt in severely depressed left ventricles seems to be more than expected. Trans-catheter closure of these defects has to be considered when right heart failure signs occur.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous mitral valve repair with the MitralClip system: determinants of outcome

Seattle heart failure model prediction in MitraClip patients

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Aims: Transcatheter mitral valve repair with the Mitraclip System has emerged as a valid therapeutic option for high risk patients with severe symptomatic mitral regurgitation (MR). The aim of the study was to investigate the role of Seattle Heart Failure Model (SHFM) predictive value in MitraClip patients.

Methods and results: From October 2008 to December 2012, 144 consecutive patients with severe MR underwent Mitraclip implantation at our Institution. All patients underwent a prospective screening pathway, including baseline SHFM assessment for 1, 2 and 5-years mortality and mean life expenctancy (MLE). Available data of 135 patients regarding SHFM predicted mortality and MLE were compared to observed mortality. Pre-operative data included mean age 71.5±10.6 years, male gender in 104 patients (77.0%), mean weight 72.6±14.9kg, ischaemic etiology in 74 patients (54.8%), mean EF 36.0±16.9%, mean systolic blood pressure 118.4±14.8 mmHg, NYHA>II in 105 patients (77.8%), QRS>120msec in 60 patients (44.4%), median furosemide dosage 75 mg (IQR 50-125), ACE-I use in 81 patients (60.0%), ARB use in 23 (17.2%), beta-blockers in 92 (68.1%), statins in 61 (45.2%), allopurinol in 41 (30.4%), aldosterone-blocker in 63 (46.7%), ICD-only in 39 (29.1%) and CRT-ICD in 34 (25.4%). Overall actuarial survival after MitraClip was 74% at 32 months. Median SHFM predicted 1, 2 and 5-years mortality were significantly higher in functional rather than in degenerative patients, respectively: 12% (IQR 7-23) vs. 8% (IQR 6-15), p=0.013; 22% (IQR 13-40) vs. 15% (IQR 11-28), p=0.011; 46% (IQR 29-73) vs. 33% (IQR 25-56), p=0.015. Median estimated MLE was 6.2 (IQR 3.6-8.8) vs. 8.1 years (IQR 5.1-9.6) for functional and degenerative MR respectively, p=0.026. For functional MR, 1 and 2-years observed mortality was significantly reduced compared with predicted SHFM, respectively 9.1% (p=0.003) and 12.1% (p<0.0001). In degenerative setting no significant difference was observed between predicted and observed mortality: 11.1% at 1-year (p=0.49) and 22.2% at 2-years (p=0.36). Overall, 1-year predicted SHFM ranged from 2 to 99% and it was associated with increased 1-year observed mortality (overall p=0.0007, functional p=0.004, degenerative p=0.002): 1-year observed mortality for SHFM quartiles q1/4 (2-6%), q2/4 (7-11%), q3/4 (12-20%) and q 4/4 (21-99%) were respectively 2.8% (1/35), 5.4% (2/37), 5.7% (2/35) and 28.6% (8/28). Functional patients were distributed as follows in each quartile: 62.9%, 70.3%, 74.3%, 89.3% respectively in q1/4, q2/4, q3/4 and q4/4. In the "high risk" SHFM q4/4 pre-operative low end diastolic diameter (EDD) and 6-minute walk test (6MWT) distance were associated with an increased survival, respectively 65.1 vs. 74.8 mm (p=0.02) and 131.7 vs. 56.7 m (p=0.04). ROC curve analyses showed that EDD ≤75 mm and 6MWT ≥120m were significantly associated with improved survival at 1 year (respectively AUC 0.80, sensitivity 66.7%, specificity 88.9% and AUC 0.83, sensitivity 100%, specificity 66.7%). Multivariate analyses confirmed EDD as a predictor of 1-year survival (p=0.0035), and showed a trend towards better 1-year survival for higher baseline 6MWT distance (p=0.09).

Conclusions: Mitral valve repair using the Mitraclip System is associated with mid-term survival benefit in respect of SHFM prediction. Higher SHFM however is associated with higher mid-term mortality and it remains a valuable tool in MitraClip patients stratification. Lower EDD and longer 6MWT distance predict 1-year survival despite high SHFM.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous mitral valve repair with the MitralClip system: determinants of outcome

Echocardiographic and clinical outcomes of central vs. non-central percutaneous edge-to-edge mitral valve repair

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Aims: To assess the echocardiographic and clinical results of MitraClip implantation in non-central degenerative mitral regurgitation (MR) compared to those with central regurgitation.

Methods and results: Multicentre registry of 173 patients treated with MitraClip between 2009 and 2012. From them, 79 patients (age 79.2±8 years, 58.2% male) were found to have degenerative mitral regurgitation, and these were included in the present analysis. Forty-nine patients (62%) had central origin MR and the remainders were classified as non-central MR (n=30, 38%). Non-central group had more severe degrees of MR (vena-contracta 6.9±2.2 vs. 8.5±2 mm, p=0.039) and higher systolic pulmonary pressures (47.3±13 vs. 57.9±18 mmHg, p=0.019). Procedural success was similar between both groups (95.5% central vs. 96.7% non-central, p=0.866). At one month the degree of improvement in MR and NYHA class was similar between both groups (MR≤2 96.0% and 96.6%, p=0.866 and NYHA ≤II 81.6% vs. 90.0%, p=0.335). At 6-month follow-up similar results were observed with regard to reduction of MR (MR >2 4.8% central vs. 8.3% non-central, p=0.679). NYHA functional class did not differ between groups although tended to be better in non-central repair (NYHA class>II 21.1% vs. 0%. p=0.128 at 6-month). Survival curves showed no difference between groups with regard to death or heart failure admission (p=0.506).

Conclusions: In experienced centres, MitraClip treatment of non-central MR can be attempted safely and with equivalent efficacy to central MR.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous mitral valve repair with the MitralClip system: determinants of outcome

Midterm effects of the MitraClip procedure on the mitral valve geometry

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Aims: The MitraClip (MC) procedure has been shown effective for the reduction of relevant mitral valve regurgitation (MR) in high risk surgical patients. The durability of this therapy might be restricted by its limited approach on the MV leaflets. The aim of this prospective study was to examine the midterm effects of the MC therapy on MV geometry as measured with 3D echocardiography.

Methods and results: In 34 high risk surgical patients with moderate to severe functional (87%) and degenerative MR (17%) 2D and 3D echocardiography was performed before and 6 months after MC procedures. MV diameters (anterior-posterior [a-p], medial-lateral [m-l]) and perimeters were determined by using a dedicated MV analysis software. After FU 79% of patients experienced a significant reduction of functional NYHA-class ≥2, with 2D-echocardiography indicating a relevant reverse left-ventricular (LV) remodelling (EF 37.1±16.3 vs. 40.2±15.4%, p=0.01; LVVd 165.3±62.3 vs. 147.2±54.4ml, p=0.04). Interestingly, only the subgroup of patients with functional MR and evidence of reverse LV remodelling experienced a significant reduction of measurable MV dimensions (m-l-diameter: 5.1±0.4 vs. 4.4±0.6 cm, p=0.03; a-p-diameter: 4.6±0.5 vs. 4.2±0.6 cm, p=0.04; perimeter: 15.7±1.9 vs. 13.6±2.1 cm, p=0.01). A cut-off value of 15ml (LVVdbaseline-LVVDFU) was able to predict a reduction of MV perimeters >2 cm with high accuracy (AUC 0.91, p<0.001).

Conclusions: In this surgical high risk population a successful MitraClip procedure led to a clinical improvement in the majority of patients (79%). In patients with functional MR, reverse left ventricular remodelling was associated with a significant decrease of MV diameters after 6 months, which may support the durability of this procedure.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous mitral valve repair with the MitralClip system: determinants of outcome

Analysis of outcomes at 12 months by mitral regurgitation etiology in the ACCESS-EUROPE phase I study

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Aims: ACCESS-EUROPE Phase I (ACCESS-EU) is a prospective, observational, multicentre study designed to gain information regarding the use of the MitraClip System and to provide further evidence of the safety and effectiveness of the MitraClip System. ACCESS-EU Phase I enrollment started in 2008 and closed in April 2011. The last follow-up occurred on June 15, 2012. One-year results by etiology have not been reported.

Methods and results: Procedural data, safety results and clinical outcomes, defined by freedom from death, freedom from mitral valve surgery, and reduction in mitral regurgitation (MR), as well as improvements in NYHA Functional Class, Six Minute Walk Test, and Quality of Life data (Minnesota Living with Heart Failure Questionnaire) are reported at 1 year for functional (FMR) and degenerative (DMR) mitral regurgitation (MR). A total of 567 patients were treated with the MitraClip procedure in the ACCESS-EU study. The majority (77%) of patients had FMR and were elderly (mean age: FMR 73±9 years, DMR 76±12 years). FMR patients had significantly higher incidence of baseline co-morbidities, including: coronary artery disease (FMR 68%, DMR 41%), cardiomyopathy (FMR 54%, DMR 23%), diabetes (FMR 34%, DMR 15%), and moderate to severe renal disease (FMR 48%, DMR 26%). At baseline, 87% of FMR patients and 74% of DMR patients were in NYHA Functional Class III/IV; MR severity ≥3+ was present in 99% of FMR patients and 97% of DMR patients. Baseline LVEF <40% (FMR 66%, DMR 9%) and logistic EuroSCORE (FMR 25±19, DMR 16±13) were significantly different between the two etiologies. Despite these baseline differences, at one year, outcomes of freedom from death (FMR 82%, DMR 83%), freedom from MR>2+ (FMR 79%, DMR 75%), and freedom from mitral valve surgery (FMR 96%, DMR 95%) were similar between the two groups. The change in six minute walk distance at 1 year from baseline (FMR 51.6±114 meters, DMR 77.4±119 meters) and the proportion of patients in NYHA Class I/II at one year (FMR 70%, DMR 81%) improved significantly regardless of MR etiology. Significant improvements in Quality of Life scores were noted for both etiologies as evidenced by a difference of 13.5 and 13.3 points between Baseline and one year for FMR and DMR patients, respectively.

Conclusions: One-year results from the ACCESS-EU Phase I study in a real-world patient population demonstrate that despite significant differences in baseline characteristics, co-morbidities and surgical risk status, patients with either FMR or DMR etiology achieve significant reduction in MR and clinical benefits following percutaneous treatment with the MitraClip device, including symptomatic and functional improvement.

Forty-five day outcome of TAVI of the lowest profile pre-package and sterilised aortic valve in the world

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Aims: The 24 mm sized Colibri TAVI valve is pre-mounted and compressed upon its delivery balloon catheter at manufacture and is packaged ensheathed within a 14 French introducer, sterilised and ready for insertion into the patient. We report the results and early clinical follow-up of the first human implantaton of the Colibri Heart Valve pre-mounted, pre-packaged TAVI valve in an initial feasibility study.

Methods and results: An elderly, frail, hypertensive, bedbound female patient with minimal effort dyspnea and recurrent syncope (functional class 4) was referred for treatment. Echo-Doppler showed severe aortic stenosis with peak gradient=154 mmHg (mean 89 mmHg), aortic valve area (AVA)=0.7 cm^2 and preserved left ventricular ejection fraction of 60%. Surgical valve replacement was not available to her. The minimum diameter of the femoral arteries was approximately 5.0 mm, precluding transfemoral approach with available TAVI systems. The local institutional ethics board approved the procedure as a humanitarian application. Under general anaesthesia, the patient underwent implantation of the Colibri Heart valve in the cardiac catheterisation laboratory under flouroscopic and transesophageal echocardiographic guidance. The aortic mean gradient decreased to 12 mmHg and the AVA increased to 2.3 cm^2. Mild paravalvular insufficiency was identified. The patient experienced prompt symptomatic relief. Follow-up echocardiogram performed at 7 days showed trace aortic insufficiency and transvalvular mean gradient of 12 mmHg. The echocardiogram at 30 days showed no aortic insufficiency, the same mean gradient of 12 mmHg and AVA of 2.2 cm^2. At 45 days of clinical follow-up the patient was fully ambulatory with improving functional capacity.

Conclusions: Transfemoral implantation of the Colibri pre-mounted and pre-packaged transcatheter aortic valve in its 14 Fr delivery sheath is feasible and efficient. In the first human case of this type, clinical outcome 45 days after implantation showed sustained benefits. The further progress of this patient will be reported when available. This case suggests that the Colibri low profile, ready-to-use TAVI technology can provide procedural efficiencies and enable the transfemoral treatment of patients with small femoral arteries. Early follow-up results of this first patient implantation are thus far consistent with the expected benefits observed in the known TAVI experience.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous valve implantation: new valves and new indications

Improved aortic valve haemodynamics following TAVI with a novel, retrievable and fully repositionable device

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Aims: Transcatheter Aortic Valve Implantation (TAVI) is an established alternative to surgery for selected patients with severe symptomatic aortic stenosis. To date, published data regarding echocardiographic outcomes following TAVI have been derived from the two commercially available prostheses (Edwards THV and CoreValve ReValving System). Here we report detailed echocardiographic outcomes following TAVI with the novel Lotus Valve System (Boston Scientific, USA); a fully retrievable and repositionable TAVI device.

Methods and results: All patients undergoing TAVI with the Lotus Valve System as part of the multicentre REPRISE I clinical trial were included in this prospective study. Detailed quantitative echocardiography was performed according to ASE/VARC guidelines immediately prior to TAVI, at hospital discharge, 30days, 3- and 6-months post procedure. All data were analysed by a central echocardiography core laboratory. 11 consecutive patients (all female, age 83.0±3.6 years, mean EuroScore 9.5±4.4%, mean STS score 4.9±2.5% and significant frailty indices; cognitive dysfunction (45%), gait speed ≥6 s (82%), grip strength ≤18 kg (64%) were evaluated. Clinical procedural success was achieved in 82% (n=9), with one post-procedural stroke and one device failure by VARC criteria (mean AV gradient >20 mmHg) despite acceptable post-procedural AVA 1.6 cm^2. 6-month follow-up echo data was obtained in all patients. As expected, there was a significant reduction in mean aortic valve gradient (53.9±20.9 mmHg vs. 13.9±3.8 mmHg, $p<0.0001$) and an increase in estimated aortic valve area (0.68±0.19 cm^2 vs. 1.55±0.17 cm^2, $p<0.0001$) 180 days post procedure. At 6-months post TAVI, two patients had paravalvular aortic regurgitation (1 trivial, 1 mild) and there was no change in mitral regurgitation grade. Interestingly, there was a reduction in left atrial volume at 6-months (86.5±23.0 vs. 72.3±23.4, $p<0.0001$) but not estimated pulmonary artery pressure (peak TR jet velocity 2.9±0.6 vs. 2.8±0.3, p=NS). LV end-diastolic diameter and LV ejection fraction remained unchanged (p=NS).

Conclusions: TAVI with the Lotus Valve System is an effective therapy with improved aortic valve haemodynamics, increased estimated aortic valve area and a low incidence of post-procedural paravalvular aortic regurgitation. Left atrial volume is also reduced post TAVI, suggesting a reduction in mean left atrial pressure. Larger patient numbers are required to assess additional changes in cardiac structure and function.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous valve implantation: new valves and new indications

First report of one-year outcomes of the REPRISE I feasibility study of the repositionable Lotus Aortic Valve Replacement System

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Aims: Although transcatheter aortic valve implantation (TAVI) demonstrates promising outcomes in treating high-risk and inoperable patients with severe aortic stenosis, implantation of currently available TAVI devices is correlated with a higher risk of stroke, vascular complications and aortic regurgitation when compared with surgical valve replacement. The repositionable and fully retrievable Lotus Valve is designed to facilitate controlled, precise positioning and minimise paravalvular aortic regurgitation. Results to 12 months post-implantation have not yet been reported.

Methods and results: REPRISE I is a prospective, single-arm, 3-centre feasibility study designed to assess acute safety and performance of the 23 mm Lotus Valve in symptomatic patients with calcified aortic stenosis and high surgical risk. The Lotus Valve was implanted in 11 female patients with a mean Society of Thoracic Surgeons score of 4.9±2.5% and a mean logistic euroSCORE 9.5±4.4%. Two patients had medically treated diabetes and five had a history of coronary artery disease. All patients were confirmed by the Heart Team to be at high risk for surgery due to frailty or associated comorbidities (gait speed ≥6s [9/11], grip strength ≤18kg [7/11], and cognitive dysfunction [5/11; defined as a score <4 on the Mini-Cognitive Assessment for Dementia]). At baseline, 6 patients were New York Heart Association Class II and 5 were Class III. Clinical procedural success was achieved in 9/11 patients (due to a major ischaemic stroke in 1 patient and a mean post-procedure gradient of 22 mmHg, above the 20 mmHg Valve Academic Research Consortium threshold, in 1 patient). Partial resheathing and repositioning was performed in 4/4; no valves required full retrieval. There were no deaths, myocardial infarctions, or repeat procedures for valve-related dysfunction up to 3 months. The 3-month Valve Academic Research Consortium safety composite was 3/11 (2 patients with non-valve-related disabling bleeding, 1 with major ischaemic stroke and vascular complication). Conduction disturbance requiring a new pacemaker occurred in 4 patients (2 with complete atrioventricular block). Only 2 patients were pacemaker dependent at 3 months. New York Heart Association Class was significantly improved at 3 months post-implant with 7 patients in Class I, 3 in Class II, and 1 in Class III. Mean aortic gradient improved from 53.9±20.9 mmHg at baseline to 13.7±3.7 mmHg at discharge and 12.0±2.2 mHg at 3 months (P<0.001). Mean aortic valve area improved from 0.7±0.2 cm^2 at baseline to 1.5±0.2 cm^2 at discharge and 1.6±0.2 cm^2 at 3 months (P<0.001). Core laboratory adjudicated paravalvular aortic regurgitation was mild in 2 patients and absent in 9 patients at 3 months.

Conclusions: Three-month feasibility results suggest that the Lotus Valve can be positioned accurately and successfully with virtually no aortic regurgitation and low clinical event rates. One-year data from REPRISE I will be presented for the first time at EuroPCR 2013.

Interventions for structural heart disease – *Wednesday May 22nd*
Percutaneous valve implantation: new valves and new indications

Percutaneous transfemoral management of severe secondary tricuspid regurgitation with Edwards sapien XT bioprosthesis: first-in-man experience

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Aims: Severe tricuspid regurgitation (TR) is associated with increased morbidity and mortality. Here we describe feasibility, as well as periprocedural and short-term outcome of a novel first-in-man approach to implant the Edwards Sapien XT as inferior vena cava (IVC) valve (between the right atrium and the hepatic vein, "single valve") and in combination with a superior vena cava (SVC) valve ("dual valve").

Methods and results: Between July and September 2012 3 patients with severe symptomatic TR and contraindications to surgical repair were treated. 2 patients received a IVC single valve 1 patient dual IVC and SVC valve implantation. The single valve procedure was performed via the right femoral vein (20 F eSheat, Novaflex). First, we prepared a landing zone by implanting a self-expanding Stent in the IVC segment downstream of the RA. To further downsize the lumen we placed a second shorter stent in the upper part of the first stent. Then, a 29 mm Edwards Sapien XT valve mounted on the Novaflex delivery system was deployed under fluoroscopic and TEE guidance. In the dual valve procedure an additional Edwards Sapien XT was implanted in the SVC. RV angiography and echocardiography confirmed intact valve function without para-valvular leak or regurgitation in all cases. There were no periprocedural or in-hospital complications. Valve function remained excellent throughout the follow-up period. No valve regurgitation or leak was detected. Free drainage of hepatic veins with only antegrade flow into the ICV was demonstrated. At 30 days there were no events according to VARC criteria. All patients improved for at least one NYHA class and signs of right heart congestion decreased significantly. Of note, in all 3 patients RV function improved, RV and RA volumes as well as the diameter of the hepatic veins decreased.

Conclusions: In summary, percutaneous single or dual caval valve implantation with the Edwards Sapien XT for severe TR is feasible and safe. The major therapeutic effect of this procedure appears to be reduction of hepatic, abdominal, and peripheral venous congestion –leading to amelioration of right heart failure. Despite our very promising short-term results, further larger controlled trials are necessary to determine the impact of this novel interventional approach on morbidity and mortality in patients with severe TR and as a non-pharmacological tool in severe heart failure.

Implantation of a second-generation transcatheter heart valve in patients with non-calcified aortic regurgitation

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Aims: Efficacy and safety of transcatheter aortic valve implantation (TAVI) in patients with calcific aortic stenosis and high surgical risk have been demonstrated. However, experience with implantation for severe non-calcified aortic regurgitation has been limited due to increased risk for valve dislocation or annular rupture. We report on the feasibility and early results of TAVI employing a second generation device in a series of patients with pure aortic regurgitation.

Methods and results: Five patients (mean age 66.4±7.1 years) underwent transapical implantation of a JenaValve (JenaValve Technology GmbH, Munich, Germany) transcatheter heart valve for moderate to severe, non-calcified aortic regurgitation. All patients were considered high risk for surgical aortic valve replacement after evaluation by an interdisciplinary heart team (logistic EuroSCORE range 3.1-38.9%). Procedural and acute clinical outcomes were analysed. Implantation was successful in all cases without relevant remaining aortic regurgitation or signs of stenosis in any of the patients. No major device- or procedure-related adverse events occurred and all five patients were alive with improved exercise tolerance at 3-month follow-up.

Conclusions: Non-calcified aortic regurgitation continues to be a challenging pathology for TAVI due to the risk for insufficient anchoring of the valve stent within the aortic annulus. This report provides first evidence that the JenaValve prosthesis may be a reasonable option in these specific patients due to its unique stent design, clipping the native aortic valve leaflets, and offering promising early results.

Outcome of patients with left bundle branch block after TAVI

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Aims: We evaluated the prognostic impact of new-onset persistent left bundle branch block (LBBB) in patients undergoing TAVI

Methods and results: A total of 191 consecutive patients who underwent TAVI with balloon- expandable or self-expandable valves were included. Patients were on continuous electrocardiographic (ECG) monitoring during hospitalisation and 12-lead ECG was performed daily until discharge. Follow-up was complete at 12 months. New-onset LBBB was observed in 25.9% of the patients after TAVI, 13.8% during the procedure and 18% remained with LBBB after a year of follow-up. The overall rate of new onset LBBB after TAVI was 25.9%, among patients that Medtronic-CoreValve was implanted, 27.9% of them developed new LBBB and 22.4% of those who Edwards-Sapient valve was implanted. (p=0.4). One year mortality was 1% without LBBB vs. 0% in patient with LBBB at discharge, (p=NS). The need for a new pacemaker implant after TAVI was 0% in patients with LBBB vs. 1% among patients without new LBBB, (p=NS).

Conclusions: New onset LBBB occurred in ~14 of treated patients; it was associated with higher need for pacemaker implants but had no impact upon cardiac prognosis over one year.

Interventions for structural heart disease – *Wednesday May 22nd*
Conduction disturbances after TAVI

Low rate of conduction disturbances and the need for permanent pacemaker after TAVI with the core-valve bioprosthesis

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Aims: To evaluate the incidence of conduction disturbances and the need for pacemaker implantation at 30 days post TAVI using the Core-valve device.

Methods and results: We conducted a retrospective single-centre analysis in 120 consecutive patients who underwent TAVI procedure with MCV between 2009-2012. Patients with pre-existing pacemakers (n=22, 18%) were excluded from the final analysis. Trans-femoral approach was used in 86 patients (88%), while subclavian and direct aortic approaches were used in 5 and 7 patients respectively. Our data were compared to the UK Core-Valve (UK-C) trial results. The decision to implant PPM post procedure was determined according to current ACC/AHA guidelines for pacemaker insertion. Our study cohort included 98 patients. The mean age was 82.1±5.9, 60% were males. The mean logistic Euro-score II and STS score was 17.2±6.8 and 12.4±4.3 respectively. Baseline clinical characteristics, electrocardiographic parameters (including rhythm, left and right bundle branch blocks (LBBB/RBBB), PR interval and QRS duration) and the indications for TAVI in our patients were similar to the UK-C data. MCV 26 mm was implanted in 54% of our patients compared to 49% in the UK-C (p=0.47), while MCV 29 mm was implanted in 39% of our patients compared to 51% in the UK-C (p=0.06). The rate of patients with ≥2nd AVB after the procedure was 2% in our study compared to 23% in the UK-C (p<0.0001). The incidence of RBBB post procedure was similar in our series and the UK-C. However, the incidence of LBBB after the procedure was 34% in our study compared to 61% in the UK-C (P<0.0001). QRS duration post procedure was increased both in our patients and in the UK-C compared to baseline, nevertheless it was found to be significantly shorter in our study compare to the UK-C (120±29 vs. 135±29 msec, p<0.0001). Permanent pacemakers were implanted in 8 patients (8.2%) up to 30 days post procedure compare to 33% in the UK-C (p<0.0001). The maximal prosthesis depth in the LVOT was significantly shorter in our cohort compare to the UK-C (6.9±2.7 mm vs. 11.1±4, p<0.0001).

Conclusions: The occurrences of conduction disturbances (advanced AV block, LBBB and prolongation of the QRS duration) and the rate of pacemaker implantation post TAVI were significantly lower in our Core-valve device cohort than previously published reports. These differences are likely related to higher positioning of prosthesis implantation in the LVOT.

Interventions for structural heart disease – *Wednesday May 22nd*
Conduction disturbances after TAVI

Impact of conduction disturbances post TAVI in real world patients: one year outcomes - the advance study

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Aims: Transcatheter aortic valve implantation (TAVI) is now considered the standard of care in extreme risk patients with severe aortic stenosis and an alternative to surgery in those considered high risk. The CoreValve ADVANCE study evaluated the clinical benefits of the CoreValve system in a fully monitored, "real world" single-arm study performed at 44 centres in 12 countries in Western Europe, Asia and South America. TAVI, like surgical aortic valve replacement, has been associated with new conduction disturbances; however the impact of these conduction disturbances after TAVI is still being studied. Therefore, it was the aim of this analysis to assess the impact of conduction abnormalities on outcomes in patients in the ADVANCE study.

Methods and results: From March 2010 to July 2011, the ADVANCE study enrolled 1015 patients (mean age 81±6 years, 51% female, mean Logistic EuroSCORE 19±12%, New York Heart Association III/IV 80%) who were evaluated by the local Heart Teams. All primary endpoint-related events were fully adjudicated according to the Valve Academic Research Consortium definitions by an independent Clinical Events Committee. At 1-year, 82.1% of patients implanted with a CoreValve system in the ADVANCE study were alive. CoreValve system implantation was associated with the occurrence of new left bundle branch block in 41.8% of patients. There was no significant impact on patient survival due to a new left bundle branch block through 1-year (p=0.68). The overall rate of pacemaker implantation was 29.3% at 1 year, and varied widely by geography: 18.6% to 38.5%. There was a significantly lower rate of pacemakers in patients implanted with the AccuTrak delivery system compared with the older delivery system (27.7% vs. 35.0%, p=0.01). The implantation of a pacemaker post CoreValve system implantation had no significant impact on 1-year patient survival (p=0.44).

Conclusions: In the ADVANCE study, the occurrence of a left bundle branch block or the implantation of a permanent pacemaker after treatment of aortic stenosis using the CoreValve system did not affect one-year survival rates.

Impact of new left bundle branch block or pacemaker implantation on outcomes following TAVI in the Australia New Zealand study

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Aims: Previous studies have suggested that a new left bundle branch block or need for pacemaker implantation post transcatheter aortic valve implantation (TAVI) is associated with reduced left ventricular functional recovery, and an increased risk of heart failure and death. We aimed to determine whether this also applies to the intermediate risk population enrolled in the CoreValve Australia-New Zealand (ANZ) Study.

Methods and results: The ANZ Study is currently enrolling patients with symptomatic, severe aortic stenosis at 10 centres in Australia and New Zealand. All patient source documentation is being fully monitored, and a Clinical Events Committee reviews all major cardiac adverse events. New permanent pacemaker data were analysed for 476 patients (age 84±6 years; EuroSCORE 17±11%; STS score 5.8±4.0%) enrolled between August 2008 and October 2012. Patients with ECG data at baseline and discharge (n=228) serve as the analysis cohort of new left bundle branch block. Left ventricular function was evaluated by echocardiography at each site. Kaplan-Meier survival analysis was performed through 2 years. Log-rank tests were used to compare differences in survival between subgroups. Left ventricular ejection fraction and the severity of mitral regurgitation at 2 years were compared between subgroups using Student's t-test or Chi-square test as appropriate. Multivariate logistic regressions were performed to evaluate predictors of new left bundle branch block and new permanent pacemaker. A new left bundle branch block did not affect 2 year all-cause survival (81.7% vs. 72.8%, p=0.49) or cardiovascular survival (85.0% vs. 80.7%, p=0.78). Also at 2 years, a new left bundle branch block did not significantly impact left ventricular function (ejection fraction: 60.3% vs. 56.2%) or the severity of mitral regurgitation. In patients with a new left bundle branch block, a new permanent pacemaker did not improve survival compared to patients not treated with a permanent pacemaker (76.4% vs. 83.7%, p=0.23). No clinically meaningful predictors of left bundle branch were found. The overall rate of a new permanent pacemaker was 31.1% through 2 years. There was no statistically significant difference in survival through 2 years for patients with or without a new permanent pacemaker (75.9% vs. 78.6%, p=0.45). The rate of new permanent pacemaker implantation decreased significantly over time. Starting with the first implant in August 2008, new permanent pacemaker rates by 6-month blocks of patient enrollment were 24.6%, 42.9%, 39.7%, 33.3%, 32.2%, 28.6%, 26.1%, and 17.2% for the most recent data collection period from February to October 2012. Implanted valve size was the only predictor of a new permanent pacemaker, with a larger valve size associated with a higher risk of a new permanent pacemaker.

Conclusions: In this study, neither a new left bundle branch block nor a new permanent pacemaker was associated with a reduced survival. A new left bundle branch block was also not associated with reduced left ventricular functional recovery post-TAVI.

Interventions for structural heart disease – *Wednesday May 22nd*
Conduction disturbances after TAVI

Implantation depth and conduction disturbances in transcatheter self-expanding aortic bioprosthesis recipients

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Aims: Conduction disturbances and pacemaker implantation after implantation of a transcatheter self-expandable aortic valve bioprosthesis are frequently occurring complications. This study evaluates Valve implantation depth in the left ventricular outflow tract as a predictor of conductions disturbances after TAVI.

Methods and results: Data was collected from the prospectively enrolled registries of the Rigshospitalet, Copenhagen, Denmark and the Prince of Wales Hospital, Hong Kong, consisting of patients undergoing transcatheter self-expandable aortic valve bioprosthesis implantation from 2007 to 2012. A total of 210 patients were included in the analysis. Valve implant depth values were divided into quartiles for comparison. By multivariate analysis, valve implant depth quartile was the strongest independent predictor of 30-day pacemaker implantation (hazard ratio 1.81; 95% confidence interval 1.18-2.77; p≤0.01), followed by PR interval (hazard ratio 1.02; 95% confidence interval 1.01-1.03; p≤0.01). Valve implant depth quartile was also the strongest independent predictor of new left bundle branch block (hazard ratio 1.52; 95% confidence interval 1.14-2.03; p≤0.01) and complete heart block (hazard ratio 1.50; 95% confidence interval 1.00-2.25; p=0.05), followed by QRS duration (hazard ratio 1.02; 95% confidence interval 1.01-1.04; p≤0.01). An implant depth >3.30 mm below the lowest coronary cusp was associated with significantly higher pacemaker implantation rates (odds ratio 1.74; 95% confidence interval 1.23-2.44; p≤0.01). An implant depth >5.70 mm was associated with higher rates of new left bundle branch block (odds ratio 1.63; 95% confidence interval 1.08-2.46; p=0.02) and complete heart block (odds ratio 1.78; 95% confidence interval 1.28-2.48; p=0.02). Neither the use of the AccuTrak system nor increasing centre experience resulted in a more shallow valve implant depth.

Conclusions: Valve implantation depth is an independent predictor of left bundle branch block, complete heart block and pacemaker implantation at 30 days in patients undergoing transcatheter self-expandable aortic valve bioprosthesis implantation. This has implications on the development of implantation techniques to minimise these important complications, which are a source of significant morbidity in this frail group of patients.

Interventions for structural heart disease – *Wednesday May 22nd*
TAVI and coronary artery disease

Incidence, predictors, and prognostic value of periprocedural myocardial injury after TAVI

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Aims: Myocardial injury is a common complication during cardiac surgery and associated with increased mortality. A significant periprocedural rise in cardiac biomarkers occurs frequently following TAVI. However, incidence, predictors, and prognostic value of myocardial injury during TAVI have not been elucidated yet.

Methods and results: 247 patients (aged 81.2±6.2 years; logistic EuroSCORE 26.8±16.8) underwent transfemoral or transsubclavian TAVI with use of a self-expanding bioprosthesis (Medtronic CoreValve N=210; Symetis Acurate N=7) or a balloon-expandable transcatheter heart valve (THV) (Edwards-SAPIEN N=30). In all patients, serum creatine kinase-MB (CK-MB) and troponin I (TnI) levels were measured before and after the procedure (1 h, 4 h, 24 h, 48 h, 72 h, and 7 days). According to the recently updated VARC-2 criteria, the definition of periprocedural (<72 h following TAVI) myocardial infarction is based on a combination of clinical criteria and significant myocardial injury (MI) which is defined as a post-procedure cardiac biomarker increase with a peak value exceeding 15 x as the upper reference limit (URL) for troponin or 5 x for CK-MB. After TAVI, there were substantial differences in the frequency of MI if only CK-MB (22.7%) or troponin (53.4%) data were included for evaluation. Peri-procedural MI was not associated with balloon aortic valvuloplasty or rapid pacing during the procedure. However, there was a significant inverse relationship between the valve size (23 vs. 26 vs. 29 vs. 31 mm) and the cardiac biomarker increase after 4 hours for the median TnI (1.95 vs. 1.46 vs. 1.24 vs. 1.32 ng/mL; P=0.005) or CK-MB level (12.6 vs. 7.5 vs. 7.0 vs. 6.6 ng/mL; P=0.003). Interestingly, the extent and duration of cardiac biomarker increase was significantly higher in patients undergoing TAVI with use of a self-expanding bioprosthesis compared to patients with a balloon-expandable THV. 30-day and 1-year mortality were reported with 4.5% and 19.8%, respectively, and were not related to the incidence of both CK-MB and TnI defined MI after TAVI (P=0.80 and P=0.20).

Conclusions: There was a marked difference in periprocedural MI rates according to CK-MB or TnI elevation. No association was present between periprocedural MI and mortality up to 3 years by either definition. The periprocedural rise in cardiac biomarkers showed an inverse association with the valve size and was significantly higher in patients undergoing TAVI with the use of a self-expanding bioprosthesis compared to patients with a balloon-expandable valve.

Interventions for structural heart disease – *Wednesday May 22nd*
TAVI and coronary artery disease

Management of concomitant coronary artery disease in patients undergoing TAVI: the UK TAVI registry

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Aims: Describe the prevalence, clinical impact and management of coronary artery disease in patients in the United Kingdom TAVI Registry.

Methods and results: All-inclusive study of patients undergoing TAVI in the United Kingdom from January 2007 to December 2011.2,588 consecutive patients were entered into the U.K. TAVI Registry. Mean age 81.31yrs(±7.57), median Logistic EUROScore 18.06(IQR: 12.08, 28.10), female predominance (53.7%). Comorbidities were common: pulmonary disease (27.9%), extracardiac arteriopathy (27.7%), diabetes mellitus (22.2%), pulmonary hypertension >60 mmHg (14.9%). Coronary artery disease (CAD) was demonstrated on invasive angiography in 1,171patients (with one, two or three vessel disease in 21.09%, 11.48% and 13.16% respectively). Left main stem involvement was less widespread at just 5.68%(n=145). Those patients with CAD were more likely to be male, have a diagnosis of diabetes mellitus, a history of myocardial infarction and extracardiac arteriopathy. On univariate analysis more extensive CAD was associated with a reduction in LVEF (p<0.0001) and a higher Logistic EuroSCORE (p=0.0001). Symptomatically the whole cohort of patients were predominately free of significant angina on initial presentation (CCS Class O in 56.67%), but profoundly limited by dyspnoea (NYHA Class III 63.50%, Class IV 19.43%). However angina was more prevalent in those patients with CAD (p<0.0001), with NYHA Class equivalent across all groups, independent of the presence or extent of CAD (p=0.18). Survival at 30 days, 1 year, 3 years and 4 years was 93.66%, 81.41%, 73.24% and 72.04% respectively. Adjusting for confounders in a multivariate model the presence and extent of CAD had no influence on early (30-days, p=0.36) or late (out to 4 years, p=0.104) survival. Patients with CAD did however have longer hospital stays (median: 7days vs. 6days, p=0.007) and a higher incidence of cardiogenic shock during their procedure (p=0.038). Procedural complication rates were otherwise similar independent of CAD status: major vascular injury (2.48% vs. 3.53%, p=0.43), CVA (0.59% vs. 0.79%, p=0.71) and myocardial infarction (0.68% vs. 0.36%, p=0.23). Hybrid PCI (defined as elective PCI in the "lead-up" to TAVI or both TAVI and PCI performed at the same procedure) was performed in only 14.69% of the CAD cohort (n=172). Those patients undergoing hybrid PCI/TAVI procedures tended to be older (p=0.009), but were less likely to be diabetic (p=0.034) or to have a history of prior myocardial infarction (p=0.038). Post-TAVI PCI (tracked using the British Cardiovascular Intervention Society UK PCI Registry) was extremely rare (1.5% of the CAD cohort, n=18; Median time to PCI - 136 days).

Conclusions: This contemporary study of coronary artery disease management in an "all-comers" patient population undergoing TAVI demonstrates that whilst often an indicator of significant underlying comorbidity the presence or extent of coronary artery disease does not directly influence short or long-term survival. This is in contrast to most surgical series where the requirement for CABG in addition to an AVR confers a decreased early and late survival. The majority of patients with AS and concomitant CAD seem to be able to be managed effectively by TAVI alone with post-TAVI PCI infrequent suggesting that symptomatically these patients respond well to isolated valve intervention.

Impact of coronary artery disease on left ventricular ejection fraction recovery following TAVI

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Aims: The objective of the present study was to assess if the presence and severity of CAD is associated with decreased LVEF recovery after TAVI. Coronary artery disease (CAD) and low left ventricular ejection fraction (LVEF) are common findings in patients undergoing transcatheter aortic valve implantation (TAVI). The impact of CAD on LVEF recovery after TAVI has not been specifically evaluated.

Methods and results: All patients with LVEF ≤50% who underwent TAVI between March 2006 and May 2012 were included in the study. The presence and severity of CAD was measured using the Duke Myocardial Jeopardy Score (DMJS). A DMJS=0 corresponds to patients without CAD or complete revascularisation and a DMJS>0 to those with incomplete revascularisation. LVEF recovery was assessed by transthoracic echocardiography, measuring the change in LVEF from baseline to 3-months post-TAVI. Myocardial viability was evaluated in a subgroup of patients using cardiac magnetic resonance (CMR) imaging pre-TAVI. Fifty-six patients were included in the study. Twenty-eight patients (50%) had a DMJS>0. At 3 months, patients with incomplete revascularisation (DMJS>0) demonstrated worse LVEF recovery post-TAVI (2.0±9.2% vs. 11.7±8.9% if DMJS=0; p=0.001). Not only the presence of incomplete revascularisation (DMJS >0) but also the severity were associated with different degrees of LVEF improvement. Patients with DMJS=0 showed the largest LVEF recovery and patients with DMJS between 2 and 4 showed better LVEF improvement than those with DMJS >4. On multivariate analysis, DMJS and presence of significant delayed-enhancement were found to be independent predictors of LVEF recovery. Patients with incomplete revascularisation exhibited a worse prognosis with higher mortality at 30-days (22.2% vs. 0% if DMJS=0; p=0.010) and 1-year (25.9% vs. 3.5% if DMJS=0; p=0.019).

Conclusions: The present study demonstrates an independent association between incomplete revascularisation and decreased LVEF recovery in patients with left ventricular dysfunction undergoing TAVI.

Interventions for structural heart disease – *Wednesday May 22nd*
TAVI and coronary artery disease

Mid-term prognostic value of coronary artery disease in patients undergoing TAVI: a meta-analysis of adjusted observational results

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Aims: Coronary artery disease (CAD) negatively affects prognosis in patients undergoing surgical aortic valve replacement, consequently being appraised in the most common used risk score. Our meta-analysis aims to clarify the association of CAD on mid-term survival in patients undergoing TAVI.

Methods and results: A systematic literature review was performed looking for studies reporting multivariate predictors of adverse outcomes in patients undergoing TAVI and pooled, when appropriate, using a random-effect method.960 citations were first screened and finally 7 studies (2472 patients)were included. Diagnosis of CAD was reported in 37% to 51% of patients and 1169 Edwards SAPIEN and 1303 CoreValve prostheses were implanted. Follow-up time was 452 (357-585) days. After a median follow-up of 452 days (357-585) 24% of patients (19-33) died, and 23 (14- 32) for cardiovascular death which was mentioned only in three studies. At pooled analysis of multivariate approach, diagnosis of coronary artery disease did not increase risk of death (OR 1.0, 95% CI, Confidence Interval, 0.67-1.50).

Conclusions: CAD does not affect mid-term TAVI outcome, and this finding should be weighted to accurately evaluate risk and strategies for patients with severe aortic stenosis.

Interventions for structural heart disease – *Wednesday May 22nd*
TAVI and coronary artery disease

Complete revascularisation is not a prerequisite for success in current TAVI practice

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Aims: Transcatheter Aortic Valve Implantation (TAVI) is an established treatment option in elderly patients with Aortic Stenosis (AS) and a high operative risk. The aim of this study is to assess in patients undergoing TAVI the prevalence and impact of incomplete coronary revascularisation.
Methods and results: A single-centre cohort of consecutive patients undergoing TAVI between November 2005 and June 2012 was evaluated for presence of significant coronary artery disease. The decision to revascularise and pursue complete revascularisation was made by heart team consensus. Two hundred and sixty-three consecutive patients with a mean age of 80±7 years and 51% male underwent TAVI with a median follow-up duration of 16 months (IQR 4.2 – 28.1 months). Significant CAD with myocardium at risk was present in 124 patients (47%) of whom 44 patients had had previous CABG and the median SYNTAX score in the 81 patients without previous CABG was 9.00 (2.38-15.63). Staged PCI was planned in 19 (15%) and concomitant PCI with TAVI in 20 (16%). The median post-procedural residual SYNTAX score of patients without prior CABG was 5.00 (0.13-9.88). Overall 99 patients (37%), 61 no-CABG and 38 CABG patients had incomplete revascularisation after TAVI. Revascularisation status did not affect clinical endpoints. Kaplan-Meier survival curves for patients with and without complete revascularisation demonstrated 1-year mortality of 79.9% vs. 77.4% (p=0.85) respectively.
Conclusions: In an elderly patient population undergoing TAVI, a revascularisation strategy selection by a dedicated heart team can generate favourable mid-term outcome obviating the need for complete coronary revascularisation.

Interventions for structural heart disease – *Thursday May 23rd*
Incidence and prevention of cerebrovascular events after TAVI

Timing and predictors of cerebrovascular events complicating the implantation of self-expanding transcatheter aortic bioprosthesis. Results from the Italian national registry

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Aims: The objective of this study was to evaluate the timing, predictive factors and prognostic value of cerebrovascular events (CVEs) after TAVI with Corevalve.
Methods and results: The study included 1320 consecutive patients who underwent TAVI with Corevalve in 7 Italian centres from june 2007 until december 2012. CVEs (distinguished in transient ischaemic attacks and strokes) were classified as acute (≤24 hours), subacute (1-30 days), or late (>30 days). CVEs occurred in 31 patients (2.4%; stroke, 1.7%) within 30 days after transcatheter aortic valve implantation and were acute in 25 patients (1.9%, stroke 1.3%). Late CVEs occurred in 19 patients (1.4%; stroke 1.1%) at a median follow-up of 8 months (25-75 percentile: 1-21 months). All CVEs were associated with all-cause mortality (HR 2.97; 95% CI 1.88-4.39); with acute events (HR 3.75; 95% CI 2.09-6.71) and <30 days events (HR 3.51; 95% CI 2.08-5.95) showing the strongest association. Multivariate predictors of acute stroke were conduction disturbances (OR 2.80; 95% CI 1.07-7.32), while hypertension showed a protective effect (OR 0.32; 95% CI 0.12-0.86). Valve postdilatation was not a predictor of acute CVE (OR 0.92; 95% CI 0.31-2.72) or stroke (OR 1.43; 95% CI 0.46-4.41). Late events were associated with atrial fibrillation at implant (OR 1.90; 95% CI 0.60-5.97) and prior CVE (OR 2.10; 95% CI 0.72-6.17), hypertension appeared to be a protective variable also in this group (OR 0.37; 95% CI 0.13-1.04). For all events in the complete follow-up period, hypertension appeared a protective variable both for all CVEs (HR 0.44; 955 CI 0.24-0.79) and for strokes (HR 0.37; 95% CI 0.19-0.71), while the strongest predictor for strokes over the complete follow-up period was atrial fibrillation at implant (HR 2.15; 95% CI 1.06-4.35).
Conclusions: In this large cohort of patients undergoing TAVI with Corevalve, the rates of acute and early (<30 days) CVEs were 1.9% and 2.4%, respectively. CVEs and strokes are strongly associated with mortality. While hypertension appears as a protective variable both for early and late events, predictors of acute events were conduction disturbances and predictors of late events were atrial fibrillation at implant and history of CVEs. In this cohort undergoing TAVI with Corevalve overall CVE rate was relatively low and procedural variables did not affect stroke rate.

Neurological events one year post TAVI in real world patients: the ADVANCE study

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Aims: The CoreValve ADVANCE study evaluated the clinical benefits of the CoreValve system in a fully monitored, "real world" single-arm study performed at 44 centres in 12 countries in Western Europe, Asia and South America in high-risk patients with aortic stenosis. Recent studies suggest that transcatheter aortic valve implantation is associated with an increase risk as compared to conventional surgery. Therefore, it was aim of the present analysis to assess the impact of TAVI using the CoreValve system on neurological events and its association with long term outcome.

Methods and results: From March 2010 to July 2011, the ADVANCE study enrolled 1015 patients (mean age 81±6 years, 51% female, mean Logistic EuroSCORE 19±12%, New York Heart Association III/IV 80%) who were evaluated by the local Heart Teams. All primary endpoint-related events were fully adjudicated according to the Valve Academic Research Consortium definitions by an independent Clinical Events Committee. Additionally, all neurological events were adjudicated by an independent neurologist. CoreValve system implantation was associated with a 30-day stroke rate of 3.0% (1.8% minor, 1.2% major strokes) and a 1-year stroke rate of 4.5% (2.3% minor and 2.2% major strokes). A total of 12 strokes (1.5%) occurred between 30-days and 1-year. Nearly all of the strokes in the ADVANCE study were ischaemic (94.7%), with all classified strokes occurring between 30 days and 1 year classified as ischaemic. There were no significant differences found in prescribed clopidogrel, aspirin, or statins use for those patients who experienced a stroke vs. those who did not between 30 days and 1-year. Female gender, history of atrial fibrillation, and procedure duration were identified as predictors of stroke at 30 days. For strokes occurring between 30 days and 1 year, a univariate analysis revealed that female gender and prior coronary artery bypass grafting were predictive factors.

Conclusions: Treatment of high-risk patients with aortic stenosis using the CoreValve system is associated with a low stroke rate at short and long term follow-up.

Cognitive trajectory after TAVI - listening to the sound of silence

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Aims: Transcatheter aortic valve implantation (TAVI) is known to be associated with "silent" cerebral injury, which could contribute to neurocognitive impairment. Considering its increasing use, thorough long-term investigation of cognitive trajectory after TAVI is paramount.

Methods and results: Repeatable neuropsychological testing (RBANS) was performed before (E1), three days (E2), three months (E3), and one year (E4) after TAVI. Baseline characteristics, procedural data, imaging parameters of brain injury (DW-MRI), and the employment of conceivable neuroprotective approaches were investigated for their impact on cognitive function. Neurocognitive performance was investigated in 111 patients (mean log. EuroSCORE: 30±13%). Cognitive function (RBANS total score) increased transiently at E2 (p=0.02) and was comparable to baseline levels at E3 and E4. Substantial neurocognitive decline (NCD) was ruled out in 107 patients (96.4%), four patients (3.6%) demonstrated NCD at E2. Persistent deficit was rare (n=2, 1.8%). Patients with NCD demonstrated worse renal function, longer procedural duration and higher incidence of post-procedural systemic inflammatory response syndrome. Interestingly, cerebrovascular events in the past history, cognitive impairment at baseline, direct TAVI, lack of cerebral embolism in DW-MRI, and the use of a dedicated cerebral embolic protection device remained without impact on neurocognitive trajectory.

Conclusions: Despite the high incidence of silent cerebral injury in patients at elevated risk for neurological sequelae, the vast majority (96.4%) of patients demonstrated preserved neurocognitive performance throughout the first year after TAVI.

Interventions for structural heart disease – *Thursday May 23rd*
Incidence and prevention of cerebrovascular events after TAVI

Angiographic imaging results of a novel cerebral protection device: anchorage matters

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Aims: Increased stroke rates and silent neuro-embolic events associated with transcatheter aortic valve implantation (TAVI) have led to the development of a structural cerebral protection device designed to be positioned in the aortic arch to shield the cerebral circulation from embolic debris during TAVI. We sought to evaluate the impact of baseline cardiac anatomy and procedural characteristics on device position and function throughout the TAVI procedure.

Methods and results: The DEFLECT I study is an ongoing, prospective, multicentre, single-arm clinical trial designed to evaluate the safety and efficacy of the Keystone Heart Embolic Deflection Device (EDD) for use during TAVI. This device consists of a nitinol mesh filter, with 250 mm sized pores, that covers all 3 aortic ar ch vessels (innominate, left common carotid, and subclavian arteries), an upper stabiliser designed to anchor in the innominate, and lower feelers that maintain EDD coverage of the cerebral vessels. It is designed to deflect embolic material downstream away from the cerebral circulation. The angiographic analysis included the first consecutive 20 patients enrolled in the trial. An independent angiographic core laboratory performed comprehensive quantitative coronary angiography of baseline and final angiograms. The angiographic analysis consisted of determining, before, during, and after the TAVI procedure, whether the EDD covered all 3 aortic arch vessels, whether the EDD upper stabiliser was anchored in the innominate artery ostium, the aortic arch classification, and various quantitative measurements. The Medtronic Corevalve was deployed in 50% of cases and Edwards Sapien in 50% of cases. Angiograms of all 20 patients were suitable for analysis. The aortic arch was classified as type I (N=7; 35%), type II (N=9; 45%), and type III (N=4; 20%). Quantitative measures included the innominate artery RVD (11.49±1.54), take off angle from innominate artery and aortic arch (73.5±26.2), take off angle from EDD after positioning (114.7±30.4), and take off angle from EDD after TAVI (120.3±27.0). Prior to TAVI, the EDD covered all 3 aortic arch vessels in 95% of cases, and the upper stabiliser was anchored properly in 85% of cases. During the TAVI procedure, the EDD covered all 3 vessels 79% of the time, and the upper stabiliser was properly anchored 79% of the time. After removal of the TAVI delivery system, there was 65% complete coverage (13/20) and 60% upper stabiliser anchorage (12/20). The only angiographic characteristic significantly associated with complete device coverage before, during, and after the TAVI procedure was whether the device upper stabiliser was anchored in the innominate artery at those respective time points (Prior: p=0.01; During: p=<0.0001; After: p=<0.0001). No baseline anatomical characteristics were associated with the ability of the device to maintain coverage.

Conclusions: The ability of the Keystone Heart EDD to maintain full 3-vessel coverage for the entire TAVI procedure correlates with anchorage of its upper stabiliser in the innominate artery and this angiographic marker can assist interventional cardiologists with device positioning. Proper patient selection and upper stabiliser anchoring at procedure initiation can ensure cerebral protection during TAVI.

Interventions for structural heart disease – *Thursday May 23rd*
Incidence and prevention of cerebrovascular events after TAVI

Novel maximum coverage embolic protection device for use in TAVI

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Aims: Stroke is a major contributor to morbidity and mortality in patients undergoing TAVI and is primarily due to intra-procedural mechanical embolisation of calcific atherosclerotic plaque. Filter-based embolic protection devices show promise as a means of addressing this devastating complication. We describe the early results of a novel embolic deflection device used in conjunction with TAVI in the first 19 consecutively enrolled patients in the DEFLECT I clinical trial.

Methods and results: DEFLECT I is a prospective, multicentre single arm study designed to demonstrate the safety and performance of a novel embolic deflection device (Keystone Heart, Ltd. Herzliya, Israel) among patients undergoing TAVI. The embolic deflection device consists of a nitinol mesh filter of 250 microns that is advanced and positioned across all major cerebral arteries in the aortic arch, and anchored in the innominate artery by an atraumatic stabilizer. Primary endpoints were device performance and in-hospital device-related safety. Secondary endpoints encompassed procedural success, device deployment time, total procedural time, as well as device-related and procedure-related safety. In addition, a powered efficacy endpoint consisted of cerebral diffusion-weighted magnetic resonance imaging (DW-MRI) performed pre-procedure and at discharge to assess for stroke and silent neuro-embolic events, as compared with historical controls undergoing TAVI without neuroprotection. The study device was intended for use in 19 patients. Baseline characteristics included 73.7% female, age 82.0±6.5 years. Device performance defined by complete coverage of all cerebral vessels until complete valve implantation was achieved in 84.2% of cases, while the protocol defined device performance criteria defined by coverage of all cerebral vessels until after removal of the TAVI delivery system was achieved in 68.4% (13/19) of cases. There were no in-hospital device-related adverse events. In-hospital procedure-related adverse events included stroke (2/19), thoracic aortic dissection (1/19), major vascular complications (1/19), minor vascular complications (5/19), bleeding (4/19), and AKI (2/19). The DW-MRI images for this cohort are currently undergoing analysis and these results will be available by the time of presentation.

Conclusions: This novel embolic deflection device is safe for use in patients undergoing TAVI and performed as intended in the majority of cases during the highest-risk period for embolic events. Additional information from the ongoing DW-MRI analysis will further clarify device efficacy.

TAVI and bleeding: focus on valve academic research consortium-2 classification

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Aims: To investigate the impact of bleeding on outcome of Transcatheter Aortic Valve Implantation (TAVI), according to the Valve Academic Research Consortium-2 (VARC-2); and to assess the prognostic accuracy of VARC-2 bleeding definition compared to Bleeding Academic Research Consortium (BARC) and Thrombolysis in Myocardial Infarction (TIMI).

Methods and results: Observational analysis from a single-centre prospective registry of patients treated by TAVI. Adverse events were defined according to VARC-2. Out of 250 TAVI patients (median age 81.2 years, 55.6% female), 108 (43.2%) had a VARC-2 bleeding, 36 (14.4%) minor and 72 (28.8%) major or life-threatening (Severe Bleeding). Independent predictors of severe bleeding were vascular complications ($p<0.001$) and low creatinine clearence ($p=0.02$). VARC-2 severe bleeding predicted early mortality and safety endpoint, while no impact was found on 1-year clinical efficacy and mortality. When compared with BARC and TIMI, VARC-2 bleeding classification showed the best compromise in term of sensitivity, specificity and accuracy in predicting earlymortality and safety.

Conclusions: VARC-2 severe bleedings are frequent and significantly related to increased early mortality and safety events. No impact was found on 1-year mortality and efficacy. When compared to BARC and TIMI bleeding classifications, VARC-2 showed the best compromise in term of sensitivity, specificity and accuracy values in prediction of 30-day adverse events.

Blood transfusion and the risk of acute kidney injury following TAVI

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Aims: Blood transfusion is associated with acute kidney injury (AKI) after transcatheter aortic valve implantation (TAVI). We sought to elucidate in more detail the relation between blood transfusion and AKI and its effects on short- and long-term mortality.

Methods and results: 995 patients with aortic stenosis underwent TAVI with the Medtronic-CoreValve or the Edwards Valve in 7 centres. AKI was defined by the Valve Academic Research Consortium (absolute increase in serum creatinine ≥0.3 mg/dl (≥26.4 µmol/l) or ≥50% increase ≤72 hr). Logistic and Cox regression was used for predictor and survival analysis. AKI occurred in 20.7% (n=206). The number of units of blood transfusion ≤24 hr was the strongest predictor of AKI (≥5 units, OR: 4.81 [1.45-15.95], 3-4 units, OR: 3.05 [1.24-7.53], 1-2 units, OR: 1.47 [0.98-2.22]) followed by peripheral vascular disease (OR: 1.48 [1.05-2.10]), history of heart failure (OR: 1.43 [1.01-2.03]), leucocyte count ≤72 hrs after TAVI (OR: 1.05 [1.02-1.09]) and EuroSCORE (OR: 1.02 [1.00-1.03]). Potential triggers of blood transfusion such as baseline anemia, bleeding-vascular complications and peri-operative blood loss were not identified as predictors. AKI and life-threatening bleeding were independent predictors of 30-day mortality (OR: 3.15 [1.56-6.38], OR: 6.65 [2.28-19.44], respectively) while transfusion (≥3 units), baseline anemia and AKI predicted mortality beyond 30 days.

Conclusions: AKI occurred in 21% of the patients after TAVI. The number of blood transfusions but not the indication of transfusion predicted AKI. AKI was a predictor of both short- and long-term mortality whereas blood transfusion predicted long-term mortality. These findings indicate that outcome of TAVI may be improved by more restrictive use of blood transfusions.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI and bleeding complication

Bleeding predictors and prognosis in patients submitted to TAVI

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Aims: Periprocedural bleeding is an important complication associated with transcathether valve replacement. The aim of this study was to identify bleeding predictors - according to the definition of Valve Academic Research Consortium (VARC)- and to evaluate the impact of bleeding on in-hospital and 2-year mortality.

Methods and results: Prospective data were collected from 136 procedures, related to 133 patients who had been submitted to Transcatheter Aortic Valve Implantation (TAVI, average age 80.9±7.7; 43% men; 34% with diabetes). Bleeding was assessed according to the definition of VARC classes 2 or 3. We used a binary logistic regression analysis to determine the bleeding predictors and a Cox logistic regression to evaluate the impact on prognosis. The incidence of bleeding VARC classes 2 or 3, were 21.3% and 15.4%, respectively. We observed an association between this outcome and the following variables: presence of peripheral arterial disease (PAD; 55.6% vs. 31.8%, p=0.022), VARC class 2 or 3 acute kidney injury (AKI2-3; 83.3% vs. 34.6%, p=0.016), coronary artery disease (CAD; 44.4% vs. 27%, p=0.0035), STS mortality score median[IQR] (6[4.3-10] vs. 4.3[3.1-7], p=0.016), median basal haemoglobin (Hb; 11[10-12] vs. 12 [11-13]mg/dL, p=0.002), median basal NT-proBNP (5204 [1835-12600] vs. 1950 [913-3440] p=0.001). By multivariate analysis the only independent predictors were Hb (OR=0.67, IC95%[0.54-0.97], p=0.037) and PAD (OR=3.72, IC95% [1.1-12-1], p=0.029). In-hospital mortality was 6.6% (n=9). This outcome was strongly associated with bleeding class 2/3 (OR=16,2, IC95% 2.0-133.9, p=0.010). 2-year mortality was 17,6% (n=24). Under a Cox logistic regression, the independent mortality predictors were diabetes (HR=2.89, IC95% [1.1-7.6] p=0.03) and haemorrhagic class 2/3 (HR=5,4, IC95% [1.86-15.6] p=0.002). Independently of in-hospital mortality, the overall prognosis is still affected by bleeding (HR=4.6, IC95% [1,4-15.1], p=0.01) and the presence of diabetes (HR=4,6, IC95% [1.04-11], p=0.04).

Conclusions: The incidence of Valve Academic Research Consortium bleeding classes 2 or 3 was important, being associated with the Hb basal values and the presence of PAD. Bleeding has an adverse impact on both in-hospital and 2-year mortality.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI and bleeding complication

Adverse impact of bleeding and transfusion rates on outcomes after TAVI

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Aims: An adverse impact of bleeding and transfusion of packed red blood cells (PRBC) on outcome after percutaneous coronary intervention is well documented. However, data on the influence of transfusion after transcatheter aortic valve implantation (TAVI) is scarce. We report on bleeding complications and transfusion rates after TAVI and its impact on outcome.

Methods and results: TAVI was performed in 458 consecutive patients at high risk for surgery employing 1st and 2nd generation balloon-expandable and self-expanding devices via transfemoral or transapical access. Outcomes were analysed according to the Valve Academic Research Consortium definitions with emphasis on bleeding, PRBC transfusion and its impact on survival. Median follow-up duration was 262.5 days. Overall, 43.1% of patients received PRBC transfusions during the postoperative course after TAVI (20.2% 1-2 PRBC, 13.1% 3-4 PRBC, 9.8% >4 PRBC), irrespective of access (transapical: 43.2% vs. transfemoral: 42.9%, p=n.s.). 24.3% of these patients suffered from major or life-threatening bleeding and 15.9% sustained major access site complications vs. 1.2% in patients who did not receive PRBC transfusion (p<0.001). Risk profile at baseline did not significantly differ between both groups (logistic EuroSCORE 23.5±14.1% vs. 21.5±13.1%, p=0.126) but the incidence of major strokes (7.2% vs. 1.2%, p=0.002) and stage-3 renal failure (4.1% vs. 0.8%, p=0.02) was higher in patients requiring transfusions. Increased all-cause mortality was noted in the PRBC cohort (14.5% vs. 3.5% at 30 days and 38.4% vs. 22.2% at 1 year, p<0.001) and correlated with the amount of transfused PRBC.

Conclusions: PRBC transfusion was frequently required after TAVI but only in part driven by access site complications and independent of transapical or transfemoral access. However, patients requiring transfusion of PRBC displayed poorer outcomes, underscoring the need for valid risk stratification tools to identify patients at risk for bleeding and transfusion.

Sheathless TAVI: an alternative approach to reduce vascular complications

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Aims: Despite encouragingly good results of TAVI, vascular complications remain the Achilles' heel of this procedure. Major vascular complications are mainly related to access vessel diameter and sheath outer diameter. Sheathless TAVI reduce access vessel trauma decreasing device diameter within the artery and avoiding artery recoil.

Methods and results: Among 51 patients treated with TAVI between July 2009 and September 2012, 9 patients, with vascular access less than 6 mm, were deemed not suitable for transapical or transaortic approach. The Heart Team opted to implant the Medtronic CoreValve through 4 cm surgical incision for femoral access and 6 cm for subclavian access, without the introducer. Mean age was 84±5 years, 4 patients (44.4%) had a previous cardiac surgical intervention with patent IMA, 2 patients (22.2%) had a previous endovascular endoprosthesis and 2 patients (22.2%) had a porcelain aorta. Procedure success was 100%, and no vascular complication occurred. Safety endpoints at 30 days follow-up showed no death or stroke or vascular complications; one patient (11.1%) needed a pace maker implant. In 7 (77.7%) cases a subclavian access (4 left and 3 right) was performed, 2 cases (22.2%) were through femoral access. All procedures were performed with local anaesthesia and minimal sedation. CoreValve is mounted onto a 18Fr delivery system (Accutrack) whose maximum outer diameter is 18 Fr (6 mm) for the first 7 cm. The outer diameter of a compatible 18Fr introducer is 7.2 mm. The difference between a sheath or sheathless procedure is only 1.2 mm but it means a reduction in access vessel diameter of 16.7%. In sheathless procedure the 6 mm delivery system passes through the vascular access for few seconds and for just 7 cm avoiding to keep into the artery, for the entire procedure, a 7.2 mm×30 cm stiff introducer. The smoother Accutrack's nose follows curvature or indentation of the artery better than the rigid introducer's dilatator reducing the risk of artery recoil or dissection. For an 18 Fr introducer, a minimal noncalcified ileo-femoral artery access of 6.5 mm and of 7.2 mm for calcified artery access is required. Sheathless procedure allows 6 mm artery access. Thanks to the flexibility of the delivery system and to its smaller diameter, it becomes possible to perform TAVI procedure even in case of significant vessel tortuosity or in case of previous aortic stent or endovascular prosthesis implantation. Avoiding introducer obstruction, subclavian sheathless access guarantees an adequate flow to the internal thoracic artery which is particularly important if this artery is used as a bypass conduit for coronary arteries.

Conclusions: Patients with major vascular complications had a 2-fold increase in mortality and vascular complication are strictly related to a sheath to femoral artery ratio. Sheathless technique, allowing a smaller 16.7% artery diameter, is an alternative to standard access and in our experience showed excellent results. The "Heart Team" should consider this option not only when conventional access is precluded, but also to avoid intricately more invasive access such as transaortic and transapical.

VARC-2 definition of acute kidney injury in TAVI lacks prognostic value compared to simpler definitions

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Aims: Acute kidney injury (AKI) occurs frequently during the hospital admission for TAVI and is associated with a worsened prognosis. There are several criteria for AKI in this context; the most recent were published by the Valve Academic Research Consortium in 2011 and 2012 (VARC-1 and VARC-2). We aimed to evaluate the prognostic value of different AKI definitions during TAVI.

Methods and results: Retrospective single-centre study of 136 consecutive TAVI patients; median age 82 years (interquartile range 78-87), 46% male sex; median glomerular filtration rate (GFR) 66 ml/min/m^2 (IQR 47-79). Previous renal replacement therapy (RRT) patients were excluded from the analysis. AKI was defined according to the conventional criteria (48h GFR decrease over 25%, 50% and 75% or RRT) and by VARC-1 and VARC-2 criteria. During 193 years of combined follow-up, 20 deaths occurred (10.4%/year incidence). AKI incidence was significantly different according to the definitions used: conventional score n=20 (16%), VARC-1 n=22 (17.9%) and VARC-2 n=38 (30.9%). By Cox regression, hazard ratios (95% confidence interval) adjusted for LV ejection fraction and STS mortality score were: conventional score 4.51 (1.68-12.1), VARC1 2.07 (0.72-5.95) and VARC2 2.06 (0.8-5.29).

Conclusions: The occurrence of acute kidney injury according to VARC1 and VARC2 criteria lacks prognostic impact. Contrarily, the usual and simpler conventional definition remains an independent mortality predictor after transcatheter aortic valve replacement.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI and kidney injury

Predictors of acute kidney injury in patients undergoing TAVI

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Aims: The existing data on the occurrence of acute kidney injury (AKI) following transcatheter aortic valve implantation (TAVI) is scarce. The aim of this study was to determine the incidence and predictive factors of moderate to severe AKI (stage 2 and 3) according to Valve Academic Research Consortium (VARC-2) criteria.

Methods and results: A total of 124 patients (44% male, mean age 81.0±7), from a single-centre prospective registry of 136 consecutive TAVI procedures, were included.. Patients with prior kidney replacement therapy were excluded. Multivariate analysis was performed by binary logistic regression, to identify independent predictors of AKI 2-3. Of the 124 patients studied 35% had diabetes, 35% left ventricular dysfunction (Ejection Fraction <50%) and the median EuroSCORE I (ES) was 16 (IQ 10-27). The mean basal estimated glomerular filtration rate (eGFR) was 66±24ml/min and the median dose of contrast used was 135 mL (IQ 80-208). The incidence of AKI of any degree was 31% with 4.8% of patients having AKI 2-3. The development of AKI 2-3 was found to be associated with baseline NT-proBNP>11,800 pg/ml (p<0.001) and the occurrence of potentially fatal bleeding (p<0.001). The median ES was tendentiously higher in this subgroup of patients (26.6 IQ 18-38 AKI 2-3 vs. 15 IQ 10-25 in the remaining, p=0.1). The independent predictive factors of AKI were potentially fatal bleeding (OR 4.29 95% CI 1.7-510.8, p=0.020) and high baseline NT-proBNP (OR=16 95% CI 1.1-230.4, p=0.041).

Conclusions: Acute kidney injury occurs in about one third of TAVI procedures, being moderate to severe in 4.8% of cases according to VARC-2 criteria. It is related to high baseline NT-proBNP and potentially fatal haemorrhage.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI and kidney injury

Acute kidney injury after transcatheter aortic valve replacement with self-expanding prosthesis: results from a large multicentre italian registry

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Aims: Transcatheter aortic valve replacement (TAVR) can be associated with varying degree of new renal impairment. The aim of this multicentre study was to determine the influence and predictors of periprocedural acute kidney injury (AKI) on prognosis after TAVR.

Methods and results: From the ClinicalService® (former Italian CoreValve registry) dataset, 1157 patients with severe aortic stenosis treated with the 3rd generation CoreValve prosthesis (Medtronic Inc, MN, USA) in 7 Italian sites, and with creatinine data available at baseline and during the post-TAVR in-hospital course were included in this analysis. All outcomes were defined according to the VARC-2 criteria. Overall, AKI occurred in 231 (20%) patients after TAVR: 15% stage 1, 3% stage 2, and 2% stage 3. At 3 years, patients with post-procedural AKI reported lower survival from all-cause (58% vs. 73%; p<0.001) and cardiovascular (90% vs. 94%; p<0.001) death. On multivariate Cox regression analysis, the development of post-procedural AKI was associated with higher risk for all-cause (HR: 1.91, 95% CI: 1.42-2.55; p<0.001) and cardiovascular (HR: 2.08, 95% CI: 1.36-3.20; p<0.001) mortality. No statistically significant differences in terms of stroke, myocardial infarction and bleeds were reported between the two groups. Female gender (HR: 1.37, 95% CI: 1.01-1.87; p<0.044) and transfusion ≥3 RBC units (HR: 1.72, 95% CI: 1.07-2.78; p<0.026) were found to be the only independent predictors of AKI.

Conclusions: Acute kidney injury is a frequent complication and significantly impact on long-term TAVR outcomes. Females and patients receiving ≥3 RBC units after the procedure should be considered at high risk for the development of AKI after TAVR.

The ratio of contrast volume to glomerular filtration rate predicts acute kidney injury and mortality after TAVI

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Aims: The ratio of the volume of contrast medium to the glomerular filtration rate (V/GFR) has been shown to correlate with higher risk of AKI after percutaneous coronary intervention but has not been evaluated in patients undergoing TAVI. The aim of this study was to assess the impact of V/GFR on acute kidney injury (AKI) after transcatheter aortic valve implantation (TAVI).

Methods and results: We calculated V/GFR in 397 patients undergoing TAVI. AKI was defined as a VARC-modified Risk, Injury, Failure, Loss and End-stage (RIFLE) kidney disease ≥2. Receiver-operator characteristic (ROC) methods were used to identify the optimal sensitivity and specificity for the observed range of V/GFR. The predictive value of V/GFR for the risk of AKI was assessed using multivariable logistic regression. The incidence of AKI was 17.9%. The mean V/GFR ratio was 3.0±2.7 in patients without AKI and 7.8±8.8 in patients with AKI ($p<0.001$). The ROC curve analysis showed fair discrimination between patients with and without AKI (C-statistic 0.85) at a V/GFR ratio of 3.2. At multivariable regression analysis V/GFR>3.2 was an independent predictor of AKI (OR 3.4, 95% CI 1.0-6.1, $p<0.001$) and long-term mortality (OR 3.3, 95% CI 2.0-5.2, $p<0.001$).

Conclusions: A V/GFR >3.2 is correlated with higher incidence of AKI and mortality after TAVI. So it is promising that this ratio can be used to calculate the maximum volume of contrast medium that can be given without significantly increasing the risk of AKI and mortality. Further study is needed to determine whether limiting contrast volume would improve patient outcome.

Prognostic impact of post-procedural hyperglycemia on acute kidney injury after TAVI

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Aims: Peri-operativehyperglycemia, in individuals with and without diabetes, has been identified as a marker of AKI in cardiac surgery patients. This aspect is not known in the TAVI setting. We sought to evaluate whether post-procedural glucose levels are associated with acute kidney injury (AKI) after transcatheter aortic valve implantation (TAVI).

Methods and results: We prospectively evaluated 422 patients undergoing TAVI. For each patient, plasma glucose level were assessed at hospital admission, 4 hours after the procedure and every day during hospitalisation. Post-procedural hyperglycemia was defined as 2 consecutive blood glucose readings of 150 mg/dL or greater during 72 hours after TAVI. AKI was defined based onthe VARC standardised endpoint definitions. The predictive value of post-procedural hyperglycemia for the risk of AKI was assessed using multivariable logistic regression. Overall, 137 (32%) patients had post-procedural hyperglycemia and 138 (33%) patients developed AKI. Hyperglycemic patients had a 2-fold higher incidence of AKI than those without hyperglycemia (48% vs. 25%, $p<0.001$). In-hospital mortality was higher in patients with hyperglycemia than in those without hyperglycemia (9.6% vs. 1.8%, $p<0.001$). At multivariable regression analysis post-procedural hyperglycemiawas an independent predictor of AKI (OR 2, 95% CI 1.3-3.1, $p=0.002$) and in-hospital mortality (OR 4.4, 95% CI 1.5-13, $p=0.007$).

Conclusions: Post-procedural hyperglycemia iscorrelated with higher incidence of AKI and mortality after TAVI. Randomised controlled trials are needed to determine whether post-procedural hyperglycemia management improves clinical outcome in patients undergoing TAVI and could become an adjunctive strategy of AKI prevention.

Interventions for structural heart disease – *Thursday May 23rd*
Intervention for prevention of stroke

Transcatheter closure vs. medical therapy for cryptogenic stroke: a meta-analysis of randomised clinical trials

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Aims: Up to 40% of ischaemic strokes are of uncertain etiology and classified as cryptogenic, with a strong association between cryptogenic stroke and patent foramen ovale (PFO) through paradoxical embolism. 3 randomised clinical trials have examined the safety and efficacy of transcatheter device closure vs. medical therapy in this patient population. The aim of our meta-analysis was to analyse and report the aggregate data for adult patients with PFO and cryptogenic stroke from all randomised trials comparing standard medical therapy vs. transcatheter closure.

Methods and results: We conducted a search of published research using MEDLINE, Embase, Cochrane Register of Controlled Trials, Scoupus, and the ISI Web of Knowledge for randomised studies comparing transcatheter closure of PFO and standard medical therapy to prevent recurrent cryptogenic strokes or transient ischaemic attacks (TIA). Reference lists and abstracts of conference proceedings and scientific meetings were searched by hand. Trials were assessed for inclusion and data was extracted by 3 independent reviewers with disagreement resolved by discussion. Primary outcome was the composite endpoint of death, stroke and TIA. We performed predefined subgroup analysis with respect to baseline characteristics including age, sex, atrial septal defect and shunt size. Data were synthesised using a random effects model and results presented as (HR) with 95% confidence intervals (CI). Heterogeneity was assessed using Q statistic and I2 statistic. We found 3 randomised controlled RCT's (CLOSURE, RESPECT and PC), 1 published study and 2 presented at conference proceedings. A total of 2303 patients with a prior history of cryptogenic stroke were randomised, 1150 to device closure and 1153 to medical therapy. Transcatheter closure was not superior to standard medical treatment in secondary prevention of strokes/TIA in patients with a PFO during a mean of 2.5 years period (maximum followup 7 years), with a non-statistically significant trend favouring device closure: Intention-to-treat HR 0.66 (0.43-1.01), p=0.056 and per protocol HR 0.59 (0.31-1.12), p=0.10; concurring with the results of each of the trials. Interestingly, we found that males had significant benefit with device closure, HR 0.48 (0.24-0.96), p=0.038. Patients with large baseline shunt (HR 0.35 (0.09-1.39), p=0.14) or atrial septal aneurysm (HR 0.67 (0.21-2.16), p=0.50) did not have significant benefit from device closure. Major bleeding rates were similar in both groups, but atrial fibrillation occurred more often in the device group OR 3.43 (1.17-10.00), p=0.024.

Conclusions: In our meta-analysis of three randomised trials (CLOSURE, RESPECT and PC), we found that transcatheter closure of PFO was not superior to the standard medical therapy, HR 0.66 (0.43-1.01), p=0.056. Males had a significant reduction in events with device closure and may be an important subgroup to study in the future. Importantly, device implantation success was high with very low complication rates attributable to the device, especially with an Amplatzer PFO device.

Interventions for structural heart disease – *Thursday May 23rd*
Intervention for prevention of stroke

Further analysis of confirmed endpoint recurrent strokes in patent foramen ovale patients in the RESPECT trial

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Aims: The Randomised Evaluation of Recurrent Stroke comparing PFO Closure to Established Current Standard of Care Treatment (RESPECT) Trial demonstrated that patent foramen ovale device closure with the AMPLATZER™ PFO Occluder was associated with reduced frequency of recurrent stroke compared to medical therapy alone. The purpose of this analysis was to determine if the medical therapy group had recurrent strokes with a radiological pattern suggestive of embolism more often than the closure group. This would provide insight into the mechanisms of the recurrent strokes.

Methods and results: RESPECT was a prospective, multicentre, randomised (1:1), event-driven trial designed to evaluate whether patent foramen ovale closure with the AMPLATZER™ PFO Occluder is superior to medical treatment in preventing recurrent ischaemic strokes or early death. Patients enrolled were age 18-60 with a qualifying stroke event within 270 days of randomisation. Entry criteria required detailed screening to exclude cardioembolic sources, large artery arteriopathy, small artery disease, and other known, non-patent foramen ovale-related mechanisms of ischaemic stroke. 980 patients were enrolled (mean age 45.9 years) from 69 sites in the United Stated and Canada. Embolism as the mechanism of recurrence was suggested if the infarct topography was 1) located deep in the brain and large or 2) superficially located (of any size). Follow-up was 2,559 patient years, with a mean (SD) 2.6 (2.0) years (interquartile range 1.0-4.1). Subjects in the medical treatment arm received 1 of 4 antiplatelet regimens (74.8%) or warfarin (25.2%). All 25 primary end point events (16 medical, 9 device) were recurrent ischaemic strokes. In time to event analyses, device therapy was associated with a hazard reduction (HR) in the intention to treat population of 0.490 (CI 0.22-1.11; P=0.08), in the per protocol population (HR 0.37; CI 0.14-0.96; P=0.03), and in the as-treated population (HR 0.27; CI 0.10-0.75; P=0.007). Among the 9 device arm ischaemic strokes in the intent to treat population, 3 occurred without a device in place. The topography of recurrent infarcts differed (p=0.04); medical therapy patients had recurrent strokes suggestive of embolism more often than did the closure group (n=12 vs. n=4).

Conclusions: In pre-specified secondary analyses of patients with a history of cryptogenic stroke and patent foramen ovale, closure with the AMPLATZER PFO Occluder demonstrated benefit over medical management alone. Event types particularly reduced in the device group were those that were likely to be caused by an embolic mechanism.

Septal defect closure using a device with biodegradable framework: chronic results in a swine model

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Aims: To study the feasibility and chronic results in swine of atrial septal defect (ASD) closure using a percutaneously delivered device with a novel biodegradable framework

Methods and results: The Solysafe® Septal Occluder has been used for closure of atrial septal defects with high closure rates, excellent tissue response and few major complications. Design, and over-the wire delivery technique provide the ability to retrieve and reposition. It was voluntarily taken from the market due to isolated cases of irregularities with the metal framework. Using the Solysafe design, a novel biodegradable framework was developed which, in the end, leaves only 'patches' on each side of the septum. The new framework, consisting primarily of poly lactic-co-glycolic-acid, is completely covered by the patches so as to eliminate the risk of embolisation during biodegradation. The device is delivered over a wire through a transseptal sheath, and is self-centring. The device was placed on the interatrial septum of pigs following defect creation via transseptal puncture and balloon dilation. Two separate studies were performed: A Good Laboratory Practices (GLP) study of 24 animals with follow-up at 3, 5, 8 and 15 months. (15M results pending). All were successfully implanted without complications. Animals received aspirin 5mg/kg/day post implant. During follow-up, one animal died of a non related cause, 1 month after implantation. All other animals were free of complications. Evaluation at termination including fluoroscopy, intracardiac echocardiography, and macro- and microscopic histologic examination showed the devices securely in place with complete closure of the defects, excellent tissue endothelialisation, and framework degradation consistent with literature reports by Zamiri et al for this identical material. There was no evidence of embolising device parts and no thrombus on the device. A non-GLP study totalling 60 animals during product development with a follow-up of median 49 days (0-222 days) with *in vivo* tests in 3-6 animals at key stages. In this series the device could not be placed in 5 animals and embolised in 2 animals post implantation. In the remaining animals, the device was successfully placed. At termination the animals were studied in the same manner as in the GLP-study. The results were identical to the GLP group: complete closure in all; excellent endothelialisation; progressive degradation with no evidence of embolising device parts; no thrombus on the device.

Conclusions: A septal closure device that occludes and then 'goes away' has long been a desirable attribute of septal devices. Development of a biodegradable patch has been accomplished. Until now, successful chronic animal testing of an effective septal closure device with biodegradable framework has not been reported. Our results demonstrate that: a biodegradable framework can be successfully incorporated in to an intracardiac device; the device can be safely, securely and consistently deployed in an ASD model; the material used in the framework will safely and progressively biodegrade without risk of particulate embolisation; the materials exhibit excellent short and medium term tissue response; initial testing in human subjects is warranted.

Interventions for structural heart disease – *Thursday May 23rd*
Intervention for prevention of stroke

Percutaneous closure of patent foramen ovale in patients with anatomical and clinical high-risk features: long-term efficacy and safety

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Aims: Patent foramen ovale (PFO) and cryptogenic stroke are highly correlated and the risk of recurrence is increased in PFO patients, despite optimal medical treatment; the best option, especially in high-risk patients, is probably transcatheter PFO closure, but the available data are still controversial. Our aims were to determine the efficacy and safety of this procedure in a cohort of high risk patients through the observation of clinical adverse events and residual shunt, and to evaluate the long term impact of residual shunt.

Methods and results: 152 patients underwent PFO closure for cryptogenic cerebral ischaemia: stroke 94 patients (61.8%), TIA 57 patients (37.5%), retinal embolism 1 patient (0.7%). Each of them presented one or more of the following risk factors: recurrent cerebral ischaemia 22 patients (14.5%), atrial septal aneurysm 117 patients (77%), severe basal shunt 90 patients (59.2%), thrombophilic factors 27 patients (17.8%), deep vein thrombosis 5 patients (3.3%). At pre-procedural TEE echcocardiography 17.7% patients had mild shunt, 23.1% had moderate shunt, and 59.2% had severe shunt. The procedure was performed successfully in all patients, under TEE guidance. At the six-months TEE follow-up, 5% patients had significant residual shunt. On mean clinical follow-up of 24 months (range 1-84 months), the neurologic recurrent events rate was 1.3% (2 patients) and in 1 patient (0.7%) a device-related complication occurred (interatrial septum erosion). At the Kaplan-Meier curve, the recurrent cerebral ischaemia free survival at the end of the follow-up was 98%. No correlation was found between residual shunt and the outcome.

Conclusions: Transcatheter PFO closure is a safe procedure even in a selected population of high risk patients, presenting satisfactory efficacy and safety. The presence of residual shunt after the procedure is not associated to an increase of recurrent neurological events.

Interventions for structural heart disease – *Thursday May 23rd*
Intervention for prevention of stroke

No predilatation before TAVI with self expandable valve: safety and feasibility

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Aims: Balloon aortic valve pre-dilatation is considered the preparatory step before transcatheter aortic valve implantation (TAVI), although it is not riskless. Aim of this work was to evaluate the safety and the technical feasibility of TAVI with self-expandable bioprosthesis performed without pre-dilatation of the native valve in patients affected by symptomatic and severe aortic stenosis (AS).

Methods and results: Between June 2011 and October 2012, 70 out off 80 consecutive patients with severe aortic stenosis of native valve treated by TAVI at our institute, were retrospectively divided into two groups according to balloon pre-dilatation: group A=TAVI with pre-dilatation (35 patients) and group B=TAVI without pre-dilatation (35 patients). Both groups had similar age, sex distribution and Logistic Euroscore I. No significant difference was observed with regard to size of valve implanted between group A and group B (size 26 mm: 20% vs. 17%; size 29 mm: 48.5% vs. 60%; size 31 mm: 31.5 vs. 23%, respectively). There was no significant difference regarding the incidence of post-dilatation or second valve implantation between two groups (51% vs. 40%, p=0.33, respectively) irrespective of valve size deployed. Residual aortic regurgitation ≥2 post TAVI was similar in two groups (0.14% in the first group vs. 0.08% in the second group, p=0.45). No ictus or other cerebrovascular events occurred.

Conclusions: TAVI with self-expandable bioprosthesis without aortic balloon pre-dilatation is feasible and safe. Further studies are warranted in order to evaluate the impact on cerebrovascular events, pace maker implantation and procedural costs.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI technical issues

Staged valvuloplasty before TAVI in patients with left ventricular dysfunction: insights from the Italian CoreValve registry

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Aims: Patients with severe aortic stenosis and left ventricular dysfunction have a dismal prognosis and are often referred for TAVI. Staged valvuloplasty before performing TAVI can be used to verify whether such very high-risk patients may benefit from the interventional treatment of the aortic stenosis.

Methods and results: We analysed 198 patients with severe aortic stenosis and left ventricular ejection fraction (LVEF) <35% who underwent TAVI with the Medtronic CoreValve prosthesis within the Italian CoreValve Registry. Of these, 150 underwent TAVI directly, while 50 patients with the highest risk profile underwent balloon aortic valvuloplasty (BAV) as a bridge to TAVI, to verify the clinical benefit of relieving the severity of aortic stenosis. The 50 patients in the staged valvuloplasty group had a significantly worse renal function (creatinine 1.4 mg/dl (IQR 1.1-1.7) vs. 1.2 mg/dl (IQR 0.9-1.6), p=0.023), lower LVEF (27±5% vs. 29±5%, p=0.022), higher rate of moderate/severe mitral regurgitation (82% vs. 64%, p=0.019), and a trend to older age (82±6 years vs. 79±9 years, p=0.071) and higher Logistic EuroSCORE (19% (IQR 12-29) vs. 16% (IQR 13-31), p=0.064). No significant difference was found between groups regarding procedural results, except for a shorter procedural time in the staged valvuloplasty group (90 min (IQR 60 -120) vs. 100 min (IQR 60 -127), p<0.001). Procedural mortality was similar (4% vs. 3%, p=0.65). In-hospital mortality was also similar between groups (10% vs. 6%, p=0.355), as well as the 30-day rate of adverse events (safety composite endpoint 70% vs. 59%, p=0.186). The 2-year clinical outcome was also similar in terms of the clinical efficacy composite endpoint (26% vs. 19%, p=0.314) and all-cause mortality (24% vs. 15%, p=0.202).

Conclusions: High risk patients undergoing staged BAV had a numerically higher incidence of events compared to patients undergoing TAVI directly. Difference did not reach statistical significance most probably because of small numbers. Considering the worse clinical profile of patients treated with BAV, we did not see such a large difference in events not to support this approach.

Transapical TAVI without prior balloon aortic valvuloplasty feasible and safe

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Aims: Currently, pre-implant balloon aortic valvuloplasty (BAV) is considered a prerequisite for successful subsequent transcatheter aortic valve implantation (TAVI). However, cerebral embolisation has been shown to originate at least in part from BAV procedures. Omitting BAV may therefore improve neurologic outcomes after TAVI and facilitate the procedure.

Methods and results: From March, 2008 through September, 2012 at total of 244 patients were treated by transapical antegrade (TA) TAVI using balloon-expandable Edwards Sapien (XT) devices. Of these, pre-implant BAV was omitted in 36 cases (TA-AVI-BAV, 14.8%). Data were prospectively entered into a dedicated database, retrospectively analysed and compared to conventional TA-AVI using the same device (TA-AVI+BAV, n=208). Overall 30-day mortality in 36 patients (age 76.9±9.2 years, 52.8% male, logEuroSCORE I 19.9±13.2%) receiving TA-AVI-BAV was 8.3% (3/36), stroke rate was 2.8% (1/36), both of which was insignificantly lower compared to TA-AVI+BAV. Procedure time was markedly reduced (88.0±32.8 min vs. 100.0±46.0 min, p=0.22) and significantly less contrast was used (133.0±44.4 ml vs. 166.0±80.9 ml, p=0.05). Valve performance at discharge was non-inferior in TA-AVI-BAV regarding severity of paravalvular leakage or transvalvular gradients (p=ns).

Conclusions: Our preliminary data suggest, BAV may be omitted in select patients scheduled for TA-AVI. This facilitated approach resulted in shortened procedure times and less contrast agent used without compromising valve performance. Effects of TA-AVI-BAV on the incidence of cerebrovascular events, other periprocedural complications or haemodynamic valve performance need to be verified in larger patient numbers before general recommendations can be made. Detailed morphological analysis of stenosed aortic valves including characterisation and quantification of valvular calcium may be needed to optimise patient selection for TA-AVI with or without prior BAV.

TAVI: when it's time to convert

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Aims: Transcatheter aortiv valve implantation (TAVI) has emerged as an important treatment for patients with severe symptomatic aortic stenosis who are at high operative risk. Two different approaches-the transfemoral and transapical techniques-are currently under intense clinical investigation. Aim of this study was the evaluation of intraoperative complications and the conversion rate to full sternotomy.

Methods and results: A total of 1825 (1153 transfemoral (TF), 672 transapical (TA)) patients underwent TAVI since July 2006 at our institution. Conversion to full sternotomy was required in 2.1% of all patients (n=38; 21 TF and 17 TA). Patient data, including intraoperative course and postoperative outcome, were collected. Follow-up data were collected in a prospective database and retrospectively analised. A total of 38 patients underwent conversion to full sternotomy during TAVI. The mean age of patients was 84.5±5.3 years, 32 patients were female (88%), and the mean log EuroScore was 21.7±16.3. The main reasons for conversion were as follows: perforation of the left ventricle in 26% (n=10; 6 TF, 4 TA); malpositioning of the valve in 24% (n=9; 5TF, 4 TA); occlusion of the coronaries in 18% (n=7; 3TF, 4TA); and rupture of the annulus in 18% of the patients (n=7; 5TF, 2TA). Perioperative mortality (30days) was 58% (n=23; 14 TF, 8 TA).

Conclusions: This trial indicates that TAVI is associated with reasonable low intraoperative complication rates. In the experience of this large single-centre study, conversion to full sternotomy was necessary in only 2% of all patients. If conversion is indicated, however, it is associated with high perioperative risk.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI technical issues

Direct-aortic access for transcatheter self-expanding aortic bioprosthesis valves implantation: single-centre experience

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Aims: Transcatheter aortic valve implantation (TAVI) has been designed to treat elderly patients with severe aortic stenosis at high risk for surgery; however these patients are also often affected by severe iliac-femoral arteriopathy, rendering the trans-femoral approach unemployable. Different alternative access should be use in these patients, the subclavian the trans-apical or a direct aortic approach.

Methods and results: At our centre from May 2008 one hundred and eighty-five patients (80 male, mean age 80±9 years) affected by severe symptomatic aortic stenosis underwent transcatheter aortic valve implantation (TAVI). After the "heart team" evaluation transcatheter aortic valve implantation with a CoreValve prosthesis was preferred in 166 patients. Forty patients (19 male, mean age 81 years) were excluded from the trans-femoral approach due to iliac-femoral arteriopathy, small size, excessive tortuosity, calcification or abdominal aorta aneurysm and underwent CoreValve implantation via a direct aortic approach through a right anterior mini-thoracotomy. Patients mean Euroscore II was 14.1%, mean left ventricular ejection fraction 54%, mean echocardiographic aortic gradient 53 mmHg. Seven patients (17%) were redo, ten patients (25%) underwent prior coronary angioplasty, twenty nine patients (72%) suffered severe renal failure, twenty patients were in atrial fibrillation. The procedure was performed through a 5 cm incision in the second intercostal space. Ascending aortic cannulation was performed with the Seldinger technique through the double purse-string sutures. A CoreValve bio-prosthesis was then carefully introduced and retrogradely implanted under angiographic and fluoroscopic guidance over the super stiff wire. Procedural success was obtained in thirty-nine patients; three patients experienced life threating bleeding according to VARC. Six patients (6/33, 18%) developed post-procedure complete atrio-ventricular block requiring permanent pacemaker implantation. Thirty days mortality was 7.5%, three patients. All other patients were discharged asymptomatic with good prosthesis function as assessed by echocardiograph after a median hospitalisation of 10 days (range 6-28 days). Mean trans-valvular aortic pressure gradient at discharge was 10 mm Hg. During a mean follow-up of 12.1±7.4 months, patients experienced functional class improvement, and returned to a normal life, limited only by their previous medical conditions. Four patients died during follow-up (one patient experienced severe idiopatic bone marrow aplasia, one patient died eight months after implantation from cachexia, one patient experience acute myocardial infarction and last patient died for severe renal failure). All patients underwent regular echocardiographic follow-up controls that demonstrated normal prosthesis performance with an average mean trans-valvular aortic pressure gradient of 9.9±5.9 mmHg at six months, with only trivial para-valvular leak.

Conclusions: Transcatheter aortic valve implantation with the direct aortic approach is safe and feasible, offering a new attractive option to treat selected high-risk patients with severe aortic stenosis and peripheral vasculopathy. The principal advantage of TAVI via a direct aortic as compared to peripheral arterial approaches are the enhanced control of the delivery system and the ability to manipulate the delivery system so that is truly co-axial to the plane of the aortic annulus.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI technical issues

Management of paravalvular aortic regurgitation after TAVI: prospective evaluation of the aortic regurgitation index

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Aims: Paravalvular aortic regurgitation (PAR) negatively impacts the prognosis following transcatheter aortic valve implantation (TAVI). Since precise quantification of PAR in TAVI patients remains challenging especially in the acute implantation situation, a multi-modal approach for the evaluation of PAR with use of haemodynamic measurements and imaging modalities is imperative to identify patients who will benefit from corrective measures such as post-dilation or valve-in-valve implantation.

Methods and results: The severity of PAR was evaluated in 303 TAVI patients by angiography, echocardiography, and the assessment of haemodynamics. The Aortic Regurgitation (AR) Index has been introduced recently from a retrospective calculation in the first 146 patients of this TAVI cohort (retrospective cohort). A cut-off value of 25 was the best predictor for both: the occurrence of more-than-mild PAR and 1-year all-cause mortality. This AR Index cut-off value was evaluated prospectively as basis of a multimodal algorithm (with combination of imaging modalities and haemodynamics) to manage PAR after TAVR in the following 157 patients (prospective cohort). Patients of the prospective cohort had a mean age of 81.5±6.1 years and were at high surgical risk reflected by a logistic EuroSCORE of 24.4±15.2%. Based on the AR Index, the occurrence of more-than-mild PAR in the prospective cohort (N=157) could be reduced significantly compared to the retrospective cohort (N=146) (6.9% vs. 15.1%; p=0.026), whereas the post-dilation rate was not significantly different (35.2% vs. 27.4%; p=0.15). By use of post-dilation, the AR Index could be increased from 17.8±5.0 to 27.6±7.5 (p<0.001) in 50 patients with significant PAR after initial deployment of the valve without excess of stroke risk (2.0% vs. 1.1%; p=0.65). The 30-day mortality rate showed a benefical trend in favour of the prospective cohort (3.4% vs. 6.8%; p=0.19).

Conclusions: A multimodal algorithm considering haemodynamics in addition to imaging modalities was useful to identify patients with significant PAR after TAVI. Post-dilation helped to reduce the procedure-related rate of paravalvular leakage significantly without increasing stroke risk.

Optimisation of placement for the transcatheter aortic Edwards Sapien valve: the two-step inflation technique

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Aims: Correct valve prosthesis positioning is of paramount importance in transcatheter aortic valve implantation (TAVI). Positioning is of particular concern when implanting balloon-expandable valves, since this valve type cannot be retrieved or relocated. Incorrect valve placement may lead to serious adverse events, i.e. high-grade aortic valve regurgitation, coronary artery obstruction and prosthesis embolisation. In order to optimise valve placement, we introduced a 'two-step inflation technique': a staged inflation of the balloon crimped valve, interrupted by angiographic verification of valve position, to allow for corrections before definite deployment. All these steps are performed under 'prolonged' rapid pacing (180-200 bpm) to stabilise output/pressure. A comparable technique has been previously described by Pasic et al. only in transapical aortic valve implantation. The transapical approach may be considered more apt for very last valve position adjustments, since this approach provides more direct control of the prosthesis. The aim of this study is to evaluate the results of the 'two-step inflation technique' with respect to achieving optimal valve implantation depth (defined as 40% of prosthesis height extending below the lower sinus border on angiography) also in patients undergoing TAVI with different approach (transfemoral, direct aortic).

Methods and results: Between September 2010 and September 2012, 77 patients (53 females, mean age 80.8±6.2 years) were treated with the Edwards SAPIEN XT prosthesis using the 'two-step inflation technique'. All patients were treated for severe aortic valve stenosis with prohibitive risk for surgery or inoperability (mean EuroSCORE-I 16.0±7.8%). TAVI was performed through transfemoral (n=55), transapical (n=14) or direct aortic approach (n=8), with predilatation routinely applied. Implantation depths were retrospectively measured on angiographic images. Mean valve implantation depth was 36.8±13.5% of prosthesis height, corresponding to 6.1±2.4 mm. Mean deviation from the defined optimal implantation depth was 10.9±8.4%, equaling 1.8±1.3 mm. Valve implantation depth diverged less than 5% from the optimum in 22 cases (28.9%), and less than 10% in 44 cases (57.9%), and less than 15% in 54 cases (71.0%). During 19 procedures (25.0%) valve position was substantially corrected after first step inflation, resulting in an implantation depth <10% from the optimum in 13 instances (including all cases of correction in the direct aortic approach). Substantial valve position adjustments were not associated with increased pacemaker dependency or stroke rates. There were 2 cases (2.6%) of ventricular fibrillation and ventricular tachycardia following valve deployment (both easily resolved by DC shock and leaving no sequelae), one case of late (3 days later) valve dislocation towards the left ventricle (too ventricular implantation), leading to death and no cases of coronary artery obstruction or high-grade aortic regurgitation.

Conclusions: The opportunity to correct valve position offered by the 'two-step inflation technique' can be valuable in a minority of TAVI procedures. When corrections are made, valve position is frequently adjusted towards an optimal implantation depth, especially in the direct aortic approach. Thereby, it may potentially prevent adverse events due to malpositioning. The 'two-step inflation technique' appears to be safe in this cohort, despite longer rapid ventricular pacing times.

Is post-dilatation useful after implantation of the Edwards valve?

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Aims: To assess the efficacy and safety of post-dilatation (PD) for the treatment of significant paravalvular aortic regurgitation (AR) after transcatheter aortic valve implantation(TAVI) of the Edwards valve.

Methods and results: A total of 470 patients (age 83.4±6.4 years, male gender 44.9%, Logistic Euroscore 21.9±12.3) undergoing TAVI with the Edwards valve were evaluated. PD was performed using the balloon delivery system with an additional 1 to 2 cc contrast mix when significant paravalvular AR was identified. The diameter of the valve was measured from cine acquisition at 3 different levels (proximal: D1, mid: D2 and distal crown: D3). PD was performed in 49 patients (10.4%). Patients with PD had similar valve size annulus diameter by transoesophagal echo ratio (1.15±0.11 vs. 1.13±0.20 vs. 1.15±0.09, p=0.88 but a smaller valve size/calculated average annulus diameter by MSCTratio (1.03±0.28 vs. 1.10±0.12, p=0.02). After PD, a reduction in at least 1 degree of AR was achieved in 81.5% of cases (pre AR grade II, III and IV in 42.1%, 55.3% and 2.6%, and residual AR grade II, III and IV in 36.8%, 10.5%, 0%, respectively). A significant increase in the prosthesis diameter was observed at the 3 valve levels (Absolute Δ3.5% to 5.4%, p<0.01). For the 23 mm valve, D2 increased from 23.0±0.4 mm to 24.1±0.5 (p<0.01). For the 26 mm valve from 25.2±0.9 to 26.6±0.9 (p<0.01). The occurence of annulus rupture (4.2% vs. 1.7%, p=0.24), cerebrovascular accidents (2.6% vs. 2.4%, p=0.63), need for new pace maker (8.3% vs. 4.3%, p=0.31), and 30-day composite endpoint (25.5% vs. 21.3%, p=0.50) and one year Kaplan Meier survival curve were similar.

Conclusions: Treatment of significant paravalvular leak using PD with the delivery balloon after Edwards valve inplantation is associated with a significant increase in valve diameter and decrease in at least one AR grade in 81.5% of cases. This promising approach to treat significant AR may improve long term outcome and need further confirmation.

Interventions for structural heart disease – *Thursday May 23rd*
TAVI technical issues

Clinical impact and predictors of prosthesis-patient mismatch in patients undergoing TAVI

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Aims: Prosthesis-patient mismatch (PPM) is regarded an index of prosthetic valve dysfunction after transcatheter aortic valve implantation (TAVI) according to VARC-2 criteria. We investigated the clinical impact and predictors of PPM in patients undergoing TAVI.

Methods and results: Procedural, clinical and echocardiographic parameters [aortic valve annulus diameter, left ventricular ejection fraction (LVEF), pulmonary artery systolic pressure (PASP)], transvalvular gradients, and effective valve orifice (EOA) were recorded at baseline and prior to discharge in 170 high-risk inoperable patients undergoing TAVI. PPM was defined as moderate when indexed effective orifice area (EOAi) ≤0.85 cm^2/m^2 and severe when EOAi <0.65 cm^2/m^2. There was a reduction in mean (49.9±15.2 to 9.3±4.1 mmHg) and peak gradients (81.5±24.4 to 17.6±7.9 mmHg). Fifty-nine patients (35%) had moderate and 13 (8%) had severe PPM. Fifteen patients (9%) suffered major vascular complications; of these, 7 (50%) had PPM (P<0.4). At 30 days 4 patients died, one had PPM. Unadjusted predictors for PPM were: female gender, height, pre-LVEF, pre-mean gradient >40 mmHg and pre-TAVI PASP. Independent predictive factors of PPM were: pre-TAVI PASP (OR: 0.972, 95% CI: 0.948-0.997, p<0.026), pre-LVEF (OR: 0.942, 95% CI: 0.907-0.978, p<0.002) and pre-mean gradient>40 mmHg (OR: 3.044, 95% CI: 1.314-7.053, p<0.009).

Conclusions: Prosthesis-patient mismatch is a frequent finding post TAVI, patients suffering from PPM did not have increased rates of death or major vascular complications compared to patients without PPM.

Interventions for structural heart disease – *Friday May 24th*
Developments in percutaneous closure of the LAA

Biological response following watchman and amplatzer cardiac plug implantation in a canine left atrial appendage model

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Aims: Left atrial appendage occlusion is an important alternative to long term anticoagulation in patients with atrial fibrillation. The Watchman and Amplatzer Cardiac Plug are the two most commonly used devices. There is paucity of data comparing the healing response and efficacy between these two devices in the either a preclinical or clinical setting.

Methods and results: Three Watchman and 3 Amplatzer Cardiac Plug were successfully deployed in the left atrial appendages of six dogs under fluoroscopic and transesophageal echo guidance and evaluated at 28 days post-implant. Prior to euthanasia, cine fluoroscopy, coronary angiography and transesophageal echo were performed in all animals. All devices were radiographed for strut discontinuities, photographed grossly, and examined by histological examination following embedding in methymethacrylate. All devices were appropriately implanted as confirmed by fluoroscopy and transesophageal echo. Minor to moderate peri-device flow was found in both devices by transesophageal echo (3/3 for Watchman, and 1/3 for Amplatzer Cardiac Plug at the time of implant and the leakage was diminished at 28-days. The disk of the Amplatzer Cardiac Plug was extended over the mitral annulus with extension over the leaflet in 2 animals, and lateral mitral regurgitation was observed in one dog. In comparison, the Watchman device remained confined to the edge of the atrial appendage. The left circumflex artery was patent post implantation in all animals. Left circumflex artery bending movement was observed in Amplatzer Cardiac Plug (1/3) but not in Watchman (0/3). There were no strut fractures in any of the devices. Histopathology examination revealed all Watchman surfaces to be completely incorporated with organising endocardial growth and was well-organised by fibromuscular tissue at the periphery of the device. However, intermittent areas of unorganised fibrin and red blood cell thrombus was observed focally close to the centre of the device. Amplatzer Cardiac Plug results were similar, but in two dogs, the outer flange had incomplete endocardial coverage, over the mitral leaflet. Histologic comparison of healing parameters (Grade 1 to 4 with no granulation tissue graded as 0 (completely healed), minimal, mild to moderate as 1 to 3 grades and totally unorganised grade 4) showed greater granulation tissue in the Watchman and less organisation with fibrin deposition and greater inflammation in Amplatzer Cardiac Plug.

Conclusions: This small pilot study demonstrates better confinement of the Watchman to the appendage and accelerated healing in comparison to the Amplatzer Cardiac Plug which showed overhang over the mitral valve and slower healing in a canine model at one month. Larger studies with longer follow-up are needed to further understand these differences.

Percutaneous left atrial appendage closure with a second generation device

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Aims: The objective of our study was to describe the initial worldwide experience with the Amulet™, the second generation of the Amplatzer™ Cardiac Plug, for left atrial appendage (LAA) closure.

Methods and results: Between July and December 2011, all patients undergoing LAA closure using the Amulet™ were included in the study. The Amulet™ has been designed to facilitate the implantation process and minimise the occurrence of complications because of strategic modifications without changing the main design of the Amplatzer™ Cardiac Plug. The indication for LAA closure was based on a formal contraindication for oral anticoagulation. All procedures were done under general anaesthesia and transesophageal echocardiography (TEE) guidance. Transthoracic echocardiography was performed 24 hours after the procedure in order to rule out procedural complications before discharge. Further follow-up was done with a clinical visit and TEE at 3 months. Ten patients (mean age 71.8±7.3; 80% males) with a CHADS2 score of 2.9±2.0 were included in the study. Four patients (40%) presented complex LAA anatomies with a 180º chicken-wing morphology in three and a very large LAA in one. The Amulet™ was successfully implanted in all patients. The mean size of the device was 24.9±5.1 mm. No device embolisation, procedural-related strokes or pericardial effusions were documented. At 3 months, clinical and follow-up TEE was available in six (60%) patients. None of them presented any clinical event and all of them showed complete LAA sealing without any degree of residual shunt.

Conclusions: In this initial series of patients, the Amulet™ showed a remarkable performance in terms of efficacy and safety as depicted by the successful implantation in all patients and the absence of procedure-related complications.

Geometry and degree of apposition a cardiac plug for left atrial appendage occlusion: a multi-slice computer tomography study

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Aims: Left atrial appendage (LAA) occlusion has emerged as a valuable alternative for stroke prevention in patients with atrial fibrillation. The Amplatzer Cardiac Plug ® (ACP, St. Jude Medical, MN, USA) is a self-expanding device with a disc-lobe configuration. Our aim was to evaluate the geometry and degree of apposition of the ACP with multi-slice computer tomography (MSCT).

Methods and results: Forty-eight patients had MSCT after LAA occlusion with the ACP at a median 8 months (interquartile range [IQR] 3 to 14 months). Axial dimensions, cross-sectional area (CSA), and perimeter of the ACP disc and ACP lobe (at 3 levels: proximal, median, and distal), and the disc-lobe angulations were evaluated. In order to assess the % degree of lobe deformation, orthogonal largest and smallest diameters of the ACP lobe were measured at each level ([largest/smallest diameter x 100] -100). Mean lobe diameters were compared to nominal lobe dimensions in order to assess the degree of lobe expansion. ACP disc and lobe apposition on the LAA walls were evaluated using a clock-face and were correlated to relevant anatomic structures (left circumflex artery [Cx], left superior pulmonary vein [LSPV]). The causes for non-apposition were also investigated. Patients with signs of device non-apposition on MSCT underwent trans-esophageal echocardiography (TEE) with colour-flow Doppler for detection of peri-device leaks. The mean ACP size was 23.4±3.2 mm. The mean disc diameter was 28.0±3.9 mm and the mean disc-lobe angulation was 13.3±6.8 degrees. The mean largest/smallest lobe diameter at the proximal, median, and distal lobe segment was 23.2±3.6/21.8±3.6, 22.9±3.7/22.5±3.7, and 23.2±3.5/21.8±3.7 mm, respectively. Mean lobe diameters were 22.5±3.6, 22.3±3.7, and 22.5±3.6 mm, respectively. The median (IQR) lobe deformation at the proximal, median, and distal segment was 4.4 (1.9-8.7), 5.9 (3.1-8.7), and 5.3 (3.2-8.6)%, respectively. The degree of lobe expansion at the proximal, median, and distal segment was 96.0±5.0, 94.9±5.9, and 96.2±5.3%, respectively. In 17 patients (35%) some degree of disc and/or lobe non-apposition was found. In the clock-face analysis (h2=Cx, h8=LSPV) the majority of non-apposition areas were at h3-h6 and h8-h10, i.e. inferiorly to the Cx and around the LSPV area. Non-apposition was not associated with the degree of lobe deformation (apposition vs. non-apposition 7.2±5.7 vs. 5.9±4.4%, p=0.36). However, non-apposition was associated with lobe expansion (apposition vs. non-apposition 93.1±7.2 vs. 97.1±2.3%, p<0.05). The causes for non-apposition were device undersizing (7/17 patients, 41%), special LAA – "chicken-wing" anatomy (7/17 patients, 41%), too shallow implant (2/17 patients, 12%), and non-perpendicular lobe position (1/17 patients, 6%). Ten patients (10/17, 60%) had a TEE at a median (IQR) 5 (2-16) months post-procedure. In 7 and 4 patients residual flow was detected around the ACP disc and lobe, respectively. The median (IQR) jet width was 1.8 (0-2.8) mm and the largest jet was 4.3 mm.

Conclusions: Multi-slice computer tomography demonstrated a 4-6% degree of axial deformation and a 94-96% expansion of the ACP lobe. Non-apposition of the ACP disc and/or lobe was found in one third of patients and was associated with more lobe expansion. Device undersizing and LAA "chicken-wing" anatomy were identified as main causes for non-apposition. None of the patients with device non-apposition had significant peri-device leaks on TEE.

Interventions for structural heart disease – *Friday May 24th*
Developments in percutaneous closure of the LAA

Endocardial occlusion of incompletely surgically-ligated left atrial appendage

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Aims: Incomplete surgical left atrial appendage ligation (ISLL) in patients who undergo mitral valve surgery or as an adjunct to a surgical Maze procedure for treatment of atrial fibrillation can lead to thrombus formation and clinically relevant thromboembolic complications. We present a new approach for percutaneous endocardial occlusion of ISLL.

Methods and results: We report on a series of 9 patients with non-rheumatic atrial fibrillation and ISLL following prior cardiac surgery. Three were diagnosed in the setting of acute embolic stroke, 2 at the time of cardiac arrhythmia ablation, and 4 during routine chest/cardiac imaging. The ISLL orifice (ostium) measured 4.7±2.7 (range: 2 - 8) x 3.1±0.6 (range: 2 - 4) mm. All patients were treated with oral anticoagulation therapy. Seven patients underwent percutaneous endocardial ISLL occlusion using a 5-, a 6-, or a 9-mm Amplatzer Septal Occluder device guided by fluoroscopy, transoesophageal echocardiography, and 3-dimensional electroanatomical mapping (fluoroscopy time: 19.2±9.5 minutes, procedure time: 111±19 minutes). Acute and long term ISLL occlusion was successfully achieved in 6 patients, in whom oral anticoagulation was eventually discontinued after 6 weeks without sequelae or embolic events during a mean follow-up of 6 months.

Conclusions: Percutaneous endocardial occlusion of ISLL can be safely achieved using an Amplatzer Septal Occluder device. Additional studies are required to evaluate the long term safety and efficacy of this new therapeutic treatment strategy in patients with incomplete surgical ligation of the left atrial appendage.

Interventions for structural heart disease – *Friday May 24th*
Developments in percutaneous closure of the LAA

Efficacy and safety of percutaneous left atrial appendage closure in patients with non-valvular atrial fibrillation: a single-centre experience

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Aims: To demonstrate the safety and efficacy of percutaneous left atrial appendage closure in patients with non-valvular atrial fibrillation having CHADS-Vasc score of ≥1.

Methods and results: All adult patients with non valvular atrial fibrillation having CHADS-Vasc score of 1 or more were considered eligible for the single-centre, prospective, non-randomised study of Watchman device if they had contraindication for warfarin, non-compliance to the warfarin, labile international normalised ratio or physician advice accordingly with patient consent. They had transoesophageal echo for evaluation of left atrial appendage size and morphology. Selected patients were enrolled for the procedure after proper consent which was conducted under fluoroscopic and transoesophageal echo guidance. Patients with successful procedure had follow-up transoesophageal echo at 45-60 days for evaluation of devise position, gap and clot formation. If no significant gap or clot were detected then warfarin would be stopped otherwise it would continue. Patients will be clinically followed initially at 3, 6 and 12 months and then yearly for stroke. Primary endpoint was the composite of death and stroke/Transient ischaemic attack and secondary endpoint was stroke/transient ischaemic attack. 84 patients were screened for percutaneous closure of left atrial appendage with Watchman device in the year 2010, 2011 and 2012. 16 patients were not considered eligible for Watchman device due to unsuitable morphology of left atrial appendage, significant comorbidities of the patients or poor general condition of the patients. Majority of our patients were male and average CHADS-Vasc score of our patients were between 3 and 4. 68 patients were considered eligible for insertion of Watchman device. Procedure was not successful in 2 patients due to complications such as left atrial appendage perforation and pulmonary vein dissection. Procedure was safe in 97% of the patients. In 66 patients with successful procedure, one had massive stroke 3-4 hours after the procedure and expired after 3 days of the procedure while another patient expired after one month due to non-cardiac causes. One patient refused for the repeat transoesophageal echo and seven patients are still waiting for the transoesophageal echo follow-up due date. 56 patients had follow-up transoesophageal echo and warfarin was stopped in 54 patients (96%) and one patient was not taking warfarin prior to the procedure due to noncompliance. One patient had clot/ gap so warfarin was continued. 3 patients experienced primary composite end point of mortality or transient ischaemic attack/stroke during mean follow-up of eight months after the procedure. Two patients expired before follow-up transoesophageal echo at 45-60 days; one due to stroke and other due to non-cardiac causes. One patient (1.5%) experienced secondary endpoint of stroke/transient ischaemic attack during follow-up after procedure although it was probably due to diffuse cerebrovascular disease.

Conclusions: Percutaneous closure of left atrial appendage with Watchman device is considered safe and efficacious. 62% reduction in stroke was detected compared with expected stroke rate according to CHADS-Vasc score in our study population.

Transcatheter percutaneous left atrial appendage closure for stroke prevention in atrial fibrillation: the Belgian Registry

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Aims: Percutaneous transcatheter left atrial appendage closure is an alternative therapeutic option for stroke prevention in patients with atrial fibrillation not candidates for anticoagulant therapy. The aim of the present study was to evaluate the feasibility, the safety of the procedure and the 1-year outcome following Amplatzer Cardiac Plug implantation in Belgium.

Methods and results: Procedural, clinical and echocardiographic data were prospectively collected among 90 consecutive patients, treated by an Amplatzer Cardiac Plug implantation for left atrial appendage closure in 7 Belgian centres between June 2009 and September 2012. The patients (56 males, 74±8 yrs) were at high risk for stroke (CHADS-Vasc=4.4±2) and for bleeding (HASBLED=3.2±1). All the procedures were guided using both fluoroscopy and transoesophageal echocardiography, under general anaesthesia. The mean size of the appendage ostium and the Amplatzer Cardiac Plug was 21±4 mm and 24±4 mm respectively. The mean number of attempts was 2.4±2. The fluoroscopy time was 22±14 min and contrast volume was 94±47 ml. Technical success was obtained in all but one patients (too large appendage). Procedural complications were 7 (4 pericardial effusions treated conservatively, 1 tamponade treated successfully by pericardiocentesis, and 2 myocardial infarctions related to air embolism in the coronary tree). In-hospital complications were 3 (1 femoral pseudoaneurysm, 1 tamponade treated successfully by pericardiocentesis and another one tamponade resulting in death). The patients were discharged at 2±1 days. Follow-up at 30-days, 6 and 12 months was obtained among 92, 82 and 65% of patients respectively: one additional tamponade treated by pericardiocentesis, two ischaemic strokes and two deaths (no procedure related) were observed. Residual leak was evaluated by transoesophageal echocardiography at the end of the procedure in 52 patients (graded as none in 42, small in 9 and large in 1of them) and was repeated at 6 months in 37 patients (graded as none in 32 and small in 5). No delayed device embolisation, dysfunction or thrombus was detected by echo up to 1-year. Overall survival was 98%, major event-free survival was 83±5% at 1 year. In our population, the patients had an expected annual stroke risk, according to the CHADS-Vasc score, at 4.7%/year; the observed stroke rate was 2.9%/year.

Conclusions: The Belgian registry shows that left atrial appendage closure using the Amplatzer Cardiac Plug is feasible and safe with encouraging results up to 1 year. Longer follow-up is needed to evaluate the long-term safety and its efficacy in reducing stroke.

Interventions for structural heart disease – *Friday May 24th*
Developments in percutaneous closure of the LAA

An analysis of the cost effectiveness of left atrial appendage closure for the prevention of stroke in patients with atrial fibrillation and absolute contraindications to warfarin therapy

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Aims: Recently the Watchman device for left atrial appendage closure (LAAC) received CE mark for stroke prevention in AF patients with contraindications to warfarin. This analysis sought to estimate the cost effectiveness of treating warfarin-ineligible AF patients with LAAC as compared to standard aspirin therapy.

Methods and results: A Markov model was developed comparing clinical outcomes and total costs between patients treated with LAAC or aspirin over 5 and 10 years based largely on clinical outcomes from the Aspirin and Plavix Registry (ASAP) and ACTIVE trials. ASAP enrolled 150 AF patients with absolute contraindications to warfarin for implantation with the Watchman device. As the registry did not include a comparator arm, event probabilities for the aspirin population were taken from ACTIVE. The 7,554 warfarin unsuitable patients enrolled in ACTIVE were less likely than ASAP patients to have a specific bleeding risk (23% vs. 67.3%), had a lower mean CHADS2 score (2.0 vs. 2.8) and were slightly younger (71.1 vs. 72.5). Inputs for aspirin disability outcomes following a stroke or intracranial haemorrhage were obtained from O'Brien 2005 and Rosand 2004. The model was populated with a cohort of 10,000 70-year old patients with a mean CHADS2 score of 2 (annual stroke risk of 4.5%) and a mean HASBLED score of 3 (annual bleeding risk of 3.74%). Clinical events included ischaemic stroke, TIA, systemic embolism, bleeding, and acute myocardial infarction as well as procedure-related events. Germany was chosen as the country of analysis because of its unique DRG for the LAAC procedure. Acute costs were taken from German DRGs and long-term disability costs were taken from the Berlin Acute Stroke Study. A 3% discount was applied to both future costs and outcomes. Economic outcomes are reported as cost per clinical event avoided and cost per life year gained. LAAC demonstrated a benefit in terms of ischaemic strokes avoided. Over 5 years, the expected rate of ischaemic strokes for this population was 3.5% and 10.3% for LAAC and aspirin, respectively. At 10 years, the expected stroke rate was 6.6% for LAAC and 20.2% for aspirin. The cost per ischaemic stroke avoided was €91,020 and €24,722 at 5 and 10 years, respectively. The cost per stroke avoided at 5 years decreased as the CHADS2 score increased: €26,658 and €12,554 for a score of 3 or 4, respectively. A reduction in mortality was also observed. At 5 years, 21% of the LAAC cohort had died compared to 23% for aspirin. At 10 years, the rate was 45% for LAAC and 50% for aspirin. The cost per life year gained for LAAC vs. aspirin was €22,694 at 5 years and decreased to €5,859 at 10 years. Sensitivity analysis was performed on clinical and cost inputs; the model was most sensitive to changes in the rate of ischaemic stroke.

Conclusions: LAAC is a cost-effective alternative to aspirin therapy in patients with contraindications to warfarin. Cost offsets achieved with LAAC become considerably more pronounced over time.

Interventions for structural heart disease – *Friday May 24th*
Developments in percutaneous closure of the LAA

Dabigatran for anticoagulation following left atrial appendage closure: the ALSTER LAA registry

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Aims: Interventional left atrial appendage occlusion with the WATCHMAN® device is increasingly used in patients with atrial fibrillation and contraindications to warfarin. This leads to the dilemma that every device needs at least a moderate anticoagulation until the endotheliasation is completed after approximately three to six months. However, the optimal strategy for anticoagulation during this period after implantation remains controversial in those patients. There is increasing evidence that the use of dual anti-platelet therapy is an option in this situation (ASAP registry, ALSTER-LAA-registry). Unfortunately, this leads to a markedly increased risk of bleeding as well and seems suboptimal for the low-flow profile of the left atrium. In this context, there is currently no data available regarding the use of the new oral anticoagulants (dabigatran, rivaroxaban, apixaban).

Methods and results: Since April 2012 all patients within the ALSTER-LAA-registry who received a WATCHMAN® device were treated with dabigatran or rivaroxaban for 3 or 6 months after implantation, depending on their individual bleeding risk. We used a reduced dosage of 75 mg dabigatran twice daily or 15 mg rivaroxaban once daily. This dose is known to be effective in deep vein thrombosis. However, it remains uncertain whether it is effective to suppress the thrombogenity of the WATCHMAN® device during the first three months after implantation. Our own and other previous series have seen approx. 5% of patients to present with a thrombus at the device both under warfarin or dual platelet therapy. Thus, echocardiographic follow-ups were performed three months after implantation in all patients with special respect to thrombus formation on the device. A total of 19 consecutive patients were treated with dabigatran or rivaroxaban since April 2012. The mean age was 72.8±2.0 years, the CHA2DS2-VASc-Score 4.7±0.4 and the HAS-BLED-Score 3.6±0.3. Nine patients had suffered from major bleedings prior to WATCHMAN® implantation, the remaining were unable to maintain stable INR levels. So far, 9 patients completed their follow-up after three months. There was no thrombus detected using transesophageal echocardiography. No patients suffered from major bleeding or thromboembolic events (the follow-up is currently being completed; until May 2013, 6 months data will be available for all patients).

Conclusions: The reported data demonstrate that dabigatran may be an alternative to warfarin during the period of endotheliasation after WATCHMAN® implantation. This regime could facilitate the use of left atrial appendage occlusion in patients with contraindications to warfarin. Due to the short follow-up period so far and the limited number of patients, these results have to be interpreted with caution. However, these experiences should give the rationale for larger registries and trials to further investigate the use of low-dose new oral anticoagulants after WATCHMAN® implantation.

Interventions for structural heart disease – *Friday May 24th*
Unfrequent indications for TAVI

TAVI in high-risk patients with stenotic bicuspid aortic valves

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Aims: TAVI shows promise in the treatment of severe stenosis of triscupid aortic valves in high-risk patients. However, bicuspid aortic valve stenosis has been considered a contraindication to TAVI. The aim of this study was to assess the feasibility and results of TAVI in patients with bicuspid aortic valve stenosis.

Methods and results: Of 85 high-risk patients with severe aortic stenosis who underwent TAVI in our centre from January 2009 to January 2013, 4 (5%) had documented bicuspid aortic valves. They were treated using a transarterial approach using the Medtronic CoreValve (3 patients) and Edwards Sapien XT systems. Patients were aged 74±6 years, in New York Heart Association functional classes III. The mean aortic valve area was 0.7±0.7 cm^2, and the mean gradient was 47±10 mmHg. The procedure was successful in all patients. One adverse event according to new Valvular Academic Research Consortium definitions occured: a pacemaker implantation was necessary in a patient treated with CoreValve system. The mean postimplantation prosthetic gradient was 8.5±1.3 mmHg, the mean aortic valve area was 1.5±0.06 cm^2, periprosthetic leaks >1 grade did not occur. After a mean follow-up period of 12±2 months, no adverse events occurred. New York Heart Association functional class improved in all patients (class I in 1 patient, class II in 3 patients). The mean prosthetic gradient and the mean aortic valve area remained unchanged.

Conclusions: Our experience suggests that transarterial Medtronic CoreValve and Edwards Sapien XT implantation is feasible in selected patients with bicuspid aortic valve leading to good haemodynamic and clinical results in 1-year follow-up.

Corevalve implantation for severe aortic regurgitation: a multicentre registry

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Aims: TAVI for severe aortic regurgitation is still an "off label" indication. Nevertheless, some preliminary experiences have been published reporting encouraging results. In this large multicentre registry, we sought to evaluate the safety/efficacy profile of the TAVI procedure by means of Corevalve implantation in inoperable patients presenting with severe aortic regurgitation (AR).

Methods and results: Among 1070 patients treated with Corevalve implantation, 19 (2.6%) presented with "pure" severe aortic regurgitation (group A). With respect to those with severe aortic stenosis (group B), these patients: 1) were significantly younger (mean age 73+10 vs. 82+6); 2) had lower incidence of ischaemic heart disease (16% vs. 46%, p=0.02); 3) were more frequently in NYHA classe 3-4(90% vs. 73%, p=0.005); 4) had higher incidence of severe pulmonary hypertension (sPAP>60 mmHg, 20% vs. 10%, P=0.001); 5) had more frequently a left bundle branch block (21% vs. 8%, p=0.03). Log Euroscore (23.8% vs. 22%) and STS score (8.1% vs. 8.8%) were quite similar. According to VARC-2 definition, procedural success was significantly lower in group A (79% vs. 94%, P=0.005), and besides the more frequent use of Corevalve 31, they had a significantly more frequent need for a second valve implantation (11% vs. 4.5%, p=0.002). Survival analyses and inherent log rank tests showed that patients in group A had a higher overall (37.8% vs. 9%, OR 40.4, CI 19.9-70.1, p<0.001) and cardiac mortality at 1 month (22% vs. 6%, OR 23.4, CI 9.4-51.4, p<0.001). Likewise, at 12 months patients treated for severe AR had a higher overall (68% vs. 22%, HR 31.2, CI 22.5-61.6, p=0.001) and cardiac mortality (48%vs 16%, HR 29.8, CI19.8-45.8 p=0.002).

Conclusions: Inoperable patients undergoing TAVI with CoreValve for severe aortic regurgitation have a significantly higher mortality compared to patients undergoing TAVI for severe aortic stenosis. Considering the ominous prognosis of patients with severe aortic regurgitation who are medically treated, TAVI still seems a reasonable choice. Of note, in this setting, conventional risk scores have an inadequate predictive value.

Self-expandable TAVI for aortic stenosis after mitral valve surgery

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Aims: Transcatheter aortic valve implantation has emerged as a valuable option to treat patients with symptomatic severe aortic stenosis not being considered for surgery because of significant comorbidities. Concerns exist about treating patients who previously underwent mitral valve surgery for possible interference between the percutaneous aortic valve and the mitral prosthesis or ring.

Methods and results: At our Centre from May 2008 one hundred and eighty-five patients (80 male, mean age 80±9 years) affected by severe symptomatic aortic stenosis underwent transcatheter aortic valve implantation (TAVI). After the "heart team" evaluation transcatheter aortic valve implantation with a CoreValve prosthesis was preferred in 166 patients, in nine of them (7 female) the procedure was performed as reoperation after prior mitral valve surgery (4 mono-leaflet, 3 bi-leaflet, 1 bioprosthesis, 1 mitral ring). The mean interval between TAVI and the last operation was 12.5 years. The median patient age was 73.6 years (range 31 to 83 years). Seven patients were female, all patients were in chronic controlled atrial fibrillation. Three patients had previous stroke without any permanent sequelae. Seven patients underwent standard femoral retrograde CoreValve implantation, two patient underwent a direct aortic implantation through a mini-thoracotomy. No CoreValve balloon post-dilatation was needed. All patients experience immediate improvement of the haemodynamic status. Procedural success was achieved in all patients; no cases of procedural death, stroke, myocardial infarction or urgent cardiac surgery occurred. No deformation of the nitinol tubing of the CoreValve neither distortion or malfunction of the mechanical valve or mitral ring occurred as assessed by echographic and fluoroscopic evaluation. No major post-operative complications occurred, one patient required post-TAVI new pace-maker implantation for complete heart block. Mean post-operative echocardiographic aortic gradient was 10±4 mmHg. Paravalvular aortic regurgitation was absent or mild in all the nine cases, mitral prosthetic function remained unaffected in all patients. Patients were discharged after a mean hospitalisation of 12 days with no 30-day mortality.

Conclusions: As reported by other Authors the presence of a mechanical valve in mitral position might complicate TAVI because of the reduction of the mitro-aortic space to accommodate the transcatheter valve and because the presence of a mechanical valve can limit the expansion of the percutaneous prosthesis. In our experience we did not observe any displacement or deformation of the nitinol frame of the CoreValve nor distortion of the housing or interference with the leaflet excursion of the mitral prosthesis as assessed by fluoroscopy and serial echocardiographic evaluation, at the same time the presence of mitral prosthesis did not affect the rate of perivalvular leak. This observation tend to suggest that in this population, self-expanding valve may guarantee more stability during implantation and probably a direct aortic access with a short distance between the entry site and aortic annulus and higher valve deployment control should be better in these patients. Our experience characterised by a multidisciplinary approach, necessary to offer the safest conditions and care for patients, shows that CoreValve implantation can be performed successfully in patients with mechanical or biological mitral valves or annuloplasty mitral ring.

Interventions for structural heart disease – *Friday May 24th*
Unfrequent indications for TAVI

Valve-in-valve implantation of a novel and small self-expandable transcatheter heart valve in degenerated small surgical bioprostheses: the Hamburg experience

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Aims: Transcatheter valve-in-valve implantation has emerged as a novel treatment option in patients with degenerated aortic bioprostheses and high surgical risk. However, valve-in-valve implantation in small aortic bioprostheses using first generation TAVI devices has frequently resulted in high post-procedural gradients and small effective orifice areas. Recently, a novel self-expandable second generation heart valve particularly suitable for small aortic annuli has become available. We report on the feasibility and early results of valve-in-valve implantation employing this novel device in a series of patients with degenerated small aortic bioprostheses.

Methods and results: 12patients from two Hamburg hospitals (age range 72 - 92 years) underwent transfemoral implantation of a 23 mm CoreValve Evolute (Medtronic, Minneapolis, MN, USA)transcatheter heart valve into failing aortic bioprostheses with internal diameters below 21 mm. All patients were considered high risk for surgical aortic valve replacement after evaluation by an interdisciplinary heart team mean (logistic EuroSCORE range 9.0-88%). Implantation was successful without relevant remaining aortic regurgitation or signs of stenosis and a marked reduction in post-procedural gradients in all patients. No major device- or procedure-related adverse events occurred during 30-day follow-up and clinical improvement was observed.

Conclusions: Failing aortic bioprostheses with small internal diameters continue to be a challenging pathology for TAVI due to the risk of high residual gradients and small aortic orifice areas. This report provides first evidence that the 23 mm Core Valve Evolute, a novel second-generation self expanding prosthesis provides an improved treatment option in these specific patients due to its low profile which resulted in promising early results.

Interventions for structural heart disease – *Friday May 24th*
Unfrequent indications for TAVI

Transcatheter aortic valve replacement for failing surgical bioprostheses: results from the SOURCE and SOURCE XT registries

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Aims: Symptomatic primary tissue failure of previously implanted surgical bioprostheses may be treated with TAVI in patients with high to extreme surgical risk. Clinical results of patients with a valve-in-surgical valve procedure enrolled in the commercial SOURCE and SOURCE XT registries are presented.

Methods and results: Valve-in-surgical valve clinical results were evaluated in 81 patients in the SOURCE (SAPIEN THV, n=22) and SOURCE XT (SAPIEN XT THV, n=59) registries who previously received pericardial or porcine surgical bioprostheses. The mean age across both patient populations was 77.7 years, with 42% being female recipients. Logistic EuroSCORE was 29.6% and STS-PROM risk score 7.8%. Baseline congestive heart failure was documented in 45.7% of patients with NYHA III/IV reported in 72.8% of patients. THV valve size distribution included size 23 (66.7%), 26 mm (27.2%) and 29 mm (6.2%). SAPIEN valves were implanted transapically in all SOURCE Registry patients. In SOURCE XT, 54.2% of TAVI devices were implanted transapically. No conversion to conventional surgery was reported in either cohort with only one coronary occlusion and one additional valve-in-valve bailout. Thirty-day all-cause mortality was 7.4%. Mean gradients at 30 days ranged between 15.5 mmHg and 26.3 mmHg. No moderate or severe paravalvular or transvalvular leaks were reported with effective orifice areas between 1.1 cm^2 and 1.3 cm^2. Additional cohort comparisons and procedural refinements will be presented.

Conclusions: Early experiences of TAVI in failing surgical bioprostheses show that the procedure is feasible with clinical outcomes that are not unlike those seen in native TAVI series. Mortality rates are similar to series where patients have similarly reported higher risk scores. Reported mean gradients are higher and effective orifice areas lower related to the variation in internal diameter and labeled valve sizes of the previously implanted porcine and pericardial devices. Pre-procedural acquisition of accurate bioprosthetic inner orifice dimensions may reduce the risk of prosthesis-patient mismatch.

Initial French experience with reduction of functional mitral regurgitation by percutaneous annuloplasty with a modified device

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Aims: Functional mitral regurgitation negatively impacts prognosis in patients with systolic heart failure. Because of the high procedural risk of cardiac surgery in these patients, percutaneous repair techniques have been recently developed. The Carillon® system is a device that is implanted into the coronary venous system, which enables plication of the mitral periannular tissue to improve coaptation of the leaflets. To assess the feasibility, safety and efficacy of the Carillon®system using the modified device and refined procedural techniques.

Methods and results: 16 patients with dilated cardiomyopathy of both ischaemic and non ischaemic origin, in NYHA class 3 or 4 with functional mitral regurgitation ≥2+ were prospectively included in this single-centre experience. In implanted patients, quantitative echocardiographic functional mitral regurgitation parameters (vena contracta, effective regurgitant orifice area, regurgitant volume, and mitral regurgitation jet area/ left atrial area ratio were measured before the procedure, at the discharge and at 1-month follow-up in addition to exercise tolerance assessment by NYHA class and 6 minutes walk test. The implantation success rate was 88% (14/16). Both non-implanted patients had left dominant coronary circulation. At 1 month, the degree of functional mitral regurgitation improvement among 4 quantitative echocardiographic measures ranged from 24% to 62%. The NYHA class improved from 3.2 to 2.3 and 6 minutes walk test increased from 306±88 to 394±118 metres.

Conclusions: Implantation of the modified Carillon® device using refined procedural techniques was safe, resulted in an improved implant rate, and was associated with FMR reduction and functional improvement.

Interventions for structural heart disease – *Friday May 24th*
Novel catheter-based therapies of mitral regurgitation

A novel nitinol based goretex device and a polymer patch technology abutting mitral valves to reduce mitral regurgitation: investigational results

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Aims: We investigated the potential application of a novel Nitinol based Goretex device and a polymer patch single valve device to reduce mitral regurgitation (MR).

Methods and results: A Nitinol device prototype which is diamond shaped with Goretex sutured along the sides was built. The device was threaded over a 5F screw-in pacemaker lead and fixed. The device has two antennas in the superior edge to position across atrial septum and to improve stability of the device. Reactionary force at the tip of the lead attached to the left ventricular apex and the reactionary force at the attachments of the antennas to the device was estimated. The device was positioned immediately above the the mitral valves after creating MR in a sheep heart preparation. This is to prevent the devices from impinging on the native mitral valve and chordal functions. Through a pigtail catheter in left ventricle contrast injection was given and MR was studied. Similarly the polymer device was studied. Fourier transmission infrared spectroscopy, EDAX and scanning electron microscopy of the polymer was done. The polymer material was chosen from commercially available Candy Fan, Mars due to its favourable stress and strain properties. Later the devices were enwrapped in pericardium and modeled. Later, two experiments were done for both devices in sheep heart preparations. Both devices were effective in reducing MR by more than 60% in visual quantification, with 1 mm deformation at 1000psi. By objective scoring the devices reduced MR from grade IV to grade I.

Conclusions: There is potential for novel devices abutting the mitral leaflets to reduce mitral regurgitation.

Interventions for structural heart disease – *Friday May 24th*
Novel catheter-based therapies of mitral regurgitation

TIARA: a novel catheter-based mitral valve bio-prosthesis short and long-term pre-clinical results

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Aims: TIARA is a novel self-expanding trans-catheter bioprosthetic mitral valve specifically designed to fit the unique complex anatomical configuration of the native mitral apparatus. The TIARA is implanted under fluoroscopic and X-plane trans-esophageal echocardiographic (TEE) guidance, using a short flexible 32F delivery catheter, via a trans-apical approach. The short term pre-clinical data have demonstrated that implantation of the TIARA valves in swine is a feasible, safe, and a relatively straightforward procedure, which results in a stable and well-functioning mitral bioprosthesis.

Methods and results: TIARA valves were successfully implanted in 29/36 (81%) domestic swine. Follow-up varied from 90 minutes to 96 hours per-protocol. Total procedure time ranged from 17 to 26 minutes, and the prosthesis deployment time ranged from 5 to 13 minutes. In the 29 successful implantations, TEE demonstrated excellent function and alignment of the TIARA prosthesis, with no left ventricular outflow tract obstruction, no pericardial effusion, no encroachment on the aortic valve, and no trans-valvular gradients. There was no evidence of conduction block or arrhythmia. Significant para-valvular leaks were only seen in cases of MV annulus-prosthesis mismatch or failed implantation. Macroscopic evaluation of the explanted hearts demonstrated stable and secure positioning of the valves in all planes of the mitral apparatus with no evidence of injury to the ventricular or atrial walls.

Conclusions: At the EuroPCR 2013 meeting we will present the long term (6 months) angiographic, echocardiographic and anatomical results of TIARA valve implantation in sheep.

Interventions for structural heart disease – *Friday May 24th*
Novel catheter-based therapies of mitral regurgitation

MitraClip therapy in heart failure patients with functional mitral regurgitation: 2.5 years results in a single centre experience

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Aims: Few clinical data of MitraClip therapy in patients with solely functional etiology have been reported. The aim of this study is to report mid-term outcomes of MitraClip implantation in inoperable or high-risk surgical candidates with functional mitral regurgitation (FMR) in our single-centre experience.

Methods and results: From October 2008, 85 consecutive patients with FMR underwent MitraClip implantation (mean age 68±9.5 years). FMR was ischaemic in 55 patients (73%). All patients underwent standardis ed assessment of mitral valve anatomy and functional status; 78.8% patients were in NYHA class III-IV. Logistic EuroScore was 21.8±16%. Comorbidities included: chronic renal failure (35.3%), AF (32%), diabetes (21.2%), COPD (24%), cerebrovascular disease (8.3%). Mean EF was 27±9.8%; LVEDD was 69.8±7.8 mm. Procedural success was 98.9%. 30-days mortality was 1.1%. Adverse events included: IABP support (17.2%), renal replacement therapy (7%), infections (4.7%). No cerebrovascular events or AMI occurred. Median length of stay was 4.8 days. At discharge 87% patients had MR ≤2+. At 12 months EF was 34.7±10.4% (p=0.003 compared to preoperative value). Actuarial survival at 2.5 years was 79.6±5.5%. Actuarial freedom from MR≥3+ at 2.5 years was 72.3±7.1%. At 1 year follow-up, 86% of patients was in NYHA class I-II. Need for postoperative IABP and postoperative acute renal failure were identified as risk factor of mortality at follow-up; presence of TR≥3+ was identified as a risk factor of MR≥3 recurrence at follow-up.

Conclusions: MitraClip therapy for FMR is a valuable alternative to surgery in high-risk patients. Although patients treated in current practice are high-risk, the procedure remains safe and effective in selected patients.

Real-world european experience with percutaneous treatment of significant mitral regurgitation: demographics and procedural outcomes

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Aims: Use of the MitraClip System as a percutaneous therapeutic option for treating significant mitral regurgitation (MR) continues to expand throughout Europe. As of December 31, 2012 a total of 5,984 patients have been treated with the MitraClip device in Europe in a real-world setting.

Methods and results: Baseline demographics, Device time and post-procedural reduction in MR severity are reported from the MitraClip European experience of patients treated between September 17, 2008 and December 31, 2012. A total of 5,984 patients were treated at 172 institutions in 18 countries as follows: 80 institutions in Germany, 25 in Italy, 9 in Great Britain, 8 in each of France and the Netherlands, 7 in Switzerland, 6 in Spain, 5 in each of Austria and Poland, 4 in Turkey, 3 in each of Denmark and Finland, 2 in each of Sweden, Belgium, and Norway, and 1 institution in each of Czech Republic, Greece and Luxembourg. Patients treated in Europe were elderly, with a median age of 76 years. At baseline, 67% of patients had functional MR. Left ventricular dysfunction was categorised as severe in 36% of patients, with LV ejection fraction <30% reported in 32% of patients. Pre-procedural MR severity was reported as MR ≥3+in 99.6% of patients. The MitraClip device implant rate was 95.6% with the following distribution of devices implanted: 263 patients (4.4%) underwent the MitraClip procedure but received no device, 3,670 patients (61.3%) were implanted with 1 device, 1,868 patients (31.2%) were implanted with 2 devices, and 183 patients (3.1%) were implanted with 3 or more devices. The median Device time was 78 minutes. Post-procedural MR severity was reported as MR ≤2+ in 94% of patients implanted with at least one MitraClip device, with 61% of patients achieving MR ≤1+. Of patients implanted with one or more MitraClip device(s), approximately 98% achieved at least a 1-grade reduction in MR severity, 86% achieved at least a 2-grade reduction in MR severity and 26% achieved a 3-grade reduction in MR severity. No change in MR severity between pre- and post-MitraClip procedure was reported in 1.5% of patients implanted with at least one MitraClip device. Fewer than 1% of patients had worsening MR severity. 183 patients underwent a second MitraClip intervention to further reduce MR. Of the 173 (95%) patients who were implanted with at least one MitraClip device at the second intervention, 83% achieved MR reduction ≤2+.

Conclusions: Patients treated with the MitraClip device in the real-world use setting are elderly and present with functional MR and impaired left ventricular function. Reduction of MR severity was achieved via percutaneous MitraClip therapy in the majority of these patients.

BEST 2013 ABSTRACT

Reverse remodelling in patients with severe mitral regurgitation and reduced ejection fraction one year after interventional edge-to-edge mitral valve repair

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Aims: We report the long-term effects of MitraClip™ implantation including cardiac remodelling in patients with reduced left ventricular ejection fraction.

Methods and results: Since September 2009, 84 high risk patients received endovascular mitral valve repair using the MitraClip™ system. Follow-up visits were arranged one, six and twelve months after mitral valve repair and included a six minute walk distance test, transthoracic and transesophageal echocardiography, evaluation of NYHA functional class, measurement of high sensitive (hs) troponin T (TnT) and brain natriuretic peptide. Until June 2012, 31 consecutive patients completed the 12 months follow-up visit and were analysed in this study.

Due to endovascular mitral valve repair, mitral valve regurgitation decreased significantly from grade 3.4±0.1 to 1.7±0.1 (P<0.0001) 12 months after MitraClip™ implantation while NYHA functional class improved from 3.2±0.1 to 1.9±0.1 (P<0.0001). Objective parameters of clinical capacity showed a significant increase in six minute walk distance (222±30 m vs. 371±21 m; P<0.001), significant decrease in hsTnT (41±8 pg/L vs. 34±4 pg/L; P<0.05) and a trend towards reduced brain natriuretic peptide (4270±960 ng/L vs. 2300±530 ng/L; P=0.13). EF remained unchanged (34±4% vs. 35±3%; ns) one month after endovascular valve repair but significantly increased over the 12 months observation period (34±4% vs. 44±3%; P=0.01), while left atrial volume significantly decreased from 192±13.4 ml to 124±11 ml (P<0.01). Left ventricular endsystolic diameter significantly decreased after 12 months (48±3 mm vs. 40±2 mm; P<0.05). Of note, patients with severely reduced EF (<30%) also showed a significant increase of the EF over the 12 months observation period (23±2% vs. 32±2%; n=17; P<0.01). Average Society of Thoracic Surgeons (STS) risk score was 13±2%, while observed 30 day periprocedural mortality was 1.8%.

Conclusions: This procedure causes a significant reduction in mitral valve regurgitation and an increase in objective parameters of clinical exercise capacity. Ejection fraction is significantly increased twelve months after valve repair, even in a subpopulation of patients with EF <30%. Present data encourage the use of endovascular mitral valve repair in high risk patients including patients with severely reduced cardiac function.

Interventions for structural heart disease
Abstracts from AsiaPCR/SingLive

Comparison of two different umbrella devices in percutaneous atrial septal defect closure

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Aims: The purpose of this study was to compare the 6-months outcome of the novel Occlutech Figulla septal occluder (FSO) with the Amplatzer septal occluder (ASO) for transcatheter atrial septal defect (ASD) closure in adults.

Methods and results: Between October 2000 and December 2010, a total of 185 patients underwent ASD closure with the FSO or the ASO and completed 6-months clinical and echocardiographic follow-up. All complications related to the procedure were reported. The FSO was used in 53 patients (mean age 50.0±17.2 years; 71.7% female), and the ASO in 132 patients (mean age 47.4±16.8 years; 68.9% female). In hospital, 2 devices embolized in each group (3.8% vs. 1.5% for the FSO and ASO group respectively). Similar rates of new-onset supraventricular tachycardias (SVT) were observed in-hospital (1.9% vs. 1.5%). During follow-up 3 patients (5.9%) in the FSO group and 4 patients (3.1%) in the ASO group reported a new-onset SVT. At six months, the residual right-to-left shunt rate (assessed with contrast transthoracic echocardiography) was significantly higher in the FSO group (total 39.5%, 25.6% minimal, 11.6% moderate, 2.3% large) compared to the ASO (total 10.6%, 7.9% minimal, 1.8% moderate, 0.9% large) ($p<0.001$).

Conclusions: The use of the FSO in percutaneous ASD closure is associated with a comparable safety profile as ASO. However, the FSO showed a higher rate of residual right-to-left shunt at six-month follow-up.

Interventions for structural heart disease
Abstracts from AsiaPCR/SingLive

Results of balloon valvuloplasty of congenital valvular aortic stenosis

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Aims: The aim of this study was to assess the effectiveness of balloon valvuloplasty for congenital valvular aortic stenosis.

Methods and results: 60 balloon valvuloplasty (BV) of valvular aortic stenosis (VAS) were performed in 55 patients, 36 male (65,5%) during from 2005 to 2012. The youngest patient was 5 years old and the oldest was 37 years old. Mean age was 15,2±7,0 years. Class III of NYHA were 30 (54,5%), and IV – 10 (18,2%) patients, loss of consciousness were at 6 (10,9%) patients. Left ventriculography and aortography diagnosed VAS in 55 patients, stage I aortic insufficiency (AI) was observed in 12 (21,8%) patients. According to tensiometry in patients with VAS the systolic peak gradient (SPG) between left ventricle and aorta ranged from 60 to 205 mmHg with average of 122,6±37,7 mmHg. Immediately after the BV in patients with VSA (n=56) the systolic pressure in the left ventricle decreased on average from 225,0±38,7 to 159,8±25,7 mmHg ($p<0,05$) and increased in aorta on average from 102,5±14,5 to 112,0±13,7 mmHg ($p>0,05$). The SPG between the left ventricle and aorta fell to 61,3%, on average from 122,6±37,7 to 47,4 ±22,1 mmHg. ($p<0,05$). In 8 (14,5%) patients, BV caused AI below stage I, at 6 (10,9%) - up to stage II. In the group of patients with initial AI below stage I (n=12) after BV it remained at the same level in 10 patients, and increased to stage II - at 2 patients. BV was re-performed in five patients with remaining SPG during the period from one week to six months after the first intervention. There was either inadequate balloon catheter size or refractory ventricular arrhythmias during first intervention. The SPG between left ventricle and aorta fell on average from 120,1± 40 to 46,5 ±24,6 mmHg ($p<0,05$). AI stage II appeared at 3 patients. Good results were obtained at 41 (74,5%) patients, satisfactory - at 8 (14,5%) and poor - in 6 (10,9%) cases. The latter were referred for open correction of the heart disease. The postoperative period has witnessed the improvement of general condition, with no complaints. Long term results were tracked at 37 (61,6%) patients of this group for the periods ranging from four months to five years. All patients noted positive dynamics of the left ventricle volume indicators.

Conclusions: Analysis of the research has shown that BV of VAS has relative safety, persistent clinical and haemodynamic effect, and in many cases may be an alternative to traditional surgery. The results of correction depend on proper selection of patients with this pathology and the adequacy of implemented interventions.

Femoral approach for transcatheter aortic valve implantation: comparison of surgical cut-down vs. percutaneous approach

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Aims: We analysed our TAVI experience comparing standard arterial surgical cut-down (SF) to percutaneous femoral access (PF) in terms of complications with different transcatheter aortic valves.

Methods and results: From May 2008, one hundred seventy patients have been treated with TAVI at our Centre, 125 patients were treated through by the femoral arteries approach all the other by an alternative approach (direct aortic, subclavian, transapical). We consider in present analysis only last consecutive 60 patients (mean age 80.6 years) treated with the CoreValve bioprosthesis (50 patients) or the Direct Flow (10 patients) through the femoral from January 2011, so after our initial learning curve of 80 percutaneous femoral approach. In both groups 30 patients were treated, no major difference in pre-TAVI characteristics were evident, mean age in PF 80.8 yy (15 female) vs. 80.5 yy (19 female) in SF group. The incidence of major vascular complication was significantly different between the 2 group (p=0.01) seven patients experience major vascular complications in PF group requiring endovascular treatment with covered stent placement, none of the patient in SF had major vascular complication. The amount of contrast use was superior in PF group 233±70 cc vs. 142±52 cc in SF patients (p<0.01). This lead to a different cost of the procedure (excluded the prosthesis), mean cost of the material was 3,630±2,798 euros in PF vs. 2,066±1,032 euros in SF. Two patients died at 30 days in PF group. There was no difference in post-implant hospital stay 11.8 in PF vs. 9.6 in SF.

Conclusions: Approaching TAVI as a heart team, having cardiologists and cardiac surgeons always involved together also in trans-femoral cases, makes it easy to perform a femoral surgical cut-down. In our experience it was safer and cost-effective in comparison to femoral percutaneous approach.

asia PCR Singapore Live
Interventions for structural heart disease
Abstracts from AsiaPCR/SingLive

Direct aortic access for transcatheter self-expandable aortic bioprosthesis valve implantation: single-centre experience

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Aims: Transcatheter aortic valve implantation (TAVI) has been designed to treat elderly patients with severe aortic stenosis at high risk for surgery; however these patients are also often affected by severe iliac-femoral arteriopathy, rendering the trans-femoral approach unemployable.

Methods and results: From May 2008 four hundred patients were evaluated for TAVI at our centre. 141 patients (64 male) with severe symptomatic aortic stenosis and no reasonable surgical option due to excessive risk, mean age 81.3±8 years, were eligible for CoreValve (137 patients) or Sapien implantation. Thirty-four patients (all affected by severe peripheral vasculopathy, including seven re-do procedures, mean STS mortality score 12±8%) underwent CoreValve implantation directly from the ascending aorta through a right anterior mini-thoracotomy. A combined team of cardiologists, cardiac surgeons with expertise in hybrid procedures, and anaesthetists performed all the procedures. In all patients after valve deployment mean aortic gradient immediately dropped to ≤5 mmHg, 30 patients had angiographic grade aortic insufficiency 1. One case was converted to the trans-femoral approach due to an extremely fragile aortic wall, but the patient died due to abdominal aorta aneurysm rupture on p.o. day 1. Procedural success was obtained in all other (33) cases, one patient experienced left ventricle tear, successfully surgically treated. Six patients required a permanent pacemaker implantation; 30-day mortality was 5.8% (2 patients). All discharged patients improved their NYHA functional class and functional capacity and echocardiograms demonstrated good valve performance up to two years, mean valve gradient 9 mmHg. Three patients died during follow-up due to cachexia and bone marrow aplasia and acute myocardial infarction.

Conclusions: Transcatheter aortic valve implantation with the direct aortic approach is safe and feasible, offering a new attractive option to treat selected high-risk patients with severe aortic stenosis and peripheral vasculopathy, including those requiring a re-do procedure, and has emerged as a valuable alternative route to trans-apical access.

Endovascular interventions – *Tuesday May 21st*
Novelties in peripheral interventions

Endovascular therapy of obesity: first-in-man study of left gastric artery embolisation

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Aims: Bariatric surgery proposed for treatment of obesity is often associated with different complications and side effects. Ghrelin, a recently discovered neuropeptide that is predominantly produced in the gastric fundus, is the only known hormone stimulating food intake. Catheter-directed left Gastric Artery Chemical Embolization (GACE) performed in animal models demonstrated decrease in blood ghrelin levels and lead to significant weight loss. Here we provide our preliminary results of the First-In-World pilot study of GACE safety and efficacy in humans.

Methods and results: 5 patients with different degrees of obesity underwent left GACE with BeadBlock Embolic Bead 300-500 mm microspheres (Biocompatibles UK Limited, Chapman House, Farnham Business Park, Weydon Lane Farnham, Surrey, GU9 8QL, UK). Esophagogastroscopy was performed in all patients before and after GACE and at 1 week follow-up to rule out significant initial gastritis or ulcer and any worsening after the procedure. Blood Ghrelin levels were also measured before the procedure as well as at 1,2,3 and 4 weeks follow-up. Observation on Ghrelin levels and patients' weight is planned at 3, 6 and 12 month follow-up. There was no case of periprocedural complications. 3 of 5 patients complained slight pain in epigastrium during first few hours after the embolisation, but control esophagogastroscopy did not reveal any impairments. All patients reported decreased appetite at 2-3rd days after procedure. Weight loss was observed in all patients at 1 month follow-up: mean initial weight –128.12±24.4 kg was decreased to 114.86±21.3 kg and mean initial Body Mass Index (BMI) – 42.26±6.8 was decreased to 37.86±5.7.

Conclusions: Short-term follow-up demonstrated that GACE is safe and feasible. Long-term results will be presented at the time of presentation. Further study enrolling larger number of patients is underway to confirm these initial findings.

Endovascular interventions – *Tuesday May 21st*
Novelties in peripheral interventions

Evaluating embolic protection strategies in a consecutive group of 55 complex atherectomy procedures

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Aims: Evaluate dual protection strategy (the concurrent use of SpiderFX Embolic Protection Device (Covidien/ev3, US) and Proteus balloon which has debris capturing capability (Angioslide, Israel) vs. mono protection strategy, which uses the latter only. In a set of lower limb atherectomy procedures we compared (i) the embolic load in various lesion types and (ii) in different atherectomy techniques; and (iii) debris capture effectiveness.

Methods and results: The mean number of particles in the total embolic shower was 269±455; mean aggregated surface area was 22±20 mm^2. The majority of particles were captured by Proteus (395±524 particles, 27±21 mm^2) and a small fraction by SpiderFX (36±41 particles, 12±12 mm^2), $p<0.001$. A similar distribution was found for the various subgroups of lesions analysed. Embolic load by lesion type: Restenotic and thrombotic lesions produced in total more than double the number of particles and surface area than non-thrombotic and *de novo* lesions ($p<0.03$). Highly calcified lesions yielded 42-44% more debris particles compared with low-grade calcification lesions, although their surface area was approximately the same. High grade stenotic lesions (75-95%) produced more (33%) debris than occluded lesions in terms of surface area, which was spread among fewer particles ($p<0.079$). Procedures done on TASC II D lesions produced approximately double the surface area of debris than TASC II B and C lesions, spread between 30% and 38% more particles, respectively ($p<0.002$). Embolic load by procedure type: Directional atherectomy produced in total the largest number of particles, for which Proteus accounts for 97% ($p<0.001$). Laser atherectomy produced 36% more debris in terms of surface area, spread over 24% less particles than directional atherectomy ($p<0.011$). In Laser atherectomy a somewhat larger proportion of particles were captured by SpiderFX compared to its performances in other procedures. Orbital atherectomy yielded the least debris of all procedure types in terms of aggregated surface area ($p<0.0032$). All this debris was captured by Proteus, as SpiderFX cannot be used with orbital atherectomy. Small particles: Debris was comprised of large (surface area >0.3 mm^2) and small particles, the latter accounting for up to 50% of the total aggregate surface area. Nevertheless, while Proteus captured large and small particles fairly evenly, small particles were largely missed by SpiderFX ($p<0.001$).

Conclusions: This study concurs with previous publications on the high embolic load generated in complex atherectomy procedures. Sub analysis unveils the importance of addressing the full range of particle sizes, both macro- and, previously disregarded, micro-emboli. Dual protection strategy, composed of SpiderFX and Proteus as complementary means, is an effective measure in capturing large quantities of embolic matter.

Effect of drug-coated balloon on porcine peripheral arteries: physiologic vascular function, safety and efficacy experiments

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Aims: Due to high incidence of stent-restenosis of peripheral vessels use of DCB came to fore. Pharmacokinetic, safety, efficacy and physiologic studies were conducted using the paclitaxel (PTX)-coated peripheral FREEWAY drug-coated balloon (DCB).

Methods and results: Fourty-two domestic pigs underwent percutaneous FREEWAY overstretch balloon dilation for 1 and 2 min of both femoral and iliac (4-5 and 6-8 mm of size) arteries. Tissue PTX concentrations was measured at 1h, 1, 3 and 9 days follow-up (FUP). Neointimal hyperplasia was quantified by computerised planimetry 5 weeks post-DCB use in a randomised (DCB vs.plain balloon) pre-clinical study. The vascular function of the iliac and femoral arteries was determined after 1h, 1, 3 and 9 days. The peripheral artery tissue drug levels were 141.9±37.9 vs. 566.3±179.9, 43.2±13.6 vs. 149.4±71.8, 23.4±8.4 vs. 30.0±16.6 and 3.2±2.4 vs. 4.0±1.1 ng/mg using 1min vs. 2 min dilation at 1 h, 1, 3 and 9 days post-DCB use, respectively. Significantly smaller neointima proliferation was seen in the arteries dilated with FREEWAY compared with plain balloon. DCB led to addiction to vasoconstriction of the peripheral vessels in a tissue PTX concentration-dependent manner. The endothelium-dependent vasodilation was impaired using both balloon types and lasted up to 3 days. Tissue PTX concentration correlated negatively with endothelium-dependent vasodilation and positively with degree of vasoconstriction.

Conclusions: FREEWAY DCB effectively reduces neointimal hyperplasia in peripheral (iliac and femoral) arteries, with higher tissue PTX level by 2 min balloon inflation time. Higher tissue PTX concentration resulted in less neointima, but impaired vascular function.

Clinical experience with ultrasound-assisted thrombolysis in patients with pulmonary embolism

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Aims: Patients presenting with massive pulmonary embolism (PE) not infrequently have a high bleeding risk because of concomitant diseases, trauma or a need for invasive procedures. On the other hand, in submassive PE, the risk to benefit ratio of systemic lytic therapy is debatable. Local enhanced thrombolysis allows the delivery of a lower dose of drug directly at the site of thrombosis. Ekosonic (EKOS Corporation, Bothell, WA, USA) is an ultrasound-assisted device for local administration of thrombolytic: ultrasonic energy causes fibrin strands to thin and loosen, exposing plasminogen receptor sites and mechanically increasing penetration of the drug. Aim of this study was to investigate its usefulness in clinical practice.

Methods and results: During the last 6 months, 6 patients underwent ultrasound-assisted loco-regional thrombolysis with the Ekosonic device. The device is positioned via a 6 Fr femoral vein access; through the same catheter, alteplase and ultrasound are delivered inside the thrombus in the pulmonary artery. Mean age was 73 years; 3 patients presented with cardiogenic shock and ECMO was implanted in 2. The remaining 3 patients had clinically submassive pulmonary embolism, but CT scan showed severe bilateral involvement of pulmonary arteries. All patients presented with right ventricular dysfunction; average systolic pulmonary pressure was 59 mmHg and troponin T level was 0.406 mcg/L (upper limit of normal: 0.038 mcg/L). Catheters were successfully positioned in all patients, with no procedural complications; both pulmonary arteries were treated in all cases, with an average dose of alteplase of 1 mg/h (0.5 per each pulmonary artery), continued for a period of 20 to 30 hours according to clinical response. So, in total, 20-30 mg of thrombolytic were administered. Average fluoroscopy time was 10 minutes. Pulmonary angiography was performed only in two patients while in the others, the catheters were positioned based on the CT scan. One in-hospital death occurred in one of the patients treated with ECMO, ten days after the procedure. The remaining patients had marked improvement of respiratory function and clinical condition; the other patient in ECMO was successfully weaned from mechanical support but was discharged in post-anoxic coma. One patient experienced a significant hematoma at site of vascular access for Ekosonic placement; two patients developed hematomas at the site of central vein catheterisation not related to the procedure. All of them were treated conservatively. CT scan was repeated post-procedure (within 3-5 days) in three patients, and showed nearly complete thrombus resolution in two patients and a moderate reduction in one. All patients showed an improvement in RV function.

Conclusions: Ultrasound assisted loco-regional thrombolysis with the Ekosonic system seems to be a safe and effective treatment for submassive pulmonary embolism and when systemic thrombolysis is relatively contraindicated in massive embolism. In patients in critical conditions it can allow other invasive procedures, such as ECMO placement, which would otherwise present a very high risk with systemic thrombolysis.

Endovascular interventions – *Tuesday May 21st*
Novelties in peripheral interventions

A feasibility study to assess if paclitaxel reduces effects of intimal hyperplasia staus post lower extremity revacularisation

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Aims: A feasibility trial to determine if Paclitaxel will inhibit intimal hyperplasia (a cell dividing process that causes the artery to build up plaque after treatment) in the lower extremities after standard of care revascularisation: angioplasty (inflation of a balloon compacting it against the artery wall), and/or stenting (a wire mesh tube that presses the plaque against the artery wall and opens the artery) and/or atherectomy (removal of plaque from the artery).

Methods and results: Single-centre, non-randomised study with the addition of Paclitaxel in the treatment of revascularisation in 50 limbs. Following standard revascularisation, the lesion(s) are treated via an infusion balloon with a pre-determined dose(s) of Paclitaxel. With each inflation of the infusion balloon, a single dose of Paclitaxel is applied to the target lesion(s) over one to three minutes. This is repeated until all of the treatment areas are treated or a maximum dose of 10 mg of Paclitaxel has been given. Follow-up assessments occurred at post op day 1, 30 days, 4 months, 10 months and 19 months. The control group consisted of a retrospective review of subjects that have received angioplasty, atherectomy or a stent and that are already being collected via our Lower Extremity Database (retrospective review of subjects that have had a lower extremity revascularisation). The first limb enrolled was May 2011. All patients enrolled in the trial signed an IRB approved informed consent. So far 37 patients have been enrolled and preliminary data indicates that Paclitaxel seems to be inhibiting intimal hyperplasia. We have seen only three patients that have had restenosis that required re- intervention.

Conclusions: Our feasibility trial was to assess the use of Paclitaxel in inhibiting intimal hyperplasia using a local delivery system. Our preliminary data shows promise indicating that Paclitaxel may have a place in the vascular realm. A larger scaled trial is needed to verify long term results.

Endovascular interventions – *Wednesday May 22nd*
In vascular disease, think global!

Systematic analysis of multiple atherosclerotic lesions: co-existence of carotid artery disease, renal artery stenosis and peripheral artery stenosis in patients suspected for coronary artery disease

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Aims: Atherosclerosis is a well-known systemic disease in which carotid artery stenosis (CAS), renal artery stenosis (RAS), lower extremity peripheral arterial disease (PAD), and coronary artery disease (CAD) are common pathological lesions; their interrelationship is, however, unclear. This study investigated multiple atherosclerotic lesions in patients suspected for coronary artery disease to understand their progression and to determine if they warranted being part of a new screening paradigm.

Methods and results: A historical cohort analysis was performed on data obtained from 1734 consecutive patients undergoing coronary angiography, which were non-emergent patients and was examined as they were suspected to have CAD between September 2010 and July 2011. Carotid and renal artery Doppler studies and ankle-brachial systolic pressure measurements were examined simultaneously to diagnose concomitant lesions and their severity. Their prevalences were evaluated using multiple logistic regression models. The mean age of patients was 71.4±8.9 years old and 69.6% were male. The prevalences of CAS, RAS, lower extremity PAD, and CAD were revealed to be 4.3%, 6.2%, 7.7%, and 65.4%, respectively. Strong interactions amongst the prevalences of these lesions were found. In addition, the extent of CAD and the prevalences of CAS, RAS, and lower extremity PAD were strongly correlated. Logistic regression modelling results also supported this observation. (Lower extremity PAD, RAS, CAD, and multi-vessel disease and left main disease(LMD) were strong independent predictors of significant CAS ($P \leq 0.001$); lower extremity PAD, CAS, multi-vessel disease, CAD, and LMD were strong independent predictors of significant RAS ($P \leq 0.001$); and CAS, RAS, CAD, multi-vessel disease, and LMD were strong independent predictors of significant lower extremity PAD ($P \leq 0.001$)). In patients with CAD (n=1134), the prevalences of CAS, RAS, and lower extremity PAD were 5.8%, 8.4%, and 10.2% respectively; 18.7% of the CAD patients had at least one additional atherosclerotic lesion.

Conclusions: The prevalences of CAS, RAS, lower extremity PAD, and CAD are strongly interrelated; CAD severity is related to that of other atherosclerotic lesions. In addition, nearly 20% of CAD patients had at least one other concomitant atherosclerotic lesion.

Effect of scooring balloons in the endovascular treatment of stenotic autogenous arteriovenous fistula lesions

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Aims: We want to compare the immediate results of high pressure (HPB); ultrahigh-pressure (UHPB) balloons and peripheral scooring balloons (PSB) for the endovascular treatment of stenotic autogenous arteriovenous (AV) fistula lesions.

Methods and results: This study consisted of 3 consecutive groups of each around 15 patients with autogenous fistulas with decreased blood flow (<500 mL/min). All underwent a fistulogram and pre, intra and post procedural blood flow measurements. First group undergoing HPB angioplasty (max. 18 Atm.), the second group undergoing UHPB angioplasty (max 30 Atm.) and the last group PSB angioplasty (majority: VascuTrak balloon, CR Bard Inc; max 12 Atm.). The data that were collected included fistula anatomy, degree of stenosis, lesion length, balloon specifications and residual stenosis-iatrogenic dammage. Single-centre prospective follow-up study where 49 patients underwent angioplasty. Technical success rate was 94.5%. The pre-intervention mean blood flow was 275 ml/min in the HPB group; 362ml/min in the UHPB group and 317 ml/min in the PSB group. The post-intervention mean blood flow was 604 ml/min in the HPB group, 663 ml/min in the UHPB group and 696ml/min in the PSB group. Major differences: largest residual stenosis: HPB group, largest amount of intraluminal tears / small ruptures: UHPB group. The PSB group had the smallest mean residual stenosis and amount of iatrogenic lesions

Conclusions: Endovascular treatment of AV fistula lesions is safe, with immediate result. Concerning amelioration of blood flow, there is no important difference between the different balloons. Using scooring balloons can reduce residual stenosis and iatrogenic lesions. Further long-term follow-up is needed to determine the durability of these results.

Endovascular interventions – *Wednesday May 22nd*
In vascular disease, think global!

Comparison of open-cell stent and closed-cell stent for treatment of central vein stenosis or occlusion in haemodialysis patients

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Aims: The purpose of this study is to compare long-term results and determine the outcomes of open-cell stent vs. closed-cell stent for central vein stenosis or occlusion in haemodialysis patients.

Methods and results: The records of 2418 patients who underwent endovascular treatment for central vein stenosis or occlusion in haemodialysis patients at Seoul Soonchunhyang University Hospital from 1997 to 2011 were reviewed. Stent placement was performed in 401 patients if conventional balloon angioplasty was unsatisfactory, due to elastic recoil (>30% residual stenosis and continued filling of collateral veins around the lesion) or occurrence of restenosis within 3 months after balloon angioplasty for the same lesion. When the thrombus in the central vein was present, the treatment of choice was a primary stent placement. There were 257 open-cell stent and 144 closed-cell stent. Angiographic findings including lesion site, central vein stenosis or occlusion, and presence of thrombosis and complication were evaluated. Primary patency rate and mean patency rate of stent were compared between two stent groups by Kaplan-Meier survival analysis. The technical success rate of stent placement was 99.3% (398 of 401 procedures). Mean procedure time for recanalisation was 53.2 min. The vessel most commonly treated was the innominate vein (n=306), followed by the subclavian vein (n=89), and jugular vein (n=6). For the open-cell stent group, central vein stenosis in 159 patients and central vein occlusion in 98 patients. For the closed-cell stent group, central vein stenosis in 78 patients and central vein occlusion in 66 patients. There were two complications of central migration of a stent that required additional stent placement and two cases of procedure-related vein rupture. For the open-cell stent group, the primary patency rate was 86.4%, 64.8%, 28.8%, and 9.3% at 3, 6, 12, and 24 months. For the closed-cell stent group, the primary patency rate was 69.1%, 38.7%, 16.0%, and 6.5% at 3, 6, 12, and 24 months. Open-cell stents and closed-cell stents had mean patency rates of 10.9±0.80 months and 8.5±10.87 months, respectively (p=0.002). An intergroup analysis demonstrated significant difference involving the subclavian vein group (p<0.001), in case of stenosis (p=0.042) and occlusion (p=0.020) and in case without thrombosis group (p=0.006).

Conclusions: The open-cell stent is effective and its performance is higher than that obtained with the closed-cell stent for treating central vein stenosis or occlusion in haemodialysis patients.

Endovascular interventions – *Wednesday May 22nd*
In vascular disease, think global!

Angiographic characterisation of the internal pudendal artery in male patients with ACS: the CAPISCA study

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Aims: To describe the angiographic profile of bilateral internal pudendal arteries, quantifying vascular lesions if present in patients admitted to hospital with an ACS. To estimate the prevalence of erectile dysfunction in patients with an ACS as the first clinical manifestation of coronary disease.

Methods and results: An observational prospective study was designed, with on-going recruitment of patients meeting the following inclusion criteria: males between ≥18 and 75 years old, ACS (defined as unstable angina with or without elevation of myocardial injury markers), invasive diagnostic strategy (by radial access) with coronary angiography demonstrating at least moderate coronay artery disease and written informed consent. Patients with chronic renal disease with a glomerular filtration rate <30 mL/min, chronic treatment with nitrates, penile anatomical abnormalities/ trauma or previous aorto-femoral bypass surgery were excluded. Anamnesis, physical examination and basic complementary tests were obtained at admission. A coronary angiography with standard technique and catheters was performed, as well as percutaneous revascularisation if pertinent. With a 4 French 140 cm length catheter angiography of both internal pudendal arteries and measurement of vessel diameters and percentage of luminal stenosis were obtained. After the procedure, the questionnaire IIEF-5 was obtained from each patient to diagnose clinical erectil dysfunction. A total of 13 male patients, median age 55 years old (IQ 49,5-56), have been included so far. Interestingly, all of them were current (46%) or ex-smokers (54%). The prevalence of hypertension was 46% and the prevalence of dyslipidaemia was 38%. A third had chronic coronary artery disease (in all cases single vessel disease with percutaneous revascularisation). The prevalence of other manifestations of vascular disease was low (8%). A 46% of the patients had elevation of myocardial injury markers. In all of them ejection fraction was preserved. A high proportion of the patients (64%) were diagnosed of erectile dysfunction by the IIEF-5 test. After coronary angiography, the single vessel disease was the most prevalent (69%), treated in all cases with a DES. The right internal pudendal artery had an average diameter of 2,6±0,7 mm, an average % of stenosis of 39% and an average length of the lesion of 17,2±12,2 mm. The left internal pudendal artery had an average diametre of 2,3±0,5 mm, an average% of stenosis of 41% and an average length of the lesión of 8±4,9 mm. We found that up to half of the patients (55%) had ≥30% stenosis and almost a quarter (23%) had ≥50% stenosis in at least one of the internal pudendal arteries. None had ≥70% unilateral stenosis. A quarter of the patients (25%) had bilateral stenosis ≥30%. The prevalence of bilateral stenosis ≥50% was low (8%).

Conclusions: The prevalence of moderate angiographic disease of unilateral internal pudendal arteries (stenosis ≥30%) is high in the studied population. However, significant unilateral disease (stenosis ≥70%) and significant bilateral disease (stenosis ≥50%) are not frequent. There is a high proportion of patients who have suffered a ACS as a first manifestation of coronary artery disease, diagnosed at the same time of previous erectile disfunction. In consequence, erectile disfunction could be an early predictor of ACS.

Endovascular interventions – *Wednesday May 22nd*
In vascular disease, think global!

Prevalence of internal pudendal artery disease in diabetic patients with erectile dysfunction and angiographically documented multi-vessel coronary artery disease

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Aims: Erectile dysfunction shares common risk factors of coronary artery disease, and is increasingly recognised as a well established risk factor for future cardiovascular events. We set out to explore the prevalence of significant atherosclerotic disease of the internal pudendal arteries in diabetic men with erectile dysfunction and angiographically documented multi-vessel coronary artery disease.

Methods and results: We enrolled 30 consecutive diabetic patients with erectile dysfunction undergoing elective coronary catheterisation. Erectile function was evaluated using the abbreviated 5-item questionnaire known as the Sexual Health Inventory for Men. Distal aortography was first performed, followed by selective internal iliac arteriography. Significant internal pudendal artery disease was defined as 50% or more luminal obstruction seen in the projection that best delineates the takeoff of the artery. The mean age of the whole series was 59.6±8.4 years. The mean duration of diabetes mellitus was 8.1±7.1 years, and the mean duration of ED was 4.3±3.2 years. Significant IPA disease (stenosis/occlusion) was found in 11 (36.7%) patients; unilateral in 6 (20%) patients, and bilateral in 5 (16.7%) ones. Significant internal iliac artery disease (stenosis/occlusion) was found in 6 (20%) patients; unilateral in 4 (13.3%) patients, and bilateral in 2 (6.7%) ones. Significant internal pudendal artery disease correlated positively with age and negatively with estimated creatinine clearance ($p<0.05$ for both).

Conclusions: In diabetic male patients with erectile dysfunction who have angiographically documented multi vessel coronary artery disease, significant internal pudendal artery obstruction (stenosis/occlusion) is rather frequent, and it correlates positively with age, and negatively with the estimated creatinine clearance.

Endovascular repair of abdominal and iliac aneurysm with preservation of pelvic flow

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Aims: Aims: This is an endovascular approach to preserve pelvic flow in the setting of common iliac aneurysm.

Methods and results: We constructed a bifurcated iliac limb by taking a 20-mm stent graft limb and deploying *ex vivo*. The distal end of the graft is modified by sewing a 10-mm and an 8-mm covered stent graft directly to the 20-mm stent graft limb, while leaving the distal ends of the 10-mm and 8-mm graft free. By doing this, it allows for more flexibility and easier selection of the 8-mm internal iliac limb. The graft is then reconstrained using a spiral wire technique. Once the graft is re-sheathed, it is inserted, orientated (with the 8-mm limb toward the internal iliac), positioned (with the most distal portion of the graft placed 2-3 cm above the ostium of the internal iliac) and then deployed. With the main retrograde wire passing through the 10-mm graft, and leave the 8-mm limb free, this is then accessed from an arm approach. The desired limb of the main body stent graft is selected through the 8-mm limb the internal iliac artery is selected. Angiograms and measurements are made and a covered self-expanding stent graft is deployed. The 10-mm limb is used to extend the graft into the external iliac, completing exclusion of the common iliac aneurysm, with preservation of both the internal and external iliac arteries. Thus far, we have performed this procedure on twelve patients, since April 2011, and all have done extremely well. The patients have been able to maintain appropriate exercise tolerance and remain free of pelvic ischaemia.

Conclusions: Bifurcated limb stent grafts appear to be a viable endovascular treatment for large common iliac aneurysm, while maintaining good pelvic blood flow and all the advantages that accompany it.

Endovascular interventions – *Wednesday May 22nd*
Endovascular aortic aneuvrysm repair: an evergrowing story

ADSORB: one year results of stentgrafts for acute uncomplicated type B dissection

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Aims: Acute uncomplicated type B dissection of the thoracic aorta are since decades treated with blood pressure lowering to 110-120 mmHg systolic and close monitoring resulting in a mortality of 10 percent. Furthermore, after 4-5 years up to 25% will develop an aortic aneurysm or need an intervention. The INSTEAD trial has shown that when introduced in the chronic phase (14 days-1 year) of an acute type B dissection, a stent graft covering the primary tear will lead to remodelling of the thoracic aorta with increase in true channel size and decrease of the false channel size after two years. In the acute complicated dissection of the thoracic aorta stent grafting has been introduced with good results. The aim of the present prospective randomised multicentre trial was to compare the best medical treatment with BMT and Gore® TAG® stent graft in patients with an acute (<14 days) uncomplicated type B dissection. Endpoint was the combination of: Incomplete or no false lumen thrombosis, Aortic dilatation and Aortic rupture (descending thoracic aorta or abdominal aorta) at one year.

Methods and results: Patients with acute uncomplicated type B dissection with a double barrel appearance and with a proximal landing zone of 2 cm were included. The onset of symptoms had to be less than 14 days and after randomisation, TAG placement should be executed within 48 hrs. Exclusion criteria were rupture, impending rupture, malperfusion leading to intestinal ischaemia, renal ischaemia, spinal cord ischaemia or leg ischaemia. Refractory pain was also judged as exclusion criterion. 31 patients were randomised, within 5 days of symptom onset, to the BMT group and 31, also within 5 days, to the BMT+TAG group. 70% (BMT+TAG) and 87% (BMT) were males. Mean age was 60.7 and 60.1 years in the BMT and BMT+TAG groups respectively. The TAG device was placed within 14 days of onset in all cases (median 5.7 days). The left subclavian artery was completely covered in 47% and in part in 17% of the cases. Median procedure time was 92 minutes (60-150 min.) No 30 day death was noted in any group. There were three crossovers from the BMT to the BMT+TAG group, all due to progression of disease (1 intestinal ischaemia, 1 retrograde dissection, 1 aortic dilatation). There were two withdrawals from the BMT+TAG group (1 withdrew informed consent, 1 had no proximal landing zone). The TAG device was placed with 100% technical success. At one year, in the BMTgroup3% had complete thrombosis and 64% had none/partial thrombosis. In the BMT+TAG group 57% had complete thrombosis and 13% had none/partial ($p<0.001$). The false channel reduced in size in the BMT+TAG group from 23 to 16 mm ($p<0.001$) whereas in the BMT group it increased from 23 mm to 30 mm. The true lumen increased in the BMT+TAG group from 24 mm to 33 mm ($p<0.001$) whereas in the BMT group it remained unchanged 24 mm to 25 mm (n.s.). There was no change in overall size of the thoracic aorta within one year and no ruptures.

Conclusions: In this, first ever, randomised trial of acute uncomplicated type B dissections, the mortality in the best medical treatment group was lower than expected from register data. The uncomplicated acute type B dissection can safely be treated with stent graft using the Gore® TAG® device. A remodelling with thrombosis of the false lumen and reduction of its size takes place in favour of stent graft, covering the proximal tear, compared to Best Medical Treatment. Larger studies would be needed in order to give answer on the short term survival.

Endovascular interventions – *Wednesday May 22nd*
Endovascular aortic aneuvrysm repair: an evergrowing story

Percutaneous treatment of abdominal aortic aneurysm using the ovation stent-graft

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Aims: To assess feasibility and efficacy of percutaneous endovascular abdominal aortic aneurysm (AAA) repair using a 14 Fr low profile stent graft with haemostasis at the puncture site through manual compression.
Methods and results: A prospective study was conducted on 20 consecutive patients (19 males and 1 females; mean age: 72,2±8,4), with AAA treated between December 2010 and March 2011 using the Ovation stent-graft system with an entirely percutaneous approach. The mean AAA diameter was 55.3±8.6 mm. Manual compression was performed to obtain postprocedural haemostasis. Clinical control was performed at 1, 3, 6 and 12 months follow-up. US Doppler control was perfomed at disharge and after 1 week to evaluate the access site. CT angiography was performed at 6 and 12 months follow-up. The stent-graft was successfully implanted in all patients using an entirely percutaneous approach. Two patient (10%) presented a type II endoleak after stent-graft implantation with a spontaneous resolution in one case and treated with coil embolisation in the other one. Manual haemostasis was achieved in all cases without complications. No surgical conversions were required. During follow-up, no aneurysm-related deaths were recorded. Through 12 months, each AAA shrunk by at least 5 mm and no device-related events were observed on imaging
Conclusions: Use of low profile 14 Fr stent-graft allow safe and effective treatment of AAAs with haemostasis of the puncture site by manual compression.

Endovascular interventions – *Wednesday May 22nd*
Endovascular aortic aneuvrysm repair: an evergrowing story

Intervention in aortoarteritis: largest experience in India

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Aims: To demonstrate that Angioplasty with or without stenting is the only sort of treatment which can save the life of the patients in addition to medical therapy with the largest experience of the world.
Methods and results: Aortoretritis is a chronic inflamtory disease in aorta and its branches which is prevelent worldwide. Its a single-centre study conducted from the year 1978 to 2012 from IPGME&R, Kolkata, West Bengal. India. We have reported the largest series of around 750 cases of non specific Aortorteritis. The male female ration was 1:6.4, and the pattern of involvement were like type I 16%, type II 8%, type III 76%, type iv 36%, type V 10%. Angioplasty done in these cases showed involvement of aortic arch, thorasic and abdominal aorta, renal artery, carotid artery, pulmonary artery, coronary artery, aortic valve (regargitation). 274 angioplasty were done in these cases. Carotid angioplasty was attempted in 40 lesions in 36 patients with 70% success rate. 1 patient had major embolic event, 3 patient had TIA. Angiographic restenosis of carotid was seen in 7 cases (17.5%). Subclavian angioplasty was attempted in 64 lesions in 58 patients. Stenting was done in 14 cases, Aortic balloon angioplasty was done in 58 patients in 52 patients with stenting in 12 lesions. Success rate was 58% restenosis rate is following: thoracic aorta 25%, abdominal aorta 38%, 120 renal angioplasty with stenting in 96 lesions was done. Restenosis rate was 18%
Conclusions: Aortoarteritis carries substantial morbidity and mortality. Medical therapy is not very effective. Angioplasty produce symptomatic improvement and prevent complications, failed angioplasty implicated high mortality.

Management of abdominal aortic aneurysms and concomitant cancer: the endovascular approach

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Aims: in this retrospective study we analyse the role of endovascular repair (EVAR) of abdominal aortic aneurysms (AAA) in patients with concomitant cancer of digestive and urinary system in terms of morbidity and mortality and beneficial outcomes in the management of malignancy.

Methods and results: Between1991 and 2011, seventy-two patients with AAA >4 cm and concomitant abdominal cancer with life expectancy >2 years, were treated. Thirty cases (group A) were submitted to open AAA repair that was simultaneous with cancer surgery in 22 (10 renal cancer, 10 prostatic, 1 gastric, and 1 liver) while in the remaining 8 cases colon cancer resection followed the AAA surgery. In group B (42 patients) EVAR was always performed before the surgical and/or pharmacological therapy of malignancy (18 colon cancer, 9 bladder, 9 prostate, 4 gastric, 1 liver and 1 lymphoma). The postoperative mortality rate was 10% in group A (2 myocardial infarction MI and 1 multi-organ failure) while it was nil in group B. The 30-days postoperative morbidity rate was 6.6% in group A (1 MI and 1 pulmonary complication) and 3.3% in group B (1 MI). No bowel ischaemia occurred in the 18 patients submitted to colorectal resection after EVAR. The time delays between EVAR and cancer treatment in groups A and B were 63 and 15 days, respectively ($p<0.0001$). No graft infection was observed in both groups. Long term morbidity and mortality was similar in group A and B.

Conclusions: the analysis of the results obtained in this retrospective study suggests EVAR, when feasible, may be considered the choice treatment in patients with AAA and concomitant abdominal cancer due to its lower perioperative mortality and morbidity when compared with open surgery. This alternative approach allows to expand treatment indications also for small AAA, in relation to the objective observation that laparotomy and radiotherapy improve the AAA rupture incidence; in our experience, 14 patients of group B had an AAA diameters raging from 4 to 4.5 cm. Furthermore this less invasive approach reduces significantly the waiting time for following cancer management. It must be underlined that, when colon-rectal resection is needed, the perfusion of at least one hypogastric artery during EVAR is mandatory to avoid sigmoid ischaemia. It is well known that abdominal surgery implies an increased risk of aortic graft infection; our feeling that EVAR could minimise the risk of this complication in comparison to conventional surgical approach either combined or sequential, is high.

Multislice computed tomography in planning of endovascular abdominal aortic aneurysms repair

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Aims: To determine the possibilities of multislice computed tomography (MSCT) in planning of endovascular abdominal aortic aneurysms repair (EVAR).

Methods and results: 36 patients with a median age of 69 years were included. Among them there were 32 (89%) men and 4 (11%) women. 28(78%) patients had infrarenal localisation of abdominal aortic aneurysms (AAA), 8(22%) patients had juxtarenal localisation of AAA. MSCT angiography of abdominal aorta and femoral arteries were performed to all patients. Measurement of AAA, diameteres femoral arteries were made by MSCT. The maximum dimensions of the abdominal aorta averaged 59±18 mm. All patients had challenging anatomy: short and severely angulated and/or conic proximal aortic neck, unsuitable distal " landing zone", thrombus, calcification and complicated morphology, complex aneurysms and dissections of iliac and femoral arteries. The possibility of EVAR procedure was estimated due to the results of MSCT measurements. 4 patients with juxtrarenal AAA were operated on with fenestrated endoprostheses (Cook Zenith Fenestrated) and in 4 patients "chimney" technique was used (including 1 patient with "sandwich" technique). Patients with infrarenal AAA were treated with different types of endoprostheses depending on anatomical challenges (Gore Excluder, Cook Zenith Flex and Medtronic Endurant) the decision being made with regard to AAA and vascular anatomy by MSCT). In cases of complicated morphology of iliac arteries subclavian/axillary access was used.

Conclusions: EVAR is the promising alternative to conventional aortic repair and is believed to significantly reduce the risk of complications, which positively affects mortality and length of hospital stay. MSCT in planning of EVAR is obligatory procedure that allows to exclude patients with unsuitable anatomy and precisely select the access path, size and type of AAA endoprostheses.

Endovascular interventions – *Wednesday May 22nd*
Aortic aneuvrysms: fundamentals to innovation

Anatomical characteristics of an infra-renal abdominal aortic aneurysm: can an aneurysm that is prone to enlargement after endovascular aneurysmal repair be predicted?

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Aims: This study was conducted to identify the anatomical characteristics of an infra-renal abdominal aortic aneurysm (AAA) that may cause a poor result of endovascular aneurysmal repair (EVAR)

Methods and results: The datasets of 60 patients were retrospectively analysed. All the patients underwent EVAR for an infra-renal AAA, followed by computed tomography angiography (CTA), at a routine schedule of more than a year. With the final follow-up CTA findings, the EVAR results were classified into three groups [Group I that showed a more than 10% aneurysm shrinkage, Group II that showed minimal (less than 10%) or no aneurysmal area change; and Group III that showed a more than 10% post-EVAR aneurysmal expansion] and then re-classified into two groups (Group A that showed no post-EVAR aneurysmal expansion and Group B that showed post-EVAR aneurysmal expansion). To define the anatomical characteristics, various anatomical variables were measured in the pre-EVAR CTA and compared between the groups. The proximal neck length was significantly shorter in Group I than in Group II and Group III (p=0.016). Moreover, the AAA in Group I showed a much larger maximum aneurysm lumen diameter (p=0.017) and area (p=0.009) than that in the other groups. The proximal neck length of Group A was significantly shorter than that of Group B (p=0.004). The AAA of Group A showed a greater longitudinal aneurysmal length (p=0.028), maximal aneurysm diameter (p=0.048) and area (p=0.025), and maximal aneurysm lumen diameter (p=0.004) and area (p=0.002) than that of Group B. In the binary regression test, the shorter proximal aortic neck length was the only statistically significant difference, with an odds ratio of 0.436.

Conclusions: An AAA with a shorter proximal aortic neck and a larger lumen diameter/area could result in AAA sac expansion after EVAR.

Endovascular interventions – *Wednesday May 22nd*
Aortic aneuvrysms: fundamentals to innovation

Pressure dynamics in aneurysmatic sac as a marker of efficiency of endovascular repair in patients with abdominal aortic aneurysm

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Aims: To determine the values of haemodynamic parameters in aneurysmatic sac in order to establish actual efficiency of abdominal aorta endovascular repair.

Methods and results: 12 consecutive patients with diagnosis of abdominal aortic aneurysm were examined. 11 patients were the men; the average age was 52.1±5.2 years. Average aneurysm size was 51,8±6,5 mm. Bifurcation endoprosthesis "Excluder" "Gore" was implanted in all patients. Dynamic measurement of pressure in aneurysmatic sac at various stages of endoprosthesis implantation was the particularity of interventions performed. Systemic invasive pressure and pressure in sac under endoprosthesis were measured directly, the curve of pressure was evaluated, and gradient between systemic pressure and pressure in sac was determined. For this purpose 4F catheter or micro catheter was installed during the operation inside the aneurysmatic sac, under endoprosthesis. Dynamics of haemodynamic parameters in the sac depended on the level of exclusion of aneurysm from the bloodstream. It was important that in case of complete exclusion of aneurysm from the bloodstream pressure in sac decreased significantly, up to 60±6.1/51.1±7.4 mm, (system pressure was 126±18.1/71,1±12,1 mm). In this case gradient of systolic pressure between the system and the sac was 60±19.8 mm. At the intermediate stage of intervention, in case of presence of endoleak of the Ist type in some patients, the pressure in sac in the whole group was 89.2±25.4/66.4±12.5 mm. Difference in systolic and diastolic pressure fixed in aneurysmatic sac appeared to be the most sensitive parameter. In case of complete exclusion of aneurysm the curve of pressure was gently sloping, the value was 9.0±3.9 mm, in case of endoleak the value was 30.0±1.0 mm.

Conclusions: This small-scale trial demonstrated that pressure in aneurysmatic sac is a sensitive marker of endovascular abdominal aorta repair efficiency. Prognostic value of parameters of pressure in aneurysmatic sac may appear useful for determination of aneurysm state in the long-term period of observation.

Endovascular de-branching of a thoracic-abdominal aneurysm

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Aims: This abstract presents an alternative endovascular approach to the repair of thoracic-abdominal aortic aneurysm (TAA).

Methods and results: We constructed a double-barreled thoracic graft, with one barrel dedicated to stent the visceral segment, while the other barrel is dedicated to the revascularisation of the infra-renal aorta. The visceral graft is constructed by modifying a standard bifurcated stent graft. Modifications were made to the ipsilateral and contra-lateral limb of the graft. Our construction dedicated a graft limb to each of the four visceral vessels. We then re-sheathed the newly constructed visceral graft and prepared for implantation. Once the visceral graft was re-sheathed, it was positioned and deployed, with the distal point of the visceral graft about 4 cm above the ostium of the celiac artery. From an arm approach, we were able to individually select each of the visceral vessels and stent them from the newly constructed visceral stent graft, thereby isolating the visceral segment from the aneurysm. We then extended the open barrel to an infra-renal position, and the remaining part of the surgery is a standard infra-renal EVAR. We have thus far treated seven patients successfully using this approach. All patients were discharged from the hospital without the need for transfusion, prolonged intubations or other heroic measures.

Conclusions: It is clear to us that the advantage of this approach are that it allows a less-invasive, reproducible and versatile approach to a very challenging surgical problem with a potentially short recovery time.

Endovascular interventions – *Wednesday May 22nd*
Aortic aneuvrysms: fundamentals to innovation

Endovascular debranching of the aortic arch for a large thoracic aneurysm with ascending and descending dissections

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Aims: An alternative approach to repair a type A dissection with large thoracic aneurysm via a total endovascular approach.

Methods and results: We approached a large thoracic aneurysm with a Type A dissections extending into the left common carotid and left subclavian artery by compartmentalising the aorta. This was done by first constructing a double barrel thoracic stent graft. A 45 mm main body thoracic graft was modified with two 24 millimeter thoracic grafts to form a double barrel thoracic stent graft measuring a total of 7 cm in length or 70 mm. Also constructed was a debranching thoracic stent graft using a 28 mm main body graft, shortening the ipsilateral limb while sewing two 10 mm grafts side-by-side to the contralateral limb. These modified grafts were reconstrained back into their original sheaths via a spiral wire technique. At this point a right subclavian 10 mm conduit as well as a right common femoral 10 mm conduit were sewn into place. The left common femoral artery as well as the left brachial artery were exposed. The right subclavian conduit was our main access. From here wires and sheaths were placed. The double barrel stent graft was first positioned and deployed. In one of the two 24 mm open barrels the 28 mm modified debranching stent graft was also positioned and deployed from the subclavian approach. This would then we extended to bridge from the debranching graft to the innominate using a standard 20 mm limb. The two 10 mm Viabahn that were sewn to the contralateral limb of the debranching graft were selected from a left carotid and left brachial approach. Wire position was verified with IVUS. ICAST stents were used to bridge from the debranching stent to the left common carotid and left proximal subclavian. From the femoral approach the other open 24 mm barrel of the double-barrel graft was selected and a standard 32 mm thoracic graft was then deployed from the proximal ascending aorta into the descending aorta with exclusion of the aneurysmal segment. We have thus far treated one patient successfully with a complete endovascular debranching of the aortic arch from the proximal aorta into the descending aorta. The patient's hospital stay was 5 days without significant complications and without conversion to open.

Conclusions: This is a novel modular reproducible method for endovascular debranching of the aortic arch from the proximal aorta to the descending beyond while retaining flow to the great vessels and appears to provide a safe, much less invasive approach to a challenging problem with obvious shortening of the recovery period and potentially reduction in morbidity and mortality.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: clinical outcome

CASSIA registry: single centre experience of carotid artery angioplasty stenting in diabetic patients. Long-term outcome

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Aims: In the last 10 years, carotid artery angioplasty stenting (CAS) became an important alternative to surgery especially in the presence of high risk factors. In particular, diabetes has been demonstrated to be a strong predictor of adverse outcome in patients (patients) undergoing CEA but its significance in predicting outcome of patients undergoing CAS has not been established.

Methods and results: Diabetic patients who underwent CAS were enrolled in the present analysis. Between january 2009 and december 2011 65 diabetic patients (mean age 74±7,5, men 58,4% (38/65), 36,9% (24/65)in insulin therapy) underwent CAS. Baseline clinical caractheristics were: hypertension 73,8% (48/65), dislipidemia 76,9% (50/65), chronic renal failure 7,6% (5/65). Concomitant coronary artery disease (CAD) was present in 58,4% (38/65) and 57,8% (22/38) of these patients had a previous myocardial infarction (MI). Finally, carotid stenosis was symptomatic in 32,3% (21/65). Cerebral embolic protection device was used in all patients (proximal occlusion in only one pt); we implanted closed cells stent design in 70,7% (46/65) and performed postdilatation routinely. The mean follow-up (FU) duration was 23,5±8,4 months and was available in 92,3% of patients (60/65). The incidence of 30-day Major Adverse Cardiac and Cerebrovascular events (MACCE) was 0; the cumulative long term outcomes were: MACCE 6,1% (4/65), death 1,5% (1/65), stroke 3% (2/65), MI 1,5% (1/65).

Conclusions: Although larger studies are needed, the data regarding our experience show that CAS is safe and effective in term of clinical outcomes also in high risk patients as those with diabetes.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: clinical outcome

Short-term and long-term outcomes of combined use of carotid stenting and endarterectomy in treating patients with carotid artery disease

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Aims: Despite the fact that today the carotid stenting and carotid endarterectomy are recognised as equal in management of atherosclerotic lesions of internal carotid artery, they continue to be actively opposed to each other with no focus on the fact that each method has its limitations determining an increased risk of an intervention. We evaluated short-term and long-term outcomes of patient-oriented approach to carotid revascularisation in real world settings.

Methods and results: A retrospective analysis of treatment of 340 patients with atherosclerotic lesions of the cervical segment of internal carotid artery that underwent carotid stenting or endarterectomy at a single-centre during the period from January 1, 2007 to December 31, 2011 was performed. All patients were divided into the carotid stenting group (170 patients: mean age was 69.2±8.9 years, 77.6% were males, 65.3% were symptomatic) and the carotid endarterectomy group (170 patients: mean age was 67.3±9.4 years, 74.1% were males, 59.4% were symptomatic). The method of carotid revascularisation was chosen by multidisciplinary team consisting of interventionist, vascular surgeon and neurologist with consideration of patients' clinical and anatomical characteristics that defined the risk of an intervention. Stenting under protection was mandatory, proximal protection was used in 60.6% of patients. The study end points included any stroke, myocardial infarction, death and the composite of any ischaemic stroke, myocardial infarction or death during 30 days after intervention and at a mean 16.4±9.5 months of follow-up. There was no significant difference between the stenting group and the endarterectomy group in the incidences of stroke (1.2% and 1.8%, respectively, p=1.0), myocardial infarction (0% and 1.2%, respectively, p=0.498), death (0% and 1.2%, respectively, p=0.498) and the composite end point (1.2% and 2.9%, respectively, p=0.448) within 30 days after intervention. There was no differential treatment effect between the stenting group and the endarterectomy group according to symptomatic status (for composite end point: 1.8% and 3.0%, respectively, p=0.670). With patient-oriented carotid revascularisation periprocedural rates of stroke, myocardial infarction, death and composite end point for all patients in the study were 1.5%, 0.6%, 0.6% and 2.1% respectively; for symptomatic patients the periprocedural rates were 1.9%, 0.5%, 0.5% and 2.4%, respectively. At a mean 16.4±9.5 months of follow-up there was also no significant difference in the rates of end points between the stenting group and the endarterectomy group (for composite end point: 5.9% and 6.5%, respectively, p=1.0).

Conclusions: The carotid stenting and endarterectomy when chosen with consideration of patient-specific risk factors demonstrate low rates of stroke, myocardial infarction, death and the composite of any ischaemic stroke, myocardial infarction or death that are not significantly different between both treatment procedures. The use of carotid stenting and endarterectomy as complementary therapies provides the best patient-oriented care for complex patient population met in daily clinical practice.

The results of the internal carotid artery stenting and carotid endarterectomy in the hospital with high volume cardiac interventions and open surgery

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Aims: Carotid Stenting (CS) and Carotid Endarterectomy (CA) are both up-to-date methods of carotid revascularisation in hospitals with high levels of such specific interventions. These two methods of treatment of carotid artery atherosclerotic lesions in non-randomised study at single-centre with high volume interventions and surgery on the heart and coronary arteries were compared

Methods and results: The Krasnoyarsk Federal Centre of Cardiovascular Surgery provides 3000 to 5000 open surgery and interventional procedures due to different heart and main vessels diseases per year. We assessed in-hospital results of treatment of 104 patients (57 for CS and 48 for CA) admitted to the centre in 2011-2012 with proximal haemodynamically significant stenosis of Internal Carotid Artery. The choice of method of revascularisation was determined by the cardiac team – invasive cardiologist, cardiovascular surgeon and neurologist. Surgical risks, the anatomy of the region and lesions, neurological status were assessed. Multispiral Computed Tomography of neck and head vessels was included in initial protocol for all of the patients. The patient's view was also taken into account. There were no difference in age (67.4±7.4 CS, 65.5±7.9 CA; p=0.21) previous stroke (26.3% CS, 14.6% CA; p=0.14) myocardial infarction (36.8% CS, 52.1% CA; p=0.12) coronary revascularisation (63.15% CS, 79.2% CA; p=0.073) diabetes mellitus (21.1% CS, 12.5% CA; p=0.247) and hypertension (98.25% CS, 100% CA; p=0.357). The CA group consists of more males (91.7% CA, 73.7% CS; p=0.017). General anaesthesia was used for CA. Distal filter protection was used for each case of stenting. There were three types of stents used: Acculink (36.8%), Cristallo Ideale (59.6%), XACT (3.5%). Two patients needed 2 stents to be implanted due to the lesion's anatomy. There were no deaths, myocardial infarctions or unsuccessful interventions in both groups. The damages of cervical nerves were in CA group in 2 cases (0% CS, 4.17% CA; p=0.12). One haemopericardium (1.8% CS, 0% CA; p=0.12) due to temporary pacing electrode perforation in CS group was treated by pericardiocentesis. Two transient ischaemic attacks with complete recovery were in CS group (3.5% CS, 0% CA; p=0.19). Strokes occurred in CA group (0% CS, 4.17% CA; p=0.12)

Conclusions: The CS and CA provide the similar results for the treatment of patients with internal carotid artery stenosis. Both methods could be accepted in the hospitals with good general experience of heart and peripheral vessels interventions and surgery despite the low volume of carotid revascularisations. Heart team collaboration and good assessment of the patient and the lesion are absolutely needed.

Carotid artery stenting: early subclinical cellular brain damage and oxidative stress

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Aims: Subclinical alterations of cerebral function can occur during or after carotid revascularisation. Cerebral injury and inflammation/oxidative stress increase during intervention. In asymptomatic patients undergoing carotid artery stenting (CAS), we investigated whether neuronal-specific enolase (NSE), S100beta protein and N-ε-(Carboxymethyl)lysine (CML), [these latter, both ligands of receptor for advanced glycation end-products(RAGE)] and the soluble form of RAGE (sRAGE), changed during follow-up after CAS.

Methods and results: Twenty-two consecutive asymptomatic patients (73±9 years, 19 males) undergoing successful CAS, were enrolled. Serum levels of NSE, S100beta protein, CML, and sRAGE were measured before intervention, one hour, and at 1- and 30-day follow-up. No transient ischaemic attack or stroke were clinically observed. We observed high pre-operative levels of NSE (13.6±4.4 µg/L) that declined significantly at 1 day after stenting (9.3±3.2 µg/L) (p=0.001). S100beta [49 (31.5-58.2) pg/mL] increased significantly at 1 hour [54.2 (51.4-102.4) pg/mL], returning at basal levels after 1 day [43.7 (28.9-61.3) pg/mL] (p=0.001). Circulating sRAGE levels [486 (251-964) pg/mL] decreased significantly at 1-day [317 (225-619) pg/mL] and persisted low at 30 days of follow-up [432 (214-905) pg/mL] (p=0.029), while CML levels did not change anytime. An inverse correlation between basal C reactive protein and sRAGE levels (r=–0.677, p=0.0091) was observed.

Conclusions: CAS in asymptomatic patients induced early subclinical cellular brain damage detected by increase of S100beta but not of NSE serum levels. At follow-up, the rise of S100beta could amplify inflammatory events triggered by stent placement and favoured by the reduction of the protective/anti-inflammatory sRAGE levels.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: clinical outcome

Endovascular treatment of carotid stenosis: 103 cases

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Aims: Ischaemic stroke is a major cause of adult disability and the 3rd leading cause of death. The purpose of this study is to determine safety, short and mid-term outcomes of CAS (Carotid Artery Stenting) during the last 5 years.

Methods and results: Between January 2006 and December 2010, 101 successful CAS out of 103 attempted procedures in 89 patients were included in this study. The indications for CAS were symptomatic carotid-artery stenosis 60% and asymptomatic stenosis of at least 80%. There were 70 men and 19 women and their age range was 50-79 years (mean 71.1). One hundred one stents (50 Protégé, 37 Precise stent, 12 Wallstent, and 2 Acculink) and distal filters (89 Spider Rx, 9 Filter-wire, 3 Embo-shield) were used. There were one death (huge ICH), 4 minor strokes (4.2%), 9 bradycardia (9.4%), and 3 groin hematoma as peri-procedural complications. Follow-up angiography was done in 58 patients (61%) for 6-58 months (mean 17.3), there was only one restenosis (1%). Clinical follow-up was done for 84 patients (88%) for 6-60 months (mean 32), there were two deaths (2.3%, one myocardial infarction, one rectal cancer), one major stroke (basilar artery, 21 months), and one minor stroke (cerebellum, 10 months).

Conclusions: CAS is and effective treatment modality and as safe as CEA for carefully selected patients. Judicious selection of the procedure is made on a case-by-case after considering the patient (physiological), lesion, and access (anatomical) factors that increase the risk of CAS and CEA in that particular patient.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: novelties in risk assessment

Predictors for successful endovascular intervention in chronic occlusion of internal carotid arteries and a scoring system to predict the success rate

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Aims: Carotid artery stenting in chronic internal carotid artery occlusion has been reported to be feasible with acceptable mid-term results. However, endovascular treatment for chronic internal carotid artery occlusion can be technically challenging. We sought to investigate predictors for successful endovascular treatment in chronic internal carotid artery occlusion.

Methods and results: We retrospectively reviewed 141 patients from 3 cardiovascular centres in Taiwan, all patients with chronic internal carotid artery occlusion and CT perfusion scan performed showing objective evidence of ipsilateral hemisphere ischaemia. All carotid endovascular interventions were performed by single operator via femoral approach, using a 8 Fr femoral sheath. We investigate few potential variables which include patient's symptoms, duration of symptoms, duration from diagnosis, lesions stumps, stumps morphology, calcification, stumps angulation, lesion length, and distal flow visibility. The procedural success rate was 64.5%. Multivariate analysis created with backward stepwise elimination showed that the independent predictors were symptoms durations (p=0.034; OR=0.45), stump angulation (p=0.049; OR=0.15), visibility of distal circulation on occlusion side (p=0.043; OR=0.37), and lesion length (p=0.001; OR=0.07). The optimal cut-off using Youden and distance was 0.559 with sensitivity of 70.13% and specificity of 79.55%. The Areas under receiver-operator characteristic curves was 0.783. A scoring system (Kao-Leong Scoring System) was created to predict procedural success rate with the total score of 11. Procedural success rate was 94.87%, 70.59%, 39.47% and 33.33% (corresponds to score of 0-2, 3-4, 5-6, more than 6 respectively).

Conclusions: Symptoms duration less than 6 months, stump angulated less than 450, visible distal flow and lesion length shorter than 30 cm were identified as independent predictors of procedural success in stenting of carotid artery chronic occlusion. The Kao-Leong scoring system could help to predict the success rate. We are looking forward in future to recruit more patients into validation set to verify the Kao-Leong Scoring system.

EuroSCORE risk model as predictor of early and 1-year results after carotid artery stenting and carotid endarterectomy

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Aims: To study early and 1-year outcomes of carotid artery stenting (CAS) and carotid endaterectomy (CEA) in patient with medical comorbidities according to Euroscore risk evaluation model

Methods and results: We retrospectively reviewed 312 patients who were treated for symptomatic carotid stenosis between 2002 and 2012 (142 CASs and 170 carotid endarterectomies CEAs). Patients undergoing CEA were older than CAS (78 years vs. 70 years, P=0.001). Embolic protection devices were used in 98.6% of cases. Depending on comorbidities all patient were divided in two groups: EuroSCORE ≤20 (n–181) and EuroSCORE >20 (n – 131). In EuroSCORE ≤20 group CAS was performed in 75 patients, CEA – in 106 patients. The 30-days stroke rate did not differ between subgroups (2.7% in CAS vs. 1.9% CEA, p>0.05). The 1-year freedom from stroke were 93.4% in CAS subgroup and 94.3% in CEA subgroup (p>0.05). There was no difference in the all-cause death rate (stroke-related, coronary, other) at 1-year follow-up (2.7% in CAS subgroup vs. 4.9%, p>0.05). In EuroSCORE >20 group CAS was performed in 73 patients, CEA – in 58 patients. There was no difference in the incidence of 30-days stroke (2.8% in CAS vs. 1.7% CEA, p>0.05). The 1-year freedom from stroke were 93.2% in CAS subgroup and 94.9% in CEA subgroup (p>0.05). The all-cause death rate among CAS patients was lower (1.4%) compared to CEA patients (12%, p=0.044). Univariate analysis in patients undergoing CAS showed that age >70 years was related with postprocedural neurological complications (p=0.046). However, age was not independent risk factors on multivariate analysis.

Conclusions: In the low-risk patients (EuroSCORE ≤20) the rates of peri-procedural, long-term neurological complications and all-cause death rate did not differ between CAS and CEA subgroups. In high-risk patients (EuroSCORE >20) there was no significant difference in the incidence of peri-procedural and long-term neurological complications between subgroups, but patients after CEA are at higher risk for any-cause related death.

Combination of OCT and virtual histology IVUS in evaluating carotid artery vulnerable plaque detected by MRI-Black blood method for carotid artery stenting

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Aims: OCT is an intravascular imaging modality to assess plaque characteristics as well as virtual histology IVUS (VH-IVUS). The aim of this study is to evaluate surface and inside of vulnerable plaque in carotid stenotic lesions which are detected as high-intensity area in T1-weighted-image by MRI (Black blood method), using OCT and VH-IVUS before carotid artery stenting (CAS).

Methods and results: We performed CAS in consecutive 8 patients (8 men, mean age of 77±5 years) with carotid artery stenotic lesions in which MRI (T1-weighted image by Black blood method) detected the plaque as high intensity area. In five patients, plaques were detected as high-intensity area in T2-weighted image of black blood-MRI as well. It has been reported that plaques which is detected as high-intensity area in both T1 and T2-weighted image of black blood-MRI are most vulnerable plaque including intra-plaque haemorrhage. Vulnerable plaque detected by MRI were evaluated by OCT and VH-IVUS before performing CAS. Distal protection devices (FiltreWire EZ™: Boston Scientific) were used in all cases. In two cases, proximal protection method (Balloon-Tipped guiding catheter) was added. Before stenting, we assessed plaque at the stenotic lesions by frequency-domain OCT (Ilumien OCT imaging system™: St. Jude Medical) without balloon occlusion and by VH-IVUS (Eagle Eye™: Volcano Therapeutics) which classified plaque into four colour components: fibrous, fibro-fatty, calcium and necrotic core (labeled green, green-yellow, white and red respectively). During OCT-image acquisition carotid blood flow was replaced by dextran or contrast medium injection from the guiding catheter at 5-6 mL/sec with an injector pump. In analysing OCT images, lipid rich plaque was defined as signal intensity-poor lesion covered by signal-rich bands that correspond to fibrous cap. Thin-cap fibroatheroma (TCFA) was defined as <65 µm of cap thickness. Using OCT and VH-IVUS, we evaluated carotid artery plaques in the cross-sections at the site of minimum luminal diameter. In all cases, OCT and VH-IVUS image acquisition was successfully obtained. In VH-IVUS images, vulnerable plaque included 53.0±5.2% fibrous plaque, 35.6±11.3% fibrofatty plaque, 2.4±1.8% calcium and 9.0±7.8% necrotic core. In OCT images, lipid rich plaques are detected in all patients, but deep inside of the plaque was not observed because OCT has a penetration depth of only 2-3 mm. Fibrous caps which covered the vulnerable plaque were detected by OCT in all cases, whereas TCFA were detected in 5 cases (62%) and ruptured fibrous cap were detected in 5 cases (62%).

Conclusions: Approximately half area of the vulnerable plaques detected by black blood-MRI consists of fibrofatty tissue and necrotic core in VH-IVUS images. Even in carotid artery, OCT is effective in evaluating superficial lipid-rich plaques and fibrous caps, especially TCFA as well as in coronary artery. Combination of VH-IVUS and OCT is useful for evaluation for surface and inside of vulnerable plaques of carotid artery.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: novelties in risk assessment

Impact of anatomical features of aortic arch and culprit carotid artery assessed by MacDonald score on the short-term outcome of carotid angioplasty and stenting

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Aims: The aim of our study was to validate the impact anatomical features of aortic arch and culprit carotid artery assessed by Macdonald' score on the short term adverse outcome of CAS procedures.

Methods and results: The study included asymptomatic patients with ≥70% stenosis of ICA or symptomatic patient with ≥50% stenosis of ICA presented to the catheterisation labs in Ferrarotto-Catania and Ragusa hospitals, Italy, during the period from October 2009 till May 2011. Patients were considered symptomatic when they had symptoms related to the culprit ICA stenosis within the last 3 months (transient ischaemic attack, stroke or amaurosis fugax). Degree of ICA stenosis was assessed according to NASCET method (ICA distal to the lesion is a reference diameter). Procedures were divided into 4 groups based on the anatomical variables of Macdonald' score; group I represented the least anatomical complexity while group IV represented the most complex anatomical features. Data of CAS procedures and short term outcome including intra-procedural and during the 1st month after the procedures were collected and analysed. The study included 104 ICA lesions in 100 consecutive eligible patients. 4 patients had CAS procedures on both sides in separate sessions. Patients were 71 males and 29 females with mean age 71.9±7.85 years and 21 patients were ≥80 years old (octogenarians). Asymptomatic ICA stenosis represented 76% of patients while symptomatic ICA stenosis represented 24%. Technical success was achieved in 103 procedures (99%), failed one procedure due to extreme complex anatomical features. Combined cerebrovascular (CV) adverse events had occurred in 5 patients (1 major stroke, 1 minor stroke and 3 transient ischaemic attacks) with estimated rate 4.8%. No cases of amaurosis fugax, myocardial infarction or death had occurred. Group I included 49 procedures and had no CV events, Group II included 44 procedures and 1 of them had CV event, group III included 9 procedures with 3 of them had CV events and group IV included 2 procedures with 1 of them had CV event. The study showed significant difference in the number of CV events in relation to Macdonald's risk group with increased number of events in higher risk groups ($X2=28.02$, $P<0.001$).

Conclusions: Anatomical features of aortic arch and culprit carotid artery assessed by MacDonald's risk score has a significant impact on the short term adverse outcome of CAS procedures.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: novelties in risk assessment

Comparison of carotid artery angioplasty stenting in diabetic patients with and without concomitant coronary artery disease in the "real world". A single centre experience

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Aims: Carotid artery angioplasty stenting (CAS) represents a valid alternative to Carotid Endarterectomy (CEA) in patients with carotid obstructive disease (COD) and high risk factors like diabetes. In presence of concomitant coronary artery disease (CAD) the optimal treatment of COD remains controversial.

Methods and results: We sought to compare and evaluate the immediate and long-term safety and efficacy of CAS in diabetic patients with or without concomitant CAD. In the present analysis, we enrolled unselected diabetic patients who underwent CAS (CASSIA-registry: Carotid Artery angioplaSty Stenting in dIabetic pAtients).65 consecutive diabetic patients underwent CAS between january 2009 and december 2011; 58,4% (38/65) with concomitant CAD (CADgroup) and 41,5% (27/65) without concomitant CAD (noCAD) group. Baseline clinical characteristics were similar in the two groups except for: hypertension 86,8% (33/38) CADgroup vs. 40,7% (11/27) noCADgroup (p=0,0002), symptomaticCOD 15,7% (4/38) CADgroup vs. 81,4% (22/27) noCADgroup (p=0,0001). Out of 38 patients with concomitant CAD (CADgroup) 60,5% (23/38) had a previous myocardial infarction (MI), 42,1% (16/38) had depressed ejection fraction (44±5,03) and 63,1% (24/38) had multivessel disease. 84,2% (32/38) of CADgroup underwent percutaneous coronary intervention (PCI) and 15,7% (6/38) CABG before CAS. Procedural characteristics: cerebral embolic protection device was used in all patients (proximal occlusion in only one pt); closed cells stent design was implanted in 84,2% (32/38) CADgroup vs. 70,3% (19/27) noCADgroup (p=0,59). The mean follow-up (FU) duration was 23,5±8,4 months and was available in 92,3% of patients (60/65). The incidence of 30-day Major Adverse Cardiac and Cerebrovascular events (MACCE) was 0 for both groups. The cumulative long term outcomes were: overall MACCE 6,1% (4/65): 7,9% (3/38) CADgroup vs. 3,7% (1/27) noCAD group (p=ns); death 1,5% (1/65): 2,6% (1/38) CADgroup vs. 0 (0/27) noCADgroup (p=ns); stroke 3% (2/65): 2,6% (1/38) CADgroup vs. 3,7 (1/27) noCADgroup (p=ns); MI 2,6% (1/38) CADgroup vs. 0 (0/27) noCADgroup (p=ns). Overall MACCE in CADgroup occurred in patients who underwent CABG.

Conclusions: Although larger studies are needed, the data regarding our experience show that CAS is safe and effective in term of clinical long terms outcomes also in high risk patients as those with diabetes and concomitant CAD.

Carotid angioplasty with stent in patients at high-risk

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Aims: Carotid angioplasty with stent (CAS) represents a less invasive alternative to carotid endarterectomy (CEA) for the treatment of carotid occlusive disease. To analyse the morbidity and mortality at 30 days and 6 months after CAS,

Methods and results: We reported results and complications in 206 patients (231 lesions), with an average age of 67.46+8.37 years, 40 patients (19.4%) more than 75 years, 66% were symptomatic, 75 patients (36%) with cerebrovascular accident (CVA) prior, 169 patients (82%) were carriers of Ischaemic Cardiopathy, closed cell stent (Wall carotid stent: Boston Sc) was used in 86%, in 213 lesions (92.2%) use cerebral protection filters recovering atheromatous material in 132 lesions (61.9%) in all the time of surgery. Loads of clopidogrel and aspirin 300 mg 325 VO, Heparin IV 70 u/Kg, pacemaker temporary prophylactically in ostial lesions, as well as neurology Evaluation carotid Doppler all patients before the study at the end of it and 12 months follow-up, the clinical success and angiography in 99.5% and 95.4% respectively; Complications: 1.9% deaths, major neurological events and minor event in 2.16% and 1.3% respectively, no myocardial infarctions (MI) in 104 patients (50.4%) do apart from the CAS Coronary Angioplasty successfully in both procedures: At following-up 26.5+23.2 (r=3-84 months) 5 patients presented by Doppler vascular restenosis submitting 2 of them (1.3%) to ATP uncomplicated, 3 patients had one CVA Major Ipsilateral and two patients minor CVA contralateral, 31 patients underwent CABG mortality occurred in 5 patients (16.1%) after CABG in all of them by cardiac event, 5 patients died; 2 IM, 2 more due to infections and the remaining unexplained.

Conclusions: Currently the CAS represents an alternative to surgery in patients with symptomatic carotid disease who have a comorbidity or unfavou rable anatomy compared to conventional EAC.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: challenging scenarios

Intracranial endovascular stents implantation of cerebral artery atherosclerotic stenoses: 91 cases

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Aims: Stroke is most common cause of life threatening neurological disease and also it is leading cause of adult disability and third leading casuse of death. Intracranial atherosclerosis is 8 to 10% of all ischaemic strokes and reported poor outcome and high rate of morbidity and mortality.

Methods and results: We evaluated 91 lesions of 84 patients (age mean 61.45, range 37-77 years, M:F=47:37) who underwent intracranial stenting between March 2004 and March 2011. The location of lesion was anterior circulation (n=79), ICA (n=41), MCA (n=38), posterior circulation (n=12). 42 lesions were Mori type A, 35 were type B, and 4 were type C. The kinds of stent were Endeavor (n=48), Vision (n=13), Flexmaster (n=10), Arthos pico (n=6), Wingspan (n=4), Tsunami (n=2), Guidant (n=3), Neuroform (n=2), Driver (n=1), Wall stent (n=1). The procedural success rate was 87.91%. Stent implantation failed in 11 cases. There were overall 7 complications (8.64%) within period of follow-up (38.23 months); these included 4 post-stent infarctions (4.93%), 1 rupture (1.23%), 2 deaths (2.46%), and 5 restenoses(6.17%). 4 of 5 restenoses were of Mori type B.

Conclusions: In selected patients, endovascular revascularisation of intracranial arteries with stent assisted angioplasty is technically feasible, effective and safe. Randomised multicentre trial comparing angioplasty and stenting with medical management alone must be performed.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: challenging scenarios

Comparative study for the impact of different carotid stent cell designs on patient outcome

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Aims: The individual characteristics of a stent may make it an attractive choice in one circumstance but render it a less desirable option in other situations, the number of carotid stents on the market rose steeply, resulting in the plentiful availability of today. This wide variety of carotid stents can sometimes make the choice of stent to treat a specific carotid lesion a difficult quest.

Methods and results: We studied thirty consecutive patients in a prospective randomised comparative study including 7 asymptomatic & 23 symptomatic patients from four centres who underwent carotid artery stenting for a soft plaque with either closed-cell (n=10 (33%)), or open-cell (n=20 [66%]) design stents from the period from august 2008 to march 2010, follow-up for 30 days and diffusion weighted MRI was done for patients post-procedure within 48 hours. In this study there were only two cases out of the 20 cases of open cell group that experienced TIA post carotid stenting and there were no cases from the closed cell group (Carotid Wallstent Monorail®) out of the 10 cases group experienced any complication.

Conclusions: In our study, closed stent cell design demonstrated statistically nonsignificant less complication at 30-days compared to open stent cell design.

Endovascular interventions – *Thursday May 23rd*
Carotid artery stenting: challenging scenarios

Stent protrusion detected by IVUS during carotid artery stenting

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Aims: It is very important to prevent stroke after carotid artery stenting (CAS). Stent protrusion could be involved in peri-procedural stroke. However, the exact rate or outcome of stent protrusion, or strategy for them is still unclear, and we examined them.

Methods and results: We performed 71 CAS procedures using intravascular ultrasound (IVUS) between May 2008 and August 2012. Clinical data were analysed retrospectively. We evaluated the rate, clinical characteristics, and outcome of stent protrusion. Age was 72.6±7.4 years old. Sixty two patients were male. Forty one, 62, and 68 patients had diabetes mellitus, hypertension, and dyslipidaemia. We used 61 PRECISE stents (Cordis) and 10 Carotid Wall stents (Boston Scientific). All cases were distally protected with filter devices. We could detect 6 stent protrusions (8.5%) by IVUS. Within 6 stent protrusion, 4 cases could not detect stent protrusion by angiography. Three were symptomatic patients. Four had severe delayed stenosis before procedure. We dilated with only balloon for 2 cases, and implanted additional stents for other 4 cases. After these managements stent protrusion disappeared and no stroke occurred. Overall stroke rate was 4.2%.

Conclusions: IVUS could detect more frequent protrusion than the incidence previously reported using only angiography. When we manage them adequately, we can reduce peri-procedural stroke. IVUS usage should be recommended to detect stent protrusion and to reduce complication.

Covered endovascular reconstruction of aortic bifurcation or cerab-technique for treating extensive aortoiliac occlusive disease

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Aims: We developed the Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB-technique for extensive and/or recurrent aortoiliac occlusive disease using V12 covered balloon expandable stents (Atrium Maquet Getinge Europe BV) to rebuild the aortic bifurcation.

Methods and results: Endovascular bifemoral recanalisation of the aortoiliac axes placement and expansion of a 12 mm V12 Large Diameter in the distal aorta (9 Fr). Pick up of the already expanded V12 stent with an large balloon (adapted to the aortic diameter). The balloon is so positioned that the distal marker is about 15 mm proximal to the distal stent margin. After positioning and expansion, the distal stent part becomes funnel-shaped. Two iliac covered stent-grafts are then placed in this segment, in a "kissing-stent" configuration and inflated. Both stents are now making a very tight combination with the aortic stent, as were they moulded together, simulating a new bifurcation. Two-centre prospective, non-randomised, follow-up study. We treated now 64 patients with acute, chronic or recurrent aortoiliac occlusive disease. Technical success rate up till now was almost 95%. Follow-up 47 - 6 months. 4 patients died of non-interventional causes. Five patients re-occluded, mainly due to progressive distal peripheral disease. They received successfully thrombolysis and treatment of the outflow problems. The other patients showed no complications

Conclusions: CERAB is safe and feasible and can be performed completely percutaneous. A larger population, longer follow-up, further haemodynamic investigation is needed. Distal peripheral outflow needs to be sufficient enough. It can be combined as a "hybrid" procedure. CERAB can be used for the treatment of recurrent or in-stent disease It is even feasible to treat lesions that extend into the iuxta and/or supra renal aortic region

Percutaneous orbital atherectomy in lieu of surgical aortic reconstruction

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Aims: Orbital atherectomy has been shown to successfully treat peripheral vascular occlusive disease of the infra-inguinal arteries, particularly in areas of intense calcification. There is a subset of patients with haemodynamically significant aortic calcific disease for whom surgical aortic reconstruction has been the standard of care. Described here are two challenging cases in which percutaneous orbital atherectomy was performed on the aorta in lieu of surgical reconstruction.

Methods and results: A retrospective review of two patients treated at one institution was performed. Pre-operative variables, risk factors, and non-invasive vascular laboratory studies were examined. Intra-operative and post-operative procedural details were examined. Two female patient, ages 65 and 73, presented with life-style limiting claudication; one had a prior endovascular infra-inguinal intervention. Both were medically maximised with antiplatelet therapy, lipid-lowering agents, and an antihypertensive regimen, and both failed non-interventional therapy. Mean pre-operative ABIs were 0.57 and 0.65 on the right and left legs, respectively. Orbital atherectomy was performed percutaneously without general anaesthesia. Post atherectomy angioplasty was performed on the aorta using 10-12 mm balloons. No stent was required in the aortic segment, although one patient required adjunctive iliac stenting. There were no intraoperative or early post-operative complications. At a mean follow-up of 21 days, both patients had symptomatic improvement. The mean post-operative ABIs were 0.93 and 0.99, an interval improvement of 0.36 and 0.34 for each side.

Conclusions: For these two challenging cases of calcific aortic occlusive disease, orbital atherectomy was shown to be safe and clinically effective. Moreover, haemodynamic improvement was achieved in these patients without the need for aortic adjunctive stenting or surgical reconstruction.

Endovascular interventions – *Thursday May 23rd*
Aorto-iliac angioplasty: what is new in 2013

The long-term outcome of S.M.A.R.T. vs. luminexx nitinol stent implantation for aorto-iliac artery disease

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Aims: Endovascular therapy (EVT) for iliac lesions with the use of stents is widely accepted. However, the long term outcome of two different nitinol stents for iliac lesions is unknown. The aim of this study was to examine the long term patency of the S.M.A.R.T. or Luminexx for the *de novo* iliac lesions.

Methods and results: This study was a multicentre retrospective analysis of a prospectively maintained database. The study enrolled consecutive patients undergoing primary stenting for *de novo* iliac artery stenosis between January 2005 and December 2009. A total of 1503 lesions in 1229 patients treated with S.M.A.R.T. or Luminexx primary stenting for iliac artery were enrolled. The primary endpoint was primary patency, while the secondary endpoints were primary assisted patency, secondary patency and major adverse limb events (MALE) that include all-cause death, myocardial infarction, stroke, major amputation and re-intervention. The mean patient age was 72.4±9.0 years; the mean follow-up interval was 27.3±17.5 months. The mean stent length was 57.1±37.3 mm and 56.8±31.3 mm in S.M.A.R.T. and Luminexx, (p=0.890, respectively). The primary patency at 5 years after S.M.A.R.T. and Luminexx was not significantly different (79.7% and 80.0%, p=0.603, respectively). Assisted primary patency and secondary patency rate was not significantly different (92.4% and 93.0%, p=0.665, 98.9% and 98.5%, p=0.860). In addition, the MALE rate was not significantly different (30.3% and 22.2%, p=0.081).

Conclusions: The current data suggest that the use of stent for the iliac artery provided good long-term patency for 5 years of follow-up regardless of whether S.M.A.R.T. or Luminexx were used.

Endovascular interventions – *Thursday May 23rd*
Aorto-iliac angioplasty: what is new in 2013

Transradial percutaneous iliac interventions, results from a multicentre study coordinated by italian radial force

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Aims: Percutaneous angioplasty for the treatment of atherosclerotic iliac disease is commonly performed via the femoral and/or brachial access routes. A transradial approach has been shown to reduce both major and minor access site bleedings after coronary interventions in experienced hands. This route has not yet been well studied for the majority of peripheral interventions, like those involving the iliac arteries.

Methods and results: This is a multicentre restrospective study performed at high volume centres with experience in transradial percutaneous interventions. Primary endpoints of the study were procedural success, complication rates and freedom from symptoms at 30-day follow-up. We also evaluated the technical feasibility of this approach regarding different devices used and lesion characteristics. One-hundred-forty-nine patients from 5 italian centres were enrolled into the study. The population had a medium risk profile, with 48% of patients having TASC 2 or 3 lesion subset. Procedural success was achieved in 98.7% of the population, and we did not register in-hospital complications. One-month freedom from symptoms was achieved in 99.4% of patients.

Conclusions: This study shows how a transradial approach is feasible and safe for the treatment of atherosclerotic iliac disease and does not increase procedural complication rates if compared to the transfemoral route, in experienced hands.

Safety and feasibility of percutaneous iliac interventions by transradial access: a single-centre experience

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Aims: Iliac interventions are usually done by transfemoral access, either retrograde or by the cross-over technique; however, this access retains a sizeable risk of local complications. Transradial approach has gained acceptance for coronary interventions because it is associated with similar results on target lesions but less entry side complications. Nowadays we have equipments of adequate length for performing iliac interventions also by transradial access. Aim of this study was to evaluate the safety and feasibility of a transradial approach to iliac angioplasty.

Methods and results: Between 1 December 2011 and 31 July 2012,54 consecutive patients (8 females; mean age 71, range 37-90 years) with suprainguinal obstructive artery disease, symptomatic for Rutherford class III claudication (n=42) or Texas grade 0-2 critical limb ischaemia (n=12), underwent iliac angioplasty by left (n=38) or right (n=16) transradial access. Direct wiring of descending aorta was accomplished in 43 patients (80%); in the remaining patients a 4 F coronary diagnostic catheter (internal mammary or Judkins right) was used to direct downward the wire. As guiding system, a 125 cm long 6 F multipurpose guiding catheter (Cordis Corporation, Bridgewater, NJ, USA; n=15) or a 120 cm long 8.5 sheathless catheter (Sheathless PV, Asahi Intecc, Aichi, Japan; n=39) was used. For dilating the lesions the 180 cm long shaft, 0.018 In compatible Pacific Extreme balloon (Medtronic, Minneapolis, MN, USA) was used, while for stenting the 180 cm long shaft, 0.018 In compatible sinus-SuperFlex-518 stent (OptiMed, Ettlingen, Germany; up to 10 mm in diameter) was used. Seventy lesions were addressed (16 occlusions, 54 stenosis; 40 on common iliac artery, 30 on external iliac artery), 61 stents were positioned in 49 patients. The overall angiographic (<20% residual stenosis) success rate was 87% (56% on occlusions, 96% on stenosis; p≤0.05). No haemorrhagic complications or local complications needing surgery were observed in the cohort of patients. At 1 month follow-up, 4 patients (7%) had asymptomatic radial occlusion. At 6 month follow-up, improvement of symptoms (>2 Rutherford class or >2 Texas grade regression) was observed in 47 patients (92%).

Conclusions: In case of difficult femoral access, transradial approach can represent a safe and feasible alternative for iliac angioplasty. Angiographic and clinical results of our study are similar to those reported in the literature about transfemoral access. Therefore transradial access can become the first choice approach for iliac procedures by operators who have an extensive experience with transradial coronary interventions.

Long-term outcome of the self-expanding stents for chronic total occlusion of the iliac artery

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Aims: Endovascular treatment (EVT) for iliac artery disease is generally recognised as the first-line procedure among less invasive therapeutic options, even for chronic iliac occlusion (CTO). Balloon-expanded stents are often used for the common iliac artery, but suchstents are susceptible to extrinsic compression and deformation. However, there have been few reports regarding the results obtained with self-expanding stents for CTO of the iliac artery. Accordingly, the purpose of this study was to evaluate the long-term results obtained with self-expanding stents for CTO of the iliac artery.

Methods and results: A retrospective study was performed of patients who underwent EVT for chronic iliac artery CTO presented from April 2007 to September 2012. Study included 82 patients with 86 occluded iliac arteries attempted recanalisation and stenting with the self-expandable stent. According to the TASC II classification, 34 limbs (40.0%) were classified as type B, 20 limbs (23.5%) as type C, and 31 limbs (36.5%) as type D. Stenting was done by using self-expanding stents with a diameter 1 or 2 mm larger than the reference vessel diameter at the lesion. The cases with proximal lesions of the common iliac artery, we release the stent about 1 cm and hold it in the aorta at the first time. And then, take off all the system with contralateral injection to decide the landing position. During the procedure, we use the Intra vascular ultrasound (IVUS) to evaluate the iliac artery diameter and plaque morphology, and also confirmed that the wire was in the true lumen. If the guide wire was not placed in the true lumen, we certainly try to get the true lumen with 2nd wire by IVUS guidance. All stents were placed in the true lumen under IVUS guidance. One hundred and twenty one stents were successfully deployed in the 86 lesions: 19 in the external iliac artery, 51 in the common iliac artery, and 16 in both arteries. There were no cases of peripheral embolisation or iliac artery rupture after the procedure. The ankle-brachial index (ABI) increased significantly from 0.55±0.19 to 0.88±0.17 after procedure (P<0.001). The mean follow-up was 27.6±17.81 months (range, 3-60 months). The primary equivalence endpoint was a primary patency rate, mortality, and limb salvage rates. Patients were followed up with the presence of a palpable femoral artery pulse, resolution of symptoms, and noninvasive vascular laboratory testing reviewed at 1, 3, and 6 months after EVT and then were evaluated at 6-month intervals. The primary patency rate was 98.5% at 5 years. Ten patients (12.1%) died at a median of 8.4 months after stent placement (range 1-18) from unrelated causes. The survival rate was 87.8%. Amputation was not required for any of the limbs. In patients who gave consent, repeat angiography was done in 59 of 86 lesions (68.7%). At the time of angiographic review, Minimum lumen diameter (MLD) was significantly increased from 5.3±1.5 mm to 5.5±1.6 mm(P<0.05). Late loss was –0.6±2.5 mm. There were no cases of stent fracture.

Conclusions: This study showed that an acceptable long-term outcome of EVT for iliac CTO was achieved by placement of self-expanding stents in the true lumen. It was suggested that stenting the true lumen under IVUS guidance can reduce complications and improve primary patency.

Endovascular interventions – *Thursday May 23rd*
Aorto-iliac angioplasty: what is new in 2013

Experimental evaluation of pharmacokinetic profile and biological effect of a novel paclitaxel microcrystalline balloon coating in the iliofemoral territory of swine

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Aims: Since the advent of first paclitaxel coated balloons (PCB), new developments have been proposed to maintain therapeutic tissue levels while decreasing particle release. In these series of studies, we evaluated the pharmacokinetic profile and biological effects after paclitaxel delivery via novel microcrystalline PCB coating (mcPCB) in porcine iliofemoral arteries.

Methods and results: In total 21 iliofemoral segments of 10 domestic swine were enrolled. In the first pharmacokinetic study, 9 mcPCB's (Pax®, Balton) were dilated for 60s and animals sacrificed after 1 hour, 3 and 7 days. Studied segments were harvested and tissue paclitaxel concentration was analysed utilising HPLC. In the tissue effects study, following self-expandable stent implantation post dilation either with mcPCB (n=10) or POBA (n=5) was performed. After 28 days angiography was performed, animals sacrificed and stented segments harvested for histopathological evaluation. The 1-hour, 3 and 7 days vessel paclitaxel concentrations were 152.9±154.5, 36.5±49.5, and 0.9±0.7 ng/mg respectively. In the tissue effects study, at 28 days stents in the mcPCB group when compared to POBA presented lower angiographic measures of neointimal hyperplasia as expressed by late loss (-0.43±0.9 vs. 0.23±1.2; p=0.24). In the histopathological evaluation, the degree of percent area of stenosis (%AS) was reduced by 42% in the mcPCB group (mcPCB: 19.8±8.7% vs. POBA: 34.2±15.7%; p<0.05). The healing process in mcPCB group was comparable to POBA with regard to fibrin deposition (0.7 vs. 0.7; p=ns), neointima maturity (1.97 vs. 1.93; p=ns), inflammation score (0.92 vs. 1;p=ns) and endothelialisation score (1.77 vs. 1.73;p=ns). The media cell loss and mineralisation tended to occur more often in the mcPCB group (60% vs. 0;p=0.08).

Conclusions: Delivery of paclitaxel via a novel mcPCB resulted in lower long-term tissue levels compared to first generation crystalline coatings. However, this technological approach displayed an important reduction of neointimal proliferation with favourable healing profile.

Endovascular interventions – *Thursday May 23rd*
Aorto-iliac angioplasty: what is new in 2013

Physician initiated multicentre belgian-german trial investigating a nitinol self-expanding stent in the treatment of transAtlantic inter-society consensus (TASC) A & B iliac lesions

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Aims: The Misago stent (Terumo) is the first nitinol self-expanding iliac stent on the market that uses a rapid-exchange catheter technology. It is the aim of this trial to investigate the long-term results for a patient cohort treated with nitinol stents only in the iliacs.

Methods and results: The primary endpoint of the study is primary patency at 12 months, which is defined as a target lesion without a haemodynamically significant stenosis on duplex ultrasound (>50%, systolic velocity ratio no greater than 2.0) and without target lesion revascularisation within 12 months. A total of 120 patients were included in the study, of which 59 patients (50.43%) presented with a TASC A lesion, 57 patients (48.72%) with a TASC B lesion and 1 patient (0.85%) with a TASC C lesion. 3 patients did not receive a TASC categorisation. A total of 91 patients (76.47%) were male, 33 patients (27.73%) had diabetes mellitus and 72 patients (60.50%) had hypercholesterolemia. The analysis is performed to present the overall results and a comparison of the TASC A cohort with the TASC B&C cohort. The overall 12-month primary patency rate was 97.4%. Comparing the demographic data in both cohorts showed no significant differences and the 12-month primary patency rates for the TASC A cohort and the TASC B&C cohort were respectively 98.3% and 96.6% (p=0.641).

Conclusions: These high patency results confirm that endovascular therapy in TASC A and B lesions is the preferred treatment and that the use of the Misago nitinol self-expanding stent (Terumo) yields a high efficacy.

EXPAND: Percutaneous transluminal angioplasty vs. primary stenting in patients with severe claudication and critical limb ischaemia with infrapopliteal vascular lesions

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Aims: The number of endovascular interventions of infrapopliteal lesions is rapidly increasing in patients with peripheral arterial disease and CLI, especially in diabetics. Current clinical guidelines from NICE and ESC recommend PTA with bailout stenting as the first choice therapy for CLI patients. EXPAND investigates the clinical impact of self-expanding Nitinol stents (SE) compared with PTA in treating infrapopliteal lesions in patients with symptomatic CLI or severe intermittent claudication.

Methods and results: EXPAND is an international, prospective, randomised, multicentre study comparing stenting with SE Astron Pulsar and Pulsar-18 vs. PTA alone (1:1). Primary endpoint is upward shift of ≥+1 (for Rutherford 3) or ≥+2 (for Rutherford 4 and 5) on the Rutherford scale at 12 months. Secondary endpoints include MAE, mortality, amputation and changes in ABI. Ninety-two subjects, 62% men, mean age 73±10 years (46-90) were randomised between June 2009 and December 2011 (45 SE vs. 47 PTA) at 11 sites. At baseline, almost all subjects presented the typical risk factors hypertension (87%), followed-by diabetes (69%) and hyperlipidaemia (69%). The majority of subjects (65%) were Rutherford 4 and 5 and 35% were Rutherford 3. Follow-up data will be available upon presentation.

Conclusions: Although enrolment had been stopped before all planned study patients could be included, this international, randomised controlled trial shows direct comparison of SE vs. PTA in treating infrapopliteal disease.

Endovascular interventions – *Friday May 24th*
Below the knee angioplasty: risk stratification and DES benefits

DES for revascularisation of infrapopliteal arteries: a meta-analysis of randomised trials

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Aims: In disease of infrapopliteal arteries, drug-eluting stent (DES) improved patency rates as compared with bare metal stent (BMS) or plain angioplasty. However, the clinical impact of DES in this vascular district remains to be defined.

Methods and results: We searched Medline, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), scientific session abstracts and relevant websites for trials investigating revascularisation of infrapopliteal arteries. Keywords were: "below the knee", "infrapopliteal artery", "angioplasty", "drug-eluting stent", "bare metal stent", "trial", and "randomised trial". Inclusion criteria were: (1) randomised design; (2) intention to treat analysis; (3) ≥6-month follow-up. Exclusion criteria were: (1) vessels treated other than infrapopliteal arteries, (2) devices used other than DES, BMS or plain angioplasty, (3) duplicated data. No restrictions (language, publication date or status) were applied. Primary endpoint was target lesion revascularisation (TLR). Secondary endpoints were restenosis, amputation and death, as per protocol defined. A total of 611 patients from 5 trials (all full-length manuscripts) were randomly assigned to DES (n=294) vs. control therapy (n=307). Median follow-up was 12 months [interquartile range 12-36]. DES compared with control therapy reduced the risk of TLR (9.6% vs. 25.0%, odds ratio [95% Confidence interval]=0.31 [0.18-0.54], p<0.001), restenosis (21.0% vs. 50.5%, 0.25 [0.15-0.43], p<0.001) and amputation (6.5% vs. 14.0%, 0.50 [0.26-0.97], p=0.04). The risk of death was not affected from DES as compared with control therapy (14.1% vs. 18.3%, 0.81 [0.45-1.49], p=0.50).

Conclusions: In disease of infrapopliteal arteries, drug-eluting stent therapy reduces the risk of reintervention and amputation as compared with bare metal stent or plain angioplasty. The risk of death is not affected from drug-eluting stent therapy.

Endovascular interventions – *Friday May 24th*
Below the knee angioplasty: risk stratification and DES benefits

Utility of clinical characteristics and risk stratification to predict early mortality in patients with critical limb ischaemia caused by isolated below-the-knee artery disease

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Aims: Revascularisation is the optimal treatment to avoid major amputation for critical limb ischaemia (CLI) patients. The presence of CLI has been reported to be strongly associated with mortality. A previous study suggests that CLI patients who are unlikely to live 2 years are better served by endovascular treatment (EVT) for the first revascularisation. In this study, we investigated the predictors of early mortality in patients with CLI due to isolated below-the-knee (BTK) artery disease and to identify patients with an estimated life expectancy of 2 years or less.

Methods and results: This was a multicentre retrospective observational study of a prospective maintained database. From March 2004 to June 2011, a total of 884 patients with CLI who underwent angioplasty for *de novo* isolated BTK artery disease were enrolled. The outcome measure was all-cause mortality within 2 years. The mean follow-up period was 20±18 months. Sixty-nine percent were male, 71% had diabetes, 62% underwent haemodialysis, 38% had non-ambulatory status, and 24% had cerebrovascular disease (CVD). The mean body mass index (BMI) was 21.6±3.3, and serum albumin level was 3.5±0.6 g/dl. Rutherford class IV was found in 192 limbs, V in 521 limbs and VI in 171 limbs. Cox multivariate regression analysis showed that BMI <18, serum albumin <3 g/dl, non-ambulatory status, ejection fraction <45%, and presence of CVD were positively associated with all-cause death within 2 years. The sum of the number of risk factors was used to classify patients into three groups: low-risk group (0-1 risk factor, n=605), moderate-risk group (2 risk factors, n=194) and high-risk group (3-5 risk factors, n=85). Kaplan-Meier survival curve showed that the freedom from all-cause death at 2 years was 79.0% in the low-risk group, 50.1% in the moderate-risk group and 30.1% in the high-risk group..

Conclusions: In patients with CLI caused by isolated BTK disease, BMI <18, serum albumin level <3 g/dl, non-ambulatory status, EF <45%, and presence of CVD were independent predictors of early mortality. Patients who have more than two of these risk factors are likely to have an estimated life expectancy of 2 years or less and may indicate EVT first revascularisation.

Endovascular interventions – *Friday May 24th*
Below the knee angioplasty: risk stratification and DES benefits

Association between leg wound site and three-year clinical outcomes of haemodialysis patients with critical limb ischaemia after below the knee intervention

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Aims: The aim of this study is to investigate the association between the site of the leg wound occurring from critical limb ischaemia (CLI) and mid-term clinical outcomes of haemodialysis patients after below the knee intervention

Methods and results: This study used data obtained from a multicentre retrospective study. Among serial 884 CLI patients who underwent balloon angioplasty for primary treatment of isolated infrapopliteal lesions from 2004 to 2011, subjects were 449 serial patients on haemodialysis with a CLI wound (ulcer or gangrene). The site of the CLI wound was observed before the initial treatment and all wounds were confirmed to be either confined distal from the metatarsals-phalanx (MP) joint to the tips of the toes or proximal from the MP joint to the ankle. Patients with wounds confined distal to the MP joint were defined as the Distal (D) group (340 patients, 340 limbs, age: 69.2±9.6 years) and those whose wounds were not confined here were defined the Proximal (P) group (109 patients, 109 limbs, age: 66.5±10.4 years). The two groups were compared for average 3.0±1.5 years clinical outcomes. For patient characteristics, There was no significant difference in the percentage of patients with diabetes mellitus (D: 75.2 vs. P: 76.5%), ipsilateral CLI limb (D: 23.9 vs. P: 21.5%), orcoronary artery disease (D: 57.8 vs. P: 58.2%). For the target vessel, there was no significant difference in the ratio of target vessels with total occlusion (D: 69.9 vs. P: 70.0%) or keeping dorsal and planter flow after balloon angioplasty (D: 32.1 vs. P: 30.6%). The percentage of getting direct flow to wound site on angiosome concent was Higher in D group than that of P group (63.5 vs. 45.9%, p=0.012). At the 3-year clinical results, The D group had a significantly higher major amputation free rate (D: 83.7 vs. P: 71.2%, Logrank, p=0.001), survival rate (D: 54.0 vs. P: 37.3%, Logrank, p=0.013) or major amputation free survival rate (D: 44.1 vs. P: 29.1.0%, Logrank, p=0.002) after balloon angioplasty estimated using the Kaplan-Meier method, compared to P group.

Conclusions: The 3-year clinical outcomes of haemodialysis patients after isolated infrapopliteal balloon angioplasty whose CLI wounds were confined distal to the MP joint was better than that of patients who had wounds proximal to the MP joint, and the limb salvage rate of patients with CLI wound that was limited to the digits was acceptable.

Wound healing prediction score in patients with critical limb ischaemia after endovascular treatment

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Aims: The aim of this retrospective study was to design a new scoring system for prediction of wound healing after endovascular treatment (EVT) in case of critical limb ischaemia (CLI).

Methods and results: We obtained data for 147 patients (174 limbs) who received EVT for CLI classified to either Rutherford category 5 or 6 from April 2007 to October 2011. A total of 188 separate wounds were treated in these patients. Univariate analysis was performed with each indicator related to wound healing. Indicators that were shown to be significant in univariate analysis ($p<0.05$) were included in multiple logistic regression analysis in order to develop an odds ratio for wound healing. The item scores were transformed from regression coefficients and computed in a total score. Multivariate analysis showed that direct blood flow to wounds (OR 9.5, 95% CI 3.6-24.8, $p<0.001$), no dependence on haemodialysis (OR 5.6, 95% CI 2.2-14.2, $p<0.001$), no gangrene (OR 5.2, 95% CI 1.9-14.1, $p=0.001$), high albumin level (≥3.0 g/dl) (OR 2.4, 95% CI 1.1-5.5, $p=0.029$) and wounds not extending to the dorsum of foot beyond metatarsals (OR 8.9, 95% CI 2.9-27.0, $p<0.001$) were independent predictors of wound healing. Each item's score ranged from 0 to 3 and the total score ranged from 0 to 10. The area under the receiver operating characteristics curve showed that there was 90.1% accuracy in the total scores predicting the likelihood of wound healing. The major amputation rates among low-risk (scores ≥7), moderate-risk (scores 4-6), and high-risk (scores ≤3) groups were 3,9%, 13.8%, and 47.5%, respectively ($p<0.001$).

Conclusions: This new scoring system (WHPS) was useful for prediction of wound healing and risk stratification for major amputation.

3 years results of endovascular therapy with a new generation nitinol stent for femoro-popliteal artery lesions. Insights from a single-centre outcome analysis of a MISAGO2 subgroup

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Aims: To investigate 3-years technical and clinical outcome after Misago™ stent implantation in patients with femoro-popliteal artery lesions classified as TASC A, B or C, and peripheral arterial disease with clinical symptoms according to Rutherford category 2 to 5.

Methods and results: From April to October 2008, 744 patients were included in MISAGO2 prospective multicentre study and followed for 12 months. A group of 45 patients (mean age 68 y, range 50-85 y) having been enrolled in our institution was followed for 3 years. In this patient cohort, forty-six lesions were treated with Misago™ RX nitinol stents: 37 lesions of the superficial femoral artery and 9 lesions of the proximal, middle and distal third of the popliteal artery were treated. 25 were high-grade stenoses with a mean length of 53 mm (range 30-145 mm) and 21 chronic total occlusions with a mean length of 74 mm (range 30-180 mm). 52% of lesions were markedly calcified. 74% of the stents were located in the distal superficial femoral or the popliteal artery, arterial segments which undergo high mechanical stress at knee flexion. Patients were given clopidogrel for 8 weeks and aspirin indefinitely. Clinical reevaluation was performed at discharge, at 6, 12, 24, and 36 months and included measurement of ankle-brachial index and duplex sonography in all patients, and angiography when indicated and on occasion. Primary Cumulative Patency Rates proven by duplex sonographic or angiographic imaging and Freedom from Target Lesion Revascularisation rates were assessed by Kaplan-Meier life table analysis: 1 year results were assessed from all 46 patients, 2 years evaluation based on 41 patients at risk, and 38 patients were still available at 3 years. The primary procedural success rate was 100%. There was no peri-interventional death, MI, stroke, or major vascular event, but one inguinal pseudoaneurysm and one hematoma requiring treatment. Pre-procedural ankle-brachial index increased significantly from 0.74±0.18 to 0.93±0.13 at 6 months and continued to be 0.93±0.10 at 36 months. In-stent stenosis occurred in nine stented lesions, seven of them during the first 12 months after the procedure. Stent thrombosis occured in two patients after 8 and 10 weeks, respectively, and was related to coagulation disorders. All patients improved in clinical symptoms and ankle-brachial index after stent therapy. Primary cumulative patency rate was 93.5%, 84.8%, 80.5%, and 74.3% at 6, 12, 24, and 36 months (standard error <10). Freedom from target lesion revascularisation rate was 95.7%, 89.2%, 84.9%, and 79.3% (standard error <10). Sustained improvement of Rutherford category was observed in 91.3%, 95.4%, 90.2%, and 85.7% of patients at the same time intervals. There was no stent fracture observed. Amputation rate was zero.

Conclusions: This study demonstrates sustained technical and clinical success with good clinical long-term results after stent therapy of femoro-popliteal artery lesions, including lesions which are at high risk for in-stent-stenosis, such as distal femoral and popliteal artery segments undergoing high mechanical stress, long lesions requiring overlapping stents, long total occlusions, and highly calcified lesions.

Endovascular interventions – *Friday May 24th*
Femoropopliteal angioplasty : could new devices improve mid term follow-up

Belgian REMEDY registry: use of bioabsorbable stents in superficial femoral artery lesions

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Aims: In the endovascular treatment of superficial femoral artery lesions the use of nitinol self expandable stents, in case of insufficient angioplasty result, is common good. But problems as in-stent stenosis or occlusion are now more and more appearing. Also, the treatment of in-stent restenosis remains a difficult and till now unresolved issue. We wanted to see if the placement of a "temporary" bio-absorbable stent can give a solution, as they disappear over time and can no longer induce intimal hyperplasia formation.

Methods and results: On going Belgian multicentre prospective follow-up study. We use the bio-absorbable semi-selfexpandable Remedy stent (Kyoto Medical Planning Co Ltd, Kyoto, Japan) for the treatment of short (≤8 cm) lesions in the superficial femoral artery. This stent is made out of a biodegradable polymer (PolY-L-Lactid-Acid) and has a zig zag helical coil stent design. At the moment it is available in 2 lengths: 36 & 78 mm on a 7 Fr device. We have treated, up til now almost 100 patients, with TASC II A & B lesions (20c% occlusions) in the SFA region. Mean lesion length: 35 mm (2-80 mm). Technical success rate :98%. There are no intervention related deaths. Follow-up is done by ulta-sound. Six months primary patency (at the moment) 70.2%, assisted patency: 88.5%. Target lesion revascularisation 17.9%.

Conclusions: Bioabsorbable stent technology might give an improvement in the mid & long-term durability of SFA endovascular treatment The early results are encouraging, but need further follow-up Better understanding and even adjustments of the kinetic and mechanical characteristics of the stent structure and design are nescessary and are under investigation.

Endovascular interventions – *Friday May 24th*
Femoropopliteal angioplasty : could new devices improve mid term follow-up

Stenting of the popliteal artery - a single centre experience with 5 year follow-up

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Aims: Popliteal artery morphology is changing while undergoing knee motion. Therefore stenting of the popliteal arterial segment (PA) in patients with peripheral arterial occlusive disease is a controversial matter, because for the fear of stent fractures due to knee motion and consecutive higher risk of reobstructions. We want to present our data of a consecutive cohort of patients with popliteal artery stenting with a maxium follow-up of 5 years.

Methods and results: From 2006 to 2009 we included patients with peripheral arterial disease Rutherford Stage 2-6 and popliteal arterial obstructions into a consecutive registry. In all patients we performed an endovascular reopening procedure of the popliteal artery and in case of an unsatisfactory result (flow limiting dissection or restenosis of >50%) secondary bail out stenting. All patients were followed up at month 6, month 12, 24, 36, 48 and 60 by clinical assessement, laboratory assessment, ankle brachial index, duplex ultrasound and x ray of the implanted stents. In case of clinical deterioration an angiography was performed with the purpose of reintervention. 105 patients with a mean age 73.11 (+10.03yrs) were included into the registry. In 36 patients (34.3%) plain old balloon angioplasty and in 69 patients (65.7%) stenting of the PA was performed. In 62 patients 1 stent, in 6 patients 2 and in 1 patient 3 stents were placed in the PA segment. Concomitant inflow treatment was performed in 64 (61%) and outflow treatment was performed in 39 (37.1%) patients. At least 1 run off vessel to the ankle was evident in 64 patients (61%). At month 6, 24 (22.9%) patients showed up with a restenosis >50% of the PA target lesion (TL). 7 (19.4%) patients with POBA treatment showed a >50% restenosis, and 17 (24.6%) stented patients. 4 stent fractures were detected at month 6, only 1 in a patient with a restenosis >50%. 7 reinterventions due to clinical deterioration had to be performed, 5 in the stent and 2 in the POBA group. At month 12 an additional 6 patients showed restenosis >50% (5 stented patients), with the need for reintervention in 1 patient. 2 additional stent fractures were detected at month 12, but none was related to a significant restenosis. At month 24, 5 patients showed a new restenosis >50%, 1 POBA, 4 stented patients, 1 with a preexsisting stent fracture since month 6. There was no need for reintervention. At month 36, 4 patients presented with new restenosis >50%, 3 stented patients. In 1 patient a clinically driven reintervention was performed, no additional stent fracture had occurred. At months 48 and months 60 no new restenosis, stent fracture or clinically driven reintervention had occurred. A total number of 39 (37.1%) reobstructions >50% of the PA TL occurred within the FU period, with the need of 9 clinically driven reinterventions (8.6%). 6 stent fractures (8.7%) have occurred within the FU period, only 1 led to a reintervention.

Conclusions: The PA segment in our cohort shows a high rate of reobstructions after endovascular treatment with a considerable rate of clinically driven reinterventions. Although stent implantation of the PA segment was related to a higher number of reobstructions >50%, this did not end up in a higher number of clinically driven reinterventions. Our data also suggest that stent fractures don´t seem to play a role in PA reobstructions and seem not to be responsible for clinically driven reinterventions.

The AURORAA registry: 1 year results using interwoven nitinol stents for extensive distal femoropopliteal occlusive disease

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Aims: In the endovascular treatment of extensive disease in the distal superficial femoral and popliteal level, you can encounter flow limiting problems, where stent placement is needed after balloon angioplasty. At the moment most of the standard bare nitinol stents will have difficulties in these areas. With the introduction of the Supera stent (IDEV Technologies, Inc., Texas, US) we may have an answer in treating those problematic lesions

Methods and results: Because of the Superas new design; with 6 interwoven nitinol wires, it has extraordinary characteristics: very flexible, kink, fracture and crush resistant together with great radial force. We have treated more then 100 patients with extensive distal femoropopliteal disease (TASC II C & D) with heavy calcifications, occlusions, recurrent disease, stent fractures etc. These lesions, that not responded to balloon angioplasty and that needed stent placement, were all treated with placement of Supera stents. Results of the single-centre prospective AURORAA registry : Follow-up done by ultrasound. Five patients died of non-interventional causes. Five patients had an occlusion due to progressive distal peripheral arterial disease. Six months primary patency was more then 90%. Twelve months primary patency was 84.7%. We observed no stent fractures or flow limiting kinking. Average lesion length: 14 cm; average stent length: 18 cm. Technical success rate: 96%.

Conclusions: The Supera stent can be a solution when the use of a "classic" nitinol stent is not indicated or favourable, especially in the femoropoliteal area. It has very good patency rates, despite the very difficult region to treat. This self expandable stent system can be a necessary complement in your tool box due to its special characteristics.

Endovascular interventions – *Friday May 24th*
Femoropopliteal angioplasty : could new devices improve mid term follow-up

Drug-coated balloon post stenting vs. standard balloon post stenting in the superficial femoral artery: results of the freeway stent study

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Aims: The restenosis rate of stents is still a major limitation of arterial interventions. The Freeway Stent Study investigates the inhibition of restenosis by Paclitaxel-eluting balloon dilatation post stent PTA vs. stenting PTA with plain balloon postdilatation in the treatment of the superficial femoral artery.

Methods and results: This is a randomised, controlled multicentre trial which is conducted by the Freeway Stent Study group in 15 centres in Germany and Austria. 200 patients are randomised either to nitinol stenting with the Freeway drug-coated balloon (DCB) or stenting with plain old balloon (POBA). The primary endpoint is the rate of clinically driven target lesion revascularisation (TLR) at 6 months. Further, several secondary endpoints like late lumen loss at 6 months, patency rate and major adverse events are investigated. 100 patients have completed the 6-month follow-up period. The results show a favourable outcome for the DEB arm in relation to the TLR rate in this patient population which presented predominately with occlusions. The results are supported by the clinical outcomes of patency rate, ABI index and presentation according to Rutherford.

Conclusions: The interims results indicate that drug-eluting balloons might provide an advantage in post dilatation of primary nitinol stenting vs. plain balloons in SFA lesions to overcome the existing limitations of peripheral artery disease treatment.

Endovascular interventions – *Friday May 24th*
Femoropopliteal angioplasty : could new devices improve mid term follow-up

Twelve month results of the BIOLUX P-I first in man study comparing a paclitaxel releasing balloon catheter vs. an uncoated balloon catheter in femoropopliteal lesions

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Aims: The aims of this first in man study was to assess safety and performance of the Passeo-18 Lux Paclitaxel releasing PTA balloon catheter vs. the uncoated Passeo-18 balloon catheter in treating stenosis and occlusion of the femoropopliteal arteries.

Methods and results: Between October 2010 and August 2011, 60 subjects with stenosis or occlusion of femoropopliteal arteries were consecutively enrolled in this international, multicentre, randomised controlled trial with an 1:1 allocation. Primary endpoint of the study was late lumen loss at 6 months assessed with quantitative vascular angiography by an independent corelab. Secondary endpoints were binary restenosis at 6 months, target lesion revascularisation, change in mean Ankle Brachial Index and Rutherford classification, and major adverse events at 6 and 12 months. Thirty-four men (56.7%) and twenty-six women with a mean age of 70.7±10.1 yrs, were enrolled at five sites. Half of the subjects (N=30) were treated with the Paclitaxel releasing balloon catheter (study group) and half (control group) with the uncoated balloon catheter. The majority of subjects presented with hypertension (73.3%), followed by smoking (68.3%), history of PAD (63.3%), hyperlipidaemia (61.7%), and diabetics (33.3%). 56.7% of the subjects were Rutherford Class 3 and 26.7% were Class 2. Late luminal loss at 6-month follow-up was 0.55 mm (DEB) vs. 1.07 mm and binary restenosis was 11.5% vs. 34.6% respectively. One year data will be available at the time of presentation.

Conclusions: Early performance data demonstrated significant reduction in late luminal loss and binary restenosis in the study group compared to the control group.

Endovascular interventions – *Friday May 24th*
Femoropopliteal angioplasty : could new devices improve mid term follow-up

Long-term outcomes after subintimal angioplasty with primary proximal stump stenting for chronic total femoral occlusions

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Aims: Subintimal angioplasty (SA) for chronic total occlusions of femoropopliteal artery has rapidly expanded, and it is considered as an acceptable alternative technique. This study was aimed to investigate the procedural and long-term clinical outcomes after SA with a routine stent placement at the proximal stump for chronic total femoral occlusions in patients with intermittent claudication or critical limb ischaemia (CLI). Also, we sought to find affecting factors for outcomes after SA with stenting.

Methods and results: Between April 2004 and April 2012, SA of chronic total femoral occlusions was performed with implantation of stents in 172 limbs of 150 patients (69±10yrs, 122 men). The primary endpoint was a cumulative free survival of reintervention, above-ankle amputation of the index limb, or restenosis (RAS). Secondary endpoint included major adverse cardiovascular event (MACE) and primary patency. Technical success was achieved in 161 limbs (94%) with a lesion length of 22.6±8.5 cm. There were no procedure-related deaths and complications requiring surgery. However, two procedures (1%) complicated by distal embolisation and arterial perforation occurred in 4 (2%). During the median follow-up period of 545 days (interquartile range, 169-1305 days), RAS-free survival rates at 1, 3 and 5 years were 77%, 58% and 44%. The primary patency rates at 1, 3 and 5 years were 78%, 59% and 45% and the MACE-free survival rates at 1, 3 and 5 years were 92%, 84% and 70%. On multivariate analysis, larger number of stents, lower postprocedural ankle-brachial index (ABI) and lower body mass index (BMI) were independent predictors of RAS events.

Conclusions: SA with routine stent implantation at the proximal stump is effective for the treatment of chronic total femoral occlusions with a high technical success rate and with few complications. In addition, most procedures provided not only high short-term RAS-free survival rate but also satisfactory long-term RAS-free survival rate. However, additional stenting beyond the proximal stump might be related to RAS events. Also, the lower postprocedural ABI and lower BMI were other independent predictors for RAS events.

Endovascular interventions – *Friday May 24th*
Femoropopliteal angioplasty : could new devices improve mid term follow-up

Midterm outcomes after self-expanding nitinol stent implantation for trans-atlantic inter-society consensus II type D lesions of the superficial femoral and proximal popliteal artery

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Aims: Although endovascular treatment (EVT) became first-line therapy for peripheral artery disease (PAD), superficial femoral artery (SFA) lesion is still controversial especially in complex lesion subset. We investigated 6-year patency rate after self-expanding nitinol stent implantation for Trans-Atlantic Inter-Society Consensus (TASC) II type D lesions of the superficial femoral and proximal popliteal artery.

Methods and results: From March 2005 to December 2011, total 2021 lesion had EVT for lower extremity PAD at our institution. Of the cohort, 48 patients 53 limbs implanted bare-metal self-expanding nitinol stent for TASC II type D SFA lesions. We retrospectively investigated the outcomes after EVT for mean 854±515 days. Primary, secondary patency and assisted primary patency rates were calculated using Kaplan-Meier method. Mean age was 73±9 years and females were 29%. Sixty percent of patients had diabetes mellitus, 25% of patients had haemodialysis and 44% presented with critical limbs ischaemia. Average ankle-brachial pressure index before procedure was 0.63±0.14 and improved to 0.93±0.15 after the procedure. Mean total stent length was 270±51 mm. mean stent diameter was 6.9±1.0 mm. Two limbs (4%) had major amputation and mortality rate was 13%. Primary, secondary patency and assisted primary patency rate was 39%, 68% and 41%, respectively.

Conclusions: More complex lesion in TASC II classification may be difficult to keep the primary patency with self-expanding bare-metal nitinol stent, but secondary patency rate seems acceptable.

Interventions for hypertension & heart failure – *Tuesday May 21st*
Renal denervation for resistant hypertension: procedural aspects, clinical effects and off label indications

The effects of renal denervation on renal haemodynamics

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Aims: The efficacy and safety of renal denervation (pRDN) is quite extensively studied. However, it remains unknown what the exact working-mechanism of the blood pressure lowering effect of pRDN is. Small animal studies have suggested an improvement of renal flow after pRDN. It can be hypothesised that a decreased microvascular resistance leads to an improved renal blood flow resulting in an improved renal perfusion, and consequently a reduced blood pressure (BP). To further investigate this topic, we performed a porcine and human pilot study.

Methods and results: In patients undergoing pRDN for resistant hypertension, intravascular haemodynamic measurements using the Combowire®(Volcano Corporation, San Diego, USA) were performed. The wire was positioned with the combined pressure / Doppler-sensor in the renal artery. Mean aortic and distal pressures were obtained during baseline conditions. Baseline average peak flow velocity (b-APV) was measured. Hereafter, maximum hyperaemia was induced using papaverine 30mg i.a.. Consequently, hyperaemic average peak flow velocity (h-APV) was obtained. Using h-APV and hyperaemic distal pressure, hyperaemic microvascular resistance (HMR) was calculated (ratio of hyperaemic distal pressure to h-APV). After these measurements, pRDN was performed. Directly hereafter, the above mentioned measurements were repeated. In addition to humans, the same measurements were performed in pigs before and directly after pRDN. At moment of submission, flow measurements were performed in 6 patients. Directly after renal denervation both b-APV and h-APV did not significantly change (mean b-APV: from 34 to 27 cm/sec; P=0.27; mean h-APV: from 48 to 41 cm/sec; P=0.47). HMR also did not significantly change (mean HMR from 2.4 to 2.7; P=0.056). In the pigs (n=3) both b-APV and h-APV increased (b-APV from 21 to 35 cm/sec; P=0.014; h-APV from 38.33 to 63.33 cm/sec; P=0.032). A numerical decrease of HMR was noted (4.8 to 1.5; P=0.266).

Conclusions: In this small human population, we did not see a direct change of renal haemodynamics. Strikingly, the opposite effect was seen in pigs, whereby a direct decreased microvascular resistance was measured after pRDN. These observations may be explained by a difference in vascular structure between healthy pigs and hypertensive patients.

Interventions for hypertension & heart failure – *Tuesday May 21st*
Renal denervation for resistant hypertension: procedural aspects, clinical effects and off label indications

Novel use of a three-dimensional mapping system to guide renal artery denervation

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Aims: Catheter-based renal artery denervation (RAD) is an effective treatment for resistant hypertension. The NavX system (Navigation & Visualisation Technology, St Jude Medical, Inc) creates 3-dimensional anatomical maps and is commonly used in cardiac ablation procedures to guide catheter position and identify ablation sites. This first-in-human study assessed the feasibility and utility of NavX 3D mapping for RAD. The rationale for NavX use was firstly to reduce the contrast load in a population of patients at high risk of renal failure. The second was to decrease radiation exposure, both to the patient and the operator. Lastly, we anticipated that 3-dimensional visualisation would allow circumferential and longitudinal placement of ablation sites increasing optimal renal nerve ablation. This could potentially impact on the incidence of non-responders to RAD (which in the literature occurs in 10% of patients).

Methods and results: Patients undergoing RAD at a single-centre were recruited to the study from September 2011 to September 2012. Consecutive patients who underwent RAD using fluoroscopy alone (Control Group, n=8) were compared to consecutive patients who underwent NavX-guided RAD (NavX Group, n=10). A radiofrequency catheter (Symplicity, Medtronic Inc) was introduced into each renal artery via femoral access. Where NavX was utilised, orthogonally located skin patches were applied to the torso with respiratory variation corrected for. NavX 3-dimensional geometry of each renal artery, and on occasion the aorta, were created. This geometry was used to both guide positioning of the Symplicity catheter and to mark renal artery ablation sites. NavX was successfully utilised in all 10 patients in whom it was attempted. There was no significant difference in baseline clinical characteristics between the two groups, including age, gender, basal metabolic index, renal function, number of anti-hypertensive medications or background co-morbidities. Mean baseline blood pressure (BP)±SD was 187±16/94±19 mmHg in the Control Group and 173±21/85±10 mmg in the NavX Group (p=0.14). Renal artery anatomy was similar between the two groups in terms of length, diameter and tortuosity. The mean contrast dose was significantly higher in the Control Group at 113±32mls vs. 76±23mls in the NavX Group (p=0.01). The mean fluorosocopy screening time was significantly longer in the Control Group at 22±11 minutes compared to 13±10 minutes in the NavX Group (p=0.05). The mean radiation dose was significantly higher in the Control Group at 202±122 Gycm^2 compared to 94±108 Gycm^2 in the NavX Group (p=0.01). NavX geometry of the aorta enabled localisation of renal arteries in cases (n=2) where it was difficult to visualise artery origin by fluoroscopy and contrast injection. Mean changes in systolic and diastolic BP at 3 month follow-up were –22/–9 mmHg and –23/–11 mmHg in the Control Group and NavX Group, respectively (p=0.99).

Conclusions: Use of NavX mapping as compared to standard renal artery denervation was found to correlate with a significant reduction in contrast load and radiation exposure. This first-in-human study demonstrates both the feasibility and potential benefits of NavX 3-dimensional mapping to guide renal artery catheter denervation.

Interventions for hypertension & heart failure – *Tuesday May 21st*
Renal denervation for resistant hypertension: procedural aspects, clinical effects and off label indications

Renal sympathetic denervation improves nocturnal dipping in hypertensive patients

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Aims: Renal sympathetic denervation is an emerging device based treatment for patients with resistant hypertension and has been shown to reduce blood pressure in this group. 'Nocturnal Dipping' is a phenomenon where a decrease in blood pressure of 10% or more occurs during sleep. Nocturnal dipping has been shown to be protective against cerebrovascular and cardiovascular disease. There is a paucity of data on the effect of renal sympathetic denervation on the circadian rhythm of blood pressure. This study aimed to assess the effect of renal sympathetic denervation on the 24 hour blood pressure profile of patients with resistant hypertension.

Methods and results: Patients with resistant hypertension scheduled for renal denervation in a single-centre were included. All patients underwent bilateral renal artery ablations using the Symplicity™ renal denervation system. 24 hour ambulatory blood pressure monitors were given to patients prior to the procedure and at 9 months post procedure. Software was used to calculate the degree of systolic, diastolic and mean arterial pressure dipping nocturnally. 12 patients had complete 9-month follow-up at the time of this submission. At baseline, 5 patients (42%) were diastolic nocturnal dippers and 3 (25%) were systolic nocturnal dippers. 24 hour ambulatory blood pressure monitors showed an overall decrease of 5 mmHg systolic and 5.5 mmHg diastolic despite a reduction in number of antihypertensive medications by over 20%. Both systolic and diastolic nocturnal dipping improved significantly. Systolic dip increased by 6 mmHg (3%) at 9 months post procedure (paired samples t-test p=0.002). Diastolic dip increased by 5.6 mmHg (6%) at 9 months post procedure (paired samples t-test p=0.022). Of the 7 patients that were classified as diastolic non-dippers at baseline, 4 patients (57%) became diastolic nocturnal dippers.

Conclusions: Renal sympathetic denervation is an effective method for management of resistant hypertension. An increase in systolic and diastolic nocturnal dipping was noted in this study. This effect may have additional cardiovascular benefits to the previously noted reduction in blood pressure with renal sympathetic denervation.

The prevalence of multiple renal arteries in hypertensive patients and its relation to blood pressure lowering effect after renal denervation

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Aims: The Symplicity HTN-2 trial showed that percutaneous renal denervation (pRDN) is a promising treatment for resistant hypertension. In this trial, patients with multiple renal arteries were excluded from treatment. In our centre, existence of multiple renal arteries is not considered to be an exclusion criterion for pRDN. The aim of present study was to determine the prevalence of multiple renal arteries in patients referred for treatment with pRDN and its relation to BP-lowering effect of pRDN.

Methods and results: Patients referred to the UMC Utrecht for treatment with pRDN who underwent magnetic resonance angiography (MRa) or computed tomography angiography (CTa) in the work-up before treatment, were included in the current analysis. In total 112 patients underwent MRa or CTa in the work-up before treatment with pRDN. Mean age was 59 years, 51% of patients was female. Seventy two per cent of the total group had solitary renal arteries at both sides, 28% has multiple arteries, most frequently at the left side. Three renal arteries were seen in 21%, 4 renal arteries in 7% of all patients. Thirty two patients were excluded from treatment (due to secondary causes, white coat effect or ineligible anatomy). There were no differences in the number of renal arteries between the group treated with pRDN and the excluded patients. Multiple renal arteries were not associated with baseline systolic BP (P=0.879) or renal function (P=0.471). At moment of submission, 6 months follow-up data were available of 52 patients: 41 patients had solitary renal arteries at both sides and 11 patients had multiple renal arteries. Office BP changed from 202±22/96±14 mmHg at baseline to 171±27/97±14 mmHg 6 months after treatment (P<0.001). The mean decrease in systolic BP was not different in the group with solitary renal arteries (–33 mmHg) as compared with the group with multiple renal arteries (–29 mmHg, P=0.257).

Conclusions: Multiple renal arteries are highly prevalent among patients referred for treatment with pRDN. There is no relation between presence of multiple renal arteries and a decrease in BP 6 months after treatment with renal denervation; therefore it seems reasonable not to exclude patients with multiple renal arteries from treatment with pRDN.

Interventions for hypertension & heart failure – *Tuesday May 21st*
Renal denervation for resistant hypertension: procedural aspects, clinical effects and off label indications

ALSTER BP registry: efficacy and safety of renal denervation including "re-do" denervations in non-responders

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Aims: The ALSTER BP registry follows all renal denervations performed at our site regarding routine follow-up diagnostics. Six months follow-up after renal denervation employing the Medtronic/Ardian Symplicity catheter and generator system is available for 55 patients. Patients were classified as responders (n=39, 71%), divided into early (n=31, 56%) and late (n=8, 15%) responders if they showed a lowering in their office-based systolic blood pressure values >10 mmHg after 6 months. Patients who did not fulfill this criteria after 6 months were classified as non-responders (n=16, 29%). We offered a second denervation procedure ("re-do") to these patients hypothesising that renal denervation had not been effective initially.

Methods and results: Patients were accepted for the procedure when the office-based blood-pressure revealed systolic blood pressure >160 mmHg and the patient was on three or more antihypertensive drugs. Available routine follow-up included measurement of the office blood pressure, 24-hour ambulatory blood pressure, lab controls including creatinine levels and glomerular filtration rate. Mean systolic pressure of the 55 patients treated with renal denervation was 184(±3)mmHg at baseline. The first procedure was safe; no major procedure related complications were reported until discharge after renal denervation. The glomerular filtration rate showed no significant change in all patients up to six months. 39 (71%) patients had a significant reduction of their office-based systolic blood pressure with a mean difference of –44(±4) mmHg (p<0,01) from baseline to follow-up after 6 months. In addition, we documented a significant reduction of –18(±5) mmHg of the mean systolic blood pressure in the 24-hour ambulatory monitoring after 6 months (p<0,01). Non-responders at 6 months were more likely to have a history of hypertension >10 years (81% of non-responders), no other correlation was observed. Until now, we have available 6-months follow-up data for seven patients that underwent a re-do procedure after being classified as non-responders. A significant reduction of the systolic blood pressure was observed in three of seven patients (=42%) at six months. One patient (14%) presented herself with a significant 75% (QCA) proximal renal artery stenosis possibly related to the repeated renal denervation procedures.

Conclusions: Based on the data of our real-world registry, the Medtronic/Ardian Symplicity renal denervation procedure is a safe and effective therapeutic option for patients with resistant hypertension. A second procedure seems to have an impact in about half of the remaining non-responders. We here report a renal artery stenosis following off-label repeat interventions. This suggests that a second intervention if necessary should possibly use different devices not relying on point-by-point ablations. Enhanced efficacy of the initial procedure through improved ablation techniques and catheters may prove helpful to increase the effectiveness of a single procedure without increasing side effects. As recently suggested, delayed scaring of the sympathetic innervation in the renal artery adventitia following high-frequency denervation probably leads to delayed effects in some patients. We find duration of hypertension to be predictive of late- and non-responders. This suggests to offer the procedure even to patients in an earlier clinical stage and not only to end-stage hypertension patients with manifest end-organ damage.

Interventions for hypertension & heart failure – *Tuesday May 21st*
Renal denervation for resistant hypertension: procedural aspects, clinical effects and off label indications

Renal denervation in stented porcine renal arteries

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Aims: The purpose of this study is to characterise to ablation results and tissue response with the Symplicity® Catheter System™ in previously stented porcine renal arteries.

Methods and results: Normal swine were enrolled in four experimental arms consisting of stented renal arteries with renal artery denervation, stented renal arteries without denervation, denervation in non-stented arteries, and naïve untreated swine. The Hippocampus™ Renal Rx Stent System was implanted in two experimental arms for 28 days which allowed for healing. The Symplicity® Catheter System™ was employed to perform renal artery denervation in stented and unstented arms, and an additional 14 days allowed for response. In stented arteries, ablation sites were selected either within stented segments or distal to stented segments. At 14 days post-denervation, terminal angiography was performed and tissues were collected for histological examination and norepinepherine determination. Ablation time was automaticaly truncated during in-stent ablation due to system safety algorythms, while most ablations performed distal to the stented segments proceeded to full ablation time. All subjects survived to termination without adverse response. Histopathology of excised renal arteries demonstrated succesfull nerve ablation in unstented arteries but ablation performed within stented segments was unsuccesful, with similar functional nerve area to untreated controls. Terminal axon quantification showed that the tyrosine hydroxylasepositively stained axon area (sympathetic nerve terminus) was significantly reduced following in-stent denervation relative to the non-ablated controls ($P<0.05$), but showed significantly less change than the ablated non-stented arteries ($P<0.05$). Renal norepinephrine concentration was reduced about 40% following in-stent ablation, relative to untreated subjects, while treatment distal to the stented segment reduced renal norepinephrine by >90% (comparable to non-stented arteries).

Conclusions: Possible interaction of radio frequency energy with an implanted stent makes it inadvisable to perform an ablation procedure in close proximity to a renal stent. Optimal renal nerve ablation within a segment of stented renal artery was not possible in the porcine model since the Symplicity Catheter Systemsafety controls terminated the procedure before the intended ablation time was reached, preventing undesirable local heating and resulting in reduced but non-optimal terminal axon density and renal norepinephrine concentration. In contrast, renal nerve ablation performed distal to the stented artery segment facilitated full duration ablation with significant reduction in renal norepinephrine, indicating a successful procedure.

Interventions for hypertension & heart failure – *Tuesday May 21st*
Renal denervation for resistant hypertension: procedural aspects, clinical effects and off label indications

EnligHTN system exerts a favourable effect on atrial and ventricular arrhythmias in resistant hypertensives

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Aims: Transluminal renal sympathetic denervation (RSD) reduces blood pressure (BP) in patients with treatment-resistant hypertension. We assessed the effect of RSD on cardiac arrhythmias in patients with resistant hypertension.

Methods and results: Fourteen patients with resistant hypertension underwent ambulatory BP measurements and Holter monitoring at baseline and 1 month after RSD using the EnligHTN ablation catheter (St. Jude Medical, CA, USA). Patients with grade II and above of the Lown-Wolf classification were considered to have complex ventricular arrhythmias while the presence of ≥3 consecutive premature supraventricular contractions was defined as paroxysmal atrial fibrillation (PAF). One month post RNA, office and 24-hour BP was significantly reduced by 38/14.1 mmHg, $p<0.001/0.003$ and 18/9.5 mmHg, $p<0.001/0.001$, respectively). Office, and average 24-hour heart rate were significantly reduced by 7 bpm, ($p=0.046$) and 6.7 bpm ($p=0.022$), respectively. Complex ventricular arrhythmias were present in 5 out of 14 patients with resistant hypertension (1 with non sustained ventricular tachycardia and 4 with ventricular couplets) at baseline but persisted only in 2 of them one month after RSD (2 patients with ventricular couplets). The number of premature ventricular contractions was significantly decreased after RSD (from 2.23/hour to 0.39/hour, $p=0.019$). Episodes of PAF were detected in 5 of 14 subjects at baseline and in 2 of those patients one month after RSD. The total number of premature supraventricular contractions was also significantly decreased after RSD from 1.62/hour to 0.72/hour ($p=0.039$). There was no relationship between the observed difference in premature supraventricular and ventricular contractions after RSD and the drop in office and 24hour BP.

Conclusions: RSD significantly reduces office and ambulatory BP and heart rate and exerts a favourable effect on atrial and ventricular arrhythmias in resistant hypertensives, supporting the concept of the "pleotropic" effects of RSD beyond the BP reduction in this setting.

An interatrial shunt device reduces left atrial pressure, improves haemodynamics and prevents adverse remodeling in an ovine heart failure model

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Aims: Increased left atrial pressure in patients with heart failure with either reduced or preserved ejection fraction leads to pulmonary congestion, dyspnea and exercise intolerance. Pharmacotherapy is limited in improving this haemodynamic state, and there is an unmet need for device-based strategies that will reduce left ventricular filling pressure and prevent pulmonary congestion. The V-wave device is designed for implantation in the interatrial septum creating a left atrial to right atrial (one way) shunt in order to decompress the left atrium when left atrial pressures are excessive. We have studied this novel device in a chronic ovine model of ischaemic heart failure.

Methods and results: LV dysfunction and heart failure were induced in 13 sheep (43.3±2.0 Kgs) by consecutive microsphere injections into the coronary arteries. The sheep were instrumented with catheters in the pulmonary artery, left atrium and right atrium for monitoring purposes. The animals were assigned to serve as controls (CTRL; n=5) or had the V-wave device deployed in the interatrial septum (intervention group [INT]; n=8). Clopidrogel 75 mg/d and warfarin were initiated following device implantation. Animals were followed weekly for up to 20 weeks with the following measurements recorded: shunt patency by Fick and echocardiography; Pulmonary Artery Pressure (PAP), Left Atrial Pressure (LAP) and Right Atrial Pressure (RAP) via the indwelling catheters; LV function and dimensions by echocardiography. After induction of LV dysfunction all animals demonstrated, as expected of this model, pathological ventricular remodeling with increased LV dimensions and reduced LVEF (60±1 to 31±2%, $p<0.05$) and haemodynamic decompensation with increased LV filling pressures (LAP 17±1 mmHg). Long-term weekly follow-up showed marked difference between the CTRL and INT groups. In the CTRL group progressive remodeling with increases in cardiac dimensions and reduced LVEF to 18±1%was noted. This was associated with an increase in LAP to 23±2 mmHg, PAP to 45±3 mmHg and early death of the animals in end-stage heart failure. The INT group demonstrated a completely different and more favourable course. All valved-devices were patent throughout the study and a Qp/Qs of 1.2 to 1.4±0.1 was recorded. LAP decreased and remained between 12 and 13 mmHg over time, RAP remained low, and PAP did not increase over time. LV dimensions did not change compared to baseline and LVEF improved from 27.5±2.9 to 46.9±5.3% after 20 weeks. 80% of INT animals were alive at 12 weeks compared to 20% of CTRL. At 16 weeks only INT animals were alive and measurements obtained at 16w and 20w were not different from those at 12 weeks. At 20w RAP was 5 mmHg, LAP 11 mmHg, PAP 24 mmHg and LVEF 48%.

Conclusions: This study demonstrates the feasibility of the V-wave interatrial shunt device. In an ovine model of heart failure, the device improved haemodynamics, ventricular remodeling, and survival over 20 weeks. Human studies of this promising device are warranted.

A cardiac resynchronisation therapy method to augment ventricular contraction using polymer based actuators and mitral regurgitation reduction with devices over left ventricular endocardial pacing wire, an *in vitro* study

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Aims: To investigate a potential cardiac resynchronisation method using high force density actuators and mitral regurgitation reduction devices.

Methods and results: A 8 cm long, 0.4 mm thick and 2 mm wide polymeric actuator strip was attached to the right ventricular pacemaker lead 4.0 cm from the edge of the leads and 035 wire and step up voltages (2 to 9V) were given. Deformation of the pacemaker lead with polymer was studied under cinefluoroscopy in air and immersing it in 0.9% saline. Cantilever function was assessed by addition of gold rings of incremental weights to the tip and beam of the polymer-surfaced area of the lead. The leads were thereafter reinforced with polymer on the lower surface. The left ventricular lead was further reinforced with a side branching 035wire Y-attachment and polymer on its surface and step up voltages were given. A novel nitinol based Gore-Tex device and polymer based technology was developed and positioned abutting the mitral valves and evaluation was done in sheep heart preparation by cinefluoroscopy. Later two experiments for each device was done similarly. Reactionary force at the junction of the antennas and the device were measured by suspension of weights. Also the reactionary force at the tip of lead joining the cardiac apex was estimated. The mean deformation at 9V for the LV, RV leads and the 035 wires was 3.5±0.2, 1.1±0.1, 1.4±0.1 mm respectively and the stopping weight was 3.8±0.2, 3.2±0.1, 3.6±0.3 g respectively. With dual surfacing of polymer and driven by separate actuation circuits simultaneously the stopping weight parameters increased to 4.8±0.2, 4.0±0.2 and 4.6±0.1g respectively (>25% each, $P<0.01$ for all). The nitinol based Gore-Tex device and the polymer device were effective in reducing mitral regurgitation significantly from Grade IV to Grade I (>60% by visual quantification). The reactionary force at the left ventricular lead tip was 1N. Based on the results a novel cardiac resynchronisation therapy method was built by addition of polymer strips to the lead tips and mitral regurgitation control devices using an endocardial screw in pacing wire.

Conclusions: There is potential for a novel cardiac resynchronisation therapy method using polymer-based actuators and devices to control mitral regurgitation.

Interventions for hypertension & heart failure – *Wednesday May 22nd*
Novel devices for acute or chronic heart failure

Interim analysis of the reitan catheter pump heart failure efficacy study: reitan catheter pump improves cardiovascular and renal function in acute decompensated heart failure

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Aims: A prospective non randomised multicentre study seeking to recruit 20 patients with ADHF with a need for inotropic or mechanical circulatory support to determine the haemodynamic and renal efficacy of the Reitan Catheter Pump (RCP) - a novel percutaneous cardio-vascular support device.

Methods and results: Prospective non randomised multicentre study seeking to recruit 20 patients with ADHF with a need for inotropic or mechanical circulatory support with: i) EF <30%; ii) Cardiac index(CI) <2.2 L/min/m^2. Outcome measures included: 1) Cardiac index (CI); 2) Pulmonary Capillary Wedge Pressure (PCWP); 3) Urine output / serum creatinine; 4) Vascular / device complications; 5) 30 day mortality. Interim analysis (n=18). The mean age of the study group was 65.5 years, composed of 16 males and 2 females. The intended RCP treatment period was 24 hours. During RCP treatment there was a 26.8% improvement in mean Cardiac Index (CI) measured at 12 hours (1.79 to 2.28 L/min/m^2 p=0.003), and a concomitant reduction in PCWP at 12 hours of 32% (26.3 to 17.6 mmHg p=0.04). RCP insertion prompted substantial diuresis. Urine output doubled over the first 24 hours compared to baseline (76 ml/hr vs. 157 ml/hr p=0.02). This was associated with an improved renal function in patients without end stage renal failure (n=17), as evidenced by a reduction in serum creatinine of 16% at 24 hours (174 to 145 umol/L p=0.00016). 2 patients previously refused cardiac transplantation were reassessed and successfully transplanted within 9 months of RCP treatment on the basis of demonstrable renal reversibility. There were no vascular or device complications. There were 4 deaths at 30 days, none of which were judged to be device related, and is more likely a reflection of severity of heart disease in this study cohort.

Conclusions: RCP support in ADHF patients was associated with improved haemodynamics, and a significant improvement in renal function. The Reitan Catheter Pump may have a role in providing percutaneous cardiovascular and renal support in the acutely decompensated cardiac patient, and may have a role in suggesting renal reversibility in potential cardiac transplant patients. Further data will be reported at recruitment completion (n=20), and will include renal biomarker data.

Interventions for hypertension & heart failure – *Wednesday May 22nd*
Novel devices for acute or chronic heart failure

Haemodynamic support using percutaneous left ventricular assist device during catheter ablation of ventricular tachycardia is associated with shorter hospital length of stay

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Aims: Although haemodynamic support using percutaneous left ventricular assist device (pLVAD) can provide effective end-organ perfusion during catheter ablation of haemodynamically-unstable ventricular tachycardia, and allow for longer mapping times during tachycardia, it remains unclear whether its use significantly impacts the hospital length of stay or clinical outcomes following catheter ablation.

Methods and results: A total of 39 consecutive unstable scar-related ventricular tachycardia ablations performed using a combined endocardial and epicardial approach by a single operator at a single-centre in 34 patients (mean age: 64±11 years, mean left ventricular ejection fraction: 34±10%, ventricular tachycardia storm: 26%, CABG: 31%, PCI: 34%), were evaluated. During ventricular tachycardia mapping, all patients received intravenous pressor therapy with dopamine. In addition, haemodynamic support was provided by either: (i) an Impella 2.5 (pLVAD) in 12 patients, (ii) IABP counterpulsation in 12 patients, or (iii) neither (control) in 15 patients. Ventricular tachycardia substrates consisted of post-myocardial infarction in 55%, non-ischaemic cardiomyopathy in 32%, arrhythmogenic right ventricular cardiomyopathy in 11%, and congenital heart disease in 2%. Baseline characteristics were similar in all 3 groups. While there was a slight trend towards shorter radiofrequency ablation times with the use of pLVAD (4,451±2,098 seconds [pLVAD] vs. 5,514±2,089 seconds [IABP] or 4,852±2,476 seconds [control]), neither ablation times nor procedure times were significantly different among the 3 groups (p=NS). On the other hand, hospital length of stay post-ablation was significantly shorter in pLVAD (2.5±0.9 days) vs. IABP (5.3±2.5 days) or control (5.7±3.2 days); p<0.05. Furthermore, ventricular tachycardia recurrence rates were similar among the 3 groups (pLVAD: 25%, IABP: 30% and control: 27%) during 19±7 months of follow-up (p=NS).

Conclusions: In patients with unstable scar-related ventricular tachycardia undergoing catheter ablation, pLVAD support was associated with significantly shorter hospital length of stay but did not improve clinical outcomes.

Interventions for hypertension & heart failure – *Wednesday May 22nd*
Novel devices for acute or chronic heart failure

Meta-analysis of percutaneous ventricular restoration (PVR) therapy using the Parachute Device in patients with ischa emic dilated heart failure

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Aims: Left ventricle (LV) remodeling after anterior wall myocardial infarction (AWMI) leads to increased LV volumes, myocardial stress, and ultimately heart failure (HF). Treatment options are limited for these high-risk HF patients. A meta-analysis of the first 100 patients treated with 6 months follow-up using the Parachute™ device will be available for presentation at EuroPCR 2013. To confirm the acute safety and acute and long-term efficacy of PVR using an expanded range of Parachute™ device sizes in patients with ischaemic HF with prior AWMI.

Methods and results: Up to 100 patients with NYHA class II-IV HF secondary to AWMI, with akinetic or dyskinetic wall motion abnormality, LV ejection fraction <40%, and have been fully revascularised were enrolled into this non-randomised trial data set from the United States and European. Major endpoints were death and repeat hospitalisation. As of December 21, 2012, 106 patients were treated. Six month FU data will be completed by May 1, 2013. Results will be available for presentation.

Conclusions: This meta-analysis of PVR using an expanded range of Parachute™ device sizes in patients with ischaemic HF and prior AWMI is anticipated to confirm the safety and efficacy of this approach to treating HF, thus supporting the initial launch in Europe.

Interventions for hypertension & heart failure – *Thursday May 23rd*
Contribution of renal denervation to the treatment of resistant hypertension: a health technology assessment perspective

Medical and interventional therapies for patients with resistant hypertension, a network meta-analysis

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Aims: New therapies, both medical and interventional, have been recently introduced for patients with resistant hypertension (HTN), but no meta analysis have been performed to investigate their relative efficacy.

Methods and results: Suitable RCTs investigating efficacy of drugs or interventions in patients with resistant HTN were searched across the Cochrane Collaboration Register, EMBASE/Scopus, and MEDLINE/PubMed. Systolic clinical pressure was the primary end point, while systolic ambulatorial pressure and diastolic clinical pressure the secondary ones. Network meta-analyses were fitted to obtain pooled effects of all pairwise comparisons. Where sufficient evidence was available to estimate it a random effect model was used, otherwise a fixed effect model was fitted. All analyses were conducted inWinBUGS. Of the 490 titles initially identified, 10 randomised controlled trials were included evaluating 7 different strategies. Compared with placebo, the largest reduction of systolic clinical pressure was obtained with renal artery denervation (RAD -27 mmHg; -39:-15) and spironolactone (-12;-22:-3 mmHg), and RAD was the technique with the highest probability (=0.88) of being ranked most effective out of the seven medication classes. The largest reduction in ambulatorial clinical pressure and in diastolic pressure was obtained respectively with chronotherapy (-10; -14;-5) and with baroflex activation (-12;-15:-8; all CI 95%): both with the highest probability of being ranked best (probabilities 0.62 and 0.99 resp.). There were no trials of RAD reporting these outcomes.

Conclusions: Renal artery denervation, chronotherapy and baroflex activation had the highest probability of lowering systolic and diastolic pressure.

Interventions for hypertension & heart failure – *Thursday May 23rd*
Contribution of renal denervation to the treatment of resistant hypertension: a health technology assessment perspective

Renal denervation in patients with resistant hypertension: current clinical trials vs. real-life use

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Aims: Renal denervation in patients with therapy resistant hypertension is a new and already widely used procedure. In Germany alone, more than 2.000 performed cases were officially registered by the Federal Statistical Office in 2011. This assessment aimed to investigate the number and kind of published clinical trials which were supposed to be the basis for this development.

Methods and results: A systematic literature research was performed in June 2012 for publications concerning renal denervation in patients with resistant hypertension. Attention was paid to incorporate a high level of search sensitivity. The search concept involved three components: Denervation, Renal, Hypertension. Inclusion criteria for the selection process involved: Clinical studies with outcomes for ≥10 patients; Guidelines, Expert consensus statements, Position papers, Systematic reviews; Publication language: English, German, French, Italian, Spanish. Exclusion criteria were: Patients' diagnosis of renal hypertension and/or haemodialysis; Animal studies; Publication types: Case reports, Reviews, Letters, Comments, News, Editorials. Databases searched were Medline and all databases provided by The Cochrane Library. Using predefined search filters limiting the results to a publication date of the past 10 years and exclude animal studies, 181 titles were found. In a next step, two reviewers performed a selection of titles and afterwards of abstracts in order to identify relevant publications. 18 publications were considered as potentially relevant and were screened in full text. Eventually, 12 of these 18 publications were found to be relevant by directly reporting results of different clinical trials. Amongst these, there was one randomised-controlled trial and 11 non-randomised trials. All trials together included less than 500 patients who had actually received the treatment according to author statements. No publication was able to provide outcome parameters for a follow-up period of more than 2 years. The clinical trial involving the highest level of evidence, i.e. the randomised-controlled trial, only provided a follow-up of six months.

Conclusions: Clinical trial data on renal denervation is still scarce and long-term durability of treatment effects has not been proven yet in larger number of patients, especially not in a high-level-of-evidence context. Nonetheless, the procedure is used in an increasing number of cases in real-life clinical practice. Obviously care providers do not rely on published clinical evidence for this treatment alone. The gap between available clinical evidence and current extent of application of this treatment has to be closed by further clinical trials from an evidence-based medicine point of view.

Interventions for hypertension & heart failure – *Thursday May 23rd*
Contribution of renal denervation to the treatment of resistant hypertension: a health technology assessment perspective

Early results following renal denervation for treatment of hypertension in a real world population: the Global SYMPLICITY registry

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Aims: The sympathetic nervous system plays an important role in the pathogenesis of a variety of diseases and conditions including hypertension, chronic kidney disease, heart failure and diabetes. Early trials of renal denervation using low-energy radio frequency delivered percutaneously showed that blood pressure was significantly reduced in patients with severe, treatment-resistant hypertension. The Global SYMPLICITY Registry which was developed from and includes the GREAT SYMPLICITY registry in Germany, is designed to evaluate the safety and effectiveness of renal denervation with the Symplicity™ renal denervation system in a real world population of patients with hypertension.

Methods and results: The Global SYMPLICITY Registry is a prospective, multicentre, single-arm, open-label study being conducted in 200 sites worldwide with an intended enrollment of 5000 patients. Patients over 18 years of age, with hypertension or other diseases where increased sympathetic tone is believed to play a role in disease pathogenesis, are treated with the Symplicity catheter according to the approved Instructions for Use. Data collected includes office-based and ambulatory blood pressure measurements, change in antihypertensive medications, estimated glomerular filtration rate (eGFR) changes, protocol-defined safety events and other tests pertaining to the individual's disease state, if available. There are currently 603 patients enrolled with approximately half being enrolled in Germany. Based on preliminary data from 313 treated patients the mean age of patients is 58.3±13.2 years 65.0% are males, all have a history of hypertension, 42.7% have diabetes mellitus (36.5% are type 2), 6.6% have HF, 7.5% have a history of atrial fibrillation, 20.8% have a history of renal disease, and 9.5% have sleep apnea. At baseline, those being treated for hypertension were taking an average of 3.7±1.0 anti-hypertensive medications. At baseline office BP is 165.0±19.9/92.2±15.8 mmHg, pulse pressure is 72.8±16.8 mmHg and heart rate is 70.5±11.9 bpm. Baseline characteristics and 3 month follow-up stratified by baseline systolic blood pressure, of approximately 200 "real world patients treated with the Symplicity catheter will be available for presentation in May.

Conclusions: Radiofrequency denervation of the renal arteries using the Symplicity™ catheter lowers blood pressure in patients with treatment-resistant hypertension. This large registry with minimal exclusion criteria will enhance our understanding of the role of this novel treatment under circumstances resembling the real world in a variety of different treatment settings.

Estimated added benefit of catheter-based renal denervation for resistant hypertension: impact of age and cardiovascular risks on unadjusted and quality-adjusted life years

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Aims: Our aim was to assess the projected impact of pre-treatment systolic blood pressure (SBP), treatment age, and cardiovascular risk profile on life year gain and quality-adjusted life year gain in simulated European resistant hypertension cohorts treated with catheter-based renal denervation plus standard of care vs. standard of care alone.

Methods and results: A recently published life-time Markov simulation model based on Framingham and other multivariate risk equations was programmed with epidemiological data on risk factors and life tables for Germany. Endpoints were life years (LY) and quality-adjusted life years (QALYs) gained for six different cohorts with combinations of 1) pre-treatment SBP of 165 mmHg and 190 mmHg; 2) treatment age of 40, 55, or 70 years; 3) low and high cardiovascular risk profile based on JNC 7 guidelines. All other input parameters were derived from the Symplicity HTN-2 trial. A regression equation based on patient-level data from this trial was used to estimate the treatment effect SBP reduction. Renal denervation was estimated to reduce a pre-treatment SBP of 165 by 30 mm Hg, and a SBP of 190 by 40 mm Hg, respectively. The projected lifetime undiscounted gains in LYs and QALYs were projected as follows: 1) for 40 year old cohorts: low CV risk profile at SBP 165/ 190 mmHg: 1.92/ 1.75 LY, 1.73/ 1.59 QALYs; high CV risk profile: 2.43/ 2.03 LYs, 2.21/ 1.83 QALYs; 2) for 55 year old cohorts: low CV risk profile: 1.62/ 1.43 LYs, 1.36, 1.22 QALYs; high CV risk profile: 1.70/ 1.45 LYs, 1.45/ 1.25 QALYs; 3) for 70 year old cohorts: low CV risk profile: 1.23/ 1.02 LYs, 0.94/ 0.80 QALYs; high CV risk profile: 1.70/ 1.24 LYs, 1.25/ 0.93 QALYs.

Conclusions: Across the studied age groups, cardiovascular risk profiles, and pre-treatment systolic blood pressure levels, catheter-based renal denervation was associated with clinically meaningful gains in life expectancy (+1.02 to 2.43 LYs) and quality adjusted life expectancy (+0.80 to 2.21 QALYs). Younger age, higher cardiovascular risk profile, and lower pre-treatment systolic blood pressure led to the most significant increases in life years and quality-adjusted life years. These model-based findings need to be confirmed in clinical trials.

Ethanol-mediated perivascular renal denervation. Preclinical validation of safety and efficacy in a porcine model

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Aims: Renal sympathetic denervation using catheter-based radio-frequency (RF) ablation is an emerging approach to treat medically resistant hypertension. We report the use of a novel endovascular approach using chemical neurolysis, via peri-adventitial injection of dehydrated ethanol (EtOH) to perform safe and effective renal artery denervation.

Methods and results: A novel, three needle-based delivery device, the Peregrine System™, was introduced via the femoral artery into renal arteries of adult swine using fluoroscopic guidance. EtOH was injected bilaterally into to the peri-adventitial region of the renal arteries. Injections included: EtOH (0.15 ml; n=3, 0.30 ml; n=3, and 0.60 ml; n=3), or saline as a sham control (0.4 ml; n=3). Naive subjects (n=7) were used as true negative controls. Follow-up was at two weeks after intervention. Procedure time averaged less than 2 min for each renal artery. Safety was also assessed via direct injection of EtOH (0.6 ml) into the renal artery (n=3; follow-up at 1, 7 and 30 days). The renal tissue norepinephrine (NE) concentration, (HPLC assay, electrochemical detection), was the primary efficacy endpoint. Other endpoints included histopathological evidence of renal artery nerve damage, renal arterial wall injury, renal toxicology and assessment of renal function and renal parenchymal damage. Measurements of renal tissue NE showed an essentially linear dose response (R2=0.95) to the EtOH volume delivered. The mean of renal NE reduction was 54%, 78% and 88% at doses of 0.15 ml, 0.30 ml and 0.60 ml, respectively ($p<0.001$ vs. controls). Histological examination revealed marked, and deep, circumferential renal nerve injury at depths of 2-8 mm from the intimal surface. Nerve injury was characterised by vacuolisation, loss of internal architecture, and the development peri-neural fibrosis. There was no evidence of device or EtOH-induced injury to the intimal or medial layers, as assessed by angiography or histology. There was no discernible injury to tissue deep to the peri-adventitial plane. There were no adverse nephrotoxic or systemic effects seen. Finally, direct injection of EtOH into the renal artery, at 200% the likely therapeutic dose, resulted in no detectable renal toxicity.

Conclusions: Circumferential and deep peri-adventital delivery of very low doses of EtOH appears to be a simple, safe, predictable and viable alternative to energy-based systems to achieve substantial renal denervation, with virtually no injury to the normal renal arterial wall.

Interventions for hypertension & heart failure – *Thursday May 23rd*
Renal denervation: novel approaches and first-in-man results

A new non-vascular treatment for resistant hypertension

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Aims: Studies show that renal denervation or the interruption of renal afferent nerve activity attenuates systemic sympathetic tone, thereby lowering blood pressure. In contrast to the widespread distribution of Efferent Sympathetic nerve fibers in the kidney, the majority of the Afferent Renal Sensory nerves are located in the renal pelvic area. The natural orifice denervation system developed by Verve Medical directs radiofrequency energy to the renal pelvis where the preponderance of afferent nerves are closely accessible. We present our early porcine studies looking at both histopathology of nerve ablation as well as levels of norepinephrine in the acute and chronic model.

Methods and results: Eight female domestic swine weighing 60-65kg underwent renal pelvic denervation via ureteral access. Three were euthanised immediately after delivery of RF energy; five animals were survived for 7 days. Renal cortical norepinephrine levels were measured in both groups of animals. We also assessed histopathology in the treated zone for confirmation of nerve damage. The animals were fasted overnight then sedated with Ketamine, intubated, and maintained on isoflurane anaesthesia throughout the procedure. A ventral midline laparotomy was performed to expose the urinary bladder. A 5 cm incision was made in the ventral aspect of the bladder to access the ureteral orifice. The VERVE Medical device was passed retrograde over a 0.035" guidewire from the bladder to the renal pelvis and RF performed. The procedure was repeated in the contralateral kidney. In 2 animals, RF energy was not applied to the contralateral kidney (sham procedure). The urinary bladder and laparotomy were closed and the animal was recovered from anaesthesia. Animals were survived for 7 days. In 2 animals, bilateral pyelogram, ureterogram, and renal angiography was performed prior to euthanasia with KCl under general anaesthesia. Immediately following euthanasia renal cortical tissue was harvested for determination of tissue norepinephrine concentration by HPLC. The kidneys were then perfusion fixed and harvested for histopathologic analysis. Animals returned to normal diet and uresis the next day. Follow-up pyelography, ureterography, and renal arterial angiography were performed in 2 animals and was unremarkable. In all animals there was a reduction of norepinephrine levels compared to control samples. Reduction of tissue norepinephrine concentration ranged from 11% to 89% with a mean reduction of 61%. Histopathology confirmed nerve ablation.

Conclusions: In this small series of acute and chronic animals, we see a promising non-vascular alternative for renal denervation. Tissue norepinephrine levels were reduced significantly following delivery of RF energy to renal pelvis tissues. In a clinical setting this procedure could be performed without systemic contrast utilisation. The catheter introduction requires little skill with no damage to surrounding tissue.

Interventions for hypertension & heart failure – *Thursday May 23rd*
Renal denervation: novel approaches and first-in-man results

Early results of first-in-man simultaneous multisite renal denervation treatment for resistant hypertension

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Aims: Renal denervation using radiofrequency (RF) energy delivered percutaneously to the renal arteries significantly lowers blood pressure in patients with treatment-resistant hypertension. A new, multi-electrode catheter has been developed that delivers RF energy through the luminal surface of the renal artery at four locations simultaneously. The catheter features a monopolar array of 4 electrodes mounted on the distal end of a nitinol shaft in a spiral configuration to allow a pre-defined and consistent ablation pattern to be delivered with each treatment. The ability to deliver RF energy at up to 4 sites at once provides a significant reduction in treatment time and may reduce radiation and contrast dye exposure compared with treatment using a single electrode. This feasibility study is designed to assess the procedural safety and effectiveness of the Spyral™ renal denervation system in patients with treatment-resistant hypertension.

Methods and results: This is a prospective, single-arm, non-randomised, open label feasibility study with a target enrollment of 50 patients. The primary endpoint of the study is acute procedure safety associated with the delivery and/or use of the Spyral renal denervation system. The primary effectiveness endpoint is change in office blood pressure (BP) from baseline to six months. To be eligible, patients must have an office systolic BP of ≥160 mmHg (≥150 mmHg for type 2 diabetics). Patients must adhere to a stable regimen of ≥3 anti-hypertensive medications (preferably including a diuretic) for a minimum of two weeks prior to screening. Exclusion criteria include type 1 diabetes, renal artery stenosis >50% or renal artery aneurysm in either renal artery, prior renal artery intervention, and an estimated glomerular filtration rate of <45 mL/min/1.73 m^2. Follow-up is scheduled at 1, 3 and 6 months and yearly to 3 years post renal denervation. To date 11 patients (mean baseline BP 184.7±16.8/93.7±12.8 mmHg) have been treated with the Spyral™ catheter and enrolment is continuing. There was one femoral artery pseudoaneurysm associated with arterial sheath insertion and no Spyral device-related adverse effects.

Conclusions: Early experience with the Spyral multi-electrode RF catheter indicates that there are no immediate safety concerns. Available 1 month and 3 month BP and safety results from all enrolled subjects will be presented at EuroPCR in May.

Long-term safety and efficacy of sympathetic renal artery denervation using a multi-electrode renal artery denervation catheter in patients with drug-resistant hypertension: twelve month results of a first-in-human, multicentre study

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Aims: Single-tip electrode radiofrequency ablation catheters have been used to achieve sympathetic fiber interruption through the renal artery wall. However, long-term results from systems designed to create predetermined stereotactic lesion pattern have not been reported. We investigated the safety and efficacy of a multi-electrode catheter ablation system (EnligHTN) developed by St. Jude Medical.

Methods and results: The EnligHTN renal denervation system has 4 electrodes attached on a basket mounted at the tip of the catheter. The basket is collapsed and can be expanded via an external mechanism once the catheter is placed in the desired location of the renal artery. The electrodes are then sequentially activated to achieve the desired lesion pattern. The basket is then pulled back and repositioned for a new set of lesions in order to optimise renal artery denervation. The EnligHTN-I first-in-human study was designed to assess the safety and efficacy of this multi-electrode ablation system in patients with drug-resistant hypertension. A total of 46 patients (average age 60±10 yrs taking an average of 4.1±0.6 medications) were enrolled in this study. Of these patients 33% were female, 98% were white, 20% had Coronary Artery Disease, 59% had hyperlipidaemia, 33% had type II Diabetes Mellitus, and 30% had history of sleep apnea. Bilateral renal nerve ablation was performed using a percutaneous femoral approach. On average 7.7±0.8 lesions were created in the right renal artery and 7.4±1.4 in the left renal artery. The median procedure time was 34 minutes. Baseline average office blood pressure was 176/96 mmHg and average 24 hr ambulatory blood pressure was 150/83 mmHg. Average reductions (mmHg) of office blood pressure at 1, 3 and 6 months were -28/10, -27/10, -26/10 mmHg ($p<0.001$) respectively and for 24hr ambulatory blood pressure -10/5, -10/5 and -10/6 mmHg ($p<0.001$) respectively. At 6 months 76% of patients were responders (at least 10 mmHg reduction in systolic blood pressure) and 33% had normalised blood pressure (<140 mmHg systolic blood pressure). At 6 months there was a small reduction in the estimated glomerular filtration rate (from 87 to 82 µL/min/1.73 m2) driven by a small increase in serum creatinine (from 78 to 83 µmol/L), but cystatin C levels improved (from 1.14 at baseline to 1.00 mg/L at 6 months). The study utilised an independent Clinical Events Committee to adjudicate all adverse events. Based on their adjudication, there were 3 device/procedure related serious adverse events reported to date which include: hypertensive renal disease progression, symptomatic hypotension and worsening of pre-existing renal artery stenosis. Twelve month efficacy and safety data will be presented at the meeting.

Conclusions: EnligHTN ablation system continues to be safe and effective in the treatment of patients with drug-resistant hypertension.

First report of the 12-month first in human results of the OneShot renal denervation system: the RHAS study

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Aims: Catheter-based selective renal sympathetic denervation has emerged as a new therapeutic option for patients with resistant hypertension. Recent studies have shown that ablation of the renal sympathetic nerves using radiofrequency (RF) energy delivered from within the renal artery is safe and effective. The aims of the study are to test the OneShot renal denervation system in humans and report for the first time the 12 month results

Methods and results: The OneShot™ device (Covidien, Campbell, CA) is a balloon-based RF system using a mounted spiral electrode with a unique feature of irrigation of the vessel lumen during treatment. The non-compliant balloon is inflated under low pressure (1 atm) in the renal artery. The electrode delivers RF energy to ablate adjacent nerve bundles with a single 2-minute treatment. The RHAS study was a single-centre feasibility study performed at Mercy Hospital in Auckland, New Zealand. Eligible patients had an office systolic blood pressure (SBP) ≥160 mmHg (≥150 if diabetic) despite a drug regimen that included two or more antihypertensive medications. Renal artery sizes were 4-7 mm. The primary endpoint was the ability to insert the OneShot™ device into each renal artery and deliver RF energy. Secondary endpoints included office SBP at 6 months. Nine patients were enrolled with a mean age of 59.5 years (55.6% male). The technical success rate was 88.9%. One failure occurred in the first enrolled patient and was due to an incorrect software setting, which inhibited delivery of RF energy. All remaining patients had both renal arteries treated with the OneShot™ device. The mean procedure time, defined as device insertion to end of treatment, was 17 minutes. The mean office SBP was 155.6±19.6, 154.4±19.6 and 143.7±13.3 mmHg, representing a change of -30.1±13.6, -33.6±21.7 and -41.9±20.2 mmHg at 1, 3 and 6 months respectively. Twelve-month results will be presented at EuroPCR.

Conclusions: The RHAS trial showed rapid and reliable delivery of RF energy for renal sympathetic denervation using the OneShot device. Twelve month results will be availble at time of presentation.

Interventions for hypertension & heart failure
Abstracts from AsiaPCR/SingLive

Alcohol septal ablation: how to evaluate the results?

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Aims: The aim of this study was to assess the clinical efficacy and safety of alcohol septal ablation in patients with hypertrophic obstructive cardiomyopathy with magnetic resonance imaging (MRI) follow-up.

Methods and results: We performed alcohol septal ablation in 114 patients with hypertrophic obstructive cardiomyopathy. The average age was 51 years±9.7; males -55 (48.2%), females -59 (51.8%). The average pressure gradient at the output of the left ventricle was 72.5±20.5 mmHg. We investigated localisation and size of myocardial infarction by magnetic resonance imaging (MRI). After the procedure pressure gradient of left ventricular outflow tract decreased from 72.5±20.5 mmHg to 30.7±14.1 mmHg. There was no mortality. Atrioventricular block occurred in one patient (1%). Contrast-enhanced MRI showed no infarct-related hyper-enhancement outside the target septal area. Left ventricle mass decreased from 320±72 g at baseline to 314±69 g at one month follow-up. Data obtained by MRI showed that septal infarct was localised in the basal part of intraventricular septum (IVS) in most cases. Only in one patient (1%) septal infarct was localised in middle and lower part of IVS. Septal infarct in most cases (70%) corresponded sub-endocardiac localisation of the right-sided part of IVS, left - sided part of IVS in 8% of patients, in 22% of cases in both parts of IVS.

Conclusions: Alcohol septal ablation is an effective and safe method of endovascular treatment of patients with obstructive hypertrophic cardiomyopathy. Magnetic resonance imaging may be especially useful for follow-up after alcohol septal ablation.

Interventions for hypertension & heart failure
Abstracts from AsiaPCR/SingLive

Alcohol septal ablation in hypertrophic obstructive cardiomyopathy: long-term echocardiographic and clinical follow-up of 84 consecutive patients treated in a single centre

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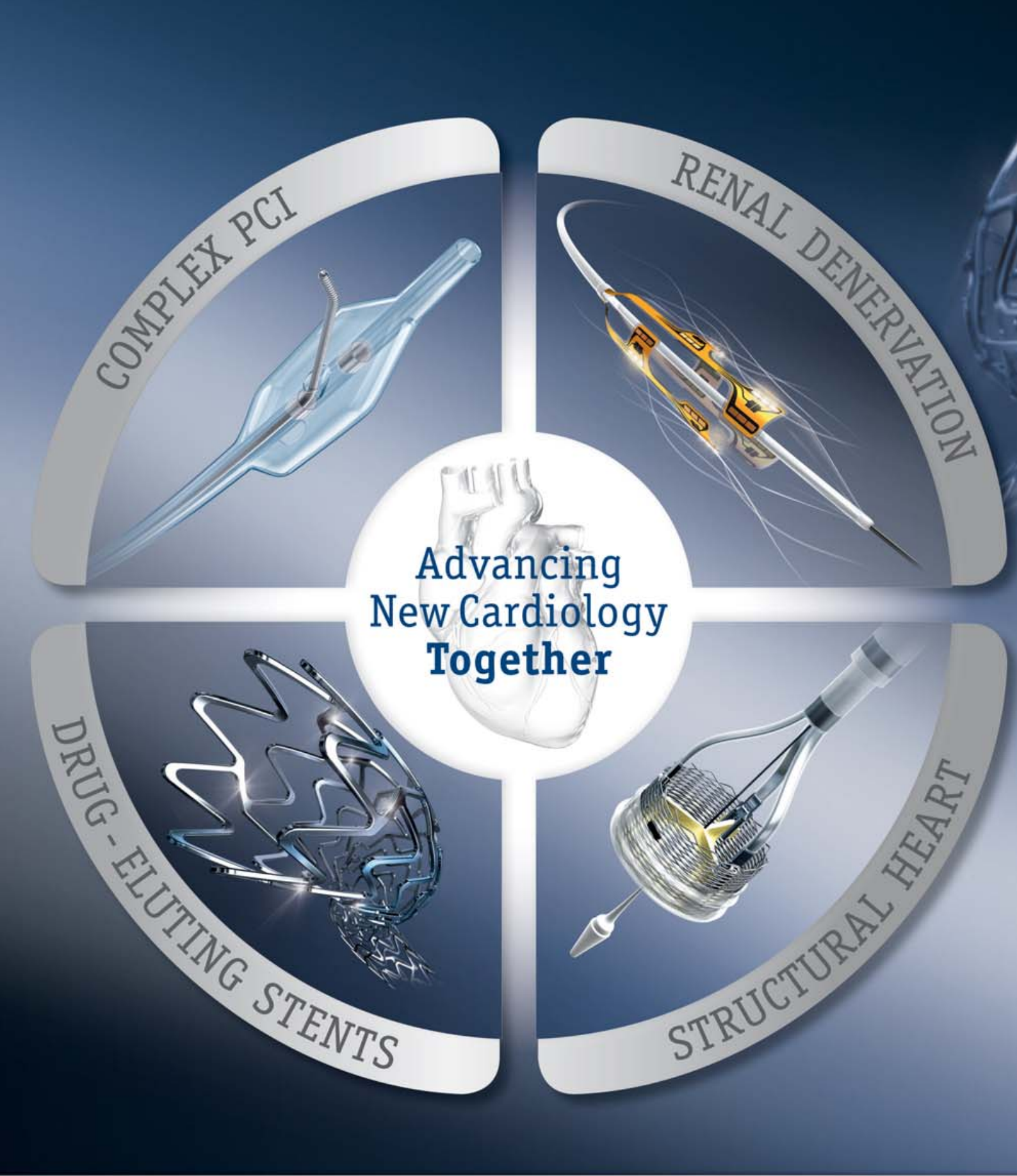
Aims: Alcohol septal ablation is a viable therapeutic option for symptomatic patients with hypertrophic obstructive cardiomyopathy. Our aim is to report clinical and echocardiographic progression in patients with hypertrophic obstructive cardiomyopathy treated by septal ablation at our centre usingcombined pressure and echo guided approach to target septal branch for alcohol ablation.

Methods and results: Patients were considered eligible if they had asymmetric hypertrophy of the septum and outflow subaortic gradient >50 mmHg at rest or after provocation. Alcohol septal ablation was performed in 84 patients who were in functional class III or VI despite optimal medical treatment. Before ethanol injection balloon occlusion test of the target septal branch was performed and if the pressure gradient fell more than 50% both at rest and after provocation it was considered positive. In case of negative occlusion test additional echocardiographic delineation of the target zone was performed. During the index procedure 0.5 to 2 ml of dry ethanol were injected after positive balloon occlusion test or when negative only if echo contrast through the balloon demonstrated contact of the opacified zone and mitral leaflet in systole. The procedure was terminated if elimination of gradient was achieved or quantity of ethanol reached 2 ml. Acute success was defined as >50% decrease of gradient at rest and post extrasystole. During clinical and echocardiographic follow-up NYHA functional class and left ventricle outflow tract pressure gradient were monitored. The patients' mean age was 55±11.6 years. In 61 the balloon occlusion test was positive and 23 required additional echocardiographic testing. In 82 patients acute success was achieved. Immediately after septal ablation outflow tract pressure gradient decreased significantly, from 77.6±38 mmHg to 19.2±19 mmHg (P<0.001), and remained low throughout the follow-up except in 12 patients. 10 patients /12%/ needed permanent pacing because of iatrogenic complete heart block. We observed no deaths during the in-hospital stay. The follow-up period varied between 3 months and 8 years. We observed recurrence of both symptoms and gradient in 10 patients and asymptomatic gradient recurrence in two patients. The symptomatic patients were successfully treated by repeat ablation (n=6) or pacing (n=3) according to the presumed reason for obstruction recurrence. Interventricular septum thickness measured by echocardiography decreased during follow-up, from 21.1±3.3 mm to 17.4±2.7 mm (P<0.0001). A significant improvement in NYHA functional class from 100% (n=84) in class III-IV to 85% (n=69) in class I-II was also observed. We didn't find any predictors of long-term success including infarct size as judged by CPK leakage. At the final follow-up we observed 3 deaths – one due to progressive cardiac insuficiency, one sudden death and one noncardiogenic (cancer-related). One ICD was implanted for unexplained syncope and 4 strokes occured in patients with permanent atrial fibrillation

Conclusions: In our experience alcohol septal ablation is effective in the long term in patients with hypertrophic obstructive cardiomyopathy at the price of nearly 10% of reintervention. No major safety concerns including increase in rate of the sudden cardiac death during was found follow-up.



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