Abstracts of EuroPCR 2014

including Nurses & Technicians

in collaboration with Euro**Intervention**



William Wijns Jean Fajadet Patrick W. Serruys



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Introduction to the scientific abstract presentations at EuroPCR 2014

Jean Fajadet and William Wijns, EuroPCR Course Directors

First and foremost, we sincerely wish to express our gratitude to our interventional peers from across the globe who choose EuroPCR as the forum to share with us the results of their scientific labours. The increase, this year, in submissions to EuroPCR reflects this interest quite well since we have received a record number of 1,052 abstracts. EuroPCR is seen to many as the premium platform for intellectual exchange and discourse, to advance one's education and to build and develop further personal existing knowledge banks. A valuable tool to aid the EuroPCR experience is the annual Abstract Book. This book is a selection of the best abstracts being presented at this year's EuroPCR. Just like the Course, this book is built "For & By" you as abstract submitter, as to state the obvious: without your contributions, this publication, indeed EuroPCR itself, would not be what it is.

When one analyses this years submissions, **Table 1**, one will certainly note that while the number of Coronary Intervention abstracts has slightly increased, it is within the field of Interventions for Structural Heart Disease that one sees a steady but continuing growth in contributions. And this is remarkable as it confirms and complements the increasing enthusiasm and interest in this field that can also be witnessed at PCR London Valves. The field of Interventions for Hypertension and Heart Failure is also on the move this year. As Course Directors we expect to see this area mature even further despite the recent bumps in the road. We also wish to highlight the start of a new abstract theme this year, called 'Nurses and Technicians'. This theme is an important addition to the wealth of information disseminated during EuroPCR and together with the foundation of a Nurses and Technicians committee this year within the EAPCI, we are sure that the EuroPCR

Table 1. Abstract submissions in categories and yearly comparisons.

Submissions	2012	2013	2014
Total abstracts	910	963	1,052
Coronary Interventions	648	664	680
Interventions for Structural Heart Disease	179	183	226
Endovascular Interventions	70	84	76
Interventions for Hypertension and Heart Failure	13	32	51
Nurses and Technicians	0	0	19

attendees will recognise the important role of a true team approach for treatment modalities in daily practice.

We would also like to draw your attention to the 296 posters, which are published online at http://www.pcronline.com/eurointervention/AbstractsEuroPCR2014. These posters will also be displayed in the dedicated Poster area of the convention centre. A significant number of these will be discussed during Moderated Sessions.

Before we conclude our foreword, it is always interesting to note the geographical origin of the submissions, **Table 2**. As expected the "established scientific powerhouses" are present in our top ten; however as the table shows, Indian interest is slowly but surely maturing and with this, we look forward to seeing our friends and colleagues from India and other emerging nations submitting more abstracts in the years to come.

Table 2. The geographical origins of the submissions.

	Country	Submissions, n	Authors, n
1	Italy	165	80
2	Japan	138	96
3	Germany	103	55
4	United States	63	41
5	United Kingdom	50	34
6	South Korea	47	29
7	The Netherlands	46	32
8	Spain	43	23
9	Poland	29	16
10	India	27	18

Whilst the Board of EuroPCR and the Programme Committee members consider this year's response to the 'call for submissions' as very impressive, we must certainly acknowledge the time and effort of our esteemed graders and also the selection committee members who gave up their valuable time to assess the submissions, respecting the tight deadlines but above all to uphold and protect the integrity of the scientific peer review. As a gesture, we have listed these 'stars' in our acknowledgement.

In conclusion, we cordially extend our warmest welcome to you, the readers, the attendees and the contributors to EuroPCR 2014. We hope that you will enjoy this year's edition.



Comparisons of the endothelial coverage after culotte stenting

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Aims: Two stent techniques for bifurcation lesion is known to have higher adverse cardiac events compared with single stenting, however, true bifurcation lesions often requires two stents to recanalise both branches especially in case with a large side branch. Culottes stenting is the most effective technique to cover the entire carina and lateral wall areas, especially when the angle of the bifurcation is shallow. However, the endothelial coverage at the site of culotte stenting, which is one of the major causes of late stent thrombosis, has not been evaluated. The endothelial coverage following culotte stenting with the latest two drug-eluting stents (Xience Prime and Resolute Integrity) were evaluated using a rabbit healthy iliac bifurcation.

Methods and results: Xience Prime (EES) and Resolute Integrity (R-ZES) were implanted in the iliac bifurcation artery with the culotte stent technique and final kissing balloon technique was performed with two 3.0 mm balloons. Stents were harvested at 14- and 28-days after the stent implantation and processed for scanning electron microscopic analysis. The area of uncovered strut at the proximal overlapped segments and carinal area were assessed. Percent uncovered strut area was significantly higher in R-ZES at 14-days (R-ZES 15.9±1.6%, EES 9.4±1.3%, p=0.03) and 28-days (R-ZES 8.9±1.6% vs. EES 3.4±1.4%, p=0.0004) after the stent implantation. Carinal areas also showed delayed endothelial coverage compared with distal single stented segments.

Conclusions: Endothelial recovery was delayed at the site of proximal overlapping and carinal segments in culotte stenting compared with the distal single stented segments, however, the extent of uncovered area in these areas was larger in R-ZES compared with EES.



Delayed coverage of DES after revascularisation of coronary CTO: observations by intravascular OCT - The ALSTER OCT-CTO registry

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Aims: Following chronic total occlusion (CTO) revascularisation patients are at increased risk for stent thrombosis. Different CTO revascularisation approaches are available at present and are developed to improve revascularisation success and safety. Techniques using re-entry and dissection techniques disrupt the vessel integrity and maybe result in a prolonged stent endothelialisation compare to non-CTO lesions. No adequate in vivo data on drug-eluting stent (DES) endothelialisation after CTO revascularisation is available. Optical coherence tomography (OCT) is able to precisely analyse stent endothelialisation. We tested the hypothesis, that CTO revascularisation leads to delayed DES endothelialisation compared to non-CTO PCI. Furthermore different CTO revascularisation approaches including antegrade wiring as well as dissection and re-entry techniques were analysed.

Methods and results: Patients (n=17) presenting for a follow-up angiography with OCT 7.3±1.4 months after CTO revascularisation and DES implantation. Results were matched to a control group (n=20) with follow-up angiography 5.6±0.4 months (p=0.83) after non-CTO PCI. Stents struts were classified by OCT (CTO vs. control, mean±SEM): Covered: 81.4±2.6 vs. 95.1±0.9%, p<0.0001; apposed/uncovered: 10.0±1.4 vs. 3.5±0.8%, p<0.0001; malapposed/uncovered: 8.5±1.9 vs. 1.4±0.4%, p<0.0001. A second OCT analysis at 12.0±1.3 and 9.8±1.1 months, respectively (p=0.2), was conducted in 4 patients per group with evidence of 86.7±1.8 vs. 96.5±0.6% covered struts, p=0.03. Subgroup analyses for different CTO revascularisation approaches found no significant differences in endothelialisation.

Conclusions: Delayed DES endothelialisation after CTO revascularisation was observed with 8.5% of stent struts malapposed at 5.6 months and 5.7% at 12 months, respectively. As uncovered struts increase the risk of stent thrombosis we propose to routinely recommend dual antiplatelet therapy (DAPT) for at least 12 months or OCT for all patients prior to stopping DAPT after CTO revascularisation.



Prevalence of neoatherosclerosis with late stent failure (thrombosis and restenosis) following BMS, 1^{st} and 2^{nd} generation DES placement: a pathologic study

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Aims: In-stent neoatherosclerosis has emerged as an important contributing factor for late stent failure; however, clinical imaging modalities have limited capability of evaluating the presence and characteristics of neoatherosclerosis. The aim of the current pathologic study was to investigate the prevalence of neoatherosclerosis with late stent failure including stent thrombosis and restenosis following BMS, 1st. and 2nd-generation DES placement. Methods and results: All available material with duration of implant >30 days (mean, 913±989 days) from our autopsy stent registry to include a total of 384 cases (mean age=61±13 years, 287 male) with 614 stented lesions in native coronary arteries (BMS=266, 1st-generation DES=285 [143 SES and 142 PES], and 2nd-generation DES=63 [7 E-ZES, 3 R-ZES, and 53 EES]) were examined by light microscopically following dehydration and embedding in methyl methacrylate and cut at 3 mm intervals. We defined atherosclerosis by the presence of foam cells in the neointima and/or presence of calcification. Prevalence of neoatherosclerosis was stratified according to the duration of implant; <1 year (n=217 lesions), prevalence of neoatherosclerosis was significantly greater for 1st-generation DES (14/111, 13%) and 2nd-generation DES (7/42, 17%) as compared with BMS (0/64, 0%) (p=0.006 for 3 groups). None of these early neoatherosclerotic lesions were associated with stent thrombosis. However, in-stent restenosis occurred in 1 of 14 (7%) lesions in 1st-generation and 2 of 7 (29%) lesions in 2nd-generation DES. Similarly, for duration of implant >1 and ≤3 years (n=218 lesions), neoatherosclerosis was more frequently observed in 1st-generation DES (57/112, 51%) and 2nd-generation DES (10/21, 48%) as compared with BMS (5/85, 6%) (p<0.0001). Thrombosis due to underlying neoatherosclerosis with plaque rupture was observed in 1 lesion (2%) with 1st-generation DES, but none of the 2nd-generation DES and BMS showed thrombosis. Restenosis with underlying neoatherosclerosis was observed in 4 lesions (7%) in the 1st-generation, whereas no restenosis was observed in BMS or 2nd-generation DES with neoatherosclerosis. For duration of implant >3 years (n=179 lesions, no 2nd-generation DES were available), the prevalence of neoatherosclerosis was still greater for 1st-generation DES (40/62, 65%) as compared with BMS (44/117, 38%) (p=0.0006), and of these, stent thrombosis from plaque rupture was seen in 4 lesions (10%) with 1stgeneration DES and in 5 lesions (11%) with BMS. In-stent restenosis with neoatherosclerosis was observed in 6 lesions (15%) with 1st-generation DES and 18 lesions (41%) with BMS. Of the 10 in-stent plaque rupture, only 4 (3 in BMS and 1 in 1st-generation DES) had in-stent restenosis.

Conclusions: In-stent neoatherosclerosis occurs more rapidly and more frequently in 1st- and 2nd-generation DES as compared with BMS and increases overtime in both BMS and DES. Since 1st- and 2nd-generation DES exhibit equivalent prevalence of neoatherosclerosis up to 3 years, careful long-term follow-up remains important even after 2nd-generation DES placement.



Euro14A-MA028

Impact of polymer type and coating location on vascular inflammation and healing: a comparative stent study in the familial hypercholesterolemic swine model of coronary restenosis

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Aims: This study characterised the impact of polymer type (durable vs. bioabsorbable) and coating location (conformal vs. abluminal) on inflammation, intimal thickness (IT) and endothelial cell (EC) healing in the Familial Hypercholesterolemic Swine model.

Methods and results: Three DES groups (Resolute Integrity, Synergy, Xience Prime) and one bare metal stent (BMS) group (Omega) were implanted into coronary arteries and followed at 30, 90 and 180 days. A total of 47 stents (9 per group at 30 and 90 days, 11 per group at 180 days) were assessed by histology in proximal, middle and distal sections per group. Para-strut inflammatory cell area (PSIA) and IT were quantified in each histological section. En face EC expression of CD31, VE-cadherin and phosphorylated endothelial cell nitric oxide synthase (p-eNOS) were quantified at the same time points (3-5 stents/group, 18 images per stent). At 30 days, PSIA (mm²) was significantly greater (p<0.05) for BMS than the DES groups, but was similar among DES groups (p>0.90). However, at 90 days, PSIA was significantly greater (p<0.01) in the DES groups than in BMS and was similar (p>0.20) among DES groups. At 180 days, PSIA was reduced in all groups with Synergy at 0.14±0.20 (mean±SD) equivalent (p=0.96) to BMS at 0.08±0.13 In contrast, PSIAs of Resolute Integrity (0.43±0.52) and Xience Prime (0.70±0.66) were significantly greater than Synergy (p<0.04) and BMS (p<0.01). IT (mm) at 30 days was significantly greater (p<0.01) in BMS compared with similar (p>0.90) levels in DES groups. At 90 days IT was not significantly different across all device groups. At 180 days, IT of 0.71±0.16 in Synergy was less than BMS (0.89±0.21; p<0.01) and Resolute Integrity, (0.84±0.10; p<0.01) but similar to Xience Prime (0.78±0.11; p=0.24). At 30 days, EC coverage was complete for all groups with CD31 typically absent at EC junctions. Expression of VE-cadherin at EC junctions was 30-50% greater on BMS, compared to SYNERGY and Xience Prime (p<0.05). Phosphorylated-eNOS was 2-3 fold less in ECs from BMS, compared to DES groups (p<0.05), with no significant differences among DES groups (p>0.05). CD31 at EC junctions was similar between BMS and Synergy (p>0.05) and was 20-25% greater than Xience Prime (p<0.05) VEcadherin on BMS was not significantly different from Synergy but was 100% and 18% greater than Resolute Integrity and Xience Prime, respectively (p<0.05). Phosphorylated eNOS expression did not differ among DES groups (p>0.05), whereas Xience Prime and Resolute Integrity were approximately 20% greater than BMS (p<0.05). At 180 days, CD31 and p-eNOS did not differ significantly across all groups (p>0.48). In contrast, VE-cadherin was 18% greater on BMS, compared to DES groups (p<0.05) with no differences among DES groups (p>0.05).

Conclusions: The abluminal deposition of bioresorbable polymer on Synergy achieves EC healing comparable or better than BMS by 90 days, with a similar inflammatory response at 180 days, and overall improved healing compared to conformal-coated durable polymer DES.

Evaluation of inflammatory reaction after the second generation everolimus- and zotarolimus-eluting stents implantation in a healthy rabbit model

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Aims: Lack of biocompatibility in the drug-eluting stent (DES) followed by hypersensitivity reaction is one of the major causes of late adverse events. The aim of the current study was to evaluate early, mid, and long-term inflammatory reaction in the latest two DES (Xience Prime EES and Resolute Integrity R-ZES) using a healthy rabbit iliac artery model.

Methods and results: EES and R-ZES were implanted in each iliac artery of healthy Japanese White rabbits (n=24). Animals were sacrificed at one-, three-, and six-month after the stent implantation for histomorphometric analysis. External elastic lamina and stent area were similar in both stents. While neointimal area was significantly less at early to mid term in EES compared to R-ZES (EES; 0.9±0.2 mm² vs. R-ZES; 1.2±0.3 mm in one month, p=0.04, 0.9±0.1 mm vs. 1.4±0.1 mm in three month, p=0.003, respectively), it was not significantly different at long term between the two stents (1.2±0.6 mm vs. 1.7±0.6 mm in 6 month, p=0.07). Inflammatory reaction was consistently low in both EES and R-ZES with no significant difference at early, mid-, and long-term (Inflammatory score 0.21 in EES vs. 0.04 in R-ZES at 1 month, p=0.06, 0.13 vs. 0.04 at 3 months, p=0.18, and 0.13 vs. 0.12, p=0.95 at 6 month, respectively).

Conclusions: Both of the second generation DES showed considerably low inflammatory reaction with no significantly difference at long-term follow-up, suggesting these stents appeared to be biocompatible.



Euro14A-MA030

Atherosclerosis progression is more frequent cause of repeat revascularisations than restenosis after the implantation of sirolimus-eluting coronary stents

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Aims: To estimate the contribution of restenosis and rapid atherosclerosis progression to the common pool of repeat interventions after the implantation of sirolimus-eluting coronary stents.

Methods and results: 260 patients with stable angina, 83,5% of them men, age 59,2±8,3 years were enrolled to study. Each patient had undergone the implantation of sirolimus-eluting coronary stents (1 to 5 stents per patients, in total 384 stents). Concentrations of high-sensitive C-reactive protein (CRP) and cholesterol in blood were estimated in each case before stenting, on a 1st and 3rd month after the intervention. All patients obtained aspirin 100 mg/d, clopidogrel 75 mg/d and atorvastatin 20 mg/d throughout the study period. Repeat angiography was performed to 158 (55,7%) patients 1 year after the stenting. Restenosis (>50% stenosis of stented segment) was revealed in 21 cases, 8 of them had undergone repeat intervention. Coronary atherosclerosis progression (appearance of a new 50% or more stenosis or at least 30% progression of previous >20% stenosis in a vessel with diameter more than 2 mm) revealed in 34 patients, 20 of them had undergone repeat intervention. Patients with and without restenosis did not differ significantly by concentrations of CRP and cholesterol in blood. Patients with progression of atherosclerosis had higher concentration of CRP in blood before the intervention than patients without progression of atherosclerosis: 1,94 [0,90-6,03] vs. 1,40 [0,67-2,43] mg/l, p<0,05. Concentration of CRP before the intervention was a predictor of atherosclerosis progression (OR 1,23; CI 1,04-1,45), but not a restenosis development. We did not reveal a significant difference in cholesterol level before the intervention in blood of patients with and without atherosclerosis progression: 4,55±1,04 mmol/l vs. 4,96±1,51 mmol/l. Subsequently a decrease in cholesterol level took place in both groups: on a 1st month after the intervention in the group without atherosclerosis progression (3,96±0,66 mmol/l) without significant inter-group difference.

Conclusions: Rapid progression of coronary atherosclerosis is more frequent cause of repeat intervention than restenosis of stented segment during the 1st year after the implantation of sirolimus-eluting coronary stents. The concentration of CRP in blood before the stenting, but not cholesterol level may predict subsequent rapid coronary atherosclerosis progression.



The relationship between Interleukin-1 β and endothelial dysfunction in patients with mTOR inhibitor-eluting stent implantation

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Aims: Patients with mammalian target of rapamycin (mTOR)-inhibitor drug-eluting stent (DES) were reported to have impaired coronary endothelial function. There is no non-invasive biomarker of coronary endothelial dysfunction. Interleukin (IL)- 1β is known to cause of endothelial dysfunction. We examined whether IL- 1β were associated with coronary endothelial dysfunction after mTOR-inhibitor DES implantation, and to investigate the possible mechanism.

Methods and results: We analysed 35 patients (67.9±8.7 years old) 10 months after receiving mTOR-inhibitor DES for ischaemic heart disease. Peripheral blood was collected and coronary endothelial dysfunction was evaluated angiographically with intracoronary infusion of acetylcholine (Ach). Endothelial dysfunction was demonstrated by increased area under the curve (AUC) of cumulative Ach concentration-diameter changes at the segments proximal and distal to the stent site. By linear regression analysis, serum IL-1β levels were associated with the magnitude of vasoconstriction to Ach distal to the stent (P<0.05), but not proximal. Moreover, serum levels of IL-1β were positively correlated with stent length (P<0.05). To determine cell type that produces IL-1β by mTOR-inhibitor, sirolimus was incubated in cultured human endothelial cells or coronary artery smooth muscle cells (CASMCs). Sirolimus increased mRNA expression of IL-1β (P<0.01) and enhanced IL-1β release into the culture media (P<0.01) in CASMCs, but not in endothelial cells.

Conclusions: Increased serum IL-1 β could detect coronary endothelial dysfunction after DES implantation. mTOR inhibition triggers IL-1 β release through transcriptional activation in CASMCs of stent site, which may lead to coronary endothelial dysfunction at distal to the stent.



Euro14A-MAO32

Influence of late vascular inflammation on long-term outcomes among patients who underwent PCI using DES

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Aims: Vascular inflammation may play a major role in occurrence of DES failure. We assessed relationship between late vascular inflammation after DES implantation and major adverse cardiac event (MACE) by using C-reactive protein (CRP).

Methods and results: Paired CRP (baseline, and 8 months after PCI as late phase) was available in 1,176 patients who underwent PCI with unrestricted use of DES (sirolimus; 500, paclitaxel; 319, everolimus;191, biolimus; 166). Elevated CRP was defined as over 0.2 mg/dl. We investigated occurrence of MACE which comprises from all cause death, non-fatal myocardial infarction, and target lesion revascularisation (TLR) among them. Of all, elevated CRP at baseline was seen in 38.1%, and it was decreased to 23.7% (including late-onset 9.3%) at late phase. By univariate analysis, occurrence of MACE was powerfully related to late phase-CRP (hazard ratio: HR; 4.63, 95% confidence interval: 95% CI; 3.51-6.11, P<0.0001) than baseline-CRP (HR; 1.82, 95% CI; 1.38-2.39, P<0.0001). Multivariate analysis revealed that elevated late phase-CRP (HR; 4.31, 95% CI; 2.98-6.24, P<0.0001) and CKD (eGFR <60 ml/min; HR; 1.70, 95% CI; 1.19-2.44, P=0.004) were independent predictor of occurrence of MACE. Prevalence of elevated late phase-CRP was different among stent types (sirolimus; 28.0%, paclitaxel; 24.8%, everolimus; 18.3%, biolimus; 15.1%, P=0.002).

Conclusions: Elevated late phase-CRP may identify high risk subset of future MACE among patients who underwent DES implantation. Second generation DES with lower late inflammation might be better for long-term success.

Comparison of transport methods for patients with STEMI to a PCI centre and the influence of delay on long-term mortality

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Aims: The pre-hospital phase is critical for patients with ST-elevation myocardial infarction (STEMI), because the length of delay before full treatment is inversely proportional to myocardial salvage. This study focused on differences in patient transportation methods and their influence on long-term mortality.

Methods and results: Patients with STEMI (n=631), admitted to our department between 2009-2011, were enrolled. Those with percutaneous coronary intervention (PCI; n=554), were divided into three groups: Group AR: first admitted to a local hospital (n=326); or transported directly to the PCI centre with (Group S; n=139), or without (Group P; n=89), a physician. Kaplan-Meier, co-variate and discriminant analysis were carried out using these groups. Cumulative (and one year) mortality rates were: Group AR: 13.5% (9.5%); Group S: 24.5% (23.0%); Group P: 9.0% (7.9%); total patients after PCI: 15.9% (13.0%). Median follow-up time 940 days; interquartile range 520-1,250 days. Transportation delay times (median (interquartile)) were: Group AR: 115 (73-180) minutes; Group S: 50 (30-90) minutes; Group P: 38.5 (20-55) minutes (p<0.001). Transportation delay time was one independent factor for long-term survival, as assessed by discriminant analysis (p<0.05).

Conclusions: Our study showed that the shortest transportation delay time was with paramedics only, ie. without a physician, which also gave the best medical outcome. This study did not show any particular advantage of transport with a physician. The recommendation should be to ensure access to fully equipped emergency medical services with paramedics efficient in advanced life support: a cheaper system but ensuring maximal benefit for patients with STEMI.



Euro14A-MAO34

Does reducing ischaemia times justify to catheterise firstly the culprit artery in every primary PCI?

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Aims: No consensus exists about which coronary artery should be firstly catheterised in primary PCIs. Initial catheterisation of the "culprit artery" (supposed by ECG) could reduce reperfusion time. However, knowledge of multivessel disease or left main (LM) disease could modify revascularisation strategy. Aim: to analyse this issue in patients with STEMI undergoing primary PCI.

Methods and results: PCIs were performed in 384 consecutive patients (63.1±13.6 years; 73.4% males) by 6 different cardiologists. Choice of ipsilateral approach (IA): starting with the suposed "cuprit artery", or a contralateral one (CA) was left to the operator. Differences between the two approaches and their influence on reperfusion time, events during admission or revascularisation strategies were analysed. Right coronary artery (RCA) was the responsible in 40.9% of cases, left anterior descending in 41.5%, circumflex in 14.7% and LM in 0.3%. IA was preferred in 52.6% of cases and CA in 47.4%. There were no differences between two approaches regarding baseline features of patients, reperfusion time, radiation exposure, mortality or hospital stay. With IA a higher volume of contrast was used (168 vs. 151 cc; p=0.018) When the left coronary artery (LCA) was the responsible, IA was more frequent (IA 76.4% vs. CA 22.6%), but when it was the RCA, CA was preferred (IA 20% vs. CA 80%, p<0.0001). With CA, bare metal stents (BMS) were more used than drug-eluting (BMS 60.8% vs. DES 39.2%) inversely than with IA (BMS 41.3% vs. DES 59.7%; p<0.0001). With CA there were more patients with LM or multivessel disease in which revascularisation was completed with surgery (4.13% vs. 2.4%, p<0.0001).

Conclusions: Initial CA does not involve higher reperfusion time or clinical events. On the contrary, the overall knowledge of coronary anatomy could imply a change in management: greater use of BMS and programmed cardiac surgery. Moreover, ECG is not always definitive to determine the culprit artery, specially in inferior myocardial infarctions. Despite the need to individualise each case, contralateral approach may be the first option with the exception of unstable patients.



Coronary vein drain time: novel angiographic parameter that integrates both epicardial and tissue level perfusion in STEMI

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Aims: Both epicardial and myocardial perfusions are equally important in clinical outcomes after reperfusion therapy for ST elevation myocardial infarction (STEMI), and the performance of emergent percutaneous coronary intervention (PCI) should evaluate both level of perfusions.

Methods and results: The goal of this study was to develop a simple, broadly applicable angiographic method that takes into account indices of epicardial and myocardial perfusion after PCI in patients with STEMI. We introduce the coronary vein drain time (CVDT), which is the total angiographic frame count needed for contrast dye to travel from coronary ostium, through epicardial artery and myocardium, and finally draining out to coronary vein. The CVDT was evaluated in patients from the STATIN STEMI trial (a prospective, randomised, multicentre trial evaluating efficacy of pretreatment of high dose Atorvastatin before primary PCI with STEMI) and compared with TIMI flow grade (TFG), corrected TIMI frame count (cTFC), and myocardial brush grade (MBG). Also, resolution of ST segment elevation (STR) and peak CK-MB were measured and correlated with each angiographic perfusion parameters. A total 171 patients with STEMI were included in this study. The infarct related arteries were mostly on LAD (98, 57.3%). All the parameters were well correlated with each other. When comparing relation with MBG, which is standard method for myocardial perfusion evaluation, the CVDT was more strongly correlated with MBG (r=0.652, p=0.001) than TFG (r=0.346, p=0.05) and cTFC (r=0.552, p=0.002). The CVDT was associated more strongly with STR and peak CK-MB than TFG and cTFC. Interosperver and intraobserver coefficients of variation assessed in 20 randomly chosen patients were 0.89 (95% CI: 0.74-0.96) and 0.86 (95% CI: 0.68-0.95) for cTFC, 0.84 (95% CI: 0.63-0.94) and 0.80 (95% CI: 0.71-0.96) for MBG, and 0.84 (95% CI: 0.63-0.94) and 0.80 (95% CI: 0.71-0.96) for CVDT.

Conclusions: The CVDT combines epicardial and tissue level perfusion after PCI in STEMI that is well associated with STR and peak CK-MB. The CVDT was highly correlated with MBG compared with TFG and cTFC. The inter- and intra observer variation were comparable with cTFC and better than MBG.



Euro14A-MAO36

Safety and effectiveness of a novel absorbable vascular closure compared to established devices: a prospective study

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Aims: To assess safety and efficacy of a novel absorbable vascular closure device (ExosealTM) in patients undergoing cardiac catheterisation with femoral access compared to collagen-based (AngiosealTM) and suture-mediated (ProglideTM) vascular closure devices, as established devices. Methods and results: This prospective, double centre study included patients undergoing cardiac catheterisation via common femoral artery access (6 French) in which haemostasis was achieved using a vascular closure device. In hospital complications were recorded (bleeding with decrease of haemoglobin >2 g/ml, complications requiring extension of hospital stay, any complication requiring procedural or surgical intervention, hematoma >3 cm). Moreover, device failure was defined as bleeding persisting after deployment of the device, requiring subsequent manual compression. From 2012 to 2013, a total of 1,013 patients (65.2±11.8 years, 69% male) were included in this study (255 AngiosealTM, 258 ProglideTM, and 500 ExosealTM). Of the performed procedures 563 were diagnostic and 450 were therapeutic. A total of 989 (97.6%) treatments processed without complications. There was a higher prevalence of complications after utilisation of ExosealTM compared to established (AngiosealTM + ProglideTM) devices (3.6% vs. 1.2%, p=0.012). We report lowest complications after application of AngiosealTM (0.4%). We observed no significant difference in device success rate between the established vascular closure devices (96.3%) and the novel device (94.8%) (p=0.28). Considering each closure system we observed highest efficacy after utilisation of AngiosealTM with significant difference compared to ExosealTM (99.2% vs. 94.8%, p=0.001). In logistic regression analysis, interventions, obesity, active smoking, and the use of ExosealTM were predictors of complications (p<0.05 for all). Conclusions: Utilisation of the novel vascular closure device (ExosealTM) is associated with higher complication rates compared to established devices. Moreover, there was no difference in device failure between ExosealTM and the established devices. Considering each vascular closure device separately, in our study AngiosealTM is the device with the lowest rate of complications and device failure.

Twelve-month follow-up and acute lumen gain following lesion preparation with a scoring balloon for unprotected left main PCI

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Aims: PCI for left main disease is particularly critical regarding initial PCI results and outcome. We hypothesised, that lesion preparation with the AngioSculpt scoring balloon (ASB) will enhance acute lumen gain and reduce major adverse cardiac and cerebrovascular events (MACCE) at 12 months. The ASB enharbours three nitinol spiral scoring wires, which "score" the plaque circumferentially in order to provide maximal lumen gain even in calcified lesions.

Methods and results: The ALSTER left main registry includes all 71 left main (LM) interventions between June 2010 and September 2012. Here we report on 33 patients (mean age 72.5 years, 82% male) with a low or medium Syntax Score who received an elective percutaneous coronary intervention (PCI) for unprotected LM disease utilising the lesion preparation concept employing the ASB by a single operator. Exclusion criteria were emergency PCIs (3 patients), PCIs done by other operators (with other techniques and no ASB, 13), no ASB for lesion preparation by the same operator (15). Another 7 patients were excluded for other reasons (mainly protected left main stenosis). The mean log EuroScore was 13.78 (±3.68, SD). 25 patients (75.76%) had distal LM stenosis, 1 shaft stenosis, 6 (18.18%) ostial LM stenosis and one functional LM stenosis (Medina 0-1-1). In 80% of the distal LM interventions (20/25) a kissing balloon maneuver was performed. In all cases only one stent was used for isolated LM or LM – main branch. Drugeluting stents (DES) were used exclusively, mostly Promus Element DES (69.7%). Clinical follow-up was done by telephone interview and/or a further visit in the clinic and assessed by MACCE at 12 months. Follow-up rate was 96.97% (32/33). 28 patients (84.85%) received a coronary angiography in the follow-up period with no STEMI or NSTEMI (with CK >500 U/I) reported. MACCE rate was 18.2% (6/33) at 12 months, Two patients (2/33; 6.1%) were treated with repeated PCI due to in-stent restenosis including DCB dilatation (target lesion revascularisation) and two more due to a proximal LAD stenosis (target vessel revascularisation). One patient received an elective bypass operation due to bifurcation restenosis deemed not feasible for re-intervention. One patient died from the consequences of an ulcerous bleeding. The MACCE rate was driven by re-interventions but not mortality or STEMI. The ASB was delivered successfully in all cases attempted partially after predilatation on the lesion with a standard compliant balloon. No distal dissections were observed. No periprocedural or postinterventional complications occurred. All interventions were analysed by Philips quantitative coronary analysis software. The mean lumen diameter was 1.36±0.09 mm (SEM) before PCI and 3.03±0.09 (SEM) afterwards, which results in an acute mean lumen gain of 1.67 mm. The mean main vessel stent diameter was 3.65±0.07 mm (SEM) while the mean reference of the vessel was 3.50±0.09 mm (SEM). All re-interventions had a below average lumen gain of 1.1 mm.

Conclusions: The concept of "lesion preparation" for unprotected left main interventions is safe with particularly low MACCE rates compared to previous data. A correlation between initial lumen gain and MACCE rate can be observed.



Euro14A-MA038

Comparison between self-apposing bare metal and paclitaxel-eluting coronary stents for the treatment of saphenous vein grafts: the ADEPT study

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physicians in deciding on how the growing pool of SVG patients should best be treated by PCI.

Aims: Due to the limitations to conventional PCI in saphenous vein grafts (SVGs) and because of conflicting evidence found in existing trails regarding SVG treatment with BMS and DES, the ADEPT study was set up to investigate the use of STENTYS self-expanding stents with (STENTYS-PES) and without drugs (STENTYS-BMS) in SVGs. ADEPT is the first multicentre, prospective, randomised study to compare the safety and performance of the STENTYS coronary BMS (STENTYS-BMS) with the paclitaxel-eluting stent (STENTYS-PES) for the treatment of SVGs. Methods and results: The STENTYS self-expanding's stent ability to adjust it's size to the often irregular shape and caliber change of the SVG (especially at the anastomosis site) could lead to better apposition compared to balloon-expandable stents. Since the STENTYS-Stent opens like a flower (from distal to proximal) this could also result into less distal embolisation. Although several studies show reduced binary restenosis rate, late lumen loss and target lesion and vessel revascularisation compared with BMS, optimal treatment (BMS or DES) in SVGs has not yet been established with regards to the benefit of treatment with BMS or DES. The physician's choice of stent is often based upon the same rational as treating native coronary arteries. For these reasons a randomised study, systematically comparing the safety and efficacy of a self-expanding BMS with self-expanding DES in SVGs, should lead to improved treatment of SVGs. ADEPT is an international, prospective, multicentre, randomised (1:1) study consisting of two arms of 40 patients each. One arm will be treated with the STENTYS BMS, the other arm with the STENTYS PES. Both study arms include patients with *de novo* lesions (>50% stenosis) in SVG with a diameter between ≥2.5 and ≤6 mm. The enrollment goal is 80 subjects in up to 10 centres. Every patient will be followed for 12 months, with a clinical follow-up at 1 and 12 months and an invasive followup with a OCA and OCT (substudy) of the SVG at 6 months. Primary endpoint will be In-stent late lumen loss measured by OCA at 6 months and the main secondary endpoints will be Major Adverse Cardiac Events (MACE) and the Target vessel failure (TVF) at 1, 6 and 12 months. At the time of procedure, the angiographic endpoints will be the lesion length, native lesion classification (AHA/ACC), presence of distal embolisation and RVD in stent/in-segment. The 6 months QCA will be used to investigate final in-stent and in-segment % diameter stenosis, MLD in-stent/insegment, binary angiographic restenosis and to look for angiographic signs of distal embolisation. For the OCT patients, data on in-stent apposition, lumen and stent area (minimal and mean) will be collected. This abstract will present data on the first 40 patients with complete 6 months data. Conclusions: The ADEPT study will provide us with randomised (BMS vs. DES) data on the use of the STENTYS self-expanding stent in SVGs. The data presented is unique and is reflecting the first 40 patients enrolled and implanted with a STENTYS stent in the SVG, including QCA and OCT (subgroup) data collected at the 6 months follow-up. It will allow us to compare the actual data to the historical data available, helping

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Successful use of biliary stents during PCI in patients with large calibre coronary arteries and venous conduits

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Aims: Percutaneous coronary intervention (PCI) of lesions in large calibre coronary arteries and saphenous venous grafts of diameter ≥5 mm can be challenging and there are no separate guidelines available to treat these vessels with PCI. Standard coronary stents of 4 mm diameter are used to treat these lesions conventionally but carry the risk of under deployment and future stent thrombosis. We report the procedural success and safety of percutaneous coronary interventions using Herculinkbiliary stents in patients with large calibre vessels of diameter ≥5 mm.

Methods and results: We prospectively studied the use of HerculinkTM biliary stents to treat large calibre vessels in 12 patients between 2010 and 2013 in our large volume non-surgical PCI centre. Patients were treated as an all-comer basis with the choice of stents left to operator's discretion. Intravascular ultrasound examination (IVUS) was carried out to assess the size of the vessel and to assess plaque burden. Of the 7,171 number of PCI procedures performed, 12 patients (0.17%) had Herculink stents deployed and this is the largest series reported so far. All were men and the mean age was (mean±SD) 59±10.2 years. Cardiovascular risk profile was; diabetes mellitus: 4(33.3%), hypertension: 7(58.3%), smoking: 7(58.3%), dyslipidaemia: 9(75%), history of MI: 6(50%) and CABG: 2(16.7%). We divided the use of Herculink stents into i) PCI to ectactic native vessels (n=8, 66.7%, RCA=7, LCx=1), ii) Venous conduits (n=2, 16.7%) and iii) bailout PCI for LMS dissection (n=2, 16.7%). Four patients had the procedure performed as an elective PCI, six patients as urgent PCI for ACS and two patients as emergency PCI (primary PCI). The procedure was performed via radial access in two thirds of the patients. Six French guiding catheters were used to deliver the stent in all but one patient who had an 8 French guiding catheter. The average vessel diameter was 6.25±0.82 mm and mean plaque burden was 75% based on IVUS examination. 18 mm length Herculink stent was used in all patients. Mean stent diameter was 5.67±0.58. Post dilatation was performed with non-compliant balloons of sizes 5.5 and 6.0 mm. There were no procedural complications after the deployment of the Herculink stent. At a mean follow-up of 26 months, there were no clinically driven target vessel revascularisations, MI or stent thrombosis.

Conclusions: Use of Herculink biliary stents to treat large calibre native coronary vessels and venous conduits was safe and effective. Adequate post dilatation and IVUS guidance could have contributed to our excellent success rates with these stents.



Euro14A-MA040

Long-term clinical outcomes after polytetrafluoroethylene-covered stent implantation for coronary perforation

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Aims: Polytetrafluoroethylene (PTFE)-covered stents have improved the in-hospital clinical outcomes of patients with coronary perforation. However, there are few reports regarding their long-term outcomes.

Methods and results: We analysed data that was prospectively collected from 19,270 patients who underwent percutaneous coronary intervention in New Tokyo Hospital between January 2004 and December 2013. We then evaluated their mid-term and long-term clinical outcomes. The study endpoints were major adverse cardiac events (MACEs), defined as cardiac death, myocardial infarction (MI), and target lesion revascularisation (TLR). Furthermore, individual parameters, including all-cause death, cardiac death, MI, TLR and stent thrombosis (ST) during the follow-up period, were evaluated. Among the 258 patients with coronary perforation, 42 (16.3%) were treated with PTFE-covered stents. The median follow-up period was 1,090 days; interquartile range, 394-1,882 days. The MACE rates were 22%, 25% and 36% at 1, 2 and 3 years, respectively. The TLR rates including in-stent occlusion detected by coronary angiography (CAG) were 17.6%, 17.6% and 22% at 1, 2 and 3 years, respectively. Although the all-cause death rate at 1 year was relatively high, at 12.6% because of complications associated with coronary perforation, the cardiac death rate was 2.8%. TLR and in-stent occlusion detected by follow-up CAG were observed in 6 patients (17.6% at 1 year), and TLR occurred within 6 months in 3 of these patients. In stent occlusion detected by CAG occurred in the remaining 3 patients, who were all treated by surgical repair and CABG. MI occurred in 1 patient because of side branch occlusion following PTFE-covered stent implantation. No definite ST was found.

Conclusions: The one-year MACE rate of 22% in this study was relatively high, which was affected by short-term outcomes due to coronary perforation. However, TLR rate and other long-term outcomes of patients treated coronary perforation with PTFE-covered stent were feasible.

Influence of clinical, angiographic and procedural variables on late lumen loss following drug-eluting balloon treatment of *de novo* coronary lesions

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Aims: This study sought to assess clinical, angiographic and procedural determinants of late loss in lumen diameter, the most frequently used endpoint in clinical trials on drug-eluting balloons, after treatment of native coronary artery disease by drug-eluting balloon only angioplasty.

Methods and results: Patients from the Balloon Elution and Late Loss Optimization (BELLO) trial who were treated by drug-eluting balloon only (without bailout stent implantation) for a single target lesion in a coronary artery with a visually estimated reference diameter <2.8 mm constituted the population of this study. Their baseline and at six-month follow-up coronary angiograms were analysed at an independent core laboratory using a validated edge detection system. Variables potentially associated with late lumen loss were assessed by linear regression yielding three predictors at univariate analysis: baseline diameter stenosis (Beta=0.009, p=0.035), drug-eluting balloon length (Beta=0.013, p=0.039) and acute lumen gain (Beta=0.363, p=0.018). At multivariable analysis, acute lumen gain was identified as the only independent predictor of late lumen loss (Beta=0.322, p=0.034). Furthermore, to account for possible outward vessel remodelling, patients were dichotomised according to positive (n=35) or negative (n=26) value of late lumen loss. Baseline characteristics were similar between the two groups. Patients with a negative late lumen loss showed a trend toward a more frequent pharmacologic treatment with an angiotensin converting enzyme inhibitor (60% vs. 39%, p=0.096), a lower diameter stenosis (70±11% vs. 75±9%, p=0.078) and a shorter drug-eluting balloon length (24.6±6.6 mm vs. 27.7±6.5, p=0.071). Moreover, these patients had a significantly lower acute lumen gain (0.83±0.25 mm vs. 1.02±0.26, p=0.007). At multivariable analysis, lower acute lumen gain was the only independent predictor of negative late lumen loss (odds ratio 0.04, 95% confidence interval 0.01-0.76, p=0.032), yielding a fair discrimination power (c-statistic=0.71).

Conclusions: In patients treated by drug-eluting balloon only angioplasty for *de novo* lesions in small coronary arteries, our data show a proportional relationship between acute gain in lumen diameter and subsequent late loss of the coronary lumen at six-month follow-up, thus supporting for this device too "the more you gain, the more you lose" tenet of interventional cardiology. Moreover, persisting significant predictive power of acute gain for negative values of late lumen loss does not support actual gain in diameter after drug-eluting balloon angioplasty.



Euro14A-MA042

Final three-year results of the prospective, randomised, multicentre PERfECT stent study

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Aims: In the PERfECT Stent Study we compared the treatment with paclitaxel coated balloon (SeQuent Please, B.Braun) plus endothelial progenitor cell capturing stent (OrbusNeich) with an endothelial progenitor cell capturing stent alone in patients undergoing PCI of a *de novo* lesion in a native coronary artery. Angiographic follow-up was performed after 6 months and showed a superiority of the additional use of a paclitaxel coated balloon with an endothelial progenitor cell capturing stent alone with respect to angiographic (late lumen loss, minimal lumen diameter, restenosis) and clinical parameters (TLR, TVR and MACE). We now demonstrate the final clinical follow-up after 3 years.

Methods and results: The PERfECT Stent Study was a prospective, double blind, multicentre, randomised trial where 120 patients with a *de novo* lesion in a native coronary artery were randomised to undergo treatment either with paclitaxel coated balloon catheter plus endothelial progenitor cell capturing stent or endothelial progenitor cell capturing stent or endothelial progenitor cell capturing stent was obtained in all 120 patients (100%). There was no difference in patients' baseline characteristics or procedural results. Treatment with paclitaxel-eluting balloon plus endothelial progenitor cell capturing stent was superior to endothelial progenitor cell capturing stent alone with a late loss of 0.34±0.45 mm versus 0.88±0.48 mm at 6 months angiographic follow-up. Restenosis rate was reduced from 23.2% to 5.1% (P=0.005) and the combined clinical end point was reduced from 17.2% to 4.8% (P=0.03), respectively. At 36 month follow-up the clinical driven target lesion revascularisation was 20.7% in the endothelial progenitor cell capturing stent alone group compared to 12.9% in the group treated with paclitaxel-eluting balloon plus endothelial progenitor cell capturing stent. The clinical end point (MACE) was lower with additional use of a paclitaxel coated balloon compared with endothelial progenitor cell capturing stent alone (14.5% versus 25.9%, p=0.12). The absolute differences in TLR and MACE between 6 and 36 months were consistent. There was no definite or probable stent thrombosis with a 3 months course of dual antiplatelet therapy.

Conclusions: Paclitaxel coated balloon angioplasty and endothelial progenitor cell capturing stent implantation is superior to endothelial progenitor cell capturing stent implantation alone for treatment of *de novo* coronary artery disease with respect to angiographic and clinical parameters. A lower target lesion revascularisation rate and combined clinical endpoint was demonstrated throughout 36 months follow-up with the additional use of a paclitaxel coated balloon. (ClinicalTrials.gov number, NCT00732953)

A propensity score matched comparative study between paclitaxel-eluting balloon and everolimus-eluting stent in small coronary vessels

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Aims: The aim of this study was to compare the long-term clinical outcomes of paclitaxel drug-eluting balloons (DEB) and everolimus-eluting stents (EES) in patients with small vessel coronary artery disease. We currently have no data available comparing DEB to second generation drug-eluting stents, which are the current standard of care.

Methods and results: The present study enrolled 90 patients with small vessel coronary disease from the DEB treatment arm of the BELLO (Balloon Elution and Late Loss Optimization) trial and 2,000 patients treated with EES in San Raffaele Scientific Institute, Milan. Propensity score matching was applied to adjust for differences in baseline clinical and angiographic characteristics, yielding a total of 181 patients: 90 patients with 94 lesions receiving DEB and 91 patients with 94 lesions receiving EES. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, recurrent non-fatal myocardial infarction, and target vessel revascularisation. After propensity score matching, baseline clinical and angiographic characteristics were similar between the 2 groups. The cumulative MACE rate at one-year was 12.2% with DEB and 15.4% with EES (p=0.538). Patients in the DEB group had similar TLR rates as compared to EES over the same interval (4.4% vs. 5.6%; p=0.720). There were no cases of definite or probable stent or vessel thrombosis.

Conclusions: The use of paclitaxel DEB appears to be associated with similar clinical outcomes as second-generation EES in small coronary artery disease. Larger studies are required to investigate this further.



Euro14A-MAO44

Clinical efficacy and safety of drug-coated balloon angioplasty as primary therapy/adjunctive therapy in primary PCI

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Aims: Primary percutaneous coronary intervention (PPCI) is the preferred reperfusion strategy for ST-elevation myocardial infarction (STEMI). Stent implantation (whether with BMS or DES) is considered as a routine during PPCI as it is associated with reduction of early ischaemia, restenosis and re-occlusion of culprit artery in comparison with pure old balloon angioplasty (POBA). Drug-eluting balloon (DEB) has emerged as a new therapeutic option to treat coronary artery disease as stent technology has certain limitations. There is however limited data on the feasibility of using DEB as primary therapy/adjunctive therapy in PPCI. We evaluated the clinical efficacy and safety of using SeQuent Please paclitaxel-eluting balloon in our cohort of South-East Asian patients undergoing PPCI for STEMI.

Methods and results: Between January 2010 to November 2013, 95 STEMI patients (83% male, mean age 59±12 years) with a total of 95 coronary lesions were treated with SeQuent Please DEB during PPCI. The PPCI strategy was to perform thrombus aspiration (for visible thrombus) followed by predilatation of lesion site before treatment with DEB. Bail-out stenting was performed only when there was significant vessel recoil/coronary dissection (>Type B dissection). Clinical outcomes are reported at 30 days follow-up. The majority of patients presented with anterior STEMI (55%) with the left anterior descending artery (LAD) being the most common target vessel (46%) for PCI. DEB was used as primary therapy in 85% of cases (72 patients with *de novo* coronary lesions and 9 patients with very late stent thrombosis) and as adjunctive therapy in the remaining 15% of patients (in combination with stents for diffuse lesions). Thrombus aspiration was performed in 53 patients (56%) with glycoprotein 2b/3a inhibitors administered in 77 patients (81%). Pre-procedural Thrombolysis in Myocardial Infarction (TIMI) flow was 0 in 62% of patients. At the end of PPCI, TIMI 3 flow was successfully restored in 99% of patients with residual stenosis of 27%. DEB-only PCI was the predominant approach (96% of patients) with the remaining 4% of patients receiving bail-out stenting for significant recoil/dissection after treatment with DEB. An average of 1.3±0.5 DEB were used per patient, with mean DEB diameter of 2.6±0.5 mm and average length of 24.3±10.7 mm. The mean inflation pressure for DEB was 10±3 atm and mean inflation time was 56±23 seconds. At 30-day follow-up, there were 3 death (3.1%). 2 patients succumbed due to cardiogenic shock and 1 died of sepsis. There was no reported target-lesion failure, target-vessel-MI or target lesion thrombosis.

Conclusions: Our preliminary experience showed that the use of DEB as primary therapy/adjunctive therapy for STEMI patients in PPCI was feasible and associated with a high rate of final TIMI 3 flow and low 30-day major adverse cardiac event. Larger studies with longer clinical follow-up are required to confirm our initial observation.



The combined use of bioresorbable scaffold or DES and drug coated balloon in bifurcation stenting

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Aims: The aim of the study is to study the clinical efficacy of the combined use of BVS or DES deployed in the main branch and the use of drug coated balloon in the side branch in bifurcation lesions

Methods and results: 125 patients with 125 bifurcations were enrolled from 2010 to 2014 with 70 men and 55 women, ranging from age 40 to 85 years. Only patients in medina 111 and 011 were included. The lesion sites were 3 left main bifurcation, 57 LAD/D1 bifurcation, 41 LCX/OM bifurcation and 24 RCA /PDA bifurcation. 99 patients were treated with DES (Everlolimus and Biolimus A9 DES) and 26 were treated with BVS in the main branch. All patients were treated with drug coated balloon (Sequent Please DCB) in the side branch. IVUS (for DES stenting) or OCT (in BVS deployment) were used in 75% of the patients. Clinical follow-up was achieved in 85% of the study group. One year TLR was 2.8% in main branch and 5.7% in the side branch. Non Q MI occurred in 1.9% in 2 patients in the side branch. No MI occurred in the main branch. No stent thrombosis or death at 1 year. MACE at 1 year was 2.8% an the main branch and 7.6% in the side branch.

Conclusions: In bifurcation PCI, one stent strategy, either a BVS or DES, deployed in the main branch combined with drug coated balloon treatment of the side branch, showed very acceptable TLR and MACE results at 1 year clinical follow-up.



Euro14A-MA046

Second generation drug-eluting balloon in 001 bifurcated lesions: one-year clinical and 7-month angiographic results

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Aims: In the DES era, the best strategy to treat 001 bifurcated lesions remains unanswered. This is the first prospective registry assessing the efficacy and safety of second generation of drug-eluting balloon (DEB) (EurocorGmbH), (3.0 μ g/m² balloon surface area), in patients with 001 bifurcated lesions placed in secondary branches.

Methods and results: After 2.7 years, 51 patients with 001 bifurcated lesion and clinical evidence of myocardial ischaemia related to the target lesion were prospectively included in this multicentre (8 centres) registry. After optimal dilatation, a PEB was inflated for a minimum of 45 seconds. Left main bifurcated lesions, severe calcification and cardiogenic shock, were the only exclusion criteria. In 2 eligible patients after regular balloon pre-dilatation the DEB could not be used and patients were excluded of the registry. Patients were 62±12 years old, 42% diabetic, 56% ACS as clinical presentation. The most frequent lesion treated was first diagonal (41%). Radial approach was done in most cases (84%). Pre-dilatation was done in all the cases, with cutting balloon in 59%. Angiographic success was 90% (by protocol in 10% of lesions a BMS was implanted because of significant acute recoil (3) or coronary dissection more that type B (2)). At 1 month (follow-up completed in all the patients) there was no adverse event (MACE). At a mean of 11.2±2.2 months (12 months completed in 81% of patients) there was 14.2% cumulative non-hierarchical MACE (1 MI, 0 cardiac deaths, 7 TLR). There was no thrombosis or occlusion. In 4 selected centres at a mean of 7.2±1.1 months, angiographic follow-up was completed in 31/36 (86%) patients; reference diameter was 2.2±0.3 mm with a binary restenosis of (6) 19.3%.

Conclusions: We report the first registry assessing 001 bifurcated lesion placed in small vessels (2.2 mm). This is a rare type of coronary lesion (inclusion period of 2.7 years) that was observed in a relative young and diabetic population. In this complex setting, second generation of PEB is a safe strategy, technically easier and it seems to be effective at mid-term follow-up with a 14% MACE at 1 year.



Comparison of Paclitaxel drug-eluting balloon and Paclitaxel-eluting stent in small coronary vessels in diabetic and nondiabetic patients - Results from the Balloon Elution and Late Loss Optimisation (BELLO) Trial

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Aims: Small vessel disease is common in diabetic patients but currently there are no available data regarding DEB in these patients. Tha aim of this study was to evaluate the impact of diabetes on the efficacy of drug-eluting balloon (DEB) as compared to paclitaxel-eluting stent (PES) for the reduction of restenosis in small in patients enrolled in the BELLO (Balloon Elution and Late Loss Optimization) trial.

Methods and results: In the BELLO trial 182 patients with lesions in small vessels were randomised 1:1 to receive DEB or PES. In the current subanalysis, patients were stratified according to the presence of diabetes. The diabetic group consisted of 74 patients (DEB=39, PES=35) and the non-diabetic group of 108 patients (DEB=51, PES=57). Angiographic endpoints examined were in-stent/in-balloon and in-segment late loss and binary restenosis at 6-months. Clinical endpoints were major adverse cardiac events (MACE; death, myocardial infarction, target vessel revascularisation) at one-year. In-stent/in-balloon late loss was significantly less with DEB as compared to PES in both diabetic (0.05±0.41 vs. 0.30±0.51 mm, p=0.033) and nondiabetic patients (0.10±0.36 vs. 0.29±0.40 mm, p=0.015). In patients with diabetes, angiographic restenosis and in-segment late loss was significantly lower with DEB as compared to PES (respectively, 6.3% vs. 25.0%; p=0.039 and -0.013±0.39 vs. 0.25±0.53; p=0.023), with no differences noted in nondiabetic patients. The cumulative MACE rate at one-year was similar between DEB and PES in both the diabetic (13.2% vs. 25%, p=0.194) and nondiabetic groups (11.8% vs. 14.3%, p=0.699).

Conclusions: Diabetes does not appear to have a negative impact on the efficacy of DEB in small vessels, which were associated with better angiographic outcomes at 6-months in this complex subgroup. Larger studies are needed to confirm these findings.



uro14A-MAO48

Primary percutaneous coronary intervention by drug-eluting balloon angioplasty: the non-randomised fourth arm of the drug-eluting balloon in ST-segment elevation myocardial infarction (DEB-AMI) trial

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Aims: To evaluate a paclitaxel drug-eluting balloon (DEB) only strategy in primary percutaneous coronary intervention (PPCI), aiming at a comparison with bare metal stent (BMS) alone, DEB followed by BMS, and paclitaxel-eluting stent (PES), as assessed in the randomized Drug-Eluting Balloon in Acute ST-Segment Elevation Myocardial Infarction (DEB-AMI) trial.

Methods and results: This study is a prospective registry with the same inclusion/exclusion criteria used in the DEB-AMI trial, as it constitutes the fourth, non-randomised, treatment arm of this trial. Patients presenting with ST-elevation myocardial infarction were allocated to DEB-only (DIOR II, Eurocor GmbH, Bonn, Germany) after successful thrombus aspiration and predilatation. Primary endpoint was 6-month angiographic inballoon/stent late-luminal loss (LLL). Secondary endpoints were in-balloon/stent binary restenosis and major adverse cardiac events (MACE: death, myocardial infarction, target-vessel revascularisation). Forty patients underwent PPCI by DEB-only. Procedural success was achieved in 97.5% with bail-out stenting required in 10.0% of procedures. In DEB-only, LLL was 0.51 ± 0.59 mm as compared to 0.74 ± 0.57 mm in BMS (p=0.44), 0.64 ± 0.56 mm in DEB+BMS (p=0.88) and 0.21 ± 0.32 mm in PES (p<0.01); in-balloon/stent binary restenosis rates were 22.2%, 23.8% (p=0.67), 28.6% (p=0.97) and 4.5% (p=0.07), respectively; and MACE rates were 17.5%, 23.5% (p=0.20), 20.0% (p=0.26) and 4.1% (p=0.90), respectively. No acute or late thrombotic events occurred in the DEB-only group.

Conclusions: PPCI by DEB-only in selected patients yielded an angiographic outcome comparable to BMS alone and DEB followed by BMS. PES proved angiographic superiority to DEB-only. DEB-only can be considered a valid treatment alternative during PPCI in patients with contraindications to drug-eluting stents.



Coronary interventions Euro 14A-MAO49

Protocol for the Objective Randomised Blinded Investigation of optimal medical Therapy versus Angioplasty in stable angina (ORBITA) trial

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Aims: 1. To compare changes in objective exercise capacity following percutaneous coronary intervention (PCI) versus placebo procedure. 2. To investigate the relationship between the assessment of ischaemia as measured by non-invasive tests, invasive tests and biomarkers and changes in objective exercise capacity following PCI.

Methods and results: While we know a great deal about delivering high quality medical therapy for patients with stable coronary artery disease, it is surprisingly unclear whether PCI gives incremental benefit even though it is a widely adopted standard therapy. Previous studies have focused on looking for benefit from PCI in terms of mortality and myocardial infarction rates. These trials have been neutral or positive with a controversial unblinded endpoint. Angina reduction was the original aim of PCI. However despite the known powerful effect of placebo, angina reduction from PCI has never been quantified in a placebo-resistant blinded randomised controlled trial. We present the protocol to the ORBITA trial, a prospective multicentre randomised double-blinded comparison of the treatment of stable angina with PCI versus placebo in 300 patients with stable angina and one or more angiographically significant coronary stenosis in a single stentable vessel performed at 3 Cardiology centres within the United Kingdom. Patients will undergo a 6 week run-in period of strict protocol-based optimisation of their antianginal medical therapies. Baseline investigation of functional capacity and myocardial ischaemic burden using cardiopulmonary exercise testing, dobutamine stress echocardiography, biomarkers and quality of life assessment will then be performed. Patients will then undergo an invasive procedure carried out under sedation to ensure that they have no knowledge of the treatment arm allocation. The physiological significance of stenosis will be assessed using pressure wire measurements. Patients will then be randomised 1:1 to PCI or a placebo procedure. The invasive cardiologist will be blinded to the results of physiological lesion assessment and the research stress tests, since the patients has already been declared clinically eligible for stenting based on symptoms, coronary angiography and any clinical non-invasive testing. All subsequent medical care givers will be blinded to the treatment arm. Patients will return 6 weeks post-procedure for repeat cardiopulmonary exercise testing, dobutamine stress echocardiography, biomarkers and quality of life assessment. After this post-procedure testing, patients and clinicians will be unblinded.

Conclusions: The ORBITA trial will provide the first bias-resistant evidence of the quantity of angina reduction and objective functional gain in exercise capacity for patients already on optimal medical therapy from PCI. If confirmed this would support the use of PCI for angina relief and improvement exercise capacity for stable coronary disease over and above medical therapy.



Euro14A-MA050

Overlapping implantation of Resolute zotarolimus-eluting stents: long-term outcomes from the RESOLUTE global clinical program

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Aims: Patients with coronary artery disease in long lesions have a more severe disease profile and experience worse outcomes following PCI. The use of overlapping stents is a surrogate marker more efficient than visual estimation or QCA to detect long lesions. We compared outcomes between patients who were enrolled in the Global RESOLUTE Program and received either overlapping or non-overlapping stents.

Methods and results: All patients who received implantation of the Resolute® zotarolimus-eluting stent (R-ZES) in 10 studies were analysed for differences in baseline characteristics and clinical outcomes based on whether they received overlapping or non-overlapping stents. Follow-up was available through 1 year in 7,618 patients, 2 years in 5,418 patients, and 3 years in 5,130 patients. Longer term follow-up will be available at the time of EuroPCR 2014 presentation for the first time from some of the component studies, including 4 years for RESOLUTE US (n=1,402) and 5 years for RESOLUTE (n=139) and RESOLUTE All Comers (n=2,349). Endpoints included target lesion failure (TLF; cardiac death, target vessel myocardial infarction, and clinically-driven target lesion revascularisation) and Academic Research Consortium definite/probable stent thrombosis. Clinical outcomes through 3 years of follow-up were adjusted using propensity scores for all baseline characteristics that were significantly different (p<0.05) between the overlapping and non-overlapping groups. The clinical and lesion characteristics of patients with overlapping stents were generally more severe than in patients with non-overlapping stents, including more current smokers (p=0.002), unstable angina or myocardial infarction (p<0.001), B2/C lesions (p<0.001), moderate/severe lesion calcification (p<0.001) and greater diameter stenosis (p<0.001). A greater proportion of patients had hyperlipidaemia in the non-overlapping group (p<0.001). Lesion length was 28.3±18.0 mm (n=1,494) in the overlapping group and 16.3±8.3 mm (n=8,022) in the non-overlapping group (p<.001). Over 3 years of follow-up, TLF and stent thrombosis did not differ between patients implanted with overlapping and non-overlapping stents. The Kaplan-Meier estimate of TLF after adjustment for baseline differences was 7.4% (n=1,016 evaluable patients) in the overlapping group and 5.4% (n=6,216) in the non-overlapping group at 1 year, 10.8% (n=579) and 8.0% at 2 years, and 12.0% (n=537) and 9.5% (n=3,825) at 3 years (p=0.099). Similarly, there were no significant differences in the occurrence of ARC definite/probable stent thrombosis: 1.0% (n=1,064 evaluable patients) in the overlapping group and 0.6% (n=6,396) in the non-overlapping group at 1 year, 1.3% (n=628) and 0.8% (n=4,514) at 2 years, and 1.3% (n=584) and 0.9% at 3 years respectively (p=0.618).

Conclusions: The overlapping group presented with a disease profile that was significantly more severe than the non-overlapping group. Nevertheless, three-year estimates of TLF and stent thrombosis in patients who received overlapping R-ZES implantation did not significantly differ from those who received non-overlapping implantation when adjusted for differences in baseline characteristics. This second generation DES achieves, unlike previous bare metal and first generation DES, a nearly complete equalisation of lesion failure and stent thrombosis in patients with single or overlapping stents.



Safety update and long-term clinical outcomes from all studies in the global RESOLUTE clinical programme

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Aims: To date, pooled outcomes from the Global RESOLUTE Clinical Program have been reported based on 5 studies with 5,130 patients enrolled who received implantation of the Resolute® zotarolimus-eluting stent. We report pooled outcomes from all RESOLUTE studies, including an additional 2,488 patients from studies not included in previous safety updates.

Methods and results: Data from all patients who received implantation of R-ZES were pooled between 10 studies. Kaplan Meier estimates were used to estimate target lesion failure (TLF; cardiac death, target vessel myocardial infarction, or clinically-driven target lesion revascularisation) and Academic Research Consortium definite/probable stent thrombosis for all patients with follow-up data through 3 years. Follow-up was available for this analysis through 3 years in RESOLUTE (n=139), RESOLUTE US (n=1,402), RESOLUTE All Comers (n=1,140), RESOLUTE International (n=2,349), and RESOLUTE Japan (n=100), 2 years in RESOLUTE Japan SVS (n=65), RESOLUTE Asia 38 mm cohort (n=109) and RESOLUTE US 38 mm cohort (n=114); and 1 year in RESOLUTE China Randomised Controlled Trial (RCT; n=198), RESOLUTE China Registry (n=1,800), and RESOLUTE Asia dual-vessel cohort (n=202). In 7,618 total patients, the mean age was 62.99±10.97 years, 75% (n=5,747) were male, 30% (n=2,317) had diabetes, and 29% had a prior MI. Kaplan-Meier estimates of TLF were 5.72% (n=7,232 evaluable patients) at 1 year, 7.26% (n=4,837) at 2 years, and 9.80% (n=4,362) at 3 years. Estimates of stent thrombosis were 0.67% (n=7,460 evaluable patients) at 1 year, 0.83% (n=5,142) at 2 years, and 0.95% (n=4,681) at 3 years. This analysis will be updated to incorporate longer term follow-up, including RESOLUTE US through 4 years and RESOLUTE and RESOLUTE All Comers through 5 years.

Conclusions: Kaplan-Meier estimates from international trials that enrolled over 7,000 patients implanted with R-ZES indicated that event rates were low in short- and long-term follow-up. Updated data with longer-term follow-up to be presented at EuroPCR 2014 will provide more insights about the safety and efficacy of R-ZES in a wide range of patients.



Euro14A-MA052

Subgroup analysis of subjects with complex B2/C lesions from the BIOFLOW-III all-comers registry with the Orsiro hybrid DES

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Aims: Subjects with B2/C lesions are known to have a higher risk for cardiac complications or restenosis. The aim of this subgroup analysis is to show that the clinical performance of the new generation Orsiro Hybrid Drug Eluting Stent in this challenging population is comparable to the overall cohort and to other state of the art DES in standard clinical care.

Methods and results: The Orsiro is a unique hybrid solution stent 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. Between August 2011 and March 2012, 1,359 subjects presenting with 1,738 *de novo* or restenotic coronary artery lesions were enrolled consecutively in this international, multicentric BIOFLOW-III Registry at 43 sites in 14 countries using the Orsiro Hybrid Drug Eluting Stent. 52% of those lesions (N=905 lesions, N=743 subjects) were classified in accordance to ACC/AHA guidelines as B2 (32%) and C (20%) lesions. Preliminary data demonstrates excellent device (98.4%) and procedure success (97.6%) in this complex population. Clinical data show a low target lesion failure rate of 5.1% (Cardiac Death 1.4%, target vessel myocardial infarction 2.5%, clinically driven target lesion revascularisation 3.1%, emergent CABG 0.0%) and definite and probable stent thrombosis rate (0.5%) up to 12-month follow-up.

Conclusions: Preliminary data in this challenging population demonstrates the device success, procedure success and target lesion failure rate to be comparable to the overall cohort and other state of the art DES. Full data will be available upon presentation.



Two-year clinical outcomes of the ultimaster DES: results of the Century study

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Aims: CENTURY study assesses the safety and performance of Ultimaster, a thin-strut cobalt-chromium sirolimus-eluting stent with an innovative abluminally, gradient coated bioresorbable polymer. Drug-eluting stents with bioresorbable polymers are expected to offer long-term safety benefits as they might reduce permanent polymers associated adverse effects.

Methods and results: The CENTURY is a multicentre, single-arm, prospective, controlled study that enrolled 105 patients with previously untreated lesions in up to 2 epicardial vessels. The primary endpoint was superiority in 6-month late-lumen loss of Ultimaster DES versus its bare metal platform the Kaname stent (historical control). At 6 months angiography, 45 and 20 patients respectively underwent IVUS and OCT assessments. Clinical follow-up is available up to one-year and will continue up to 5 years. The Ultimaster proved superior to Kaname stent with in-stent late loss at 6 months of 0.04±0.35 mm versus 0.75±0.43 mm, respectively (p<0.0001), also reflected in significantly lower binary restenosis rate of 0.9% versus 16.9% (p<0.001) and confirmed by IVUS assessed neointimal volume obstruction of 1.2±1.9% vs. 26.0±11.6% (p<0.0001). The mean struts coverage assessed by OCT was 96.2% with 1.66±4.02 malapposed stent struts. Overall target lesion failure at one-year was 3.8% in Ultimaster and 8.5% in Kaname treated patients (p=0.11) with TLR of 1.9% and 6.7%, respectively (p=0.06). There were no late stent thromboses. 2 years follow-up is currently ongoing and data will be available at the time of presentation.

Conclusions: Ultimaster DES offers substantial advantage in suppression of neointimal proliferation over bare metal platform and showed good safety and effectiveness in the studied populations.



Three-year clinical outcomes in the primary stenting of totally occluded native coronary arteries III (PRISON III): randomised trial comparing sirolimus-eluting stents with zotarolimus-eluting stents for the treatment of total coronary occlusions

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Aims: A randomised trial was conducted comparing Sirolimus-eluting stents (SES) with two Zotarolimus-eluting stents (ZES; Endeavor and Resolute) in patients with total coronary occlussions (TCO). At 8 months, SES showed superior angiographic outcome, with respect to late lumen loss, compared to Endeavor ZES and comparable outcome to Resolute ZES. This study evaluates the clinical outcome three-year after successful recanalisation and stent implantation in patients with TCO.

Methods and results: The PRISON III trial compared SES versus ZES (Endeavor and Resolute) in two study phases. In the first phase, 51 patients were randomised to receive SES and 46 Endeavor ZES. In the second phase, 103 and 104 patients were randomised to SES or Resolute ZES. respectively. Between one and three-year there were only a few additional clinical events in all groups. As a result, the rate of cardiac death 4.1% vs. 0%, myocardial infarction 6.1% vs. 4.3%, target lesion revascularisation 12.2% vs. 19.6% p=0.49, target vessel failure 14.3% vs. 19.6% p=0.68 and definite or probable stent thrombosis 4.1% vs. 2.2% was comparable between SES and Endeavor ZES at three-year. In the second study phase, there were no cardiac deaths in both groups and the rate of myocardial infarction 3.0% vs. 2.0%, target lesion revascularisation 10.0% vs. 5.9% p=0.42, target vessel failure 10.0% vs. 7.9% p=0.79 and definite or probable stent thrombosis 1.0% vs. 0% was similar between SES compared to Resolute ZES.

Conclusions: Our study data indicated that the worse angiographic performance of Endeavor ZES relative to SES in terms of late lumen loss at 8 months did not translate into a significant increment in clinical events. At three years, clinical outcome was similar between both SES compared to Endeavor ZES and SES versus Resolute ZES in patients treated for total coronary occlusions.

Clinical and angiographic experience with a novel thin strut cobalt chromium carbon coated stent

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Aims: Bare metal stents continue to be used for the interventional treatment of coronary artery disease. We report the clinical and angiographical results of a multicentre, single- arm evaluation of safety and feasibility of the MOMO stent (Japan Stent Technology Co, Okayama Research Park Incubation Centre, Okayama, Japan).

Methods and results: The MOMO stent is a novel thin – strut cobalt- chromium carbon – coated stent for the treatment of *de novo* coronary artery disease. In this prospective, non- randomised single-arm study 30 patients presenting with stable angina pectoris (Canadian Cardiovascular Society 1 to 4) or unstable angina (Braunwald classification I B-C, II B- C or III B-C), demonstrating single – or double heart vessel disease with a maximum of 2 lesions to be treated by stenting were recruited into the study from six centres. Patients with lesions ≤20 mm in length and with a target vessel diameter of ≥2.5 mm were eligible. Angiographic follow-up was performed in 25 patients. Quantitative coronary angiography was used to measure acute gain and late luminal loss. Primary endpoint was late luminal loss and binary stenosis (≥50% stenosis by quantitative coronary angiography) at 6 months. A secondary endpoint was major adverse cardiac events (MACE), a composite of cardiac death, non-fatal myocardial infarction and/or target vessel revascularisation. Thirty-five lesions were treated with 40 stents. Mean lesion length was 12.3 mm and mean reference vessel diameter 3.01 mm. Mean stent diameter and length were 3.2 mm and 16.3 mm respectively. Balloon predilatation was mandatory. Mean maximal deployment pressure was 13.3 atm. There was a need of 1.14 stents per lesion, mainly due to edge dissections (1 proximal, 3 distal) prompting additional overlapping study stent implantation. The technical success rate was 97.22%. One stent could not be delivered due to proximal tortuosity and haemodynamic instability of the patient. At 12 months MACE rate was 20%. Target vessel revascularisation was performed in 4 patients (13.33%) during 12 month follow-up, two of these showing symptomatic recurrence and two due to the presence of a ≥70% stenosis at angiographic follow-up. No recurrent myocardial infarction, stent thrombosis or death was observed. In-segment mean late luminal loss was 0.66 mm (Q1, Q3: -0.95, -0.25 m) and binary sten

Conclusions: This study demonstrates proof of concept of the safety and feasibility of the MOMO cobalt- chromium carbon - coated stent for patients with *de novo* lesions presenting with stable and unstable coronary artery disease.



Euro14A-MA056

Coronary angioplasty efficiency in patients with multivessel coronary disease depending on the length and diameter of the stents implanted

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Aims: The aim of the study is to estimate the frequency of restenosis and thrombosis in patients with multi-vessel coronary disease depending on the length and diameter of the stents implanted in groups of patients undergoing angioplasty with two or more bare metal, drug-eluting stents or hybrid stenting.

Methods and results: A retrospective study was conducted of 210 patients with multi-vessel coronary disease who were treated with implantation of 2 or more stents at medical centre "Nork-Marash" between January 2007 and 2010. Special attention was paid to the coronary lesion narrowing types, stent implantation techniques as well as to the type, diameter, and length of the stents. Stents with a diameter of 2.5 mm were implanted in 5% of the patients (n=24), 2.75 mm-16.7% (n=80), 3 mm-33.9% (n=162), 3.5 mm-38.1% (n=182) and 4 mm (n=30). 14-24 mm length stents were implanted in 48.7% of patients (n=233), 24-38 mm-32.6% (n=156), 8-14 mm-16.7% (n=80), and a 38 mm-1.9% (n=9) respectively. The patients underwent three-year follow-up surveillance. In the group of patients with 2.5 mm diameter stent implantation restenosis rates were twice higher when compared to the group of patients with 2.75 mm stent implantation (95% CI: 3.5% -31.1%), 3 times –compared to the group of patients with 3 mm stent implantation (95% CI: 2.1%-34.5%) and almost 6 times more – than in the group of patients with 3.5 mm stent implantation (95% CI: 5.4%-37.3%). Incidence of thrombosis was 4 times more frequent in the group of patients with implantation of 2.75 mm diameter stent when compared to the one with 3 mm diameter stent implantation (95% CI: 1.5%-8.1%). Depending on the length of implanted stents, restenosis was registered in 6.25% of cases of 8-14 mm stent and 6.7%-14 mm stent implantation. The rates for thrombosis were 1.25% and 1.5% respectively. The lowest efficiency was registered in the group of patients treated with the implantation of only bare-metal stents when compared to the groups of patients with only drug-eluting stent deployment or hybrid stenting. In the group of patients treated with the 2.75 mm diameter stents, restenosis rates were significantly higher when compared to the group of patients treated with drug-eluting stents (95% CI: 4.9%-71.9%).

Conclusions: Major adverse cardiac events (MACE) rates were higher in the groups of patients with the implantation of stents with the dimatere less 3 mm and length 14 mm. Thus for the treatment of multivessel coronary desease it is more preferable to use stents with the diameter 3 mm or more and with the length up to 14 mm.

Frequency domain OCT as a research tool and for guidance of coronary stenting with biodegradable scaffold

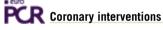
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Aims: To evaluate the role of frequency domain optical coherence tomography (FD-OCT) in guiding PCI procedures with biodegradable vascular scaffold (BVS) implantation.

Methods and results: The indications for OCT examination, parameters assessed and subsequent changes in the procedural strategy were retrospectively analysed in order to describe how OCT was used to guide the procedure. Out of 36 patients 47 consecutive lesions (AHA class B2 or C) were treated with BVS under OCT guidance. Almost all the patients presented with stable angina (94.4%). The mean lesion length was 20.2 mm and the left anterior descending (LAD) was the vessel more frequently treated. Procedural data showed an high predilatation balloon/artery ratio (1.1) and high post dilatation inflation pressure (21.1±3.1 atm). Seventy-seven OCT pullback were performed. No technical failure or adverse events were reported. The most frequent indication for OCT examination was post stenting assessment (n 56; 72.7%) leading to further post dilatation because of BVS underexpansion in 28 (59.6%) lesions. Eighteen pullback were performed before treatment in mainly order to size the predilatation balloon and the scaffold.

Conclusions: In our experience OCT was safe and effective in guiding PCI with BVS implantation. This technique provided crucial information for correcting scaffold under-expansion not evident on the angiogram. Real world BVS evaluation along with growing operators' experience in the field will foster even more our understanding on scaffold's technical performance. Operators should be encouraged to use OCT guidance in challenging anatomical settings in order to achieve high technical success rates with this novel device and shed more light on the mechanisms of BVS failure. A larger series of patients are expected to be enrolled and presented at the time of the EuroPCR congress.



Euro14A-MA066

Anatomic and functional outcome 12 months after bioresorbable scaffold implantation for the treatment of acute coronary syndromes

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Aims: Data on the periprocedural and short-term outcome after implantation of bioresorbable scaffold (Absorb, Abbott Vascular) in the setting of acute coronary syndromes have been previously reported by our group and others. We describe the 12-months morphologic (optical coherence tomography, St Jude) and function outcome.

Methods and results: Thirty-seven Patients (62±13 years old, 32 males, 2 diabetics) underwent coronary angiography at 12 months after scaffold implantation in thrombotic plaques (8 unstable angina, 14 NSTEMI, 16 STEMI). Optical coherence tomography was performed in all vessels; endothelial function (intracoronary infusions of three different doses of acetylcholine) and endothelium-independent vasodilation (intracoronary nitroglycerin, 200 microgr) were tested in 30 patients. The culprit lesion was identified in all cases. The minimum thickness of the fibrous cap covering the lesion was 0 to 550 micrometer (mean 220±114 microm). Incomplete scaffold expansion was evidenced in 7 cases and malapposition in 8. The minimum lumen area was 2 to 11 mm². There were 3 cases of in-scaffold restenosis, all due to incomplete expansion, all treated with re-PTCA and implantation of a metallic stent. At least one dose of acetylcholine caused vasodilation >3% in 17 lesions, and vasoconstriction in 10. Nitroglycerin caused vasodilation in 15 lesions (%change in diameter in response to acetylcholine 1: 0.7±6.1 (-10.2 to 13.6)%; acetylcholine 2:1.3±6.2 (-12 to 18)%; acetylcholine 3: 0.2±7.3 (-11 to 27)%; nitroglycerin:4.6±6.9 (-6.9 to 26)%). A combination of fibrous cap thickness >150 micrometers associated with acetylcholine-induced vasodilation was seen in 8 lesions.

Conclusions: 12 months after scaffold implantation, the majority of lesions was sealed by a fibrotic cap, suggesting anatomical stabilisation of the plaque. Physiological endothelium-dependent vasodilation was observed in about half of the cases. A combination of the two, demonstrating a structural and functional normalisation of previously ruptured plaques, was seen however in a minority of cases.

OCT guided bioresorbable scaffold implantation - A path towards optimisation of results

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Aims: The newer intravascular imaging modalities are proven to be essentiatial for optimal stent deployment. The aim of this study is to access the results of BVS implantation guided by OCT as compare to cine angiography and quantative coronary angiography (QCA).

Methods and results: The total of 52 cases (January to October 2013) underwent BVS (Abbott Vascular, Santa Clara, USA) implantation and were assessed by OCT (C7, 6 Fr compatible dragon fly catheter). The QCA and cine angiography was done with Phillips FD 10 Allura catheterisation laboratory machine. Post procedure the Stent Boost was done for all cases, marker to marker overlap checked by Stent Boost and fluoroscopy. The OCT was found to be superior to cineangiography for assessment of lesion characteristics. Edge dissections were more commonly seen in OCT but significant dissections required stenting in only 4.9% cases. The under expansion or malapposition of stent needed high pressure dilatation was noted in 36% cases as compared to cineangiography in 22.9% cases. The observed limitation of OCT were required more contrast injections which can increase risk of nephropathy, more procedural time and poor tissue penetration. The three days in hospital and 30 days follow-up we observed 0% event rates i.e. death, stent thrombosis, myocardial infarction, target vessel revascularisation and emergency need of CABG.

Conclusions: Preparation of vascular bed with NC balloon pre dilatation of vessel is necessary prior to BVS deployment. The post procedure high pressure dilatation with large sized NC is also crucial for optimal results. Pre procedure OCT helps access vessel diameter and lesion characteristics. The post procedure OCT has edge over cineangography to evaluate edge dissection, stent expansion, malapposition and thrombus identification. The OCT guided BVS implantation is safe and results in better outcomes in a large vessel diameter and good opposition of stent struts to the vessel wall. The outcomes of OCT guided BVS implantation are better. The limitation of this study is the small number of cases and more longer-term follow-up is necessary.



Euro14A-MA068

Bioresorbable scaffolds acute performance in the real-world: insightful OCT analysis of scaffold expansion and new phenomenon

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Aims: Everolimus-eluting bioresorbable vascular scaffolds (BVS) demonstrated promising results in highly selected populations, however little is known of its performance (i.e., expansion) in the "real-world" clinical setting. Therefore, this study sought to evaluate the acute BVS-vessel interactions using optical coherence tomography (OCT).

Methods and results: Consecutive patients who underwent de novo PCI with a single BVS implantation/lesion, followed by OCT assessment at out hospital were included in this study. The predicted area (derived from the predicted diameter) according to the deployment pressure provided in the compliance chart of each scaffold was recorded and compared with actual area in all analysed cross-sections. Qualitative plaque assessment was performed by dividing each cross-section into 4 quadrants, with each quadrant being labelled according to its most prevalent plaque component, as follows: normal, fibrous, calcified, and lipid plaque. Cross-sections were divided in tertiles of expansion (Actual Area/Predicted Area <70%, 70% ≤Actual Area/Predicted Area ≤80%, and Actual Area/Predicted Area >80%) and plaque components were quantified and compared among the tertiles. A total of 28 patients (31 BVS) were included and 663 cross-sections (0.4% of exclusions due to the presence of residual blood impairing the analysis) were analysed. The presence of calcified plaque was significantly more common in the lowest (9.7%) compared with the mid (8.8%) and highest (6.3%) tertiles of scaffold expansion (p=0.003 and p=0.001 for lowest vs. mid, and lowest vs. highest, respectively). Conversely, a progressive increase in the percentage of lipid (i.e., soft) plaque was revealed in lowest (8.9%), mid (14%), and highest (17.1%) tertiles of expansion (p=0.229 and p=0.445, respectively). Seventeen (54.8%) scaffolds were elongated (i.e., actual length longer than the predicted length) after implantation. The mean elongation percentage was 8.0%. Higher rates of calcified plaque (13.44±21.09% vs. 2.51±4.43%, p=0.309) and lower percentage of lipid plaques (6.67±8.04% vs. 21.30±23.46%, p=0.250) were identified, respectively, although not statistically significant in elongated compared with non-elongated (N=14) scaffolds. No adverse events were observed among these two groups. The potential clinical implications of BVS elongation could be, as follows: 1- missing adequate position in ostial lesions (i.e., extending the scaffold to the left main without intention to do so), 2- longer than predicted overlapping segments, and 3- landing the stent in a diseased segment (i.e., adjacent to the normal target landing

Conclusions: From the analysis of real-world population, 1- Compliance chart information is unreliable to optimise BVS PCI results, 2- Calcified plaques may impair adequate BVS expansion, and 3- BVS may elongate after deployment.

Do biodegradable ABSORB stents offer the same acute results of second generation metallic stents in complex lesions? Insights from 100 matched OCT studies

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Aims: Thick polymer-based BVS have different mechanical properties than thin second generation DES. Data on acute performance of BVS are limited to simple coronary lesions treated in trials with strict inclusion criteria. The aim of our study was to compare the acute performance of the PLLA ABSORB Bioresorbable Vascular Scaffold (BVS) with second generation metallic drug-eluting stents (DES) in complex coronary artery lesions.

Methods and results: Fifty complex coronary lesions (all type ACC/AHA B2-C) treated with BVS undergoing a final optical coherence tomography (OCT) examination were compared to an equal number of matched lesions treated with second generation DES. The following stent performance indices were assessed with OCT: mean and minimal area, residual area stenosis (RAS), incomplete strut apposition (ISA), tissue prolapse, eccentricity index, symmetry index, strut fracture and edge dissection. One-hundred lesions from 73 patients were analysed. A higher balloon diameter/reference vessel diameter ratio was used for predilatation in the BVS group (p<0.01). Most of BVS and DES were post-dilated with short non compliant (NC) balloons of similar diameter. OCT showed in the BVS group a higher tissue prolapse area (p=0.08) and greater incidence of ISA at the proximal edge (p=0.05) with no difference in the overall ISA. The RAS was 20.2% in the BVS and 21.7% in the DES (p=0.32). The minimal and mean lumen area were similar in the two groups. Two cases of strut fractures occurred after BVS while none was observed in DES.

Conclusions: Based on OCT BVS showed similar acute performance to second generation DES. The different approach for lesion preparation and routine use of OCT guidance during BVS expansion may have contributed to this favourable acute mechanical performance.



Euro14A-MA070

The effect of coronary artery plaque composition, morphology and burden on absorb bioresorbable scaffold expansion and eccentricity - A detailed analysis with OCT

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Aims: Suboptimal stent expansion is known to correlate with future adverse cardiac events. There is currently limited information regarding Absorb bioresorbable vascular scaffold (BVS) expansion characteristics. Optical coherence tomography (OCT) allows for high-resolution assessment of plaque morphology and composition as well as assessment of BVS expansion. This study evaluates coronary plaque composition, morphology and burden and their effect on Absorb BVS expansion using optical OCT.

Methods and results: Twenty OCT-guided BVS implantations in patients with unstable angina pectoris were examined. 200 μm longitudinal cross-sections of each BVS were analysed for lumen contours and plaque characteristics. The relationship between each plaque characteristic and Scaffold Expansion Index (SEI) or Scaffold Eccentricity Index (SEC) were analysed by repeated measures ANOVA. 2,334 frames totalling 462.6 mm of BVS were analysed. 44 fibrous and 265 calcific plaques were identified. A lower SEI was significantly associated with greater calcific plaque (CP) area (mean SEI 78.9% vs. mean SEI 80.0%, p<0.001), thickness (78.5% vs. 80.4%, p<0.001) and lower CP depth (78.3% vs. 80.2%, p<0.001). A lower SEC was significantly associated with larger fibrous plaque (FP) area (0.84 vs. 0.85, p<0.001), thickness (0.83 vs. 0.86, p<0.001), arc angle (0.84 vs. 0.85, p<0.001), greater calcium plaque area (0.83 vs. 0.86, p<0.001), CP thickness (0.83 vs. 0.86, p<0.001), CP angle (0.84 vs. 0.85, p<0.001) and lower CP depth (0.84 vs. 0.85, p<0.001). Greater FP area was associated with greater SEI (81.0% vs. 80.0%, p<0.001), even after adjustment for target vessel size. Greater FP angle (80.7% vs. 78.3%, p<0.001) and quadrants occupied were also associated (80.0% vs. 78.5%, p>0.002) with greater SEI.

Conclusions: BVS expansion and eccentricity are significantly impacted by plaque composition, morphology and burden.



Vascular responses at the edges of the DESolve novolimus-eluting bioresorbable scaffold: serial OCT observations from the pivotal, prospective, multicentre, DESolve NX study

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Aims: Lumen loss and significant qualitative plaque changes, particularly an increase in fibro-fatty tissue components, have been demonstrated at the edges (5-mm distal and proximal) of metallic drug-eluting stents. Polymeric bioresorbable scaffolds (BRS) have different biological behavior in comparison to metallic stents. In the current study, we sough to investigate the vascular responses at the edges of the DESolve PLLA-based novolimus-eluting BRS.

Methods and results: The DESolve NX study enrolled 126 patients treated with the DESolve BRS. Six-month invasive OCT was performed in 40 patients. Serial (baseline and 6 months) OCT images were available for 38 patients. Quantitative and qualitative changes in the 5-mm distal and proximal scaffold edges were examined by OCT at 0.6-mm interval. Overall, 37/38 (97.4%) distal and 34/38 (89.5%) proximal edges had suitable serial OCT images for analysis. No significant changes were observed in the lumen areas at both the distal (lumen area change: -0.32±8.14% (95% CI: -2.44 to 2.56, p=0.671) and proximal (lumen area change: -3.03±12.12% (95% CI: -7.21 to 1.50, p=0.085) edges over the course of 6 months. Lipid-rich plaques were seen in 17 (23.9%) out of the total 71 analysed edges at baseline [4/37 (5.6%) at distal edges and 13/34 (38.2%) at proximal edges]. At 6 months, lipid plaques were still evident 17 edges. However, significant reductions in the longitudinal (-0.57±0.79 mm; 95% CI: -0.97 to -0.16, p=0.006) and circumferential (-20.81±18.01 degrees; 95% CI: -30.07 to -11.55, p=0.001) distribution of lipid plaques were observed from baseline to 6 months. In addition, a significant increase in mean fibrous cap (FC) (129.41±52.97 μm; 95% CI: 102.17 to 156.64, p<0.0001) and minimum FC (88.23±57.57 μm; 95% CI: 58.63 to 117.84, p=0.001) thicknesses were also observed up to 6 months. No new lipid plaque developed from post-procedure to 6 months.

Conclusions: The DESolve novolimus-eluting BRS demonstrated favourable vascular responses at the adjacent segments outside the scaffolded area. Lumen area was maintained over the course of 6 months, without signs of constrictive remodeling. No signs of lipid accumulation were seen up to 6 months. Indirect signs of lipid plaque stabilisation were identified, as translated by reduction in lipid longitudinal and circumferential distribution and increase in the protective FC thickness. Whether these favourable plaque compositional changes were a direct consequence of the vascular response to the polymeric scaffold or due to better medical therapy adherence is a matter of further investigation.



Euro14A-MA072

OCT assessment of the mid-term vascular healing response following everolimus-eluting bioresorbable scaffold implantation in myocardial infarction. The bioresorbable scaffolds STEMI-FIRST OCT study

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Aims: Bioresorbable vascular scaffolds are a novel treatment for obstructive coronary lesions aiming to reduce late stent complications observed in metal stents. The everolimus-eluting bioresorbable scaffold has demonstrated a favourable healing response in patients with stable disease with low incidence of incomplete strut apposition and high coverage rates, in the absence of overt neointimal proliferation. Acute implantation imaging analysis showed encouraging results, however, the vascular healing response after bioresorbable scaffold implantation in myocardial infarction has not been studied yet. We aimed to assess the vascular healing response by optical coherence tomography (OCT), 6 months after implantation of everolimus-eluting bioresorbable scaffold in patients with ST-elevation myocardial infarction (STEMI).

Methods and results: The BVS-STEMI-FIRST OCT study is a single-centre single-arm, investigator-driven pilot cohort study. A total of 30 patients previously admitted with STEMI and treated with everolimus-eluting bioresorbable scaffold at the index procedure are intended to be enrolled. Patients will be followed clinically for the occurrence of adverse cardiovascular events and are scheduled to undergo coronary artery catheterisation with OCT study of the scaffolded vessel. The primary endpoint is the incidence of incomplete strut apposition and strut coverage at 6-month follow-up by invasive coronary imaging with OCT. Additional imaging endpoints include morphometric scaffold and vessel measurements, healing score, incomplete strut apposition distance and volume, neointimal thickness and area, coverage thickness, reduction in black core area, and late strut discontinuity. Clinical endpoints include death (cardiovascular and all-cause), reinfarction, target lesion revascularisation and stent thrombosis, as well as composites of these events. Quantitative angiographic analysis will also be performed with angiographic endpoints including late loss and binary restenosis. So far, 25 patients have been enrolled. Enrolment and image analysis is ongoing and results will be presented at the time of the meeting.

Conclusions: The BVS-STEMI-FIRST OCT study is a single-centre single-arm, investigator-driven pilot cohort study aiming to provide hypothesis-generating observations about the healing response of bioresorbable scaffold in myocardial infarction. Detailed results of the study will be presented at the time of the meeting.



Optical frequency domain imaging guidance for coronary stent implantation in comparison with intra ultrasound guidance

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Aims: Intravascular ultrasound (IVUS) has been used as a guidance of stenting. Optical Frequency Domain Imaging (OFDI) has high resolution and superimposed technology on cineangiogram. The aim of this study was to assess the fesibility of OFDI-guided stent implantation.

Methods and results: Total of 25 *de novo*, consecutive, elective stenting lesions (22 patients) were enrolled in this study. OFDI and IVUS images were recorded before intervention. IVUS images were blinded for operators. Stent implantation was performed under OFDI-guidance alone. IVUS confirmation was performed after the procedure and further treatment was permitted based on IVUS results. One-month after the procedures, strategy of stent deployment was re-built by the same operator with the IVUS record before intervention. Selected stent length and diameter were equal between OFDI-guidance and IVUS-guidance (O;23.8 mm vs. I;23.3 mm, p=0.53, O;3.38 mm vs. I;3.33 mm, p=0.41). The selected landing point difference of OFDI-guidance and IVUS-guidance were 1.8 mm at proximal edge and 0.8 mm at distal edge. Distal protection device was deployed 4 cases according to OFDI images. Additional inflation was performed after final IVUS in 2 cases. There was no complication (perforation, slow-flow/no-flow, dissection to need additional stenting) during procedure and no in-hospital MACE (death, QMI/nonQMI, subacute stent thrombosis).

Conclusions: OFDI-guidance is comparable to IVUS-guidance for elective stent implantation.



Euro14A-MA074

Operator assessed supportive value of stent strut segmentation and short movie loop presentation in 3D OCT imaging

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Aims: We aimed to investigate if on-line capable 3D OCT segmentation of stent struts or short 3D OCT movie loop presentation are perceived as aiding factors for spatial perception of stent struts when rendered directly from high longitudinal resolution OCT pullbacks.

Methods and results: A clinical dataset of 5 frequency-domain OCT (Ilumien Light lab, St. Jude, USA) scans acquired at 10 mm/s and 9 scans at 15 or 20 mm/s, (Lunawave, Terumo, Jp) of segments stented with bioresorbable vascular scaffold or metallic stents were analysed by dedicated OCT software for on-line 3D reconstruction. The region of interest was rendered in 3D both directly and with stent segmentation and enhancement. Still images and movie loops of the reconstructions were graded for best visualisation by three senior operators with clinical 2D-OCT experience but limited 3D OCT knowledge. Compared with stent enhanced 3D OCT still images, 3D OCT still images without stent enhancement were graded superior in 9 (64.3%), 11 (78.6%) and 13 (92.9%) cases out of 14 by operator A, B and C respectively. Short 3D OCT movie loops improved visualisation in 13 (92.9%), 14 (100%) and 13 (92.9%) cases compared with still images, and in 8 (57.1%), 8 (57.1%) and 13 (92.9%) cases compared with stent-enhanced 3D OCT movie loops.

Conclusions: On-line feasible 3D OCT movie loops improved spatial perception of stent strut positions compared with 3D OCT still images. Segmentation and 3D rendering of stent struts did not improve interpretation of still images and movies compared to fast, high quality 3D rendering of high longitudinal resolution OCT pullbacks.



Euro14A-MA075

Outcomes of everolimus-eluting stent incomplete stent apposition: a serial OCT analysis

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Aims: The aim of the present study was to evaluate the natural course of acute incomplete stent apposition (ISA) after second-generation everolimus-eluting stent (EES) as compared with first-generation sirolimus-eluting stent (SES) by using OCT.

Methods and results: From the OCT sub-study of the RESET trial, we identified 77 patients (EES=38 and SES=39) who successfully underwent serial OCT examination at post-stenting and 8-12 months follow-up. The presence of ISA was assessed in the OCT images, and ISA distance was measured from the centre of the strut blooming to the adjacent lumen border. ISA was observed in all EES and SES at post-stenting, and it was persistent in 26% of EES and 38% of SES at 8-12 months follow-up. Maximum ISA distance was significantly decreased during follow-up period in both EES (315±94 μm to 110±165 μm, p<0.001) and SES (308±119 μm to 139±194 μm, p<0.001). Receiver-operating curve analysis identified that the best cut-off value of OCT-estimated ISA distance at post-stenting for predicting late-persistent ISA at 8-12 months follow-up in EES and SES was >355 μm and >285 μm, respectively.

Conclusions: The second-generation EES showed better healing of acute ISA in comparison with the first-generation SES. OCT can predict late-persistent ISA after DES implantation and provide useful information to optimise PCI.



Euro14A-MA076

Comparison between the cobalt-chromium everolimus-eluting metallic stent (EES) and platinum-chromium EES using OCT at 8-month follow-up

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Aims: Current 2 different everolimus-eluting metallic stents (EESs) have a feature of the same durable polymer but the different platform alloy, cobalt-chromium (CoCr) or platinum-chromium (PtCr). However, there have been not many reports in comparison with both these stents. The aim of this study was to evaluate the stent performances between CoCr-EES and PtCr-EES by optical coherence tomography (OCT).

Methods and results: 68 CoCr-EESs in 56 patients (group C) and 24 PtCr-EESs in 19 (group P) were enrolled in this retrospective study. There were no significant differences in clinical and procedural characteristics between both groups except for the larger HbA1c levels (NGSP) in group C (6.8 vs. 6.1%, P<0.05). Non-restenotic and non-overlapped 14,401 stent struts of 1,377 cross sections in group C and 5,297 of 522 in P were evaluated by OCT at 8 months follow-up after stent implantation. The thinner neointimal thickness (NIT), the lower percentage of uncovered struts (%US), and the lower frequency of malapposed struts (%MS) were seen significantly in group C compared with P (91.0 \pm 74.4 vs. 112.2 \pm 111.0 μ m, P<0.01; 13.4 vs. 21.5%, P<0.01; 2.3 vs. 3.1%, P<0.01, respectively). Moreover, both the NIT without US and that without MS were also thinner in group C than P (105.0 \pm 70.2 vs. 143.0 \pm 106.3 μ m, P<0.01; 92.7 \pm 74.4 vs. 115.5 \pm 111.1 μ m, P<0.01, respectively). However, there were no significant differences in the average of NIT area and %NIT area assessed by a serial cross-sectional analysis between group C and P (0.81 \pm 0.38 vs. 0.86 \pm 0.58 mm², P=NS; 13.9 vs. 16.0%, P=NS, respectively).

Conclusions: The results of an OCT analysis in this study revealed that the NIT, the US, and the MS were favourable to CoCr-EES rather than PtCr-EES. Those of an OCT cross-sectional analysis, however, showed the NIT area and %NIT area were significantly not different among both groups.



Euro14A-MA077

Randomised comparison of a biolimus-eluting biodegradable polymer stent and a sirolimus-eluting durable polymer stent - Serial matched analysis by OCT

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Aims: First generation drug-eluting stents have been associated with late adverse vessel wall features and increased risk of stent thrombosis. Use of drug-eluting stents with a polymer which is degradable within the first year may be associated with a more favourable vessel wall response at one-year follow-up.

Methods and results: In this sub-study of the randomised comparison of the biolimus-eluting biodegradable polymer Nobori stent (Terumo, Japan) versus the sirolimus-eluting durable polymer Cypher Select+ stent, (Cordis, US), the SORT-OUT V study, serial optical coherence tomography (OCT) analysis was performed at baseline and 12 month follow-up and analysed by two observers, blinded and with frame level matching. A total of 123 patients were included in the OCT study. Of these, 2 patients died, two had coronary events with no OCT acquired and 23 were excluded due to drop out, contraindications to follow-up OCT, or poor image quality. Serial OCT was available in 96 patients, 45 Nobori, and 51 Cypher treated patients. Indication for PCI was STEMI in 31% vs. 45% in Nobori vs. Cypher. Primary endpoint was percentage of cross sections with more than 1/3 uncovered struts in Nobori vs. Cypher treated patients (to be presented at EuroPCR14). Neointimal thickness (NIT) was 0.18±0.06 vs. 0.17±0.05 (p=0.63) in Nobori vs. Cypher. Persistent clustered malapposition was found in 5 (11%) vs. 8 (16%) of patients (p=0.51), and late acquired clustered malapposition was found in 1 (2%) vs. 3 (6%) (p=0.37) in Nobori vs. Cypher treated patients. Increased extra stent lumen with at least moderate aneurysm formation (evaginations) was detected in 6.7% vs. 23.5% (p=0.02) of Nobori vs. Cypher stented patients.

Conclusions: By serial 12-month OCT assessment, the biolimus-eluting biodegradable polymer Nobori stent had more favourable vessel wall response than the sirolimus-eluting durable polymer Cypher Select+ stent. The 12-month healing of acute incomplete stent apposition was similar for the two stents.



Euro14A-MA078

L/H ratio predicts the rate of uncovered stent strut evaluated by OCT

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Aims: In patients after implantation of second generation, drug-eluting stent (DES), although the stent restenosis tends to have reduced, at the expense of uncovered stent struts. These are involved with very late stent thrombosis and require dual anti-platelet therapy. Optical coherence tomography (OCT) imaging can clearly visualise stent apposition and neointimal coverage of stent struts. The aim of this study is to evaluate the uncovered stent struts which are estimated by OCT as they may predict the duration of DAPT.

Methods and results: We investigated stent struts coverage of everolimus-eluting stent (EES) or biolimus A9-eluting stent (BES) after 6 months using OCT. Thirty-five consecutive patients (29 males/ 6 females, 69±8 y.o) were researched to receive either EES (n=15) or BES (n=20). We evaluated the stent apposition, stent coverage and neointimal thicknesses (NIT). OCT images were acquired successfully. The mean percentages of uncovered stent struts were 8.6% for EES versus 11.9% for BES (P=0.30). There were no significant differences of completely apposed and malapposed stent struts and NIT. The frequency of uncovered stents struts were related LDL/HDL ratio (L/H ratio). In both group, the higher the L/H ratio the more the uncovered struts increased. Especially, in EES group, there is a correlation between L/H ratio and the uncovered stent struts. (correlation coefficient=0.53, P=0.03). In patients with BES, L/H ratio demonstrated a trend toward the ratio of uncovered stent struts (correlation coefficient=0.48, P=0.03).

Conclusions: EES and BES showed the rate of uncovered stent strut is equal at 6 months after stent implantation. We suggest that L/H ratio can predict the rate of uncovered stent struts.



Euro14A-MA079

Side branch healing patterns of a dedicated coronary bifurcation stent: a oneyear OCT follow-up study

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Aims: The bare-metal Tryton Side Branch (SB) StentTM (Tryton Medical, Durham, NC, USA) is used with a drug-eluting stent (DES) in the main branch (MB) to treat bifurcation lesions. More insights in neo-intimal hyperplasia (NIH) growth patterns of the Tryton treatment strategy are necessary to decide if the device needs to be drug-coated and, even more importantly, on which part of the stent in order to improve the device further.

Methods and results: Ten patients treated with the Tryton side branch stent in combination with Xience DES in the MB returned for follow-up angiography. During angiography, optical coherence tomography (OCT) pullbacks were obtained from the MB and side branch (SB). QCA measurements were performed pre-, and post-stenting and during follow-up using dedicated bifurcation software (QAngioXA version 7.3, Medis, Leiden, The Netherlands). A per-strut OCT analysis was performed including the NIH thickness per-strut and the assessment of incomplete apposition and strut coverage. Successful OCT-pullback from the MB was obtained from all patients and from the SB in six patients. In-stent minimal lumen diameters (MLD) of the proximal part of the MB DES, distal part of the MB DES, and the Tryton SB part were 1.15±0.67, 1.21±0.60, and 1.03±0.54 mm, respectively pre-procedural, and 3.09±0.60, 2.43±0.42, and 1.92±0.30 mm, respectively post-procedural, resulting in acute gains of 1.78±0.94 (proximal MB), 1.18±0.45 (distal MB), and 0.81±0.42 mm (SB). During follow-up, MLDs were 2.81±0.56, 2.19±0.49, and 1.43±0.33 mm, respectively, resulting in late luminal loss (LLL) of 0.27±0.31, 0.24±0.28, and 0.49±0.32 for the proximal MB, distal MB and SB, respectively. OCT analyses showed overall an uncovered strut rate of 0.7% and an incompletely apposed strut rate of 0.8%. Most incompletely apposed struts were found at the bifurcation region, in the luminal half facing towards the SB (6.2% of all struts in that region were incompletely apposed). Average per-strut NIH thickness in the proximal MB, distal MB and SB were 0.14±0.11, 0.19±0.11, and 0.34±0.19 mm, respectively. Finally, we observed different growth patterns in the Tryton SB stent part: in one-third of the cases, NIH thickness was on average smaller in the 3 mm closest to the carina compared with the distal (>3 mm) SB stent part; in another one-third of the cases, NIH thickness was larger in the <3 mm compared to the distal part. In the remaining cases, NIH thickness was equal

Conclusions: We found that vascular healing of the bare-metal Tryton in the SB was less favourable than the vascular healing of the DES in the MB, although this healing response is comparable with historical data on conventional BMS. Furthermore, Tryton use did not influence healing responses of the Xience everolimus-eluting DES in the MB (MB DES healing was comparable with historical data on DES healing), including the proximal MB region where both stents overlap. Lastly, we found different NIH growth patterns within the SB which might be taken into account when the device is further improved by drug-coating.



Euro14A-MA080

Neointimal maturity after bioresorbable polymer-based sirolimus-eluting and permanent polymer-based everolimus-eluting stents implantation assessed by OCT

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Aims: We previously reported that optical coherence tomography (OCT) gray-scale signal intensity (GSI) analysis can differentiate between stent coverage with mature tissue (smooth muscle cell-rich) versus immature tissue (hypocellular fibrin-rich). Utilizing this technique, we compared neointimal maturity at 9 months among bioresorbable polymer-based sirolimus-eluting Orsiro and permanent polymer-based everolimus-eluting Xience Prime stents in patients enrolled in the BIOFLOW II study.

Methods and results: BIOFLOW II was a 2:1 randomised trial comparing the performance of the ORSIRO versus the Xience Prime DES for the treatment of *de novo* coronary lesions. Of 54 patients included in the OCT substudy, 38 patientshad OCT raw data available and were eligible for GSI analysis. Offline analysis of contiguous cross-sections was performed at 1 mm longitudinal intervals within the stented segment. For each cross-section the neointimal region of interest (ROI) above each stent strut was manually delineated and 256-level GSI was measured for every pixel within the ROI. Overall 38 lesions (27 with Orsiro, 11 with Xience Prime) and 3,772 ROIs (3,501 ROI with Orsiro, 1,271 with Xience Prime) were analysed. Tissue coverage was classified as mature or immature according to mean OCT GSI using a cut-off value of 91.6 that was previously established. Estimated maturity was 58.8% [95% CI: 13.5-92.9%] in Orsiro and 64.2% [95% CI: 8.9-97.0%] in Xience Prime (p=0.62).

Conclusions: At 9 months after DES implantation approximately 60% of stent tissue coverage can be classified as mature. There were no significant differences in the rate of mature tissue coverage between Orsiro and Xience Prime. Future studies should examine changes in tissue maturity over time.

Assessment of coronary artery calcification by conventional fluoroscopy. A very simple and inexpensive way to predict coronary revascularisation in patients scheduled for routine coronary angiography

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Aims: To test the ability of semiquantitative assessment of coronary artery calcification by conventional fluoroscopy to detect coronary artery disease (CAD) and predict coronary revascularisation in patients scheduled for routine invasive angiography due to suspected or known CAD. To date, cardiac computed tomography angiography (CCTA) is the clinical gold standard technique for the quantification of coronary calcium. However, such equipment is not available in every small peripheral hospital, so that in such a setting fluoroscopy may be a useful alternative for assessment of coronary calcification.

Methods and results: Between September 2012 and June 2013, 262 consecutive patients underwent invasive coronary angiography due to suspected or known CAD. Patients with previous revascularisation by PCI or CABG were excluded from analysis. Evaluation of coronary calcification was performed using standard projections (right anterior oblique (RAO) 30° and left anterior oblique (LAO) 40°) and a semiquantitative scale: 0=no; 1=minimal, 2=mild, 3=moderate and 4=severe coronary calcification (calcification score 0-4). Conventional atherogenic risk factors were registered and a risk score was built in every patient including the presence of 1: age ≥70 years, 2: male gander, 3: arterial hypertension (blood pressure ≥140/90 mmHg or antihypertensive therapy), 4: hyperlipidaemia (triglycerides≥190 mg/dL, LDL-cholesterol≥115 mg/dL or antilipidaemic treatment), 5: diabetes mellitus (HbA1c>6.5% or antidiabetic treatment), 6: typical angina at clinical presentation and 7: ST segment depression at stress ECG (conventional atherogenic risk score 0-7). The presence of significant CAD (≥75% stenosis) by angiography and subsequent revascularisation procedures were registered. 154 (59%) patients were male and mean age was 68±13 years. 81 patients (31%) showed typical angina and 79 (30%) had diabetes mellitus. Coronary calcification was absent or minimal in 146 (56%) patients, whereas 65 (25%), 30 (11%) and 21 (8%) exhibited mild, moderate and severe calcification, respectively. After coronary angiography 108 (41%) patients underwent coronary revascularisation by PCI (n=89) or CABG (n=19). Semiquantitative assessment of coronary calcification exhibited significantly higher accuracy for the prediction of subsequent coronary revascularisation compared to the conventional risk score (ΔAUC=0.16; SE=0.04; z-factor=4.2, p<0.001). Similar results could be obtained for the estimation of stenosis ≥75% (ΔAUC=0.15; SE=0.04; z-factor=3.8, p<0.001). Of patients with absent or minimal calcification n=27 (19%) underwent subsequent revascularisation, compared to n=81 (70%) of those with mild or higher grade coronary calcification (p<0.001 for proportions). Conclusions: Semiquantitative assessment of coronary artery calcification by conventional fluoroscopy seems to be a practical, non-invasive and extremely inexpensive technique for the assessment of coronary calcification, surpassing the ability of regular clinical algorithms to predict significant CAD. Patients with mild or higher grade calcification by fluoroscopy exhibit a very high rate of subsequent revascularisation procedures.

Coronary interventions

Euro14A-0P002

In vitro validation of two bifurcation algorithms of quantitative coronary angiography in calibrated phantoms: comparison with a CAAS system and with a QAngio XA

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Aims: Quantitative coronary angiography (QCA) algorithms dedicated for bifurcation lesions has been developed to overcome the limitations of single vessel analysis. The purpose of the study is to validate two bifurcation software in the calibrated phantom models.

Methods and results: Six plexiglas phantom were designed, each of them mimicking a coronary vessel with three successive bifurcation lesions, wherein at least one vessel segment had a percent diameter stenosis (%DS) of >60%. The five most frequently occurring Medina classes (1,1,1), (1,1,0), (0,1,0), (0,1,1) and (1,0,0) were used in the design. The direction of the side branch relative to the main vessel was based on relevant literature. The phantoms were precision manufactured using computer-aided design and machining techniques. Because of the high drilling accuracy (within 10 um), the 3D luminal surface description of the phantom could be used to determine the true lumen dimensions values of the final geometry. The phantoms were filled with 100% contrast agent and imaged with a biplane gantry. The angiography of bifurcation was analysed using the Cardiovascular Angiography Analysis System (CAAS 5.10, Pie Medical Imaging, Maastricht, The Netherlands) and QAngio XA software package (Version 7.3, Medis Medical Imaging System BV, Leiden, The Netherlands) for two dimensional bifurcation segmental analysis including the edge segments analysis. In OAngio XA software, the two bifurcation models (T-shape and Y-shape) are available. Selection of the algorithms was automatically done by the software. Minimal lumen diameter (MLD), reference vessel diameter (RVD), percent diameter stenosis (%DS) of proximal main vessel (PMV), distal main vessel (DMV) and side-branch (SB) segments were compared with the true values for vessel segments. Bland-Altman plots comparing 54 vessel segments to the phantom values for MLD showed that the limit of agreement for CAAS and QAngio XA were -0.046 to 0.0091 and -0.084 to 0.042 mm, respectively. The average of differences from true values of CAAS and QAngio XA for MLD, RVD, and %DS were 0.013 ± 0.03 mm vs. 0.048 ± 0.03 mm (p=0.44), -0.050 ± 0.05 mm vs. 0.11 ± 0.05 mm (p=0.021) and -0.94% vs. 2.63% (p=0.0002), respectively. In QAngio XA, the differences from the true values of RVD and %DS were in 3 cases quite prominent (1.70 mm >0.08 mm and 43.07% > 0.66%, 3.23 mm > -0.03 mm and 5.32% > -0.32%, 2.62 mm > -0.09 mm and 18.51% > 2.86%) when Y-shape algorithms were automatically applied in Medina class (0,1,0) bifurcation. When T-shape algorithms were used in all cases, the average difference of %DS was reduced up to

Conclusions: Both software measured MLD accurately when compared to the true value dimensions. When two algorithms (T-shape, Y-shape) were selected automatically, QAngio XA demonstrated a higher RVD and %DS than CAAS and the true values. Usage of T-shape algorithms improved the accuracy of RVD and %DS, therefore T-shape algorithm could be recommended as a first choice for bifurcation analysis with QAngio XA system.



The efficacy of stent boost technique during the post-balloon dilatation after stent implantation in reducing the stent-edge restenosis

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Aims: Recently, StentBoost (Philips Electronics) technique enhances the image of coronary stent struts and allows us to recognise the appropriate position of the post-balloon dilatation after stent implantation at the proximal and distal stent edges. However, the efficacy of this technique was not elucidated. The purpose of this study was to evaluate the efficacy of StentBoost technique during the post-dilatation after stent implantation in reducing the stent-edge restenosis after percutaneous coronary intervention (PCI).

Methods and results: Consecutive 581 patients undergoing PCI with Everolimus-eluting stents from 2010 to 2012 in our institution were studied retrospectively. The patients were divided into the following 2 groups: the non-StentBoost group (February 2010-October 2011, n=362) and the StentBoost group (September 2011-October 2012, n=219). Four hundred fifty seven patients underwent follow-up coronary angiography 6-12 months later after the PCI and 796 stent-edge lesions were finally analysed. Restenosis was defined as >50% stenosis detected by quantitative coronary angiography. There was a tendency toward the lower restenosis rate in the StentBoost group compared to the non-StentBoostgroup [1.6% (5/304 lesions) vs. 4.3% (21/492 lesions), respectively, P=0.0627]. At the proximal edge, the restenosis rate was significantly reduced in the StentBoost group compared to the non-StentBoost group [0.99% (3/304 lesions) vs. 3.86% (19/492 lesions), respectively, P=0.033]. At the distal edge, there was no significant difference in the restenosis rate between the two groups [0.66% (2/304 lesions) vs. 0.41% (2/492 lesions), respectively, P=0.9731.

Conclusions: StentBoost technique enables us to perform the appropriate positioning of the post-balloon dilatation after stent implantation, which can reduce the injury at the peri-stent area resulting in the lower rate of the proximal stent edge restenosis.



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Coronary computed tomography angiography in patients with NSTEMI - Diagnosis, treatment strategy and outcome

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Aims: Coronary computed tomography angiography (CCTA) could contribute in the decision of treatment strategy and risk-stratification in patients with non-ST segment elevation acute coronary syndrome. We aimed to assess the diagnostic accuracy and prognostic value of CCTA in patients with non-ST segment elevation myocardial infarction (NSTEMI).

Methods and results: We prospectively included 400 patients presenting with NSTEMI who underwent 64-slice CCTA. CCTAs were evaluated for the presence of obstructive coronary artery disease and compared with invasive coronary angiography. Further the ability of CCTA to place patients in guideline defined treatment groups: no/medical treatment, percutaneous coronary intervention or coronary artery bypass graft, was evaluated. Patients were followed for a minimum of 2 years. The study endpoint was a combination of death, re-hospitalisation due to myocardial infarct, or symptom driven coronary revascularisation. Sensitivity, specificity, positive and negative predictive value to detect ≥50% coronary artery stenosis on a patient basis was 99, 81, 95 and 96% and CCTA defined appropriate treatment strategy in 86%, overestimated in 13% and underestimated in 1% of the patients. During a median follow-up time of 50 months, there were no events in patients without any plaque on CCTA. Using a Cox proportional hazards model adjusting for known risk factors, the presence of an occluded artery by CCTA was associated with adverse outcome, (Hazard ratio: 1.8, Confidence interval 1.1-2.9).

Conclusions: Coronary CT angiography can be used for non-invasive assessment of obstructive coronary artery disease and outcome in patients with acute coronary syndrome, and could guide selection of treatment strategy.



Accuracy of coronary plaque morphology determined by *ex vivo* coronary computed tomography: co-registered with histopathology

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Aims: Previous studies have suggested that coronary computed tomographic angiography (CCTA) can be used to evaluate coronary plaque morphology for future prediction of acute coronary events. However, validation of high-definition CCTA and morphology have been performed. **Methods and results:** 45 coronary arteries from 15 sudden coronary death autopsy cases are available for assessed by *ex vivo* high-definition CCTA and histology. *Ex vivo* CCTA was performed following perfusion fixation of the coronary arteries from the hearts. Arteries were decalcified and processed for histopathology at 3 mm intervals and co-registered with CCTA. A total of 35 CCTA cross sectional images have been co-registered with histopathology sections. Co-registration was achieved using comparison of longitudinally reconstructed images of CCTA and post mortem radiography of the entire coronary tree. Among 35 histological sections, calcification, and lipid pool including necrotic core were observed in 24 (69%), and 19 (54%), respectively. Relative to histopathologic assessment, CCTA demonstrated a high correlation of vessel area (R²=0.60, p<0.001), lumen area (R²=0.58, p<0.001), plaque area (R²=0.69, p<0.001), and calcification area (R²=0.55, p<0.001). Calcification area in CCTA was very similar to that by histology (median 0.3 mm² [0-2.8] vs. 0.33 mm² [0-1.1]). The sensitivity and specificity of calcification, lipid pool or necrotic core, and fibrous plaque by CCTA were 83%, 58%, 71% and 100%, 75%, 89%, respectively.

Conclusions: This study demonstrates that high-definition CCTA is a highly promising tool for the non-invasive assessment of human coronary artery plaque morphology. To our knowledge this is the first high-definition CCTA and histologic correlation of plaque composition showing greater sensitivity and specificity for calcification and fibrous plaque types. Further in depth analysis of the data including subanalysis of low attenuated plaque into <30 HU, less than 60 HU, and less than 90 HU as well as vessels remodeling will be presented during Euro-PCR 2014, which will involve greater number of co-registered sections.



Euro14A-0P006

Final five-year report of the RESOLUTE all-comers randomised study

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Aims: Long-term outcomes of new-generation DES are important because of these devices' wide use and permanence in the patient's vessel. Randomised studies clearly separate the effects of the device from other influences, and all-comers populations can demonstrate whether DES are safe and effective in real-world patients with complex disease. RESOLUTE All Comers was a noninferiority, randomised study of 2 new-generation DES in an all-comers population with follow-up planned through 5 years.

Methods and results: Patients enrolment involved minimal exclusion criteria. Enrolled patients were randomised (1:1) to receive implantation of the Resolute® zotarolimus-eluting stent (R-ZES) or Xience V® everolimus-eluting stent (EES). Dual antiplatelet therapy (DAPT) was prescribed per current guidelines. The primary endpoint was one-year target lesion failure (TLF; cardiac death, target vessel myocardial infarction [TVMI], or clinically-driven target lesion revascularisation [TLR]). Secondary endpoints included the components of TLF and Academic Research Consortium (ARC) definite/possible stent thrombosis. Follow-up was conducted for 5 years. The study met the primary endpoint of noninferiority between R-ZES and EES in TLF at 1 year (respectively, 8.2% and 8.3%, p<0.001). Follow-up data are currently available through 4 years, and the five-year outcomes will be available for presentation at EuroPCR 2014. Clinical outcomes through 4 years were available for 98% of enrolled patients. At 4 years there were no statistically differences between the study stents. The rate of TLF was 15.2% with R-ZES and 14.6% with EES (p=0.679). Cardiac death was 5.4% and 4.7% (p=0.444), TVMI was 5.3% and 5.4% (p>0.99), and TLR was 7.0% and 6.5% (p=0.615) in the R-ZES and EES groups, respectively. DAPT usage was 12% in both groups (p=0.838) at 4 years. The rate of ARC definite/probable stent thrombosis events respectively in R-ZES and EES (p=0.814) from years 1 to 4.

Conclusions: Follow-up rates at 4 years in RESOLUTE All Comers were very high, with a 2% rate of patient attrition. The rates of clinical events and very late stent thrombosis using R-ZES and EES were low through 4 years of follow-up. The results of the RESOLUTE All Comers study indicate that new-generation DES are safe and effective in long-term follow-up. The final five-year report of RESOLUTE All Comers will further advance the understanding of how these devices affect long-term clinical outcomes.



Long-term clinical outcomes of 'complete, reasonably complete, and incomplete' revascularisation after percutaneous intervention of unprotected left main coronary artery disease with DES

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Aims: The study sought to assess the five-year clinical outcomes of complete- (CR), reasonably complete- (RCR), and incomplete- revascularisation (ICR) in patients with unprotected left main coronary artery (ULMCA) disease treated with drug-eluting stents (DES).

Methods and results: This prospective registry enrolled 910 consecutive patients with ULMCA disease undergoing DES implantation. CR included patients who had as successful revascularisation of all diseased segments with diameter ≥1.5 mm (the SYNTAX definition). RCR included patients who did not receive revascularisation for the diseased segments with diameter between 1.5 mm and 2.5 mm. ICR included patients who did not achieve revascularisation for all diseased segments of diameter ≥2.5 mm. The primary endpoint was the incidence of major cardiac adverse event (MACE: a composite of cardiac death, myocardial infarction [MI] and all-cause revascularisation) at five-year follow-up. CR was achieved in 386 (42.4%), RCR in 227 (25.0%), and ICR in 297 (32.6%) patients. Patients with ICR had worst outcomes than those with CR or RCR (MACE: 29.6% vs. 22.5% vs. 15.5%, p<0.001; all-cause death: 12.5% vs. 7.0% vs. 6.2%; p=0.006). After propensity score matching, patients with CR vs. RCR had similar incidences of MACE (Hazard ratio [HR]: 1.16, 95% confidence interval [CI]: 0.78-1.74, p=0.46) and mortality (HR: 1.27, 95% CI: 0.61-2.63, p=0.53). On multivariable logistic regression analysis, ICR appears to be a surrogate marker of clinical characteristics, comorbidities and complex coronary anatomy.

Conclusions: ICR, a marker of poor clinical and anatomical characteristics, is associated with adverse outcomes. Patients achieving RCR have long-term clinical outcomes similar to those achieving CR.



Euro14A-0P008

Outcomes from the largest multicentre prospective registry of DES with bioabsorbable polymer

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Aims: The purposes of the study was to validate the performance of Nobori DES in unselected patients from everyday clinical practice in wide geographic areas, to evaluate worldwide utilisation of DES, to detect rare events in fully representative patient population and to identify predictors of major adverse cardiac events.

Methods and results: E-NOBORI is a prospective, single-arm, multicentre, observational registry enrolling over 8,000 patients (13,052 lesions) across Europe, Asia and Latin-America. All patients in whom treatment with DES was indicated and agreed to participate in the registry were included. All patients were treated by Nobori DES following a local routine practice. Clinical follow-ups were performed at on month, one year and two years. Data were entered electronically and extensively monitored. All adverse events are adjudicated by an independent clinical event committee. The primary endpoint of the study is target lesion failure (TLF) defined as a composite of cardiac death, target vessel myocardial infarction (MI) and clinically driven target lesion revascularisation (TLR). Baseline characteristics showed an average patient age of 63 years, 76% were males, 33% had diabetes mellitus, 73% had history of hypertension, 64% had hypercholesterolemia, 51% were smokers and 8% had renal failure. Previous cardiac history revealed MI in 29% of patients while 37% of patients had undergone earlier revascularisation (PCI 30%, CABG 7%). 10% had past history of STEMI and 18% NSTEMI. Lesion characteristics revealed 12 ostial lesions, 6.3% true bifurcation, 30% calcified lesions, 3.0% chronic total occlusions and 54% complex (defined as type B2 or C) lesions. Thrombus was detected in 11% of lesions. Mean lesion per patient was 2.0 with mean stent per lesion 1.2. Multivessel treatment was performed in 23.5% of the patients. Analysis of clinical outcomes at one year showed 1.2% cardiac death, 1.1% MI, 1.2% TLR, 1.7% TVR, 3.0% TLF and 3.4% TVF. Stent thrombosis was recorded in 0.42% of patients.

Conclusions: E-NOBORI provides the largest "real life" data on clinical outcomes of DES with biodegradable polymer and sheds light on modern PCI practices across continents. Nobori DES showed excellent one-year clinical outcomes in patients, representative of every day practice. Despite the limitations inherent to this type of registry, exceptionally high follow-up rate reinforces the validity of the results. Our findings add further evidence to safety and efficacy of DES with biodegradable polymer.

Stent thrombosis, bleeding and dual antiplatelet therapy: long-term report from the large multicentre e-BioMatrix registry

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Aims: We report for the first time the two-year clinical results from the e-BioMatrix study, an international, multicentre registry, which was designed to evaluate clinical outcomes of patients treated with one or more BioMatrix or BioMatrix Flex drug-eluting stent (DES). The stent is a stainless steel platform, with an abluminal biodegradable polymer coating that releases Biolimus A9, and morphs into a bare metal stent after 6-9 months. While stent thrombosis (ST) has been thoroughly investigated, the incidence and outcome of major bleeding (MB) and its relation to antiplatelet treatment in a real-world population of patients undergoing PCI using contemporary DESs has received far less attention. The study sought to determine the respective impact of stent thrombosis and major bleeding on patient outcome, in the context of dual antiplatelet treatment (DAPT).

Methods and results: From April 2008 to August 2011, 5,653 were enrolled in the study. The analyses were carried out on 5,471 patients who met the inclusion/exclusion criteria. The primary endpoint was Major Adverse Cardiovascular Events (MACE) defined as a composite of cardiac death, myocardial infarction (MI) and clinically-indicated target vessel revascularisation (TVR) at 12 months. Secondary endpoints were MACE at 30 days, 6 months, 2 and 3 years, ARC defined (ST) and total revascularisation rates at 30 days, 6 months, 12 months, 2 and 3 years. DAPT treatment was mandatory for 6 months and favoured up to 12 months. Mean patient age was 63±11 years, 24% of patients were diabetic, 44% presented with unstable angina or NSTEMI, and 35% with acute or sub-acute STEMI. At two-year follow-up, MACE rate was 6.7% (cardiac death 1.5%, MI 2.4%, clinically-indicated TVR 4.2%). 41 patients (0.8%) suffered from at least one definite or probable ST while 108 patients (2%) suffered a MB. DAPT compliance at 2 years was 25%

Conclusions: While ST has now become a rare event, it remains associated with significant mortality. The incidence of major bleeding remains preoccupying, and warrants improved tailoring of DAPT in DES recipients. The complete two-year follow-up analysis will be available at the time of the meeting and will especially focus on the relationship between stent thrombosis, major bleeding, DAPT interruption and mortality associated with both events



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Biodegradable polymer sirolimus-eluting versus permanent polymer everolimuseluting stents in patients with coronary artery disease: five-year outcomes from a randomised clinical trial

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Aims: Both biodegradable polymer siromlimus-eluting stents (SES) and permanent polymer everolimus-eluting stents (EES) offer potential for enhanced late outcomes in comparison with permanent polymer stents. However long-term comparative efficacy data between these devices remains a notable scientific gap. The aim of the current study was to compare the efficacy and safety of biodegradable polymer sirolimus-eluting stents (SES) with permanent polymer everolimus-eluting stents (EES) in patients enrolled in the ISAR-TEST 4 (Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents) trial at five-year follow-up.

Methods and results: In the setting of an investigator-initiated, real-world randomised trial with broad inclusion criteria patients were randomised to treatment with SES (n=1,299) or EES (n=652). The primary endpoint was the device-oriented composite of cardiac death, target vessel-related myocardial infarction (MI), or target lesion revascularisation (TLR). The main secondary endpoint was definite/probable stent thrombosis. Follow-up was performed out to 5 years. Overall there was no significant difference between SES and EES concerning the primary endpoint (20.5% versus 19.5%, hazard ratio=1.04, 95% CI: 0.84-1.29; P=0.71). In terms of safety, rates of definite/probable stent thrombosis (1.2% versus 1.4% respectively; HR=0.83, CI: 0.37-1.91; P=0.67) and cardiac death or target vessel MI (8.9% versus 8.9% respectively; HR=0.99, 95% CI: 0.72-1.37; P=0.97) were similar in both groups. Rates of TLR were also comparable in both groups (13.9% versus 12.6%, hazard ratio=1.11, 95% CI: 0.85-1.45; P=0.46). **Conclusions:** Both biodegradable polymer sirolimus-eluting and permanent polymer everolimus-eluting stents showed comparable long-term clinical outcomes. Rates of stent thrombosis remained low with both stents out to 5 years.

Stent thrombosis in new-generation DES in patients with STEMI undergoing primary PCI

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Aims: To evaluate stent thrombosis (ST) rate up to 3 years in patients with ST-elevation myocardial infarction (STEMI) treated by primary PCI with new generation drug-eluting stents (n-DES) as compared with bare metal stents (BMS) and old generation drug-eluting stents (o-DES) enrolled in the Swedish Coronary Angiography and Angioplasty Registry (SCAAR).

Methods and results: From January 2007 to January 2013, 34,147 patients with STEMI were treated by PCI with n-DES (N=4,811), o-DES (N=4,271) or BMS (N=25,065). The risks of early/late (up to 1 year) and very late definite ST (after 1 year) were estimated. Cox regression landmark analysis showed a significantly lower risk of early/late ST in patients treated with n-DES (Hazard ratio (HR) 0.65; 95% confidence interval (CI): 0.43-0.99, p=0.04) and o-DES (HR 0.60; 95% CI: 0.41-0.89, p=0.01) when compared with the BMS group. The risk of very late ST was similar between the n-DES and BMS groups (HR 1.18; 95% CI: 0.47-2.99, p=0.72), while a higher risk of very late ST was observed with o-DES when compared with BMS (HR 2.29; 95% CI: 1.26-4.18, p<0.01).

Conclusions: Patients treated with n-DES have a lower risk of early/late ST than patients treated with BMS. The risk of very late ST is low and comparable between n-DES and BMS up to 3 years follow-up, while o-DES treatment is associated with an increased risk of very late ST.



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Stent thrombosis after STEMI treated with primary PCI and dual antiplatelet therapy with ticagrelor or clopidogrel

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Aims: Stent thrombosis is a life-threatening. Newer P2Y12 antagonists have been developed to increase safety in patients with acute coronary syndromes. We compared one-year risk of definite stent thrombosis and cardiac death in patients with ST-segment elevation myocardial infarction (STEMI) treated with primary percutaneous coronary intervention (PCI) and dual antiplatelet therapy with aspirin and either ticagrelor or clopidogrel for 12 months.

Methods and results: From June 2010 to June 2012 all patients with STEMI treated with primary PCI at Odense University Hospital were identified from the Western Denmark Heart Registry. From June 2010 to June 2011 the standard dual antiplatelet therapy was aspirin and clopidogrel (600-mg loading dose, 75 mg daily thereafter): "clopidogrel group" and from June 2011 to June 2012 the standard dual antiplatelet therapy was changed to aspirin and ticagrelor (180-mg loading dose, 90 mg twice daily thereafter): "ticagrelor group". This change in use of type of P2Y12 antagonist was performed simultaneously in the Region of Southern Denmark covering 1.2 million inhabitants. STEMI patients were pretreated pre-hospital in the ambulance. We assessed the one-year risk of definite stent thrombosis and cardiac death after PCI with stent implantation. We used a Cox regression model to compute hazard ratio (HR). Of 1.309 patients treated with primary PCI, 1,184 (90.5%) had at least 1 intracoronary stent implanted. The study cohort consisted of 1,184 patients with STEMI, of whom 596 (50.3%) patients were in the "ticagrelor group" and 588 (49,7%) patients were in the "clopidogrel group" Mean age did not differ significantly between STEMI patients treated with ticagrelor compared to clopidogrel (63.6±13.1 years vs. 64.6±12.6 years; p=0.21). Anterior STEMI or bundle-branch block MI was found in 267 (44.8) in the ticagrelor treated patients and in 270 (45.9%) in the clopidogrel treated patients (p=0.48). TIMI flow before intervention did not differ significantly between the two groups and 185 (31.0%) of the ticagrelor treated patients compared to 191 (32.5%) of the clopidogrel treated patients (p=0.63) had TIMI 3 flow in the infarct related coronary artery before the intervention. In the ticagrelor group 545 (91.4%) of the patients were treated with a drug-eluting stent compared to 526 (89.5%) in the clopidogrel group (p=0.25). Overall, at 1 year, 13 events (1.1%) of definite stent thrombosis were recorded. Ticagrelor compared with clopidogrel reduced definite stent thrombosis (3 [0.5%] versus 10 [1.8%] events [HR=0.29 95% Confidence Interval (CI) 0.08-1.06]. The definite stent thrombosis in the ticagrelor treated patients occurred acute (n=1), and subacute (n=2) and in the clopidogrel treated patients the definite stent thrombosis occurred acute (n=4), subacute (n=5) and late (n=1). One-year cardiac mortality rate was significant lower in the "ticagrelor group" n=25 (4.2%) compared to the "clopidogrel group" n=42 (7.1%) [HR=0.58 95% CI: 0.36-0.95].

Conclusions: In an observational all-comer study, treatment with ticagrelor as compared with clopidogrel reduced the rate of definite stent thrombosis and cardiac death in STEMI patients treated with primary PCI.

Acute, subacute, and late failure rates determined from CVPath Institute autopsy registry of BMS, 1st and 2nd generation of DES

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Aims: Many clinical prospective and retrospective randomised and registry studies have been reported for the failure modes of BMS and DES. However, the gold standard for the assessment of stent failure, both early and late remains dependent on pathologic analysis. Therefore we assessed a large CVPath Registry of coronary stents involving 476 patients with over 778 stented lesions.

Methods and results: The mean age of the 476 patient was 62±13 years (range 29-96 years), 353 men and 123 women; the mean duration of implant was 709±928 days. Of the 778 lesions 319 had been treated with BMS, 373 with 1st Generation DES [Sirolimus Eluting Stent (SES)=177, Paclitaxel Eluting Stent (PES)=200]; and 96 with second generation DES. [Endeavor (E-ZES)=13; Resolute (R-ZES)=8; and Xience (EES)=75]. All stented arteries had been radiographed and embedded in methyl methacrylate plastic and serially sectioned. We assessed the prevalence of acute thrombosis by duration of implant; <30 days (n=147 stents), there was no significant difference between BMS (37.2%) and 1st generation DES (36.3%), however the prevalence was less in the 2nd generation DES (18.5%) (p=0.15); with implant duration 31 to 365 days (n=227 stents), thrombosis rate was significantly higher in 1st generation DES (22.5%) than in BMS (4.7%) or 2nd generation DES (4.5%) (P=0.0006); with implant duration >365 to 1,080 days (n=184) the thrombosis rate was highest in the 1st generation (16.1%) as compared to BMS (1.1%) or 2nd generation (0%) (P<0.0001) and remained higher in the 1st generation (17.5%, BMS=2.4%. p=0.006) beyond 1,080 days, although no 2nd generation stents were available at this time point. Restenosis on the other hand was significantly higher in BMS with implant duration >30 to 365 days (41.2%) as compared to DES 1st or 2nd generation (16.7%, and 18.1%) (P<0.0001), and >365 to 1,080 days restenosis rates again remained highest in BMS (30%) than the 1st generation (11.9%) as or 2nd generation DES (5.3%) (P<0.0001), and for stents implanted >1,080 days, similarly restenosis remained the highest for BMS (33.9%) as compared to 1st generation DES (10.5%, P<0.0001). Stent fracture was significantly more frequent in 1st generation DES (31.4%) as compared to 2nd generation DES (8.5%) or BMS (8.7%) (P<0.0001).

Conclusions: Thrombosis rates are similar between BMS and 1st and 2nd generation DES when implant duration is <30 days. However, beyond >30 days thrombosis rates were highest in the 1st generation DES versus BMS and 2nd generation DES. On the other hand restenosis rates are highest in BMS at all time periods however, restenosis rates remain between 10 to 15% for 1st and 2nd generation DES up to one year. These results show that 2nd generation DES are significantly better for the prevention of thrombosis but the restenosis remain high between 31 to 365 days. Despite improvement fracture rates in 2nd generation remain close to 10%. Therefore, DES needs further improvement.



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Bioresorbable scaffold thrombosis in an all-comer patient population

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Aims: To describe the incidence and characteristics of patients with device thrombosis following ABSORBTM bioresorbable vascular scaffold (BVS) implantation in all-comers.

Methods and results: Between April and December 2013, a total of 351 BVS were implanted in an all-comer population. Three cases of BVS thrombosis (0.9%) were identified. All were definite, early thromboses. We present detailed baseline patient characteristics, procedural data and concomitant medical treatment. All patients were preloaded with generic clopidogrel 300 mg and aspirin 320 mg, and received clopidogrel 75 mg and aspirin 80 mg daily thereafter. The first case is a 78-year-old diabetic man with stable angina. Angiography showed diffuse right coronary artery (RCA) disease, with 2 distinct lesions in the mid (80%, type A) and distal (70%, type B1) segments. Both lesions were predilated (2.5×20 mm balloon at 16 atm) and 2 non-overlapping BVS (both 2.5×28 mm at 14 atm) were implanted. Postdilatation was performed with a non-compliant (NC) balloon (3.0×15 mm at 12 atm), for a final balloon-to-artery ratio (BAR) of 1.08 (mid RCA) and 1.00 (distal RCA). Final result was considered optimal. Seven days later, the patient presented with STEMI due to BVS thrombosis in the mid RCA. Thrombectomy was performed. OCT showed no dissection, BVS fracture, malapposition or underexpansion. Eptifibatide was administered and balloon dilatation of the mid RCA BVS was performed. Final TIMI flow was III. The second case is a 37-year-old diabetic man with stable angina. Coronary angiography showed a 70% type B1 lesion in the first diagonal. The lesion was predilated (2.5×15 mm balloon at 10 atm), followed by implantation of a BVS (2.5×28 mm at 16 atm). Postdilatation was performed (2.75×20 mm NC balloon at 14 atm), for a final BAR of 1.00. Final result was considered optimal. Four days later, the patient presented with NSTEMI at another hospital, and was transferred to our centre on the seventh day. BVS thrombosis in the diagonal (TIMI 0 flow) was diagnosed. Since the patient was asymptomatic, no PCI was performed. Medical treatment was preferred. The third case is a 76-year-old diabetic man with stable angina and 2-yessel disease (mid left anterior descending (LAD) chronic total occlusion, 80% type B1 lesion in the distal RCA). He underwent PCI of the LAD (two overlapping DES) and distal RCA. The RCA lesion was predilated (2.5×12 mm balloon at 12 atm) and a BVS (3.0×28 mm at 7 atm) was implanted and postdilated (3.0×12 mm NC balloon at 22 atm), for a final BAR of 1.25. Final result was considered good at the time of PCI. Four days later the patient presented with STEMI due to BVS thrombosis in the RCA. The two DES in the LAD were patent and thrombus-free. Thrombectomy catheters could not be advanced and balloon dilatation was performed. Signs of dissection were then observed, distal to the BVS. Eptifibatide was administered. Two overlapping DES were implanted (2.5×18 and 2.5×12 mm), partially within the BVS, and postdilated. Final flow was TIMI III. Offline review of the initial angiography suggested some degree of underexpansion in the distal segment of the BVS. Importantly, none of the patients reported non-adherence to antiplatelet therapy. All patients were switched to ticagrelor 90 mg twice daily after BVS thrombosis and were event-free on follow-up.

Conclusions: Early experience suggests that the use of BVS in all-comers is associated with an early thrombosis rate comparable to that of DES.

Impact of therapeutic hypothermia on coronary flow

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Aims: Recent reports suggest an increased risk of stent thrombosis (ST) in patients treated with mild therapeutic hypothermia (HT). Increased platelet activation and a potential inefficiency of antiplatelet therapy may explain the increased risk of ST in HT. Other aetiologic mechanisms may play a role in the occurrence of thrombotic events. Experimental models have demonstrated a relationship between HT and endothelial dysfunction. Endothelial disorders have been associated with coronary-flow impairment and therefore thrombotic events. The objective of our study was to analyse the impact of HT on coronary microcirculation by comparing the coronary flow measured by Thrombolysis in Myocardial Infarction frame count (TFC) with and without HT.

Methods and results: From January 2010 to March 2013, 55 patients with out-of-hospital SCD were admitted in our institution and treated with HT (mean age 55.4±15 years, 67% male). Of them, 39 (70.9%) patients had ST-segment elevation myocardial infarction (STEMI) and underwent primary PCI. The HT protocol was accomplished as previously described. We selected those patients in whom two coronary angiographies (with and without HT) were performed. Five patients (12.9%) were included in the analysis. In every patient, a clear distal anatomic landmark was selected as the region of interest to quantify the TFC, and measurements were repeated in both normothermia and HT. In case of STEMI or ST, the coronary flow was always measured in a non-infarct related artery. Coronary angiography technique including catheter shape, catheter diameter, automatic contrast injection flow, and projection were the same for every paired angiography. An experienced reviewer blinded to the temperature condition assessed the TFC. TFC values were compared using t-test for repeated measures with SPSS® v.18.0. Mean age was 58.8 years (Range 42-72), and 4 (80%) were male. There was no significant difference in clinical status including heart rate, blood pressure, and the use of inotropics during angiographies in hypothermia or normothermia. Patients with cardiogenic shock were treated with IV norepinephrine and/or dobutamine infusion according to guidelines. Coronary angiography in normothermia was performed after SCD with a diagnosis of STEMI in 80% of patients. Coronary angiography in HT was indicated in 80% of patients because a suspicion of ST. Despite the small number of patients, a noteworthy trend towards a higher TFC was observed in hypothermia compared to normothermia (11.6 vs. 8.0; p=0.066).

Conclusions: The results of our study suggest that mild HT might slow down coronary flow and endothelial dysfunction seems to be the most plausible explanation considering the previous published data. Further studies with higher statistical power are needed to confirm this finding and clarify the association between hypothermia and endothelial dysfunction.



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Impact of a mechanical circulatory support program in the survival of patients with cardiogenic shock due to an acute myocardial infarction that underwent primary angioplasty

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Aims: Primary angioplasty is the best reperfusion therapy for ST elevation myocardial infarction. Patients in cardiogenic shock benefit from mechanical reperfusion, but their mortality remains high even after the placement of an intra-aortic balloon. There is no clear information regarding whether an ongoing Mechanical Circulatory Support Program (MCSP) might improve the long term outcome of these patients. We have analysed the clinical impact of a MCSP in this setting.

Methods and results: We have compared the in-hospital and 1 year survival of patients in cardiogenic shock in the setting of a primary angioplasty with inserted intra-aortic balloon in two different periods of time. The first period before and the second after the implantation in our hospital of a MCSP. This program included the incorporation of a specially trained staff and the availability of the extracorporeal membrane oxygenation device (ECMO) and the left ventricular or biventricular assist devices (LVAD, biVAD). Following inclusion criteria required: STEMI, cardiogenic shock by clinical and haemodynamic data, primary angioplasty and intra-aortic balloon inserted. Patients with cardiogenic shock due to mechanical complications were excluded. We included 42 consecutive patients in the first period "pre-MCSP" and 56 in the second period "post-MCSP". Clinical baseline characteristics were very similar in both groups except for a wider use of drug-eluting stents in the second period (19% vs. 40%; p=0.03). In the "post-MCSP" group 9 (16%) patients needed an ECMO and 8 (14.3%) a ventricular assist device. Six patients were included in the cardiac transplant list in the "pre-MCSP"group and four in the "post-MCSP" group. Three patients in each group finally underwent a cardiac transplant. In-hospital survival was 45.2% in the "pre-MCSP"group compared to 66.1% in the "post-MCSP" group (p=0.03). The 12 months survival was 39.9% in the "pre-MCSDP"group vs. 59.5% CI: 1.04-7.5: p=0.03).

Conclusions: The implementation of a mechanical circulatory support program improves significantly the prognosis of patients in cardiogenic shock in the setting of a primary angioplasty.



Extracorporal life support in patients suffering from acute ischaemic cardiogenic shock

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Aims: This retrospective study examines the effect of extra corporal life support (ECLS) in patients suffering from cardiogenic shock due to acute myocardial infarction despite successful coronary revascularisation. Our hypothesis is that intermittent ventricular unloading by ECLS therapy and paused or reduced application of catecholamines may lead to improved recovery of damaged myocardium and may enhance survival.

Methods and results: We included 12 consecutive patients into our retrospective trial at our cardiovascular centre from February 2012 to April 2013. The mean age of the patients was 54.8±12.7 years. After successful percutaneous coronary intervention, we treated them with ECLS without intra-aortic balloon pump for 110±66 hours. As control group, we analysed 12 consecutive patients who were treated with intra-aortic balloon pump for the same clinical condition from January 2011 to January 2012. 8 out of 12 ECLS patients survived after 30 days, accounting for a survival rate of 67%. In contrast, only 4 out of 12 patients of our control group were alive after 30 days leading to a survival rate of 33%. In the ECLS group, 5 patients suffered from complications due to ECLS, which ranged from puncture site bleeding to pulmonary haemorrhage and compartment syndromes, in contrast to one critical leg ischaemia in the IABP group.

Conclusions: Patients suffering from severe progressive cardiogenic shock after successful revascularisation by percutaneous coronary intervention might benefit from ECLS therapy regarding survival.



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Intra-aortic balloon pump counterpulsation in patients with large acute anterior myocardial infarction complicated by persistent ischaemia: CRISP AMI revisited

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Aims: The recent CRISP AMI trial investigating the potential beneficial effect of intra-aortic balloon pump (IABP) counterpulsation as adjunct to PCI in anterior STEMI did not show a significant difference in infarct size or all-cause mortality at 6 months. One of the major limitations in this study was the large number of patients (40%) with small infarctions reflected by summed ST-elevations of <6 mm. The aim of this subanalysis was to investigate the effect of IABP counterpulsation in patients with electrocardiographic signs of large anterior STEMI, in particular those patients with large anterior STEMI and signs of persistent ischaemia despite successful PCI.

Methods and results: For this substudy, patients were included if the qualifying electrocardiogram (ECG) showed a summed ST-deviation ≥15 mm. Persistent ischaemia was defined as <50% ST-resolution on the ECG post-PCI. Primary end points were all-cause mortality at 6 months, and the composite endpoint of death, cardiogenic shock or new or worsening heart failure at 6 months. Out of the study population of 337 patients, 146 patients had large anterior STEMI and were included in this analysis. Thirty-three patients had signs of persistent ischaemia. Of these 146 patients, 65 patients were treated with IABP as adjunct to PCI (45%). There were no statistically significant differences in baseline characteristics between the two groups. The mean age was 56±13 years, most patients were male (86%). The mean summed ST-deviation was 24±9 mm. Although statistically not significant, all-cause mortality was numerically different between the two groups (1 patient (1.5%) in IABP plus PCI group and 6 patients (7.4%) in the PCI alone group; log-rank P=0.10), and there was a trend towards statistical significance when focusing at the subgroup of patients with persistent ischaemia (0 patients (0%) died in the IABP plus PCI group versus 5 patients (25%) in the PCI alone group; log-rank P=0.06). At 6 months, 2 patients (3.1%) in the IABP plus PCI group and 10 patients (11.8%) in the PCI alone group reached the primary endpoint of death, cardiogenic shock or new or worsening heart failure (log-rank P=0.04). In patients with persistent ischaemia, the population (N=33) was too small for the numerical difference to reach statistical significance (1 patient (7.7%) in the IABP plus PCI group versus 6 patients (30%) in the PCI alone group; log-rank P=0.14).

Conclusions: This subanalysis of the CRISP AMI trial shows that 40% of the patient population included in the original study were actually a low risk population, diluting the possible beneficial effect of IABP on outcome. However, in case of large myocardial infarction, IABP decreases the combined endpoint of all-cause mortality, cardiogenic shock and new or worsening heart failure at 6 months and improves outcome.

Haemodynamic effects of 40 cc versus 50 cc intra-aortic balloon counterpulsation pumps in clinical practice

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Aims: Several major trials including SHOCK-II and CRISP-AMI have questioned the clinical utility of intra-aortic balloon counterpulsation pump (IABP) in decompensated heart failure, shock, and acute coronary syndromes. None of these studies examined the impact of IABP use on invasive haemodynamics nor analysed IABP functionality. More recently, the larger capacity 50 cc IABP was introduced into practice. Our aim was to compare the haemodynamic effects of the 50 cc and 40 cc IABPs in real-world clinical practice.

Methods and results: 26 consecutive subjects treated with a 50 cc-IABP were compared to 26 age-, gender-, and body surface area- matched patients receiving a 40 cc-IABP between January 2012 and January 2013. IABP indications included cardiogenic shock (48%), acute coronary syndrome (32%), cardiac arrest (8%), or high risk coronary revascularisation (12%). IABP tracings were analysed within 24 hours of implant in all patients. Pulmonary artery catheter data was available before and after IABP implant in 20 subjects. Baseline demographics were similar between groups including body surface area (2.0±0.1 vs. 2.0±0.2, 40 cc vs. 50 cc, p=0.2) Compared to the 40 cc IABP group, 50 cc-IABP recipients showed higher augmented diastolic blood pressure (134±26 vs. 114±20 mmHg, 50 cc vs. 40 cc, p<0.01), greater systolic unloading (13±7 vs. 8±4 mmHg, 50 cc vs. 40 cc, p=0.02), higher estimated diastolic pressure time index, and a larger reduction in pulmonary capillary wedge pressure (PCWP: 4±7 vs. 11±5 mmHg, 40 cc vs. 50 cc, p=0.03) compared to the 40 cc IABP group. Percent diastolic augmentation defined as [(augmented diastolic pressure - non-augmented diastolic pressure)/ nonaugmented diastolic pressure] was significantly higher among 50 cc IABP recipients (Cardiac index increased similarly in both groups after IABP placement compared to baseline values (40 cc IABP: 2±0.5 vs. 2.7±0.7 L/min/m², pre vs. post, p=0.02; 50 cc IABP: 1.7±0.3 vs. 2.4±0.4 L/min/m², pre vs. post, p<0.01). 58% of subjects achieved <10 mmHg of LV unloading in the 40 cc group compared to 27% in the 50 cc group (p<0.05). The magnitude of LV unloading correlated inversely with PCWP (R=0.48, p<0.05) and directly with baseline systolic blood pressure (R=0.62, p<0.05) or the magnitude of diastolic augmentation (R=0.65, p<0.05).

Conclusions: In real-world practice, greater haemodynamic unloading and diastolic augmentation was observed among 50 cc versus 40 cc IABP recipients. These data suggest that trials using the 40 cc IABP may have had a significant number of non-responders to IABP therapy. Future trials may consider using the 50 cc IABP and strict haemodynamic analysis should be performed in trials evaluating the clinical efficacy of percutaneously delivered circulatory support.



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Micro-circulatory adenosine responsiveness improves following primary PCI - Implications for pressure wire assessment of the infarct-related artery

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Aims: Microcirculatory dysfunction at the time of primary percutaneous coronary intervention (pPCI) can alter the hyperaemic response to adenosine and make Fraction Flow Reserve (FFR) assessment unreliable. We were interested to assess the dynamic nature of the hyperaemic response by assessing the index of microcirculatory resistance (IMR) during pPCI.

Methods and results: Forty-one patients presenting to the pPCI service with an occluded coronary artery (LAD 23, RCA 11, LCx 7) that had at least TIMI 1 flow restored by the guide-wire were studied. Coronary transit time (Tmn) by thermodilution and distal (Pd) and aortic (Pa) pressures were measured at rest and during adenosine induced hyperaemia (140 mcg/kg/min). Measurements were taken after the lesion was wired (W), after thrombectomy (T) and finally after stent deployment (S). Coronary wedge pressure (Pw) during stent balloon occlusion and central venous pressure (Pv) were measured. IMR was calculated as ((Pa-Pv)*Tmn)*((Pd-Pw)/(Pa-Pw)) corrected for collaterals. The ability of the microcirculation to respond to adenosine was assessed as ΔIMR (hyperaemic IMR – rest IMR). Hyperaemic Tmn shortened (1.39±0.87 vs. 0.46±0.29, p<0.0001) and Pd (59.3±19.7 vs. 81.0±19.8, p<0.0001) and FFR (0.54±0.20 vs. 0.96±0.05, p<0.0001) were significantly higher following pPCI, although CFR was not significantly improved after pPCI (1.09±0.53 vs. 1.35±0.64, p=0.05) and nor was hyperaemic IMR (35.6±31.8 vs. 40.8±30.9, p=0.26). However, the ability of the microcirculation to respond to adenosine did significantly improve at each stage of pPCI (ΔIMR W: -4.7±4.2 vs. T: -10.8±5.0 vs. S:-16.8±3.9, p=0.04).

Conclusions: Microcirculatory dysfunction blunts the hyperaemic response to adenosine that may result in underestimation of FFR. Recovery of the hyperaemic response is apparent following pPCI that may allow more accurate FFR assessments of the stent result to be made.



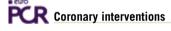
Long-term outcome after deferral of revascularisation in patients with intermediate coronary stenosis and grey-zone FFR

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Aims: The safety of deferring revascularisation of intermediate coronary stenosis with fractional flow reserve (FFR) of 0.75-0.80, the so-called "grey zone", remains debatable. The aim of this study was to assess the safety of deferring revascularisation for patients with FFR of 0.75-0.80 compared with those with FFR of >0.80.

Methods and results: We assessed long-term outcomes of 150 patients with angiographycally intermediate stenosis deferred from revascularisation on the basis of FFR of 0.75-0.80. Target vessel failures (TVF) defined as a composite of cardiac death, target vessel related myocardial infarction, and ischaemia-driven target vessel revascularisation were evaluated during follow-up period. A total of 56 patients had coronary lesions with FFR of 0.75-0.80 and 94 patients had those with FFR of >0.80. There was no difference in baseline clinical characteristics between the two groups. Patients with FFR of 0.75-0.80 had more left anterior descending lesions than those with FFR >0.80 (75% vs. 44%, p=0.001). During a median follow-up period of 3.0 (2.1-4.0) years, the incidence of TVF was higher in patients with FFR of 0.75-0.80 than those with FFR of >0.80 (16% vs. 3%; hazard ratio, 5.2; 95% confidence interval, 1.4 to 19.5; p=0.015). All TVF consisted of target vessel revascularisation, except for one case of cardiac death in patients with FFR of 0.75-0.80.

Conclusions: Patients with FFR of 0.75-0.80 were at higher risk of TVF mainly due to target vessel revascularisation than those with FFR of >0.80.



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Impact of patients' haemodynamic status on the accuracy of FFR measurement

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Aims: Fractional flow reserve (FFR) is a surrogate invasive index to assess the ischaemic potential of coronary stenoses. FFR is calculated as the ratio of average distal coronary (P_d) to aortic pressure (P_+) during maximal hyperaemia. Mean central venous pressure (P_v) is neglected in the formula, as considered of little impact when low and within the normal range. We aimed at investigating the impact of P_v over a wide range on FFR measurement.

Methods and results: We obtained measured FFR (FFR $_{meas}$ =P $_{d}$ P $_{a}$) and corrected FFR (FFR $_{corr}$ =P $_{d}$ -P $_{v}$ P $_{a}$ -P $_{v}$) in 1,593 intermediate coronary stenosis of 1,181 patients undergoing left and right heart catheterisation because of: a) ischaemic heart disease (639 [54%]); b) heart failure (597 [51%]); c) valve disease (583 [49%]). Average blood pressure was 91±17 mmHg and median P $_{v}$ was 7 mmHg (5; 10). The correlation between FFR $_{corr}$ and FFR $_{meas}$ was excellent (R=0.985, p<0.001). Median FFR $_{meas}$ (0.85 [0.78; 0.91]) was slightly but significantly higher than median FFR $_{corr}$ (0.83 [0.76; 0.90], p<0.0001). The median difference between FFR $_{corr}$ and FFR $_{meas}$ was 0.01 (0.01; 0.02). Values of FFR $_{meas}$ above the cut-off of 0.80 turned to an FFR $_{corr}$ below 0.80 in 92 (6%) stenoses overall, and in 29 (9%) (p=0.021 vs. overall) stenoses of patients with P $_{v}$ higher than 10 mmHg. No stenosis went from a FFR $_{meas}$ >0.80 to a FFR $_{corr}$ <0.75.

Conclusions: FFR values above the gray zone (i.e. >0.80) did not turn to values below the gray zone (i.e. <0.75) in any case, suggesting that the impact of the haemodynamic status on FFR measurement is indeed negligible, even in patients with markedly increased P...

Major determinants for myocardial ischaemia in the left anterior descending coronary artery with angiographic intermediate stenosis

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Aims: It remains unknown whether the atherosclerotic disease extent of the conductive vessel correlates with functional severity of intermediate coronary artery stenosis. We assessed the relationship between total coronary atheromatous plaque volume and fractional flow reserve (FFR) in patients with intermediate stenosis of the left anterior descending coronary artery (LAD).

Methods and results: An IVUS study and FFR measurements were performed in 130 patients with intermediate stenosis of proximal or mid LAD on coronary angiography. Percent total atheroma volume (%TAV) was calculated as the percentage of total vessel volume occupied by total atheroma volume on IVUS. A significant correlation was observed between %TAV and FFR (r=−0.71, p<0.001). Minimum lumen area (MLA) correlated moderately with FFR (r=0.54, p<0.001). The independent predictors of FFR<0.8 were %TAV (odds ratio[OR]: 1.29, 95% confidence interval [CI]=1.18–1.40, p<0.001) and MLA (OR:0.37, 95% CI=0.16–0.85, p=0.019). A receiver-operating characteristic curve suggested %TAV ≥39.0% (sensitivity 85%, specificity 83% and area under curve [AUC]=0.90) and MLA ≤2.6 mm² (sensitivity 72%, specificity 70% and AUC=0.75) as the best cut-off values for FFR 0.80. Both % TAV (<39.0%) and MLA (≥2.6 mm²) were not significant in 44.6% of the patients, and only 5.2% of them showed FFR<0.8. In contrast, both % TAV (≥39.0%) and MLA (≤2.6 mm²) were significant in 29.2% of the patients, and 86.8% of them showed FFR<0.8.

Conclusions: Volumetric quantification of the atherosclerotic disease extent of the coronary artery, expressed as IVUS-derived %TAV, showed a strong correlation with FFR. Diffuse atherosclerosis and segmental stenosis of the conductive vessel are major determinants for the presence of myocardial ischaemia in angiographic intermediate stenosis of the LAD.



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Clinical impact of IVUS guidance in DES implantation for unprotected left main coronary disease: pooled analysis at patient level of 4 registries

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Aims: We sought to investigate the clinical impact of the use of intravascular ultrasound (IVUS) during revascularisation of patients with left main disease with drug-eluting stents (DES). Whether the use of IVUS during the procedure adds a clinical benefit remains unclear. There is only one previous observational study with relevant limitations supporting the value of this strategy.

Methods and results: We performed a patient level pooled analysis of 4 registries of patients with left main disease treated with DES in Spain. A propensity score matching method was used to obtain matched pairs of patients with and without IVUS guidance. A total of 1,670 patients were included and 505 patients (30.2%) underwent DES implantation under IVUS guidance (IVUS group). By means of the matching method, 505 patients without the use of IVUS during revascularisation were selected (no-IVUS group). No significant differences were observed between these matched groups in clinical or procedural characteristics. Survival free of cardiac death, myocardial infarction and target lesion revascularisation at 3 years was 88.7% in IVUS group and 83.6% in no-IVUS group (p=0.04) for overall population and 90% and 80.7% respectively (p=0.03) for the subgroups with distal left main lesions. The incidence of definite and probable thrombosis was significantly lower in IVUS group (0.6% vs. 2.2%; p=0.04). Finally, IVUS guided revascularisation was identified as independent predictor for major adverse events in overall population (HR 0.70, 95% CI 0.52-0.99; p=0.04) and in the subgroup with distal lesions (HR 0.54, 95% CI: 0.34-0.90; p=0.02).

Conclusions: The results of this pooled analysis show an association of IVUS guidance PCI with better outcomes in patients with left main disease undergoing revascularisation with DES.

Changes of vessel remodeling and plaques type during lipid lowering therapy in diabetic versus non-diabetic patients - Study with 3D intravascular ultrasound and virtual histology

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Aims: Comparison of changes in plaque type and vessel remodelling during lipid-lowering therapy using 3D IVUS and virtual histology in diabetic (DM) compare to non-diabetic patients (non DM).

Methods and results: Retrospective study from the database of serial (baseline and 12 months follow) IVUS studies including patients with stable coronary artery disease. IVUS/VH data suitable for geometrically-correct 3 D reconstruction and quantitative analysis were retrospectively identified from a database containing 50 patients with serial IVUS (with 12 months follow-up). Morphologic (plaque phenotype) and volumetric indices of each coronary vessel were derived from geometrically-correct end-diastolic 3D vessel representations obtained via angiography-IVUS image fusion. Each vessel was partitioned in a number of adjacent non-overlapping 5 mm segments (chunks) covering the entire length of the IVUS pullback. We quantified risk profile of every chunks according to plaque phenotype (5 points for thin cap fibroatheroma –TCFA, 4 for thick cap fibroatheroma, 3 for fibrocalcified plaque, 2 for fibroatheroma and 1 for pathologic intimal thickening). Risk score for whole examined segment were calculated as a mean value of individual risk scores from every chunks. 32 patients (11 DM ones) fulfilling criteria for accurate geometrically correct 3D reconstruction were retrospectively identified from a database. In such patients 280 five millimeters segments were analysed. The higher occurrence of negative remodeling (remodeling index 0.93 vs. 1.01, p<0.001), decrease of lumen (–0.8 mm³ vs. 0.24 mm³, p<0.001), higher incidence of thin cap fibroatheroma (TCFA) during baseline (41.2% vs. 26.4%, p=0.004) and during follow-up (59.3% vs. 39.7%, p=0.003), higher risk score in baseline (2.7 vs. 2.2, p=0.007) and during follow-up (3.7 vs. 2.6, p<0.001) with only non significant changes of relative plaque volume in both groups (–0.09% vs. 0.3%, p=0.78) were found in DM vs. non DM patients. Most obvious change of plaque phenotype was shift from fibrous plaque to TCFA in DM patients (58.3% vs. 41.7%, p=0.002)

Conclusions: In DM patients, negative remodeling, decrease of lumen area, higher occurrence of TCFA plaque phenotype (mainly coming from fibrous plaque) and higher risk score for plaque were observed during lipid lowering therapy, while changes of plaque volume were not significant in either group.



Euro14A-0P027

Serial greyscale and virtual histology IVUS findings in patients undergoing primary PCI with biodegradable polymer biolimus-eluting stents versus BMS: results of the COMFORTABLE AMI IVUS substudy

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Aims: Early generation drug-eluting stents (DES) have been associated with delayed arterial healing and positive remodeling when implanted in patients with ST-elevation myocardial infarction (STEMI). Vascular remodeling and changes of plaque composition behind stent struts have not been investigated among STEMI patients treated with new generation biodegradable polymer DES.

Methods and results: Serial IVUS at baseline and 13 months was performed in a total of 80 STEMI patients (42 biolimus-eluting stents (BES) and 38 bare metal stents (BMS)) undergoing primary PCI at five European centres. All patients received evidence base medical treatment and were treated with high dose rosuvastatin (40 mg per day). Stented segments were imaged with IVUS using the Eagle Eye (Volcano Corporation) catheter (20 MHz) and were analysed by an independent Corelab. Statistical analyses were performed at lesion level. The external elastic membrane (EEM) decreased in both treatment arms (BES –0.46 mm² [–1.4 to 0.39] vs. BMS –1.11 mm² [–2.27 to 0.04], p=0.05). This was related to a reduction in plaque media area (BES –0.59 mm² [–1.6 to 0.4]) vs. BMS (–1.25 mm² [–2.18 to –0.16], p=0.07). Neointimal volume was lower in BES (0 mm³ [0 to 0.5 mm]) compared to BMS (29.0 mm³ [11.9 to 88.4]), p<0.001. A reduction of the necrotic core component in the plaque behind the struts was observed with BES (–0.51% [–2 to 0.63]) but not with BMS (3.64% [0.97 to 6.21]), p<0.001.

Conclusions: The absence of positive remodeling (defined by any increase in EEM area) and a reduction in necrotic core suggests a favourable arterial healing profile of BES when implanted into culprit lesions of STEMI patients treated with high dose of rosuvastatin.



IVUS echogenicity analysis of the paclitaxel-eluting absorbable magnesium scaffold (DREAMS)

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Aims: The aim of this study is to explore the application of IVUS derived parameters to act as a surrogate monitoring the absorption and degradation process of a paclitaxel-pluting absorbable magnesium scaffold (DREAMS) implanted in human coronary arteries. The ultrasonic changes of this scaffold are assumed to have a strong relationship towards its degradation and bioresorbption process.

Methods and results: Serial IVUS data of the BIOSOLVE-I study was analysed by applying differential echogenicity analyses, a method which previously showed that visual changes of the ultrasonic appearance of bioresorbable scaffolds can be quantitatively identified. In post-implantation IVUS images, the struts of the magnesium scaffold appear as clearly visible and quantifiable hyperechogenic spots without, unlike calcified areas, causing any acoustic shadowing. Echogenicity analyses of pre- and post-implantation scaffolded segments showed a significant increase of % hyperechogenicity caused by the scaffold from 9 to 22% (p<0.001); respectively. At 6 months the % hyperechogenicity decreased significantly from 22 to 16% (p<0.001). At further time points the scaffolded segments showed still a continuous further decrease of % hyperechogenicity, however, levelling off to a non-significant change between 12 and 18 months, 13 vs. 12% (p=0.5).

Conclusions: The magnesium scaffold shows a continuous decrease of its ultrasonic appearance over time and the quantitative differential echogenicity evaluation supports that the DREAMS absorption is likely to be completed at 6-months. The exact relationship between these ultrasonic changes and the degradation and bioresorbption process of the magnesium scaffold is still under investigation.



Euro14A-0P029

Predictors for excessive underestimation of distal reference lumen diameter during IVUS-guided PCI

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Aims: Distal reference lumen diameter (DRLD) measured by IVUS might be often underestimated because of decreasing antegrade coronary flow. The aim of this study was to elucidate the independent predictors associated with this phenomenon.

Methods and results: We retrospectively investigated 1,464 consecutive lesions (1,382 patients who underwent IVUS (3.5 Fr Eagle EyeTM) - guided PCI for stable angina pectoris between 2010 and 2012). We calculated the diameter difference before and after stent implantation (DD=final DRLD – initial DRLD) and defined DD<0 as Non-underestimated lesions (N-group) and DD>0 as underestimated lesions (U-group). We compared between N-group and U-group, and elucidated the independent predictors associated with excessive underestimation of DRLD (DD ≥0.25). U-group were 763 lesions (52.1%). Baseline characteristics showed some differences between N-group and U-group including minimum lumen diameter (MLD), minimum lumen area (MLA), lesion length (LL) and initial DRLD. The excessively underestimated lesions were 259 lesions (33.9% in U-group). Multivariate analysis revealed that right coronary artery (HR 1.44, p=0.031), eccentric lesion (HR 1.74, p=0.001), MLA <3.3 mm² (HR 1.63, p=0.016), LL>20 mm (HR 1.52, p=0.012), initial DRLD <2.0 mm (HR 3.50, p<0.0001) and final DRLD<2.8 mm (HR 2.19, p=0.005) predicted an increased risk of excessive underestimation of DRLD.

Conclusions: In this retrospective study, the underestimation of DRLD was associated with specific lesion morphologies. We have to consider repeat IVUS measurement after stenting.



Incidence and predictors of radial artery occlusion after transradial coronary angiography and PCI

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Aims: To investigate the incidence and predictors of the long-term complication "radial artery occlusion" after transradial coronary angiography and percutaneous coronary intervention (PCI).

Methods and results: Between January 2010 and June 2012, 604 patients underwent transradial coronary angiography or PCI in our institution. Of these 604 patients, 395 (21.7% female, 88.3% male) agreed with an angiological follow-up examination including color duplex ultrasonography and non-invasive angiological tests. They were examined between October 2012 and October 2013. There were 86 females (21.7%) and 309 males (88.3%), mean age of the examined patients was 66 years (range 41-90 years). Mean interval between coronary angiography and angiological examination was 20 months (±8.37). The indication was acute coronary syndrome in 73 of 395 patients (18.48%), 201 patients had a PCI (50.88%). At least 3000IE unfractionated Heparin was administered intraarterially; in case of PCI Heparin dosage was adapted according to activated clotting time. The maximal sheath size (Terumo Radifocus Introducer II, Terumo Medical Corporation) was 5 French on 249 patients (63%) and 6 French on 146 patients (37%). Crossover to transfemoral approach was needed in 21 patients (5.3%). Patent haemostasis was achieved using the TR Band (Terumo Medical Corporation). Mean compression time was 4.17 (±1.26, range 1.5-10) hours. Mean procedure time was 51.2 minutes (±36.38). Occlusion of the radial artery was diagnosed using color Duplex ultrasound in 7 patients (1.77%, 95% CI: 0.05-0.31). Sheath size (OR 0.67, 95% CI: 0.13-3.50), sheath upsizing (OR 1.08, 95% CI: 0.21-5.69), compression time (OR 0.87, 95% CI: 0.45-1.67), gender (OR 0.59, 95% CI: 0.70-5.00), heparin dosage (OR 0.98, 95% CI: 0.85-1.11) and procedure time (OR 0.99, 95% CI: 0.97-1.01) did not show a significant correlation with radial artery occlusion. Patients treated by PCI had a lower incidence of radial artery occlusion (OR 0.34, 95% CI: 0.66-1.80). Oscillographic finger amplitudes were decreased in 3 patients with occluded radial artery. None of the patients with occluded radial artery had symptoms.

Conclusions: Radial artery occlusion on long-term-follow-up after transradial coronary angiography or PCI is a rare complication with a good prognosis and no clinical or haemodynamic significance for the perfusion of the fingers. Sheath size, sheath upsizing, compression time, gender, heparin dosage and procedure time were not correlated with radial artery occlusion.



Euro14A-0P031

Radial artery pseudoaneurysm after cardiac catheterisation: peculiarities and non-surgical treatment results

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Aims: Radial artery pseudoaneurysm is a very rare complication after performing transradial catheterisations, there is very little information therefore about this pathology and its optimal treatment. The purpose of this study is to describe radial artery pseudoaneurysm clinical features, risk factors and the results of a non-surgically therapeutic management.

Methods and results: To achieve our aims, we prospectively collected all consecutive radial artery pseudoaneurysms that occurred in our lab from 2004 to 2013. During this period 16.808 catheterisms were done (radial access in 96.5%). There were 5 radial artery pseudoaneurysms (incidence: 3x10,000 cases). Four patients (80%) were anticoagulated during the procedure and a 6 French sheath was used in the 80% of the cases. An internal forearm hematoma that occurred immediately after catheterisation was observed in four (80%) of these patients. All cases consulted after initial discharge after 10±5 days. Four because of the development of an erythematous mass at the puncture site and one because of an spontaneous pulsatile bleeding at the puncture site compatible with radial artery pseudoaneurysm external wall rupture. Diagnosis was confirmed by echography. Importantly the outer wall of the pseudoaneurysm had a very thin thickness (1±0.15 mm). Nonsurgical treatment was effective in 100% of cases (60% with mechanical compression and 100% of the two cases in which we used thrombin injection due to initial failure of the mechanical compression). Importantly in all patients the mechanical compression was performed through a direct compression of the radial artery pseudoaneurysm, as is recommended for femoral pseudoaneurysms. This caused the rupture of the radial artery pseudoaneurysm external wall in 2 cases (40%). An asymptomatic acute radial occlusion occurred after thrombin injection in one patient.

Conclusions: Radial artery pseudoaneurysm is a very rare complication but potentially harmful due to the risk of external bleeding because to the rupture of its fragile outer wall. The appearance of an internal bruise on forearm after the initial compression is an important sign that should alert us about the possibility of a subsequent radial artery pseudoaneurysm development, specially if the patient was anticoagulated and if big sheaths were used during the procedure. A non-surgical approach is an effective strategy, starting initially with mechanical compression and if this fails use a thrombin injection. However unlike femoral pseudoaneurysms, we should avoid the direct compression of the radial artery pseudoaneurysm in order to avoid the radial artery pseudoaneurysm rupture. We recommend performing a radial artery compression but proximal to the radial artery pseudoaneurysm.



Prognostic impact of radial versus femoral accesses for PCI in patients with ACS - effects of gender

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Aims: The purpose of this observational study was to evaluate whether the prognostic effects of radial artery access (RA) differs between males and females undergoing PCI due to STEMI and 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 Swedenbetween 2005-2011. We evaluated 30-days mortality in 10,007 patients, N=4,386 in RA (22.8% women) and N=5,621 (31.0% women) in FA (P<0.001). 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. Interaction test was performed between gender and access site. 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 3,761 patients (37.6%) with STEMI and 6,246 (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). This reduction was equal for men (HR 0.58; 95% CI: 0.39-0.89) as well as for women (HR 0.69; 95% CI: 0.43-01.1).

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



Euro14A-0P033

New access to facilitate endovascular operations: first-in-man study

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Aims: Performing endovascular manipulation preferably using the radial and cubital accesses. We propose a new arterial access on the back surface of the hand in the anatomical snuffbox. Artery catheterisation of the hand in the anatomical snuffbox preserves intact the radial artery in the forearm for subsequent potential surgical interventions.

Methods and results: In the investigation were included 656 patients, which were made the catheterisation of the deep palmary branch of radial artery (DPB RA) in the anatomical snuffbox. The technique of the catheterisation of the DPB RA is similar to the radial artery catheterisation. The puncture performed in the place of it's the best pulsation in the anatomical snuffbox. The catheterisation of the DPB RA left side performed in 20% of patient, right side – 80%. Men – 78,5%, mean age – 62.5 years and women – 21.5% with mean age of 66 years. The follow-up period was 14 months. In the investigation we developed and used an algorithm of catheterisation of the DPB RA: patient is righty or lefty, pulsation of a radialis, a ulnaris, DPB RA, NIBP on the both hands, Allen's test, pulsation of the DPB RA with alternately compression of a radialis and a ulnaris, ultrasound investigation of forearm vessels (in distal part) and wrist with determination of artery's diameters. The was no pulsation of the DPB RA (before catheterisation) in 2% of patients. Recatheterisation (2 and more) of the DPB RA in 9,4% of patients. The control of post-puncture occlusion of the DPB RA – 60% of patients. Removal of introducer after finishing the procedure - 98,9% of patients. The types of diagnostic and treatment procedures: CA and FFR – 31,9%, CA and PTI – 31,6%, PCI – 23,3%, other – 13,2%. Time of fluoroscopy during CA – 6,58 min, Kerma – 1022,19 mGy. Time for the catheterisation of the DPB RA reduced more than 2 times after performing 50 and more procedures. Analysis of dependency between time for the catheterisation of the DPB RA and frequency of performed procedures, showed that time for puncture of DPB RA increased more than 3 times during 1 procedure in 7 and more days. Complications: hematoma of wrist and forearm –0,8%, oedema –0,2%, occlusion of DPB RA without ischaemia of fingers –1,5%, numbness – 0,6%, dissection – 0,3%, artery-venous fistula – 0,2%, TIA – 0,2%, stroke – 0,2%, aneurysm – 0,2%, death – 0,5%.

Conclusions: The approach of the DPB RA has the similar dignities and disadvantages as the radial approach. Catheterisation of the DPB RA preserves the radial artery in the forearm intact for subsequent potential surgical interventions. This approach reducing the risk of ischaemia fingers through saving of blood flow in surface branch of radial artery. There is no haemostatic devices at real time and imposition of tours compressive bandage in the wrist prevents fingers oedema and stasis.

Feasibility and efficacy of repeated transulnar approach for PCI

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Aims: Transulnar approach (TUA) is used as an alternative to transradial approach TRA for diagnostic and therapeutic coronary procedures. The aim of the present study was the evaluation of feasibility and efficiency of repeated transulnar (rTU) catheterisation from the same artery.

Methods and results: From December 2010 to May 2013 we evaluated 704 consecutive patients (79.6% men, age 58.1±9.3 years) in whom diagnostic or therapeutic coronary procedures were performed via ulnar approach. Out of these patients a rTU procedure was performed in 50 patients, 38 (76%) patients were men and 12 (24%) women, mean age was 57.8±9.7 years. 6 Fr catheters were used in 39 (78%) of cases, 5F in 11 (22%), therapeutic procedures were performed in 36 (72%). In PCI patients single-vessel PCI was performed in 26 (72.2%) patients, double-vessel PCI in 9 (25%) patients and triple-vessel procedure in 1 (2.8%) patient. The average time between the primary and repeat approach was 28.3±56.8 days (from 1 day to 6 months). The puncture success rate was 96%, the reason for the puncture failure in 2 cases was severe artery spasm and inability to insert the wire, one patient was switched to contralateral TRA and one patient to contralateral TUA. Vascular access time was 2.4±2.1 min and there was not significant difference in comparison with the initial puncture time. There were not local complications such as severe bleeding, ulnar artery perforation at puncture site. None of the patients had ischaemic or neurologic symptoms in the hand. There was not ulnar pulse loss.

Conclusions: The repeated transulnar approach for diagnostic and therapeutic coronary intervention is safe and effective. It is associated with a high success rate and extremely low complications rates.



Euro14A-0P035

Predictive performance of SYNTAX Score II in patients with left main and multivessel coronary artery disease: analysis of CREDO-Kyoto registry

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Aims: Presently, for patients with unprotected left main or complex CAD, the prevailing guidelines advise the heart team to use the SYNTAX Score alone or combined with the STS Score as a tool to make an objective risk stratification. The SYNTAX Score II provides individualised estimates of four-year mortality after coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI) that can help in decision-making between these revascularisation methods. The purpose of our study was to validate the SYNTAX Score II in patients with three-vessel and/or ULMCA disease in a real-world multicentre registry with distinct regional and epidemiological characteristics.

Methods and results: Long-term mortality was analysed in 3,896 patients undergoing PCI (n=2,190) or CABG (n=1,796) from the CREDO-Kyoto (Coronary REvascularization Demonstrating Outcome Study in Kyoto) PCI/CABG registry cohort-2. The performance of SYNTAX Score II was evaluated using the concordance-index (c-index); calibration plot; reclassification table; and Net Reclassification Index (NRI). The overall Kaplan-Meier estimated mortality at four-year follow-up was 14.7%. The SYNTAX Score II discriminated well in both CABG and PCI patient groups (c-index: 0.70 95% CI 0.68-0.72 and 0.75 95% CI 0.72-0.78) surpassing the anatomical SYNTAX Score (c-index: 0.50 95% CI 0.47-0.53 and 0.59, 95% CI 0.57-0.61). The SYNTAX Score II showed the best discriminative ability to separate low-, medium- and high-risk tertiles and calibration plots showed good predictive performance for CABG and PCI groups. The overall reclassification provided by the SYNTAX Score II had a NRI of 0.5 (P<0.01) indicating that 50% of patients had a net better classification for higher and lower risk categories using the SYNTAX Score II versus the anatomical SYNTAX score.

Conclusions: The SYNTAX Score II demonstrated solid prognostic accuracy, both in CABG and in PCI patient groups, and – compared with the anatomical SYNTAX score alone – was more befitted to stratify patients for late mortality in a real-world complex CAD Eastern population.



Secondary revascularisation in patients with prior CABG: Impact of the CABG SYNTAX score in a real world population

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Aims: With the rapid development of surgical and PCI techniques, a substantial increase in the number of revascularisation procedures in patients who had previous CABG has increased in recent years. Recently the CABG SYNTAX Score, an objective measure of anatomical complexity and revascularisation post CABG was reported. We sought to determine the influence of the CABG SYNTAX score in the incidence of secondary revascularisation and to determine its impact upon mortality in an unselected group of patients with previous CABG undergoing cardiac catheterisation

Methods and results: Between January 2012 and January 2013, 121 patients with previous CABG were referred to cardiac catheterisation in our centre due to recurrence of angina. The study population was subdivided into those that had low-risk (<22) and into those that had high-risk (≥22) CABG SYNTAX score (n=56 and n=65, respectively). The primary endpoint was all-cause mortality at a median follow-up of 13 months (IQR range: 11.3-14.0 months). Mean CABG SYNTAX score was 31.3±7.7 and 14.7±4.9 in the high-risk and low-risk group, respectively. Most of the preoperative characteristics were similar in the two groups, including baseline characteristics and clinical presentation, but high-risk group had more frequently NSTEMI than low-risk group (36.9% vs. 19.6%; p=0.045). Patients in the high-risk group had a larger number of unprotected coronary lesions (2.6±1.1 vs. 1.8±1.1; p<0.01), fewer patent grafts (0.6±0.8 vs. 1.1±0.8; p<0.01) and a higher standard SYNTAX score (44.1±9.6 vs. 29.3±9.8; p≤0.01) than patients in the low-risk group. There was no difference in the incidence of secondary revascularisation between groups (60% in the high-risk group vs. 45% in the low-risk group; p=0.10), and PCI was the preferred technique in both groups (93% in the high-risk group and 96% in the low-risk group; p=0.79). Thirty-day mortality was higher in the high-risk group (13.8% vs. 1.8%; p=0.02). Kaplan-Meier analysis revealed that patients with high-risk CABG SYNTAX score had significantly higher all-cause mortality rates (32.3% vs. 7.1%, p<0.01) during follow-up. Multivariate analysis identified age (OR: 1.07 [CI: 1.01-1.14]; p=0.016) and CABG SYNTAX score (OR: 5.73 [CI: 1.68-19.56]; p<0.01) as independent predictors of mortality during follow-up.

Conclusions: In patients with prior CABG surgery undergoing cardiac catheterisation, the anatomical coronary disease complexity and the degree of revascularisation measured by the CABG SYNTAX score have an immediate and mid-term prognostic role and is an independent predictor of 1 year all cause mortality.



Euro14A-0P037

Predictive value of the new 'clinical' SYNTAX score II and the potential impact of clinical and anatomical features in decision making for patients undergoing unprotected left main angioplasty

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Aims: The SYNTAX score II, which includes prognostically important clinical variables, emerged to overcome the limitations of the purely anatomical SYNTAX score in the choice of the best revascularisation strategy for patients with complex coronary artery disease. We aimed to validate and compare the performances of the SYNTAX I (SI) and SYNTAX II (SII) as predictors of major cardiovascular events (MACE) in patients who underwent unprotected left main angioplasty (ULMA) as well as to evaluate the clinical impact of the SII guided revascularisation strategy reclassification.

Methods and results: Single centre retrospective analysis of 132 patients (79.5% men, mean age 65.8±12 years) who underwent ULMA between March 1999 and December 2010. Both scores were calculated using the online calculator and the published SII nomogram (presupposes independent calculation for each revascularisation strategy). We estimated the discriminative ability for MACE at 4 years of both scores by ROC curve analysis. The areas under de curve (AUC) were compared by the De Long et al. method. To assess the predictive validity, the scores were dichotomized at their best discriminative values and individually inserted into Cox regression models with other significant variables. We analysed the outcome of patients whose SII score favoured surgical revascularisation (CABG). The median SI was 22 IQ [3.5-17.65], the median SII predictor of risk associated with CABG (CABG SII) was 8.49 IQ [4.6-18.77], the median SII predictor of risk associated with angioplasty (PCI SII) was 7.2 IQ [3.5-17.65]. There were 35 MACE (26.5%) at 4 years of follow-up. The AUC were 0.613 with the best discriminative value >23 for SI; 0.606 with the best discriminative value >6.86 for SII CABG and 0,674 with the best discriminative value >6.77 for SII PCI. There were no significant differences between the AUC for the three scores (p>0.08). All scores were shown to be independent predictors of MACE with HR 2.89 95% CI (1.27-6.58) for SI, HR 2.97 95% CI (1.31-6.75) for CABG SII and HR 3.3 95% [1.33-811] for SII PCI. Patients whose SII favoured CABG had a MACE rate of 29% and those not reclassified had a MACE rate of 24.7% (p=0.54).

Conclusions: Both versions of the SYNTAX score showed a poor discriminative ability for MACE occurrence at 4 years in the studied population. The patients in whom SYNTAX II favoured surgical revascularisation did not have more MACE rate.



Impact of coronary CTO on the clinical outcomes in patients with unprotected left main and/or three-vessel coronary artery disease and a SYNTAX score ≥33

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Aims: Limited data are available on the impact of chronic total occlusion (CTO) lesions on the clinical outcomes in patients with complex coronary artery disease. This study was designed to evaluate the impact of CTO lesions on the long-term outcomes of the patients with unprotected left main (ULM) and/or three-vessel coronary artery disease and a SYNTAX score \geq 33 after PCI with DESs.

Methods and results: Of 558 consecutive patients with ULM and/or three-vessel disease treated with PCI with DESs between March 2003 and December 2010, we identified 115 patients with ULM and/or three-vessel disease and a SYNTAX score ≥33 and investigated the long-term clinical outcomes including all-cause death, cardiac death, target vessel revascularisation (TVR), and major adverse cardiac and cerebrovascular events (MACCE) defined as all-cause death, myocardial infarction, stroke, and TVR. Previous PCI or CABG, ULM coronary artery treated with BMSs, and acute myocardial infarction were excluded. The mean age was 69.3±11.6 years, with 74.8% male gender. The mean SYNTAX score and left ventricular ejection fraction (LVEF) were 39.2±5.5 and 53.1±10.9, respectively. The median follow-up duration was 4.0 (interquartile range, 2.6-6.1) years. Of 115 patients, 64 patients included the presence of CTO lesions (1 CTO lesion, 47 patients; 2 CTO lesions, 13 patients; 3 CTO lesions, 4 patients) and 85.1% of all CTO lesions were located in the proximal-mid coronary major epicardial vessels. Moreover, we compared the longterm clinical outcomes between the 64 patients with CTO lesions (CTO group) and 51 patients with non-CTO lesions (non-CTO group). There were no significant differences in baseline characteristics including age, sex, hypertension, diabetes mellitus, dyslipidaemia, peripheral artery disease, prior cerebrovascular event, renal failure, acute coronary syndrome, second-generation DES use, and SYNTAX score except the LVEF and the presence of ULM disease between 2 groups. The patients with CTO lesions were significantly more likely to have had a lower LVEF and a reduced prevalence of ULM disease (50.2% vs. 56.8%, P=0.001 and 34.4% vs. 80.4%, P<0.001, respectively). Of all 85 CTO lesions of 64 patients, 78 CTO lesions of 58 patients were successfully recanalised (procedural success rates: 95.1%), 4 CTO lesions of 4 patients were not recanalised, and 3 CTO lesions of 2 patients were not treated. The complete revascularisation rate of the patients with CTO lesions was equivalent to that of the patients with non-CTO (73.4% vs. 76.5%, P=0.83). At 4 year, all-cause death, TVR, and MACCE were less frequently observed in patients with CTO group as compared with non-CTO group (all cause death: 12.0% vs. 29.2%, P=0.044, cardiac death: 8.7% vs. 14.1%, P=0.40, TVR: 30.5% vs. 51.3%, P=0.024, and MACCE: 38.0% vs. 68.1%, P=0.002, respectively)

Conclusions: In patients with ULM and/or three-vessel disease and a SYNTAX score ≥33 after PCI with DESs, the presence of CTO was associated with significantly lower event rates. This impact of CTO on the clinical outcomes was mainly affected by the lower TVR rate.



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One-year outcomes of Japan unprotected left main coronary artery disease PCI strategy on new generation stents (J-Lesson) registry

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Aims: The SYNTAX study showed significant improvement in the efficacy of PCI for unprotected left main coronary artery (ULMCA) disease. However, the study also pointed out that even in the era of DES, there are many postoperative cardiac events in cases with complicated lesions. The procedure success rate and the incidence of late revascularisation reflect the importance of assessment of lesion characteristics, and clinical efficacy of intravascular ultrasound (IVUS) guided PCI has been reported. The aim of the present study is to observe the incidence of major adverse cardiac and cerebrovascular events (MACCE), target vessel failure (TVF), and stent thrombosis out to 3 years after the procedure in patients who underwent PCI with everolimus-eluting stents for ULMCA disease and lesions involving the ULMCA in Japan.

Methods and results: J-Lesson is a prospective multicentre PCI registry with a new generation DES, everolimus-eluting stent (XIENCE V/ PROMUS*) in ULMCA disease and lesions involving the ULMCA. Major exclusion criteria included severe renal dysfunction (serum creatinine=2.0 mg/dL), a low left ventricular ejection fraction of less than 30%, acute myocardial infarction or CK (CPK) levels exceeding twice the institutional upper limit of normal, and chronic total occlusions (CTO) in the LMCA. Angiographic and IVUS findings including SYNTAX score are evaluated independently by core laboratory. A total of 438 patients with ULMCA disease was enrolled in this registry. Mean age was 70.8±9.7 years and male was 82.7%. Present disease was mainly stable angina pectoris, and prevalence of diabetes mellitus was 40.4%. Comorbidity was frequent (OMI 18%, Stroke 8.9%, PAD 7.5%, history of PCI 36.8%). Number of treated lesions was 1.7±0.8 per patients. For ULMCA disease, 1.4±0.6 stents was deployed (21.6±7.4 mm in length and 3.25±0.36 mm in size). Lesion location at distal bifurcation was present in 365 (83.3%), and two stent technique was performed in 61 cases (16.7%). Debulking procedure by rotablator was performed in 5.7%. IVUS usage was quite frequent. Pre and post procedural IVUS observation was 91% and 94%, respectively. Mortality at 3 months was 0.5% (cardiac death 1, non-cardiac death 1). Stent thrombosis was observed in 1 case (0.2%). TLR was 1 case associating with stent thrombosis.

Conclusions: In Japan, IVUS-guided PCI for ULMCA disease is frequent and initial outcomes of PCI for ULMCA is acceptable. At the meeting, 1 year outcomes based on the SYNTAX score will be presented. This study will provide the important information regarding the clinical efficacy of IVUS guided PCI for ULMCA.



The ratio of contrast volume to estimated glomerular filtration rate is predictor of contrast-induced acute kidney injury after primary PCI

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Aims: We have previously demonstrated that age, baseline renal function and ejection fraction are pre-procedural predictors of Contrast-Induced Acute Kidney Injury (CI-AKI) in the setting of primary PCI, whereas the potential impact of renal function-adjusted contrast dose remains not fully explored. To date, Maximum Accepted Contrast Dose (MACD) based on the Cigarroa formula and Contrast Volume to eGFR ratio (CV/eGFR) have been proposed to calculate a maximum CV not to be overcome, although a universally accepted cutoff for CV/eGFR has not been endorsed. The CV/eGFR has the advantage to be a pharmaco-kinetically derived measure of the risk of CI-AKI. We investigated the association between CV/eGFR and the occurrence of CI-AKI in a consecutive population of patients undergoing primary PCI.

Methods and results: CI-AKI was defined as an absolute increase in serum creatinine ≥0.5 mg/dL or an increase ≥25% from baseline within 72 hours after the administration of contrast medium. A multivariate logistic regression analysis was carried out to assess independent predictors of CI-AKI. Receiver-operating characteristic (ROC) curve analysis was performed to assess accuracy of CV/eGFR as predictor of CI-AKI, as expressed by the AUC. The cutoff value was identified at the point where the sum of sensitivity and specificity was the highest according to the Youden index [(sensitivity+specificity)-1]. 470 consecutive patients were prospectively enrolled. We observed 25 (5.3%) cases of CI-AKI. These patients were older (73±10 vs. 61±12 years, p<0.001), had more severe impairment of haemodynamic status (Killip score 1.4±0.8 vs. 1.1±0.5, p=0.01) and worse basal renal function (eGFR 53±19 vs. 94±32 mL/min per 1.73 m², p<0.001) than patients without CI-AKI. In addition, patients with CI-AKI had a higher prevalence of hypertension and diabetes and a higher troponin at admission (22±68 vs. 8±39, p=0.01). Mean procedural CV was 164±63 ml; the incidence of CI-AKI was not higher across different quartiles of CV and, notably, no patient exceeded the MACD. Despite patients developing CI-AKI had not received an absolutely higher total contrast volume (165±79 vs. 163±62 mL, p=NS) nor a higher number of stents, they had received a much higher renal function-adjusted CV (CV/eGFR 3.62 vs. 1.96, p<0.001). Conversely, the difference in CV/MACD, as calculated by the Cigarroa formula, was not significant (0.52 vs. 0.40, p=0.07). By using ROC curve analysis for CIN risk according to CV/eGFR ratio, the AUC was 0.77, with the best cutoff value set at 2.5 (72% sensitivity and 78% specificity). Of note, CIN incidence was much higher (15%, p<0.001) in patients in the highest quartile of CV/eGFR ratio, corresponding to the cutoff indicated by the ROC curve (>2,5). At univariate analysis, several variables were associated with the occurrence of CIN. At multivariable analysis, however, only age (OR 1.08, p=0.023), ejection fraction (OR 0.95, p=0.026), troponin at admission (OR 1.01, p=0.038) and CV/eGFR above the threshold or in the highest quartile (OR 5.13, p=0.004) remained independent predictors of CIN.

Conclusions: Contrast volume remains a key risk factor for CI-AKI and our study supports the need for minimising contrast dose in patients with STEMI undergoing primary PCI. A CV restricted to no more than twice and a half the baseline eGFR might be valuable in reducing the risk of CI-AKI.



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Contrast-induced nephropathy in patients undergoing primary PCI

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Aims: Contrast-induced nephropathy (CIN) is the third leading cause of acute renal failure in hospitalised patients and has a negative prognostic impact with increased mortality and hospital stay. The incidence of CIN in patients undergoing primary percutaneous coronary intervention (PCI) is higher than in programmed procedures. In this scenario, CIN prevention measures are less applied than in programmed PCIs, probably because the urgency of primary PCI and the intention of reduce ischaemia times. Our aim was to analyse CIN in patients undergoing primary PCI and the role of hydration in its prevention.

Methods and results: 384 patients with acute myocardial infarction (AMI) who underwent primary PCI were randomly assigned to receive either hydration with normal saline: 1 ml/kg/hour since the begining of the procedure and 24 hours after it (SS group) or not (NS group). Contrast-induced nephropathy (CIN) was defined as a 25% or 0.5 mg/dL increase in serum creatinine ≥within 48-72 hours following the procedure. Mean age was 63.1±13.6 years, and 73.4% of the patients were male. 47.2% had hypertension, 22.6% diabetes mellitus, 12.4% renal dysfunction and 12.4% anaemia. Mean creatinine clearance was 88.8±38.46 ml/min. All patients received iodixanol contrast with a mean contrast volume of 174±73 cc. There were no significant differences between the two groups regarding baseline features. 49.4% of patients were included in SS group and 50.6% in NS group. An intention to treat analysis was performed with 30.2% of crossover between groups. NIC was observed in 14% of patients: 19.4% in the NS group and 7.9% in the SS group (p=0.016). CIN was a predictor of death (17.94% vs. 2.9%; p<0.0001) and extrarenal depuration measures (15.38% vs. 0%; p<0.0001). The other predictors of CIN in the univariate analysis were the feminine gender (p=0.005), advanced Killip class (p=0.025), hypertension (p=0.001), anemia (p=0.028), the higher creatinine prior the procedure (1.1 vs. 0.9 mg/dl; p=0.01), the higher age (68.5 vs. 62.7; p=0.009) and the lower haemoglobin prior the procedure [OR=0.72 (0.59-0.88); p=0.001] and the presence of hypertension [OR=0.31 (0.14-0.66); p=0.003], the haemoglobin prior the procedure [OR=0.72 (0.59-0.88); p=0.001] and the presence of hypertension [OR=0.429 (0.19-0.96); p=0.04].

Conclusions: Hydration during primary PCI, implies a relative reduction of risk of CIN of 59.2%. Patients who presented CIN had increased mortality and need of extrarenal depuration measures. Given the higher incidence of CIN in emergent procedures, and the morbidity that it implies, we should improve prevention measures in these patients.

Long term prognosis of contrast-induced acute kidney injury: a prospective analysis with three-year follow-up

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Aims: Contrast-induced acute kidney injury (CI-AKI) is associated with a worse outcome after PCI. Commonly used definitions are: a relative increase in Serum Creatinine (SCr) of at least 25% from the baseline values (definition 1), an absolute increase in SCr concentration of at least 0.5 mg/dL (definition 2), and an absolute increase in SCr of at least 0.3 mg/dL (definition 3), all presenting within 48-72 hours. The present study has two main aims: a) to prospectively describe the outcomes at a mean follow-up of 3 years in a population at high-risk of CI-AKI development undergoing percutaneous coronary procedures; b) to clarify which definition of CK-AKI correlates best with long-term events.

Methods and results: Monocentric, prospective, observational study enrolling patients presenting with need for urgent or elective coronary angiography and at least one of these risk-factors for CI-AKI: age ≥75; diabetes; stages 2 or 3 chronic kidney disease (NKF) and ST-segment elevation myocardial infarction (STEMI). Biochemical determinations were assessed at baseline under preventive hydration and 12, 24, 48 and 72 hours thereafter. Blood examinations were repeated also at 1 month and subsequently every 6 months up to 3 years after discharge, as per established protocol. Primary clinical end-point was a composite of death, MI and need for dialisys. We enrolled 216 patients (72% males; mean age 70 years) followed for a median of 1,121 days. The main indication for coronary angiography was acute coronary syndrome (60%), namely NSTEMI (n=47; 22%), STEMI (n=46;21%) and unstable angina (n=37;17%). Thirty-nine patients (18.1%) developed a relative increase in SCr of at least 25% from the baseline values (definition 1). Sixteen patients (7.4%) presented an absolute increase in serum creatinine (SCr) concentration of at least 0.5 mg/dL (definition 2). Finally, 37 patients (17.1%) developed CI-AKI defined as an absolute increase in SCr of at least 0.3 mg/dL. At three-year follow-up we observed 15 deaths (6.9%): of those 10(4.6%) were due to cardiovascular causes and 5(2.3%) to other causes. Nine patients (4.2%) had myocardial infarction, while 7(3.2%) experienced a major stoke. Finally 6 subjects (2.8%) needed chronic dialitic therapy. The three CI-AKI definitions were evaluated with Cox-Regression models in order to define which one performs better for the prediction of three-year primary end-point. Increments of at least 25% of SCr from baseline within 48-72 hours (definition 1) does not associate significantly with the considered events at long-term (p=0.81; HR: 1.110; 95% CI: 0.454-2.717). Similarly, absolute increments of SCr of at least 0.5 mg/dl from baseline values does not appear to be a valuable predictor for three-year outcome (p=0.74; HR: 1.224; 95% CI: 0.371-4.037). Interestingly, there is a significant association between long term-events and CI-AKI assessed by definiton 3 (absolute increments from baseline SCr of at least 0.3 mg/dl within 48-72 h; p=0.04; HR: 2.168; 95% CI: 1.193-4.734). At Kaplan-Meier analysis patients diagnosed with CI-AKI by definition 3 had 73.4±7.6% survival free from any death, MI or dialisys at 3 years, while CI-AKI negative patients had 87.3±2.6% event-free survival (p=0.04 at Log-Rank test).

Conclusions: In this sample of 216 patients at risk for CI-AKI we observed a 13.9% occurrence of death, MI or dyalisis at 3 years. Definition 3 for CI-AKI correlates best with long term events and is associated with 73.4% three-year event-free survival.



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Clinical outcomes of elderly south-east Asian patients (age >70 years) versus non-elderly patients in primary PCI for STEMI

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Aims: The local population in Singapore is ageing rapidly as the number of persons aged >65 years will escalate from 9% in 2008 to approximately 19% of local population in 2030. As a result, primary percutaneous coronary intervention (PPCI) for elderly patients with ST-elevation myocardial infarction (STEMI) is increasing and continues to be a therapeutic challenge. There is limited data on the clinical characteristics and in-hospital outcomes of elderly South-East Asian patients undergoing PPCI for STEMI in contemporary clinical registries.

Methods and results: From January 2009 to December 2011, 958 patients (86% male, mean age of 58±12 years) presented to our hospital for STEMIand underwent PPCI. They were divided into two groups: Elderly group defined as age >70 years (n=186) and Non-elderly group defined as age <70 years (n=772). Data were collected retrospectively on baseline clinical characteristics, mode of presentation, door-to-balloon (D2B) time, angiographic findings, therapeutic modality and hospital course. The elderly group constituted 19% of the study population with mean age 76.3±5.0 years. There was a higher proportion of female gender (32% vs. 9%, p <0.0001) and ethnic Chinese patients (80% vs. 60%, p<0.0001) in the elderly group when compared with their younger counterparts. The elderly group was less likely to be smokers and have a significantly higher prevalence of hypertension. The rates of antecedent diabetes mellitus, hyperlipidaemia and previous MI were similar between both groups. The types of MI (anterior, inferior, posterior) at presentation also did not differ between both group. Both groups had similar symptom onset-to-reperfusion time (elderly group: 256±198 mins vs. 249±211 mins, p=NS) but the mean D2B time was significantly longer in the elderly group (75±33 mins vs. 67±35 mins, p<0.005). Both groups did not differ in their mode of presentation (whether by self-transport: use of emergency ambulance services (%): 33: 67 vs. 36: 64, p=0.44). The elderly group had a significantly higher incidence of triple vessel disease (47% vs. 31%, p<0.0001) and obstructive left main disease (6% vs. 2.1%, p=0.01) on coronary angiography when compared to the non-elderly group. The use of radial artery access, glycoprotein 2b/3a inhibitors and drug-eluting stents during PPCI were also significantly lower in the elderly group. In-hospital mortality was significantly higher in the elderly group (11% vs. 4%, p=0.0003). However, there was no difference in the incidence of cardiogenic shock between both groups.

Conclusions: Our registry showed that the in-hospital mortality rate in elderly South-east Asian patients undergoing PPCI for STEMI was high. They had more extensive coronary artery disease, a longer D2B time and lower use of contemporary pharmaco-invasive treatment during PPCI which could account for their poorer prognosis. Further studies into the optimal STEMI management strategy for these elderly group of patients are warranted.



Importance of primary PCI for the oldest patients with acute myocardial infarction

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Aims: Older patients (defined as patients with age \geq 75 years old) represent around 30% of all admissions for acute myocardial infarction (AMI), and the mortality rate in this population is more than twice that of non-older patients (age \leq 75 years old). However, several previous studies have shown the effectiveness of primary coronary intervention (PCI) even in the older AMI patients. In addition, aging society in Japan, a lot of oldest (very) old AMI patients (age \geq 85 years old) have been treated by primary PCI. However, clinical importance and effect of primary PCI for the oldest old AMI patients was not well evaluated.

Methods and results: From January 2013 to November 2013, we enrolled consecutive 479 AMI patients (mean age 68±13, male gender 77%) from Mie ACS Registry in Japan. They were categorised into three groups. (non-older patients mean patients with age <75: n=308, older patients meaning patients with 75≤ age=85: n=55) Primary PCI was performed over 88% enrolled patients (non-older patients 89%, older patients 87% and oldest (very) old patients: 84%, respectively). Overall 30 days in-hospital mortality was 8.6% in AMI patients with primary PCI. (non-older patients: 6.1%, older patients: 14.4% and oldest (very) old patients: 10.2%, respectively) Kaplan-Meier survival analysis of three groups provided the statistical significance of prognosis between three groups. (Log-rank test, p value of <0.03) However, older patients provided the poor prognosis of increased 30 days in-hospital mortality with hazard ratio (HR) of 3.0 compared to the non-older patients. (95% CI: 1.1-8.4, P<0.01), oldest (very) old patients did not show the significant difference in 30 days in-hospital mortality compared to the non-older patients and older patients. In multivariate analysis, Killip classification and serum-creatinine were independent predictor for 30 days in-hospital mortality. (HR 3.9, 95% CI: 1.3-11.6, p<0.02, and HR 2.3, 95% CI: 1.6-3.3, respectively)</p>

Conclusions: In this study population, higher age was not associated with the higher 30 days in-hospital mortality. Aggressive primary PCI for the oldest old AMI patients may provide the better prognosis similar to the younger patients.



Euro14A-0P047

Everolimus-eluting stent versus bare-metal stent in elderly (≥75 years) versus non-elderly

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Aims: To investigate the outcomes following primary PCI (PPCI) with BMS or everolimus-eluting stent (EES) in elderly (≥75 years) vs. non-elderly (<75 years) patients with STEMI enrolled in the EXAMINATION (Evaluation of the Xience-V stent in Acute Myocardial INfArcTION) trial.
Methods and results: The EXAMINATION trial randomised 1,498 STEMI patients to BMS or EES. The primary patient-oriented end point was the combined of all-cause death, any-recurrent myocardial infarction (MI) and any-revascularisation at one-year. The secondary end-point included the device-oriented combined of cardiac death, target-vessel MI and target-lesion revascularisation. These end points and their components were compared between elderly and non-elderly. Among patients enrolled in the trial, 245 (16.3%) were elderly, allocated to BMS (n=132) or EES (n=113), while the remaining 1253 (83.7%) were non-elderly, allocated to BMS (n=615) or EES (n=638). Elderly had more frequently diabetes (p<0.001), hypertension (p<0.001), prior stroke (p=0.001), higher Killip Class at presentation (p<0.001) while had a lower body mass index (p<0.001) and ejection fraction (p<0.001) compared to non-elderly. In addition elderly required a higher number of stent (p=0.011), generally smaller (p=0.003), longer (p=0.020) and overlapped (p=0.028) as compared to non-elderly. Similar baseline clinical, and procedural characteristics were reported between BMS or EES patients within age groups. At one-year, both the patient and the device-oriented end-points were observed more frequently in elderly vs. non-elderly group (24.5% vs. 10.5%, p<0.001 and 15.9% vs. 5.1%, p<0.001). In non-elderly, both patient and device-oriented endpoints were lower in EES vs. BMS (12.4% vs. 8.8%, p=0.03 and 6.7% vs. 3.6%, p=0.01); however, no differences were found in elderly. On multivariate analysis age ≥75 years was an independent predictor (HR 2.19[95% CI 1.594-3.016], p<0.0001) of the patient-oriented end-point at one-year.

Conclusions: In STEMI patients undergoing PPCI, advanced age (\geq 75 years) is associated with worse outcomes. EES seems to provide better outcomes than BMS only in <75 year-old patients.



PCI with radial approach in a population older than 85 years hospitalised for ACS: a single-centre experience

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Aims: The proportion of elderly population in the patients admitted for ACS is growing. There is evidence that the age is one of the most predictors of adverse outcomes. The benefit of percutaneous coronary revascularisation in very old patients has been poorly investigated.

Methods and results: Retrospective analysis of consecutive patients with more than 85 years admitted to our hospital for ACS between January 2007 and June 2013 who underwent PCI. Baseline characteristics of the patients, ACS datas, procedural informations, need of access shift, vascular complications were recorded. 206 patients >85 yy with ACS underwent PCI in this period (10% of the SCA population admitted at the intensive coronary care unit). 57% were female. The mean age was 87.2 yy (13% were nonagenarian patients). 56% of the patients were admitted for STEMI, 44% for NSTEMI. The radial access was performed in 62% of the patients, witha percentage increase from year to year (2007: 8%, 2008: 11%, 2009: 58%, 2010: 74%, 2011: 87%, 2012: 88%, 2013: 93%). No radial access site complications occurred. The success rate of the procedure was 95%. The arterial shift from radial to femoral occurred in 3% of the patients. The culprit vessel was: 4% unprotected left main, 45% the left anterior descending, 20% the circumflex, 27% the right coronary artery,1% the intermedium, 3% saphenous vein graft bypass. In 20 patients (9%) was performed a PCI without stent. The number of stent per patient was 1.3. The number of DES: 28 (10%). The use of Glycoprotein Ilb/IIIa inhibitorswas 2%. Major bleeding, major stroke, and need for dialysis were respectively <2%, <1%, <1%. The in-hospital mortality in STEMI and in NSTEMI group treated with PCI was respectively 8% and 2%.

Conclusions: In our experience the percutaneous coronary revascularisation strategy in elderly patients is feasible. The transradial artery approach for treatment of elderly ACS patients over 85 years are safe with high success rate. This approach can improve safety and patient comfort.



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Favourable outcomes in octogenarians treated with bioresorbable polymer DES

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Aims: The elderly usually have higher prevalence of comorbidities, are underrepresented in clinical trials and more often experience complications during and after revascularisation procedures. There is a trend towards increased number of PCI procedures in the elderly, but this trend is hampered by higher short- and long-term morbidity and mortality. The challenge evolves in the era of DES due to effects of dual antiplatelet therapy. Our aim was to evaluate clinical outcomes of patients older than 80 years, compared to their younger counterparts, when bioresorbable polymer DES is used for their treatment

Methods and results: Large, prospective, single-arm, multicentre, observational e-NOBORI registry was created to validate the safety and efficacy of bioresorbable polymer DES in unselected patients. Within the study group, 654 patients (7.44%) were older than 80. Primary endpoint of the study was freedom from target lesion failure (TLF) defined as a composite of cardiac death, target vessel related myocardial infarction (MI) and clinically driven target lesion revascularisation (TLR) at 1 year. All adverse events (including stent thrombosis) are adjudicated by an independent clinical event committee. The elderly patients were less frequently male (62.08% vs. 77.45%; p<0.0001), had higher prevalence of hypertension, renal failure, peripheral arterial disease, previous PCI and cardiac surgery, and were more often presented as acute coronary syndrome, especially NSTE – ACS (ACS 44.04% vs. 39.34%; p=0.0182; NSTEMI 23.55% vs. 17.35%; p<0.001). The lesions treated in the elderly were more likely to be ostial (14.76% vs. 11.39%; p=0.0014), moderately or severely calcified (43.86% vs. 28.97%; p<0.0001), and treated with rotational atherectomy (2.19% vs. 0.97%; p=0.0003). The procedural success was very high in both groups, but still lower in the elderly as compared to younger patients (98.14% vs. 99.00%; p=0.0398). The elderly had higher incidence of in-hospital death (0.92% vs. 0.25%; p=0.0024), while there were similar rates of myocardial infarction (0.31% vs. 0.42%; p=NS) and repeated revascularisation during index hospitalisation. The occurrence of TLF at one month was similar (1.83% vs. 1.08%; p=NS). Twelve months follow-up was completed for 97.09% of the elderly and 98.83% of the younger patients. At one year, the elderly more often discontinued dual antiplatelet therapy, and aspirin was used in 92.93% vs. 96.82% in younger patients (p<0.0001). Although one-year mortality was higher in the elderly group (3.73% vs. 1.47%; p<0.0001), the incidence of primary endpoint –TLF, was similar in two groups (3.58% vs. 2.82%; p=NS). In addition, older patients had more bleeding and vascular complications at 12 months (2.67% vs. 1.05%; p=0.0002) and higher rate of serious bleeding with haemoglobin drop of ≥5 g/dL (29.41% vs. 9.52%; p=0.0263). Total rates of stent thrombosis were low and similar in both groups (0.47% vs. 0.54%; p=NS).

Conclusions: Despite advanced age, multiple comorbidities, and complexity of treated lesions, clinical outcomes are similar in octogenarians treated by bioresorbable polymer DES compared to their younger counterparts. Low rates of TLF and stent thrombosis after one year further support the use of this stent in elderly.



Usefulness and safety of intracoronary administration of nicorandil for evaluating FFR in Japanese patients

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Aims: FFR is a useful index for determining the functional significance of epicardial coronary stenosis and may facilitate clinical decision making in patients with an equivocal coronary stenosis. Therefore, determining an efficient and safe method to achieve hyperaemia is important for evaluating FFR. We investigated the usefulness of intracoronary bolus administration of nicorandil (NIC) compared with intravenous administration of ATP in the evaluation of FFR.

Methods and results: The FFR was measured at maximal hyperaemia induced by ATP at 150 microgram/kg/min through a large forearm vein or by intracoronary bolus administration of 2-mg NIC. We had its beginning with the hyperaemic dose check in 14 vessels of 11 patients of study patients. 92.9% reached hyperaemia by intracoronary bolus administration of 2-mg NIC. A total of 130 vessels of 101 Japanese patients suspected angina pectoris were investigated: 84 left anterior descending arteries (LAD), 27 left circumflex arteries (LCX), and 19 right coronary arteries (RCA). FFR values using NIC were strongly related with those using ATP in all the vessels (regression coefficient [beta]=0.974, R²=0.933, P <0.001). This relation of FFR values obtained with ATP and NIC was found in each vessel, LAD, LCX, and RCA (LAD: beta=0.981, R²=0.930, P <0.001, LCX: beta=0.956, R²=0.886, P <0.001, RCA: beta=0.884, R²=0.924, P <0.001, respectively). Additionally, we checked side effects and the time to evaluate FFR values by administration of ATP or NIC. There were no hypotension cases requiring vasopressor, with ATP or NIC administration, and there was one transient second-degree atrioventricular block after ATP administration; however, this event was not clinically significant. The time to hyperaemia after ATP administration was significantly longer than that after NIC administration (197.9±23.8 s vs. 18.9±9.6 s, respectively; P <0.001).

Conclusions: Intracoronary bolus of 2-mg NIC is sufficient to achieve hyperaemia, and that it is better than intravenous administration of ATP, because the use of NIC reduced the handling time for FFR. Moreover, intracoronary bolus administration of 2-mg NIC was as safe as the intravenous administration of ATP. Intracoronary administration of NIC to evaluate FFR is more useful than and as safe as intravenous administration of ATP in Japanese patients.



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Patterns of use and clinical utility of FFR in patients referred for coronary angiography: the POST-IT (POrtuguese Study on The Evaluation of FFR-gulded Treatment of coronary disease) prospective multicentre registry

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Aims: We aimed to describe the patterns of use of FFR in a real world population and to which extent the information gained from it would have an impact on the final patient management strategy.

Methods and results: From March 2012 to November 2013, 918 consecutive patients referred for coronary angiography, in whom at least one lesion was interrogated by FFR, were prospectively enrolled in a nationwide multicentre registry in 19 hospitals. Information on demographics, clinical setting, angiography, FFR evaluation, and revascularisation procedure (if applicable) was collected in a dedicated electronic Case Report Form. As part of the inclusion algorithm, operators were asked to establish a treatment plan for each lesion (revascularisation, medical therapy or non-invasive stress test) based on all available information, before FFR determination. At the end of the procedure, agreement between the final and initial strategies was recorded perlesion and per-patient. Although the main indication for angiography was suspected stable coronary disease, 35.4% of the patients were evaluated in the setting of an on-going or recent ACS. The overall prevalence of prior functional non-invasive testing or MSCT was 46.7%. A total of 1,294 lesions were assessed (1.4/patient), most of which were located in the left anterior descending coronary artery (54.6%); 46% were type B2/C and in 73% the diameter percent-stenosis ranged from 50 to 70% (average 60±13%). The overall per-lesion success rate of FFR evaluation was 99.4% (1,286/1,294). Average FFR was 0.81 in the whole cohort; of note, 10% (51/510) of the lesions with an FFR <0.80 were deferred, whilst only 3.5% (27/776) measuring >0.80 were treated. The proportion of patients allocated to each treatment strategy at baseline was 39% for medical therapy, 35% for PCI, 4% for CABG and 22% for a subsequent non-invasive stress test. After FFR was known, treatment strategy changed in 45.0% of all lesions and in 44.3% of the patients. Treatment strategy change according to each initial decision was as follows: 27% for medical therapy, 29% for PCI and 44% for CABG. A final decision (47% medical treatment, 40% PCI and 13% CABG) was made in all patients (n=202) that had been ini

Conclusions: In this nationwide multicentre registry, that included a significant proportion of ACS patients, assessment of coronary lesions using FFR, changed management strategy in almost half of the cases. These results highlight the potential clinical and economic implications of FFR evaluation, across a wide range of patients with both stable and unstable coronary artery disease. (POST-IT. ClinicalTrials.gov identifier: NCT01835808).

FFR versus angiography in guiding management to optimise outcomes in NSTEMI clinical trial: relationships between FFR and angiographic stenosis severity at baseline

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Aims: Treatment decisions in the invasive management of patients with non-ST elevation myocardial infarction (NSTEMI) are usually made based on subjective visual interpretation of the coronary angiogram. We aimed to assess the relationships between coronary stenosis severity and myocardial fractional flow reserve (FFR) in NSTEMI patients. We hypothesised that functional assessment of coronary stenosis severity with fractional flow reserve (FFR) would differ markedly with angiography.

Methods and results: FAMOUS-NSTEMI (NCT01764334) is a prospective multicentre randomised double-blind controlled trial in patients with ≥ 1 coronary stenosis $\ge 30\%$ severity (threshold for FFR measurement). Stenosis severity was assessed visually by the cardiologist in the catheter laboratory. FFR was measured in all coronary arteries with a stenosis $\ge 30\%$ severity including culprit and non-culprit lesions. A visual estimate of stenosis severity of $\ge 70\%$ (50% left main coronary artery) and an FFR≤0.80 were taken as thresholds for an obstructive lesion. 350 patients were randomised between October 2011-May 2013 in 6 UK hospitals. The participant characteristics are: mean±SD age 62±11 years, 74% men, 15% treated diabetes, 11% prior PCI and 13% prior MI. On average each patient had 1.9±0.8 angiographically diseased coronary arteries (left main coronary artery 10%, right coronary artery 58%, left anterior descending/diagonal artery 54%, circumflex/obtuse marginal 64%) and an FFR<=0.80 was recorded in 62% of all lesions (n=700). Missclassification between visual assessment of lesion severity occurred in ~30% of all lesions. 14(4%) lesions described as >90% stenosis severity had an FFR<=0.80 and 5(2%) mild lesions 30-50% severity had an FFR<=0.80.

Conclusions: Overall, there was marked discordance between stenosis severity and FFR. Compared to FFR, visual assessment over-estimated angiographic lesion severity in a high proportion of cases. This relationship was at least as discordant as in the FAME trial population.



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Deferral of PCI according to FFR versus routine DES implantation in intermediate coronary stenosis: a randomised trial

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Aims: In patients with an intermediate coronary stenosis, long-term clinical outcomes of deferral of PCI based on FFR≥0.75 was not randomly compared to routine DES implantation in DES era. We evaluated the five-years clinical outcomes of deferral strategy of PCI for functionally nonsignificant coronary lesions by a randomised trial

Methods and results: This trial was performed in 7 medical centres in Korea. 228 patients scheduled for PCI of an angiographically intermediate coronary stenosis (50~75%) were randomly assigned to FFR-guided PCI or routine-PCI strategy. After randomisation, patients assigned to FFR-guided underwent DES implantation for an indicated lesion only if the FFR was less than 0.75 (FFR-PCI group, n=29). If FFR was ≥0.75, patients were assigned to deferral of PCI (FFR-defer group, n=85). Whereas, those assigned to routine-PCI strategy underwent DES implantation without FFR measurement for an indicated lesion (routine-PCI group, n=114). The primary endpoint was death from any cause, nonfatal myocardial infarction, and repeat revascularisation at 5 years. Five-years event rate was similar between the FFR-defer and routine-PCI groups (14% versus 18%), but was significantly higher in the FFR-PCI group (31%). Also, target lesion related events (target lesion revascularisation or target lesion related myocardial infarction) was similar between the FFR-defer and routine-PCI groups (14% versus 18%), but was significantly higher in the FFR-PCI group (21%) at 5 years.

Conclusions: In patients and lesions with functionally nonsignificant coronary stenosis, deferrals of PCI have excellent long-term clinical outcomes in DES era as well as BMS era. A FFR-guided strategy can reduce unnecessary PCI which doesn't improve clinical outcomes.

Agreement in the treatment of intermediate coronary stenosis among interventional cardiologists

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Aims: An intermediate coronary lesion was defined as a stenosis between $\ge 40\%$ and $\le 70\%$. The fractional flow reserve (FFR) by pressure guidewire is indicated to assess the haemodynamic significance of moderate stenosis in the absence of functional information. The aim of this study is to analyse the interobserver variability in visual assessment of angiographically intermediate coronary lesions by interventional cardiologist experts, and their comparison with the functional severity by pressure guide.

Methods and results: Analysis of patients with intermediate coronary lesions undergoing coronary angiography between January 2009 and March 2011 admitted for ACS. Guide pressure was performed in all cases. Lesions were considered significant if FFR was ≤0.75. All lesions were visualised independently by three expert interventional cardiologists with at least 5 years of experience, who rated the coronary lesions in "severe" and "not severe". The degree of agreement was measured using the kappa statistic. We included 93 intermediate lesions belonging to 79 patients. 73.4% were men, mean age 61±9 years. The most common reason for admission was unstable angina. All lesions with positive pressure wire were revascularised, except in one case due to technical difficulties. Lesions with negative pressure wire were not revascularised. Of the 93 lesions, 19 (20.4%) lesions were considered responsible for coronary event. The overall kappa between observers was 0.263 (95% CI, 0.124-0.402, p=0.0001) and between observers and assessing FFR 0.153 (95% CI, 0.049-0 258, p=0.0003). No significant difference between the percentage of total agreement between observers when the lesion was functionally significant versus when the pressure wire was negative (35.4% vs. 48.5%, p=0.189). The visual assessment tends to overestimate the severity of lesions compared with FFR, existing over 21.5% classified as severe injuries by the Observer-1, 23.7% by the Observer-2 and 17.2% for the Observer-3.

Conclusions: There is great variability in the visual assessment of intermediate coronary lesions. This means that in clinical practice functionally non-significant coronary lesions could be treated unnecessarily, which could result in possible complications for the patient. The use of FFR is limited by the additional time needed and the current facility for the treatment of the coronary lesions, which favours to be treated even in a time less than that required for evaluation, or to defer the decision to clinically evaluate its impact, revascularisation postponing for a second time, resulting in the need for a new procedure, the greater number of days of hospitalisation, higher complication rate and higher economic costs.



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FFR guided PCI on long coronary lesions: 9-month follow-up results

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Aims: The aim of the present study was to evaluate immediate and long-term haemodynamic and clinical results of PCI on long coronary lesions in patients with diffuse coronary atherosclerosis.

Methods and results: 73 consecutive patiens with coronary lesions ≥30 millimeters were enrolled into the prospective, nonrandomised, single-centre clinical study. The primary endpoint was functional result (FFR) at 9 months. Secondary endpoints included target lesion revascularisation (TLR) and angiographic in-stent late lumen loss (LL) by quantitative coronary angiography (QCA) at 9 months. Baseline clinical characteristics included mean age of 67.81±9.95 years, 72.6% male, 20.5% diabetes. All patients had significant lesions with FFR 0.61±0.12. 60 (82.2%) patients had index lesion in left anterior descending artery (LAD). All study lesions were treated with new generation Biolimus A9, Everolimus and Zotarolimus-eluting stents. The average length of the stented segment was 51.3±14.6 mm. 100% angiographic and 94.5% haemodynamic (FFR >0.8) procedure success was achieved. The average value of FFR immediately after the procedure was 0.88±0.06. A slight postprocedural elevation of cardiac biomarker values was observed in all investigated patients, 5 (6.8%) of them were classified as PCI related MI. The clinical, angiographic and FFR follow-up was scheduled at 9 months. 39 of study patients already completed the follow-up. There were no acute coronary syndromes in the study group, 3 (7.7%) patients had ischaemia driven target lesion revascularisation, with stabile angina and FFR <0.8. The average FFR at follow-up was 0.86±0.09, there was no significant difference compared with FFR measurement immediately after the procedure (p=0.13). In-stent LL was 0.3±0.1 mm.

Conclusions: Despite a tendency of higher in-stent LL, good haemodynamic result and acceptable rate of repeated revascularisation demonstrated PCI with new generation DES to be a good option for treating long coronary lesions.



R Coronary interventions Euro14A-0P056

Diagnostic accuracy of FFR to detect coronary ischaemic lesions in daily practice

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Aims: Clinical trials have shown low rates of clinical events in patients undergoing PCI of ischaemic lesions only as determined by a fractional flow reserve <0.8. However there is few data showing the diagnostic accuracy of FFR in real world practice

Methods and results: Since 3/11 until 7/13 a total of 324 coronary lesions were assessed by FFR in 238 patients in a single-centre following standard recommendations for FFR assessment (i.e. Adenosine continuous IV infusion at $140 \mu g/Kg/min$ rate). From this data set, we retrospectively assessed 202 lesions from 145 patients who had a baseline SPECT. Diagnostic accuracy of FFR was calculated using SPECT as the gold standard to detect myocardial ischaemia. Male were 73%, mean age was 64 ± 9 . 39% of patients had DM, 93% hypertension, 94% dyslipidaemia and 81% were non-smoking. Almost 40% of patients had silent ischaemia. QCA analysis in all lesions showed RVD= 2.7 ± 0.6 mm, and %DS= 66 ± 13 . IVUS MLA= 2.92 ± 0.9 and FFR 0.8 ± 0.10 . True positives were 49, true negatives 59, false negatives 50 and false positives 49. Sensitivity of FFR was 47% and specificity 54%. Positive and Negative predicted values were 46% and 54% respectively.

Conclusions: In this single-centre retrospective analysis of coronary lesions assessed by FFR in patients with a baseline SPECT, FFR did not show an adequate accuracy to detect myocardial ischaemia inducible coronary lesions.



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Operator dependency of the radiation exposure in cardiac interventions: effects of radiation reducing principles

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Aims: Occupational radiation exposure is a concern of catheterisation lab operators. Many interventionists have a less than ideal understanding of the risks of radiation and are not aware of the simple methods for decreasing radiation exposure. In this study we aimed to evaluate differences in radiation exposure of five operators, two of whom working with as low as reasonably achievable' (ALARA) principle.

Methods and results: In this prospective single-centre experience, radiation doses of five operators were measured by real-time dosimetry during 240 procedures over a period of 14 weeks. Two of these operators (Group 1 operators; operator 1 and 2) followed the main instructions of ALARA principle which included 1) Adequate instead of best possible image quality, 2) Optimal beam collimation to the region of interest, 3) Minimisation of radiographic beam time and 4) Less irradiating angulations. Other operators (Group 2 operators operator 3, 4 and 5) worked in a standard manner. Angiography unit was programmed to an automatic radiation reducing mode which was used in all procedures independent of the operator. Among these 240 procedures, 143 were coronary angiography, 70 were angiography followed by PCI, 18 were PCI and the remaining 9 were other procedures including pacemaker implantation, atrial septal defect closure, ventricular septal defect closure and mitral balloon valvuloplasty. Mean radiation dose of all procedures were compared between two groups and between each operator by independent sample T test and one way ANOVA. Mean radiation dose of the procedures by group 1 operators was significantly lower than the radiation dose of procedures by group 2 operators (95.21±125.30 mGy n=120 procedure vs. 346.76±383.54 mGy, n=120 procedure; p=0.000). When the operators were compared separately, mean radiation doses were 40.15±48.54 mGy for operator 1, 102.48±130.56 mGy for operator 2, 171.25±74.14 mGy for operator 3, 325.37±377.97 mGy for operator 4 and 409.15±408.75 mGy for operator 5 (p=0.000).

Conclusions: Consistent realisation of radiation reducing principles in invasive cardiology and individual self surveillance in daily routine enabled 4-10 fold decrease in radiation exposure.



Reference levels of radiation exposure in primary PCI: a single-centre experience

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Aims: There is a great variability regarding radiation doses received by patients in interventional cardiology because of the complexity of the procedure, the operator skill and the characteristics of the equipment and the procedure. Because of this issue, 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 primary percutaneous coronary interventions (pPCI). The purpose of this study is to propose reference levels of radiation exposure in primary PCI from the experience of a high volume university hospital.

Methods and results: We prospectively studied 384 consecutive patients with STEMI who underwent primary PCI between July 2012 and November 2013 in our interventional cardiology unit. We analysed the dose-area product (DAP), the fluoroscopy time, the DAP per minute of fluoroscopy (DAP/min) and the overall duration of procedures. We consider the third quartile as our reference level of radiation exposure in these procedures. Mean age was 63.1±13.6 years, and 73.4% of the patients were male. Mean BMI was 27.6±5.2 kg/m² (27.9% of patients were obese and 44.9% overweight). Median DAP was 72.8 Gyxcm² (1,9-572) for procedures with a median duration of 55 minutes (7-214) with a median fluoroscopy time of 10 minutes (0.5-59.4). Median DAP/min was 6.88 Gyxcm² (1.7-172). The third quartile of DAP, DAP/min, fluoroscopy time and duration of the procedure was 101 Gyxcm², 10 Gyxcm², 15 minutes and 70 minutes respectively.

Conclusions: In our experience, reference levels of radiation exposure in primary PCIs should be 101 Gyxcm² of DAP and 10 Gyxcm² of DAP/min. Reference parameters of fluoroscopy time and overall duration of the procedure should be 15 minutes and 70 minutes respectively. Because of the lack of published data and recommendations on this subject, multicentre studies are needed to define reference levels of exposure to ionizing radiation in the different types of interventional cardiology procedures regarding their complexity.



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A randomised trial comparing dual axis rotational versus conventional coronary angiography in a population with a high prevalence of coronary artery disease

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Aims: To compare the safety, radiation dose, and contrast volume between dual axis rotational coronary angiography (DARCA) and conventional coronary angiography (CCA).

Methods and results: From November 2012 to February 2013, 201 patients were randomly assigned to either CCA (n=100) or DARCA (n=101). Exclusion criteria included acute coronary syndrome (ACS), prior PCI or CABG. CCAs were performed in 4 acquisition runs for the left coronary artery and 2 to 3 acquisition runs for the right coronary artery, whereas DARCAs were performed in a single run for each coronary artery. Baseline demographics and clinical characteristics were similar for both groups. The overall prevalence of CAD was 77.6%. The DARCA group had a significant reduction in the amount of contrast, 60 mL (IQR 52.5 to 71.5) vs. 76 mL (IQR 68 to 87), p<0.0001); and radiation dose by Air Kerma, 269.5 mGy (IQR 176 to 450.5) vs. 542.1 mGy (IQR 370.7 to 720.8), p<0.0001. There were fewer patients requiring additional projections in the DARCA group: 54% vs. 75%; p=0.002.

Conclusions: In a population with a high prevalence of CAD, DARCA was safe and resulted in a significant decrease in contrast volume and radiation dose.



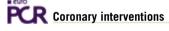
Patient and operator radiation dose using a pelvic lead shield during transradial angiography

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Aims: To determine the efficacy of a 0.5-mm lead apron across the patient's abdomen in addition to standard operator protection for the reduction of scatter radiation on operator radiation exposure and to measure also patient radiation dose.

Methods and results: We randomly assigned 202 patients undergoing coronary angiography to a group with pelvic lead shielding and a group without. In each procedure 8 dosimeters were used to measure operator radiation dose [under the lead apron, outside the thyroid shield and at the left side of the head] patient dose at the level of the umbilicus [above and beneath the lead apron] and 2 on the acrylic shielding and one on the image intensifier to measure scattered radiation. Both groups were similar in Body Mass Index, procedures performed and number of sequences. Usage of lead shielding statistically significantly reduced the radiation dose of the operator at all 3 sites measured: under lead apron: 0.02 ± 0.05 vs. 0.06 ± 0.17 , on thyroid collar: 0.37 ± 0.35 vs. 0.64 ± 0.79 and left side of head 0.24 ± 0.21 vs. 0.36 ± 0.35 . However the radiation for the patient was doubled 3.9 ± 10.95 vs. 1.51 ± 2.65 , p<0.001.

Conclusions: The use of a pelvic lead shield during radial angiography reduced the operator radiation exposure at multiple measurement sites. However there was an increased exposure to the patient. This balance has to be further investigated before the widespread of this method.



Euro 14A-0P061

Radiological exposure for patient and operator using radial or femoral approach

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Aims: The femoral approach remains the most popular for invasive coronary procedures, but the radial technique is associated with significant decrease in vascular complications rate. The aim of the study was to determine the influence of the most common percutaneous access sites – radial and femoral arteries - on the operator performing coronary angiography (CA) and percutaneous coronary interventions (PCI) radiological exposure and the radiation dose received by patients. Access site related complications and feasibility of both radial and femoral access procedures were investigated as well.

Methods and results: Patients admitted to Interventional Cardiology Department who were scheduled for coronary angiography followed by PCI, when applicable. Radiological exposure measurements have been performed in 39 patients (mean age 66, range 52-81 years). Twenty seven procedures corresponded to the radial access and 12 procedures to the femoral one. The doses to the left eye lens, both fingers, wrists and knees were measured during single procedure for every operator included in the study. Thermoluminescent dosimeters (TLDs) were used to measured doses in terms of Hp(3) and Hp(0.07) for the eye and extremities, respectively. Additionally, information on other factors that can affect the doses like various protective measures (for example transparent lead screen attached to the ceiling or lead glasses), fluoroscopy time, KAP (Kerma-Area Product) values and cumulative dose - were collected. The later is correlated with the patient dose and is used in the study to analyse patient exposure. For the extremities, the highest mean doses to the operator were observed on the left finger or on the left wrist depending whether radial or femoral artery is used. When the radial access was used the mean doses to the left finger were 0.100 mSv (median 0.100 mSv) and 0.189 mSv (median 0.110 mSv) for CA and PCI procedures, respectively while when the femoral one was used the corresponding mean doses to the left wrist were 0.043 mSv (median 0.039 mSv) and 0.045 mSv (0.040 mSv). As far as left eye lens is concerned the highest mean doses were observed during PCI procedures for the radial access (0.061 mSv with median dose 0.055 mSv) while the lowest one for CA procedures performed using femoral access (0.023 mSv with median dose 0.015 mSv). To analyse the effect of access site on the operator doses all doses measured during single procedure were normalized to KAP values. Statistically significant differences between two analysed percutaneous access sites with respect to normalized dose were recorded for left finger, right finger and right wrist (p<0.0004). The corresponding ratios of median doses observed when the radial access was used to those corresponding to the case of femoral access are: 3.9, 3.6 and 2.3. As regards patients the mean cumulative dose and fluoroscopy time values for all gathered diagnostic CA procedures were 193 mGy and 2.6 min, respectively while for all therapeutic ones 486 mGy and 8.4 min. According to coronary angiography using radial access mean cumulative dose (CD) for patient were 227 mGy with the median 172 mGy and for femoral access 125 mGy with the median 120 mGy (p=0.057).

Conclusions: The first results of the study suggest that radiation dose received by operator was greater in radial access, while for the patient there was no statistically significant difference.

Comparison of cine and fluoro coronary angiography: time to reduce radiation and perfection

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Aims: X-ray exposure of patients during coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA) may have some deleterious effects. Use of last-image-hold (LIH) mode in fluoroscopy, which enables the last live image to be displayed continuously when the radiation is terminated, could reduce radiation when compared with cine angiography. There is no previous study comparing coronary angiography radiation doses and image quality between fluoro angiography and conventional cine angiography techniques with new angiographic equipment.

Methods and results: We compared cumulative DAP, cumulative air Kerma, Fluoroscopy time (t), contrast use and image quality between fluoro angiography and conventional cine angiography techniques. 46 patients were enrolled into LIH group and 82 patients were prospectively enrolled into cine angiography group according to operator's decision. Cases were performed by 6 operators having >100 PCI case experience. Results were compared by student t-test. Mean cumulative air kerma was higher in cinegroup than LIH group (660.462 vs. 141.1998 mGy, p<0.0001). Mean cumulative DAP was higher in cine group than LIH group (50058.98 mGyCm² vs. 11349.2 mGyCm², p<0.0001). Mean fluoroscopy times were higher in cine group than LIH group (3.8707 min vs. 1.66 min, p=0.0047). Mean contrast use was higher in cine group than LIH group (112.07 cc vs. 88.15 cc, p=0.0008). Body mass Indices were not different between cine and LIH goup (28.7178 kg/m² vs. 30.2539 kg/m², p=0.0738). Cardiologists assessed LIH images sufficient for decision making and in only one of the LIH cases additional cine images were taken for better images.

Conclusions: Radiation doses, contrast use and fluoroscopy times are lower in fluoroscopic LIH angiography than cine angiography. Fluoroscopic LIH images conventionally have inferior diagnostic quality when compared to cine coronary angiography but with new angiographic systems with improved LIH image quality these images may be adequate for diagnostic coronary angiography.



Euro14A-0P063

Study of radiation dose and contrast based on route of access and height in patients undergoing coronary angiography/angioplasty

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Aims: To assess number of patients undergoing coronary intervention via different route of access and radiation dose/contrast dose used based on route of access and height of the patient

Methods and results: We obtained the data from the X-Ray request cards and ICM system. All patients who needed coronary angiography/ angioplasty both acute admission and elective cases were included. Patients who needed EP studies and or devices were excluded from the study. We looked at the following parameters: patient numbers, sex, height, route of access, radiation dose, screening time, contrast used and operator. Total 338 patients had coronary angiography/intervention over one month period. Male were 244 (72%) and female were 94 (28%). 31 patients, (9.1%) did not have their height/weight recorded on request cards/ICM. All had their radiation dose/contrast recorded. 127 procedures were performed from right femoral arterial access, with 52 diagnostics 58 interventional procedures. 12 diagnostics+graft and 5 with intervention+IVUS/FFR Intra aortic balloon pump and /or rotablator. The average height of the patients was 67.5 inches, average screening time was 7.1 minutes, average radiation dose was 4757.2 mSv and average contrast used was 147 ml. From left femoral arterial access 9 procedures were performed (diagnostics=0, diagnostics+graft=2, intervention=6, and intervention+pressurewire/FFR=1) Average height of the patients was 67 inches, average screening time was 10.1 minutes, average radiation dose used was 6366.6 mSv and average contrast used was 171.6 ml. 163 procedures were performed from right radial arterial access (78 diagnostics, 81 intervention, Intervention pressure wire/IVUS=4). Average height of the patients was 68.1 inches, average screening time was 7.8 minutes, average radiation dose used was 5494.3 mSv and average contrast used was 142 ml. 39 procedure were performed from left radial access (20 diagnostics, 12 intervention, 6 diagnostics and graft studies, 1 with intervention and FFR) Average height of the patient was 65.7 inches, average screening time was 6.7 minutes, average radiation dose was 4663.5 mSv and average contrast volume used was 130 ml.

Conclusions: Radiation dose and contrast depends on type of the procedure. In selected patient with short stature left radial access both for diagnostics/intervention has low radiation dose and low contrast volume.

High diagnostic performance of non-invasive FFR in patients with calcified and non-calcified coronary arteries

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Aims: Non-invasive fractional flow reserve derived from coronary CT angiography (FFRCT) has been shown to be superior to both coronary CT angiography (CT) and invasive coronary angiography (ICA) for the diagnosis of lesion-specific ischaemia using FFRcath as the reference standard. The diagnostic performance of FFRCT in relation to coronary artery calcification has not yet been determined.

Methods and results: Among 254 patients with stable coronary artery disease enrolled in the prospective, international HeartFlowNXT study, 214 had calcium scoring performed. All patients underwent CT, FFRCT, ICA and FFRcath with blinded independent analysis. Lesion-specific ischaemia was defined by FFRCT or FFR ≤0.8, while CT and ICA stenosis >50% were considered obstructive. Diagnostic performance of CT, ICA and FFRCT for patients with Agatston score of [A] zero (n=27), [B] 1-300 (n=117) and [C] >300 (n=70) were compared using FFRcath as the reference standard. 442 vessels were assessed in 214 patients (64±10 years; 62% male), with ischaemia (FFRcath ≤0.80) present in 60 (28%). Mean (±SD, range) Agatston score was 302 (±468, 0-3599). Per-patient diagnostic accuracy, sensitivity and specificity (95% CI) for ischaemia in [A]: for CT were: 41% (25-59), 100% (51-100), 30% (16-51), for ICA were 52% (34-69), 100% (51-100), 44% (26-63) and for FFRCT were 85% (68-94), 75% (30-95) and 87% (68-96) respectively; [B]: for CT were 52% (43-61), 91% (77-97), 36% (27-47), for ICA were 68% (60-76), 82% (67-92), 63% (52-72) and for FFRCT 83% (75-89), 85% (70-94) and 82% (72-89) respectively; and [C]: for CT were 49% (37-60), 91% (72-98), 29% (18-43), for ICA were 53% (41-64), 96% (78-99), 33% (22-48) and for FFRCT were 77% (66-85), 86% (67-95) and 73% (59-83) respectively. FFRCT had higher accuracy and specificity than CT and ICA at each level of coronary calcification studied.

Conclusions: FFRCT provides superior diagnostic performance compared to CT and ICA in both calcified and non-calcified coronary arteries with high accuracy and specificity. FFRCT provides a non-invasive method to accurately identify patients with or without ischaemia.



Euro14A-0P065

FFR calculation from 3-dimensional quantitative coronary angiography and TIMI frame count: a fast computer model to quantify the functional significance of moderately obstructed coronary arteries

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Aims: Myocardial fractional flow reserve (FFR) is an indispensable tool to identify individual coronary stenoses causing ischaemia. Measuring FFR by pressure wire has a small risk of injuring vessels during wire manipulation. The use of pressure wires significantly increases the operational cost of diagnostic angiography. Calculation of FFR from X-ray angiographic data alone may increase the utility of FFR assessment. The aim of the study was to present a novel computer model for fast computation of and to evaluate it in patients with intermediate coronary stenosis.

Methods and results: This was an observational and multicentre study. Consecutive patients with intermediate coronary stenoses undergoing pressure wire-based FFR measurements were analysed by a core laboratory. Three-dimensional quantitative coronary angiography (3D QCA) was performed and the mean volumetric flow rate at hyperaemia was calculated using TIMI frame count combined with 3D QCA. Computational fluid dynamics was applied subsequently with a novel strategy for the computation of FFR. Diagnostic performance of the computed FFR (FFRQCA) was assessed using wire-based FFR as reference standard. Computation of FFRQCA was performed on 77 vessels in 68 patients. The interrogated vessels had an average diameter stenosis of $46.6\pm7.3\%$ and an average FFR of 0.82 ± 0.11 , with lesions involving coronary bifurcation in as many as 64.9%. Abnormal FFR ≤0.8 was measured in 23 vessels (29.9). FFRQCA correlated well with FFR (r=0.81, p <0.001), with a mean difference of 0.00 ± 0.06 (p=0.541). Applying the FFR cut-off value of ≤0.8 to FFRQCA resulted in 18 true positives, 50 true negatives, 4 false positives, and 5 false negatives. The area under the receiver-operator characteristics curve was 0.93 (95% CI: 0.86-0.99) for FFRQCA, 0.73 (95% CI: 0.61-0.85) for minimum lumen area, and 0.65 (95% CI: 0.51-0.79) for percent diameter stenosis.

Conclusions: Computation of FFRQCA is a novel method that allows the assessment of the functional significance of intermediate stenosis. It may emerge as a safe, efficient and cost reducing tool for evaluation of coronary stenosis severity during diagnostic angiography.



Comparison of computationally calculated FFR using three-dimensional anatomical models of coronary stenoses created with three different methods to demonstrate the importance of accurate anatomy reconstruction

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Aims: Computational fluid dynamics modelling of patient-specific coronary arteries remains limited by image resolution and the phasic nature of coronary flow. The aim of this study was to investigate the significance of anatomical accuracy in the ability of computational models to calculate hyperaemic pressure gradients.

Methods and results: 21 vessels in 19 patients covering a wide range of disease severity (measured FFR=0.85±0.14) underwent OCT and angiographic imaging. 3D reconstructions of the anatomy were created using angiography only, OCT only and by co-registration of angiography and OCT. Angiographic reconstruction is quick and easy, but the in-plane resolution is low and does not allow for imaging the lumen in great detail. OCT-only reconstruction represents the lumen wall in great detail, but contains no information on vessel tortuosity and curvature. The co-registration of angiography and OCT combines the two methods to achieve a model of great anatomical accuracy, but is more time-consuming and not fully automated. Invasive simultaneous pressure and flow velocity recordings were made under adenosine-mediated hyperaemia using a pressure-flow wire (Combowire, Volcano Corp.). The patient-specific pressure and distal flow velocity data was applied in phasic simulations using the anatomical models to calculate the distal phasic pressure waveform and FFR for the three types of reconstruction. The results from the three sets of simulations were compared to the invasively measured FFR values. Mean FFR was 0.85 with range 0.69-0.96. 66.7% fell into the clinically important intermediate range (FFR 0.7-0.9). Using angiography alone, the correlation between computed FFR and measured FFR was poor (r=0.048, p=0.84), using OCT alone the correlation was (r=0.12, p=0.6). When angiography and OCT were co-registered, the relationship was significantly better (r=0.58, p=0.003), with 77% of cases being in agreement between measured and computed FFR.

Conclusions: The results of this study indicate that accurate anatomical reconstruction plays an important role in the ability of computational models to predict FFR. The presented results suggest that geometrical features such as the lumen shape and curvature must be reliably represented in 3D anatomy reconstructions used in computational models in order to obtain valid results. For this reason, high-resolution 3D imaging data are required as the base of the reconstruction.



Euro14A-0P067

Efficacy of contrast medium induced Pd/Pa ratio in predicting functional significance of intermediate coronary artery stenosis assessed by FFR

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Aims: The need of adenosine administration for the achievement of maximal hyperaemia limits the widespread application of Fractional Flow Reserve (FFR) in the real world. We hypothesised that Pd/Pa ratio registered during sub-maximal reactive hyperaemia induced by conventional non-ionic radiographic contrast medium (Contrast Medium induced Pd/Pa Ratio: CMR) can be sufficient for the assessment of physiological severity of stenosis in the vast majority of cases. The aim of the present study was to test the accuracy of CMR in comparison to FFR

Methods and results: 104 intermediate coronary stenoses were prospectively and consecutively enrolled. CMR was obtained after intra-coronary injection of 6 ml of radiographic contrast medium, while FFR was measured after administration of adenosine. Despite CMR values were significantly higher than FFR values (0.88 [IR 0.80-0.92] vs. 0.87 [IR 0.83-0.94], p<0.001), a strong correlation between CMR and FFR values was observed (r=0.94, p<0.001) with a close agreement at Bland Altman analysis (95% CI of disagreement: −0.029 to 0.072). ROC curve analysis showed an excellent accuracy of CMR cut-off of ≤0.83 in predicting FFR value ≤0.80 (AUC 0.97 [CI 95%, 0.91-0.99, specificity 96.1, sensitivity 85.7]. Moreover no FFR value ≤0.80 corresponded to a CMR ≥0.88.

Conclusions: CMR is accurate in predicting the functional significance of coronary stenosis. This could allow limiting use of adenosine to obtain FFR to doubtful cases. In particular, we suggest to consider significant a CMR value≤0.83, not significant a CMR value≥0.88 and to induce maximal hyperaemia using adenosine for FFR assessment when CMR is between 0.84 and 0.87.

Doppler-derived hyperaemic microvascular resistance predicts the occurrence of microvascular injury and microvascular perfusion deficits after angiographically successful primary PCI

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Aims: Between 40 and 50% of patients presenting with ST-segment Elevation Myocardial Infarction (STEMI) develop microvascular injury (MVI) despite complete angiographic restoration of epicardial flow. The purpose of this study was to investigate whether hyperaemic microvascular resistance (HMR) immediately following angiographically successful percutaneous coronary intervention (PCI) is related to both occurrence of MVI at cardiovascular magnetic resonance (CMR) and reduced myocardial perfusion at positron emission tomography (PET) as measured in the days following myocardial infarction.

Methods and results: 60 STEMI patients were included in this prospective study. Immediately after successful PCI, intracoronary pressure-flow derived HMR measurementswere performed. CMR cine and late gadolinium enhanced (LGE) imaging and H215O PET imaging were performed 4-6 days after successful PCI. Using CMR, MVI was defined as a subendocardial recess of myocardium with low signal intensity within a gadolinium-enhanced area. Myocardial perfusion was quantified using H215O PET. To define normal values of HMR, 16 patients referred for invasive coronary angiography served as a control group. Complete datasets were available in 48 patients of which 24 developed MVI. HMR in the culprit artery in patients with MVI was significantly higher than that in patients without MVI (MVI: 3.33±1.50 vs. no MVI: 2.41±1.26, p=0.03). Multivariable analysis showed that HMR was predictive for MVI (p=0.04). High HMR also correlated with decreased myocardial blood flow (MBF) on PET (CFR<2.0: 3.26±1.41 vs. CFR≥2.0: 2.24±1.19; p=0.03).

Conclusions: Elevated Doppler-flow-derived HMR directly following successful primary PCI correlates with CMR-defined MVI and decreased myocardial blood flow measured by PET at follow-up.



Euro14A-0P069

Contrast-induced hyperaemia as an alternative to adenosine-induced hyperaemia in the evaluation of FFR in coronary lesions

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Aims: Being able to evaluate the functional importance of coronary lesions with a pressure wire without inducing pharmacological hyperaemia with adenosine has gained increased interest. Coronary contrast medium allows a hyperaemic stimulus and may be an alternative to adenosine in a significant proportion of patients, as previously showed. We intended to evaluate the diagnostic accuracy of fractional flow reserve after contrast hyperaemia (FFRcont), as compared to conventional FFR evaluated after adenosine hyperaemia (FFRad).

Methods and results: 98 lesions (66 patients, mean age 63,9±10,5 years, 46 males) were prospectively evaluated, using pressure-wire (St. Jude Medical). The lesion baseline pressure gradient (Pd/Pa) was measured. FFRcont was evaluated after an intracoronary bolus of 10 cc of contrast medium. FFRad was evaluated after maximal coronary hyperaemia with adenosine infusion (central vein). FFRcont values were strongly correlated with baseline Pd/Pa (R² 0,83, p<0,0001) and with FFRad (R² 0,86, p<0,0001). The best cut-off point in the ROC curve to predict a FFRad <0.80 was 0.84 (AUC ROC 0,965, 95 CI 0,936-0,994; sensitivity 97,4%, specificity 84,7%, positive predictive value 80,9%, negative predictive value 87,7%, global accuracy 89,8%). All lesions with an FFRcont >0.85 (n=47) had an FFRad>0.80 (negative predictive value 100%); all lesions with an FFRcont <0.80 (n=25) had an FFRad <0.80 (positive predictive value 100%). As a result, "extreme" values of FFRcont (<0.80 and >0.85) allowed a correct prediction of FFRad in 72 lesions (73.5%). In 9 lesions, FFRcont was repeated with a 5 minutes interval, and the observed results were similar (Spearman rho 0,99, p<0,0001).

Conclusions: FFR measured after an intracoronary bolus of contrast medium has a high accuracy to predict FFR values after adenosine-induced hyperaemia. This technique allows the correct evaluation of functional severity in more than 70% lesions, obviating the need of adenosine-induced hyperaemia in a high proportion of patients. Adenosine can be reserved for patients with intermediate (0.80 to 0.85) FFR values after contrastinduced hyperaemia.



Coronary FFR measurement using contrast media: an alternative to adenosine

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Aims: FFR measurement requires to induce coronary hyperaemia in order to maximise blood flow across the stenosis, usually with adenosine (aFFR). However, adenosine can be contraindicated in some patients, can induce conductive and rhythmic complications (transient AV block or ventricular fibrillation), and represents an extra cost. Injection of contrast media, routinely performed to validate FFR guidewire placement, also induces hyperaemia and could be an alternative method to measure FFR (cFFR) but there is no data defining a threshold value. The objective of the study was to determine and to validate a threshold value of cFFR (as compared to aFFR) in patients with coronary artery stenosis (CAS) requiring haemodynamic invasive analysis.

Methods and results: This prospective multicentric study included 99 lesions in 73 consecutive patients with stable coronary disease. Patients with acute coronary syndrome within the previous month, chronic renal failure limiting contrast injection, anemia (Hb <10 g/l), tachycardia >90 bpm, bradycardia <45 bpm, hypertension (SBP>140 mmHg after nitrate infusion), significant aortic stenosis, or any condition associated with LV wall thickness >11 mm by echo, non controlled heart failure, and contra-indication to adenosine (asthma, pulmonary hypertension) were excluded. We performed measurements of cFFR and aFFR as follows: 1) baseline pressure value; 2) cFFR after IC contrast injection (Iomeprol or Iodinaxol, 10 ml intracoronary for left coronary artery or 6 ml for right coronary artery); 3) aFFR after IC injection of adenosine (150 µg IC for left coronary artery, 100-120 μg for right coronary artery). The first cohort (cohort A) included 26 patients (age 71±10 years, 70% male) with 34 lesions (51±11% stenosis, LAD n=14, CX n=12, RCA n=8) and was used to characterise the correlation between aFFR and cFFR and to determine the cFFR threshold value that accurately detected significant lesions (defined as aFFR value ≤0.8). Then we studied 47 consecutive subjects (age 68±11 years, 76% male) with 65 lesions (51±9% stenosis, LAD n=36, CX n=18, RCA n=11), (cohort B) as a validation group. From the cohort A, we showed that although cFFR induces slightly lower hyperhemia as compared to aFFR (0.84±0.10 vs. 0.82±0.12, p=0.44), it was significantly correlated with aFFR (Pearson's R=0.9; P<0.001). Receiver operator curve analysis revealed that the optimal cFFR threshold value was 0.85 (sensitivity=95%; specificity=73%; area under the curve: 0.92±0.05, p<0.001). We then prospectively tested this cut-off value in the cohort B. We found 27 significant lesion by aFFR (aFFR≤0.80) and 36 significant lesions by cFFR (cFFR≤0.85). Using this threshold, cFFR correctly classified 56/65 lesions. The sensitivity, specificity, positive and negative predictive values were respectively 100%, 76%, 75% and 100%. Significant complications occurred during aFFR in 4 patients: ventricular fibrillation (n=1), atrial fibrillation (n=1) and third degree atrioventricular block (n=2), and none after cFFR.

Conclusions: cFFR is an easy alternative method to induce hyperaemia and to avoid IC adenosine injection. A cFFR threshold value of 0.85 provides excellent sensitivity and negative predictive value.



Euro14A-0P071

Single-bolus regadenoson injection versus central venous infusion of adenosine to induce maximum coronary hyperaemia for measurement of FFR

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Aims: In coronary artery disease, Fractional Flow Reserve (FFR) measured with intravenous (IV) adenosine is the gold standard for assessing myocardial ischaemia. However, due to its non-trivial preparation, high price and need for a central venous sheath, use of adenosine to induce maximum hyperaemia may be a barrier. Abandoning maximum hyperaemia reduces diagnostic accuracy to approximately 80% compared to FFR. Therefore, endeavours to find new, easy-to-use pharmacologic stimuli are indisputable. Regadenoson is an A2A-receptor selective hyperaemic stimulus known for its rapid onset and simple administration. Aim of this study was to compare the hyperaemic effect of single bolus regadenoson injection to central venous adenosine infusion for FFR measurement. In addition, duration of steady state hyperaemia was studied, central versus peripheral venous regadenoson injections were compared and safety and reproducibility of repeated injections was investigated.

Methods and results: One hundred patients scheduled for FFR measurement were enrolled. FFR was first measured by IV adenosine (140 μ g/kg/min), thereafter by IV bolus regadenoson injection (400 μ g), followed by another measurement by IV adenosine and a second bolus injection of regadenoson. The administration of regadenoson injections was randomised to central or peripheral venous. Mean age was 66±8 years, 75% of the patients were male. The target stenosis was located in the LM, LAD, LCX, and RCA in 7%, 54%, 20% and 19% respectively, with a reference diameter of 3.2±0.6 mm. There was no difference in FFR measured by adenosine or by regadenoson, irrespective whether the latter was administered centrally or peripherally (Δ FFR=0.00±0.01, r=0.994, p<0.001). Onset of maximum hyperaemia occurred within 30 s, irrespective of the way of administration. Duration of maximum hyperaemia was variable (10-600 s). No noticeable side-effects of either drug were observed.

Conclusions: Maximum myocardial hyperaemia can be achieved easily, rapidly, and safely by one single intravenous bolus of regadenoson administered either centrally or peripherally. Repeated regadenoson injections are safe. The hyperaemic plateau is variable.



The physiological response of high dose adenosine

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Aims: The use of different diagnostics methods such as Intravascular Ultrasound (IVUS) and Fractional Flow Reserve (FFR) are currently increasing in patients undergoing coronary angiography. FFR is the most validated method and is associated with a better outcome for the patient. In order to achieve a reliable measurement, FFR is performed during hyperaemia, mediated by an Adenosine infusion of 140 ug/kg/min. Studies suggests that higher doses of Adenosine may improve the accuracy of FFR, but also correlates to a higher incidence of atrioventricular block, decrease of blood pressure, increase of heart frequency (HF) and discomfort for the patient. The aim of this study was to investigate the physiological response of high dose Adenosine, to observe the occurrence of arrhythmias and to evaluate patient discomfort measured by the Visual-Analogue-Scale (VAS). Methods and results: 12 patients undergoing FFR were consequetively included in this prospective, descriptive trial. All patients received two doses of adenosine, 140 µg/kg/min (normal dose) and after a approximately two minutes of recovery, 220 ug/kg/min (high dose). All FFR measurements were performed for two minutes while Mean Arterial Pressure (MAP) and heart rate (HR) were monitored. After each measurement, the patients were asked to score VAS at a scale 0-100. When the patients received normal dose Adenosine, there was a decrease in MAP of 2.42±4.42 mmHg, an increase in HF of 7.67±8.55 and a VAS score of 17±22.04 (mean±SD). One case of transient AV-block was observed. When the patients was administered high dose Adenosine, there was a decrease in MAP of 9.5±9.23 mmHg, an increase in HF of 8.42±8.62 and a VAS score of 85±19.7 (mean±SD). We observed 4 cases of transient AV-block. Analyzing normal dose versus high dose, there was a significant decrease in MAP (p=0.03) and a significant higher VAS score (p=0.002) during high dose regime. There was no significant difference in the occurrence of AV-Block nor increase of heart frequency. In addition, there were no statistically significant difference in FFR results between normal dose and high

Conclusions: High dose Adenosine significantly decrease mean blood pressure and increase VAS score and in addition, AV-block was more common. Even though the effects of Adenosine is swiftly transient, the haemodynamic difficulties and patient discomfort issues must be considered, and urges development of adenosine-free technologies like Instantaneous Wave Free Ratio (iFR).



Euro14A-0P073

The evolution of coronary flow reserve, index of microcirculatory resistance and FFR after STEMI

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Aims: This study investigated the relationship between invasive measures of the coronary circulation (coronary flow reserve (CFR), the index of microcirculatory resistance (IMR) and fractional flow reserve (FFR)) after ST-elevation myocardial infarction (STEMI) and contrast-enhanced cardiac magnetic resonance imaging (CMR) parameters of microvascular obstruction/haemorrhage (MVO) and final infarct size after primary percutaneous coronary intervention (PPCI).

Methods and results: 46 STEMI patients had pressure wire assessment immediately following successful PPCI, at day 1 and 6 months. 32/46 patients had MVO assessment on CMR at day 1 and 38/46 patients had final infarct size (FIS) assessment at 6 months. Median CFR (interquartile range [IQR]) was 1.5 (1.1-2.3) at PPCI, 2.3 (1.8-2.7) at day 1 and 3.4 (2.3-3.8) at 6 months (p<0.001). Median IMR (was 32.2 (19.4 to 55.5) at PPCI, 25.2 (17.5-41.0) at day 1 and 18.4 (15.5-25.8) at 6 months (p<0.001). In patients with larger FIS CFR was significantly lower at 6 months (p=0.02), with no difference in IMR (p=0.82). MVO at day 1 was present in 29% of patients with smaller FIS and 75% of patients with larger FIS (p=0.01). FFR was 0.94 (0.88-0.98) at PPCI, 0.92 (0.88-0.97) at day 1 and 0.90 (0.84-0.94) at 6 months (p<0.001) while the resting gradient remained stable over time (p=0.22) and there was no evidence of angiographic restenosis on quantitative coronary angiography. FFR significantly reduced in those patients with MVO between PPCI and 6 months (p=0.006) but did not change significantly in those without MVO (p=0.21).

Conclusions: In patients with STEMI treated with PPCI coronary microcirculation partially recovers within 24 hours and further by 6 months. CFR at 6 months is significantly higher in patients with smaller FIS. While the resting gradient seems to be a robust measure, which is not influenced by the coronary microcirculation, FFR significantly reduces from baseline to 6 months, especially in patients with MVO indicating that sufficient vasodilation is not possible in patients with severely impaired coronary microcirculation.



Longest available clinical follow-up of a cohort of "real-world" patients treated exclusively with DES: results of 12-year of the DESIRE (Drug-Eluting Stents In the REal world) registry

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Aims: 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 5,500 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 98.2% 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

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.



Euro14A-0P075

Real-world clinical performance of the sirolimus-eluting coronary stent system in Saudi patients: results from the multicentre SCORES registry

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Aims: The SCORES registry is designed to collect clinical outcome data from real-world Saudi patients receiving Supralimus-Core® sirolimus-eluting stent (SES) in daily practice.

Methods and results: This was a multicentre, observational, non-randomised, post-marketing surveillance registry, which included 482 daily practice patients, exclusively treated with biodegradable polymer-coated SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) were enrolled between January-2008 and November-2013. Primary end-point was: clinical incidence of major adverse cardiac events (MACE) up to four year. Clinical follow-up was completed in 458 patients (95.0%) up to four-year follow-up. A total of 482 patients were enrolled to the SCORES (Supralimus-Core Saudi) registry, with a mean age of 55.0±10.4 years. Of the whole study group, 257 (53.3%), 278 (57.7%) and 249 (51.7%) of patients had diabetes mellitus, hypercholesterolaemia and hypertension. Indications for percutaneous coronary intervention (PCI) were unstable angina in 173 (35.9%) of the patients, stable angina in 75 (15.6%) and cardiogenic shock in 2 (0.4%) of the patients. Of the lesions treated, 411 (58.2%) were classified as American College of Cardiology/American Heart Association type B2 or C. A total of 706 target lesions were treated, including 71 (10.1%) bifurcations, 98 (13.9%) total occlusion, 99 (14.0%) calcification, and 40 (5.7%) restenotic lesions. A total of 993 Supralimus-Core® stents were implanted at index procedure (2.06 stents per patient) with an average diameter and total stent length of 2.93±0.39 mm and 22.66±6.93 mm, respectively. Primary events developed in 30 patients (6.2%) up to four years consisting of 4 (0.8%) cardiac deaths, 19 (3.9%) target lesion revascularisation, 6 (1.2%) target vessel revascularisation and 1 (0.2%) stent thrombosis.

Conclusions: The present registry demonstrates satisfactory and sustained up to four-year clinical safety and efficacy profiles as evidenced by the low rates of MACE for the Supralimus-Core® SES, in unrestricted Saudi patients.



Real-world experience of a polymer-free rapamycin-eluting stent in very small coronary arteries: five-year results from a prospective registry

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Aims: The long-term impact of treating *de novo* coronary lesions in very small vessels is unknown. This report examines the five-year efficacy and safety of the polymer-free microporous rapamycin-eluting stent system YUKON-Choice (Yukon-DES, Translumina, Hechingen, Germany) in such patients.

Methods and results: From 01/2006-09/2008 all consecutive patients receiving a 2.0 mm Yukon-DES were prospectively enrolled in our registry. 6-months angiographic and long-term clinical outcomes were analysed. The primary endpoint was cumulative long-term major adverse cardiac events (MACE). 187 patients with 195 lesions (232 stents) were included in our registry. Mean age was 65.7±10 years (73% male). Risk factors included hypercholesterolaemia (64.7%), hypertension (82.9%), and diabetes (37.4%); table 1. Indication for percutaneous coronary intervention was acute coronary syndrome in 20.9%. 58.9% of the lesions were of Type B2/C, target vessel was left anterior descending artery in 25.4%, and 17.9% were total occlusions. Lesion length was 20.4±5.5 mm. A total of 161 patients (85.6%) underwent 6-months angiographic follow-up, binary restenosis was noted in 27.3%. At 5 years clinical outcomes of 169/187 (90.4%) followed patients were: cardiac death 5.9%; myocardial infarction 3.0%; and target vessel revascularisation 28.9%. The cumulative five-year incidence of MACE was 37.9% (7.1% per year). Incidence of stent thrombosis (ST) was 3.02% [definite 2.59%; probable 0.43%]. Incidence of very late (>1 year) definite/ probable ST was 0.86%.

Conclusions: Our registry data suggests that the implantation of YUKON-DES in very small coronary arteries is feasible and safe, but binary restenosis and target vessel revascularisation were frequently observed.



Euro14A-0P077

Implantation of a biodegradable polymer biolimus-eluting stent in patients with STEMI is associated with decreased cardiac mortality and major adverse cardiac events (MACE) compared to a permanent polymer sirolimus-eluting stent: five-year follow-up results from the all-comers LEADERS trial

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Aims: The study sought to investigate the five-year clinical outcomes of biodegradable polymer biolimus-eluting stents (BES) in treating patients with acute myocardial infarction (MI), compared with durable polymer sirolimus-eluting stents (SES) from the all-comers LEADERS trial. **Methods and results:** Among 1707 patients enrolled in the prospective, multicentre, all-comers LEADERS trial, a total of 573 patients were presented with AMI (Non-ST-elevation MI (n=298) or ST-elevation MI (STEMI) (n=275)) and were treated either with a BES (n=280) or a SES (n=293). Their baseline characteristics were similar between BES and SES groups except higher rates of off-label use in the BES group (SES 83.6%, BES 89.6%, p=0.034). At five-year follow-up, the BES was associated with a significant reduction in the patient orientated composite endpoint of all death, MI, or any revascularisation compared to the SES (34.7% vs. 39.9%, risk ratio: 0.84 [95% confidence intervals: 0.71-0.98], p=0.02). The rate of definite stent thrombosis in the BES was lower than in the SES (4.3% vs. 6.8%, risk ratio 0.61 [95% confident intervals: 0.30-1.25], p=0.18). In the STEMI subgroup, there were significant lower rates of cardiac death (3.0% vs. 11.4%, risk ratio 0.25 [95% confident intervals: 0.08-0.75], p=0.013), and major cardiac adverse events (MACE) defined as composite of cardiac death, MI, or clinically indicated TVR (12.6% vs. 25.0%, risk ratio 0.47 [95% confident intervals: 0.26-0.83], p=0.01) in the BES compared with the SES. The rate of definite stent thrombosis in the BES was lower than the SES (3.7% vs. 8.6%, risk ratio 0.41 [95% confident intervals: 0.15-1.8], p=0.098).

Conclusions: The new generation BES with biodegradable polymer compared to SES with durable polymer provided significant five-year follow-up improvements in clinical safety and efficacy outcomes in patients with acute MI. The benefit appeared more significant in the subgroup of patients with STEMI. (ClinicalTrials.gov, number NCT00389220)



Safety and efficacy of Resolute zotarolimus-eluting stents versus everolimuseluting stents: a meta-analysis of 5 randomised trials including 9,899 patients

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Aims: Contemporary drug-eluting stents (DES) represent the standard of care for patients undergoing percutaneous revascularisation. It is still debated, however, whether the safety and efficacy profile of Resolute zotarolimus-eluting stents (R-ZES) is comparable to everolimus-eluting stents (EES) that are considered the benchmark for safety at this point in time.

Methods and results: We searched PubMed and conference proceedings for reports of randomised comparisons of R-ZES and EES until December 2013. Five trials were identified: RESOLUTE All-Comers, TWENTE, ISAR-LM 2, DUTCH-PEERS, and HOST-ASSURE – including a total of 9,899 patients. Random-effects meta-analyses were performed comparing clinical outcomes in R-ZES treated patients and EES treated patients up to maximum available follow-up. Analyzed endpoints were ARC definite or probable ST, cardiac death, and target-vessel myocardial infarction (TV-MI) for safety, and target vessel revascularisation (TVR) for efficacy. Compared with EES, R-ZES had similar risks of ST (RR 1.21, 95% CI 0.81-1.81), cardiac death (RR 1.05, 95% CI 0.82-1.34), TV-MI (RR 1.08, 95% CI 0.86-1.36), and the composite of cardiac death and TV-MI (RR 1.08, 95% CI 0.91-1.28). A landmark analysis at 1 year showed that the risk of ST was comparable with R-ZES and EES at 1 year (early/late ST: RR 1.30, 95% CI 0.77-2.21) as well as beyond the first year of follow-up (very late ST: RR 0.84, 95% CI 0.36-1.94). As it relates to efficacy, the risk of TVR was similar with R-ZES and EES up to longest available follow-up (RR 1.03, 95% CI 0.87-1.22). No evidence of heterogeneity was observed across trials (I-squared=0% for all analysed endpoints).

Conclusions: According to this meta-analysis of 5 randomised trials including 9,899 patients, R-ZES have similar safety and efficacy as compared to EES, with no differences in risks of ST, cardiac death, TV-MI and TVR.



Euro14A-0P079

Long-term clinical results from the DESSOLVE I first-in-human trial and the DESSOLVE II randomised trial of a sirolimus-eluting stent with fully absorbable polymer

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Aims: Long-term clinical follow-up of new drug-eluting stents is essential to ensure continued safety in patients treated with these DES in clinical practice. Two clinical trials of the MiStent SES are currently in long-term follow-up; the DESSOLVE I clinical trial, a first-in-human study of 30 patients conducted at 5 sites evaluating the MiStent SES, and the DESSOLVE II clinical trial, a 2:1 randomised study of 184 patients conducted at 26 sites in evaluating the MiStent SES as compared to the control stent, the Endeavor Sprint.

Methods and results: The MiStent SES uses a unique combination of a crystalline formulation of sirolimus and a rapid, fully absorbable polymer on a thin-strut, cobalt chromium stent platform. The polymer coating is eliminated from the stent in 45-60 days with complete tissue absorption within 90 days; however, uniquely, the crystalline sirolimus continues to maintain tissue levels of sirolimus up to 9 months. In the trials, patients with discrete *de novo* lesions up to 27 mm in length in native coronary arteries were enrolled and followed for clinical events at predefined intervals. MACE, defined as all death, Q and non-Q wave myocardial infarction and all target vessel revascularisation. Additional secondary safety endpoints, including target lesion revascularisation, target vessel failure, target lesion failure and stent thrombosis were also collected and evaluated. Current clinical follow-up is through three-years for DESSOLVE I and 2-years for DESSOLVE II. For DESSOLVE I, MACE for MiStent was 3.3% at 8 months through 2 years with one non-target vessel non-Q wave MI reported. For DESSOLVE II, MACE for MiStent and Endeavor was 4.3% versus 6.7% (p=0.49) respectively at 9 months, 5.1% versus 8.3% (p=0.51) at 12 months and 6.7% versus 13.3% (p=0.167) at 2 years. Evaluation of clinical outcomes of the MiStent SES at 3 years for DESSOLVE I and 2 years for DESSOLVE II will be presented.

Conclusions: The MiStent SES is a unique DES that continues to demonstrate a sustained safety profile at 2/3-year follow-up.



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

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Aims: The EXCELLA BD Trial was designed to evaluate the long term safety and efficacy of the Elixir DESyne® BD Novolimus Eluting Coronary Stent System (CSS) with a bioabsorbable polymer compared to the Endeavor Zotarolimus Eluting Coronary Stent System

Methods and results: 149 patients were randomised 3:1, either to the Elixir DESyne BD Novolimus Eluting CSS loaded with 5 mcg 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 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 in-stent late lumen loss (LLL) assessed by qualitative coronary angiography (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 additional angiographic endpoints at 6 months including: in-segment LLL, percent diameter stenosis, minimal lumen diameter post-procedure, 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 (DoCE 2.7% vs. 3.2%, p=1.00). Sustained low event rates were observed through 24 months (DoCE 2.7% vs. 3.2% p=1.0), Clinical results through 36 months and complete angiographic and IVUS results will be presented.

Conclusions: The first report of long term (36 months) clinical results and complete angiographic and IVUS results of the DESyne BD Novolimus Eluting Coronary Stent with biodegradable coating will be presented.



Euro14A-0P082

Coronary calcification is a predictor of worse prognosis in patients with obstructive coronary artery disease undergoing PCI

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Aims: There is robust data that lesion calcium is related with a higher rate of target vessel revascularisation following bare metal or drug-eluting stent (DES) implantation. However, there is no evidence about the implications of coronary calcification on hard clinical end points at long term follow-up in the DES era. The aim of the present analysis is to investigate the prognostic impact of coronary lesion calcification in patients undergoing percutaneous coronary intervention with DES

Methods and results: The current analysis included data from 6,296 patients enrolled in 7 contemporary clinical DES trials. The presence of severe coronary calcification was detected by an independent academic research organization (Cardialysis, Rotterdam, the Netherlands) in the X-ray angiographic images and used to classify patients to those with an without severe lesion calcification. The clinical outcomes at three-years follow-up [i.e., all cause mortality, death-myocardial infarction (MI), and the composite end-point of all cause death-MI-any revascularisation] were collected and compared between the two groups. Severe lesion calcification was a common finding in the studied population as it was seen in 1 out of 5 patients. Patients with heavily calcified arteries had an increased mortality (10.8% vs. 4.4%, P<0.001) and incidence of death-MI (22.9% vs. 10.9%; P<0.001) and death-MI-any revascularisation (31.8% vs. 22.4%; P<0.001). In the multivariate logistic regression analysis, that included all the predictors of worse outcomes including the Syntax score, the presence of severe coronary calcification was an independent predictor of poor prognosis (Hazard ratio: 1.42 95% CI: 1.07-1.88, P=0.015 for death; 1.26, 95% CI: 1.05-1.53, P=0.016 for death-MI and 1.18, 95% CI: 1.01-1.39, P=0.037 for death-MI-any revascularisation).

Conclusions: The presence of severe lesion calcification is an independent predictor of worse outcomes in patients undergoing PCI with a drugeluting stent. It appears that severe coronary calcification provides additional prognostic information to the Syntax score propably because it indicates advanced atherosclerotic changes.



Very high pressure dilatation for undilatable coronary lesions: indications and results with a new dedicated balloon

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Aims: The inability to fully dilate calcified lesion might result in an increased risk of stent restenosis and thrombosis. Increasing the pressure beyond the recommended limits during dilatation of resistant lesions often accentuates non-uniform balloon expansion with the consequent over-dilatation of the more compliant segments (dog-boning effect). Conventional non-compliant (NC) balloons have more predictable responses and uniform dilatation than semi-compliant balloons but the 20 to 30 ATM limit that they reach can be insufficient. A variety of technologies such as rotational-atherectomy have been developed, however, the complexity and the cost of these devices have hindered their widespread use. This registry tested the safety and efficacy of a dedicated, super-high pressure non-compliant balloon (OPN, SIS Medical AG, Winterthur Switzerland) in a consecutive series of highly resistant coronary lesions.

Methods and results: We retrospectively evaluated a consecutive series of 91 lesions in which conventional non-compliant balloons at maximal pressure failed to achieve an adequate post-dilatation luminal gain and were therefore treated with an OPN-balloon up to 40 ATM. Out of the 91 lesions, 54 were heavy fibrocalcific lesion (59.3%) and 7 were ISR (7.7%) with incomplete initial stent expansion as main mechanism; in the remaining 30 cases the OPN balloons were used after stent deployment for stent optimisation (33%). Minimum lumen diameter (MLD) and percentage of diameter stenosis (%DS) were measured at baseline, after NC-balloon, OPN-balloon and stent implantation. Acute gain after conventional NC-balloon was defined as MLD (mm) post NC conventional balloon – baseline MLD (mm). Acute gain after OPN balloon was defined as MLD post OPN balloon (mm) – baseline MLD (mm). Incremental gain after OPN balloon was defined as MLD post OPN balloon (mm) – MLD post conventional NC balloon (mm). A total of 128 NC-balloons were used (1.4 per lesion). In all cases the dilatation performed with the conventional NC-balloon failed to achieve an adequate balloon expansion and luminal gain. After the failed attempt the OPN balloon with the same diameter of the conventional NC balloon was inflated up to 40 ATM. A total of 91 OPN balloons were used (1 per lesion). Angiographic success was achieved in 84 lesions (92.3%). All the remaining lesions received rotational-atherectomy with the exception of 2 cases in which rotational-atherectomy was not attempted because of small vessel size and excessive tortuosity. MLD and acute gain were significantly greater and % DS was significantly lower post OPN balloon inflation compared with post conventional NC balloon inflation (1.7 \pm 0.8 mm vs. 2.4 \pm 0.9 mm, p <0.001; 1.1 \pm 0.7 mm vs. 1.9 \pm 0.8 mm, p <0.001; 41.1 \pm 15.8% vs. 20.2 \pm 14.9%, p <0.001). These results were achieved with no increase in balloon size but with a higher inflation pressure (37.2 \pm 2.7 atm vs. 21.4 \pm 2.8 atm, p <0.001).

Conclusions: When conventional NC-balloons fail the new OPN-dedicated high-pressure balloon provides an effective and safe alternatively strategy for dilatation of resistant coronary lesions.



Euro14A-0P084

Clinical outcome of rotational atherectomy in complex calcified coronary lesions: data from the large multicentre Italian registry ROTATE

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Aims: Rotational atherectomy (RA) is widely used for treating calcified coronary lesions. Nevertheless clinical data about in hospital safety and efficacy and Major Adverse Cardiac and Cerebrovascular Event (MACCE)-free survival during follow-up remain limited. The ROTATE (ROTational AThEerectomy) multicentre Italian registry was developed to assess the short and long term outcome after RA in a large real world population.

Methods and results: From April 2002 to August 2013 a total of 453 consecutive patients (585 lesions), treated with rotational atherectomy, were collected in the multicentre ROTATE registry. Mean age was 70.8±6.6 years, 37.0% patients had diabetes mellitus and 35.1% patients had glomerular filtration rate lower than 60 ml/min. 43.9% patients had a previous myocardial infarction and 41.7% had a previous PCI. Lesion type, according to AHA/ACC classification was B1 in 4.8%, B2 in 25.4% and C in 69.9%. Chronic total occlusions were 8.2% of total. Femoral approach was the most used approach (87.6%) while the trans-radial approach was used in 12.4% of cases. More than one quarter of all procedure (28.4%) were IVUS-guided. Use of of intra-aortic balloon pump was needed in 39 patients (8.6%). Mean burr size was 1.54±0.23 with a burr/artery ratio of 0.54±0.08. Median total stent length per patient was 32.5±19.1 mm. The majority of patients were treated with first and second generation DES, only 8.1% did not received a DES (6.1% BMS, 2% no stent). Mean fluoroscopy time and contrast amount was respectively 43±24 minutes and 317±151 ml. Procedural complications occurred in 30 patients (6.6%), mainly coronary dissections (60.8% of total). We did not find any significant difference between the incidence of complication and AHA lesion type (7.4% in type C, 4.3% in type B2 and 4.5% in type B1 p=ns). In hospital death occurred in 0.9%, MI in 8.8% (respectively 7.3% nonQ wave and 1.5 Q wave), stroke in 1.0%, and TIMI bleedings in 2.4%. The incidence of in-hospital major adverse events (MACE) defined as death, MI and target vessel revascularisation was 10.6%. At a multivariate analysis, procedural complications (OR 4.24; CI 95% 1.75-10.28; p=0.001) and incomplete revascularisation (OR 2.22; CI 95% 1.08-4.55; p=0.030) were independent predictors of in-hospital events. The one- and three-year overall survival (Kaplan-Meier estimate) was 97.7% and 90.4% while MACCE (death, MI, stroke and revascularisation)-free survival was respectively 90.3% and 76.5%. Multivariate analysis using the Cox proportional hazards model showed that age (OR 1.08; CI 95% 1.03-1.12; p<0.001), diabetes (OR 2.97; CI 95% 1.64-5.38; p<0.001) and left ventricular ejection fraction (OR 0.96; CI 95% 0.94-0.99; p=0.006) were independent predictors of MACCE-free survival.

Conclusions: ROTATE registry represents the largest European data set of patients treated with RA in the DES era. RA appears to be feasible and effective, with a high rate of procedural success and favourable short and long term outcome even in this very complex real world population.

Coronary orbital atherectomy for treating *de novo*, severely calcified lesions in patients with impaired renal function: an ORBIT II 30-day sub-analysis

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Aims: It is well documented that peri-procedural complications, including myocardial infarction, occur more frequently in patients with impaired renal function following percutaneous coronary intervention. Since the ORBIT II trial enrolled patients that are typically excluded from clinical trials, including patients on dialysis, in this analysis we evaluate procedural and 30-day outcomes in patients with impaired renal function treated with the Coronary Diamondback 360° Orbital Atherectomy System (OAS) to prepare *de novo*, severely calcified coronary lesions prior to stent deployment.

Methods and results: ORBIT II patients were divided into two groups based on the estimated glomerular filtration rate (eGFR, mL/min/1.73 m²) at baseline: Group I (impaired renal function), eGFR<90 (n=333) and Group II (normal), eGFR≥90 (n=108). Patients in group I were older (p<0.0001) and as expected, the mean eGFR for group I was less than group II (65.0 vs. 109.1, p<0.0001). In addition, the total length of calcium in the treated lesion was significantly longer in group I (p=0.01). The occurrence of successful stent delivery (97.3% and 99.1%, p=0.46) and <50% residual stenosis (98.5% and 99.1%, p=1.0) were similar between groups I and II, respectively. Statistically similar rates of severe dissection (4.2% and 0.9%, p=0.13), perforation (2.1% and 0.9%, p=0.69), persistent slow flow (1.2% and 0.0%, p=0.58), and abrupt closure (1.8% and 1.9%, p=1.0) were observed in groups I and II, respectively. Freedom from major adverse cardiac events (MACE) at 30-days as estimated by Kaplan Meier was less in the group with impaired renal function (87.4% vs. 96.3%, p=0.02) as was freedom from myocardial infarction (88.0% vs. 97.2% p=0.01). Patients in groups I and II had similar freedom from cardiac death (99.7% vs. 100.0%, p=0.10) and target vessel revascularisation (98.8% vs. 98.1%, p=0.62).

Conclusions: Despite the older demographic and longer length of calcium, patients with impaired renal function who were pretreated with the OAS had similar rates of successful stent delivery and less than 50% residual stenosis. The impaired renal function patients had more 30-day MACE events driven predominately by myocardial infarction, however the rates were low when compared to previous PCI studies including severely calcified lesions.



Euro14A-0P086

The efficacy and clinical outcome of rotational atherectomy with second generation DES

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Aims: Treatment of calcified lesions with balloon angioplasty has been associated with a low success rate and high procedural complications. Rotational atherectomy (RA) improved acute results, but a high restenosis rate remained a problem. Therefore, the purpose of this study was to evaluate the clinical and angiographic outcome of patients with complex and calcified lesions treated with a combination of RA and second-generation drug-eluting stent (DES) implantation.

Methods and results: Consecutive 55 patients received combination therapy of RA and second-generation DES implantation at *de novo* lesion of native coronary artery with severe calcification between June 2009 and December 2012. Zotarolimus-eluting stents (ZES), biolimus-eluting stent (BES), and everolimus-eluting stents (EES) were used in 14, 7, and 34 patients, respectively. 39 patients (ZES, BES, and EES were used in 12, 6, 21 patients) received one-year follow-up angiography. The clinical and angiographic outcome was compared among those 3 groups of different DES. Only one patient was dead (a cause was unknown). Target lesion revascularisation (TLR) rate was 0% among 3 groups. The late loss was larger in ZES than in BES or EES (ZES vs. BES vs. EES: 0.37±0.20 mm vs. 0.20±0.10 mm vs. 0.16±0.15 mm, p<0.05). Consecutive 55 patients received combination therapy of RA and second-generation DES implantation at *de novo* lesion of native coronary artery with severe calcification between June 2009 and December 2012. Zotarolimus-eluting stents (ZES), biolimus-eluting stent (BES), and everolimus-eluting stents (EES) were used in 14, 7, and 34 patients, respectively. 39 patients (ZES, BES, and EES were used in 12, 6, 21 patients) received one-year follow-up angiography. The clinical and angiographic outcome was compared among those 3 groups of different DES. Only one patient was dead (a cause was unknown). Target lesion revascularisation (TLR) rate was 0% among 3 groups. The late loss was larger in ZES than in BES or EES (ZES vs. BES vs. EES: 0.37±0.20 mm vs. 0.20±0.10 mm vs. 0.16±0.15 mm, p<0.05).

Conclusions: The clinical outcome of 3 second-generation DES used in combination with RA was very good, although the culprit lesions were complex with severe calcification. Combination therapy of RA and second-generation DES appeared acceptable.



Comparison between transradial and femoral approach for rotational atherectomy in contemporary practice: large single-centre experience

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Aims: Transradial access is often avoided for rotablation atherectomy (RA) because of concern over limitations of guiding catheter (GC) size. Longterm clinical outcomes of patients undergoing RA with either of these approaches are not well known in the current era of PCI. The aim of this study was to compare the procedural success rates, in-hospital and long-term clinical outcomes in patients undergoing RA via radial and femoral routes. Methods and results: We retrospectively studied consecutive patients who underwent RA from April 2008 to October 2013 in a high volume tertiary cardiac centre. Procedure related bleeding was graded as per the Bleeding Academic Research Consortium (BARC) definition, MACE was defined as composite endpoint of death. MI, stent thrombosis and target lesion/vessel revascularisation. A total of 254 patients underwent RA (72%) radial and 28% femoral) procedure during the study period. The median follow-up period was 28 months (IQR 29 months). The mean age was not significantly different between those having radial and femoral approaches (70.8 vs. 71.9 p=0.67). Cardiovascular risk factors including diabetes, smoking, hyperlipidaemia and hypertension were comparable between the two groups. Significantly smaller size GC was used in the radial compared with the femoral group (6.4±0.5 vs. 6.8±0.7, p=0.001) although the average size of the burr was not different between the two groups (radial vs. femoral, 1.47 vs. 1.52 mm respectively, p=0.08). Moreover, there was no significant difference between the groups in the number of stents, stent lengths and diameters. The procedural success rates was similar in the radial and femoral groups (96.7 vs. 94.6%, p=0.44) In-hospital complications were double in femoral than in radial RA (18.9% vs. 9.0%, p=0.03). Access site complications were almost 3 times higher in the femoral group (16.2% vs. 6.1%, p=0.02). There was no major bleeding (BARC score >2) in radial group compared to 4.1% in femoral patients (p=0.002). A significantly higher proportion of elective PCI patients were discharged on the same day in the radial approach (79.2% vs. 53.8%, p=0.001). There was no significant difference between radial and femoral approaches in the in-hospital and long-term MACE events (2.2% vs. 0.0%, p=0.20 and 17.8% vs. 12.2%, p=0.27 respectively).

Conclusions: In this large real world study population, we have shown that it is feasible to perform PCI with RA via radial approach with very high success rates, lower access site complications and similar long-term outcomes compared to femoral procedure. A significantly higher proportion of patients in the radial group were discharged on the same day with potential cost savings.



Euro14A-0P088

Clinical outcome of rotational atherectomy with radial approach: data from the multicentre Italian ROTATE registry

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Aims: Aim of this study is to evaluate the feasibility and effectiveness of rotational atherectomy (RA) performed by TR approach in comparison with transfemoral (TF) access in our multicentre italian ROTATE registry.

Methods and results: In this retrospective multicentre registry of 453 patients treated with RA between April 2002 and August 2013 were recruited. Data about vascular access was available in 437 patients (96.5%). In 54 (12.4%) cases, the procedure was performed by TR access whereas in 383 (87.6%) by femoral approach. There was no difference between the two groups (TR vs. TF) in terms of age (69.4±10.5 vs. 70.3±8.9 years, p=0.49), gender (female: 17.0% vs. 11.2%, p=0.13), clinical presentation (ACS: 37.0% vs. 32.6%, p=0.52) and diabetes prevalence (35.3% vs. 37.1%, p=0.79). History of peripheral artery disease was more frequent in radial group (27.8% vs. 14.9%, p=0.017) whereas no difference in prevalence of prior MI (44.4% vs. 43.9%, p=0.93), previous PCI (38.9% vs. 42.6%, p=0.61) and previous CABG (23.1% vs. 27.2%, p=0.53) was observed between TR and TF group. Between the two groups, there were no difference in incidence of unprotected left main (3.2% vs. 6.4, p=0.136), bifurcation lesions (22.2% vs. 20.6%, p=0.79) and complex lesions (type C AHA classification: 71.2% vs. 70.3%, p=0.96) was observed. In our registry we found that in the TR group a 6F guiding catheter was used in 78,6% while a 7F technique was used in 21,4% whereas in the TF group the size of guiding catheter used was respectively 16,7% for 6F, 67,8% for 7F and 15,5% for 8F. In our experience the most used burr size was the 1.5 mm (50,1%) while the use of burr larger than 1.75 mm was only 11.1% of the all cases. Contrast amount (303 \pm 137 vs. 321 \pm 154, p=0.42) and fluoroscopy time (39±20 vs. 41±23, p=0.65) was no different between the two groups. No significant differences were observed in procedural complications (perforation, dissection, slow/no flow) between the two groups (TR 5.6% vs. TF 6.8%, p=0.73). In hospital death (1.9% vs. 0.8%, p=0.41), MI (9.4% vs. 9.2%, p=0.98), stroke (0.80% vs. 1.2%, p=1) and the composite end-point of death, MI, stroke, target lesion revascularisation and target vessel revascularisation (MACCE) (11.1% vs. 10.7%, p=0.92) was similar in the two groups. At median follow-up of 724 (IR 322-1488) days we observed 3 (8.8%) deaths in the TR vs. 34 (9.8%) in the TF group (p=0.65). The three-year MACCE-free survival did not show significant differences between TR and TF group (80.4% vs. 74.7%, p=0.43).

Conclusions: Our data shows that RA by TR approach could be safely performed, even in complex subset of patients, with good in-hospital and long-term outcomes. Considering that in our experience in 89% of cases RA was performed with a burr size smaller than 2 mm, compatible with a 6F guide catheter, routinely use of TR approach can be useful also in patients needing RA.



Impact of platelet volume and platelet reactivity on thrombotic events in ACS patients on clopidogrel or prasugrel after PCI

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Aims: High platelet reactivity (HPR) and high mean platelet volume (HPV) are known risk markers for thrombotic complications in clopidogrel-treated patients after PCI. However, their interaction and association in predicting adverse events with regards to prasugrel treatment is unknown. We aimed to study the clinical impact of HPR and HPV in a cohort of ACS patients after PCI receiving either clopidogrel or prasugrel.

Methods and results: This study was a post-hoc analysis from a single-centre, prospective registry in that 741 consecutive, clopidogrel-pretreated ACS patients undergoing successful PCI were enrolled between September 2011 and August 2012. ADP-induced platelet reactivity was measured 12-36 hours after PCI with the Multiplate device together with mean platelet volume. In the registry, patients with HPR (>46U) were switched over to prasugrel or were treated with high-dose clopidogrel, while those without HPR continued 75 mg clopidogrel. There was no correlation between platelet reactivity and mean platelet volume (r: 0.05, p=0.19) after PCI. At one year, the risk of all-cause death, myocardial infarction, stent thrombosis or stroke was significantly higher in patients with HPR (HR: 1.67, 95% CI: 1.11-2.51, p=0.016). Similarly, HPV (ROC-estimated cutoff: 9.44 fl) was a significant predictor of the composite endpoint (HR: 1.84, 95% CI: 1.21-2.80, p=0.004) in the univariate model. Independent contribution to ischaemic events of both HPR and HPV were confirmed in a bivariate Cox-regression model. In clopidogrel-treated patients, both HPR and HPR were significant predictors of the composite endpoint (HR: 2.27 95% CI: 1.45-3.55, p<0.0001 and HR: 2.05 95% CI: 1.33-3.17, p=0.001, respectively). However, these markers failed to predict adverse outcomes in ACS patients switched to prasugrel (HR: 0.90, 95% CI: 0.44-1.81, p=0.76 and HR: 0.70, 95% CI: 0.15-3.38, p=0.66).

Conclusions: HPR and HPV independently predict the one-year risk of thrombotic events in ACS patients after PCI. However, our results suggest that these associations are prominent only in clopidogrel-treated patients, while might be diminished among those who are switched over to prasugrel.



Euro14A-0P090

Effectiveness of switching Prasugrel's 'low responders' to Ticagrelor after ACS

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Aims: This study aimed to assess the effectiveness and safety of switching from Prasugrel to Ticagrelor patients identified as Prasugrel low-responders one month after ACS.

Methods and results: 540 patients admitted for ACS with coronary stent implantation and discharged on Prasugrel 10 mg were screened. Prasugrel response was assessed one month after discharge using Platelet Reactivity Index Vasodilatator Stimulated Phosphoprotein (PRI VASP). High on-Treatment Platelet Reactivity (HTPR) was defined as PRI VASP>50%. Patients with HTPR were enrolled and switched to Ticagrelor 90 mg twice a day. They were re-tested a month later. The primary endpoint was defined as: comparison of degree of platelet inhibition and incidence of HTPR one month after switching to Ticagrelor 180 mg daily in patients with HTPR on Prasugrel therapy. The safety endpoint was the incidence of non access-site bleeding complications under Ticagrelor as compared with Prasugrel therapy, using the Bleeding Academic Research Consensus definition. Between March 2010 and November 2013, 19 patients were defined as HTPR on Prasugrel 10 mg one month after ACS, with a mean PRI VASP of 59,3%. Among these patients, 14 were switched to Ticagrelor 180 mg daily and, at one month, we observed a significant decrease in PRI VASP, with a mean value at 19,6% (p<0,001). No patients remained HTPR and 4 patients (28,4%) were identified as Very Low on-Treatment Platelet Reactivity (VLTPR) (PRI VASP<10%). No ischaemic events were reported after switching, while 3 patients (21%) suffered from bleeding complications (2 BARC1 and 1 BARC2 bleedings) during Ticagrelor therapy.

Conclusions: Switch to Ticagrelor in Prasugrel's 'low responders' patients is an effective strategy, leading to an adequate platelet inhibition in a large majority of patients. This biological tailored approach could be useful in preventing ischaemic complications, in this specific high risk population, potentially increasing bleeding risk. This hypothesis needs to be confirmed in large clinical studies.



Comparison of double (360 mg) Ticagrelor loading dose with standard (60 mg) Prasugrel loading dose in STEMI patients: the rapid activity of platelet inhibitor drugs (RAPID) primary PCI 2 study

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Aims: In STEMI patients, residual platelet reactivity soon after a loading dose of prasugrel or ticagrelor is higher than that reported for healthy volunteers or subjects with stable coronary artery disease and the majority of primary percutaneous coronary intervention (PCI) procedures with bivalirudin monotherapy are performed without proper platelet inhibition. However, ticagrelor loading dose is just the daily dose, while prasugrel loading dose is 6-fold the chronic daily dose. We hypothesised that an increased ticagrelor loading dose may result in a faster and more effective platelet inhibition as compared with the standard prasugrel loading dose.

Methods and results: Fifty patients with STEMI, pretreated with intravenous aspirin, undergoing primary PCI were randomised to receive prasugrel 60 mg loading dose (n=25) or ticagrelor 360 mg loading dose (n=25). Residual platelet reactivity was assessed by VerifyNow at baseline and 1, 2, 4 and 12 hours after drug loading dose. At the time of loading dose, 90% of enrolled patients had an Aspirin Reactivity Unit value <550. P2Y12 reaction units (PRU) 1 hour after the loading dose (study primary end-point) was 236 (129-289) and 248 (115-304) in prasugrel and ticagrelor group, respectively (p=0.899). High residual platelet reactivity (PRU ≥240) was found in 43% and 56% patients (p=0.386) at 1 hour and in 30% and 32% patients (p=0.907) at 2 hours, respectively. There was no significant difference in bleeding, arrhythmias or dyspnoea episodes in the 2 groups.

Conclusions: In patients with STEMI undergoing primary PCI, double (360 mg) ticagrelor loading dosewas well tolerated but failed to achieve a faster and more intense platelet inhibition as compared with the standard prasugrel loading dose. Intravenously administered aspirin achieved a very early inhibition of acid arachidonic pathway. ClinicalTrials.gov Identifier:NCT01805570



Euro14A-0P092

Clinical outcome after PCI and ticagrelor or clopidogrel in patients with ACS in a real world setting

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Aims: Dual antiplatelet therapy, aspirin in combination with a P2Y12 antagonist, has been shown to reduce occurrence of ischaemic events after coronary stent implantation in randomised clinical trials. We compared one-year safety and effectiveness among patients with acute coronary syndromes (ACS) having either primary percutaneous coronary intervention (PCI) due to ST-segment elevation myocardial infarction (STEMI) or sub-acute PCI due to NSTE-ACS and dual antiplatelet therapy with either ticagrelor or clopidogrel for 12 months.

Methods and results: From June 2010 to June 2012 all ACS patients treated with PCI at Odense University Hospital were identified from the Western Denmark Heart Registry. From June 2010 to June 2011 the standard dual antiplatelet therapy was aspirin and clopidogrel (600-mg loading dose, 75 mg daily thereafter): "clopidogrel group" and from June 2011 to June 2012 the standard dual antiplatelet therapy was changed to aspirin and ticagrelor (180-mg loading dose, 90 mg twice daily thereafter): "ticagrelor group". This change in use of type of P2Y12 antagonist was performed simultaneously in the Region of Southern Denmark covering 1.2 million inhabitants. STEMI patients were pretreated pre-hospital and NSTE-ACS patients were pre-treated in-hospital before the angiogram. We assessed the one-year risk of cardiac death, non-cardiac death, myocardial infarction, target lesion revascularisation and definite stent thrombosis after PCI with stent implantation. We used a Cox regression model to compute hazard ratio (HR), controlling for potential confounding (age, diabetes, indication for PCI, previous PCI and previous myocardial infarction). The study cohort consisted of 2,335 patients with ACS, of whom 1,134 patients were in the "ticagrelor group" (STEMI n=596 (52.6%) and NSTE-ACS n=538 (47.4%)) and 1,201 patients were in the "clopidogrel group" (STEMI n=588 (49.0%) and NSTE-ACS n=613 (51.0%)). One-year cardiac mortality rate was lower in the "ticagrelor group" n=39 (3.5%) compared to the "clopidogrel group" n=68 (5.7%) [HR 0.60 95%] Confidence Interval (CI) 0.41-0.89]. This difference was only significant in STEMI patients treated with primary PCI [HR=0.58 95% CI 0.36-0.95] but not in patients with NSTE-ACS treated with sub-acute PCI [HR=0.61 95% CI 0.32-1.17]. Non-cardiac death did not differ significantly between the two groups "ticagrelor group" n=31 (2.8%) compared to the "clopidogrel group" n=35 (3.0%) [HR 0.93 95% CI 0.57-1.51] during the 12 months follow-up. No significant difference in myocardial infarction was found between the "ticagrelor group" n=36 (3.2%) and the "clopidogrel group" n=46 (3.8%) [HR=0.82 95% CI 0.53-1.27]. The rate of definite stent thrombosis was reduced in the "ticagrelor group" n=5 (0.5%) compared to the "clopidogrel group" n=17 (1.4%) [HR=0.31 95% CI 0.11-0.84]. The numbers of definite stent thrombosis were (acute/subacute/late) "ticagrelor group": 1/3/1 and "clopidogrel group" 5/10/2.

Conclusions: In an observational all-comer study, treatment with ticagrelor as compared with clopidogrel in ACS patients significantly reduced the rate of cardiac death and risk of definite stent thrombosis.

Benefits from new adenosine-diphosphate antagonists as compared to clopidogrel in patients with stable angina or acute coronary syndrome: a meta-analysis of randomised trials

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Aims: New P2Y12 receptor inhibitors have provided new and more potent antiplatelet strategies, although raising several concerns on possible increase of bleedings. Aim of current meta-analysis was to evaluate efficacy and safety of new adenosine diphosphate (ADP) antagonists as compared to clopidogrel in elective or ACS patients managed invasively.

Methods and results: Literature archives (Pubmed, EMBASE, Cochrane) and main scientific sessions abstracts were scanned for randomised trials comparing new ADP –antagonists to clopidogrel in patients with ACS or stable angina. Primary endpoint was mortality. Secondary endpoints were: 1) non fatal myocardial infarction (MI); 2) recurrent ischaemia symptoms or ischaemia driven revascularisation (RI/IDR); 3) stent thrombosis (ST); 4) safety endopoints, defined as for TIMI Major Bleeding criteria. A total of 8 randomised clinical trials were finally included, for a total population of 67,851 patients. Mean follow-up was 7.6 months, ranging from 48 hours to 30 months. New ADP-antagonists significantly reduced mortality (3.1% vs. 3.6%, OR [95% CI]=0.86 [0.79,0.94], p=0.0008, phet=0.18), with greater impact of oral drugs. Similar benefits were found for MI (6,1% vs. 7%; OR [95% CI] (Random-effect model)=0.88 [0.79, 0.98]p=0.01, phet=0.02), recurrent ischaemia (2.7% vs. 3.1%; OR [95% CI]=0.85 [0.77,0.93], p=0.0005, phet=0.09) or stent thrombosis (1.1%vs 1.7%; OR [95% CI]=0.60 [0.51-0.71], p<0.00001, phet=0.13). By meta-regression analysis no relationship was observed between benefits in mortality, new MI, recurrent ischaemia and stent thrombosis with new ADP-antagonists and patients' risk profile (beta [95% CI]=-0.01 [-0.30-0.27], p=0.94; beta [95% CI]=-0.05 [-1.49-1.43], p=0.96); beta [95% CI]=0.19 [-0.18-0.57], p=0.31 and beta [95% CI]=-0.08 [-0.86-0.70], p=0.84, respectively).

Conclusions: Present meta-analysis shows that the new ADP-antagonists prasugrel, ticagrelor and cangrelor are associated to significant reduction in mortality, reinfarction, recurrent ischaemia and stent thrombosis in comparison to clopidogrel alone, without a significant increase in bleeding complications.



Euro14A-0P094

Atherosclerotic plaque type and acute vessel injury predict the occurrence of interstrut cavities and major coronary evaginations at medium-term follow-up in second-generation DES: a frame by frame serial OCT analysis

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Aims: OCT-detected interstrut cavities (IC) and major coronary evaginations (ME) have been reported at long-term follow-up after early-generation DES implantation and have been linked to late stent thrombosis. Our study sought to assess the incidence of IC and ME at 9-month follow-up after second-generation DES implantation, and to investigate predictors of this inappropriate pattern of vessel wall healing, using serial OCT imaging. Methods and results: IC were defined as outward bulging of the vessel wall ≥250 µm beyond the stent contour. ME were considered if IC extended ≥3 mm along the longitudinal axis of the stented segment. Fifty patients with 50 lesions, treated with second-generation DES (26 Biomatrix® biolimus- and 24 Xience® everolimus-eluting stents) underwent OCT imaging immediately after stent implantation and at 9-month follow-up. The clinical presentation at the time of stent implantation was STEMI in 38%, NSTEMI in 32% and unstable or stable angina (UAP/SAP) in 30%. In a subset of patients (37/50 lesions), a good quality OCT pullback from before stent implantation was available. Using dedicated software for the registration of serially acquired OCT pullbacks, a frame by frame comparison of baseline and follow-up images was performed. In 36% of lesions, at least one cross-sectional image showed IC at follow-up. MEs were detected in 10% of lesions. Lesions with IC had a significantly lower mean neointimal hyperplasia (NIH) area (0.6±0.3 vs. 0.8±0.4 mm², p=0.008) and percentage NIH area (7±2% vs. 12±7%, p=0.006), compared to lesions without IC. A significant correlation between the number of frames showing IC and the incidence of uncovered (r=0.41; p=0.003) and late 'acquired' malapposed struts (r=0.57; p<0.001) was found; whereas there was no correlation between IC and late persistent malapposition (r=0.08; p=0.59). Thin cap fibroatheroma (TCFA) rupture before stent implantation and stent struts overlying a lipid pool post-intervention were strongly associated with the presence of IC at follow-up [OR (95% CI) 5.1 (1.2-22.7), p=0.04 and 6.5 (2.2-10.8), p=0.003, respectively]. Acute injury to the vessel wall after stenting, such as intra-stent dissection or tissue protrusion, more frequently led to the occurrence of IC [OR (95% CI) 1.7 (1.02-2.7), p=0.04 and 2.4 (1.3-4.5), p=0.008, respectively].

Conclusions: Interstrut cavities and major coronary evaginations, detected by OCT, are not limited to early-generation DES. IC correlate well with other OCT-findings suggesting delayed arterial healing, such as late 'acquired' malapposition and uncovered stent struts. The presence of TCFA rupture before stent implantation, and stent struts overlying a lipid pool and acute vessel injury after stenting predict the occurrence of IC at medium-term follow-up.



Comparison of neointimal coverage of biolimus-eluting stent and everolimus-eluting stent at 1, 2, 3 and 4-month follow-up: evaluation by OCT

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Aims: Second-generation drug-eluting stents (DESs) have been used to optimise the results of percutaneous coronary intervention in terms of efficacy and safety now. The Everolimus-eluting stent (EES) is a flexible cobalt chromium alloy with 81 μ m strut thickness, and coated with a durable polymer, designed to release 87% of the everolimus in the first 90 days after deployment. On the other hand, Biolimus-eluting stent (BES) has thick struts (137 μ m), and the drug, biolimus A9, is immersed in a biodegradable polymer which is applied solely to the abluminal surface of a flexible stainless steel stent platform. The drug-polymer matrix is designed to release the drug simultaneously with the polymer degradationin a process lasting between 6-9 months. Confirming complete neointimal coverage after DES implantation is clinically important, because incomplete stent coverage is responsible for stent thrombosis. However, the short-termanalyses of neointimal coverage in patients with EES and BES have not been reported. The aim of this study was to compare vessel responses at 1, 2, 3 and 4-month follow-up after EES or BES implantation using OCT. Methods and results: A total of 54 stents (29 BES and 25 EES) in 35 patients with *de novo* native coronary lesions were enrolled in this study. OCT examination was performed at 1-month (n=13), 2-month (n=16), 3-month (n=14) and 4-month (n=11) follow-up after BES or EES implantation. Cross-sectional OCT images were analysed at 1 mm intervals. The strut apposition to the vessel wall and neointimal coverage (covered struts/ total struts × 100) were evaluated by OCT. Mean neointimal hyperplasia (NIH) thickness and % NIH ((stent area – lumen area) / stent area × 100) were also measured. At 1-month follow-up, around 60% of BES struts were covered with neointima, even though BES struts was thicker and drug release was slower. The percentage of neointimal coverage with BES was significantly higher than that of EES at 1, 2 and 3 months. Complete neointimal coverage was observed at 4-mo

Conclusions: The neointimal coverage of BES was faster than that of EES within 3 months. These data suggest that the relatively rapid vascular healing might be related to a biodegradable polymer in abluminal coating of BES.



Euro14A-0P096

Vascular responses to DES with biodegradable polymer versus durable polymer: an OCT sub-study of the NEXT

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Aims: Efficacy and safety data comparing durable polymer everolimus-eluting stent (EES) with biodegradable polymer biolimus-eluting stent (BES) are currently limited. The aim of the present study was to compare vascular healing response between EES and BES by using optical coherence tomography (OCT).

Methods and results: In the NOBORI Biolimus-Eluting Versus XIENCE V / PROMUS Everolimus-Eluting Stent Trial (NEXT), a formal OCT sub-study investigated 91 patients (55 EES-treated lesions in 48 patients and 51 BES-treated lesions in 43 patients) with 8-12 months follow-up imaging at 18 centres. A total of 980 frames with 8,996 struts in EES and 907 frames with 8,745 struts in BES were analysed. In the stent strut level analysis, more than 90% of struts in both EES and BES were covered by neointima. Mean neointima thickness in EES and BES was 105 ± 82 μm and 91 ± 80 μm, respectively (p <0.001). In the stent-treated lesion level analysis, the percentage of uncovered struts ($3\pm7\%$ vs. $9\pm10\%$, p <0.001) and the frequency of stent-treated lesions with any uncovered struts [28 (51%) vs. 42 (82%), p <0.001] were significantly lower in EES compared with BES. Although the percentage of frames with >30% uncovered struts was not different between the two stents ($4\pm10\%$ vs. $6\pm11\%$, p=0.375), the maximum length of segment with uncovered struts was significantly shorter in EES compared with BES (1.0 ± 1.4 mm vs. 3.1 ± 3.2 mm, p <0.001). The percentage of malapposed struts ($0.2\pm0.8\%$ vs. $1.3\pm2.8\%$, p=0.006) and the frequency of stent-treated lesion with any malapposed struts ($0.2\pm0.8\%$ vs. $0.2\pm0.8\%$ vs. 0.3 ± 0.5 mm, p=0.030). The frequency of intra-stent thrombus was not different between EES and BES [0.4% vs. $0.2\pm0.8\%$ vs. 0.3 ± 0.5 mm, p=0.030). The frequency of intra-stent thrombus was not different between EES and BES [0.4% vs. $0.2\pm0.8\%$ vs. 0.3 ± 0.5 mm, p=0.030). The frequency of intra-stent thrombus was not different between EES and BES [0.4% vs. $0.2\pm0.8\%$ vs. 0.3 ± 0.5 mm, p=0.030). The frequency of intra-stent thrombus was not different between EES and BES [0.4% vs. 0.24% vs. 0.24

Conclusions: Incomplete vascular healing characterised by the presence of uncovered struts by neointima and malapposed struts was less common in EES compared with BES.



Coronary interventions Euro14A-0P097

Time-related changes in neointimal tissue coverage following a new generation sirolimus-eluting stent implantation: an OCT observational study

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Aims: DES have become the treatment of choice for patients with symptomatic coronary artery disease undergoing PCI. Although this technology has reduced rates of restenosis and late lumen loss compared with BMS it has been associated with delayed healing that might result in a small but statistically significant increase in Late and Very Late Stent Thrombosis. The aim of our study was to evaluate the time-related changes in vascular response following implantation of a new generation biodegradable polymer Sirolimus-eluting stent with an amorphous silicon carbide coating (PROBIO-system) allowing higher biocompatibility and faster re-endothelisation (Orsiro, Biotronik AG, Switzerland).

Methods and results: This prospective observational Registry enrolled only patients with STEMI and multi-vessel disease, thus candidates for a two-step procedure. PCI of the culprit lesion was performed with at least one Orsiro stent. The second procedure was deferred according to the severity of the non-culprit lesion and the presence of symptoms and signs of residual ischaemia to 30 days, 90 days and 180 days. During the second procedure the stent deployed at the infarct-related site was analysed by Frequency Domain Optical Coherence Tomography (FD-OCT). From January 2012 to December 2012, 260 patients underwent primary PCI. 16 of the 95 patients with multivessel disease underwent OCT evaluation of the device implanted in the culprit lesion. OCT analysis was performed off-line by two blinded operators. Coverage and apposition of the stent struts was analysed with strut- and cross section-level. 3060 struts were analysed. Of these, 1,065 struts (Group-II), 874 struts (Group-III) and 1,130 struts (Group-IIII) were analysed at 30, 90 and 180 days, respectively. Stent lengths and diameters were similar in the three groups. The percentage of uncovered stent struts was 19.6% at 30, 1.3% at 90 and 1.8% at 180 days (p<0.001 I vs. II and vs. III; p=ns II vs. III). The percentage of malapposed struts were 5.1% at 30, 6.2% at 90 and 4.8% at 180 days (p=ns for all group). Of the malapposed struts 53.7% were covered at 30 days, while 81.5% and 88.9% were covered at 90 and 180 days respectively (p<0.01 I vs. II and vs. III; p=ns II vs. III). The percentage of cross section containing thrombus was 6.2% at 90 days and 5.7% at 180 days (p<0.001 I vs. II and vs. III; p=ns II vs. III). The percentage of cross section containing thrombus was 6.2% at 30 days. No thrombus was detected at 90 or 180 days. Neointimal thickness covering stent struts increased from 0.25±0.21 mm² at 30 days to 0.81±0.68 mm² and to 0.94±0.85 at 90 and 180 days, respectively (p<0.001 I vs. II and vs. III; p=ns II vs. III).

Conclusions: Our data show that the new generation Orsiro stent coated with the PROBIO system promotes early development of strut coverage and absence of visual thrombus already at 3 months follow-up without no further significant improvement at 180 days. This pilot OCT evaluation might suggest a low incidence of late adverse events and anticipate safe outcome after early withdrawal of dual antiplatelet therapy.



Euro14A-0P098

Tissue characteristics at edge segments predict neointimal coverage of struts after DES implantation: an OCT study

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Aims: The normal to normal coverage of the culprit lesion with coronary stents is an ideal approach to avoid stent-related complications, but previous studies with intravascular ultrasound have shown that approximately 10% of stent edges were landing on the plaques with vulnerable characteristics. On the other hand, inadequate neointimal coverage of the stent struts is one of the risks for late stent thrombosis, especially in drugeluting stent (DES). Using optical coherence tomography (OCT), we studied the morphological characteristics of coronary segment adjacent to both proximal and distal edges, and evaluated their influence on the neointimal coverage of the strut in chronic phase.

Methods and results: We studied 95 culprit coronary lesions (acute coronary syndrome=17, stable angina pectoris=78) in 76 patients (65.9 y/o, 81% men) who were treated with OCT-guided DES implantation. OCT tissue characteristics were evaluated within 5 mm outer segment of both proximal and distal edges after DES implantation. The second OCT examination was performed on 9.2 months after implantation, and neointimal coverage of struts was assessed within 5 mm inner segments from each stent edge. An uncovered strut was defined as having the signal thickness less than 30 µm from the centre of strut. Culprit lesion was distributed in left anterior descending (53.7%), right coronary artery (25.3%), left circumflex (18.9%), left main trunk (1.1%) and high lateral (1.1%) arteries. Of total 9522 struts, there were 706 uncovered struts (7.4%), and 263 malapposed struts (2.8%). In addition, of all apposed stent strut, uncovered struts were detected in 4.8% within distal and 6.0% within proximal edges. For further statistical analysis, edge segments were classified into two categories according to the ratio of uncovered struts, as the poorlycovered group (highest quartile with % uncovered struts), and the well-covered group (the remaining lower quartiles with % uncovered struts). As to OCT tissue characteristic, 1) normal arterial wall was significantly less observed in the poorly-covered group at both distal and proximal edges. 2) Lipid pool was more frequently observed in the poorly-covered group than the well-covered group at both distal and proximal edges (58.3% vs. 28.2%, P=0.0077 and 91.3% vs. 59.7%, P=0.0044, respectively). 3) Thin-cap fibroatheroma (TCFA) and calcium deposition were also more frequently observed in the poorly-covered group than the well-covered group (8.7% vs. 0%, P=0.0114, 26.1% vs. 8.3%, P=0.0257, respectively) at proximal stent edge. Logistic regression analysis revealed that existence of lipid pool at distal and proximal edges (odds ratio (OR): 4.21, 95% confidence interval (CI): 1.63-11.47, p=0.0029 and OR: 7.08, 95% CI: 1.88-46.40, p=0.0023, respectively), and calcium deposition at proximal edge (OR: 3.88, 95% CI: 1.09-13.95, p=0.0367) were independent predictors for uncovered strut. TCFA at proximal edge was also predictive (p=0.0159), but OR was not calculated because of low sample number.

Conclusions: Lipid pool, TCFA and calcium deposition at proximal edge were predictors of uncovered struts. Although mechanism should be further elucidated, placement of proximal edge on such tissue characteristics should be avoided.



Impact of calcified plaque for stent struts distribution of the bioresorbable everolimus-eluting device: OCT analysis

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Aims: The aim of this study was to evaluate the impact of underlying plaque morphology on strut distribution of the bioresorbable vascular scaffolds (BVS) 1.1 consisting of a polymer backbone, versus metallic everolimus-eluting stents (EES) using optical coherence tomography (OCT).

Methods and results: Among 37 patients who underwent elective percutaneous coronary intervention (n=22 in BVS group, n=15 in EES group), a total of 1114 OCT frames (BVS: 590 frames; EES: 524 frames) post procedure were assessed by OCT. Non-uniform strut distribution (NSD) was defined as a frame with maximum inter-strut angle '120°. The percentage of frames with NSD to all frames was similar between two groups (25.8% [160/590] in BVS group vs. 27.3% [143/524] in EES group, p=0.95). In the EES group the arc of calcium behind stent struts in frames with NSD was not significantly different compared to that in frames with uniform strut distribution (USD) (34.8±50.0° vs. 34.0±48.7°, p=0.88). However, the arc of calcium in the BVS group was significantly greater in frames with NSD as compared to those with USD (86.1±63.4° vs. 19.7±39.5°, p<0.0001). On multivariable analysis, after adjustment for post-dilatation balloon size and maximum inflation pressure, the calcium arc (>75°) was identified as an independent predictor of NSD after BVS implantation (odds ratio [OR]: 12.6, 95% confidence interval [CI]: 8.2-19.5, p<0.0001).

Conclusions: The presence of a calcified plaque behind BVS struts appears to be an independent predictor for NSD, particularly when the calcium arc >75°. For calcified lesions, meticulous lesion preparation, including use of dedicated devices, may help prevent NSD after BVS stent implantation.



Euro14A-0P100

Insights into the mechanisms of action of the rotational atherectomy: an OCT study

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Aims: The aim of our study is to characterise, using OCT, the morphologic features of calcific plaques after rotational atherectomy, adjunctive balloon angioplasty and stenting.

Methods and results: A total of 34 consecutive patients who had undergone angioplasty using rotational atherectomy were included. The 44 lesions treated were classified according to the indication of rotational atherectomy as massive calcification (n=18), calcific nodule (n=16), uncrossable (n=5) or non-dilatable lesions (n=5). An OCT study was done before atherectomy in 14 lesions, after a rotational atherectomy in all 44 lesions, after a balloon dilatation in 2 lesions and post stenting with post dilatation in all lesions. The treated lesions were located in the right coronary artery (n=21), in the left anterior descending (n=18) and the left circonflex artery (n=5). The OCT appearance of the lesions after atherectomy is very specific of the substrate encountered by the burr: sharp cuts with smooth surface in presence of calcifications and irregular boundaries and less delimitated cuts in presence of fibrotic lesions. Peeling of the intima at the beginning of the burr action is constant regardless of the type of lesion. Mean calcium arc was 318°, mean calcium thickness was 1.03 mm. Mean diameter of the ablation as measured by OCT was 1.65 mm and mean burr size was 1.72. Mean burr to artery ratio was 0.56. Sixteen lesions required 2 burrs. Dissections were unusual (11% of lesions) and observed mainly in uncrossable lesions (80%). After stenting, deep medial dissections are frequent especially in calcific nodules and contribute significantly to lumen enlargement while the area of ablation in the calcified part of the plaque remained unaltered. After systematic post dilatation, incomplete stent apposition was encountered in 2 lesions (4.5%)

Conclusions: OCT represents a unique opportunity for studying *in vivo* the mechanism of action of rotational atherectomy in different types of lesions. Insights from this study allowed us to tailor our approach to treat calcific lesions.

Incidence, predictors and impact of stent malapposition in patients with acute STEMI treated with current generation DES

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Aims: Incomplete stent apposition (ISA) detected by Optical Coherence Tomography (OCT) is a common finding in patients with ST-segment elevation myocardial infarction (STEMI). However, the predictors and the impact of ISA after current generation drug-eluting stents (DES) remain unclear. We sought to investigate incidence, mechanisms and clinical impact of ISA in patients with STEMI treated with current generation DES. Methods and results: From January 2011 to January 2012, 114 STEMI patients (114 culprit lesions) undergoing primary percutaneous coronary interventions with everolimus-eluting stents (EES) were prospectively evaluated. Serial OCT imaging of the infarct-related artery were obtained after thrombus aspiration, immediately after EES-implantation and at 9-month follow-up. Clinical outcomes defined as major adverse cardiac and cerebrovascular events (MACCEs), a composite of cardiac death, recurrent myocardial infarction, stroke, and ischaemia-driven target-lesion revascularisation, were determined at 30 days and at 1 year, Acute ISA occurred in 82 (71.9%) EES-treated lesions, Of these, 36 (43.9%) ISA resolved at 9-month follow-up. Notably, persistent ISA occurred in 46 (56.1%) lesions with a median malapposition area at index and follow-up of 0.26 mm² (interquartile range [IQR] 0.12-0.59) and 0.10 mm² (IQR 0.05-0.23), respectively. Newly-acquired ISA (NA-ISA) was detected at 9-month in 39 (34.2%) EES-treated lesions. While NA-ISA was localized mostly at the stent body (82.0%), persistent ISA was most (78.0%) prominent at the stent edges, (p>0.001). No differences in clinical-procedural characteristics and in culprit lesion phenotypes (rupture/erosion) were observed between patients with and without NA-ISA. Conversely, NA-ISA was associated with longer underlying thin cap fibroateroma (3.20 mm vs.1.80 mm, p=0.032) and larger volume of the red thrombus remaining after thrombus aspiration (0.69 mm³ vs.0.00 mm³, p=0.020), respectively, as compared with non NA-ISA. The rate of post dilatation after EES implantation (17.0% vs. 49.0% p=0.021) was less frequent in lesions who developed NA-ISA. At 9-month follow-up NA-ISA was associated with less neointimal volume (8.72 mm³ vs.18.5 mm³, p=0.001) and higher rate of OCT frames with ≥30% uncovered struts (21.1% vs. 5.9%, p<0.001). At multivariate analysis, the only independent predictor of NA-ISA was the absence of post-dilatation after stent deployment [OR 3.0, (CI 95%1.18-7.7), p=0.021]. There was no difference in MACCEs between patients with or without ISA at one-year clinical follow-up.

Conclusions: In STEMI patients treated with EES OCT-detected ISA is a frequent finding. The persistent ISA occurs mainly at the stent edges and is mostly limited in area. Conversely, NA-ISA is prevalent at the stent body. The lack of post-dilatation after stent deployment was the only independent predictor of NA-ISA. ISA development was not associated with increased risk of clinical events at 1 year. Larger studies at longer clinical follow-up are warranted to evaluate its clinical impact.



Euro14A-0P102

A randomised comparison of PCI guided by frequency domain OCT and angiography: OPUS-CLASS cohort B study

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Aims: Although frequency-domain OCT (FD-OCT) has been introduced recently in clinical practice, safety and efficacy have yet to be fully established. OPUS-CLASS Cohort B was a randomised, multicentre study that aimed to compare the safety and efficacy of FD-OCT-guided PCI to angio-guided PCI in daily clinical setting.

Methods and results: The cohort B study enrolled 60 patients (4 centres) for whom PCI was planned. All patients were randomly assigned to either the FD-OCT- or angio-guided PCI group. FD-OCT was planned for all patients in the post- PCI and follow-up phase (6-24 months). In angio-guided group, PCI was performed without reviewing of FD-OCT images during the procedure. Quantitative FD-OCT measurements were obtained at the cross-sectional level (lumen area, stent area, malapposed area and volume, prolapse/neointimal area and volume) and strut level (maximum length of malapposition, malapposed strut rate, uncovered strut rate) at an interval of 1 mm. Malapposition was adjudicated when the distance from strut to lumen was over (10 + "polymer and strut thickness") micrometers. A strut was adjudicated as uncovered when its coverage was less than 10 micrometers. An in-hospital clinical event occurred in only one patient in the angio-guided group as a result of side branch occlusion. In total, 11,739 struts in 59 patients were analysed post PCI and 9837 struts in 45 patients (17 patients with diabetes; 37 patients underwent everolimus-eluting stent [EES] implantation) were analysed at follow-up. There were no significant differences in the patient and lesion characteristics between the two groups. Among the patients who underwent post dilation (N=44), the mean inflation pressure was higher in the FD-OCT-guided group (18.7±3.4 atm vs. 15.6±4.1 atm, p=0.008). Overall, there was no significant difference in FD-OCT measurement data between the two groups in the post and follow-up phases. Among the diabetic patients who underwent EES implantation, neointimal area was significantly smaller in the FD-OCT-guided group (0.51±0.19 mm² vs. 0.87±0.40 mm², p=0.044).

Conclusions: The results of this study indicate that OCT-guided PCI enables safe stent implantation and high-pressure post-dilation. In PCI using EES for diabetic patients, neointimal proliferation may be ameliorated by FD-OCT guidance.



Impact of optical coherence tomography-guided PCI on the neointimal coverage and malapposition following Resolute zotarolimus-eluting stent implantation: randomised comparison with angio-guided intervention (CONSTANT trial)

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Aims: To assess the impact of optical coherence tomography (OCT) guidance on stent strut coverage following drug-eluting stent (DES) implantation.

The utility of OCT guided percutaneous coronary intervention (PCI) has not investigated adequately during DES. **Methods and results:** A total of 105 lesion in 101 patients were randomly assigned into OCT guided (n=51 lesions of 50 patients) or angiography guided arm (n=54 lesions of 51 patients) and were performed follow-up OCT examination at 6 months after resolute zotarolimus-eluting stent (R-ZES) implantation. The primary endpoint was the percentage of uncovered struts on 6-month OCT and secondary endpoints were the percentage of malapposition on 6-month OCT. The percentage of uncovered struts of OCT guided armwas significantly lower than that of angiography guided arm [1.60±1.84 (median: 1.06)% vs. 4.51±5.43 (median: 2.38)%, p=0.0004] on 6-month follow-up OCT. The incidence of occurrence â'¥5.9% of uncovered struts was significantly lower in OCT guided arm than angiography guided arm [2 (3.9%) vs. 14 (25.9%), p=0.002]. In addition, the percentage of malapposed struts was significantly lower in OCT guided arm [0.19±0.51 (median: 0.0)% vs. 0.98±2.53 (median: 0.0) %, p=0.027). **Conclusions:** The randomised OCT study demonstrated that OCT guided PCI significantly reduced the incidence of uncovered stent strut at 6 months compared to angiography guided PCI. These findings might suggest that OCT guided PCI had a beneficial role of stent strut coverage.



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Frequency of early resolved, persistent and early acquired malapposition three days after implantation of a self-expanding or balloon-expandable stent in a STEMI population: insights from OCT analysis in the APPOSITION II study

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Aims: The APPOSITION II study demonstrated that strut malapposition at 3 days after implantation is significantly lower with a self-expanding stent than with balloon-expandable stents in the setting of ST-elevation myocardial infarction (STEMI). However, it was not fully investigated if the malapposition at 3 days was already present at baseline or acquired later.

Methods and results: The current analysis is a sub-study of the APPOSITION II study, in which 80 patients presenting with STEMI were randomised to receive a self-expanding stent (STENTYS) (n=43) or a balloon-expandable stent (VISION, or Driver) (n=37). This analysis included 69 patients (self-expanding arm, n=35; balloon-expandable stent arm, n=34) who had serial Optical Coherence Tomography (OCT) post-procedure and at three days after primary percutaneous coronary intervention (PPCI). To evaluate the temporal evolution of incomplete stent apposition (ISA) in the same location of the stent the stented region was segmented and matched at different time points using fiduciary landmarks. The segment with at least 2 consecutive cross-sections that contained ISA struts was defined as an ISA segment. ISA distance was measured strut-by-strut and ISA area was measured frame-by-frame; maximal ISA distance and ISA volume were calculated in each ISA segment. A total of 238 corresponding segments (self-expanding stent: 114, balloon-expandable stents: 124) were identified in 138 serial pullbacks. Post-procedure, acute ISA was observed in 27 segments (23.7%) in the self-expanding stents and 51 (41.1%) in the balloon-expandable stents (P=0.04). In the self-expanding stent arm, 37.0% (10/27) of acute ISA persisted at 3 days, while 63.0% (17/27) had resolved. In three segments, new ISA developed in the first 3 days. In the balloon-expandable stent arm, 72.5% (37/51) of acute ISA was observed persistently at 3 days, while 27.5% (14/51) had resolved. At 3 days, new ISA were identified in 18 segments. The maximum ISA distance decreased by 64.6±25.2 μm in the self-expanding stent arm, while it increased by 85.4±19.9 μm in the balloon-expandable stent arm (P<0.001). The volume of ISA decreased by 0.18±0.48 mm³ in the self-expanding stent arm, while it increased by 0.21±0.14 mm³ in the balloon-expandable stent arm (P<0.001). ISA at 3 days was observed in 13 segments (11.4%) of the self-expanding stent arm and 55 segments (44.4%) of

Conclusions: Acute ISA was observed more frequently in the balloon-expandable stents compared with the self-expandable stent. During the first 3 days after PPCI, ISA tended to resolve in the self-expanding stent, while it increased in the balloon-expandable stent. As a result, the difference in the frequency of ISA between the two arms was more pronounced at 3 days than at post-procedure.

Incomplete stent apposition causes high shear flow disturbances and delay in neointimal coverage as a function of strut to wall detachment distance

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Aims: Lack of re-endothelialisation and neointimal coverage on stent struts has been put forward as the main underlying mechanism leading to late stent thrombosis. Incomplete Stent Apposition (ISA) has been frequently observed in patients with very late stent thrombosis after DES implantation, suggesting a role of ISA in the pathogenesis of this adverse event. The aim of this study was to evaluate the impact of different degrees of ISA severity on abnormal shear rate and its association with healing response at follow-up.

Methods and results: We characterised flow profile and shear distribution in different severities of ISA with increasing strut-wall detachment distance (ranging from 100 μm to 500 μm). Malapposition was categorised as mild (\leq 100 μm), moderate (\geq 100 μm, \leq 300 μm), intermediate (\geq 300 μm) or severe (\geq 500 μm) based on their maximal ISA detachment distance. Protruding strut and strut malapposed with mild and moderate detachment (ISA detachment distance \leq 300 μm) produced less blood flow disturbances as compared with more severe ISA (300-500 μm and \geq 500 μm). In-vivo impact on strut coverage was assessed retrospectively using Optical Coherence Tomography evaluation on 72 stents (48 patients) sequentially at baseline and after 6 months follow-up. Analysis of coverage revealed an important impact of baseline strut-wall ISA distance on the risk of incomplete strut coverage at follow-up. Malapposed segments with an ISA detachment \leq 100 μm at baseline showed complete strut coverage at follow-up whereas segments with a maximal ISA detachment distance of 100-300 μm and \geq 300 μm had 6.1% and 15.7% of their struts still uncovered at follow-up respectively (p \leq 0.001). More severely malapposed segments with maximal ISA distance \geq 300 μm represent a greater concern as they affect not only larger areas of blood flow with higher shear, but also have a higher likelihood of delayed healing with ISA struts persistent at follow-up. There was a strong correlation between baseline Shear Rate and mean percentage of uncovered strut and persistent ISA at follow-up in each ISA category (p=0.006), suggesting a possible role of shear on delayed healing of ISA strut.

Conclusions: Flow disturbances and risk of delayed strut coverage both increase with ISA detachment distance. Insights from this study are important for understanding malapposition as a quantitative, rather than binary phenomenon (present or absent), and to define the threshold of ISA detachment that might benefit from optimisation during stent implantation.



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Feasibility and repeatability of OCT measurements of pre-stent thrombus burden in patients with STEMI treated with primary PCI

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Aims: Intracoronary thrombus can be visualised using optical coherence tomography (OCT) imaging. Although the assessment of atherothrombotic (AT) burden with OCT has been performed after stent implantation, intravascular thrombus is disrupted by stent deployment and confounded by the development of intrastent plaque prolapse. We therefore investigated the feasibility and repeatability of thrombus quantification prior to stent implantation in STEMI patients treated with primary PCI.

Methods and results: We enrolled subjects in an OCT substudy of the TOTAL trial of aspiration thrombectomy or PCI alone in STEMI. OCT was performed during primary PCI immediately after reestablishment of TIMI 2-3 flow and after stent implantation. The stented segment was analysed at 0.4 mm intervals. Thrombus burden (TB), thrombus volume (TVol), post-stent atherothrombotic burden (ATB) and atherothrombotic volume (ATVol) were determined. OCT analysis was blind and without knowledge of clinical or angiographic data. Pre-stent and post-stent imaging was feasible in 25 out of 27 patients. Analysis for interobserver variability was performed on 1,549 and 1,586 cross-sections, from the pre- and poststent OCT pullbacks, respectively. Analysis of intraobserver variability was performed on 15 patients using 920 and 921 cross-sections from the pre- and post-stent pullbacks, respectively. The interval from the first reading to the second reading was 4 weeks at minimum. In Bland-Altman analyses of interobserver variation, the mean pre-stent TB was 8.76% and 8.97% (limits of agreement -2.6-2.2%) and the mean TVol 14.85 mm³ and 14.99 mm³ (limits of agreement -3.8-3.5 mm³), for observer 1 and observer 2, respectively. The mean post-stent ATB and ATVol values were 7.48%/ 8.00% (limits of agreement -3.25-2.20%) and 17.69 mm³/18.81 mm³ (limits of agreement -9.30-7.05 mm³), respectively, for observer 1/ observer 2. In Bland-Altman analyses of intraobserver variation, the mean pre-stent TB was 8.06% and 7.35% (limits of agreement -1.72-3.15%) the mean TVol 14.15 mm³ and 12.81 mm³ (limits of agreement -3.18-5.85 mm³), for the first and second rounds of analyses of observer 1, respectively. The mean post-stent ATB and ATVol values were 7.35% / 7.54% (limits of agreement -2.65-2.28%) and 18.28 mm³/19.38 mm³ (limits of agreement -9.23-7.04 mm³), respectively, for the first and second rounds of analyses of observer 1. There was a good correlation between prestent TB and TVol (r=0.93) and between pre-stent TB and the pre-stent quadrants with thrombus (r=0.94). There was only minimal correlation between pre-stent TB and post-stent ATB (r=0.54) or pre-stent TV and post-stent ATVol (r=0.71).

Conclusions: Measurement of pre-stent TB and TVol by OCT during the primary PCI of STEMI is feasible, reliable and reproducible. Pre-stent TB is highly correlated with the pre-stent number of quadrants with thrombus, but not with post-stent ATB, which indicates that pre-stent measurements might be of additional value when assessing the thrombus burden in STEMI.



Long-term follow-up of reticulated platelets levels following STEMI

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Aims: Reticulated platelets represent young, hyperactive platelets, with increased mean volume and a greater number of dense granules than older circulating platelets. Reticulated platelets have been shown to increase in situations of increased platelet turnover, such as acute myocardial infarction and stroke. We have recently shown that the proportion of circulating reticulated platelets inversely correlates with response to antiplatelet medication after ST-elevation myocardial infarction (STEMI). However, data is lacking with regards to the long-term dynamics in levels of reticulated platelets. Our aim was to examine the long term levels of reticulated platelets after STEMI and the association with platelet reactivity. **Methods and results:** Patients with STEMI treated with primary percutaneous intervention and prasugrel were tested for levels of reticulated platelets using flow cytometry with Thiazole Orange staining. Additionally, platelet reactivity was assessed using the VerifyNow P2Y12 assay and the Multiplate analyser. Tests were performed at baseline, one month after and six to twelve months following the acute event. Forty-six patients were included (mean age 56.5±5.5, 25% women, 17% diabetes). Levels of reticulated platelets were 17.1±6.1% at baseline,13.1±9.7% after one month and 12.7±7.5% after 6-12 months (average 10.2±3 months, 30.4% current follow-up) after the STEMI (P=0.057 for comparison of reticulated platelets levels at last and first exams). Overall, taking the 3 time-points together, platelet reactivity was strongly correlated with levels of reticulated platelets according to VerifyNow PRU (Pearson's r=0.45) and moderately correlated according to VerifyNow percent inhibition (r=-0.38).

Conclusions: There is a trend for a gradual decrease in levels of reticulated platelets following STEMI. This may be clinically important, and associated with the well-established reduced incidence of thrombotic events at later stages after an acute myocardial infarction. Further, larger studies are warranted to assess the clinical significance of this phenomenon.



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Long-term effects of dual-antiplatelet therapy in patients with first generation DES implantation

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Aims: Dual-antiplatelet therapy was used to minimise the risk of stent thrombosis after implantation of DES. We evaluated the long-term effects of dual-antiplatelet therapy in the patients with 1st generation DES implantation.

Methods and results: Among patients who underwent successful PCI with DES between September 2003 and August 2006, a total of 435 patients completed 5 years of dual-antiplatelet therapy and were enrolled in the study. The patients were randomised to aspirin and clopidogrel (clopidogrel group, n=208) vs. aspirin and cilostazol (cilostazol group, n=227) after one year of aspirin and clopidogrel combination therapy. The primary end points were the incidence of stent thrombosis and bleeding between one year and five years. Secondary end points were the major adverse cardiac events (MACE), including stent thrombosis, all cause mortality, non-fatal myocardial infarction, non-fatal stroke, target lesion revascularisation, target vessel revascularisation, and the incidence of bleeding. The incidence of stent thrombosis between one year and five years was two cases (0.9%) in all patients and stent thrombosis only occurred in the cilostazol group. There were no significant differences in major adverse cardiac events. The risk of bleeding between one year and five years tend to have higher in clopidogrel group than cilostazol group (8.2% vs. 4.0%, p=0.064).

Conclusions: Stent thrombosis did not occur in the clopidogrel group. The risk of bleeding was higher in clopidogrel group compared with cilostazol group.

Discontinuation of dual antiplatelet therapy over 12 months after ACS increases risk for adverse events in patients treated with PCI: systematic review and meta-analysis

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Aims: Duration of dual anti-platelet therapy following Acute Coronary Syndrome (ACS) hospitalisation remains to be defined, both for patients treated medically and for those undergoing Percutaneous Coronary Intervention (PTCA). Conflicting data about optimal dual anti-platelet therapy duration have been reported. Thus we performed a meta-analysis to assess safety of dual anti-platelet therapy interruption over 12 months.

Methods and results: PubMed, Cochrane and Google Scholar were systematically searched for studies including patients presenting with ACS, and treated either with dual anti-platelet therapy longer than or shorter than 12 months. Multivariable-adjusted risk estimates for death and recurrent ACS with stopping dual anti-platelet therapy after 12 months (odds ratios [OR] 95% confidence intervals [CI]) were pooled after logarithmic transformation according to random-effect models with inverse-variance weighting. 5 studies with 49,586 patients were included. Median age was 66 (64-67) years, with 67% (65-75) males. Myocardial infarction (MI) represented the admission diagnosis for 88% (60-100) of the patients, and 66% (50-74) were treated with stenting. After a follow-up of 2.1 years (1.5-2.7), 40% (35-46) still on dual anti-platelet therapy after 12 months and the rates of death or recurrent ACS were 16.6 (14.5-17.0). Risk of adverse events for patients stopping dual anti-platelet therapy after 1 year was significantly increased (OR=1.19 [1.07-1.32]) for those receiving stents, but not for patients managed medically (OR=1.13 [0.95-1.35]). The increased risk did not vary according to age, gender, myocardial infarction as admission diagnosis and kind of stent.

Conclusions: Interruption of dual anti-platelet therapy over 12 months after ACS increases the risk of adverse events for patients treated with PTCA, but not for those managed conservatively, independently from baseline features and admission diagnosis. This hypothesis generating finding should be tested in randomised controlled trials.



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Clinical outcomes with short-term versus standard 12-month dual antiplatelet therapy duration after DES implantation: a meta-analysis

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Aims: Current guidelines recommend up to 12 months dual antiplatelet therapy (DAPT) after drug-eluting stents (DES) implantation, however optimal DAPT duration after DES implantation is still a matter of debate. We aimed to evaluate clinical outcomes with short-term (<12 months) DAPT as compared to standard 12-months DAPT in patients treated with DES.

Methods and results: In December 2013, we searched PubMed and conference proceedings for randomised trials directly comparing short-term (<12 months) versus 12-months DAPT after DES implantation. We identified 3 trials: EXCELLENT (6-months vs. 12-months DAPT, N=1,443), RESET (3-months vs. 12-months DAPT, N=2,117), and OPTIMIZE (3-months vs. 12-months DAPT, N=3,119) – including a total of 6,679 patients with 12-months follow-up. Random-effects meta-analyses were performed comparing clinical outcomes at 12 months in patients allocated to short-term DAPT and patients allocated to 12-months DAPT. The primary safety endpoint was bleeding. The primary efficacy endpoint was the composite of cardiac death and myocardial infarction. The secondary safety endpoint was definite or probable stent thrombosis according to ARC criteria. At 12 months, short-term DAPT was associated with a reduced risk of any bleeding (RR 0.68, 95% CI 0.47-1.00) and a trend towards a reduced risk of major bleeding (RR 0.59, 95% CI 0.30-1.10) as compared to 12-months DAPT. With respect to efficacy, risks of cardiac death or myocardial infarction (RR 1.10, 95% CI 0.82-1.47) and stent thrombosis (RR 1.30, 95% CI 0.50-3.36) did not differ between patients allocated to short-term DAPT compared with 12-months DAPT. Noteworthy, landmark analyses at the time of DAPT interruption showed that risks of cardiac death or myocardial infarction (RR 0.96, 95% CI 0.60-1.58) as well as stent thrombosis (RR 1.34, 95% CI 0.17-10.76) did not differ between the two groups after DAPT interruption up to 12 months follow-up. No evidence of heterogeneity was observed across trials (I-squared=0% for all analysed endpoints).

Conclusions: Compared with standard 12-months DAPT, short-term DAPT reduces the risk of bleeding without compromising efficacy, as indicated by similar risks of cardiac death, myocardial infarction and stent thrombosis throughout 12-months follow-up.

Prospective multicentre registry of six-month dual antiplatelet therapy after new generation DES implantation: ESTROFA-DAPT study

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Aims: Drug-eluting stents (DES) have been related to a certain risk of late thrombosis. The recommended duration of dual antiplatelet therapy (DAPT) with DES is 12 months. DAPT is not free from complications and is expensive. Small trials suggest that a 6 month DAPT period could be enough with new generation DES. There are no large clinical registries assessing the safety of such approach.

Methods and results: All consecutive patients treated with non-first generation DES were prospectively included in 18 different centres. Patients had to fulfill one of the following inclusion criteria: silent ischaemia, stable angina, low risk non-ST segment elevation myocardial infarction or acute coronary syndrome where 12 months DAPT was discarded due to high bleeding risk. A total of 1,024 patients have been included with age 67.5±10.6 years, 23.3% women, 41% diabetic and 25.8% with ACS. Among these 354 patients have already completed 12-month follow-up. In this cohort the incidence of definite or probable thrombosis at 12 months was 0.57% (1 definite thrombosis at 2 months and 1 probable thrombosis at 7 months). The incidence of cardiac death and myocardial infarction at 12 months was 2.5%. Events reported between 6 and 12 months were 3 cardiac deaths (2 heart failure and 1 sudden death) and 2 non-ST elevated myocardial infarctions (one related with stent restenosis and the other without angiography considered a probable stent thrombosis). Using the ESTROFA-2 database (4,768 patients treated with new generation DES, 4,355 of them with 12 months DAPT) we performed a propensity score matching with this registry. In ESTROFA-2 the incidence of definite or probable thrombosis at 12 months under 1 year DAPT was 0.7%

Conclusions: A DAPT period of 6 months after non-1st generation-DES implantation in selected population results safe with a very low rate of events between the 6^{th} and 12^{th} month.



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Impact of dual antiplatelet therapy on clinical outcomes one year after implantation of bioresorbable polymer DES

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

Methods and results: Information from 2 large prospective, multicentre, multinational, single-arm, observational NOBORI registries on duration of DAPT was available for 11278 patients. DAPT was continued at 1 year for 8124 patients (DAPT), 3154 had stopped DAPT at different time intervals (no-DAPT): before 1-month - 313 patients (DAPT<1M), between 1 m and 12 m - 2841 patients (DAPT<12M). We analysed impact of DAPT duration on clinical outcomes at one year. In the DAPT cohort there were more male patients, higher frequency of diabetes and multivessel treatment. No-DAPT patients were older, had more often hypertension, renal failure and previous stroke. DAPT patients had more lesions at bifurcations and CTOs. Access site in DAPT cohort was more often femoral. TLF rate at 1 year in DAPT<1M subgroup was 6.8% (Cardiac Death-CD: 3.6%, TV-MI: 2.3% and TLR: 2.3%); DAPT<12M it was 1.3% (CD 0.3%, TV-MI 0.4% and TLR 0.7%), while in DAPT subgroup TLF rate was 2.1% (CD 0.1%, TV-MI 0.8% and TLR 1.4%). Target vessel failure rate was lowest at 1.7% in DAPT<12M subgroup, followed by DAPT group with 2.7% and DAPT<1M with 8.1%. As expected, definite and probable stent thrombosis rate was significantly higher in DAPT<1M subgroup 1.6%, while it was low in DAPT<12 and in DAPT subgroup (0.28%), p<0.01.

Conclusions: Our results indicate that continuation of DAPT within the first month of stent implantation remains crucial. After the first month, shorter duration of DAPT does not have a negative impact on one year clinical outcomes and that such practice is a feasible treatment option for patients who have received new generation DES. Whether bioresorbable polymer and abluminal coating, as applied on Nobori DES, have some effects on these findings remains to be seen when results of dedicated randomised studies become available.



The influence of social class on adherence to dual anti-platelet therapy post PCI and subsequent outcomes

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Aims: The aim of this study was to test the hypothesis that patients in the low socio-economic class, probably due to financial reasons or level of education, are less compliant to dual anti-platelets therapy (DAPT) post PCI after ACS.

Methods and results: Consecutive patients who had PCI over a six-month period in the only tertiary Heart Hospital in Qatar were followed-up for eighteen months. The adherence to DAPT was determined by the prescription refill post discharge. Our institutional and national policy dictated the minimum duration of DAPT was for 12 months. Therefore, the patients who did not renew the prescription through our hospital could not receive it elsewhere. We compared the prescription renewal rate between the high (Group 1) and the low (Group 2) social class groups (primary endpoint). Readmission rates and mortality were also recorded (secondary endpoints). Five hundreds fifty-seven patients were included. There was no difference in the composition of male gender between the high and the low social class groups (83.6% vs. 87.5%, p=0.19). At 2 months post-discharge, there was no significant difference in the adherence to DAPT in both groups (Group 1=78%, Group 2=83%, p=0.13). At 12 months, there was significantly less compliance in Group 2 (70.4% vs. 80%, p=0.009). For secondary endpoints, Group 2 displayed lower readmissions rate over 18 months (21% vs. 31.5%, p=0.005), higher mortality at 6 months (3.3% vs. 0.7% p=0.026) but lower at 18 months (1.1% vs. 3.5%, p=0.062).

Conclusions: Low social class is associated with non-adherence to 12 months of DAPT and higher 6 months mortality post-angioplasty. Further study is required to determine why there is a higher re-admission rate and 18-month mortality rate in the high social class.



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Long-term outcome after 1st and 2nd generation DES for the treatment of coronary CTO: insights from a large registry of 1,330 consecutive patients

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Aims: Second-generation drug-eluting stents (DES) have reduced the occurrence of target vessel revascularisation (TVR) and stent thrombosis compared to first-generation DES but the clinical impact in chronic total occlusion (CTO) is poorly described. We aimed to compare long-term outcome after 1st and 2nd-generation DES in patients with CTO.

Methods and results: Of 1,343 consecutive Patients who underwent PCI for CTO between 2004 and 2012, long term outcome was evaluated after successful DES implantation. Major adverse cardiac events (MACE) including cardiac death, target vessel revascularisation (TVR) and myocardial infarction (MI) were compared between patients treated with 1st (sirolimus and paclitaxel) and 2nd generation DES (everolimus, zotarolimus and biolimus). Procedural success was achieved in 1000 (74.4%) patients of whom 943 (70.2%) received at least one stent. DES were implanted in 873 patients (65%) who defined the study population. Patients treated with 1st generation DES (583 patients, 66.9% of the whole population) had a higher rate of current smoking (28% vs. 20% p=0.007), were more frequently treated for left anterior descending CTO (37% vs. 29% p=0.018) and had shorter stent length (46±25 vs. 51±25 mm, p=) compared to patients treated by 2nd generation DES. Age, gender, diabetes, and LVEF were similar between groups. Median follow-up was at 4.1 years (IQR: 2.4-6.5 years). Patients treated with 2nd generation DES had lower MACE rate compared to 1st generation DES (12.7% vs. 21.3%, respectively, p=0.003). The decrease in MACE rate was driven by lower TVR (8.7%, vs. 13.4%, respectively p=0.04) whereas cardiac death and MI were similar between groups (p=0.32 and p=0.15, respectively). Cumulative event rates by Kaplan-Meier analysis showed lower incidence of TVR among patients treated by 2nd generation stents (p Log Rank=0.02).

Conclusions: In patients successfully treated by PCI for CTO, 2nd generation DES are associated with better long-term clinical outcome, when compared to 1st generation DES. This is mainly driven by lower TVR rates.



Recanalisation of true coronary CTO: results of everolimus-eluting stents compared with zotarolimus-eluting stents

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Aims: Successful recanalisation of a coronary chronic total occlusion using a new generation drug-eluting stent has demonstrated superiority over bare metal and first generation drug-eluting stents. We evaluate different second-generation DES in terms of angiographic and clinical outcomes in chronic total occlusions.

Methods and results: In this prospective registry study, a total of 138 patients with successful chronic total occlusion recanalisation in a native coronary artery were included. Chronic total occlusion was defined as duration of occlusion ≥3 months and thrombolysis in myocardial infarction flow 0. everolimus-eluting stents were implanted in 78 patients and zotarolimus-eluting stents (Resolute Integrity) were used in 60 patients. Dual antiplatelet therapy was prescribed for 6 months. Follow-up angiography was scheduled at 6 months. Clinical follow-up was done at 12 months. The primary angiographic outcome measure was late lumen loss. Secondary angiographic outcomes were reference diameter, minimal lumen diameter and percent diameter stenosis were evaluated. The primary clinical outcome measure was target lesion revascularisation rate. Furthermore, major adverse cardiac events (MACE) as a composite of cardiac death, myocardial infarction not clearly attributable to a non-target vessel and target lesion revascularisation was obtained. The baseline characteristics were similar in both groups. Diabetes mellitus was present with use of everolimus-eluting stents in 31% and zotarolimus-eluting stents in 30% (p=0.92), renal insufficiency in 15% versus 13% (p=0.73), respectively. Number of implanted stents did not differ with 2.9±1.5 everolimus-eluting stents (range 1-7) and 2.8±1.2 zotarolimus-eluting stents (range 1-7; p=0.95) resulting in similar total stented segment with 71±35 mm for everolimus-eluting stents and 73±35 mm for zotarolimus-eluting stents (p=0.79). Inflation pressure did not differ with 15.0±2.4 atm versus 15.6±3.1 atm (p=0.28), respectively. Angiographic follow-up was obtained in 85% of the study population. Late lumen loss was 0.45±0.69 for use of everolimus-eluting stents compared with 0.61±0.72 for use of zotarolimuseluting stents, p=0.16. Binary angiographic restenosis rate defined as diameter stenosis of more than 50% at follow-up angiography was 13.6% with use of everolimus-eluting stents compared with 20.5% with use of zotarolimus-eluting stents (p=0.35). There was no stent thrombosis with everolimus-eluting stents or with zotarolimus-eluting stents. Within 12-month clinical follow-up the need for TLR was similar with 8.0% for everolimus-eluting stents versus 10.9% for zotarolimus-eluting stents (p=0.22). Furthermore, there was no difference in the occurrence of major adverse cardiac events with 10.7% versus 12.7% (p=0.72), respectively.

Conclusions: The use of modern DES after recanalisation of true chronic total occlusions results in a low rate of binary restenosis rate. In this prospective observational registry study the angiographic and clinical results were comparable with use of everolimus-eluting stents compared with zotarolimus-eluting stents.



Euro14A-0P117

Efficacy and safety of biolimus-eluting stents with biodegradable polymers for the treatment of CTO arteries

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Aims: Due to low success rates, periprocedural complications and higher risk for restenosis the recanalisation of chronic total occlusions of coronary arteries (CTO) remain a challenging task in interventional cardiology. Furthermore several studies have revealed that restenosis and late stent thrombosis are linked to the polymer layer of drug-eluting stents. We therefore tested whether drug-eluting stents with completely biodegradable polymers are applicable for the treatment of CTO's.

Methods and results: In order to test this hypothesis we retrospectively examined in a monocentric analysis data of 95 CTO patients who were exclusively treated with biolimus-eluting stents with fully biodegradable polymers in the past 24 months. CTO was defined as total occlusion of a coronary artery for more than 3 months and TIMI 0 flow in the occluded segment. Primary study endpoint was late loss at the initial occlusion site after 6 months. Secondary clinical endpoints included a composite of cardiac death, myocardial infarction and target vessel revascularisation after 6 months (MACE). 151 CTO procedures were performed in the past 24 months. 122 CTO's were successfully recanalised which corresponded to a success rate of 81%. The mean occlusion length of 29±14 mm was treated with an average stent length of 68±31 mm. 95 of the successfully recanalised CTO patients received biolimus-eluting stents with biodegradable polymers. Meanwhile 69 patients have concluded angiographic and clinical 6 months follow-up. Late loss at the initial occlusion site was 0,19±0,46 mm. Binary restenosis with the need for reintervention occurred only in 4 patient (5.8%). Cardiac death was documented in 1 patient. In addition to that, one patient suffered from a stent thrombosis with a consecutive myocardial infarction during follow-up. Therefore the MACE rate was calculated with 10%.

Conclusions: First results of our monocentric analysis indicate that biolimus-eluting stents with fully biodegradable polymers are associated with little late loss and low MACE rates in complex CTO lesions. Future studies in larger, independent patient cohorts are necessary to confirm our results.



One-year clinical outcomes with biodegradable polymer biolimus-eluting stent in coronary CTO: comparison with durable polymer everolimus-eluting stent

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Aims: Recent pivotal studies have shown that biodegradable polymer biolimus-eluting stent (BES) is as safe and efficacious as the current standard of a thin-strut everolimus-eluting stent (EES) with a durable biocompatible polymer. However, the effectiveness of BES in a real-world setting of chronic total occlusion (CTO) lesion is currently unclear. We compared one-year clinical outcomes after the use of BES versus EES for the treatment of CTO lesions.

Methods and results: Between February 2011 and June 2012, we underwent percutaneous coronary intervention with the BES (1,276 patients with 1,752 lesions) or EES (1,045 patients with 1,446 lesions) were analysed. Of these, 152 patients with 157 lesions (9.0%) and 137 patients with 142 lesions (9.9%) had CTO lesions. The primary endpoint was the cumulative rate of major adverse cardiac events, defined as a composite of cardiac death, myocardial infarction, definite stent thrombosis, clinically driven target lesion revascularisation (TLR) at one-year. Baseline characteristics were similar between the BES and EES groups. Total stent length did not differ between the 2 groups (52.8±26.0 mm vs. 52.7±30.1 mm, p=0.98). Diabetic patients and haemodialysis patients were similar between the 2 groups (46.5% vs. 44.3%, P=0.75; 3.2% vs. 2.8%, P=0.95, respectively). At one-year, cumulative incidence of MACE and clinically driven TLR were not significantly different between the 2 groups (4.5% vs. 3.5%, p=0.62; 3.8% vs. 2.8%, p=0.60, respectively). Stent thrombosis was similar between the BES and EES groups (0.6% vs. 0%, p>0.99).

Conclusions: One-year clinical outcome after biodegradable polymer BES implantation in CTO lesions is not significantly different from that after durable polymer EES. This study suggests that both BES- and EES-use are feasible with efficacy and safety in a real-world setting of CTO lesions.



Euro14A-0P119

Second generation of bioresorbable everolimus-eluting scaffold for coronary CTO: six-month clinical and multi-detector computed tomography coronary angiography results

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Aims: Coronary Chronic Total Occlusions (CTOs) are associated with diffuse disease and long stented segment. The Everolimus-eluting bioresorbable vascular scaffolds (BVS; Abbot Vascular, CA. USA) have been shown to be effective in the context of selected patients and simple lesions. This is a prospective, pilot study assessing the safety, performance and efficacy of the BVS, in percutaneous CTO revascularisation, under guidance of intravascular imaging techniques.

Methods and results: From February to December 2013,30 true CTOs lesions (Euro-CTO club definition) treated with BVS were included in this prospective registry. Exclusion criteria were: reference diameter less than 2.5 or more than 4.0 mm and bifurcated lesions with a big side branch (>2.5 mm) in which the operator planned to perform two stent technique. Severe calcified lesions were left to the operator's discretion. Patients were on dual antiplatelet therapy. Target lesions were scaffold after mandatory pre-dilatation and IVUS analysis. Patients were followed clinically at 1, 6, 12, 18, and 24 months, optical coherence tomography (OCT) study will be performed after BVS implantation and at 12 months. A multi-slice computed tomography (CT) coronary angiography were performed before the intervention and at 7 and 18 months. The mean age was 61±9.5 years old. 83% were male. 16.7% were diabetic 19% had a previous PCI. Most of patients were stable at presentation (93.4%). An MRI was done in 65% of patients before CTO revascularisation. The most frequent lesions treated were the RCA (43%) and LAD (40%). According to the Japanese-CTO score of complexity most of lesions were classified as intermediate (47%) or difficult-very difficult (26%). 40% were moderate-severe calcified lesions. Pre-dilatation was done in all cases; using a cutting balloon in 76% and rotablator in 3 cases. In most cases (89%) the strategy was antegrade. 52% performed with a 6F catheter and in half of the cases by radial approach. The total scaffold length implanted per lesion was of 48.2±20.4 mm. All the scaffolds were delivery and deployment successfully. By OCT, final minimum scaffold area and lumen stenosis were of 7.33±1.4 mm² and 11.2±6.4%, respectively. There were no significant areas of strut malapposition. We did no report any adverse event at 1 month. At a mean of 5.2±2.3 months no MACE was reported and multi-slice CT-scan did no report any significant restenoses.

Conclusions: BVS for CTO recanalisation demonstrates excellent feasibility, safety and mid-term patency. Appropriate lesion preparation remains the key to aid adequate expansion of these scaffolds in this setting.



PCI in left main stenosis in Sweden: a report from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR)

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Aims: The aim of this study was to characterise the trends and frequency of PCI due to left main (LM) stenosis in Sweden between 1999 and 2012. Methods and results: We extracted data from SCAAR (Swedish Coronary Angiography and Angioplasty Registry) and identified 485,595 coronary angiographies between 1999 and 2012. In 72,104 procedures there was a significant LM stenosis judged by the physician. Treatment of stenosis with PCI was performed in 5,813 LM. 41% of the patients had previously been treated with CABG. From 1999 to 2012 the number of PCI have increased from 98 to 810 procedures per year, the use of stent increased from 47% to 90%, and the use of DES increased from 0% to 79%. IVUS was used in 12% of the procedures. The indication for the coronary angiography was in 32% stable angina, 49% NSTE-ACS and 17% STEMI. The all-cause one-year mortality was 17% and the overall incidence of restenosis was 11%.

Conclusions: In Sweden, PCI in LM stenosis is uncommon. However, the number of PCI in LM stenosis has increased throughout the years. The most common indication for PCI in LM stenosis was ACS.



Euro14A-0P121

Gender differences in clinical outcome of patients with unprotected left main disease

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Aims: Although percutaneous intervention (PCI) for unprotected left main disease (ULM) is a common practice, the impact of gender differences remains unclear. In order to clarify the impact of gender differences in patients with ULM, consecutive patients treated with drug-eluting stents (DES) for ULM were analysed.

Methods and results: Between April 2002 and August 2011, 1,032 consecutive patients undergoing PCI using first and second generation DES for ULM stenosis were retrospectively analysed. Of these, 20.6% of the patients was female. There was no significant difference in clinical, angiographic and procedural characteristics between males and females. Women had more comorbidities such as diabetes mellitus, renal dysfunction, higher age and higher EuroScore. Furthermore, pre reference diameter (RD), post minimum stent diameter and post RD were smaller in females than in males. Target lesion revascularisation (TLR) for main branch seemed to be higher in females despite significant difference??? Furthermore, the occurrence of cardiac death was higher in females than in males (adjusted Hazard ratio; 1.723, 95% CI; 1.034-2.871, p=0.03).

Conclusions: In patients with ULM disease, females had more comorbidities and smaller LM, resulting in an increased risk of clinical events.

Primary PCI for left main stem occlusion: analysis of the British Cardiovascular Intervention Society registry

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Aims: There is limited published data regarding outcomes of patients presenting with unprotected left mainstem occlusion (ULMSO). We aim to evaluate in-hospital outcomes and one-year mortality of patients presenting with ULMSO treated with primary percutaneous coronary intervention (PPCI).

Methods and results: 400,985 PCI cases were recorded in the British Cardiovascular Intervention Society database of all PCI cases in the UK from January 2007 to August 2012. 1,473 patients underwent emergency unprotected left mainstem (LMS) PPCI (1.6% of all PPCI). 389 patients having emergency PPCI (0.44% of all PPCI) presented with ULMSO (occlusive disease defined as TIMI flow 0/1 and stenosis >75%). These ULMSO patients were compared with 733 emergency patients treated with non-occlusive LMS disease defined as TIMI flow ≥2 or stenosis <75%. All-cause mortality was tracked by the office of national statistics and life status was available at 7, 30, 90 and 365 days following intervention. 86,672 patients had PPCI during the observation period with a 5.7% 30-mortality. The approximate incidence of ULMSO PPCI is 11 cases/year/100,000 population. Presentation with ULMSO was associated with a doubling in the likelihood of peri-procedural shock (60% vs. 29%; p<0.001) and/or IABP support (56% vs. 29%; p<0.001) compared to those with non-occlusive LMS disease. In-hospital (40% vs. 18%; p<0,001), and one-year mortality (54% vs. 32%; p<0.001) was higher in patients with ULMSO compared with patients presenting with a patent LMS. one-year mortality in the ULMSO groups was 2.5-fold higher in those with peri-procedural cardiogenic shock (CS; 72% vs. 29%; p<0.001). However, late mortality rates were independent of initial haemodynamic status (30-day vs. one-year mortality was 58% vs. 72% respectively in the ULMSO group with CS and 21% vs. 29% respectively in those without CS).

Conclusions: In patients undergoing PPCI for ULMSO, acute outcomes are poor and additional therapies are required to improve outcome. However long-term outcomes for survivors of ULMSO are encouraging.



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Clinical outcomes in patients with left main disease treated with bioresorbable polymer DES

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Aims: Percutaneous coronary intervention (PCI) in patients with left main disease was shown to be associated with higher risk of adverse events. Our aim was to compare in-hospital and one-year clinical outcomes in real-world patients with and without left main stenting with bioresorbable polymer drug-eluting stent (DES).

Methods and results: We analysed data of unselected patients who received Nobori® bioresorbable polymer DES within the large, prospective, single-arm, multicentre, observational e-NOBORI registry. The primary end point was target lesion failure (TLF) defined as composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (TLR). All events were adjudicated by an independent clinical events committee. A total of 8,820 patients were included in the analysis, of which 251 (2.85%) underwent PCI for left main disease. Protected left main PCI was performed in 33.7% of the cases. Patients in the left main group were older (66.47±11.84 vs. 63.02±11.87, p<0.001), had more often hypertension (78.9% vs. 72.7%, p=0.03), previous cardiac surgery (25.8% vs. 6.1%, p<0.001) and multivessel PCI (56.6% vs. 22.5%, p<0.001). In the group with no left main PCI, rate of current smokers was higher (27% vs. 18.3%, p=0.004) as well as ST-segment elevation myocardial infarction (STEMI) at presentation (9.6% vs. 5.2%, p=0.02). Treatment of bifurcation lesions was more prevalent in patients with left main PCI (15.6% vs. 6%, p<0.001). There was a trend towards higher rate of in-hospital and one-month TLF in patients treated with PCI for left main disease, albeit no statistically significant difference was reached (1.6% vs. 0.6%, p=0.068 and 2.4% vs. 1.1%, p=0.06). One-year follow-up revealed similar rates of TLF in both groups of patients (left main 4.45% vs. no left main PCI, while in patients with no left main PCI the incidence rate was 0.44% (p=0.3).

Conclusions: Implantation of Nobori® bioresorbable polymer drug-eluting stent in patients undergoing PCI for left main disease is associated with very low rates of adverse events at one-year follow-up. There was no difference in clinical outcomes between patients who underwent PCI for left main disease and those undergoing PCI without left main stenting.



Comparison of long-term outcomes between the first and second generation DES implantation for unprotected left main coronary artery bifurcation lesions

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Aims: To investigate the clinical outcomes of drug-eluting stent (DES) implantation for unprotected left main coronary artery (ULMCA) bifurcation lesions with 1st generation DES and 2nd generation DES.

Methods and results: This is a single-centre, retrospective study. Between April 2007 and April 2013, a total of 10755 percutaneous coronary intervention (PCI) were performed in our hospital. Among these, we performed elective DES implantation for 190 stable angina patients with *de novo* ULMCA bifurcation lesions. 67 Sirolimus-eluting stents (SES), 17 Paclitaxel-eluting stents (PES), 20 Zotarolimus-eluting stents (ZES), 57 Everolimus-eluting stents (EES) and 29 Biolimus A9-eluting stents (BES) were implanted. We compared the clinical outcomes of 1st generation DES (SES and PES; 84 patients) with 2nd generation DES (ZES, EES and BES; 106 patients). The main end point was the occurrence of major adverse cardiac events (MACE). Stent patency was assessed by either coronary arteriography or coronary CT angiography. Clinical outcomes were analysed by Kaplan-Meier estimation. 9 cases in 1st generation DES (10.7%) and 12 cases in 2nd generation DES (11.3%) were treated with 2 stent strategy. Patient and lesion backgrounds are similar in both groups. 1st generation DES and 2nd generation DES were followed up for 1,079±673 days and 547±377 days. The two study groups did not differ significantly in the composite of all MACE, all-cause death, cardiac failure, myocardial infarction, and target lesion revascularisation (TLR) during the follow-up. Kaplan-Meier survival curves showed that freedom from MACE at 2 years were 85.7% in 1st generation DES and 91.3% in 2nd generation DES. (P=0.27) Target lesion revascularisation rate at 2 years were 8.7% in 1st generation DES and 5.1% in 2nd generation DES. (P=0.39)

Conclusions: 2nd generation DES offer no significant advantage over 1st generation DES in long-term outcomes after ULMCA bifurcation stenting.



Euro14A-0P125

Single stent and final kissing versus two stents Culotte technique and final kissing in the treatment of true bifurcation left main lesions

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Aims: To analyse the six-month restenosis rate after two different treatment strategies of the true bifurcation left main stenosis: one stent+final kissing and two stents culotte technique.

Methods and results: 94 patients with true bifurcation left main stenosis (when ostium of both Left Anterior Descending (LAD) and Circumflex artery (CX) are involved) were included. All patients were randomised to different techniques of left main stenting: one stent method (n –54), two stents using Culotte method (n –42). The endpoints were: left main restenosis rate, ostial LAD restenosis rate, ostial CX restenosis rate at six months. Univariate analysis was performed to determine risk factors of restenosis. All 94 patients had true bifurcation left main stenosis with lesion spreading into both LAD and CX: 31 patients had LAD stenosis > 50% and CX stenosis <50%, 37 patients had LAD stenosis <50% and CX stenosis >50% and 28 patients had LAD stenosis >50% and CX stenosis > 50%. 6 months after PCI the left main restenosis occurred in 3 (5.6%) patients in one-stent group and in two (4.8%) patients in two-stents Culotte group (p=ns). There was no difference in LAD ostial restenosis rate between two groups – 2 (3.7%) in one-stent group and 1 (2.4%) in two-stents Culotte group (p=ns). The incidence of CX ostial restenosis rate was remarkably higher in one-stent group – 7 (13%) compared to two-stents Culotte group 1 (2.4%), (p<0.05). Univariate analysis showed that one-stent technique was related to CX ostial restenosis rate. The significance of CX stenosis at baseline failed to demonstrate any influence on the incidence of CX ostial restenosis.

Conclusions: In true left main bifurcation lesions, the preferable PCI strategy is a two stent Culotte technique with final kissing in view of a high risk of CX ostial restenosis with a single stent+final kissing strategy.

Dedicated bifurcation type-A two-diameter DES in the treatment of distal left main stem stenosis: International registry

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Aims: Coronary artery disease of left main stem (LMS) is a particular form of atherosclerosis, and the most optimal treatment is still debated. The aim of this study was to assess the effectiveness and safety profile of the distal LMS stenosis treatment with the dedicated bifurcation stent BiOSS: in subgroup I paclitaxel-eluting BiOSS® Expert (Balton, Poland) and in subgroup II sirolimus-eluting BiOSS® LIM (Balton, Poland).

Methods and results: The enrollment of patients with coronary artery disease and NSTE-ACS started in January 2010 in three centres in Bulgaria, Poland and Spain. Decision for LMS stenting was based on the Heart Team consensus. Patients with STEMI were excluded from the study. Provisional T-stenting was the obligatory strategy. Double antiplatelet therapy was applied for 12 months. Control angiography was planned at 12 months in all patients. The primary end point was the rate of death, myocardial infarction, in-stent thrombosis or target lesion revascularisation (TLR) at 12 months after PCI. Here, we present 6-month clinical data from both groups and complete angiographic data from BiOSS® Expert group. At the time of EuroPCR 2014 angiographic data from BiOSS® LIM will be available in 70%. 158 patients were enrolled (62 in BiOSS® Expert group and 96 in BiOSS® LIM group). The average age was 65.7±12.5 yrs and 19.7% were female. PCI in NSTE-ACS was performed in 17.8% of patients, Moreover, 73.4% were with hypertension, 81.4% with dyslipidaemia, 32.1% with diabetes, 39.2% with prior MI, 43.3% with prior PCI and 17.4% with prior CABG. The mean SYNTAX score was 21.52±6.58 and EuroScore II – 1.73%±1.6% (NS differences between subgroups). True bifurcations were treated in 70.1% of cases. All BiOSS® stents were implanted successfully. The nominal stent parameters were as follows: BiOSS® Expert subgroup - 4.07±0.26 mm (proximal diameter) x 3.36±0.26 mm (distal diameter) x 16.61±1.72 mm (length) and BiOSS® LIM subgroup - 3.90±0.4 mm (proximal diameter) x 3.17±0.39 mm (distal diameter) x 16.81±2.06 mm (length). Side branch stent was implanted in 25.9% and 21.4% of patients, respectively. Almost 62% of procedures were performed radially, whereas 38% were performed by the femoral route. In 17% of cases a 7F catheter was used, and in 83% a 6F. After 12 months in BiOSS® Expert group angiographically driven TLR rate was 9.6%, whereas clinically driven TLR was 3.2%. In BiOSS® LIM goup data are pending - at 6 months there were no death or MI. Moreover, in BiOSS® Expert group angiographic data disclosed that the late lumen loss was as follows: in the main vessel -0.21±0.1 mm, in the main branch -0.26±0.12 mm and in the side branch -0.14 ± 0.09 mm.

Conclusions: Dedicated bifurcation BiOSS® stents seem feasible devices with promising effectiveness and safety profile in distal LMS stenosis. Complete BiOSS® LIM angiographic data will answer the question whether the drug used or stent design is more important.



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Upstream prasugrel loading in patients with STEMI referred for primary PCI - Does time matter?

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Aims: Prasugrel is an irreversible P2Y12 platelet receptor blocker. Studies have shown that prasugrel 60 mg achieves peak platelet inhibition at 30-60 minutes. In an ST-segment elevation myocardial infarction (STEMI), this may take longer. Patients referred for primary percutaneous intervention (PCI) following STEMI are loaded with prasugrel 60 mg as per our local protocol. The timing of this dose varies depending on referral source. Some patients receive the loading dose upstream at the referring hospital and others receive this dose on arrival at our centre. We aimed to compare differences in outcome in patients referred for primary PCI based on where they received the prasugrel loading dose upstream in a referring hospital (group 0) or in our cath lab immediately before primary PCI (group 1). Outcome measures were coronary Thrombolysis in Myocardial Infarction (TIMI) flow at baseline and at the end, corrected TIMI frame count (cTFC), ST segment resolution on electrocardiogram (ECG) and in-hospital mortality.

Methods and results: We performed a retrospective observational study of STEMI patients at our tertiary centre. Between July 2012 and November 2013, a total of 55 patients received upstream prasugrel prior to primary PCI (group 0). We identified 143 patients loaded with prasugrel in our cath lab immediately before primary PCI between July and December 2012. We then formed 55 matched patients (group 1) using propensity score matching done by the nearest neighbour (1:1) method without calipers. Median "symptom onset to balloon time" (STBT) was 68 minutes greater in group 0, consistent with delay resulting from transfer from a referring hospital. Patients in group 0 (upstream administration) were given prasugrel on average 41 minutes earlier that patients in group 2 (cath lab administration). More patients in group 0 had TIMI 3 flow at baseline angiogram (10 patients - 18%) compared to group 1 (4 patients - 7%), p=0.09. Additionally, more patients in group 0 had baseline TIMI 2/3 flow (20 patients - 36%) compared to group 1 (11 patients - 20%). The latter showed a trend towards statistical significance (p=0.06). There was no significant difference between groups 0 and 1 with respect to the final cTFC (28.2 versus 30.0, p=0.5), final TIMI 3 flow (40 patients versus 47 patients, p=0.10) and median ST segment resolution (2.0 mm, versus 2.0 mm, p=0.5). Additionally there was no difference in the in-hospital mortality between the two groups (1 patient versus 2 patients, p=0.56)

Conclusions: We have demonstrated in this small observational pilot study that administering prasugrel upstream in patients with STEMI referred for primary PCI resulted in a clear trend towards improved TIMI flow at the baseline angiogram. There were no other differences in angiographic or ECG markers nor in-hospital mortality. However, by virtue of presenting initially at a non-interventional hospital, the group of patients receiving upstream prasugrel had significantly longer ischaemic times reflected by a longer STBT. This factor may have negated any potential positive effect of upstream prasugrel treatment. There is a compelling need to study this issue by means of a randomised controlled trial.



Impact of new P2Y12 blockers on platelet reactivity and clinical outcomes after acute coronary syndrome: insight from a large single-centre registry

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Aims: We retrospectively studied the impact of new P2Y12 inhibitors (Prasugrel, Ticagrelor) introduction on platelet reactivity and clinical outcomes after Acute Coronary Syndrome (ACS) from a large single-centre registry.

Methods and results: Consecutive patients admitted for ACS since 2007 and discharged on dual antiplatelet therapy were enrolled. Biological response was assessed one month after discharge by PRI VASP and ADP-induced aggregation (%ADP). Patients were classified according to PRI VASP as Very low on-treatment platelet reactivity (VLTPR) (PRI VASP ≤10%), low on-treatment platelet reactivity (LTPR) (PRI VASP ≤20%) and high on-treatment platelet reactivity (HTPR) (PRI VASP >50%). Ischaemic and bleeding complications were reported. 1,999 patients were analysed, 605 before (March 2007-February 2010) and 1,394 after introduction of new P2Y12 blockers (February 2010-August 2013). After introduction, we reported a significant lower PRI VASP values (38%±0.53 vs. 42%±0.81 p=0.001), %ADP aggregation (52%±0.4 vs. 54%±0.6 p=0.03) and HTPR incidence (22% versus 34% OR [95% CI]: 0.65 [0.53-0.80]; p<0.001). Conversely, incidence of VLTPR and LTPR were significantly higher after new P2Y12 inhibitors introduction: 6% versus 3% (OR [95% CI]:2.0 [1.2-3.3]; p<0.01) and 19% versus 8% (OR [95% CI]:2.8 [2.0-3.9]; p<0.001) respectively. Clinical follow-up confirmed biological findings with higher incidence of bleeding 10% versus 5% (OR [95% CI]:2.1 [1.4-3.2]; p<0.01) and lower incidence of stent thrombosis 1.3% versus 3.3% (OR [95% CI]: 0.39 [0.20-0.73]; p<0.01) with new P2Y12 blockers.

Conclusions: New P2Y12 inhibitors introduction modified both platelet reactivity and clinical outcome of ACS patients, with higher rate of hyper responders and bleeding, and lower rate of non responders and thrombotic events.



Euro14A-0P129

Prasugrel versus Ticagrelor in acute coronary syndrome: a randomised comparison

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Aims: European guidelines recommended the use of Prasugrel or Ticagrelor in ACS patients as first choice. The present biological study was designed to compare the effectiveness and safety of Prasugrel versus Ticagrelor in patients undergoing PCI for ACS.

Methods and results: In this randomised study, consecutive patients admitted for ACS in our institution were assigned to received a loading dose of Prasugrel 60 mg or Ticagrelor 180 mg and were treated at discharge with Prasugrel 10 mg once a day or Ticagrelor 90 mg twice a day. Antiplatelet response was assessed one month after ACS with Platelet Reactivity Index VASP (PRI VASP) and ADP-induced platelet aggregation (%ADP). LTPR was by PRI VASP ≤20%. Primary end point was the comparison of degree of platelet inhibition and incidence of LTPR in patients treated with Ticagrelor or Prasugrel, one month after an ACS. Between March and June 2013, 96 patients (48 in each arm) were randomly assigned to Prasugrel or Ticagrelor for ACS. We observed 14% of bleeding complications (n=13 patients), 8 in the Ticagrelor cohort versus 5 in the Prasugrel therapy group. At one month, PRI VASP (20.2±9.9% vs. 25.8±11.5% p=0.01) and %ADP (37.9±10.3% vs. 48.9±10.8% p<0.01) were significantly lower under Ticagrelor therapy than under Prasugrel therapy. We observed LTPR status in 33% of the patients under Prasugrel and in 58% under Ticagrelor (p=0.01). Interestingly there was a trend in favour of an increased bleeding risk at one month on Ticagrelor (17% vs. 10% p=0.15).

Conclusions: The present study suggests that Ticagrelor is associated with higher platelet inhibition and higher incidence of 'hyper response' than Prasugrel one month after ACS, possibly exposing patients to higher risk of bleeding complications.



Randomised assessment of the ONSET and OFFSET of the antiplatelet effects of Ticagrelor versus Clopidogrel in patients with chronic kidney disease performing haemodialysis

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Aims: Patients with chronic kidney disease (CKD) and particularly those receiving haemodialysis (HD) are poor responders to clopidogrel. Ticagrelor is a reversibly binding P2Y12 receptor antagonist. Early dose-finding studies suggested a faster onset and greater inhibition of platelet aggregation with ticagrelor than with clopidogrel. We sought to assess the functional impact of ticagrelor in CKD patients receiving maintenance HD

Methods and results: In a single-centre, prospective, randomised, crossover study, seventeen patients undergoing regular maintenance HD were assigned to receive ticagrelor (180-mg load, 90-mg BID maintenance dose) or clopidogrel (600-mg load, 75-mg/d maintenance dose) for 14 days and after 14 days of washout period, cross-over treatment assignments for another 14 days. Platelet function was evaluated before and afterantiplatelet therapy with light transmittance aggregometry and with VerifyNow™ P2Y12 assay. Platelet activation markers (sCD40L and sP-selectin) were also assessed. Greater IPA (20 μmol/L ADP, final extent) occurred with ticagrelor than with clopidogrel at 1, 5, 48 hours after loading and at 2 weeks; by 5 hours after loading, a greater proportion of patients achieved >50% IPA (76.5% versus 17.6%, p=0.04) and >70% IPA (41.2% versus 5.9%, P=0.002) in the ticagrelor group than in the clopidogrel group, respectively. A faster offset occurred with ticagrelor than with clopidogrel (P=0.003). At 48 hours after the last dose, mean IPA was −15.8% for ticagrelor versus −154% for clopidogrel (P=0.022). By 1 hour after loading, mean PRU was 152 for ticagrelor versus 400 forclopidogrel (p<0.001).

Conclusions: Ticagrelor achieved more rapid and greater platelet inhibition than clopidogrel; this was sustained during the maintenance phase and was faster in offset after drug discontinuation.



Euro14A-0P131

Alternative strategies to aspirin and clopidogrel for patients presenting with ACS: a network meta-analysis

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Aims: Alternative strategies to aspirin and clopidogrel for patients presenting with Acute Coronary Syndrome (ACS) have been recently evaluated, with studies investigating both new antiplatelet drugs and new oral anticoagulation therapy.

Methods and results: Suitable randomised trials focusing on different choices of antiplatelet and anticoagulant therapy were systematically searched and abstracted. The risks of MACE (a composite end point of death, myocardial infarction and repeated revascularisation), death and major bleeding were appraised within a hierarchical Bayesian model computing absolute rates (AR) and odds ratios (OR), with 95% confidence intervals. 10 studies with 53513 patients were included. Ticagrelor, prasugrel and rivaroxaban significantly reduced risk of MACE (HR 0.8 0.01-0.85; HR 0.9 0.03-0.95 and HR 0.8 0.02-0.9) when compared with aspirin and clopidogrel, while ticagrelor and rivaroxaban reduced risk of death (HR 0.8 0.7-0.9; HR 0.8 0.7-0.9). Ticagrelor had a reduced rate of major bleeding when compared to prasugrel (HR 0.8 0.6-0.9) and to rivaroxaban (HR 0.4 0.1-0.5; all CI 95%).

Conclusions: Ticagrelor and rivaroxaban reduced mortality when compared to aspirin and clopidogrel, while ticagrelor decreased the risk of bleeding when compared to prasugrel and rivaroxaban.



Prognostic impact of CTO in men and women - a report from the Swedish coronary angiography and angioplasty registry

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Aims: Chronic total coronary occlusion (CTO) is a frequent finding in patients with ischaemic heart disease. Our aim was to evaluate at the level of one whole nation whether the prognostic impact of CTO on long-term survival differs between male and female patients.

Methods and results: The study population included all consecutive patients registered in the SCAAR registry (Swedish Coronary Angiography and Angioplasty Registry) from 2005 to 2012 who underwent angiography or PCI in Sweden. Patients with previous coronary artery bypass graft surgery were excluded. The patients with CTO and without CTO were compared using Cox proportional-hazards regression adjusted for the following covariates: age, indication, extent of coronary artery disease, smoking, hypertension, hyperlipidaemia, diabetes, year of intervention, prior infarction, prior PCI, hospital and complications. Interaction test was performed between the presence CTO and gender to detect possible effect modification of gender on prognostic impact of CTO. The total of 89,871 patients were included in the study of which 14,441 had a CTO. There were 3,221 women and 11,220 men who had CTO. Median follow-up was 3 years. The total number of events was 10,796. CTO was an independent predictor of mortality (HR 1.29; 95% CI 1.22-1.37; P<0.001). The interaction test between gender and CTO was not significant (P=0.46). CTO was associated with increased mortality as well in women (HR 1.15; CI 95% 1.05-1.25) as in men (HR 1.19; CI 95% 1.12-1.26).

Conclusions: Our study is based on the largest CTO cohort so far. The presence of CTO carries a similar prognosis in male and female patients.



Euro14A-0P133

IDEAL registry

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Aims: An observational registry of long & extra long length (>33 mm) Pronova XR stents.

Methods and results: The total stent length per lesion and individual patient has an impact on the TLR (target lesion revascularisation) TVR (Target vessel revascularisation) outcome. Sirolimus-eluting stent compared with bare metal stent for long lesion treatment is associated with reduced restenosis rates. Between July 2012 and July 2013, 30 consecutive Pronova XR stents with effective lengths >33 mm were included in the study. All patients were clinically followed at 30 days, 3 months and 6 months interval. 23 of these underwent check angiography after 6 months of implant and 3 also underwent IVUS during follow-up angiography. The primary end point was late lumen loss and death. Secondary end points were MACE (Death, MI or TVF) Stent Thrombosis (as per ARC definition), persistent Stenosis. 56% diabetic Patients. 53.3% Acute coronary Syndrome. 46.6% Stable Angina. Average diameter 3.08 mm, Average stent length was 46.03 mm. (33 mm-2,2 38 mm-1,43 mm-5,48 mm-25) No overlapping stents were done. All 30 patients are alive & well. Follow-up angiography showed well flowing stent with minimal lumen loss in 22/23 cases. Only developed restenosis in Pronova XR focally. (This patient underwent CABG for severe long instent restenosis in other vessel with non Pronova stent.) There was no stent thrombosis.

Conclusions: Pronova XR in this complex long length setting showed excellent 6 months results (ISR one in 23 in angiographic follow-up). There was no stent thromboses.



Impact of small vessel disease on long term clinical outcomes after PCI in patients with unprotected left main coronary artery disease

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Aims: The Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery (SYNTAX) score, which is a summation of score in each lesion with diameter stenosis ≥50% in all lesions of vessel diameter ≥1.5 mm, has been proven to predict long-term clinical outcomes after PCI in patients with unprotected left main coronary artery disease (uLMCAD). Because small coronary vessels mostly supply small myocardial territories, there was sometimes no functional significance for these lesions in spite of severe stenosis by visual estimation. We ascertained whether small vessel disease (SVD) had an impact on long-term clinical outcomes after PCI in patients with uLMCAD, or not.

Methods and results: We evaluated 373 patients who underwent PCI with drug-eluting stents (DES) for uLMCA stenosis ≥50% from Sejong General Institute PCI database between April 2003 and December 2011. Thirty-three patients who presented with cardiogenic shock were excluded. SVD was defined when it caused 50% reduction in luminal diameter by visual assessment in any lesions of vessel diameter ≥1.5 mm and ≤2.25 mm. The primary effectiveness endpoint was major adverse cardiac and cerebral events (MACCE), defined as the composite outcomes of all-cause mortality, non-fatal myocardial infarction (MI) and non-fatal ischaemic stroke and target vessel revascularisation. 41.7% of the overall study population had SVD. The SVD group had higher Euro, SYNTAX, and residual SYNTAX scores, and longer stent length, and higher rates of diabetes, hypertension, and triple vessel disease, compared to No-SVD group. SVD group had mean 1.6±0.9 SVD lesions, and only 13.4% of these lesions was treated. Untreated SVD constituted 53% of residual SYNTAX score. During a median 33 months, MACCE occurred in 68 patients (20.0%); 25 (17.6%) in the SVD group and 43 (21.7%) in the No-SVD group (P=0.314 by log-rank test). In multivariate analysis, the presence of SVD was not associated with a higher incidence of MACCE (hazard ratio: 0.64, 95% confidence interval: 0.34-1.21).

Conclusions: SVD was found in about 40% of patients who underwent PCI for uLMCAD. It was almost not treated, constituted a substantial portion of the residual SYNTAX score but had no effect on clinical outcomes.



Euro14A-0P135

Impact of coronary ostial lesions for clinical outcomes after PCI

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Aims: It is well known that the right coronary artery ostium (RCA-os) is anatomically different from unprotected left main ostium (ULM-os). However, there is little data regarding the comparison of clinical outcome of percutaneous coronary intervention (PCI) between RCA-os and ULM-os. Therefore, to clarify the difference of impact between each ostial lesion, clinical outcomes following PCI between patients who were treated for RCA-os and those for ULM-os were compared.

Methods and results: Between January 2004 and December 2011, 1021 consecutive patients treated for ostial lesions were included in this analysis. After exclusion of patients treated for both RCA-os and ULM-os, 189 patients with RCA-os and 602 patients with ULM were enrolled. The study endpoints were major adverse cardiac event (MACE) during follow-up period (median follow-up 37.4 months) which were defined as target lesion revascularisation (TLR), all cause death and MI. Furthermore, the composite of MACE were evaluated. TLR for ULM-os was considered as treatments for restenosis of ULM-os itself. Baseline and procedural characteristics were not significantly different between the 2 groups. The occurrence of MACE was significantly higher in the RCA-os than the ULM-os due to the high rate of TLR (p<0.001, HR=6.349, 95% CI 3.980-10.129). In contrast, all cause death was significantly higher in the ULM-os than the RCA-os (p=0.004, HR=5.627, 95% CI 1.748-18.107).

Conclusions: The TLR rate was significantly higher in patients with RCA-os than in those with ULM-os, while all cause mortality was significantly higher in ULM-os compared to RCAos.



Proximal LAD PCI: single-centre long-term outcomes 2003-2013

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Aims: The 2010 ESC guidelines on myocardial revascularisation state that for patients with significant disease in the proximal left anterior descending artery (pLAD), CABG is the preferred revascularisation strategy (class I, evidence Level A) and that PCI is less strongly supported (class IIa, evidence level B). The 2011 ACC/AHA guideline for PCI does not differentiate between modes of revascularisation for isolated pLAD disease. We have analysed all PCI procedures performed at this institution with reference to involvement of the pLAD and long term outcome.

Methods and results: All PCI procedures performed at our institution between January 2003 and January 2013 were analysed. We excluded cases if the index procedure was a primary PCI for STEMI. However, primary PCI for STEMI following an index procedure was included as repeat revascularisation. We present data for 9790 patients undergoing 10,891 PCIs, 64% were for an ACS presentation and 36% for stable angina. Of these, 25% involved the pLAD and 72% non-pLAD disease (non-pLAD), the remainder underwent PCI to the left main stem and were not analysed further. Minimum follow-up was 1 year, median follow-up was 6.2 years and five-year follow-up was available for 5844 (60%). Patients with pLAD versus non-pLAD PCI were of similar age (median age 62 (IQR 54-72) vs. 63 (IQR 56-71)), more likely to be male (73% vs. 71%, p=0.04) but less likely to have diabetes (13.6% vs. 16.6%, p=0.002), pLAD patients were less likely to have had previous MI (18.3% vs. 26.3%, p<0.001), previous PCI (6.1% vs. 9.9%, p<0.001) or previous CABG (1.2% vs. 10.4%, p<0.001). Patients with pLAD disease were more likely to undergo multi vessel PCI (29.4% vs. 18.4%, p<0.001). Use of DES was greater in the pLAD PCI group (77.4% vs. 66.1%, p<0.001). Mortality at 1 year for pLAD vs. non-pLAD PCI was 2.3% vs. 2.1% (p=0.67) and mortality at 5 years was 9.5% vs. 12.0% (p=0.02). The rates of repeat revascularisation at any time were 8.9% for pLAD and 9.6% for non-pLAD (p=0.41). However, the rate of target vessel revascularisation was lower in the pLAD patients (4.4% vs. 5.8%, p<0.001). There were similar rates of subsequent CABG in both groups (2.3% in pLAD vs. 2.7% in non-pLAD, p=0.24). These comparisons were similar in the ACS and stable angina groups. In patients with diabetes the rates of repeat revascularisation (pLAD 9.4% and non-pLAD 10.2%, p=0.68) and target vessel revascularisation (pLAD 4.8% and non-pLAD 6.0%, p=0.44) were not significantly different. This was not a randomised comparison of PCI vs. CABG for pLAD and represents real world outcomes. Data for repeat revascularisation comes from patients who returned to this unit and exclude those who may have attended a different centre. Local geography means that this should be a small

Conclusions: Our data suggest that the long term results for PCI to the pLAD are at least as good as the results for non-pLAD PCI, even in patients with diabetes. The rates of repeat revascularisation by PCI or CABG are markedly lower than in studies cited in the 2010 ESC revascularisation guideline which were mainly based on PCI by balloon angioplasty. The ESC guidelines are not based on contemporary outcomes of PCI for pLAD disease.



Euro14A-0P137

Outcomes by day and night for patients bypassing the emergency department presenting with STEMI identified with a pre-hospital electrocardiogram

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Aims: Pre-hospital EKG at the point of first medical contact (FMC) and subsequent emergency department (ED) bypass direct to the catheter laboratory is one mechanism of optimising reperfusion times for patients with ST-segment elevation myocardial infarction (STEMI). Questions remain over the feasibility and safety of this approach, especially during off hours. To determine if the time of day in relationship to standard working hours is associated with differences in in-hospital and 30 day mortality and key reperfusion times in patients identified with STEMI at the point of FMC, bypassing ED, undergoing PPCI for STEMI.

Methods and results: We included 720 consecutive patients who had presented with STEMI triaged directly from the field to the catheter laboratory between June 2004 and May 2013. This represented 27% of our total STEMI cohort during this time. Vital status was reported as of August 2013. The mean age was 65±14 years, and 75.1% were male. 459 cases occurred in hours and 261 during off hours. Both groups were well matched. Overall mortality in hospital and at 30 days did not significant differ for patients being triaged in hours, versus off hours (3.4% in hours and 3.1% off hours; p=N/S). Symptom onset-to-arrival to the heart attack did not significantly differ for patients during off hours (100 minutes off hours (IQR 78-174) vs. 110 minutes in hours (IQR 75-199), p=N/S). Call-to-balloon time was not significant affected by the time of presentation: 150 minutes in hours (IQR 111-239) and 154 minutes during off hours (IQR 115-225) p=N/S. Overall door-to- balloon time was 36 minutes (IQR 25-51), 34 minutes during in hours IQR 24-49) and 40 minutes during off hours (IQR 29-55) p=N/S. The overall false positive rate was only 13.1%, with no significant difference in hours vs. off hours (12.2% vs. 14.6%, respectively, p=N/S).

Conclusions: In a unit with an established field triage system facilitating ED bypass, reperfusion times and mortality are not significantly influenced by whether the patient presents during standard working hours, or outside of these hours.



Exclusive primary PCI without thrombolysis for patients transferred from centres without interventional capabilities

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Aims: Studies have demonstrated a benefit of primary percutaneous coronary intervention (PPCI) over thrombolysis in treatment of ST-elevation myocardial infarction (STEMI). However, in clinical practice patients presenting to non-interventional centres often receive thrombolysis prior to transfer for PPCI ('drip and ship'). This study aimed to compare outcomes in patients transferred from non-interventional centres, to patients presenting directly to an interventional-capable centre, when a systematic protocol of PPCI-for-all was undertaken within a large health care service.

Methods and results: Consecutive STEMI patients (n=2,498) who either presented directly to a single interventional-capable centre (Control Group, n=1330) or were transferred to the same centre for PPCI (Transfer Group, n=1.168) were prospectively recruited. The interventional centre serviced a population of 1.8 million with patients transferred from 7 peripheral centres (ranging 12-34 kilometres from interventional centre) and 2 remote centres (located 117 and 189 kilometres from interventional centre). Thrombolysis was used only at remote centres in patients presenting within 3 hours of symptom onset (n=43, excluded from analysis). Patients were followed at 30 days, then 6 monthly intervals for 2 years. The primary endpoint was one-year total mortality. Secondary endpoints included door-to-balloon time (door of 1st centre patient presented to), thrombolysis in myocardial infarction flow (TIMI) III flow score post-PCI, in-patient left ventricular ejection fraction (LVEF), 30-day total mortality, non-fatal repeat MI and target vessel revascularisation (TVR). Baseline age, gender and medical co-morbidities were similar between the Transfer and Control groups. Medium symptom-to-door time was 95 [interquartile range (IQR) 53-170] and 91 (IQR 60-161) minutes in the Transfer and Control groups, respectively (P=0.760) with 77% in both groups presenting within 3 hours of symptom onset. Median door-to-balloon time was 143 minutes (IQR 119-192) and 90 minutes (IQR 65-122) in the Transfer and Control groups, respectively (P<0.001). TIMI III flow was achieved in 95% and 94% of Transfer and Control patients, respectively (P=0.248). Aspirin and clopidogrel/prasugrel was given in 95% and 88% of patients, respectively. Aboximab was used in 77% of patients and Tirofiban in 5%. There was a mean number of 1.2 stents per patient with 47% consisting of drug-eluting stents. Kaplan-Meier one-year total mortality was 8.3±0.9% and 11.0±0.9% in the Transfer and Control group, respectively (P=0.073), Mortality at 30 days was 3±0.5% and 4.5±0.6 in the Transfer and Control group, respectively. Early LVEF was 48±12% and 49±12% in the Transfer and Control groups, respectively (P=0.217). Non-fatal repeat MI and TVR occurred in 3.9% and 4.2% (P=0.366) and 4.9% and 5.6% (P=0.232) of Transfer and Control patients, respectively.

Conclusions: A systematic management protocol of transfer with PPCI for all patients who present to non-interventional capable centres results in total mortality comparable to patients who present directly to an interventional-capable centre. Despite longer delays to reperfusion in patients transferred from peripheral centres (likely a reflection of the large geographical area), this was not found to increase total mortality, post-PCI TIMI flow, early LVEF, repeat MI or TVR.



Euro14A-0P139

The impact of haemoglobin reduction on short- and long-term mortality following primary PCI for STEMI: analysis from a real-world STEMI population

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Aims: Mortality following ST-elevation myocardial infarction has declined significantly with the advent of primary PCI (PPCI). Concurrent use of antiplatelet agents has further decreased complication rates and mortality; however, these agents confer an increased bleeding risk, an independent risk factor for mortality. This retrospective study assesses the effect of blood loss on short- and long-term mortality and its association with clinical characteristics in a real world population of patients undergoing primary PCI at a tertiary referral centre in the United Kingdom.

Methods and results: All patients accepted for PPCI between September 2009 and November 2011 were eligible for inclusion in the study. Patient data were obtained from our Cardiac Services Database System (Phillips CVIS) and mortality data were gathered from the Summary Care Record (SCR) database. Statistical comparisons of continuous variables were made by one-way ANOVA. Categorical variables were compared using the chi-squared test. A P value of <0.05 was considered statistically significant. 1,403 patients with recorded admission and discharge haemoglobin levels were included in this retrospective analysis. Patients were stratified into three groups based on haemoglobin reduction values. Baseline and procedural characteristics and clinical outcomes were compared according to the degree of haemoglobin reduction. 374 (26.7%) patients had no change in haemoglobin (group 1), 517 (36.8%) had mild reduction in haemoglobin between 0.1-1 g/dl (group 2), and 512 (36.5%) had significant haemoglobin reduction of >1 g/dl (group 3). Patients with a reduction in haemoglobin were more likely to be female (p-value=0.021), older ((mean age±SD 67.5±13 (p-value <0.0001)) and have prior history of myocardial infarction ((n=51 (10%) (p-value=0.031)). Patients with a significant reduction in haemoglobin were more likely to have received abciximab. Rates of abxicimab use were 30.5% (n=114), 31.1% (n=161) and 40.6% (n=208) in group 1, 2 and 3 respectively) (p=0.0001). Radial access was used in 113 (30.2%) patients, 147 (28.4%) patients and 130 (25.4%) patients in group 1,2 and 3 respectively and there was no significant difference in the reduction in haemoglobin between these 3 groups (p-value=0.263). Most importantly, thirty-day mortality was significantly higher in the group with a haemoglobin reduction of >1 g/dl (n=42, 8.2 (%)) compared to the patients with mild reduction in haemoglobin between 0.1-1 g/dl (n=12, (2.3%)) and in patients who had no change in haemoglobin (n=15, (4%)) (p-value <0.0001). The overall mortality was significantly higher in the group with a haemoglobin reduction of >1 g/dl (n=79, (15.4%)) compared to those with a mild reduction in haemoglobin between 0.1-1 g/dl (n=46, (8.9%)) and in patients who had no change in haemoglobin (n=36, (9.6%)) (p=0.0019) (hazard ratio=1.8, 95%) CI 1.2-2.5) during a mean follow-up period of 2.1 years.

Conclusions: Our retrospective analysis in a large cohort of patients confirms recent data suggesting an adverse association between a reduction in haemoglobin following PPCI and long-term mortality. Further work is required on strategies to reduce bleeding risk and hence improve clinical outcome following primary PCI.



Minimalist immediate mechanical intervention for STEMI in daily practice: a single-centre experience

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Aims: Despite considerable progress in recent years, stent implantation during STEMI could be associated with coronary emboli or microvascular obstruction, due to the highly thrombotic environment. Moreover PCI during STEMI remains a major risk factor for inadequate stent deployment or undersizing, which can favour stent thrombosis and subsequent target vessel revascularisation. The Minimalist immediate mechanical intervention (MIMI) strategy aims to restore normal anterograde flow in the culprit artery after manual thrombectomy, more or less associated with balloon angioplasty, and to defer potential stent implantation after a few days of optimal antithrombotic therapy. The goal of the present study was to assess the applicability of this strategy and its impact on treatment modalities of STEMI in daily practice.

Methods and results: All consecutive patients admitted for acute STEMI in our institution between June 2010 and June 2013 were included in this observational registry. All patients underwent first a deocclusion of the culprit lesion if needed (manual thrombectomy and/or balloon predilation, under double antiplatelet therapy + heparin) in order to restore antegrade flow in the culprit vessel The MIMI strategy was considered in case of obtaining an optimal reperfusion, that was defined by angiographic TIMI grade flow >2 in culprit artery + regression of ST segment elevation >50% + cessation of pain. Patients who benefited from the MIMI option underwent a secondary angiographic control after a few days of optimal antithrombotic therapy with adjunctive angioplasty and stent implantation if needed. The other patients were included in the control/standard therapy group. Clinical, biological and angiographic characteristics were compared between groups. Clinical follow-up data were subsequently collected after hospital discharge A total of 279 patients were retained in the analysis of which 20% (N=56) benefited from the MIMI strategy I. The patients were significantly younger (57.9±2 versus 63.1±1 years, p=0.02), more frequently male and smoker in the MIMI group compared to the others. After deocclusion, the TIMI grade flow was higher (2.91±0.04 vs. 2.42±0.06, p<0.001) and the culprit lesion residual stenosis less severe (56.6±2.8% versus 67.8±1.5%, p=0.001) in the MIMI group compared to the standard group. The average delay between the two procedures was 4.3±3.2 days in the MIMI group. A significant thrombus burden reduction was observed in these patients after optimal antithrombotic therapy. The mode of revascularisation significantly differed between the 2 groups: the use of drug-eluting stent was more frequent in the MIMI group than in the standard group (52% vs. 28.5%, p<0.001). Moreover, 28.5% of the MIMI patients did not receive any stent on the culprit lesion (vs 9% in the standard group, p<0.001). Patients from the MIMI group had a favourable outcome after discharge: the actuarial survival from major adverse cardiovascular events (death+ stent thrombosis+ recurrent myocardial infarction+ target vessel revascularisation) was 96.3% at 12 months. **Conclusions:** The MIMI strategy seems safe and applicable in some selected STEMI patients. This option decreases the use of systematic culprit

Coronary interventions

Euro14A-0P141

Pressure-controlled intermittent coronary sinus occlusion in acute STEMI: promising preliminary results of the Prepare-RAMSES trial

lesion stenting and was associated with a low rate of major adverse cardiovascular events.

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Aims: Pressure-controlled intermittent coronary sinus occlusion (PICSO®) aims at improving microvascular reperfusion after primary PCI (pPCI) for STEMI, potentially augmenting infarct size reduction. Prepare-RAMSES was a non-randomised safety and feasibility study of PICSO in STEMI patients, concomitantly exploring its effects on myocardial function and infarct size (IS) by cardiovascular magnetic resonance (CMR).

Methods and results: We included patients who underwent successful pPCI of a left anterior descending coronary artery culprit lesion for a first STEMI. A PICSO Impulse catheter (Miracor Medical Systems, Vienna, Austria) was placed in the coronary sinus through a femoral vein approach, and PICSO was provided for 90 minutes. PICSO quantity was defined as the sum of the coronary sinus pressure modulation for all PICSO cycles. To evaluate PICSO efficacy, patients were divided into a low and high PICSO quantity group. CMR was performed at 2-5 days after pPCI and at 4-month follow-up to measure left ventricular (LV) volumes, left ventricular ejection fraction (LVEF), and IS. For exploratory CMR analyses, historical control patients were matched on age, BMI, culprit lesion location, ST-segment deviation, symptom-to-balloon time, and days to CMR. A total of 30 patients were enrolled in the trial. PICSO could be initiated in 19 patients (63%). No device-related serious adverse events were reported. Paired CMR data was available in 13 patients for myocardial function, and in 11 patients for IS analyses. Baseline LVEF was 45.6±8.9% and 43.7±5.9% for PICSO and control patients, respectively (p=0.53), and improved over time with 5.9±13.4%, and 7.4±9.7% (p=0.75). Baseline LV volumes and change in LV volumes over time were also similar between groups. IS at baseline was 21.9±9.8% of the LV in the PICSO group, and 23.2±9.5% in the control group (p=0.75). There was a 30.4±15.5% reduction in IS from baseline to follow-up in the PICSO group, compared to 25.7±9.4% in the control group (p=0.41). No difference in baseline IS existed between patients in the high and low PICSO quantity group (22.0±7.9% vs. 21.8±12.0%, respectively; p=0.97). Interestingly, IS reduction from baseline to follow-up was significantly higher for patients with high PICSO quantity (41.6±8.2%) compared to those with low PICSO quantity (21.1±14.1%; p=0.019). Moreover, while there was no difference in baseline IS between the high PICSO quantity patients and their matched controls (22.0±7.9% vs. 20.1±8.3%, respectively; p=0.71), there was a significantly higher IS reduction in the PICSO group compared with the control group (41.6±8.2% vs. 27.7±9.9%, respectively; p=0.043). The low PICSO quantity group demonstrated similar IS at baseline compared to the matched control group (21.8±12.0% vs. 25.9±10.3%, respectively; p=0.55), and similar IS reduction over time (21.1±14.1% vs. 24.1±9.6%, respectively p=0.67).

Conclusions: PICSO is safe in the setting of STEMI, although feasibility of the technique is subject to technical improvements. Exploratory analyses suggest that the effect of PICSO on infarct size reduction depends on the provided PICSO quantity, and that PICSO may augment infarct size reduction after pPCI for STEMI when the quantity of PICSO provided is sufficient.



Abbreviated versus standard eptifibatide infusion in ST-elevation myocardial infarction: outcomes and predictors of complications

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Aims: To determine the safety and bleeding outcomes of abbreviated compared to standard infusions of the glycoprotein IIb/IIIa inhibitor eptifibatide in the setting of primary PCI for STEMI.

Methods and results: We analysed a retrospective cohort of 93 STEMI patients who received abbreviated (<18 hours) infusion of eptifibatide and compared them to 91 STEMI patients with standard (18 hours) infusion in primary PCI, from June 2009 to June 2011, at a single cardiac centre. Detailed chart review of demographic and clinical characteristics, times to intervention, complications, electrocardiographic (ECG) findings, bleeding, ejection fraction (EF), and stent thrombosis data was performed. Descriptive statistics were utilised to outline safety and efficacy outcomes. A p- value <0.05 was considered significant. There was no significant difference between the two groups in complications including GI bleeding, hematoma larger than 5 cm, fistula or pseudo-aneurysm, retroperitoneal haemorrhage (RPH) or haemoglobin drop more than 50 g/L. Closure devices were deployed more in abbreviated infusion (65% vs. 44%, p-value: 0.004). There was a trend towards improved ST elevation resolution >50% in standard infusion (78% vs. 66%, p-value: 0.06) and CK peaked higher in abbreviated infusion (2088.9±1982 vs. 1565±1545, p-value; 0.05). There was no significant difference in stent thrombosis or EF (47.25%±9.46 vs. 49.4%±9.2 for abbreviated and standard infusion respectively, p-value: 0.12). There was no significant difference in transfusion (3% vs. 5% for abbreviated and standard infusion respectively, p-value: 0.44) or death (3.2% vs. 1.1% for abbreviated and standard infusion respectively, p-value: 0.37).

Conclusions: Abbreviated duration glycoprotein IIb/IIIa inhibition may be a safe and novel alternative to standard infusion during STEMI. Although there was no significant difference in bleeding or vascular complications between abbreviated and standard infusion groups, along with a trend towards better ST resolution and lower CK in standard infusion group, but there was no significant difference in stent thrombosis, EF or death between the two groups. Further large prospective randomised controlled trials are indicated to study this approach to reduce bleeding in this high risk population.



Euro14A-0P143

Prognostic impact of heparin crossover across the spectrum of NTSE-ACS patients

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Aims: Switching a previously initiated heparin to another in the catheterisation laboratory (heparin crossover, HC) is discouraged in current NSTE-ACS guidelines because of increased bleeding reported in clinical trials. We sought to analyse a real-world population for an impact in mortality and bleeding associated with HC during PCI.

Methods and results: We analysed 889 consecutive patients admitted in a large-volume centre with NSTE-ACS managed invasively who underwent PCI with stent implantation, between 2009 and 2011. Clinical, laboratory, procedural and angiographic variables were retrieved from a prospective registry. HC was defined as any anticoagulant switch prior to or during PCI. Outcomes were defined as mortality at 30-days and a composite of hematocrit drop ≥12% or blood transfusion if hematocrit drop ≥10% was used for bleeding events. Bleeding risk was assessed with the CRUSADE score. Outcomes were compared using Chi-square test and a multivariate logistic regression model was used for independent predictors of 30-day mortality. The majority of patients (709 [80%]) were diagnosed with non-ST segment elevation myocardial infarction (NSTEMI); 89% were in Killip class I and 4.5% (n=40) had atrial fibrillation. Most patients (93%) were loaded with aspirin and clopidogrel, a glycoprotein IIb/IIIa inhibitor was used in only 2.0% of the procedures and transfemoral vascular access was the most widely used (71%; n=635). The prevalence of multivessel coronary artery disease was 62% and a drug-eluting stent was implanted in 71% of the cases. Pre-procedural anticoagulation consisted of enoxaparin in 836 (94%) and non-fractionated heparin in 53 (6%) patients. Thirty-day mortality was 2.1% (n=19) and study defined bleeding rate was 1.1% (haematocrit drop ≥12% occurred in 10 patients and 7 patients received blood transfusions). HC occurred in 678 (77%) patients and was not associated with increased mortality (2.1 [HC group] vs. 2.5% [non-HC group], p=0.782) or bleeding outcomes (0.30 [HC group] vs. 0.60% [non-HC group], p=1.0). In multivariate analysis, only the CRUSADE score (OR 5.17; 95% CI 1.18-22.6) and prior MI (OR 5.40; 95% CI 2.09-13.9) were independent predictors of 30-day mortality.

Conclusions: Despite current guidelines, heparin crossover still occurs in a significant proportion of NSTE-ACS patients undergoing PCI. However, this finding did not translate into increased mortality or bleeding rates.



Routine bivalirudin is superior to unfractionated heparin+bailout GP IIb/IIIa inhibitors in patients with STEMI scheduled for primary PCI: a subgroup analysis of the EuroMAX trial

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Aims: In the HORIZONS trial, in-hospital treatment with bivalirudin reduced bleeding and mortality in primary percutaneous coronary intervention (PCI) compared with heparin and routine glycoprotein IIb/IIIa inhibitors. It is unknown if this advantage of bivalirudin is observed in comparison with heparin only + bailout GP IIb/IIIa inhibitors.

Methods and results: In the EuroMAX study we randomised 2,218 patients with ST-segment elevation myocardial infarction (STEMI) during transport for primary PCI to bivalirudin (with prolonged infusion after PCI) or to heparins (unfractionated or low-molecular-weight heparin) with optional glycoprotein IIb/IIIa inhibitors. Primary and principal secondary outcomes were the composites of death or non–CABG-related major bleeding, and death, reinfarction or non–CABG-related major bleeding, respectively, at 30 days. In this retrospective analysis we compared patients with heparin+routine upstream GP IIb/IIIa (H+RUGP, n= 649) inhibitors versus heparin without routine GP IIb/IIIa inhibitors but with bail-out GP IIb/IIIa inhibitors (H+BOGP, n=460) in 25.4% and routine upstream bivalirudin (RUSBV, n=1089). The 30-day combined rate of death and major bleed were: 7.6% for H+RUGP (P vs. RUSBV=0.034), 9.8% for H+BOGP (P vs. RUSBV=0.0006) and 5.1% for RUSBV. Individual rates of death, major bleed and myocardial infarction were similar between groups.

Conclusions: Routine bivalirudin, started during transport for primary PCI, reduces death and major bleeding compared to patients treated with heparin only + bailout GP IIb/IIIa inhibitors during PCI and as well as patients treated with heparin and routine upstream GP IIb/IIIa inhibitors.



Euro14A-0P145

First-in-man report of twelve-hour continuous intravenous adenosine infusion in STEMI patients undergoing primary PCI: assessment of feasibility and effects on coronary flow reserve

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Aims: Coronary microvascular dysfunction is frequent after STEMI. We investigated the feasibility of a prolonged intravenous (iv) infusion of adenosine post-primary PCI (PPCI) and assessed effect on coronary microcirculation the next day.

Methods and results: We prospectively enrolled 10 STEMI patients after PPCI who received adenosine 70 μg/Kg/min through a peripheral vein for 12 hours after PPCI, and underwent invasive assessment of coronary flow reserve (CFR) on the infarcted-related-artery (IRA) on completion of PPCI and one day later with the pressure wire (Certus, St Jude Medical, St Paul, MN, USA). The adenosine group was then compared with a 1:1 ratio with a well matched historical control group from prior studies in our unit. Groups were matched for age, sex, cardiovascular risk factors, ST-segment elevation on 12 leads ECG pre PPCI, IRA, Killip class, TIMI flow, FFR, IMR and CFR at the time of PPCI, LV ejection fraction at 24 h post-PPCI, and antithrombotic treatment. Ten pateints were recruited. 9 patients underwent invasive assessment of the coronary microcirculation at PPCI. 6 underwent repeat coronary angiography and coronary microcirculation assessment at Day 1. Mean duration of adenosine infusion was 9.5 hours. 7/10 patients tolerated 12 hours infusion of adenosine with a mean systolic blood pressure 130 mmhg, mean diastolic blood pressure 65 mmHg, max heart rate 120 beats/min, min heart rate 45 beats/min. No significant bradycardia or AV block was observed, and no patient required temporary pacing. 3 patients received 3 hours adenosine infusion, due to shortness of breath (SOB) and hypotension. However, hypotension did not recover after stopping adenosine infusion and SOB only slightly reduced. At 24 hours post-PPCI, there was a trend for a smaller enzymatic infarct size (assessed by peak troponin) in the adenosine group [50 (30-50) vs. 60.7 (46.5-189), p=0.07]. After PPCI and at day 1, median (IQR) CFR did not differ between the groups: [1.4(1.1-2) vs. 1.9 (1.4-2.2), p=0.35] and [2.4(2.2-3.8) vs. 2.4(1.5-3.1), p=0.46]. However, there was a significantly higher increase in CFR (CFR day 1-CFR PPCI) in the adenosine group compared with the control group [1.3(0.85-1.97) vs. 0.5(-0.05-0.96), p=0.03].

Conclusions: Prolonged twelve hours of intravenous adenosine infusion is feasible and safe after PPCI and may be associated with a significant improvement in the microcirculation. Further studies are warranted to define the value of this strategy in STEMI treatment.



Long-term outcomes and efficacy of bivalirudin versus heparin in elective percutaneous interventions

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Aims: Bivalirudin has been shown to reduce major bleeding and provide better results in patients undergoing emergency percutaneous coronary interventions (PCI) via transfemoral access as compared to unfractionated heparin (UFH). Currently there are no data regarding the clinical benefits of bivalirudin compared to UFH as an adjunctive therapy in elective PCI.

Methods and results: 127 patients underwent elective PCI after a 300-mg dose of clopidogrel administered at least 2 hours before the procedure. The patients were randomised to bivalirudin and a transfemoral access (n=65) or to UFH and a transradial access (n=62). The groups were comparable regarding the age (60.7±6.5 vs. 58.9±7.1, respectively, p=0.199), incidence of diabetes mellitus (15,3% vs. 14,5% respectively, p=0.967), arterial hypertension (97,1% vs. 93,5%, respectively, p=1.0) and baseline bleeding risk according to the Mehran's score (14±7 vs. 13±6, respectively, p=0.451). The cases of all deaths, myocardial infarctions (MI), urgent target-vessel revascularisations (TVR) due to myocardial ischaemia and MACE (the total of all death, MI, TVR and major bleeding cases) within 30 days and 1 years after the randomisation or major bleedings during the index hospitalisation were reviewed. At 30 days the bivalirudin group (only transfemoral access during PCI, n=65) and the UFH group (only transradial access during PCI, n=62) did not differ in the incidence of death (no cases in both groups), TVR (1.5% vs. 1.6%, respectively, p=0.998), MI (3.1% vs. 1.6%, respectively, p=0.899), major bleedings during the hospital stay (4.6% vs. 3.2%, respectively, p=0.899) and MACE (4.6% vs. 3.2%, respectively, p=0.675). One year outcomes in bivalirudin group and UFH group did not differ in the incidence of death (0% vs. 1.6%, respectively, p=0.946), MI (7.7% vs. 6.5%, respectively, p=0.656), TVR (7.7% vs. 4.8%, respectively, p=0.785), MACE (15.3% vs. 11.3%, respectively, p=0.677).

Conclusions: Transradial PCI with UFH has the same incidence of adverse events at 30 days and 1 year as transferoral PCI with bivalirudin for elective patients.



Euro14A-0P147

Clinical outcome of patients with multivessel disease and moderate to severe aortic stenosis undergoing PCI

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Aims: In patients with multivessel disease (MVD) and moderate to severe aortic stenosis (AS), guidelines recommend aortic valve replacement (AVR) with coronary artery bypass graft surgery (CABG). Yet, this treatment strategy is not always feasible in patients with advanced age and comorbidities, favouring a less aggressive approach. We aimed at investigating the clinical outcome of patients with MVD plus AS initially treated with percutaneous coronary intervention (PCI) followed by provisional AVR

Methods and results: Out of 306 patients with MVD plus moderate to severe AS included, 163 (53%) were treated with CABG plus AVR (Gr 1), 42 (14%) with PCI (Gr 2), 101 (33%) conservatively (Gr 3). Clinical characteristics were similar among the 3 groups, with the exception of age (Gr 1, 73±8 vs. Gr. 2, 76±12 vs. Gr 3, 79±9 years, p=0.001) and previous CABG (Gr 1, 5 [3%] vs. Gr. 2, 8 [19%] vs. Gr 3, 29 [29%], p<0.001). Left ventricular ejection fraction (Gr 1, 68±16% vs. Gr 2, 66±17% vs. 65±18%, p=0.432) and number of vessel disease (Gr 1, 2.3±1.0 vs. Gr 2, 2.3±1.0 vs. 2.0±1.0, p=0.1) was similar among the 3 groups. At a median follow-up of 52 months, overall death was significantly increased along the 3 groups (Gr 1, 17 [10%] vs. Gr. 2, 10 [28%] vs. Gr 3, 31 [31%], Log-Rank: 21.04, p<0.0001). At Cox-regression analysis adjusted for age and previous-CABG, a significantly increased risk of death was observed both in Gr 2 (HR: 3.74 [1.61;8.70], p=0.002) and Gr 3 (HR: 1.70 [1.23;2.36], p=0.001) compared to Gr 1. Of note, 19 (45%) patients of Gr 2 underwent AVR at the follow-up, and 5 (5%) patients of Gr 3 underwent transcatheter AVR (TAVR).

Conclusions: Patients with combined MVD and AS treated with PCI followed by provisional AVR remain at increased mortality risk, which is even higher to that of patients managed conservatively.



Isolated left anterior descending artery in-stent restenosis: comparison between treatment with PCI-DES and CABG with left internal mammary artery

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Aims: The treatment of isolated In-stent restenosis (ISR) of the left anterior descending artery (LAD) can be performed either with PCI with drugeluting stent (DES) or with surgical bypass with left internal mammary artery (LIMA). So far, no data are available comparing these two revascularisation techniques in this particular clinical context. We compared clinical outcomes (MACCE: Major Adverse Cardiac Cerebrovascular Events) and procedure related complications of PCI with DES (DES group) to surgery with LIMA (CABG group) for the treatment of patients with isolated LAD-ISR.

Methods and results: We enrolled 141 consecutive patients with isolated LAD-ISR: 70 patients in PCI group and 71 in CABG group. Continuous and categorical data were compared with t-Student and X2-test, respectively. Kaplan-Meier method was used for comparisons during follow-up whereas Cox regression analysis to assess predictors of new revascularisations. The two groups were well-matched for main clinical characteristics. DES-ISR was present in 79% and BMS-ISR in 21% of cases in the PCI group, while DES ISR was found in 21% and BMS ISR in 79% in the CABG group,(p<0.001). A three-year clinical follow-up was achieved in>90% in both groups. MACCE were observed in 22.8% of patients in PCI group and 30.9% in CABG group (log-rank p=0.38). Target-vessel revascularisation (TLR) was observed in 8.5% patients in the PCI group whereas LIMA failure in 8.4% in the CABG group (P=0.9). Non-TVR revascularisations occurred in 8.6% and 14.1% of patients in the PCI and CABG group, respectively (p=0.22). At multivariable Cox regression analysis, predictors of any revascularisation were chronic renal failure (HR 1.32; 95% CI 1.09-1.51), LDL-cholesterol levels (HR 1.29; 95% CI 1.09-1.51) and HbA1c levels (HR 1.59; 95% CI 1.0-1.90). When compared with PCI group, CABG group was characterised by higher rates of in-hospital complications/need for transfusion (1.4% vs. 28.1%, p<0.0001) and length of hospitalisation (2.1 vs. 5.7 days, p<0.0001).

Conclusions: Isolated LAD ISR may be effectively treated either PCI with DES and CABG with LIMA. However, CABG treatment is characterised by higher rates of in-hospital complications and requires longer hospitalisation.



Euro14A-0P149

Hybrid treatment for aortic stenosis and stable coronary artery disease: minimally invasive sutureless aortic valve replacement and delayed PCI

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Aims: Patients with degenerative aortic valve disease may present with associated coronary artery disease. While minimally invasive aortic valve replacement has been linked to improved surgical outcomes compared with full sternotomy approach, coronary artery disease requiring concomitant coronary artery bypass grafting (CABG) increases the operative mortality. We aimed to analyse the outcomes of hybrid approach (minimally invasive aortic valve replacement and percutaneous coronary intervention (PCI)) in patients with aortic valve stenosis and coronary artery disease. Methods and results: Between March 2011 and November 2013, 310 patients have been treated for degenerative aortic valve disease with Perceval S sutureless aortic valve replacement. Of them, 90 (29%) patients presented coexistent coronary artery disease. In 23 (26%) patients who presented with two- or three-vessel coronary artery disease, CABG and aortic valve replacement have been performed in full sternotomy. In the remaining 67 (74%) patients tailored approach was undertaken. In 3 (4.5%) patients with acute coronary syndrome direct PCI with coronary stent implant was performed before minimally invasive aortic valve replacement (PCI/MIAVR group). In 22 (32.8%) (13 female; mean age 78.6 years) patients with stable coronary plaques and asymptomatic for angina, deferred PCI treatment was programmed (MIAVR/PCI group). For the rest of 42 (62.7%) patients, due to too distal or subcritical coronary lesions, no invasive, but only medical treatment was proposed for coronary artery disease. All patients in the MIAVR/PCI group received sutureless AVR through right anterior minithoracotomy. Mean New York Heart Association functional class was 2.5±0.52. Mean left ventricle ejection fraction was 57% (range 27-65%). Mean transaortic gradient averaged 44 mm Hg. Mean EuroSCORE was 8 and mean Log EuroSCORE was 11.5. Mean cardiopulmonary bypass time was 86.5 min with aortic cross clamping time of 56.1 min. Mean duration of mechanical ventilation was 6.1 h and mean intensive care unit stay was 1.2 day, 1 (4.5%) case of perioperative acute coronary syndrome occurred in a patient with severe left ventricle dysfunction, ischaemic cardiomyopathy and venous coronary grafts occlusion (previous CABG) and it was treated by immediate PCI. No major surgical complications, no mortality occurred in the MIAVR/PCI group. 1 (4.5%) patient with advanced atrioventricular block was treated with pacemaker implant. Mean hospital stay was 7 days. All the 22 patients successfully underwent PCI/stenting following aortic valve replacement (range 6-124 days; mean 42 days).

Conclusions: In patients with severe aortic stenosis associated with clinically stable one-, two- or three-vessel coronary artery disease, suitable for percutaneous treatment, staged hybrid treatment may be an option. Deferred PCI with coronary stenting could be performed safely. This tailored approach allows minimally invasive aortic valve replacement for patients who otherwise should undergo full sternotomy.

PCI versus CABG for left main coronary artery disease in patients with ACS

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Aims: The aim of this study was to compare short and long-term clinical outcome of patients with NSTEMI/STEMI and unprotected left main coronary artery (ULMCA) disease treated with PCI using drug-eluting stents (DES) versus CABG. The current guidelines for treatment of patients with NSTEMI or STEMI and unprotected left main coronary artery disease are not conclusive and refer either to PCI or CABG. Although most cardiologists would favour PCI in the acute setting, only few studies have addressed the accuracy of this decision with respect to short and long-term result.

Methods and results: All patients from the Drug Eluting Stents for Left Main Coronary Artery Disease (DELTA) Registry with NSTEMI (n=318) and STEMI (n=61) were included in this analysis. 272 were treated with PCI and 107 with CABG. A propensity score analysis was performed to adjust for baseline differences in the population. Major adverse cardiac and cerebrovascular events (MACCE) and MACCE components were analysed at 60 and 1000 days after the initial treatment. At 60 days CABG was associated with an increased incidence of overall MACCE (hazard ratio [HR]: 2.25; 95% confidence interval [CI]: 1.05 to 6.1, p=0.04), whereas the components of MACCE such as death (HR: 1.91; 95% CI: 0.76-4.78; p=0.17), myocardial infarction (MI) (HR: 0.67; 95% CI: 0.04 to 10.7; p=0.77), cerebrovascular accidents (HR: 71.3; 95% CI: 0.01 to 6.3×106; p=0.47), as well as TVR (HR: 1.08; 95% CI: 0.07 to 17.2; p=0.96) were not significant different between treatment groups. At 1000 days, overall MACCE (HR: 1.177; 95% CI: 0.69 to 2.02; p=0.55), death (HR: 1.35, 95% CI: 0.68 to 2.67; p=0.4), MI (HR: 0.17; 95% CI: 0.2 to 1.3; p=0.09), cerebrovascular accidents (HR:1.25; 95% CI: 0.25 to 6.2; p=0.79) or TVR (HR: 0.25; 95% CI: 0.03 to 2.1; p=0.2) were not significantly different between the treatment groups.

Conclusions: Patients with ULMCA and acute coronary syndroms showed a clinically comparable long-term outcome between PCI and CABG with an early clinical benefit for PCI.



Euro14A-0P151

Experience with bioresorbable scaffolds in a variety of bifurcation lesions: strategies procedural and 30-day outcomes

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Aims: Experience using bioresorbable scaffolds is increasing however data on their use in bifurcation lesions is limited. Our aim was to evaluate the feasibility and short term safety of the ABSORB bioresorbable scaffold in a variety of bifurcation lesions.

Methods and results: Data from our registry revealed the use of the ABSORB bioresorbable scaffold to treat 10 bifurcation lesions in 10 patients at our centres between May 2013 and December 2013. The mean age was 57. All 10 patients were male and 5 were diabetics. One of the bifurcations involved the left main stem, 6 the left anterior descending artery, 2 the circumflex artery, and 1 the right coronary artery. There were 4 cases with a Medina classification of (1 1 0), 2 with a classification of (0 1 1), and 1 with a classification of (1 1 1), (1 0 1), (1 0 0), or (0 0 1). A two wire approach was used in all cases. The mean scaffold diameter was 2.95 mm. A provisional 1 scaffold strategy was employed in 8 patients. In 3 of these, single sequential balloon inflations to the main and side branch were used for optimisation of the bifurcation. A 2.0 mm compliant balloon was used for the side branch in all of these cases. One of these was then converted to a kissing inflation technique. In 3 cases, kissing balloon inflation was performed. The mean diameter of the side branch balloon in these cases was 2.0 mm. In 3 cases the side branch did not require any balloon inflation. A two scaffold strategy was employed in 1 patient using a T-stenting and protrusion technique. This was optimised by kissing balloon inflation using a 2.5 mm balloon to the side branch. In one patient a bioresorbable scaffold was deployed to the main vessel and a Xience Prime to the side branch using a double-kiss crush strategy. Final kissing inflation was performed with two 2.5 mm balloons, both at 6 atmospheres. The mean post-dilation pressure at the main vessel was 19.4 atmospheres (range 14-24 atmospheres) while the mean post-dilatation pressure at the side branch was 8 atmospheres (range 6-10 atmospheres) for both the sequential single balloon and kissing balloon strategies. OCT was used in the two cases involving two stent strategies. Lesion success occurred in all cases with no significant residual stenosis at the bifurcation in any case. TIMI 3 flow was noted at the end of the procedure in both the main vessel and side branch in all cases. There were no cases of peri-procedural myocardial infarction. There was no death, myocardial infarction, scaffold thrombosis or target lesion revascularisation at 30 days follow-up. Clinical follow-up is ongoing to a minimum of 24 months.

Conclusions: Excellent procedural and short-term clinical outcomes were achieved with bioresorbable scaffolds in a variety of bifurcations. Multiple strategies were used including 2 stent strategies and optimisation by kissing balloon inflation. While further evaluation is necessary, our early experience suggests treatment of bifurcation lesions with the ABSORB bioresorbable scaffold to be feasible and safe.



Expansion of bioresorbable scaffold use to coronary bifurcation lesions

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Aims: The aim of this study was to evaluate short-term clinical outcomes of bioresorbable vascular scaffolds (BVS) implanted in coronary bifurcation

Methods and results: We evaluated 86 consecutive patients (94 bifurcation lesions) treated with BVS for bifurcation lesions between May 2012 and December 2013. Mean age was 62.1 years and 88.4% were male. True bifurcations (Medina 1.1.1/1.0.1/0.1.1) were observed in 60.6%. The majority of bifurcation site was the left anterior descending artery/diagonal branch (72.3%). Seven (8.1%) cases of in-stent restenosis involving bifurcations were present. Intracoronary vascular ultrasound was used in 77.7%. Pre-dilation and post-dilation were performed in 97.9% and 100%, respectively. Initial bifurcation strategies were as follows: provisional single-stenting (n=69) of which T-stenting with small protrusion technique (TAP) (n=5), systematic double-stenting (n=17) and BVS implantation only at side-branch ostium (n=8). Final kissing inflation with small protrusion of a side-branch balloon into main branch (balloon inflation pressure in a side branch ≤8 atm.) was performed in 14.1% (n=9/64) after single-stenting and in 54.5% (n=12/22) after double-stenting or TAP, respectively. Angiographic success was achieved in all but 1 (98.8%) case which was treated with single-stenting with final TIMI flow 2 in the side branch. Furthermore, a BVS was substituted for a drug-eluting stent in 2 cases where BVS could not be delivered to the side-branch across the main-branch BVS. Peri-procedural myocardial infarction (CK-MB >5×) was observed in 8 (9.3%) cases. At median follow-up of 183 days, there were 1 (1.2%) non-cardiac death, 1 (1.2%) target-vessel myocardial infarction in a patient sustaining definite scaffold thrombosis after stopping all anti-platelet therapy at 2 months, 5 (5.8%) target lesion revascularisations, and 6 (7.0%) target vessel revascularisations.

Conclusions: These results suggest that treatment with BVS for coronary bifurcation lesions is associated with acceptable clinical outcomes. Careful final kissing balloon inflation may not cause critical BVS disruptions contributing to adverse clinical events.



Euro14A-0P153

Implantation of Absorb bioresorbable scaffolds using a provisional stenting technique for the treatment of coronary bifurcation lesions

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Aims: Bioresorbable scaffolds (BVS) are being increasingly used for the treatment of complex lesions. In a previous report, BVS use was associated with higher incidence of occlusion of small side branches. We report on the outcome after provisional stenting treatment with BVS for bifurcation

Methods and results: Patients treated in our centre with at least one BVS for bifurcation lesions between Mai 2012 and December 2013 were retrospectively identified. Ostial lesions and lesions treated using double stenting techniques were excluded. A total of 55 bifurcation lesions in 53 patients (age 62±13, 44 males, 12 diabetics) were included in the database. 24 patients had a stable presentation, 4 unstable angina, 15 NSTEMI and 10 STEMI. The lesion involved the left descending coronary artery in 32 cases, the circumflex in 19 cases, and the right coronary in 4. Predilation was performed in all cases. The BVS was successfully implanted in all cases, without need for a second stent. The side branch received additional postdilation in 5 cases. QCA data showed a good result in the stented branch (minimum lumen diameter before stenting: 1.02±0.7 mm; after stenting: 2.43±0.6 mm) without side branch occlusion (minimum lumen diameter before stenting: 1.12±0.6 mm; after stenting: 1.36±0.6 mm). In 7 cases, the diameter of the side branch was <1 mm after BVS implantation in the main branch. There was no case of side branch occlusion. **Conclusions:** Bifurcation lesions can be treated with BVS with a good procedural outcome when a provisional stenting technique is planned;

randomised studies with this and other bifurcation techniques are necessary.

Immediate, mid-term follow-up patency and clinical outcomes of coronary side branches covered by an everolimus-eluting bioresorbable scaffold

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Aims: Limited information is available regarding the fate of the side branches when they are covered by a bioreabsorbable vascular scaffold. The increased strut thickness of the bioreabsorbable vascular scaffold might be associated with a higher incidence of side branch occlusion and, therefore, contribute to the development of periprocedural myocardial infarction. The objectives of our study were to analyse the patency of side branches covered by a bioreabsorbable vascular scaffold, to assess the clinical impact of side branch occlusion and to study the fate of such side branches at follow-up.

Methods and results: One-hundred sixteen patients with 151 lesions involving at least 1 side branch take off treated by bioreabsorbable vascular scaffold were included in this study. Side branches were considered minor when the diameter was less than 1 mm, intermediate when the diameter ranged from 1 to 2 mm and large when the diameter was more than 2 mm. The assessment of side branches patency was carried out by angiography inmediately after bioreabsorbable vascular scaffold implantation. Side branch occlusion was defined as a reduction in TIMI flow to grade 0 or 1. Serial determinations of troponin Iand creatin kinasa were obtained after the procedure and major cardiac events were recorded. A coronary computed tomography angiographywas scheduled for every patient with covered intermediate or large side branches around 6 months after the treatment. We indentified 307 jeopardized side branches originating from the scaffolded segment: 152 (49%) minor, 95 (31%) intermediate and 60 (20%) large side branches. After bioreabsorbable vascular scaffold implantation, occlusion was documented in 24 (8%) side branches; 17(11%) minor and 7 (7%) intermediate, while all side branches bigger than 2 mm remained patent with TIMI flow 2 or 3. Regarding the clinical events, 1 patient presented a non- Q myocardial infarction due to an intermediate side branch occlusion, which was not rescued. No others advers clinical events were registred. At follow-up, the overall cardiac events rate was very low (2.6%). One patient died from definitive bioreabsorbable vascular scaffold thrombosis due to the interruption of the dual antiplatelet therapy and others 2 patients had an in-segment proximal restenosis around 6 months after the procedure. The rest of the patients remain free of symptoms after 12±3 months of clinical follow-up. To date, 43% of intermediate and 83% of large side branches have been reevaluated and all of them remained patent.

Conclusions: Covering side branches with bioreabsorbable vascular scaffold seems a safe procedure, with a very low rate of occlusion and clinical impact when important side branches are jailed. These favourable results are maintained at short and mid term follow-up. However, studies are needed at long term to confirm these findings.



Euro14A-0P155

Biovascular scaffolding of distal left main trunk: experience from the multicentre prospective RAI registry

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Aims: Little is known about biovascular scaffold (BVS) behaviour when implanted in proximal elastic coronary arteries such as the left main trunk (LM). To this day, there is no report on intraprocedural outcome and medium term follow-up on BVS implantation in this segment.

Methods and results: We analysed the outcome of all consecutive patients with distal LM disease involving the bifurcation, treated with single BVS under IVUS guidance and enrolled in the multicentre RAI registry. Patients with moderately or highly calcific lesions were excluded. Nine patients, mean age 61±10 yrs, entered current analysis. Two patients had diabetes and 2 had myocardial infarction as clinicalpresentation, with 7 patients suffering stable or unstable angina pectoris. Average coronary calcification degree was mild and mean percent diameter stenosis 67%. All lesions were predilated with a semicompliant balloon of the same diameter (4 patients) or by 0,5 mm smaller than BVS; all BVS were postdilated with a larger noncompliant balloon (0,5 mm). A single-scaffold strategy was pursued in all patients, and only 1 patient underwent final kissing balloon inflation due to suboptimal result at the ostium of the circumflex artery. At the end of procedure, we observed 1 case of acute recoil and 4 cases of BVS underexpansion (44%), which corresponded to the degree of local calcification. At IVUS analysis, mean area at the proximal segment of LM was 8,1±1,56 mm², whereas it was 7,6±1,63 mm² at the site of bifurcation. All patients were discharged uneventfully. At clinical follow-up (average 6 months) 1 patient had recurrent angina and target lesion revascularisation; IVUS analysis showed late occurring scaffold recoil and no neointimal hyperplasia.

Conclusions: BVS use in distal LM was associated with a high rate of scaffold underexpansion or acute/late scaffold recoil despite aggressive postdilation. An adequately powered study is deemed necessary to understand if this occurrence is associated with further adverse clinical events.



Genotype and platelet function test guided antiplatelet therapy in ACS

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Aims: The present study was designed to assess the effect of genotype and platelet function test guided antiplatelet therapy in patients with acute coronary syndrome (ACS).

Methods and results: Forty-six ACS patients undergoing percutaneous coronary intervention (PCI) were screened with Cytochrome P 450 2C19 *2, *3 loss-of-function polymorphism and platelet function test (clopidogrel), defining high on-treatment platelet reactivity as platelet reaction unit >230. According to genotyping and platelet function test, we decided on antiplatelet agents. Those with homozygous loss-of-function allele and high on-treatment platelet reactivity, we switched clopidogrel over to prasugrel (10 mg/day) (Group 1). And, those with normal genotyping (*1*1) and normal platelet function (platelet reactivity, homozygous loss-of-function allele and high on-treatment platelet reactivity, homozygous loss-of-function allele and normal platelet function, and normal genotyping and high on-treatment platelet reactivity were randomised to prasugrel (10 mg/day) (Group 2) or clopidogrel (75 mg/day) (Group 3). We checked platelet function test again 1 month later. After randomisation, prasugrel was associated with a significantly lower platelet reactivity than clopidogrel (PRU 271±44 to 88±42 versus 196±78 to 163±75; P<0.001). And, there was no high on-treatment platelet reactivity patient in prasugrel group compared to clopidogrel (2/19 to 0/21 versus 8/25 to 5/25; P=0.03). We achieved similar antiplatelet effects in the Group 1 and 4 after 1 month.

Conclusions: Genotype and platelet function test guided anti-platelet therapy is effective in controlling platelet reactivity in patients with ACS. Furthermore, prasugrel showed excellent antiplatelet effects in patients with Cytochrome P 450 2C19 loss-of-function allele or high on-treatment platelet reactivity.



Euro14A-0P157

Increased mean platelet volume is associated with non-responsiveness to clopidogrel

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Aims: Prior studies have demonstrated significant individual variability of platelet response to clopidogrel, which effects clinical outcome. In patients with stable coronary artery disease, smoking, diabetes mellitus, elevated body mass index and renal insufficiency significantly impact response to clopidogrel. The determinants of platelet response to clopidogrel in patients with acute coronary syndrome are unknown.

Methods and results: Adenosine diphosphate induced platelet aggregation, hs C-reactive protein, platelet count and mean platelet volume were determined 72 hours post clopidogrel loading in 276 consecutiveacute myocardial infarction patients. Patients with adenosine diphosphate platelet aggregation ≥70% were considered to be clopidogrel non-responders. Eighty-four patients (30%) were clopidogrel non-responders and 192 (70%) were responders (Adenosine diphosphate induced platelet aggregation: 81±17% vs. 49±17% respectively, p<0.001). Both study groups were comparable with respect to age, gender, prior cardiovascular history, prior aspirin use and risk factors for coronary artery disease, including smoking (42% for both groups) and diabetes mellitus (26% vs. 22%, respectively, p=0.4). Responders and non-responders had similar angiographic characteristics, indices of infarct size, and similar hs-C reactive protein (29±34 vs. 28±34 mg/l, p=0.7) and creatinine (1.08±0.4 mg % vs. 1.07±0.4, p=0.9) levels. On the contrary non-responders had significantly larger mean platelet volume (9±1.2 fl vs. 8±1 fl respectively, p=0.0018), and when patients were stratified into quartiles based on mean platelet volume, Adenosine diphosphate induced platelet aggregation increased gradually and significantly across the quartiles of mean platelet volume (p<0.001).

Conclusions: Increased mean platelet volume associated with platelet activation, predicts non-responsiveness to clopidogrel among patients with acute coronary syndrome.



Safety of protamine sulphate administration following PCI

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Aims: Protamine sulphate reverses unfractionated heparin (UFH) action and is used in various clinical scenarios. Vascular access site complications following transfemoral percutaneuous coronary interventions (PCIs) contribute to procedure-related morbidity and mortality. Long sheathindwelling time is a risk factor for their occurrence. Protamine given after successful PCI is controversial due to presumed increased risk of in-stent thrombosis (IST) and is not used routinely. The benefits of rapid reversal of UFH action include early sheath removal, which could minimise the risk of local complications and shorten immobilisation time. Femoral closure devices add cost and have their own contraindications and complications. The aim of our study was to determine the safety of protamine given to neutralise UFH following successful transfermoral PCIs in

Methods and results: We studied 815 PCI patients who underwent coronary stent implantation via transfermoral or transradial route depending on operator's decision. Patients with IABP or if PCI duration >1 hr were not included. All patients received an intravenous bolus of UFH 5000 IU before PCI. Transfemoral PCIs patients were given an intravenous infusion of protamine (25 mg over 15 minutes) at the end of the procedure (protamine group). This group was compared with transradial PCI patients who did not receive protamine (control group). We assessed the incidence of acute IST (within 24 hours). Protamine group comprised 402 patients (53% males, age 68±11) and control group: 413 patients (68% males, age 66±10), otherwise similar in baseline characteristics. Indications for PCI in protamine group vs. control group: 61 (15.2%) vs. 47 (11.4%) STEMI, 180 (44.8%) vs. 203 (49.1%) NSTEACS and 161 (40%) vs. 163 (39.5%) stable angina (all p=ns). Stents used: 37.6% vs. 36.3% DES, 62.4% vs. 63.7% BMS, respectively (p=ns). Intracoronary bolus of abciximab 20 mg was used as an additional antiplatelet agent in 34 (56%) of STEMI cases in protamine group and 32 (68%) in controls (p=ns). All femoral and radial sheaths were removed immediately following PCI. Patients could mobilise 4-6 hours following femoral sheath removal. One patient developed angioedema after protamine administration with no long-term sequelae. There was no difference in the rate of acute IST - one case in each group.

Conclusions: 1. Reversal of unfractionated heparin action immediately after PCI with protamine sulphate does not increase the risk of acute IST. 2. It is an easy, cheap and safe method which enables prompt femoral sheath removal and could therefore reduce immobility time and patient discomfort.



Euro14A-0P159

Perioperative cardiac risk following minor surgery under discontinuation of all antiplatelet therapy in patients with prior DES implantation

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Aims: To investigate perioperative cardiac risk following minor surgery with discontinuation of all antiplatelet therapy in patients with prior DES

Methods and results: Among 1226 patients treated with DES, 111 minor surgical procedures were performed with cessation of all antiplatelet therapy. We investigated perioperative occurrence of major adverse cardiac events (MACE) defined as a composite of cardiac death, myocardial infarction and stent thrombosis. The mean interval from DES implantation to surgical procedure was 674±393 days (28 procedures within 1 year, 40 from 1 to 2 years, and 43 beyond 2 years). Three cases developed MACE (1 myocardial infarction: 280 days; and 2 stent thrombosis: 405, 930 days) in the perioperative period (3/111, 2.7%).

Conclusions: These results suggested that the perioperative cardiac risk following minor surgery with discontinuation of antiplatelet therapy was not negligible and an adverse cardiac event could occur even over a chronic time period after DES implantation. Our data would support the recommendation against discontinuation of antiplatelet therapy for minor surgery after DES implantation.



Impact of obesity and the metabolic syndrome on response to Clopidogrel or Prasugrel and bleeding risk in patients treated after coronary stenting

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Aims: This study aimed to analyse the impact of body mass index (BMI) and the metabolic syndrome (MS) on responses to clopidogrel or prasugrel and bleeding risk after ACS.

Methods and results: 1542 consecutive patients undergoing coronary stenting were included (287 clopidogrel 75 mg, 868 clopidogrel 150 mg, and 387 prasugrel 10 mg). Platelet reactivity was assessed 1 month after discharge using PRI VASP. 336 (21.8%) patients were obese (BMI ≥30 kg/m²) and we observed higher platelet reactivity associated with higher BMI across thienopyridine regimens. Incidence of high on-treatment platelet reactivity (HTPR) (PRI VASP >50%) was higher in obese than non-obese patients (p<0.05 for all regimens). Conversely, incidence of low ontreatment platelet reactivity (LTPR) with prasugrel therapy (PRI VASP <20%) was lower in obese than non-obese patients: 13% (12/93) vs. 33% (97/294); OR [95% CI]: 0.30 [0.16-0.58]; p<0.001. Accordingly, incidence of BARC bleeding complications was higher in non-obese than in obese patients: 10% (119/1206) vs. 6% (20/336); OR [95% CI]: 1.7 [1.1-2.8]; p=0.03. This impaired response was only observed in obese patients with the MS while obese with the MS had significantly higher platelet reactivity than other obese patients with all regimens (p<0.01). Obese without the MS had no significant difference of platelet reactivity compared with non obese patients.

Conclusions: In conclusion, the present study confirmed that BMI has a strong impact on response to clopidogrel and prasugrel with higher HTPR incidence, lower LTPR incidence and lower bleeding complication in obese patients. However, among obese patients, the presence of the MS strongly affects response to antiplatelet agents, indicating that the metabolic status might be a better predictor of platelet inhibition than BMI.



Euro14A-0P161

Morphine is associated with a delayed activity of oral antiplatelet agents in patients with STEMI undergoing primary PCI

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Aims: Analgesia with morphine is recommended in patients with ST-segment elevation myocardial infarction (STEMI), including those undergoing primary percutaneous coronary intervention (PPCI). Suboptimal antiplatelet effect during and after PPCI is associated with increased thrombotic complications including stent thrombosis. A potential drug-drug interaction between morphine and oral antiplatelet agents has been hypothesised. This study sought to assess platelet inhibition after a loading dose of the currently recommended antiplatelet agents in STEMI patients, prasugrel and ticagrelor, according to morphine use.

Methods and results: Three-hundred STEMI patients undergoing PPCI receiving either prasugrel (n=95) or ticagrelor (n=205) loading doses had residual platelet reactivity assessed by VerifyNow 1, 2, 4, and 8 hours after loading dose. Patients treated with morphine (n=95, 32%) had a higher incidence of vomit (15% vs. 2%; p=0.001). P2Y12 Reactivity Units (PRU) 2 hours after the loading dose (study primary end-point) was 217 (101-274) and 107 (30-226) in patient with and without morphine (p<0.0001); the difference between the 2 study groups persisted after excluding patients with vomit (p<0.001). The PRU differences was still present at 4 hours (p=0.029) but disappeared at 8 hours (p=0.726). High residual platelet reactivity (PRU \geq 240) at 2 hours was found in 45% and 22% patients with and without morphine (p<0.0001) and did not differed between prasugrel and ticagrelor patients. The independent predictors of high residual platelet reactivity at 2 hours were morphine use (OR 2.91 [1.71-4.97], p<0.0001) and age (OR 1.03 [1.01-1.05], p=0.010). Morphine remained significantly associated with high residual platelet reactivity after propensity score adjustment (C statistic, 0.68; 95% CI, 0.66-0.70; p=0.879 for Hosmer-Lemeshow test).

Conclusions: In patients with STEMI, morphine use is associated with a delayed onset of action of the oral antiplatelet agents. This association persisted after adjusting for the propensity to receive morphine and after excluding patients with vomit. The effect was consistent in prasugrel and ticagrelor patients. A restricted morphine use in STEMI patients seems to be recommended.



Furn14A-0P162

Residual stenosis of side branch and long-term clinical outcomes in coronary bifurcation lesions treated with one-stent technique: results from the COBIS (coronary bifurcation stenting) II registry

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Aims: This study sought to investigate the association between residual stenosis of the side branch (SB) ostium and long-term clinical outcomes in coronary bifurcation lesions treated with 1-stent technique.

Methods and results: 2,897 consecutive patients undergoing percutaneous coronary intervention using drug-eluting stents for bifurcation lesions with SB ≥2.3 mm were enrolled from 18 centres in Korea between January 2003 and December 2009. Of these, we selected patients treated by 1-stent technique. Patients with final Thrombolysis in Myocardial Infarction flow grade <3 in the SB were excluded. Clinical outcomes were compared between patients with residual stenosis of the SB ostium ≤50% (group I) and those with residual stenosis of the SB ostium <50% (group II). The primary outcome was a composite of cardiac death, myocardial infarction (MI), or target lesion revascularisation (TLR). SB residual stenosis ≥50% was observed in 616 (29.8%) of 2065 bifurcation lesions after the index procedure. With a median of 35 months of follow-up, the primary outcome occurred in 56 patients (9.1%) of the group I and in 107 patients (7.4%) of the group II (adjusted hazard ratio [HR], 1.31; 95% confidence interval [CI], 0.89-1.92; P=0.17). The rates of TLR were not significantly different between the 2 groups (6.7% versus 6.1%; adjusted HR, 1.17; 95% CI, 0.75-1.79; P=0.50). However, cardiac death or MI tended to occur more frequently in the group I than in the group II (3.2% versus 1.9%; adjusted HR, 1.92; 95% CI, 0.94-3.89; P=0.07).

Conclusions: Residual stenosis of the SB ostium is not associated with TLR in bifurcation lesions treated by 1-stent technique. However, its impact on cardiac death or MI needs to be studied in further analysis.



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Long-term clinical outcomes after conservative versus aggressive strategy for provisional side branch intervention in coronary bifurcation lesions

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Aims: The optimal provisional approach for coronary bifurcation lesions has not been established. We compared long-term follow-up results of conservative versus aggressive strategies for provisional side branch (SB) intervention in coronary bifurcation lesions.

Methods and results: A total of 258 patients with a bifurcation lesion were randomised to a conservative or aggressive SB intervention strategy with drug-eluting stents. The criteria for SB intervention after main vessel stenting differed between the conservative and aggressive groups. Left main bifurcation lesion. In the conservative group, SB ballooning followed by kissing ballooning was performed only if there was diameter stenosis >75% in the SB after main vessel (MV) stenting. SB stenting was performed only if there was diameter stenosis >50% or type B or greater dissection in the SB after ballooning. In the aggressive group, SB ballooning followed by kissing ballooning was performed only if there was diameter stenosis >50% in the SB after MV stenting. SB stenting was performed only if there was diameter stenosis >30% or type B or greater dissection in the SB after ballooning. Non-left main bifurcation lesion. In the conservative group, SB ballooning followed by kissing ballooning was performed only if there was Thrombolysis In Myocardial Infarction (TIMI) flow <3 in the SB after MV stenting. SB stenting was performed only if there was TIMI flow <3 in the SB after ballooning. In the aggressive group, SB ballooning followed by kissing ballooning was performed only if there was diameter stenosis >75% in the SB after MV stenting. SB stenting was performed only if there was diameter stenosis >50% in the SB after ballooning. Target vessel failure (TVF) defined as the composite of cardiac death, spontaneous myocardial infarction (MI), or target vessel revascularisation (TVR) was the primary end point. Left main bifurcation lesions were noted in 114 patients (44%) and true bifurcation lesions in 171 patients (66%). The crossover rate to the 2-stent technique was significantly lower in the conservative group than in the aggressive group (7.0%). versus 30.0%, p<0.001). At 3 years, TVF occurred in 11.7% of the conservative group versus 20.8% of the aggressive group (p=0.049). The incidence of cardiac death or MI was significantly lower in the conservative group than in the aggressive group (0.8% versus 6.2%, p=0.036), but there was no significant difference of TVR between the groups (10.9% versus 16.2%, p=0.22). The crossover to the 2-stent technique was independent predictor of TVF (HR 2.95, 95% CI 1.59 to 5.48, p<0.01) and cardiac death or MI (HR 5.28, 95% CI 1.41 to 19.83, p=0.01).

Conclusions: The conservative strategy for provisional SB intervention, compared with the aggressive strategy, provides better long-term clinical outcomes, mainly due to lower crossover rate to the 2-stent technique.



Three-year clinical follow-up of the PYTON (prospective evaluation of the TRYTON side-branch stent with an additional XIENCE-V everolimus-eluting stent in coronary bifurcation lesions) study

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Aims: Dedicated bifurcation stents have been proposed as a potential alternative for treatment of true coronary bifurcation lesions. This study sought to evaluate the healing responses with optical coherence tomography, and angiographic and clinical outcome after bifurcation stenting with the TRYTON Side-Branch stentTM

Methods and results: Twenty consecutive patients with coronary bifurcation lesions and significant involvement of the side-branch (SB) were treated with the TRYTON Stent in the SB and an additional XIENCE-VTM everolimus-eluting stent in the main vessel (MV). At 9 months, the percentage of uncovered struts assessed with OCT, angiographic late luminal loss (LLL), and in-stent and in-segment restenosis, were determined. Clinical follow-up was performed at 1 and 3 years. The clinical endpoints included the rate of major adverse cardiac events (MACE) and their components (all-cause death, myocardial infarction (MI) and ischaemia-driven target lesion revascularisation (TLR), guided by a fractional flow reserve in the MV or the SB of <0.80), target vessel revascularisation (TVR), non-target lesion revascularisations (non-TLR) and stent thrombosis. Clinical follow-up was obtained in all patients (n=20). At 3 years, 6 patients had undergone TVR (30%), of which 4 were TLR (20%). One patient had clinically silent and haemodynamically non-significant restenosis at the ostium of the SB. All 4 cases of haemodynamically significant in-stent restenosis (ISR) occurred in the first year post stenting, with 2 presenting clinically silent (detected at planned angiographic and OCT follow-up at 9 months). In these 4 cases of ISR the proximal MV stent edge was involved with additional involvement of the SB ostium in 2 cases. Three patients suffered an MI (15%), two of which were peri-procedural and without clinical consequences. The third MI was in a patient who developed new Q-waves on the electrocardiogram as well as severe anterior hypokinesia, secondary to a silent sub-occlusive restenosis in the MV. Following revascularisation, the patient's ventricular wall motion abnormalities normalised, with complete resolution of the Q-waves. There was 1 non-cardiac death (5%) 28 months after stent implantation, attributable to progressive interstitial lung disease. There were no stent thromboses. The composite MACE rate at 3 years was 30

Conclusions: In this study with careful clinical and angiographic follow-up, percutaneous coronary revascularisation with TRYTON stents did not meet expectations of contemporary bifurcation lesion treatment. All cardiac events occurred during the first year of follow-up with in-stent restenosis presenting clinically silent in a large proportion of cases. No new cardiac events were seen between 1 and 3 years of follow-up.



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Very long-term effect of bifurcation treatment with a biolimus A9-eluting dedicated stent based on the pooling of the five-year results from two prospective, multicentre trials (DIVERGE and AXXESS PLUS)

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Aims: Although various dedicated bifurcation stents are commercially available, the true clinical advantage between different treatment options remains unclear. Both the DIVERGE and AXXESS PLUS trials aimed to evaluate the safety and efficacy of AxxessTM, a self-expanding dedicated bifurcation Biolimus A9-eluting stent with abluminal biodegradable polymer coating, for the treatment of *de novo* bifurcation lesions in native coronary arteries. We report the patient level pooling of the five-year clinical data from both studies. We investigate the long-term effect of the Axxess stent on the clinical outcomes.

Methods and results: The DIVERGE and AXXESS PLUS studies are both prospective, multicentre, single-arm trials and have similar clinical and angiographic inclusion and exclusion criteria. In order to harmonize the two populations we decided to include only patients having received the conical shaped Axxess stent alone or Axxess with additional Cypher stents. The final sample size is thus 298 patients for the DIVERGE study and 102 patients for the AXXESS PLUS study, for a total sample size of 400 patients. We analysed as well the different treatment options. The main objective was to compare patients with only the main branch stented to patients with both the main branch and side branch stented in order to see if a difference appears when comparing the pooling to the results from other studies evaluating clinical events between simple and complex techniques. As the patient's allocation to one of the two treatments might have been influenced by baseline characteristics, we performed a propensity score analysis to minimise the effect of confounding between treatment assignment and baseline covariates. We looked at a Major Adverse Cardiovascular Events (MACE defined as a composite of any death, Q-Wave or non Q-Wave myocardial infarction (MI), or ischaemia-driven target lesion revascularisation (id-TLR)) and stent thrombosis (ST) at 5 years. We found no statistical significant difference between the two groups in MACE (MB: 14.7% vs. MB+SB: 22.4%, adjusted hazard ratio=1.368 p=0.16) and its components and in definite stent thrombosis (MB: 1.5% vs. MB+SB: 3%, adjusted hazard ratio=1.00, p=0.99). We also compared the time of procedures (expressed in minutes from insertion in the groin to removal of the guiding catheter) between the two groups and found that these are equivalent to the procedure times found when using conventional stenting techniques in bifurcations, despite the fact that thorough lesion preparation is mandatory with self-expanding stents.

Conclusions: The dedicated Axxess self-expanding bifurcation stent has proved to be safe and effective out to 5 years. Moreover it has been shown that utilising the Axxess stent is equivalent in terms of clinical event rates and procedural times to current bifurcation techniques including when sidebranch stenting is involved. We can conclude that the Axxess dedicated bifurcation device can be considered as a simple, safe and effective technique for the treatment of bifurcations. No other dedicated bifurcation stent has clinical data in this large number of patients out to 5 years. The complete analysis will be available at the time of the presentation.

Self-expanding DES in coronary bifurcation lesions at 12-month follow-up: results from the Open II trial and comparison with the British bifurcation coronary trial

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Netherlands; 7. Triemli Hospital, Zurich, Switzerland; 8. Kerckhoff Heart Center, Bad Nauheim, Germany; 9. Gentofte Hospital, Hellerup, Denmark; 10. Klinikum Bognhausen, Munich, Germany; 11. Polyclinique les Fleurs, Ollioules, France; 12. Erasmus Medical Center, Rotterdam, The Netherlands; 13. Stentys, Paris, France; 14. Klinikum Neuperlach, Munich, Germany

Aims: Results of PCI in coronary bifurcation lesions with balloon expandable stents are often impaired by lack of support at carina, strut deformation, malapposition, or excessive metallic burden when treated with 2 stents. The self-expanding STENTYS DES, designed for a provisional approach, has shown high procedural success and low short term major adverse cardiac events rate in the OPEN I study. We assessed the long term efficacy of the STENTYS DES in a real world population, and compared the results at patient level with the landmark British Bifurcation Coronary (BBC) trial.

Methods and results: In the ongoing OPEN II study, 217 patients who received the STENTYS Paclitaxel-eluting stent in routine coronary bifurcation stenosis were enrolled in 21 European centres and are followed up prospectively at 6 and 12 months. Main exclusion criteria include Medina class 0,0,1, chronic total occlusion, unprotected left main, and STEMI. Mean age was 66±11 years, 78% male. Diabetes was present in 30% of patients, previous PCI in 36%, and unstable angina in 39%. 51% of patients had an ejection fraction lower than 55%. Medina class 1,1,1 was found in 36% of the patients. STENTYS DES was implanted successfully in 98% of the patients. Stenting of the side branch was performed in 12% of the procedures. Kissing balloon technique was used in 22% of the procedures. The lesion length was 18±7 mm in main branch, as per QCA, and reference vessel diameters were 3.1 mm (proximally) and 2.3 mm (distally). Revascularisation was successful in 99.5% in the main branch, and 96.7% in the side branch.

Conclusions: The OPEN II study is the largest study assessing the self-expanding STENTYS DES in bifurcation lesions in a routine clinical setting. The rate of adjudicated major adverse cardiac events at 12 months, as well as target vessel failure and the results from the OCT substudy at the initial procedure time point will be presented.



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Comparison of two different drug-eluting balloons in an all-comers cohort of patients with in-stent restenosis

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Aims: No data concerning the comparison of different drug-eluting balloons in an all comers cohort exist. Therefore two different drug-eluting balloons were analysed for the treatment of in-stent-restenosis concerning safety and efficacy for the first time.

Methods and results: In randomised clinical trials, paclitaxel-coated balloon angioplasty was superior to uncoated balloon angioplasty for the treatment of in-stent-restenosis in bare metal stents (BMS) as well as for the treatment of in-stent-restenosis in drug-eluting stents (DES). No data concerning safety and efficacy of different drug-eluting balloons in an all comers cohort exist. In a single-centre retrospective, non-randomised study an all comers cohort of 517 patients, who underwent percutaneous coronary intervention (PCI) with a paclitaxel coated balloon was analysed. Either Pantera Lux (Biotronik) or Sequent Please (BBraun) drug-eluting balloons were used. The indication for PCI was in-stent-restenosis with relevante symptoms and/or proven ischaemia in 396 patients. 252 patients were treated with Pantera Lux, 144 patients were treated with Sequent Please. Concerning patients characteristics no significant differences were observed bewteeen both groups. Follow-up period was 12 months. The Primary endpoint was a composite safety endpoint, consisting of myocardial infarction, target lesion revascularisation, cardiac death and cerebral ischaemia (MACCE). Secondary endpoint consisted of target lesion revascularisation only, as a singular paramater defining efficacy. The Pantera Lux group (n=252) included 169 patients with in-stent-restenosis in BMS and 83 patients with in-stent-restenosis in DES. The Sequent Please group (n=144) included 94 patients with in-stent-restenosis in BMS and 50 patients with in-stent-restenosis in DES. 12 months follow-up was obtained in 316 patients (Panter Lux, n=206; Sequent Please, n=111). Pantera Lux group: Primary endpoint occured in 19 (14,2%) patients with paclitaxelcoated balloon in BMS and in 15 (20,8%) patients with paclitaxel-coated balloon in DES. Secondary endpoint occured in 14 (10,4%) patients with paclitaxel-coated balloon in BMS and in 12 (16,7%) patients with paclitaxel-coated balloon in DES. Seugent Please group: Primary endpoint occured in 14 (20,1%) patients with paclitaxel-coated balloon in BMS and in 6 (13,6%) patients with paclitaxel-coated balloon in DES. Secondary endpoint occured in 8 (11,9%) patients with paclitaxel-coated balloon in BMS and in 5 (11,4%) patients with paclitaxel-coated balloon in DES. No significant difference was seen between both groups concerning primary and secondary endpoints. During the follow-up period 4 patients died of cardiac cause. 2 in the Pantera Lux group and 2 in the Seugent Please group.

Conclusions: Sequent Please and Pantera Lux drug-eluting balloons performed comparably in a real world all comers cohort of patients with instent-restenosis in BMS or DES.

Single centre prospective observational registry with drug-eluting balloons to treat instent restenosis and *de novo* coronary lesions: a 4-month angiographic follow-up and 12- to 24-month clinical follow-up

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Aims: This registry aims to highlight our experience with drug-eluting balloons (DEB) in the treatment of in stent restenosis (ISR) and *de novo* lesions in vessel smaller than 3 mm. It was a real world prospective observational registry, enrolling unselected and consecutive patients referred to our centre for coronary angiography with indication to coronary revascularisation and suitable for drug-eluting balloon use, according to the German Consensus Group.

Methods and results: Our study was conducted in a single-centre by five resident operators. All patients presenting to our institution from October 2011 to January 2014 with significant ISR and/or de novo lesion in vessel ≤3 mm, who were eligible to receive DEB treatment, were included in the registry. The study schedule was as follows: 4-month angiographic follow-up for the first 100 patients; post-discharge, 6-, 18- and 24-month telephone call and 12-month clinical ambulatory follow-up for all patients to monitor clinical adverse events. Post-procedural and follow-up endpoints include cardiac death, myocardial infarction and target lesion revascularisation. A total of 200 patients were treated with DEB in 218 lesions during study period; significant number having major risk factors for coronary artery disease, 40% diabetics; 82% hypertensive; 66% hyperlipemic; 59% multivessel disease). Average age was 65.9 years. 39.5% of the patients had ISR, 45% small vessel disease (≤2.5), 10% ostial lesions, 12% bifurcation lesions. Multi vessel disease was present in 67.5% of patients. Average lesion length was 16 mm. Only 4 procedures with drug-eluting balloon were switched to stenting. "SeQuent® Please" (B.Braun) and "Pantera Lux" (Biotronik) paclitaxel-eluting balloons were used. Dual antiplatelet therapy was recommended for 3 months. 100 patients were angiographically followed for a median of 123 days. No patients died or were admitted for STEMI/NSTEMI in that period. 12% of the patients received target lesion revascularisation (TLR) (80% clinically driven, 20% angiography+fractional flow reserve driven) and successfully performed a re-PCI (one third of this with DEB). Re-PCI occurred for re-ISR in 67%; 33% of re-PCI were caused by restenosis in de novo lesions. In 118 patients with 12-month clinical follow-up 4 had hospital re-admission for angina (besides those treated at 4-month follow-up), 3 of these required re-PCI in all cases due to re-ISR. 56 patients have 18-month follow-up performed with telephone call, only 2 of these had angina and required a re-PCI (for recurrent ISR). A little group of 19 patients had 24-month telephone call follow-up, only one had angina but refused hospital admission.

Conclusions: Our experience highlight safety and efficacy of DEB in the treatment of ISR and *de novo* lesion, also ostial and bifurcation, for patients having significant risk factors for coronary artery diseases. 12- to 24-month follow-up give important reassurance on the good long-term results, especially for *de novo* lesions treatment. Poorer results were seen in the treatment of recurrent ISR. Further studies are needed to define the real DEB indications in the treatment of coronary artery disease.



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Optimal treatment of DES restenosis: DEB versus second generation DES

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Aims: The optimal treatment of drug-eluting stent restenosis (DES-ISR) remains unclear. Several modes of treatment ranging from plain-old balloon angioplasty to repeat use of DES have yielded disappointing results with high rates of recurrence. Despite this, the default practice in most centres is to implant another stent. Deployment of additional stents results in multiple layers of metal, which may be the nidus for further restenosis and stent thrombosis. Drug-eluting balloons (DEB) are emerging as an effective treatment for restenosis. Recently published trial comparing DEB vs. first-generation DES suggested that DEB was non-inferior to DES. However, there is no data comparing DEB versus second generation DES in the treatment of DES-ISR.

Methods and results: We evaluated all PCI procedures between January 2009 and December 2011, involving DES-ISR that were treated either with DEB (In.Pact Falcon™ paclitaxel-eluting DEB, Medtronic Inc., Minneapolis, MN, USA) or second generation DES. All lesions were adequately pre-dilated before using DEB or deploying the stent. The measured end-points during the follow-up period were cardiac death, target vessel myocardial infarction (TV-MI), target lesion vascularisation (TLR), target vessel vascularisation (TVR) and major adverse cardiac events (MACE) defined as composite of cardiac death, MI and TVR. During the study periods, 247 patients (302 lesion) with DES-ISR were treated with PCI. The mean age of patients was 66.1±9.4 years (range: 39-86) and 216 (87%) were male. In the overall group, first-generation DES-ISR accounted for 52.6% (n=159) and second generation DES-ISR accounted for the rest (47.4%, n=143). 166-patients (198-lesions) underwent implantation of second generation DES, 81-patients (104-lesions) underwent treatment with DEB. There were no significant differences in the clinical characteristics, except for higher number of patients with diabetes in the DEB group (DEB: 47% vs. DES: 33%; p=0.03. The mean length of DEB was significantly longer than the DES (35.4 mm vs. 19.8 mm; p<0.001). During the median follow-up period of 18.3 (IQR; 13.2-25) months, there were no significant differences in the clinical end-point between DEB and DES groups. Cardiac death; 2 (3%) vs. 3(1.8%); p=ns; Target vessel MI: 1 (1.2%) vs. 1 (1.2%); p=ns; TVR: 18 (22.2%) vs. 30 (18.1); p=ns; TLR per patient: 20 (19%) vs. 36 (21.7%); p=ns; MACE: 18 (22%) vs. 32 (19.3%); p=ns. The estimated MACE rates at 18-months were, DEB: 26.1% vs. DES: 20.3%; log-rank p=0.09. No patient in the either group had definite or probable stent thrombosis. On the multivariate cox regression analysis, use of DEB or DES in DES-ISR was not the predictor of MACE (Hazard ratio: 1.43 95% CI: 0.73-2.83; p=0.3).

Conclusions: Our study demonstrated no significant differences in clinical outcomes between DEB and second generation DES in the treatment of DES-ISR. These results are encouraging despite higher number of diabetics in the DEB group and lesions in the DEB group required longer balloons. The luxury of drug-elution without the need of stent struts and polymer makes this technology attractive over DES. In addition, unlike DES, it does not require long-term therapy with DAPT. These results should encourage operators to consider DEB in DES-ISR.

Acute and mid-term effects of the angiosculpt scoring balloon for the treatment of bare-metal in-stent restenosis: insights from serial OCT analysis of the PATENT-C trial

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Aims: The optimal management strategy for ISR treatment is undefined. By providing immediate, direct, and uniform drug-delivery to the vessel wall without the need of a polymer, and avoiding multiple layers of metallic material, drug-coated balloons (DCB) have been considered a viable treatment option for this complex entity. By means of serial OCT analysis, we aim to assess the acute and mid-term effects of the AngioSculptTM scoring balloon for treatment of BMS ISR.

Methods and results: The "Treatment of Coronary In-stent Restenosis by a Paclitaxel Coated AngioSculpt™ Scoring Balloon – PATENT-C" is a prospective, controlled, multicentre, randomised, single-blinded trial that included 61 patients with BMS ISR (≥70% angiographic stenosis) presenting with stable or unstable angina, or evidence of myocardial ischaemia in functional tests. After ISR pre-dilation with a standard non-compliant balloon, enrolled patients were randomised to treatment with the AngioSculpt™ scoring balloon (no drug coating) or a drug-coated AngioSculpt™ (paclitaxel 3.0 µg/mm²). The population included in the current analysis consists of 10 patients, from one of the participating centres, who were submitted to serial OCT evaluation at the following time points: (1) baseline before intervention, (2) after dilation with the AngioSculpt™, (3) 15 minutes after the scoring balloon, and (4) at 6-month follow-up. Quantitative and qualitative OCT analysis will be performed at 0.6-mm interval along the in-stent segment across all time points. Acute lumen gain is defined as lumen area (LA) immediately after scoring balloon – LA at baseline, while acute recoil is determined as the changes in LA obtained immediately and 15 minutes after scoring balloon dilation. Late lumen loss is defined as the final LA 15 minutes after the scoring balloon inflation – the LA at 6-month follow-up. An assessment of the degree of dissection/cuts promoted by the balloon inflation will be provided. The restenotic tissue will be qualitatively characterised as normal (homogeneous, high-backscattering OCT signal), heterogeneous (focal changes in optical properties with various backscattering patterns), or neoatherosclerotic (lipid-laden or calcified neointima). Smoothness of the lumen contour, presence of neointimal rupture and intraluminal material, and presence of microvessels will also be assessed.

Conclusions: The current analysis aims to provide mechanistic information regarding the acute and mid-term effects of the AngioSculptTM scoring balloon for the treatment of BMS ISR by means of serial OCT analysis. OCT images are currently under analysis, and the full results will be presented at EuroPCR 2014.



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Safety and efficacy of treatments for in-stent restenosis: a network meta-analysis of randomised controlled trials

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Aims: The optimal treatment for patients presenting with in-stent restenosis remains to be defined, given the large spectrum of alternative strategies. We performed a network meta-analysis of randomised controlled trials to compare safety and efficacy of the different treatments for in-stent restenosis. Methods and results: All randomised controlled trials investigating different treatments for patients presenting with in-stent restenosis were included. Major adverse cardiac events (a composite end point of death, myocardial infarction, target lesion revascularisation, myocardial infarction and stent thrombosis) were the primary end point, while its components the secondary ones and where appraised within a hierarchical Bayesian model computing odds ratios. Non compliant/semi compliant balloons were evaluated in 11 studies with 1,149 patients, bare metal stent in one study with 224 patients, rotablator in one study with 146 patients, sirolimus-eluting stent in 9 with 1,017 patients, paclitaxel-eluting stent in 7 with 1,048 patients, paclitaxel coated balloon in 4 studies with 282 patients, everolimus-eluting stent in 1 study with 32 patients, and brachytherapy in 5 with 716 patients. After a median of 12 months (10-14), paclitaxel coated balloon performed not inferior to sirolimus-eluting stent, paclitaxel-eluting stent, all of them being superior to non compliant and cutting balloon. This reduction in major adverse cardiac events was mainly driven by reduction in target lesion revascularisation obtained by paclitaxel coated balloon, paclitaxel-eluting stent, sirolimus-eluting stent when compared to other strategies. Rates of myocardial infarction did not differ between various treatments, as those of stent thrombosis, apart from a reduction of stent thrombosis offered by paclitaxel coated balloon when compared to cutting balloon (odds ratio 0.28: 0.02-0.9, all confidence interval 95%).

Conclusions: Paclitaxel coated balloon performed similar to first generation drug-eluting stent for treatment of in-stent restenosis, being superior to cutting and non compliant balloon.



ACEF score to risk stratify patients undergoing **PCI** of coronary **CTO**

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Aims: The Age, Creatinine, and Ejection Fraction (ACEF) score can reliably predict clinical outcomes in patients undergoing elective percutaneous revascularisation (PCI) of non-occlusive coronary stenoses. We aimed at assessing the prognostic value of the ACEF score in patients undergoing successful PCI of coronary chronic total occlusion (CTO).

Methods and results: ACEF score was calculated in 587 consecutive patients treated with PCI of CTO that was successful in 433 (74%) patients (success group) and failed in 154 (26%) patients (failure group). Patients from both groups were divided according to the following ACEF score tertiles: 1st ACEF<0.950, 2nd ACEF from 0.95 to 1.207, 3rd ACEF tertile>1.207. Clinical endpoints up to 24 months follow-up were major adverse cardiac events (MACE), overall death, non-fatal myocardial infarction (MI) and clinically driven target vessel revascularisation (TVR). Median follow-up, available in 558 patients (95%), was 24 months (8-24 months). In the success group, higher MACE rate was significantly associated with increasing ACEF score tertile (1st ACEF=7%, 2nd ACEF=13%, 3rd ACEF=18%, p=0.02). MACE-free survival was significantly decreased with increasing ACEF tertile (Log-Rank: 5.58, p=0.018). In the failure group, lower MACE rate was significantly associated with increasing ACEF tertile (p=0.042). This was mainly driven by significant decreasing rate of TVR along the ACEF tertiles (1st ACEF=34%, 2nd ACEF=19%, 3rd ACEF=10%, p=0.007). Compared to the success group, in the failure group MACE rate was significantly higher in the 1st ACEF tertile (p<0.001), and similar in the 3rd ACEF tertile (p=0.57).

Conclusions: ACEF score represents a simple tool in the prognostication of patients successfully treated with PCI of CTO. In addition, it identifies those patients who would not derive any significant clinical harm despite failed percutaneous revascularisation of the CTO.



Euro14A-0P173

Impact on technical success of multi-detector computed tomography coronary angiography-guided PCI in coronary CTO: TACCTO prospective randomised trial

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Aims: Computed tomography coronary angiography (CTCA) has been used as an imaging technique for planning CTO recanalisation by a considerable number of operators. However, there is no randomised trial assessing clinical benefit in improving procedural success of a CTCA investigation prior to CTO recanalisation. We performed a prospective randomised trial so as to assess clinical impact of CTCA in improving immediate procedural results.

Methods and results: Between February 2012 and January 2014, 100 eligible patients who were scheduled for percutaneous recanalisation of a true CTO (Euro-CTO definition) and without contraindications for CTCA, were included in the study (TACCTO). All patients underwent CTCA and were randomised to be or not to be aware of the result of the CT-scan prior to CTO recanalisation. Therefore, CTCA versus conventional coronary angiography (CCA) group were compared regarding immediate procedural success. By protocol we pre-defined the same 10 CTO key characteristics by CCA and CTCA based on previously published angiographic and tomographic independent predictors of failure. Two experienced interventional cardiologist and two imaging specialists with a large experience interpreting CTCA in CTO, who were unaware of the CTCA and CCA respectively. analysed CTO characteristics. Consensus was needed for each assessed parameter. In the CTCA group, all the CT scans were discussed between the operator of CTO procedure and the imaging specialist prior to the interventional procedure. All interventional procedures were performed by experienced and interventional strategy was left to the discretion of the operator. A 64-CT detector was used for all studies. The mean age was 62±10 years old. According to the Japanese-CTO score of complexity 51% of lesions were classified as difficult or very difficult. 52% were severe calcified lesions and RCA was the most frequent lesion treated. In most cases (88%) the strategy was antegrade. 58% performed with a 7F catheter and in 77% contralateral injection was performed. The total stent length implanted per lesion was of 51.6±20.3 mm (2.2±0.55 scaffolds per lesion). In all cases last generation DES were implanted (30% with everolimus BVS scaffold). The CCA group had more dyslipidaemia (83.3 vs. 61.7% p=0.02) compared to the CTCA group. There were no significant differences in angiographic-lesion and procedural characteristics and there were no differences in the Japanese CTO complexity score. Technical success was achieved in 90.5% of the patients in the CTCA group and 86.4% of those in the CCA group (p=0.77). According to the J-CTO score 2 subgroups of complexity were done: a) easy-intermetiate and b) difficult-very difficult. In sub-group a), procedural success was achieved in 100%. In sub-group b), procedural success was achieved in 80% of the patients in the CTCA group and 73.7% of those in the CCA group (p=0.85).

Conclusions: According to the results of this prospective randomised trial, in our current era, with new CTO material and techniques, it seems that in centres with expert CTO operators, the information provided by CTCA could be useful, but did not provide a significant impact in procedural results.

Impact of the number of chronic total occluded arteries on 12-month mortality in patients with non-STEMI

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Aims: The purpose of the present study was to evaluate the effect of the number of chronic total occlusion (CTO) on 12-month mortality in patients with NSTEMI and multivessel coronary artery disease (MV CAD).

Methods and results: The consecutive records of 947 patients with NSTEMI with performed coronary angiography, admitted to the Clinic between 2006 and 2011 were analysed. The inclusion criteria were presence of MV CAD and availability of 12-month observation period. Patients with a history or qualified to CABG during current hospitalisation were excluded from further analysis. The differentiation between CTO and acute occlusion was determined by the compilation among the morphology of the occlusion, electrocardiographic recording and a possible history of previously documented acute coronary events in the same territory. Clinical characteristic, in-hospital and 12-month outcomes of 484 patients were analysed according to the number of CTO in coronary angiography. We divided patients into three groups: CTO=0 - without CTO, CTO=1 - with only one documented CTO, and CTO>2 - with more than one CTO. The CTO=0 group included 271 (56%), CTO=1 group 165 (34%) and CTO>2 group 48 (10%) patients. Significant differences in clinical and angiographic characteristic of the groups were observed. Patients from CTO>2 group had significantly higher risk according to GRACE score than CTO=0 (p<0.001) and CTO=1 groups (p=0.03). In-hospital death rates were respectively 3.7% for CTO=0, 4.8% for CTO=1 and 12.5% for CTO≥2 group, respectively (0.035). In the post hoc analysis considerable difference between CTO=0 and CTO≥2 groups (p=0.01) and not significant trend between CTO=1 and CTO≥2 (p=0.059) were shown. The rates of myocardial re-infarction, target vessel revascularisation, stroke and major bleeding during the hospitalisation were similar in all analysed groups. Mortality in 12-month observation period was 11.1% for CTO=0, 15.1% for CTO=1 and 25.0% for CTO≥2 groups (p=0.031). Statistically significant difference was reported between CTO=0 and CTO≥2 groups (p=0.008). In the multivariate analysis of entire study population, independent factors influencing 12-month mortality were identified: serum creatinine at admission (per 10 umol/L more; HR: 1.04; 95% CI: 1.02-1.06; p<0.001), white blood cells at admission (per 1 th/uL more; HR: 1.10; 95% CI: 1.03-1.17; p=0.002), CTO of RCA (HR: 2.62; 95% CI: 1.31-5.25; p=0.006), PCI of infarctrelated artery (HR: 0.45; 95% CI: 0.24-0.83; p=0.011), cardiogenic shock during hospitalisation (HR: 3.14; 95% CI: 1.27-7.78; p=0.013), left ventricular ejection fraction (per 1% more; HR: 0.97; 95% CI: 0.95-1.00; p=0.044) and prior stroke (HR: 2.10; 95% CI: 1.01-4.40; p=0.048). The number of CTO was not an independent factor of 12-month mortality (per one CTO more; HR: 0.84; 95% CI: 0.53-1.34; p=0.465).

Conclusions: Despite the fact that the number of CTO was associated with higher mortality, it was not an independent factor influencing 12-month prognosis in the study population.



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The key to retrograde success: identifying obstacles in retrograde PCI of coronary CTO

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Aims: Well developed coronary collaterals to a chronically occluded coronary artery territory have been demonstrated to have prognostic benefits. In spite of improving prognosis, maintaining tissue viability and reducing the risk of LV impairment and infarct size, coronary collaterals are frequently insufficient to render patients free of angina. A further advantage of a good collateral circulation is to afford retrograde access for chronic total occlusion PCI. Retrograde PCI is an advanced technique requiring considerable skill and experience at chronic total occlusions. Our aim is to identify the limiting steps in retrograde PCI and assess the learning curve and success rate. This will help us obtain further understanding of the main obstacles during these challenging procedures and aid further education, training, development and success in the treatment of chronic total coronary occlusions. Methods and results: We reviewed chronic total occlusion procedures and identified and reviewed all retrograde coronary interventions done at five UK PCI centres over a two year period. We reviewed a total of 739 interventions for chronic total occlusion, 241 of which had a retrograde attempt at the intervention and 141 (59%) of those were successful via a retrograde channel. Further 36 cases (25%) were subsequently successful. The right coronary artery was most commonly treated in 69% of cases. Over this two year period (between 2010 and 2012), the percentage of chronic total occlusions treated retrogradely increased from 19 to 35%. Failure method was divided into the following categories: Failure to cannulate or navigate collateral, failure to cross collateral with equipment, failure to cross CTO with wire and join lumens, failure to cross CTO with equipment or failure to externalise the wire - as well as other obstacles such as exceeding maximum contrast load or complications. The failure method changed with time from being mainly failure to identify and wire septals/collaterals at the beginning of the period to being more commonly failure to enter true lumen from retrograde subintimal space or to externalise the wire. Retrograde success became more common over this period, from 54 to 62% per procedure overall and with each centre demonstrating a learning curve. Procedure was abandoned because of perforation in 2% of cases but there were no life threatening complications.

Conclusions: At these five UK centres there has been a sharp increase in retrograde coronary interventions over the last two years with improved success rate. Initial retrograde success rate was 59% but a further 25% of cases were subsequently successful highlighting that more than one attempt and combination of antegrade and retrograde skills is often required. In recent years there have been advances in equipment such as microcatheters and exchange wires but increased experience and training of operators is likely to play the largest part in improving success of retrograde treatment of chronic total occlusions.

Decision-making treatment can determine the prognosis in patients with coronary CTO

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Aims: Chronic total coronary occlusions (CTO) are a common finding among patients with coronary heart disease. Even though there is clinical data that support revascularisation in order to improve the outcome, less than 10% of patients diagnosed with a CTO are sent for revascularisation. To analyse the effect of the treatment offered to these patients on their long term outcome.

Methods and results: Between June 2010-December 2012 all consecutive patients admitted to our institution for a coronary angiography who had a CTO were included in a registry. Demographics, cardiac history data and several risk scores [ACEF, Global Syntax (GS), Clinical Syntax creatinine (CSC), Logistic Syntax (LS), CTO syntax score (CTOSS)] were recorded. We divided the population into three groups: 1 assigned to a medical therapy, 2 to PCI and 3 to CABG. A clinical or telephone follow-up was made. 714 patients were included. Global population clinical characteristics: 66.9±10.9 years old, 86% men, 52% former smokers, 71% hypertension, 39% diabetes mellitus, 60% dyslipidaemia, 36% previous STEMI, 14% ongoing STEMI and 10% previous CABG. Angiographic characteristics: 78% had one vessel occluded, 79% multivessel disease and 12% left main disease. The treatment choice was left to the discretion of the clinician in charge of the patient. 357 patients were assigned to medical therapy, 199 to PCI and 155 to CABG. There were no differences between groups in terms of sex, hypertension, diabetes mellitus, number of occluded vessels or CTOSS. Patients referred to medical therapy were older (69.8±10.7 versus 62.8±10.5 in group 2 and 65.4±9.9 in group 3, p<0.001). Ongoing STEMI was more frequent in group 1 (19% versus 11 in group 2 and 8 in group 3, p=0.003). Three vessel disease were more usual in group 3 (85.2% versus 63 in group 1 and 68 in group 2, p>0.001), left main disease was more frequent also (25% versus 9 in group 1 and 7 in group 2, p<0.001). Group 1 had significantly higher ACEF (1.93±0.83 versus 1.58±0.78 in group 2 and 1.46±0.47 in group 3, p<0.001), CSC (47.4±34.4 versus 38±32.3 in group 2 and 45.8±26 in group 3, p=0.004) and LS (14.9±7 versus 13.8±5.8 group 3 and 11.5±7.6 in group 2, p<0.001). GC was significantly higher in group 3 (30.1 \pm 11.8 versus 23.3 \pm 12.7 in group 1 and 21.7 \pm 11.96 in group 2, p<0.001). We achieved follow-up in 93% of patients (mean duration 1.85±0.84 years) without any statistical difference between groups. There were no differences with respect to the incidence of STEMI. 44% patients in group 1, 49% in group 2 and 5.2% in group 3 were referred for PCI of a different vessel than the CTO vessel (p<0.001). Cardiac death occurred in 13% in group 1, 5% in group 2 and 3.8% in group 3 (p<0.001). All causes of death occurred in 17% in group 1, 7.5% in group 2 and 5.2% in group 3 (p>0.001).

Conclusions: Patients with complex anatomy have better outcome if they are referred for CABG. Patients treated with medical therapy have the worst clinical profile and therefore the worst outcome with higher incidence of death and STEMI during the follow-up. In high risk selected patients, perhaps those with less complex anatomy or with less comorbidity, might benefit from revascularisation.



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Coronary artery collateral circulation: defining the anatomy in a CTO population

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Aims: Despite a large body of research assessing the physiological role of collaterals in Chronic Total Occlusions, the underlying anatomy remains poorly defined. We aim to define the anatomy and applicability of collaterals within a population with chronic total occlusions.

Methods and results: We studied the coronary artery blood supply of 402 patients with 425 chronic total occlusions referred to five tertiary referral centres in the United Kingdom over a three year period. Assessment was performed by an experienced panel of interventional cardiologists specializing in chronic total occlusion PCI (each performing more than 75 cases per year); all visible collaterals with a Renthrop grade coronary connection 1 or greater were recorded. A subgroup of chronic total occlusions (n=142) was assessed in terms of interventional capability, defined as whether the collateral supply was able to facilitate retrograde access. We described 42 different collateral patterns; 18 in right coronary artery chronic total occlusions, 12 in the left anterior descending and 12 in the Circumflex artery. Septal collaterals from the left anterior descending artery to the posterior descending in right coronary artery occlusions and from the posterior descending artery to left anterior descending artery septals (in left anterior descending artery occlusions) were most commonly identified as having 'interventional capability'.

Conclusions: We have described the collateral circulation within a large population of chronic total occlusions. Recognition of the relative likelihood of a collateral pathway with a chronic total occlusion is likely to be of significant benefit to interventional cardiologists. In many cases of retrograde PCI the most challenging part of obtaining retrograde access is identifying a suitable collateral channel. Knowing where to look and the relative likelihood of a suitable channel being present may significantly expedite the procedure.



The fate of collateral channel in failure cases of the treatment of coronary CTO with retrograde approach

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Aims: In the treatment of chronic total occlusion (CTO), whether collateral channel can keep in good condition in failure cases after retrograde approach has an impact on the result of reintervention. The aim of this study is to evaluate the condition of collateral channel in failure cases after retrograde approach in the treatment of CTO and to understand its features.

Methods and results: The condition of the collateral channel was evaluated. Baseline visibility was compared to visibility at follow-up. When the collateral channel was visible, the change of its grade (CC0 to CC1) was also evaluated. Bypass graft was excluded as collateral source. From September 2004 to December 2012, 1,171 CTO cases were treated in our hospital. In 45 cases, the procedure was unsuccessful although the guidewire and microcatheter could pass through the channel by aretrograde approach. Twenty three cases underwent repeat angiography. Nine of 23 used a septal channel and 14 used an epicardial channel. In septal channel cases, 5 of 9 disappeared at follow-up. In epicardial channel cases 1 of 14 had disappeared (p<0.05). In both groups, there was no change in the condition of visible channel before procedure and follow-up.

Conclusions: The septal channel, which is a representative and convenient channel in the retrograde approach, collapses more easily than the epicardial channel once the procedure fails with the retrograde approach. Attention has to be paid to channel selection in the treatment of CTO.



Euro14A-0P179

Non-target vessel haemodynamics of coronary CTO are not related to extent of collateral donation, implications for the influence of revascularisation on the FFR

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Aims: Marked changes in non-target vessel FFR post recanalisation of chronic total coronary occlusions have been reported, but the consistency of the phenomenon remains uncertain, if a large change in FFR were universal we might expect an association between non-target vessel haemodynamics and extent of collateral donation of the non-target vessels. We sought to compare microvascular resistance and coronary flow between each non-target vessel prior to PCI of a chronic total coronary occlusion.

Methods and results: Prior to angioplasty of a chronic total coronary occlusion in 22 patients, simultaneous pressure and flow were measured at rest and during hyperaemia in the distal and proximal segment of each non-target vessel. Absolute coronary flow, coronary flow reserve, hyperaemic microvascular resistance and fractional flow reserve were calculated. Blinded to haemodynamic measurements, the predominant (or major) collateral donor vessel was selected and each vessel was graded by the size of the largest collateral branch which originated from it by collateral connection (CC) grade (0=no continuous connection, 1=threadlike connection, 2=side branch like connection). Haemodynamic measurements were compared between the major and minor collateral donor vessels. Continuous data is expressed as mean (standard deviation), mean differences are expressed as mean (confidence interval of the difference). Comparisons between groups were made using a paired t-test. All patients had right dominant coronary anatomy. The target vessel was the left anterior descending artery in 9 patients, circumflex artery in 2 and right coronary artery in 11. All target vessels were filled by a modified Rentrop grade of >2 (2 n=12, 3 n=10). Collateral connection grade for the major and minor collateral donor vessel were as follows: major: 2=11, 1=11, 0=0; minor 2=3, 1=8, 0=11. The Mean Duke Jeopardy Scores for the entirety of each non-target vessel were not significantly different between groups (major=3.27 (1.91), minor=4.09 (1.44)). Mean diameter stenosis and fractional flow reserve did not differ significantly between groups. There was no significant difference in any of the measured haemodynamic indices between groups: hyperaemic microvascular resistance (mmHg/cm/s): major=2.01 (0.95), minor=2.19 (0.87), mean difference -0.18 (-0.74-0.38, p=0.51); hyperaemic absolute flow (ml/min): major=168.8 (97.7), minor=189.4 (126.9), mean difference 20.6(-30.7-72.0, p=.41); resting absolute flow adjusted for rate pressure product: major=105.8 (61.3) minor=111.6 (58.7), mean difference (-21.0-32.6, p=0.66); coronary flow reserve: major=2.11(0.61), minor=2.13 (0.78), mean difference -0.03(-0.36-0.42, p=0.88).

Conclusions: The mechanism for a large rise in non-target vessel FFR post CTO angioplasty must involve a fall in coronary flow, and therefore resistance to flow, across a coronary stenosis. These results would suggest that the expected change in haemodynamics as a result of recanalisation of a chronic total occlusion are likely to be relatively small. The relationship between pressure gradient and flow of a coronary stenosis may be the major determinant of the size in change in FFR.



Microvascular resistance is not increased after angioplasty of coronary CTO and vasodilatory capacity of the microvasculature is preserved

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Aims: Whilst it seems clear that the endothelium distal to a chronic total coronary occlusion is dysfunctional in the immediate aftermath of PCI, it is not clear whether microvascular resistance and function is restored immediately, or whether this is also impaired. We sought to investigate microvascular resistance at rest and hyperaemia prior to and shortly after PCI of a chronic total coronary occlusion.

Methods and results: In 10 patients undergoing PCI to a chronic total coronary occlusion, simultaneous pressure and flow velocity were measured using a Volcano ComboWire distal to the point of occlusion pre and post recanalisation. Post-recanalisation measures were compared with an unobstructed reference vessel subtending viable myocardium in the same patient. Hyperaemic microvascular resistance and coronary flow reserve as well as resting and hyperaemic instantaneous minimal microvascular resistance during the 'wave free period' were compared. Continuous values are expressed as mean (standard deviation) or median (interquartile range) and comparisons made with a paired t-test or Wilcoxon signed rank sum test, depending on conformity to a Gaussian distribution. Pre-PCI microvascular resistance was assessed in the target (chronically occluded) vessel in 9/10 patients. There was a significant redunction in hyperaemic microvascular resistance after PCI: pre PCI median 5.26(3.50-5.51) mmHg/cm/s, post-PCI median 1.51(1.25-3.44) mmHg/cm/s, p=0.028. We did not detect a significant difference in the reference vessel: pre-PCI median 2.15 (1.53-2.63), post-PCI median 1.72(1.34-2.02) p=0.31. There was no significant difference between reference and target vessels in hyperaemic microvascular resistance post-PCI, hyperaemic microvascular resistance was within the normal physiological range of <2 mmHg/cm/s in 7/10 target vessels (median 1.42(0.98-3.44) mmHg/cm/s) and 9/10 reference vessels (median 1.81(1.40-2.60) mmHg/cm/s), p=0.65. Similarly, there was no difference in coronary flow reserve (target vessel mean 1.96(0.70), reference vessel 2.22(0.98), p=0.57. Minimal instantaneous microvascular resistance measured during the 'wave free period' did not differ between target and reference vessel either at rest: target vessel median 2.31(1.45-2.90) mmHg/cm/s, reference vessel median 3.75(1.89-4.32) mmHg/cm/s, p=0.28; or hyperaemia: target vessel median 0.90(0.56-1.80) mmHg/cm/s, reference vessel median 1.05(0.87-1.30), p=0.96

Conclusions: This small study suggests that target vessel microvascular resistance decreases rapidly after PCI of chronic total coronary occlusions and the vascodilatory capacity of the microcirculation in response to Adenosine rapidly returns to normal in a high proportion of cases. Although physiological lesion assessment for clinical decision making in this setting is limited by endothelial dysfunction in the epicardial vessel, and is probably best avoided; these results have implications for the interpretation of clinical studies, and support the validity of those that have measured recruitable collateral function after PCI of chronic total coronary occlusions.



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The mechanism of left ventricular functional improvement caused by PCI for coronary CTO: analysis by two-dimensional speckle tracking echocardiography

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Aims: Three possible benefits of successful percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) lesions are improvement in symptoms, improvement in left ventricular function, and improvement in survival. Previous reports revealed that the improvement of left ventricular function is caused by improved wall motion of dysfunctional but viable myocardium in the perfusion territory of CTO. The purpose of this study is to evaluate the impact of CTO-PCI on global left ventricular function including CTO territory and collateral channel-source territory with two-dimensional (2D) speckle tracking echocardiography.

Methods and results: A single-centre prospective observational study was performed from July 2012 to November 2013. 42 consecutive patients (65±10 years, 34 males) with silent myocardial ischaemia undergoing primary PCI for CTO lesions in our institution were analysed. To evaluate the impact of CTO-PCI on left ventricular function, we performed 2D speckle tracking echocardiography (automated function imaging by Vivid S6, GE Healthcare) to assess the global longitudinal strain (GLS), regional longitudinal strain (RLS) of CTO territory and collateral channel-source territory, and left ventricular ejection fraction (LVEF) with the biplane Simpson's method before and 1 day after the CTO-PCI. A 17-segment model was used to analyse the longitudinal strain. Procedural success was obtained in 36 (86%) patients (11 patients for left anterior descending artery, 6 patients for left circumflex artery, and 19 patients for right coronary artery). Thirteen cases with poor images for automated function imaging were excluded, and a total of 23 cases were finally analysed in this study. Improvement of LVEF by CTO-PCI was not obtained (Pre-PCI vs. Post-PCI; 59±15% vs. 60±14%, P=0.369). 2D-speckle tracking echocardiography revealed that RLS of CTO territory and GLS were significantly improved after CTO-PCI (RLS of CTO territory, -12.6±4.4% vs. -14.1±5.3%, P=0.0315; GLS, -12.7±3.6% vs. -14.2±3.9%, P=0.027). RLS of the perfusion area of collateral channel-source artery was also significantly improved by revascularisation of CTO lesion (-13.7±3.9% -15.1±4.2%, P=0.018). **Conclusions:** The improvement of left ventricular function provided by successful PCI for CTO is caused by not only improved LV function of CTO territory but also improved LV function of collateral channel-source area. This might be one of the mechanisms of left ventricular reverse remodeling caused by CTO-PCI.

ABSORB everolimus-eluting bioresorbable scaffold in coronary interventions: six-month results of a single-centre "real world" registry

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Aims: The safety and efficacy of the ABSORB bioresorbable vascular scaffold (BVS) has been documented in lower-risk lesions, however outcome data in more complex lesions and in "real world" patient population is limited. The aim of this study was to evaluate the angiographic success and 6-months clinical outcome after BVS implantation in both simple and complex lesions in stable patients and acute coronary syndrome patients.

Methods and results: All consecutive patient with de novo coronary artery disease and treated with BVS between August 2012 and August 2013 were included in this single-centre registry. Acute and 6-months outcomes assessed were angiographic success, cardiac death, myocardial infarction (MI), stent thrombosis (ST), target lesion revascularisation (TLR), target vessel revascularisation (TVR) and target vessel failure (TVF). Angiographic success was defined as <30% residual stenosis in the target lesion, assessed by quantitative coronary angiography (QCA), and thrombolysis in myocardial infarction (TIMI) 3 flow in the intended target vessel. TVF was defined as a composite of the device oriented endpoints of all-cause mortality, any MI or TVR. A total of 135 patients (59.1±10.8 years, 72.6% male, 20% diabetic) were enrolled and 164 lesions were treated. Indication for PCI was stable angina in 63 patients (46.7%), non ST-segment elevation acute coronary syndrome (NSTE-ACS) in 49 patients (36.3%) and STsegment elevation myocardial infarction (STEMI) in 17 patients (12.6%). The majority of lesions (60%) were located in the left anterior descending (LAD). In total 102 (62%) of the lesions had type B2 or C AHA/ACC lesion classification were treated including: 2 left main lesions, 13 chronic total occlusions, 5 ostial and 24 bifurcation lesions. Pre-procedural QCA analyses showed a mean percentage diameter stenosis of 68% (±17%) and postprocedural analyses showed a mean in scaffold percentage diameter stenosis of 18% (±7%). In seven lesions, post-procedural stenoses were more than 30%, resulting in a 96% angiographic success. Two patients were lost to follow-up. Median follow-up duration was 193 days [Q1-Q3: 181-205.5]. At six months the individual clinical endpoint of cardiac death occurred in one patients (six-month cumulative event rate 0.9%), MI in four (3.2%), TLR in seven (5.9%) and TVR in ten (8.4%). All MI events resulted from definite ST (six-months cumulative definite ST rate of 3.2%). Three cases of scaffold thromboses were defined as sub-acute, whereas one was defined as late, which ultimately resulted in cardiogenic shock and cardiac death. Two cases of ST resulted from dual anti-platelet therapy (DAPT) cessation, one was caused by a distal edge dissection of the implanted scaffold and in one patient the "instruction for use" to perform pre-dilatation of the lesion prior to scaffold placement was neglected. In summary, the composite endpoint of TVF occurred in ten patients resulting in a six-month cumulative event rate of 8.4%.

Conclusions: Based on the results of the current study we believe that implantation of the ABSORB BVS in a "real world" patient population is applicable and associated with good angiographic success and acceptable clinical outcomes at six-months. Based on our experience we would like to emphasize the importance of the use of DAPT over a minimum period of twelve months after scaffold placement and observing instructions for use.



Euro14A-0P183

Bioresorbable scaffold is associated with a low rate of coronary events in an all-comer population in the Middle East

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Aims: We report on the use of BVS in a prospective cohort of all-comer patients, including those with ST-elevation myocardial Infarction (STEMI), at a tertiary Hospital in Sharjah, (UAE).

Methods and results: During 15 months, all consecutive patients presenting a significant degree of myocardial ischaemia who were to be treated by percutaneous coronary intervention were eligible for use of BVS; including patients with STEMI and non-STEMI (NSTEMI). Some patients were excluded due to economic reasons and the cost of BVS. The cohort was followed prospectively and major adverse coronary events (MACE: cardiovascular death, MI, stent thrombosis and target lesion revascularisations) were systematically assessed. Between March 2012 and June 2013, a total of 140 patients were treated by BVS at our academic centre. The mean population age was 53.8 years and 81% were male. Risk factors included type 2 diabetes (n=32, 23%), hypertension (n=75, 54%), dyslipidaemia (n=66, 47%), obesity (Body Mass Index>30 (n=21, 15%). Indication for percutaneous coronary intervention was STEMI (n=46, 33%), NSTEMI (n=44, 31%), unstable angina (n=33, 24%), and stable angina (n=17, 12%). Patients were treated for single, double or triple vessel disease in 72%, 12% and 16%; respectively. Mean SYNTAX score in the population was 17±9. Finally, 221 BVS were implanted (1.6/patient) mainly in the LAD (n=82, 59%), the RCA (n=30, 21%) and the circumflex artery (n=24, 17%). BVS were 3.5 mm (n=83, 38%), 3.0 mm (n=82, 37%) and 2.5 mm (n=56, 25%) in diameter and 12 mm (n=16, 7%), 18 mm (n=95, 43%) and 28 mm (n=110, 50%) in length. Pre-dilation was performed more often than post-dilation (88% vs. 69%, respectively, p<0.05). At 1 year, the rate of major adverse cardiac events was 7.2% (n=10) including a 4.3% mortality (n=6), no myocardial infarction (n=0, 0%) no stent thrombosis (n=0, 0%) and 2.9% ischaemia-driven target lesion revascularisation (ID-TLR) (n=4, 2.9%). The patients with ID- TLR were all treated by another PCI and no had no further cardiovascular events.

Conclusions: In our tertiary centre, the unrestricted use of BVS for all-comers in relatively high risk patients (STEMI and NSTEMI in 64%) is associated with a low risk of MACE at one year without myocardial infarction or stent thrombosis. Longer clinical and angiographic follow- up is currently ongoing.



Single-centre experience with the first 500 everolimus-eluting bioresorbable scaffold implantations in all comers: procedural and in-hospital outcomes

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Aims: ABSORB bioresorbable vascular scaffold (BVS) is a promising drug-eluting device. The aim of this study is to evaluate the safety and efficacy of ABSORB BVS in a real-world clinical setting, including but not limited to PCI in NSTE-ACS, STEMI, in-stent restenosis, chronic total occlusions and saphenous venous grafts.

Methods and results: ABSORB BVS became the default drug-eluting device at our centre on April 1st, 2013. Demographic, clinical and angiographic data were prospectively collected for all patients undergoing PCI, and included in the institutional interventional registry. Patients were systematically assessed for BVS eligibility based on clinical and anatomical criteria, and reasons for not using BVS were specifically collected. Monitored inhospital outcomes include major adverse cardiovascular events and bleeding complications. We will report on the first consecutive 500 all-comer patients who received a BVS at our centre. The control group will be patients treated during the same period with other stent types. As of December 31st, 2013, 351 BVS have been implanted.

Conclusions: By presenting data from consecutive real-world patients, this single-centre experience will contribute to the increasing scientific knowledge regarding BVS technology.



uro14A-0P185

ABSORB FIRST: an interim report on baseline characteristics, acute performance from the first 500+ patients from a prospective, multicentre, global registry

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Aims: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb BVS) (Abbott Vascular, Santa Clara, CA) has been previously established with clinical data up to 5 years (Cohort A), 3 years (Cohort B), 2 years (n=250, EXTEND), and 1 year (n>500, EXTEND). However, these trials treated patients with relatively simple lesions. ABSORB FIRST is designed to evaluate more complex lesions and patients in a post-approval, 'real world' setting.

Methods and results: ABSORB FIRST is a prospective, multicentre, global registry to evaluate the safety and performance of Absorb BVS in the 'real-world', all-comer patient and lesion population as per Instructions for Use. This study aims to evaluate 1800 patients with *de novo* lesions at approximately 90 sites in multiple global geographies. Treatment strategy is determined by physician and limited to lesions in vessels without prior intervention. The key clinical endpoints include cardiac death, myocardial infarction (MI), revascularisation, target lesion failure (TLF), major adverse cardiac events (MACE) and target vessel failure (TVF). All reportable adverse events are 100% monitored and clinical events are independently adjudicated. This first interim report presents results up to 7 days post PCI in the 510 patients enrolled to date. Compared to the Cohort A, B and EXTEND, the patients in ABSORB FIRST show a greater risk profile with higher rates of dyslipidaemia (70.5%), hypertension (73.4%), diabetes (25.3%), family history of premature CAD (41.6%), multi-vessel disease (48.4%), and prior cardiac interventions (26.1%). There is also a high proportion of patients with moderate/severe calcified lesions (22.2%), bifurcations (10.6%), and Class B2/C lesions (46.8%). The mean pre-procedure reference vessel diameter (RVD) from 602 treated lesions was 3.13±1.24 mm with the mean lesion length18.06±9.01 mm. The number of vessels treated per subject was 1.7±0.8. The clinical device success and procedure success rates were 98.9% and 98.7%, respectively. No death and scaffold thrombosis were reported within 7 days of the index procedure and the rate of MI was 0.2%.

Conclusions: The interim results from this first large, real-world, multicentre, global registry show excellent device and procedure success rate of Absorb BVS. Despite a high proportion of complex patients and lesion, BVS demonstrated low rates of cardiac death, scaffold thrombosis, and in-hospital MI. These findings confirm the safety and performance of Absorb BVS in challenging 'real world' patients.

Impact of post-dilatation on one-year clinical outcomes of a large cohort of patients treated with the Absorb bioresorbable scaffold

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Aims: We sought to determine the impact of post dilatation (PD) on clinical outcomes in a large cohort of patients treated with the Absorb bioresorbable scaffolds (BRS) only. Although BRS may have important benefits, their deployment requires more aggressive lesion preparation compared to the best metallic DES due to different radial force and crossing profile. In addition, the benefits of post dilatation (PD) have not been systematically studied, with reports of fracture if the BRS expansion limits are exceeded by excessive PD.

Methods and results: We evaluated all consecutive patients enrolled in the multicentre, single arm ABSORB EXTEND Study up to 07/2013. The study allowed treatment of up to 2 coronaries (diameter 2.5 to 3.5 mm) and the use of overlapping scaffolds (lesion length up to 28 mm). Patients with severe lesion calcification/tortuosity were excluded. Aggressive lesion pre dilatation (balloon to artery ratio of 0.9-1.0) was mandatory and PD was left to the operator's discretion (if performed, non-compliant balloons up to 0.5 mm larger than the Absorb had to be used). Patients were grouped according to whether PD was performed or not, and the one-year incidence of TLF, MACE and scaffold thrombosis were compared. A total of 768 patients were enrolled and PD was performed in 526 (68.4%). There were no significant differences between the PD group and no-PD group in baseline characteristics, moderate calcification (13.7% vs.12.7%, p=0.7) and incidence of B2/C lesions (43.9% vs. 41.8%), as well as lesion length (12.3 mm vs. 12.1 mm, p=0.6) and RVD (2.6 mm for both groups, p=0.2). Residual in-scaffold stenosis (15.4±6.5% with PD, 14.9±6.1 without PD, p=0.3) and the need for bailout scaffold/stent (4.2% with PD, 4.5% without PD, p=0.8) were also comparable. Clinical device success was 99% in both groups. At 1 year, there was no difference in TLF (5.4% in the PD vs. 2.6% in the non-PD group, p=0.13); all individual components of TLR, death, and MI were also similar. There were no significant differences in MACE and def/probable stent thrombosis between the two groups. Further variables will be presented.

Conclusions: These results reflect very similar final angiographic and clinical results achieved with or without post-dilatation in the treatment of low to moderately complex lesions. This analysis is limited by the lack of randomisation and the inconsistent application of PD based on investigator's discretion. Further randomised studies are needed to determine the effect of PD on outcomes, especially in more complex lesions and when used in real world practice.



Euro14A-0P187

Long-term clinical data of the BIOSOLVE-I study with the paclitaxel-eluting absorbable magnesium scaffold (DREAMS) and multi-modality imaging analysis

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Aims: In order to assess the long term safety, clinical performance and the bioabsorption process of the paclitaxel-eluting absorbable magnesium Scaffold (DREAMS) three-year clinical data and multi-modality imaging outcomes are reported.

Methods and results: Forty-six subjects were enrolled in the first-in-man BIOSOLVE-I study in two different cohorts with clinical follow-up at 1, 6, 12, 24 and 36 months; angiographic and IVUS follow-up for cohort 1 at 6-month and for cohort 2 at 12-month. A subgroup of patients underwent OCT and vasomotion testing. The primary endpoint is Target Lesion Failure (TLF) at 6-month for cohort 1 and at 12-month for cohort 2. For some patients also 18-month and 24-month imaging data are available. TLF rate at 36-month was 6.8% including 2 TLRs and 1 peri-procedural MI occurring at the 12-month follow-up angiography; no events emerged from 12- to 36-month. No cardiac death or scaffold thrombosis was observed. Vasoconstriction after acetylcholine at 6-month (delta=-10.04%; p=0.0008 versus baseline) followed by vasodilatation after nitroglycerine (delta=8.69%; p<0.0001 versus baseline) demonstrates the uncaging aspect of the absorption process with no further change at the 12-month follow-up. Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 39.5% (p=0.0015) remaining stable from 6- to 12-month follow-up. This decrease is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material. Echogenicity data using the decrease in intensity of the ultrasound signal to quantify the change in strut structure demonstrate a continuous decrease in % hyperechogenicity over the follow-up period, with the most pronounced changes within the first 6 months (22 to 16% p<0.001).

Conclusions: DREAMS shows excellent safety and efficacy data with no death and no scaffold thrombosis up to 3 years in the BIOSOLVE-I trial. Multi-modality imaging documented the absorption process and the uncaging aspect of this device already at 6 months.

Multicentre evaluation of the novolimus-eluting, fully bioresorbable coronary scaffold: one-year clinical and imaging endpoints

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Aims: Bioresorbable vascular scaffolds represent an exciting advance in percutaneous coronary intervention (PCI), providing an initial coronary scaffold which is eventually resorbed by the body. 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: The DESolve Nx BCSS is a novel drug-eluting bioresorbable vascular scaffold that combines a poly-L-lactide-based (PLLA-based) scaffold coated with a biodegradable PLLA-based polymer and the drug Novolimus, a macrocyclic lactone mTOR inhibitor which has demonstrated potent anti-proliferative properties in previous clinical trials using Elixir's metallic Novolimus-eluting coronary stents. The drug dose is 5 mcg per mm of scaffold length and is available in three diameters (3.0, 3.25 and 3.5) and three lengths (14, 18 and 28 mm). A total of 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 Revascularization, (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 also at 6 months. Additionally, imaging was conducted in the subset of patients at 12 months using multislice computed tomography (MSCT) to assess the long-term scaffold, lesion and vessel characteristics. Device Success and Procedure Success were 95.2% and 100% respectively demonstrating feasibility. MACE was 3.25% with no definite stent thrombosis, and the in-scaffold late lumen loss was 0.21±0.34 mm demonstrating the safety and effectiveness of this novel device. Clinical and MSCT results through 12 months as well as longer term imaging will be presented.

Conclusions: The DESolve® Nx Novolimus-Eluting BCSS demonstrated safety and efficacy in this study through 6 months. A report of the clinical and MSCT outcomes through 12 months as well as longer term imaging will be presented.



Euro14A-0P189

Complications and long term outcome of PCI in coronary chronic total occlusions

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Aims: PCI in chronic coronary total occlusions (CTO) is rapidly increasing. Procedural complications in CTO such as myocardial infarction (MI), bleeding from puncture site and pericardial effusion are not uncommon. In addition, complications may increase length of hospital stay and be a predictor for long term outcome. The aim of this retrospective study was to analyse complications during and after PCI of a CTO, to evaluate the correlation of complications to length of hospital stay (LoHs) and the correlation of long term outcome in terms of major adverse cardiac and cerebral events (MACCE).

Methods and results: All patients during 2010-2013 (n=174) treated by the CTO-team at Lund University Hospital, Sweden, were retrospectively analysed. A linear correlation model was used to investigate the correlation between complications, LoHs and 6 months MACCE. Based on previous experience, we considered the use of Norepinephrine to be an indicator of haemodynamic instability during the procedure. The total in-lab complication rate was 18%. The most common complication was haemodynamic instability (6.3%), followed by pericardial effusion (4.1%), major bleeding (1.72%) and minor bleeding (1.70%). One death occurred periprocedurally due to dissection of the left main followed by cardiac arrest. Post procedural ICU complication rate was 49.4%. Minor bleeding was most common (20.7%), followed by myocardial infarction (9.8%), the combination of MI and minor bleeding (6.9%) and haemodynamic instability (3.4%). 5 cases of post procedural major bleeding and one death occurred. The total LoHs was 1.0 days [1.0-2.0] (median, interquartile range 25-75%). There was a total MACCE rate of 22.4% (n=39). Target lesion failure was most common (n=8, 4.7%) followed by death all cause (n=5, 2.9%). There was no correlation between periprocedural complications and MACCE (p=0.69) or between complications post procedure and MACCE (p=0.20). A significant correlation was found between the periprocedural use of Norepinephrine and MACCE (p=0.004). Finally, there was also a correlation in complications during procedure and LoHs (p=0.03).

Conclusions: In this retrospective analysis, we found a higher incidence of complications in PCI of a CTO compared to register data of standard PCI, but no correlation between complications and long term outcome. We found a correlation between haemodynamic instability treated by Norepinephrine and MACCE, emphasising that haemodynamic issues during the procedure should be taken seriously and stringent follow-up recommended. Post procedural complication rate of minor bleeding is remarkable, but not correlated to an increased length of hospital stay nor to long term outcome.



Impact of final kissing balloon inflation following single stent strategy in unprotected left main lesion

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Aims: Final kissing balloon inflation (FKBI) is a mandatory technique in unprotected left main (ULM) revascularisation with 2-stent strategy. However, there is no consensus regarding the necessity of FKBI in single-stent strategy. Therefore, to assess the need of FKBI for single-stent strategy in ULM lesion, we compared clinical outcome between patients treated using single-stent strategy with FKBI and those without FKBI.

Methods and results: A total of 654 consecutive patients who had ULM lesion were treated using drug-eluting stent between April 2005 and August 2010. Of these,470 patients were eligible in this study after exclusion of 21 patients with ostial ULM and 163 patients treated using 2-stent strategy. In patients using single-stent strategy, 357 patients were proceeded with FKBI (FKBI group) and 113 patients were without FKBI (no-FKBI group). The end point of this study is the occurrence of Major Adverse Cardiovascular Event (MACE) defined as composites of all cause death, target lesion revascularisation (TLR) and MI. Furthermore, overall TLR, TLR for main branch (TLR-MB) involving ULM to left anterior descending artery and TLR for side branch alone (TLR-SB) involving left circumflex (LCx) at one-year were evaluated. Patient and lesion characteristics were similar between the 2 groups. Following single-stent strategy, 36 patients (8.9%) necessitated an additional bailout stenting for ostial LCx stenosis. In the total population, the occurrence of MACE at 1 year was similar between the two groups (7.4% in the FKBI group and 11.9% in the no FKBI group, log rank p=0.112). The incidences of overall TLR, TLR-MB and TLR-SB at 1 year were also similar between FKBI group vs. no-FKBI group (7.0% vs. 9.3%, p=0.44, 2.5% vs. 4.7%, p=0.24 and 5.0% vs.5.6%, p=0.81, respectively).

Conclusions: Single-stent for ULM disease was feasible at mid-term follow-up. However, FKBI had no impact on clinical outcome following ULM revascularisation with single-stent strategy.



Euro14A-0P191

Evaluation of two-year clinical outcomes from post-market trials with everolimus-eluting cobalt chromium stents in diabetics

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Aims: Diabetes mellitus is a consistent predictor of cardiac adverse events in patients undergoing percutaneous coronary intervention. This study evaluated the two-year follow-up of a large cohort of diabetic patients with coronary artery disease who underwent coronary intervention with XIENCE V Everolimus Eluting Stent (EES) (Abbott Vascular, Santa Clara, CA). This large group represents 'real world' patients as studied in the post marketing surveillance studies.

Methods and results: Patient-level data from SPIRIT V, SPIRIT Women, XIENCE V India and the XIENCE V China single arm study were pooled. For this analysis, baseline and outcome rates in non-diabetic (N=5238) and diabetic (N=2402) patients were compared. Those with diabetes were further subdivided into: on insulin only (N=572), on oral medication alone (N=1,455), and on no medication (N=325). Outcome rates were derived from Kaplan-Meier estimates. Subjects in the diabetic group are likely to be older and female with more risk factors such as hypertension, prior MI, and prior cardiac intervention than those in the non-diabetic group; these differences are statistically significant (p <0.05). Within the diabetic group, the subjects treated with insulin show a trend of higher rates of the same risk factors when compared to those treated with oral or no medication, some with statistical significance. The diabetics, especially those requiring insulin, are a more complex group. When comparing between diabetics and non-diabetics, the outcome measures of any death (3.2% vs. 1.6%), cardiac death (2.0% vs. 1.1%), myocardial infarction (4.3% vs. 3.2%), target lesion revascularisation (2.7% vs. 1.6%), target lesion failure (6.7% vs. 5.0%), and definite/probable stent thrombosis (0.8% vs. 0.4%) are statistically significantly lower (p<0.05) in non-diabetics. Within the diabetic group, the subjects treated with insulin show higher rates of the outcome measures than those treated with oral medication (death: 5.8% vs. 2.4%, cardiac death: 3.4% vs. 1.7%, myocardial infarction: 6.2% vs. 3.9%, target lesion revascularisation: 4.3% vs. 2.2%, target lesion failure: 9.8% vs. 6.0%, stent thrombosis: 1.1% vs. 0.7%); the outcome rates in the diabetics not treated with medication are similar to those treated with oral medication.

Conclusions: This large patient level pooled analysis of diabetic patients with complex coronary artery disease treated by XIENCE V EES in the 'real world' setting demonstrated favourable outcomes and low clinical event rates up to two-year follow-up. These rates are higher than the rates in non-diabetic patients.

Safety and clinical performance of the hybrid Orsiro DES in the treatment of subjects with single *de novo* coronary artery lesions-II (BIOFLOW-II) - One-year substudy results of the diabetic and small vessel cohorts

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Aims: Both diabetic patients and patients with small vessel disease are known to have a higher risk for cardiac complications. The aim is to compare the clinical efficacy of the Orsiro Hybrid Drug Eluting Stent (Orsiro) with the Xience PrimeTM Everolimus Eluting Stent (Xience) at 12 months in these high risk populations. The BIOTRONIK Orsiro stent is a novel stent platform eluting sirolimus from the biodegradable polymer PLLA (BIOLute) applied to the surface of a thin-strut (60 μm) Silicon-Carbide coated Cobalt-Chromium stent.

Methods and results: A total of N=458 subjects (63.4 \pm 10.0 SD 36-80 yrs) were enrolled in the BIOFLOW-II study, registered at clinicaltrials gov (NCT01356888). All subjects were stratified for diabetes and then randomly assigned (2:1) to receive the Orsiro or the Xience stent. The diabetic subgroup accounted for 28.3% N=128 (Orsiro N=84, Xience N=44) of all subjects. All subjects with a lesion reference vessel diameter \leq 2.75 mm were included into the small vessel cohort, accounting for 35.4% N=162 (Orsiro N=101, Xience N=61) of all subjects. Clinical follow-up visits are performed at 1, 6, 12 months and annually for up to 5 years after the procedure. The Target Lesion Failure (TLF) rate in the small vessel cohort was statistically significantly lower in the Orsiro group at 12 months (P=0.0365, 5.0% Orsiro, 15.1% Xience). No statistical significance was observed in the TLF rate in the diabetic cohort at 12 months (P=0.7201, 6.0% Orsiro, 4.5% Xience)

Conclusions: The clinical event rate in the small vessel cohorts was statistically significantly lower in the Orsiro group at 12 months. In the diabetic subgroup the clinical event rate was low and comparable between Orsiro and Xience Prime™ through 12 months.



Euro14A-0P193

Clinical outcomes of diabetic patients treated with bioresorbable polymer DES: data from e-NOBORI registry

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Aims: The debate on the optimal revascularisation strategy and choice of drug-eluting stent (DES) in diabetic patients with coronary artery disease is ongoing. Bioresorbable polymer drug-eluting stents may potentially improve clinical outcomes in these high-risk patients. We sought to compare long-term outcomes in patients with Insulin-dependent (IDDM) vs. Non-insulin dependent diabetes (NIDDM) treated with bioresorbable polymer DES.

Methods and results: Among the 2922 diabetic patients treated with bioresorbable polymer Nobori stent within the large e-NOBORI multicentre registry, 826 patients (28%) had IDDM and 2096 (72%) were with NIDDM. The primary endpoint of e-Nobori registry is a target lesion failure (TLF) defined as cardiac death, myocardial infarction (MI) and target lesion revascularisation (TLR) at 1 year post-procedure. Baseline characteristics of IDDM and NIDDM patients were similar except that in IDDM group there were more female patients (32.3% vs. 26.7%; p<0.01) and there was higher prevalence of renal failure (19.7% vs. 9.8%; p<0.01) and peripheral vascular disease (16.6% vs. 9.0%; p<0.01). IDDM patients also had more frequent previous MI (12.6% vs. 9.8%; p<0.05) and previous cardiac surgery (11.3% vs. 8.0%; p<0.01). Lesion characteristics were similar between both groups except thrombus presence observed less frequently in IDDM patients (7.6% vs. 10.7%; p<0.01) and these patients had less B2 type lesions (28.5% vs. 31.6%; p=0.05). Total number of lesions treated and number of stents used per lesion was higher in IDDM group (2.3±1.6 vs. 2.1±1.4; p<0.01 and 1.19±0.49 vs. 1.15±0.43; p<0.05 respectively). At one-year follow-up there was no significant difference in rates of TLR (2.3% vs. 1.6%; p=0.09), target vessel MI (1.2% vs. 0.8%; p=0.25) and TVR non-TLR (1.0% vs. 0.6%; p=0.25). TLF rate observed at 1 year was higher in IDDM patients (6.4% vs. 3.1%; p<0.01), mainly because of higher rate of cardiac death (3.3% vs. 1.2%; p<0.01). Rate of stent thrombosis (definite and probable) was low and similar in both groups (0.85% vs. 0.81%; p=0.92).

Conclusions: Although, as expected, presence of IDDM increased the risk for worse clinical outcomes, overall rates of adverse events observed in this registry was low. Comparable rates of TLR and target vessel related MI in IDDM and NIDDM patients, brings additional evidence supporting the use of bioresorbable polymer DES in this vulnerable patient population.

Feasibility of everolimus-eluting bioresorbable scaffolds in diabetics

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Aims: Everolimus-eluting bioresorbable vascular scaffolds represent a new approach to treating coronary artery disease and their role in diabetics is unclear so far. Diabetes is associated with diffuse coronary artery disease as well as worse clinical outcome after stenting with metallic stents. Thus this study aimed to evaluate feasibility and short-term clinical outcome after implantation of bioresorbable vascular scaffolds in diabetics. Methods and results: All patients with diabetes who had been treated with BVS in the vicinity of our all-comers registry (ACAS) were included in this prospective registry evaluation, regardless of their clinical presentation. Patients with unsuccessful procedures were excluded as well as patients treated with a metallic stent in the same procedure. Target parameters were target vessel failure, major adverse cardiac events including target lesion revascularisation, cardiac death, myocardial infarction and emergency coronary bypass graft surgery. Follow-up was performed by telephone call and/ or office visit. A total of 68 patients were included, of whom 12.7% had a STEMI, 22.5% a NSTEMI, 15.5% presented unstable angina and 45.1% stable angina. Mean age was 67 (61-73) years, 29.4% were female, 95.6% suffered from hypertension. Of all patients, 32.5% patients had insulin-dependent diabetes, all other patients were treated with oral antidiabetics or diet alone. Median procedure time was 50 min (39.5-69), mean contrast volume was 179.2 mL (±92.7) and mean fluoroscopy time was 14.2 minutes (±8.2). A total of 101 bioresorbable vascular scaffolds were implanted with a mean number of 1.5±0.9 per patient. One procedure related dissection occurred, which was successfully treated with another bioresorbable vascular scaffold. During hospital stay one patient experienced a subacute scaffold thrombosis. This patient was also treated with another bioresorbable vascular scaffold. Median follow-up duration was 85.5 (48-143.5) days. One target lesion revascularisation occurred and one patient died from myocardial infarction, related to a target vessel failure, which was treated by PCI. Consequently the rates of target vessel failure, target lesion revascularisation and total major adverse cardiac events were 4.4, 2.9 and 4.4%, respectively.

Conclusions: Since the experience with bioresorbable vascular scaffolds in specific subsets is limited, this study confirms safety of bioresorbable vascular scaffold implantation in diabetics. Furthermore our results demonstrate satisfying short-term clinical outcome. Nevertheless, long-term data is required for final evaluation.



Euro14A-0P195

Impact of strut thickness in stent implantation for small coronary artery disease: a prospective randomised trial of biolimus-eluting stent versus everolimus-eluting stent

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Aims: It is unknown whether strut thickness is associated with clinical and angiographic results in small vessel disease. The purpose of this randomised study was to assess clinical and angiographic benefits of biolimus-eluting stent (BES, Nobori) with a thick strut (135 μ m) compared with everolimus-eluting stent (EES, Xience V/ Promus) with a thin strut (81 μ m).

Methods and results: We examined 187 consecutive patients who underwent PCI for lesions with a diameter of 2.75 mm or less in our hospital between July 2011 and November 2012. Patients were randomly assigned to receive BES (97 patients) or EES (90 patients). Clinical outcome and angiographic parameters at 8 months were compared between the 2 groups. Baseline characteristics were well balanced between the BES group and the EES group. The mean reference diameter of the lesion was 2.40±0.35 mm and the lesion length was 28.7±12.7 mm. Stent implantation was successful in all patients. Acute lumen gain was similar between the BES group and EES group (1.57±0.61 mm vs. 1.63±0.69 mm, p=0.50). After angiographic follow-up at 8 months, there was no significant difference in the restenosis rate between the BES group and the EES group (7.8% vs. 2.8%, p=0.19). Moreover, no difference was observed between the two groups in terms of major adverse cardiac events (MACEs) at 8 months, defined as a composite of death, myocardial infarction and target vessel revascularisation (7% vs. 11%, p=0.27). In addition, there was no statistical difference between the two groups in 8-month angiographic parameters such as minimum lumen diameter (2.22±0.34 mm vs. 2.28±0.47 mm, p=0.40), percent diameter stenosis (9.4±10.2% vs., 11.1±12.6%, p=0.40) and late lumen loss (0.32±0.41 mm vs. 0.32±0.31 mm, p=0.97).

Conclusions: BES implantation for small coronary artery disease may lead to comparable clinical and angiographic results at 8 months as compared with EES implantation.



Use of Absorb bioresorbable scaffolds for the treatment of coronary ostial lesions

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Aims: We set out to evaluate the acute clinical and angiographic outcomes of bioresorbable vascular scaffold (BVS; Absorb, Abbott Vascular) implantations in aorto-ostial, left anterior descending artery (LAD)-ostial and circumflex coronary (RCX)-ostial lesions. Previous studies show that this subset of lesions has higher rates of both acute and long-term complications, and that the rate of inaccurate stent placement is very high.

Methods and results: Lesions involving the ostium of one of the three main coronaries treated with BVS in our centre between May 2012 and December 2013 with a BVS were included. 32 patients with 34 ostial lesions (mean patient age 62±12, 31 males, 4 diabetes) were included in the database. The lesions involved the ostium of the right coronary (RCA, 18), the LAD (11), or the RCX (5). 14 patients had a stable presentation, 2 unstable angina, 8 NSTEMI and 8 STEMI. Predilation was performed in all cases. At quantitative coronary analysis, the reference diameter prior to PCI was 2.6±0.7 mm (complete occlusion in 4 patients) and the minimum lumen diameter was 0.9±0.6 mm. Lesion length was 12.5±8.8 mm. After BVS implantation, the reference diameter was 3.2±0.5 mm, and the MLD was 2.6±0.5 mm, with an acute gain of 1.7±0.7 mm. There was no periprocedural complication. At 6 months follow-up (currently available in 23 patients), there was 1 sudden death, 1 in-scaffold thrombosis, and 2 non-target vessel revascularisations.

Conclusions: The higher incidence of severe calcification and high risk of inaccurate stent placement make ostial lesions a particularly complex subset. Use of BVS might be associated with the advantage of avoiding permanent metal struts protruding in the aorta or the left main coronary. The present data demonstrate that this strategy is feasible and safe, and that it is associated with good procedural outcomes.



Euro14A-0P197

Long-segment stenting (≥28 mm) with everolimus-eluting bioresorbable scaffolds in patients with stable coronary artery disease

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Aims: Everolimus-eluting bioresorbable vascular scaffolds are an upcoming technique in the interventional treatment of coronary artery disease. It is known that the total length of conventional metallic stents implanted is an independent predictor of stent thrombosis. However, this has not been investigated in patients treated with a bioresorbable vascular scaffold.

Methods and results: Long-segment stenting was defined as a total scaffold length of at least 28 mm, regardless of the number of bioresorbable vascular scaffolds used. All patients within the scope of our all-comers registry (ACAS), which were successfully treated with at least one bioresorbable vascular scaffold and fulfilled this criterion were included in this analysis. Major adverse cardiac events included target lesion revascularisation, cardiac death, myocardial infarction and emergency coronary bypass graft surgery. A total of 72 patients were treated. Median age was 62.5 (55-69.3) years, 16.7% were female, 80.6% suffered from hypertension and 34.7% from diabetes. 18.1% underwent catheterisation due to STEMI, 27.8% due to NSTEMI, 12.5% due to unstable angina and 41.7% due to stable angina. Median procedure time was 63 (48-80.3) min, mean contrast volume was 216.3 mL (±94.9) and mean fluoroscopy time was 17.7 (±9.6) min. The treated vessels were LAD in 47.2%, RCX in 22.2% and RCA in 30.6% of the cases. A total of 135 bioresorbable vascular scaffolds were implanted with a mean number of 1.9±0.9 scaffolds per patient and a mean total scaffold length of 45.2±21.4 mm per patient. 1.9±1.6 pre-dilatations per patient and in 37.5% post-dilatation were performed. Median follow-up time was 93 (44-140) days. One myocardial infarction in a previously untreated vessel and one in-scaffold thrombosis due to a lack of dual antiplatelet therapy were noted. Hence target lesion revascularisation and major adverse cardiac events rates were 1.4% and 2.8%, respectively.

Conclusions: Given the dissolving character of bioresorbable vascular scaffolds they might have a potential benefit even in long lesions. Our findings demonstrate that long-segment stenting with bioresorbable vascular scaffolds is feasible and can be performed with reasonable clinical short-term outcome. However long-term data is required.

Everolimus-eluting bioreasorbable scaffold implantation in CTO recanalisation using retrograde approach: a first case series

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Aims: Several studies showed the benefits of successful recanalisation of chronic total occlusion (CTO) lesions. Use of retrograde percutaneous recanalisation of CTO has further increased the success rate with favourable in-hospital outcomes. The use of bioresorbable vascular scaffold (BVS) in CTO recanalisation using retrograde approach has not yet been reported. We therefore assessed the safety and feasibility of BVS in this very complex subset of patients.

Methods and results: Ten consecutive patients who underwent BVS ABSORB™ implantation in retrograde CTO PCI between May 2013 and September 2013 were included. The procedures were performed in 5 centres (4 centres in Italy and 1 in Switzerland) by 2 expert CTO operators. All patients had CTO in 1 or more native vessels. The indication for the procedure was angina or proven stress-related ischaemia. In-hospital major adverse cardiac events (MACE) defined as cardiac death, myocardial infarction, and target vessel revascularisation. Patients were clinically followed up at 1, 6, and 12 months. Most patients were men (9 patients, 90%) with mean age of 66.7±8.3 years. Notably, 10% of the patients had prior CABG, and nearly half of all patients had prior PCI (40%). Mean left ventricular ejection fraction was 51.3±8,7% and mean serum creatinine was 1.0±0.4%. The target vessel in most patients was the right coronary artery (80%). Bilateral femoral was the most used approach (80%). Mean lesion length was 70±14.3 mm. Primary retrograde CTO recanalisation was employed in all cases. The retrograde vessel was most commonly a septal collateral channel, followed by epicardial vessels. Subintimal dissection techniques (controlled antegrade and retrograde tracking [CART] and reverse CART) were used in 50% of successful cases, whereas in the remaining cases retrograde wire crossing was performed. The Corsair microcatheter was used in 90% of cases and more than one-half of all procedure were IVUS-guided. Mean total stent length was 85 mm ranging from 56 to 114 mm. Mean fluoroscopy time was 125 min, ranging between 92 and 150 min and total contrast volume used was 433 ml (range 400 to 500 ml). None of the patients had any MACE during the period of follow-up (mean 197.9 days, ranging from 129 to 228 days). There were no acute or subacute stent thrombo sis during follow-up.

Conclusions: In this first reported series we observed that BVS implantation during CTO procedures performed by retrograde approach is feasible and safe with a favourable short-term outcome. The retrograde approach technique, with externalisation of retrograde guidewire that provides an excellent support for delivery of stents, allow BVS implantation in very complex and long lesions. The absorption of the stent could potentially lead to a recovery of the endothelial and smooth muscle function of the vessel, and the stent reabsorption could avoid any possibility of late malapposition solving the dilemma of "choosing the optimal stent size during PCI for a total occlusion".



Euro14A-0P199

Immediate and early results following everolimus-eluting bioresorbable scaffold implantation for the treatment of in-stent restenosis

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Aims: In-stent restenosis (ISR) has been historically considered a challenging problem for interventional cardiologists. In this context, the use of an everolimus-eluting bioresorbable vascular scaffold (BVS, ABSORB, Abbott Vascular, Santa Clara, CA, USA) appears attractive as it enables vessel scaffolding and anti-restenotic drug delivery while avoiding the addition of further permanent metal layer. These features, can potentially reduce the risk of recurrent ISR and stent thrombosis at follow-up. Aim of this study was to investigate the feasibility and early clinical outcomes following BVS implantation for the treatment of ISR.

Methods and results: A collaborative, retrospective cohort analysis was performed on all consecutive patients that underwent PCI with BVS implantation for ISR in 3 Italian Centres. ISR was defined as a luminal diameter stenosis >50% within the stent or within 5 mm of the stent edges. Procedural success was defined as BVS implantation at the ISR site with less than 30% angiographic residual stenosis and absence of in-hospital major adverse events (cardiac death, Q-wave myocardial infarction or need for emergent revascularisation). Clinical events were defined according to the Academic Research Consortium definitions. Between April 2012 and December 2013, 232 patients (295 lesions) underwent BVS implantation. Among these, 25 patients (10.7%) were treated for 30 ISR lesions of whom 16 (53.4%) bare-metal ISR and 14 (46.6%) drug-eluting ISR. According to the angiographic ISR pattern, 15 (50%) lesions were focal and 15 (50%) diffuse, while 7 (23.3%) ISR lesions were located at a bifurcation site. Mean patient age was 68.3±12.3 years. Six (24.0%) patients were diabetics and 4 (16.0%) had chronic kidney disease. All the patients underwent PCI for stable (20, 80%) or unstable (5, 20%) angina. Intracoronary imaging was performed in 14 lesions (46.6%) while pre-dilatation and post-dilatation were performed before and after every BVS implantation. The mean number of BVS implanted per patient was 1.6±0.7, while mean BVS length per patient was 34.8±18.4 mm. Procedural success was obtained in all the cases. No intra-procedural or acute BVS-in-stent thrombosis was reported nor in-hospital BVS-related clinical events. At a median of 7 (IQR 1-13) months follow-up, 2 clinically-driven TLR (8.0% per patient and 6.6% per lesion) were reported due to recurrent-ISR at the BVS-in-stent implantation site. The re-ISR were successfully managed by re-PCI with drug-eluting balloon inflation. No cardiac death, Q-wave MI or EEBVS-in-stent thrombosis occurred at follow-up.

Conclusions: Although preliminary, this initial experience demonstrates that BVS can be utilised for the treatment of ISR with acceptable results at least at early follow-up. Further larger studies are needed to fully assess the safety and efficacy of BVS in complex lesions such as ISR.

A bioabsorbable everolimus-eluting coronary stent system for the treatment of complex coronary in stent restenosis: a prospective open-label trial

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Aims: The treatment of coronary in-stent restenosis (ISR) is still a relatively common problem for which a satisfactory solution is far to be found. The use of drug-eluting stents (DES) has been criticized by the risk of adding a second layer of struts in the arterial wall and exposing the patients to an increased thrombosis risk. The use of drug-eluting balloon (DEB) has been criticized because the eluted-drug stays in the arterial wall only for few weeks, a period of time not sufficient to eliminate the risk of a recurrent restenosis on the long term, and the frequent presence of an incomplete angiographic result requiring bailout stenting. A possible solution for these issues is, the use of Bioabsorbable vascular scaffold (BVS, ABSORB Abbott Vascular, Santa Clara, CA, USA). These stents provide short-term vessel scaffolding combined with prolonged drug delivery capability. The aim of this study was to investigate the safety of BVS for the treatment of coronary ISR.

Methods and results: Between January 2013 and June 2013, 27 patients (31 lesions), presenting a coronary ISR suitable for BVS implantation, were enrolled in a single arm, prospective, open label study at two centres in Italy. Primary end point was the occurrence of target vessel revascularisation (TVR) at 6 months. Secondary end point was the composite of death, myocardial infarction and TVR at 6 months. Main clinical and angiographic characteristics were as follows: mean age 63±9.0 years; diabetes mellitus 40%; chronic renal disease 11%, mean ejection fraction 46.4±8.5%; UA/NSTEMI 62%; STEMI 7%; Stable CAD 30%. A diffuse ISR pattern was present in 70% of the patients; the majority of the lesions was post DES ISR (67%). Mean lesion length was 31.1±16 mm. A number of 1.4 stents were implanted per lesion. Lesion pre-dilatation was mandatory, and post dilatation was needed in 60% of cases. In those patients in which procedural OCT evaluation was performed, it demonstrated proper stent expansion with minimal rate of struts malposition. BVS was successfully implanted in all patients, with no major procedural complications, no dissection occurred and final flow was TIMI 3 in all lesions. Over the 30 days follow-up no MACE occurred. At six months follow-up the cumulative MACE rate was 18,5% (5 patients). One patient died for non-cardiac reason and one patient died due to a possible stent thrombosis, thus resulting in overall mortality of 7,4% at six months. Cardiac death, myocardial infarction and TVR occurred in 3,7% (1 patient), 0% and 11,1% (3 patients) of patients respectively.

Conclusions: Our data suggest that BVS is safe and technically feasible for the treatment of ISR in patients presenting with both stable and unstable CAD. Despite the fact this registry deals mostly with long and diffuse coronary ISR lesions, the occurrence of clinically driven revascularisation at six month was promisingly low. These data could be considered hypothesis generator for a larger and randomised clinical trial.



Euro 14A-0P201

Everolimus-eluting bioresorbable scaffolds for treatment of patients presenting with STEMI bioresorbable scaffolds STEMI first study

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Aims: The aim of the present study is to investigate the angiographic and clinical outcomes following the implantation of the everolimus-eluting bioresorbable vascular scaffolds (BVS) for treatment of patients presenting with ST-segment elevation myocardial infarction

Methods and results: The present report is a prospective, single arm study evaluating the safety, feasibility and performance of BVS for treatment of patients presenting with STEMI. Baseline quantitative coronary angiography and post-implantation optical coherence tomography (OCT) data were evaluated. Clinical outcomes will be reported at 6-month follow-up. The intent-to-treat population comprises a total of 49 patients. Mean door-to-balloon time was 31.3±19.5 min. All patients were treated with unfractionated heparin at the dose of 70-100 UI/kg and dual antiplatelet therapy (aspirin plus, prasugrel in 45 patients, clopidogrel in 4 patients). Manual thrombectomy was performed in 38 patients. In 16 cases direct stenting was performed. A total of 65 scaffolds were implanted (12 patients received overlapping scaffolds – overlap was systematically intended to be minimal). The scaffolds lengths used were 12 mm, 18 mm and 28 mm, with scaffolds diameters 2.5 mm, 3.0 mm and 3.5 mm. Mean scaffold length per-lesion was 26.40±13.86 mm, mean scaffold diameter per lesion was 3.2±34 mm. A highly supportive wire was used in 5 cases and radial approach was performed in 26 patients (53.0%). The procedural success was 97.9% (48/49 patients), in one patient the delivery of the BVS was unsuccessful and a metallic DES was implanted. Clinical success was 97.9% (48/49 patients). The quantitative coronary angiography (reported only in patients implanted with BVS), showed in 50.0% of the patients a pre-procedure TIMI-flow 0 and a reference vessel diameter (RVD) 2.94±0.77 mm. In the non-totally occluded vessels the RVD was 2.62±0.63 mm, with a MLD of 0.75±0.44 mm and a mean diameter stenosis of 70.8±12.5%. After thrombectomy and balloon dilatation TIMI-flow grade 0 was present in 2.5% and 0.0% of patients respectively and TIMI-flow III in 52.5% and 59.3%% of the cases respectively. After scaffold implantation there were no cases of TIMI-flow 0 and a TIMI-flow III was achieved in 91.7% of patients, the mean post-procedure in-scaffold % diameter stenosis was 14.7±8.2%, in-scaffold MLD was 2.44±0.49 mm. No angiographically visible residual thrombus was observed at post-procedure. OCT analysis performed in 31 patients showed that the post-procedure mean lumen area was 8.02±1.92 mm², minimum lumen area 5.95±1.61 mm², mean incomplete scaffold apposition area 0.118±0.162 mm², mean intraluminal defect area 0.013±0.017 mm², and mean percentage malapposed struts per patient 2.80±3.90%. Scaffolds with >5% malapposed struts were 7. An interim analysis at 1-month follow-up showed a single clinical event, a non-target vessel revascularisation due to a non-Q-wave myocardial infarction. Clinical outcomes at 6-month follow-up will be available at the time of the presentation. Conclusions: The use of BVS in patients presenting with acute myocardial infarction was observed to be safe and feasible. Angiographic and OCT data

showed optimal acute results with high rate of TIMI III flow, low residual stenosis and good apposition of the scaffold. Six-month clinical outcomes will be available at the time of the presentation.



Early outcomes following primary PCI with everolimus-eluting bioresorbable scaffold implantation in young STEMI patients

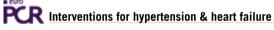
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Aims: The everolimus-eluting bioresorbable vascular scaffold (BVS ABSORB, Abbott Vascular, Santa Clara, CA, USA) has been designed to overcome the limitations of metallic stents. Although BVS has been tested in elective patients with stable angina showing promising results up to four-year follow-up, very limited data are available on the use of this device in ACS. Aim of this study was to investigate the feasibility and the early clinical outcomes following BVS implantation in young (<65 years) STEMI patients undergoing primary PCI.

Methods and results: As a part of an ongoing multicentre collaborative, prospective data collection on patients undergoing BVS implantation, a cohort analysis was performed on all STEMI patients that underwent primary PCI with BVS implantation. Procedural success was defined as BVS implantation at the "culprit" lesion site with less than 30% final residual stenosis and final distal TIMI 3 flow without in-hospital major adverse cardiovascular events (cardiac death, myocardial infarction or need for emergent revascularisation). Clinical events were defined according to the Academic Research Consortium definitions. Dual anti-platelet therapy after the BVS implantation was planned to have a duration of 12 months. Between April 2012 and December 2013, 58 STEMI patients underwent primary PCI with BVS implantation. Intracoronary imaging guide was performed in 2 (3.4%) cases. Four (6.8%) patients received 2 BVS implanted in overlap. Mean patient age was 54.9±10.5 years, while 45 (77.5%) patients were male and 3 (5.1%) diabetics. Pre-procedural TIMI flow was: 0-1 in 34 (58.6%), and 2-3 in 24 (41.3%) patients respectively. Manual thrombectomy was performed in 25 (43.1%) patients while pre-dilatation and BVS post-dilatation in all the cases. Mean BVS length per patient was 20.3±4.9 mm while mean BVS diameter was 3.1±0.4. Procedural success was obtained in 57 (98.2%) patients, because one experienced a reinfarction due to sub-acute BVS thrombosis (5 days after the index procedure) which was successfully managed with balloon only PCI. At a median of 3 months (IQR 1-11) follow-up, one patient experienced a non fatal sub-acute BVS thrombosis 18 days after the index procedure. No other major adverse cardiovascular events (cardiac death, MI, TLR, TVR) were reported.

Conclusions: Despite the limited number of selected cases, this experience suggests that BVS implantation in young STEMI patients can be successfully performed with acceptable immediate and early outcomes. Larger studies with longer follow-up are needed to fully assess the safety and efficacy of BVS in this sub-set of patients.



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Euro14A-MA001

Effects of percutaneous transluminal renal angioplasty on blood pressure evaluated with 24-hour monitoring

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Aims: The aim of this study was to clarify the effects of percutaneous transluminal renal angioplasty (PTRA) on blood pressure (BP) response by 24-hour BP monitoring, and identify preoperative features that predict a sufficient BP response to PTRA.

Methods and results: Out of 1,753 consecutive patients underwent coronary angiography, 706 patients with hypertension were followed by abdominal aortography for etiological screening of hypertension in a single cardiovascular centre from Jan 2010 till Dec 2013. Among patients with angiographically significant stenosis, 31 patients with more than 20 mmHg translesional pressure gradient at renal artery under hyperemic condition underwent PTRA. Ambulatory blood pressure monitoring (ABPM) was performed before and 1 month after PTRA, and patients were categorised as 'Responders' depending on average systolic BP decrease more than 10 mmHg. Although there was no significant difference in BP at admission between 13 Responders and 18 Non-responders (systolic, 148±18 vs. 144±18, p=0.47; diastolic, 70±9.3 vs. 68±13, p=0.59; mean, 96±7.8 vs. 93±13 mmHg, p=0.46), baseline BP on ABPM was significantly higher in Responders (systolic, 148±10 vs. 126±16, p<0.01; diastolic, 80±7.2 vs. 70±8.1, p<0.01; mean, 102±6.4 vs. 89±10 mmHg, p<0.01). Even in-hospital BP 2 days after PTRA was not different between the groups (systolic, 130±19 vs. 132±17 mmHg, p=0.71; #systolic, -19±17 vs. -11±15 mmHg, p=0.23), Responders achieved 16±6.7 mmHg decrease in systolic BP on ABPM 1 month after PTRA, yet did not in Non-responders (-7.0±13 mmHg, p<0.01). On clinical backgrounds and prehospital medication, there was no statistical difference. Also, translesional pressure gradient at hyperemic condition detected by pressure wire was not statistically different between the groups (36±32 vs. 30±24 mmHg, p=0.60). In terms of echorenographic parameters, acceleration time (AT) at baseline was significantly lower in Responders (72±19 vs. 94±26 msec., p=0.012), yet other parameters including renal/aorta ratio (RAR), peak systolic velocity (PSV) or resistive index (RI) were not significantly different between the groups (RAR, 3.7±1.7 vs. 3.6±1.9, p=0.92; PSV, 218±94 vs. 205±92 cm/sec., p=0.71; RI, 0.8±0.1 vs. 0.8±0.1, p=0.46). Assessment of hormonal parameters suggested that neither plasma renin activity (PRA), aldosterone concentration (PAC) nor BNP were preoperative predictors of BP response to PTRA (PRA, 3.8±5.3 vs. 2.6±4.3 ng/mL/h, p=0.52; PAC, 79±29 vs. 59±39 pg/mL, p=0.11; BNP, 80±75 vs. 169±197 pg/mL, p=0.13). However, interestingly, baseline renal function was significantly worse in Responders (serum creatinine, 1.47±0.67 vs. 0.99±0.34 mg/dL, p=0.026; eGFR, 36±19 vs. 55±23 mL/min/1.73 m², p=0.019).

Conclusions: The present study demonstrated that office BP did not represent patients' daily haemodynamic status, and high 24-hour BP was a potent predictor for sufficient BP response to PTRA. These findings may help clinicians to optimise risk-benefit profile of PTRA and reduce unnecessary intervention.



Euro14A-MA002

Safety and performance of the next generation EnligHTN renal denervation system in patients with drug-resistant, uncontrolled hypertension: three-month results from a first-in-human multicentre study

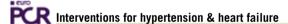
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Aims: Catheter-based renal artery denervation therapy has become established as a therapeutic option in patients with resistant hypertension. We further investigated the safety and performance of the next generation EnligHTNTM Renal Denervation System (St. Jude Medical) in patients with drug-resistant, uncontrolled hypertension.

Methods and results: The EnligHTN Renal Artery Ablation Catheter has 4 electrodes attached on a basket mounted at the tip of the catheter. The next generation EnligHTN RF Ablation Generator utilises a novel algorithm for the delivery of 1 minute of radiofrequency energy, optimised for simultaneous delivery of therapy through all 4 electrodes, with an interactive, intuitive user interface. Renal denervation was performed on 39 patients across 6 centres meeting the following inclusion criteria: 18-80 years of age, a systolic BP ≥160 mmHg, an average daytime systolic ambulatory BP ≥135 mmHg, on three or more antihypertensive agents (including a diuretic), and renal artery diameter ≥4 mm and length ≥20 mm. Patients with dual main renal arteries based on CT angiography were excluded. The primary endpoints are 1) to characterise the rate of serious procedural and device related adverse events from date of procedure through 6 months post procedure and 2) the change in office BP at 6 months post procedure. The secondary endpoints include the changes in 24 hour ambulatory BP and the characterisation of renovascular safety and renal function change over time from baseline. Renal artery CT angiography was repeated at 6 months in all patients. Through a femoral artery, a guiding catheter and then the multi-electrode ablation catheter were introduced in a renal artery, and RF energy was delivered simultaneously for 60 seconds across all 4 electrodes. Thereafter, the catheter was withdrawn slightly and rotated, and the denervation sequence repeated. This process was then repeated on the contralateral renal artery. To date 35 of 39 patients have completed 3-months of follow-up post procedure. No serious device or procedure related adverse events have been observed as adjudicated by an independent Clinical Events Committee. There were no clinically significant changes in renal function through 3-months as observed in eGFR, serum creatinine, cystatin C, or urine albumin-to- creatinine ratio. 3-month office BP reductions from

Conclusions: Accumulated results from all sites will be presented at the meeting. After 3-months follow-up post procedure in this first-in-human study, we conclude that data demonstrates the next generation EnligHTN Renal Denervation System continues to be safe, rapid, and effective in the treatment of patients with uncontrolled hypertension.



Euro14A-MA003

Differential impact of multi-electrode catheter-based renal sympathetic denervation on indexes of short-term blood pressure variability in patients with resistant essential hypertension

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Aims: Transluminal renal sympathetic denervation (RDN) reduces blood pressure (BP) in patients with treatment-resistant hypertension. We assessed the effect of RDN on indexes of short-term blood pressure variability (BPV) in patients with resistant hypertension.

Methods and results: Thirty-one patients with drug-resistant uncontrolled hypertension, participants in the EnligHTN I study (office BP 178.3/94.3 mmHg, 24-hour BP 147.5/81.2 mmHg), underwent ambulatory BP measurements at baseline and 6 months after RDN using the EnligHTN ablation catheter (St. Jude Medical, CA, USA). Twelve patients who met the EnligHTN I criteria matched for office BP with constant number and dosage of antihypertensive drugs during follow-up served as the control group. For each patient, we calculated the standard deviation (SD) of all systolic and diastolic BP recordings during 24-hour, daytime and nighttime, weighted 24-hour BP SD, average real variability (ARV) of 24-hour systolic and diastolic BP and the time rate of systolic and diastolic BP variation defined as the first derivative of the BP values against time. At 6 months post RDN, office BP and 24-hour BP was reduced by 25.6/10.3 mmHg (p<0.001/<0.001) and by 10.2/6 mmHg (p<0.001/0.001 for both cases) respectively whereas maximum values of systolic and diastolic BP were decreased from 185/106.5 to 170.8/97.7 mmHg (p<0.001/0.001 respectively). Office and 24-hour BP remained unchanged in the control group at 6 months follow-up (from 171.4/91.4 vs. 172.1/90.2, p=ns and from 145.3/83.8 vs. 144.7/86.0, p=ns, respectively). No significant changes were observed in SDs of 24-hour systolic and diastolic BP 6 months after RDN (from 15.9/10.5 to 15.9/10.8 mmHg), as well as in the daytime and nighttime SDs (p=NS for all). In contrast, the rates of systolic and diastolic 24-hour BP variation were significantly decreased 6 months after RSD (from 0.40/0.30 to 0.34/0.24, p=0.030/0.006 respectively). Likewise, significant changes occurred in the daytime and nighttime rates of systolic and diastolic variation after RDN. We observed no significant difference in any of the above mentioned BPV parameters in the control group. Twenty three patients (74.2%) were responders based on a reduction of office systolic BP>10 mmHg after RDN. Responders compared t

Conclusions: RDN exerts a distinct impact on short-term BPV indexes, as assessed by ABPM, in patients with drug-resistant uncontrolled hypertension. Although standard BPV indexes remained practically unchanged after RDN, the rate of systolic and diastolic BP variation was significantly decreased 6 months after RDN. These novel indexes might also be used as predictors of response.

Preliminary experience with an irrigated balloon-based radiofrequency device for catheter-based renal sympathetic renal denervation

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Aims: Several recent studies have shown that renal denervation is a safe and effective treatment for drug-resistant hypertension. We report our 12-month experience with the Covidien One-Shot irrigated balloon-based system.

Methods and results: Participants were between 18-80 years of age with office systolic blood pressure ≥160 mmHg (≥150 mmHg for patients with Type 2 diabetes) on ≥3 antihypertensive agents (including a diuretic). Using these criteria, 20 patients were identified and treated with the Covidien One-Shot, an irrigated radiofrequency-based balloon catheter. Patients were followed up at 1-3-6-12 months after the ablation treatment. Follow-up included patient review by a hypertension specialist, blood pressure measurement at the time of the review as well as blood and urinary sampling for glucose, urea electrolytes, microalbuninuria and brain natriuretic peptide. 24-hour ambulatory blood pressure monitoring was also undertaken prior to clinic review. All 20 patients underwent post procedure 1-month follow-up with 24-hour ambulatory blood pressure monitoring. This demonstrated an average systolic drop of 21±23 mmHg and an average diastolic drop of 6±4 mmHg. Thirteen patients completed 6-month follow-up. 24-hour ambulatory blood pressure monitoring at that point showed an average systolic drop of 39±19 mmHg and an average diastolic drop of 18±13 mmHg. Echocolour Doppler imaging of renal arteries at 6 months showed no evidence of renal artery stenosis. There was no significance difference in renal function at 6-months as assessed by creatinine clearance (mean Cockcroft-Gault eGFR84±27 mL/min, p=0.062).

Conclusions: This small study suggests that renal denervation using the Covidien One-shot renal denervation system appears to be efficacious for the treatment of resistant hypertension in this real-world population. Larger studies and longer follow-up are required to confirm these findings.



Euro14A-MA005

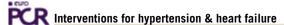
Estimating acute renal denervation procedural efficacy - Does electrical stimulation on renal arterial autonomic nerves really work?

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Aims: Transluminalrenal sympathetic denervation (RDN) reduces blood pressure (BP) in patients with treatment-resistant hypertension but it remains a blind procedure in the cath lab. Electrical stimulation of the renal arterial autonomic nerves has been identified as an end point of ensuring renal fiber disruption. We experimentally assessed the effect of electrical stimulation on renal arterial autonomic nerves before and after RDN by using multi-electrode renal ablation system.

Methods and results: A 7F introducer was inserted into each femoral artery in 10 juvenile farm swines under deep general anaesthesia. RDN was performed using the EnligHTN ablation catheter (St. Jude Medical, CA, USA) inserted from the right femoral artery. BP was continuously monitored from the left femoral artery. Electrical autonomic nerve stimulation at 20-Hz frequency, 5-ms pulse duration, and 15-mA output was applied for 60 s to 3 minutes via the distal pair of a quadripolar catheter introduced via the right femoral artery and placed successively in the ostium, proximal, middle and distal part of each renal artery before and after RDN. Renal angiograms performed before and after RDN were normal in all cases showing no apparent injury. Electrical stimulation was also applied using different settings (frequency of 20 Hz, with an amplitude of 15 V and pulse duration of 10 ms) as well as an open irrigation catheter. BP and heart rate remained unchanged after electrical stimulation of either 1, 2 or 3 minutes duration applied in the ostium, proximal, middle and distal part of each renal artery. There was also no response to electrical stimulation of either renal artery after RDN.

Conclusions: Although electrical stimulation of the renal arterial autonomic nerves has been reported as an end point of effective RDN in dogs, different settings of electrical stimulation of the renal arterial autonomic nerves in farm pigs failed to affect either BP or heart rate.



Euro14A-MA006

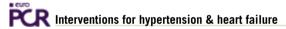
Results of unilateral catheter-based renal sympathetic denervation employing the Symplicity system

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Aims: Renal denervation has become a routine therapy option for hypertensive patients suffering from systolic blood pressure >160 mmHg despite three or more drugs in Europe. Since arterial hypertension is often associated with severe atherosclerosis some candidates present with renal arteries that preclude "Symplicity" denervation mostly because vessel diameter is <3 mm. However in some patients unilateral renal denervation seems possible. Until now there is no data available on this approach. Here we report a retrospective analysis of eight procedures that have been performed unilaterally.

Methods and results: All patients that received renal denervation have been included in the ALSTER BP registry. Procedural details and baseline characteristics were documented. Routine data were collected either from outpatient visits or by telephone interview from referring physicians. Reasons for unilateral denervation were severe atherosclerosis (3/8), anatomical variability (2/8), prior stent implantation in the area of ablation (1/8), preprocedural dissection (1/8) and state after nephrectomy (1/8). The mean office blood pressure at baseline was 188/86 mmHg (±13/13), mean systolic ambulatory blood pressure 162 mmHg (±23 mmHg). The average number of antihypertensive drugs taken was 5(±1). Seven patients suffered from diabetes (88%). Six patients (75%) showed a reduction of systolic blood pressure >10 mmHg six months after the procedure, one patient was lost to follow-up. The mean reduction of the systolic office blood pressure was 34 mmHg (±13 mmHg). The number of antihypertensive drugs was not changed during follow-up. Glomerular filtration rate as marker for renal function showed no significant difference.

Conclusions: Renal denervation is a safe and effective therapy option even if performed unilaterally. In clinical practice the most common reason for a unilateral procedure is severe atherosclerosis of the renal arteries. Initial data support the notion that even unilateral denervation may be successful; this approach needs to be tested in larger studies.



Euro14A-MA007

Beneficial effects of multi-electrode catheter-based renal sympathetic denervation on left ventricular mass, diastolic function and neurohormonal activation in resistant hypertension

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Aims: In this study we investigated whether multi-electrode catheter-based renal sympathetic denervation (RDN) has favourable effects on left ventricular structural and functional indices, as well as on neurohormonal activation reflected by N-terminal pro B-type natriuretic peptide (NT-proBNP).

Methods and results: Twenty patients with resistant hypertension [age: 57±10 years, 13 males, office blood pressure (BP): 180/96±19/16 mmHg under 4.4±0.6 drugs] who underwent RDN and 10 patients [age: 54±8 years, 6 males, office BP: 189/99±11/13 mmHg under 4.5±0.5 drugs] who served as controls were followed-up for 6 months. A full transthoracic echocardiographic study was performed in all patients and left ventricular mass was calculated using the Devereux formula and was indexed for body surface area and height. Moreover, blood sampling was performed in order to estimate NT pro-BNP levels. Apart from office systolic and diastolic BP reduction by -41±19 mmHg and -16±12 mmHg, respectively, (p<0.001 for both), RDN decreased mean interventricular septum thickness from 12.1±1.2 mm to 11.6±1.2 mm (p=0.04) and left ventricular mass index from 136±20 g/m² (56.5±8.7 g/m².7) to 123±22 g/m² (51.2±9.2 g/m².7) (p=0.004) at 6 months. Left atrial diameter and volume were reduced from 42.1±4.3 mm to 41.0±3.6 mm (p=0.002) and from 62.3±13.5 ml to 51.8±9.5 ml (p=0.001), respectively. Regarding diastolic function RDN caused an increase in mitral valve EÎ'/AÎ' ratio from 0.62±0.28 to 0.82±0.39 (p=0.021) and a decrease in the E/EÎ' ratio from 14.8±5.9 to 11.7±3.1 (p=0.009). Furthermore, RDN resulted in a statistically significant reduction in NT-proBNP levels from 85±34.4 pg/ml to 58.6±36.9 pg/ml (p<0.001). No significant changes in all the above parameters were observed in the control group (p=NS).

Conclusions: In resistant hypertensive patients RDN besides BP reduction causes favourable cardiac remodeling and attenuation of neurohormonal overdrive as reflected by decreased NT-proBNP levels. These results suggest pleiotropic cardiovascular benefits of RDN therapy in the setting of resistant hypertension.

In-stent renal denervation using the TIVUS™ system: worldwide first cases

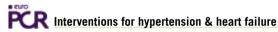
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Aims: To assess the TIVUSTM System for treatment of patients with severe resistant hypertension post renal stenting.

Methods and results: Renal sympathetic denervation was introduced as a treatment for resistant hypertension. TIVUSTM (Cardiosonic, Israel), an innovative ultrasonic energy catheter-based renal denervation technology, is currently being studied in humans. Patients with renal artery stenosis were excluded from all studies of RDN, due to inherent limitations of both Radiofrequency (RF) and other Ultrasound occlusive technologies. TIVUSTM presents an advanced modality for renal denervation, enabling efficient RDN while preserving arterial integrity. Pre-clinical studies performed in a swine model confirmed thermal, angiographic and histological safety for multiple activation sites of the TIVUS catheter inside renal artery metal stents. We now present the first two reported cases of human renal denervations performed through a renal stent. Patient A-70 YO Male, diabetic, post right renal stenting (2007), severe resistant HTN despite 4 daily anti-HTN medications. Baseline Office BP (OBP) 178/68 mmHg, mean 24-hr Systolic ABPM 160 mmHg. Patient B- 67 YO Male, diabetic, post left renal stenting (2009), resistant HTN despite 4 daily anti-HTN medications. Baseline OBP 150/83 mmHg, mean 24-hr Systolic ABPM 135 mmHg. Both patients underwent bilateral ultrasonic renal denervation. including multiple in-stent applications. Ultrasonic excitations were administered both within and further distally to the stented segment. The procedure was technically successful and uneventful. During Follow-up (FU): No adverse events were recorded for both patients. Patient A: At 1 & 3-month FU, OBP decreased by 43/7 and 51/7 mmHg, respectively. Patient B: At 1-month FU, OBP decreased by 14/9 mmHg.

Conclusions: The TIVUS ultrasound-based technology presents an advanced modality for RDN, avoiding vessel wall contact and sparing the endothelium. Its advantages now include a promise for safe and effective in-stent treatment in high risk, resistant HTN patients post renal artery



Renal denervation with a percutaneous bipolar radiofrequency balloon catheter significantly reduces 24-hour ambulatory blood pressure in patients with resistant hypertension: results from the REDUCE-HTN Study

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Aims: The objective of the REDUCE-HTN Clinical Study was to evaluate the performance of the Vessix Renal Denervation System (Boston Scientific, Natick, MA) in treating medication-resistant hypertension. Secondary outcome measures include the reduction in 24-hour ambulatory blood pressure at 12 months.

Methods and results: The REDUCE-HTN trial is a prospective, multicentre, single-arm study. Patients with office-based systolic blood pressure ≥160 mmHg despite compliance with ≥3 antihypertensive medications at maximally tolerated doses were treated with the Vessix System, which consists of a radiofrequency generator and a balloon catheter mounted with an array of bipolar radiofrequency electrodes. Twenty four hour ambulatory blood pressure monitoring was conducted at baseline and at 6 and 12 months following the renal denervation procedure. Mean baseline office blood pressure was 182.4±18.4/100.1±14.0 mmHg among enrolled patients (N=146; age 58.6±10.5 years, 61% men, 28.1% with type 2 diabetes). Baseline 24-hour ambulatory blood pressure was 153.0±15.1/87.5±13.2 mmHg (n=103); 90% of patients had systolic pressure >135 mmHg. At 6 months, mean ambulatory pressure was reduced by -8.4±14.4/-5.9±9.1 mmHg (n=69; p<0.0001) and 12-month results to date show a mean reduction of −10.1±15.3/ −6.2±8.3 mmHg (n=32; p<0.001). Patients with baseline ambulatory systolic pressure ≥160 mmHg had a mean reduction of -16.5 mmHg at 6 months (n=22), whereas those with baseline pressure <160 mmHg had a mean reduction of -0.85 mmHg (n=47). Ambulatory systolic pressure <135 mmHg was achieved in 25% of patients at 6 months and 26% at 12 months.

Conclusions: Results from ambulatory monitoring at 6- and 12-months post-procedure support the efficacy of the Vessix System in treating resistant hypertension.

PCR Interventions for hypertension & heart failure

Euro 14A-0P204

Longer term safety and efficacy of catheter-based renal sympathetic denervation using a multi-electrode renal artery denervation catheter in patients with drug-resistant essential hypertension: 24-month results of a first-in-human, multicentre study

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Aims: Drug-resistant hypertension is a growing problem around the world. Percutaneous sympathetic renal artery denervation is emerging as an approach for the treatment of patients who do not respond adequately to optimal medical therapy. 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 EnligHTN-I first-in-human study was designed to assess the safety and efficacy of this multi-electrode ablation system in patients with drugresistant hypertension. A total of 46 patients (average age 60±10 yrs taking an average of 4.7±1.0 medications) were enrolled in this study. 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, 6, 12 and 18 months were -28/10, -27/10, -26/10, -27/11 and -24/10 mmHg (p<0.001) respectively. For the 24 hr ambulatory blood pressure reductions at 1, 3, 6, and 12 was -10/5, -10/5, -10/6 and -7/4 mmHg (p<0.001 for 1,3,6 and P<0.0094 for 12 months) respectively. At 18 months 77% of patients were responders (at least 10 mmHg reduction in systolic blood pressure) and 23% had normalized blood pressure (<140 mmHg systolic blood pressure). The study utilised an independent Clinical Events Committee to adjudicate all adverse events. Based on their adjudication, there were 4 device/procedure related serious adverse events in 3 subjects reported to date which include: hypertensive renal disease progression, symptomatic hypotension, worsening of pre-existing renal artery stenosis and new stenotic lesion. Twenty-four month efficacy and safety data will be presented at the meeting. **Conclusions:** We conclude that data demonstrates that the EnligHTN ablation system continues to be safe and effective in the treatment of patients with drug-resistant hypertension.

PCR Interventions for hypertension & heart failure

Euro14A-0P205

The Paradise renal denervation system: initial clinical results from the ACHIEVE study

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Aims: The Paradise® Renal Denervation System (ReCor Medical, Palo Alto, CA) delivers ultrasound energy to perform targeted circumferential denervation of the renal afferent and efferent sympathetic nerves with the goal of achieving a reduction in systemic arterial blood pressure (BP), and mitigating end organ effects due to sympathetic over-activity. The Paradise System has been designed to deliver energy to create an optimised tissue thermal profile to achieve targeted ablation of nerves surrounding the renal artery, while preserving the integrity of the renal arterial wall through a unique cooling mechanism. Clinical evaluation of the safety and effectiveness of the Paradise System is on-going. Initial results on the first 50 patients enrolled in the ACHIEVE post-market clinical study will be presented.

Methods and results: The ACHIEVE study is a prospective, multicentre, non-randomised, post-market study designed to evaluate the long term clinical outcome of renal denervation with the Paradise System in patients with resistant hypertension, as defined by the 2007 ESH/ESC Guidelines. Renal arteries must be ≥20 mm in length and ≥4 mm in diameter. Exclusions include renal artery stenosis, and moderate to severe renal insufficiency. Eligible patients are treated bilaterally with the Paradise system (up to 3 treatment emissions per renal artery) and followed for 12 months. Safety endpoints include access site and access-related vascular injury; renal artery complications; renal complications; arterial and venous thromboembolic events; systemic effects. Efficacy endpoints include change in office and ambulatory systolic and diastolic BP; change in medication intake; change in pulse pressure and nocturnal dipping; and change in quality of life measures. Currently nine clinical centres in Europe are actively recruiting patients. Mean age at treatment is 64±10 years (range 45-86 years) and 57% of patients are male. The mean follow-up duration is 193±92 days. At baseline, mean office systolic BP is 175±20 mmHg (n=50) and mean ambulatory systolic BP is154±12 mmHg (n=42). Early data demonstrate a sustained decrease in baseline systolic BP over time with an average reduction of −14 mmHg at 1 month post treatment (n=34), increasing to −16 mmHg at 6 months (n=17). As previously demonstrated, excluding patients whose office systolic BPs at baseline were <160 mmHg, resulted in a larger treatment effect with average decreases over time of −19 and −22 mmHg at 1 and 6 months post treatment respectively. Responder rate at 6 months (defined as a decrease in systolic BP≥10 mmHg) is 70%. The average decrease in ambulatory BP at 6 months is −10 mmHg (n=14). The most commonly reported adverse event is procedural-related pain. There have been no reports of renal artery stenosis; renal complications; or thromboembolic events.

Conclusions: Initial results from the ACHIEVE post market study are consistent with initial clinical feasibility data and demonstrate that The Paradise System can be used safely to effectively reduce blood pressure in patients with resistant hypertension.

Renal denervation using the novel therapeutic intra-vascular ultrasound (TIVUS $^{\text{TM}}$) catheter system – Preliminary report of first-in-man safety and performance study

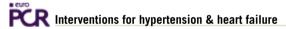
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Aims: To assess the TIVUS System safety and performance in patients with severe resistant hypertension.

Methods and results: Hypertension (HTN) is a world-wide epidemic. Catheter-based renal denervation is in growing use for treatment of resistant HTN. The TIVUSTMSystem (Cardiosonic, Israel) - an innovative modality applying ultrasonic energy for catheter-based renal denervation (RDN) was recently developed and studied in humans. It enables efficient RDN while preserving artery integrity, in contradistinction to RF-based technology. Following extensive histology & physiology studies in swine, the TIVUSTM System was now evaluated in a clinical setting as part of the First-In-Man study. TIVUSTM-I is a prospective, multicentre, non-randomised, single-arm, open-label clinical study. The study cohort of patients met the following eligibility criteria: >3 anti-HTN medication including a diuretic, mean office blood pressure (OBP) >160 mmHg, average 24-hour systolic ambulatory BP monitoring (ABPM) >135 mmHg and patient compliance. Eligible anatomy included renal arteries >4 mm diameter and >20 mm length. If stenosis or aneurism were present, treatment was allowed when appearance was <50% and according to interventionalist discretion. Clinical endpoints include procedural, cardiac and kidney safety with patients followed to one-year. A total of 18 patients. 14 (78%) male, underwent TIVUS RDN. Fifteen patients were enrolled in the clinical study and 3 treated under compassionate use applications (two patients post renal stent and one with impaired renal function). All patients presented with resistant hypertension based on 2-weeks monitoring period, medication compliance and 24-hour ABPM. Overall, the population is representative of hypertensive patients resistive to drug therapy. Baseline mean OBP was 174.3/88.4 mmHg, with an average of 4.7/1.3 anti-hypertensive medications. Patients underwent bilateral ultrasonic RDN (median treatment points of 8). The procedures were technically uneventful with no device-related complications. At all post-procedure time points both mean systolic and diastolic BP were lower than baseline blood pressure. At 1, 3-month follow-up, patients' OBP decreased by 28/10 mmHg (N=18), 25/10 mmHg (N=16), respectively. Two patients required anti-HTN medication reduction.

Conclusions: The data currently available supports technical success with absence of device-related complications and a positive lasting reduction in BP for the treated patients. The novel ultrasound based TIVUSTM System performed safely with BP reductions well within the RDN expected range, which may reduce the patients' cardiovascular risk.



Euro14A-0P207

Preliminary results from the REALISE trial show endovascular ultrasound renal denervation ultrasound associated with decrease in sympathetic overactivity

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Aims: Catheter-based renal denervation has emerged as a method for treating the overactivity of the sympathetic nervous system. The PARADISE system (ReCor Medical, Palo Alto, CA) is a unique therapeutic non-focused ultrasound system designed to perform circumferential renal denervation while preventing damage to the renal artery. The purpose of the REALISE trial is to evaluate the safety and efficacy of the PARADISE system in patients suffering from resistant hypertension.

Methods and results: The REALISE trial is a 20-patient prospective study conducted by multidisciplinary teams at two sites in France. Patients suffering from resistant hypertension as defined by the ESH-ESC guidelines (office blood pressure above 140/90 mm Hg with a minimum of 3 antihypertensive drugs including a diuretic) were screened and eligibility further confirmed by home and/or ambulatory measurements. Renal denervation was performed bilaterally with the PARADISE system, delivering 2 to 3 ultrasound emissions in each artery. All patients underwent CT-scan or MRI at baseline and follow-up to assess the renal arteries. Preliminary results indicated that 63% of enrolled and treated patients were under spironolactone therapy. Bilateral denervation was performed by delivering an average of 5.7 ultrasound emissions in each subject (average heating time 3.3 minutes per subject). Sedatives and analgesics were administered during the intervention and the treatment was well tolerated by all patients. Preliminary results at 12 months were comparable to published data on radiofrequency renal denervation with an average reduction in office and ambulatory blood pressure of -27/-6 mmHg and -15/-7 mmHg, respectively. Autonomic testing showed that muscle sympathetic nerve activity (MSNA) decreased by 20% after denervation with improvement of baroreflex sensitivity and reduction of peripheral chemoreflex activity. Systematic imaging of the renal arteries showed no arterial stenosis or arterial damage at follow-up.

Conclusions: Endovascular ultrasound renal denervation appears to be a safe and effective treatment for resistant hypertension. Beyond blood pressure reduction, ultrasound renal denervation was associated with reduction of sympathetic activity. Results on all 20 patients from the REALISE study will be presented at the conference.

Safety and effectiveness of catheter-based renal sympathetic denervation for the treatment of resistant hypertension: 12-month results of the RAPID study

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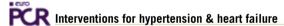
Frankfurt, Germany; 5. 5St. Franziskus-Hospital, Munster, Germany; 6. Ziekenhuis Oost-Limburg, Genk, Belgium;

7. Universitatklinikum, Bonn, Germany; 8. Hospital San Raffaele, Milan, Italy; 9. 9University of Heidelberg Medical Klinik III, Heidelberg, Germany; 10. Universitair Medisch Centrum, Utrecht, The Netherlands; 11. Erasmus MC Thoraxcenter, Rotterdam, The Netherlands

Aims: The aim of the RAPID study is to evaluate the safety and effectiveness of the OneShotTM Renal Denervation System for the treatment of resistant hypertension.

Methods and results: RAPID is a prospective, multicentre, single-arm study that enrolled 50 patients (mean age 63.0 years, 58.0% male) at 11 clinical sites in Europe and New Zealand. Eligible patients had an office systolic blood pressure ≥160 mmHg and were on a regimen of ≥3 antihypertensive medications including a diuretic. Patients were scheduled for follow-up at 1, 3, 6, 12, 24 and 36 months. The mean baseline office systolic and diastolic blood pressure measurements were 181.6 ± 20.8 and 95.5 ± 15.5 mmHg, respectively. Patients were on a mean of 5.1 antihypertensive medications at baseline. The median procedure time, defined as time from initial arterial access to closure, was 48 minutes (range 32-71 minutes) and the median OneShot system ablation time was 4.0 for both arteries, 2.0 minutes per artery. Renal artery denervation with the OneShot system significantly reduced office blood pressure from baseline to 1, 3, and 6 months by -17/-7, -17/-7 and -20/-8 mmHg (p<0.0001/p=0.0009, p=0.0002/p=0.0014 and p<0.0001/p=0.0002). A drop of ≥10 mmHg in office systolic blood pressure was achieved in 59.6%, 54.5% and 61.7% of patients at 1, 3 and 6 months, respectively. The 24-hour ambulatory blood pressure measurement was also significantly reduced by -11/-6 at 6 months compared to baseline (p=0.0085/p=0.037). At discharge, there were no serious adverse events related to groin and vascular access or renal injury. There were 3 Clinical Events Committee-adjudicated device-related adverse events, 2 (flank pain and bradycardia) resolved within 72 hours, and a third (access site inflammation) was associated with closure device use.

Conclusions: The results of the RAPID study demonstrate safe delivery of radiofrequency energy for renal sympathetic denervation and continued efficacy as evidenced by a significant reduction in blood pressure out to 6 months. Twelve-month outcomes of the RAPID study will be presented at EuroPCR.



Euro14A-0P209

Renal artery denervation with a new simultaneous multielectrode catheter for treatment of resistant hypertension: six-month results from the SYMPLICITY Spyral First-in-Man Study

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Aims: The Symplicity SpyralTM multielectrode renal denervation system was designed to reduce treatment time and resource use while providing a safe and effective treatment for lowering blood pressure.

Methods and results: The Spyral system tested in this study features a unipolar array of 4 electrodes mounted on a nitinol shaft in a spiral configuration and delivers radiofrequency energy simultaneously to 4 treatment sites in a controlled configuration. This prospective, nonrandomised, open label, first in man feasibility study enrolled subjects with resistant hypertension defined as an office systolic blood pressure of ≥160 mm Hg (≥150 mm Hg for type 2 diabetics) despite adherence to an antihypertensive regimen of at least 3 drug classes (preferably including a diuretic). Exclusion criteria included an estimated glomerular filtration rate of <45 mL/min/1.73 m², type 1 diabetes mellitus, renal artery stenosis of >50%, renal artery aneurysm, and prior renal artery intervention. The protocol specified one renal denervation treatment per artery with planned radiofrequency energy delivery of 60 seconds per artery. Subjects were followed at 1, 3 and 6 months and will be followed yearly to 3 years post renal denervation. The primary safety endpoint is acute procedure safety associated with the delivery and/or use of the Spyral catheter. The primary effectiveness endpoint is change in office BP from baseline to six months. Among the first 40 subjects, mean age was 62 years, 60% were men, 43% had type II diabetes mellitus, and baseline estimated glomerular filtration rate was 84±22 mL/min/1.73 m². Baseline systolic and diastolic blood pressure was 182±17 mm Hg and 95±12 mm Hg, respectively, and the mean number of antihypertensive drug classes was 4.6±1.2. Device success rate was 100%, and procedure success rate was 93% due to 3 vascular complications at the access site, none of which were related to energy delivery. The mean renal denervation procedure time was 24 minutes (defined as the time from RDN catheter insertion to guide catheter removal). One additional femoral artery pseudoaneurysm occurred 3 days post treatment; subject was readmitted and successfully treated with compression. No new renal artery stenosis or hypertensive emergencies occurred, and there was no clinically meaningful change in renal function. The change in office-based blood pressure was $-16\pm20/-7\pm12$ mm Hg at 1 month, (N=40), and $-15\pm23/-7\pm10$ mm Hg at 3 months (N=29), p<0.01 for all

Conclusions: The SYMPLICITY Spyral First-in-Man Study showed acceptable acute and 3 month safety while providing a significant reduction in office blood pressure compared to baseline. Renal denervation using the Symplicity Spyral multielectrode catheter was safely delivered in a short procedure time. Available 6 month follow-up results on 50 subjects will be reported in May.

Safety and effectiveness of renal artery denervation in real world patients with diabetes mellitus and uncontrolled hypertension: results from the global SYMPLICITY registry

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Aims: The Global SYMPLICITY Registry was designed to assess the safety and effectiveness of the SymplicityTM renal denervation system in patients with uncontrolled hypertension alone or with concomitant conditions also characterised by sympathetic nervous system overdrive such as diabetes mellitus. Radiofrequency renal artery nerve ablation has been shown in clinical trials to safely lower blood pressure in patients with resistant hypertension (uncontrolled blood pressure despite use of 3 or more antihypertensive drugs including a diuretic) including patients with type 2 diabetes. Furthermore, early data from patients with impaired glucose tolerance and resistant hypertension indicates that renal denervation can also improve glucose metabolism and insulin resistance in diabetic patients.

Methods and results: The Global SYMPLICITY Registry is a prospective, open-label, multicentre study of hypertensive patients treated per the Symplicity Instructions for Use. Office and 24-hour ambulatory blood pressure change, measures of glucose tolerance, serum chemistries, vascular complications and other protocol-defined safety events are collected. Patient selection is at the discretion of the treating physician according to local guidelines. The Global SYMPLICITY Registry will enroll approximately 5,000 patients. Outcomes are compared between patients with and without type 2 diabetes mellitus. Approximately 33% of the first 450 patients enrolled in the registry and followed to 6 months have type 2 diabetes. Patients with diabetes are older (mean age 63 vs. 60 years, p<0.0001), have a higher BMI (31.9 vs. 30.1, p<0.0001), a higher rate of renal dysfunction (36.2%) vs. 27.3%, p<0.01) and more cardiac disease (57.0% vs. 45.8%, p<0.001) than patients without type 2 diabetes. Baseline office blood pressure was 164.5/86.2±21.4/14.2 mmHg in diabetic patients and 163.9/90.2±25.2/16.8 mm Hg in non-diabetic patients. There were similar significant drops from baseline in office blood pressure at 6 months post-procedure for both groups (-13/-5 mm Hg for diabetic patients and -11/-4 mm Hg for non-diabetic patients all p<0.01). For patients with diabetes fasting glucose was 160 mg/dl at baseline and 130 mg/dl at 6 months (p<0.0001). Renal function remained stable in both groups with an estimated glomerular filtration rate of 72.8 and 78.0 ml/min/1.73 m² at baseline and 71.4 and 75.1 ml/ min/1.73 m² at 6 months in patients with and without diabetes. The overall rate of adverse vascular event including dissection, and pseudoaneurysm was low (1.0%) and similar between groups. Hypertensive crisis occurred in 0.8% of patients overall. There were no cases of new renal artery stenosis. Conclusions: Renal denervation with the Symplicity catheter significantly and similarly lowered blood pressure in real world patients with uncontrolled hypertension with and without concurrent diabetes mellitus. Outcomes according to diabetes status in ~1,000 patients followed through 6 months will be available for presentation including assessment of HbA1c, glucose tolerance and insulin sensitivity following renal denervation therapy.

Interventions for hypertension & heart failure

Euro14A-0P21

Safety and performance of the EnligHTN renal denervation system in patients with uncontrolled hypertension: one-month results of the first 100 patients in the EnligHTN II study

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Aims: Percutaneous sympathetic renal artery denervation is emerging as an approach for the treatment of patients with resistant hypertension. Single-tip electrode radiofrequency (RF) ablation catheters have been used to achieve sympathetic fiber interruption through the renal artery wall. However, longer-term, real world results from Renal Denervation trials with larger number of patients and sites including moderate HTN and medication intolerant patients have not been reported. We further investigated the safety and efficacy of a multi-electrode catheter ablation system (EnligHTN) developed by St. Jude Medical.

Methods and results: The EnligHTN-II study is a post-market clinical investigation to further evaluate the safety and effectiveness of the EnligHTN Renal Denervation System in patients with uncontrolled hypertension. Patients meeting baseline and enrollment criteria were assigned to one of three groups; Group A, office systolic BP ≥160 mmHg and estimated GFR ≥45 mL/min per 1.73 m², Group B, office systolic BP ≥140-159 mmHg and estimated GFR ≥45 mL/min per 1.73 m² and Group C, office systolic BP ≥140 mmHg and estimated GFR ≥15 mL/min per 1.73 m². For all three groups subjects were required to be on at least 3 anti-hypertensive medications (including 1 diuretic), or to have documented drug intolerance to 2 or more of the 4 major classes of anti-hypertensives (ACE/ARB, Calcium Channel Blockers, Beta Blockers, or Diuretic) and to be unable to take 3 anti-hypertensive drugs. The results of the first 100 patients that had a procedure with 1-month follow-up will be summarized by entire cohort and by sub-group (A-C). A total of 100 patients (average age 62.2±10.1 yrs taking an average of 3.87±2.02 medications) were included in this sub-analysis. Of these patients 39% were female, 32.3% had Coronary Artery Disease, 43% had hyperlipidemia, 20% had type II Diabetes Mellitus, and 11% had history of sleep apnea. Bilateral renal nerve ablation was performed using a percutaneous femoral approach. The mean ablation time was 43.4±17.5 minutes. Baseline average office systolic blood pressure was 171.3±21.1 mmHg and average 24 hour ambulatory blood pressure was 154.9±16.4 mmHg. As of 20 Dec 2013, there were 89 1-month follow-up visits completed. The average reduction in office BP (OBP) was −11/−6. Out of these 89 subjects, 75 subjects were able assigned to one of the 3 groups according the protocol. The average reduction in OBP per group is as follows; Group A −17/−8, Group B −5/−2 and Group C −5/−5. The data will be refreshed prior to the meeting to include patients with 1 month of follow-up data. Safety data as adjudicated by

Conclusions: In this real world post market study, we conclude that data demonstrates that the EnligHTN ablation system continues to be safe and effective in the treatment of patients with uncontrolled hypertension.



Cost-effectiveness of catheter-based renal sympathetic denervation for treating resistant essential hypertension in Germany

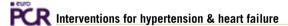
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Aims: There are 2.8 million Germans suffering from blood pressure which remains above goal despite treatment with 3+ medications. Recently, renal denervation with the Vessix system has been shown to be effective at reducing blood pressure in these medication resistant hypertensive patients (RHT). This analysis sought to estimate the long-term clinical impact of blood pressure reduction in terms of reduced incidence of cardiovascular disease (CVD) and end-stage renal disease (ESRD) and the cost effectiveness of the Vessix system.

Methods and results: A Markov model was developed to quantify the impact of reduction in systolic blood pressure (SBP) on the incidence of coronary heart disease, congestive heart failure, stroke and ESRD over a patient's lifetime. Patient characteristics and estimated blood pressure reduction were taken from the Vessix REDUCE HTN trial of renal denervation. SCORE risk charts and Framingham study data were used to establish the initial risk of CVD which was found to be nearly 30% over 10 years. Meta-analysis of blood pressure drug trials was used to estimate risk reduction from a 30 mmHg reduction in SBP, which was determined to be 50-80%, depending on patient age. Data on ESRD was taken from the literature. Costs were taken from published DRG values and the literature. Reduction in SBP of 30 mmHg, as seen in the Vessix trial, was predicted to avoid 1,443,836 CVD and ESRD events in the 2.8 million patients with RHT. This reduction in events is likely to provide a 59-year old patient undergoing RDN an additional 1.7 years of life and 0.88 quality-adjusted life years (QALY). The procedure was estimated to be cost saving to the health system over a patient's lifetime. At 10 years, the incremental cost per life year gained (LYG) was 5,899€ and per QALY gained was 7,986€. Probabilistic sensitivity analysis of 5,000 iterations of this model using a 59 year old patient found a mean gain in life expectancy of 1.73 years (95% CI: 1.43-2.05) and 0.88 QALYs (95% CI: 0.72-1.05). RDN was estimated to be cost effective (<35,000€/QALY) in patients up to age 84. There was a 51% probability the procedure would be cost saving over a lifetime and a 78% probability that total incremental costs would not exceed 2,000€ over a lifetime.

Conclusions: RHT represents a substantial health risk to the patient and lowering SBP in these patients is already a priority in many European countries. This analysis suggests renal denervation with the Vessix system is a highly cost effective treatment for this difficult to manage and high risk population.



Euro14A-0P213

Multi-modality intra-arterial imaging assessment of the vascular trauma induced by four different catheter-based renal sympathetic denervation systems

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Aims: Renal denervation is a promising treatment for resistant hypertension. Preliminary reports have demonstrated procedure-induced vascular injury by several renal denervation catheters. As new systems are being introduced, the impact of catheter design on the occurrence of acute vascular injury remains unknown. By using quantitative angiography, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) we aimed to assess the acute vascular response in renal arteries of patients undergoing renal denervation for the treatment of resistant hypertension with 4 different systems.

Methods and results: This is a single-centre prospective observational study. The study population consisted of 13 patients that underwent bilateral renal denervation with 4 different renal denervation systems; Symplicity (Medtronic, Minneapolis, MN) (n=3), Vessix V2 (Boston Scientific, Natick, MA) (n=2), Paradise (Recor Medical, Palo Alto, CA) (n=5) and Oneshot (Covidien, Dublin, Ireland) (n=3). All patients underwent OCT post renal denervation and 10 patients underwent IVUS pre and post denervation. Angiographic, IVUS, and OCT analysis were performed offline. Angiographic and IVUS analysis included morphometric renal artery measurements pre and post denervation. OCT analysis included assessment of markers of vascular trauma (dissection, thrombus, oedema). In angiography, only one dissection (in the Oneshot group) was visualised, while luminal irregularities were observed in 6 arteries, with no differences between the groups. No differences were observed for reference and minimal lumen diameter or % area stenosis post-denervation compared to pre-denervation. These differences did not reach significance in subgroup analysis. IVUS pullbacks were available for 19 arteries pre-denervation and for 20 arteries post-denervation. In the entire cohort, there were no differences in mean and minimum lumen or vessel area between post-denervation and pre-denervation. There was however a trend towards an increase (1.44±3.03, p=0.052) of % intima-and-media volume. 23 OCT pullbacks were acquired, with a total of 3,851 frames screened. Out of them, 2,802 frames (72.8%) met the quality criteria and were analysed. Dissections were detected in 8 pullbacks, all associated with the use of balloon catheters (47.1% for balloon devices versus 0 for Symplicity; p=0.06). The percentage of frames with dissection was 11±20%, without difference among the groups. The mean dissection angle was 53.9±28.4°. Thrombus was detected in 17 arteries (73.9%), with an incidence of thrombus containing frames of 10±10%, and a mean thrombus area of 0.08±0.05 mm². Mean thrombus area was slightly larger in the Symplicity group (mean area: 0.17±0.05 mm²; p<0.05 for all comparisons). Oedema was observed in 16/23 arteries (69.5%); mean percentage of frames with oedema was 13±16% without significant differences between the groups. Balloon-to-artery ratio was significantly positively correlated to the percentage of frames with dissection (b=76.3, r²=0.30, p=0.02). Luminal irregularities with a seemingly benign aspect on angiography were associated with dissections visualised by OCT in 71% of the cases

Conclusions: A varying extent of vascular injury was observed after renal denervation in all systems. Vessel dissections were observed only in arteries treated with balloon catheters and were associated with a high balloon-to-artery ratio and vessel wall irregularities on post-procedural angiogram.

PCR Interventions for hypertension & heart failure

Euro14A-0P214

Metabolic syndrome is accompanied by sympathetic overdrive and arterial stiffness in resistant hypertensive patients

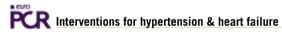
Dimitriadis K., Tsioufis C., Kordalis A., Koutra E., Kasiakogias A., Mazaraki A., Kintis K., Kefala A., Nikolopoulou L., Stefanadis C.

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Aims: Resistant hypertension is related to sympathetic overdrive and arterial stiffening, while there are scarce data whether metabolic syndrome further potentiates sympathetic activity and vascular abnormalities in this setting. The aim of this study was to assess the effect of the metabolic syndrome on muscle sympathetic nerve activity (MSNA) and arterial stiffness in resistant hypertensive patients.

Methods and results: We studied 24 patients with resistant hypertension [age: 58±10 years, 15 males, office blood pressure (BP): 178/94±15/12 mmHg, 24-hour BP: 149/84±15/11 mmHg, under 4.2±0.5 drugs] that underwent transthoracic echocardiographic study and blood sampling for assessment of the metabolic profile. Metabolic syndrome was defined according to the Adult Treatment Panel III criteria and arterial stiffness was evaluated on the basis of carotid to femoral pulse wave velocity (PWV). In all participants sympathetic drive was assessed by MSNA estimations based on established methodology (microneurography). Resistant hypertensive patients with metabolic syndrome (n=11) compared to those without (n=13) exhibited higher waist circumference (108.1±5.4 vs. 94.6±9.2 cm, p=0.001), fasting glucose (131.8±2.9 vs. 94.6±2.1 mg/dl, p<0.05), office systolic BP (186±17 vs. 171±15 mmHg, p<0.001) and left ventricular mass index (134.2±18.1 vs. 124.6±17.2 g/m², p=0.001). Moreover, metabolic syndrome patients compared to those without were characterised by greater levels of carotid to femoral PWV (11.7±0.8 vs. 9.3±1.1 m/sec, p<0.001) and sympathetic nerve traffic as reflected by MSNA levels (84.2±2.8 vs. 75.1±2.2 bursts per 100 heart beats, p<0.001). In all participants MSNA was related to waist circumference (r=0.38, p=0.002) and office systolic BP levels (r=0.35, p<0.05) but there was no association with PWV values

Conclusions: In resistant hypertensive patients, metabolic syndrome is associated with high MSNA and PWV levels. In this clinical context renal sympathetic denervation that targets sympathetic overdrive constitutes a promising novel therapeutic modality.



Euro14A-0P215

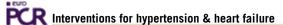
Dose-dependent, ethanol-mediated (perivascular) catheter-based renal sympathetic denervation (PVRD) in a porcine model; evaluation of renal tissue norepinephrine, histological nerve injury, and immunohistochemistry

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Aims: Various approaches are being developed to perform renal sympathetic denervation as a treatment for resistant hypertension. The preclinical evaluation of the technologies typically utilises the porcine model. We report the use and comparison of three methods to determine effectiveness of alcohol-mediated denervation in this model.

Methods and results: Renal denervation was performed in the porcine model using ethanol delivered to the adventitial and peri-adventitial space of the renal artery with the Peregrine SystemTM, a novel endovascular, three micro-needle device. The effectiveness of renal denervation was assessed by measurement of renal norepinephrine (HPLC), and evaluation of the treated renal nerves using standard histology (H&E, Movat's pentachrome). Immunohistochemistry was also used to evaluate the extent of denervation; Tyrosine Hydroxylase (TH) a functional indicator for norepinephrine synthesis and Neurofilament Protein (NFP) for recognition of axons within nerve fascicles. Three escalating doses of ethanol were evaluated at the two week time point: 0.15 ml; n=3, 0.30 ml; n=3 and 0.60 ml; n=3. Naïve and sham control animals were used for renal norepinephrine measurement and histology. Two weeks after treatment, the decrease in renal norepinephrine (NE) showed an essentially linear response (R2=0.95) to the EtOH volumes delivered. The mean renal NE reductions were 54%, 78% and 88% at doses of 0.15 ml, 0.30 ml and 0.60 ml, respectively (p<0.0001 vs. controls). Using standard histology, nerve damage was scored semi-quantitatively from 0-4 ("none" to "marked"). The mean nerve injury scores for the three doses were; 2.7, 3.4 and 3.7 respectively, compared to 0 for the controls. The immunostaining reactions to TH and NFP were scored semi-quantitatively from 0-2 ("no reaction" to "strong reaction"). The mean scores for reaction to TH were; 1.0, 0.8, and 0.2 for the three dose volumes compared to 2.0 for the controls. The mean scores for NFP were; 1.0, 0.6 and 0.7 for the respective treatments compared to 2.0 for the controls.

Conclusions: Perivascular delivery of micro volumes of ethanol creates a dose-dependent drop in renal NE level. In a blinded evaluation, there was a strong correlation between histopathological injury score and drops in NE as well as effects on TH and NFP.



Electrode irrigation protects the artery wall while maintaining injury to renal nerves

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Aims: Preclinical studies of radiofrequency (RF) renal denervation have largely been empiric, focusing on characterisation of soft tissue and nerve injury against the backdrop of spatial nerve distribution around the targeted renal artery. Such empiric studies provide invaluable safety and efficacy assessment but provide limited insight into the mechanisms underlying these therapies and the determinants of variable responses in animals and humans. We developed *in vivo* and computational models to correlate ablation zones with specific RF electrodes and understand how local electrode irrigation affects injury of the renal artery wall and of peri-adventitial soft tissue.

Methods and results: RF ablations, using two or three spatially discrete electrodes, were conducted in swine using Thermocool irrigated tip catheter (Biosense Webster, CA) with (IR) and without (NIR) irrigation. Arteries were harvested at 7d and serial sectioned every 300 µm and quantified histomorphometrically to identify maximum ablation zones associated with each electrode. A computer model was developed to predict temperature and injury gradients based on electrode power and duration, tissue architecture with its associated heat and electric conductivities, and heat clearance by flowing blood and irrigant. Modeling predicts that RF power delivery to the artery wall peaks at interfaces between high conductivity and low conductivity tissues, including the external elastic lamina (EEL). As a result, temperature peaks beyond the EEL and arterial wall injury zones are determined by the balance between heat diffusion into the media and heat clearance by luminal blood and irrigation. Notably, modeling predicts that heat clearance by luminal blood flow is inefficient at protecting the artery wall. On the contrary, local irrigation of the treating electrodes with room temperature saline is predicted to protect the media without affecting the peri-adventitial ablation zone. Model predictions were confirmed by histomorphometry of lesion geometry and nerve injury with and without irrigation during RF ablation. Surface irrigation lowered affected luminal circumference (IR 13.7±19.1% vs. NIR 40.8±7.2%, p=0.095), affected circumference at the EEL (IR 27.0±19.8% vs. NIR 42.2±5.2%, p=0.151), and media thinning (IR 25.7±22.6% vs. NIR 42.9±15.6%, p=0.199). RF ablation effects in the nerve-rich adventitia were less sensitive to irrigation: width (IR 3.8 mm vs. NIR 4.8 mm) and depth (IR 5.1 mm vs. NIR 3.4 mm). Morphologic nerve changes within the ablation zones were comparable with and without irrigation and were considered to be marked and necrotic/degenerative.

Conclusions: Computational modeling explains variable patterns of tissue ablation as arising from variations in tissue anatomy, electric conductivity and local perfusion. Local electrode irrigation siphons heat that diffuses from the peri-adventitia into the artery wall, above and beyond the cooling effects of luminal blood flow. As a result, irrigation can protect arterial integrity and reduce injury at the intima surface and within the artery wall while providing comparable nerve injury.



Euro14A-0P217

The effect of catheter-based renal sympathetic denervation on left ventricular hypertrophy: one-year follow-up with cardiac magnetic resonance imaging

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Aims: Renal denervation (RDN) is a promising treatment for hypertension. Up to now, the effect of RDN on hard endpoints is unknown. As an intermediate hard endpoint we investigated the effect on left ventricular (LV) hypertrophy assessed by cardiac magnetic resonance imaging (cMRI). cMRI was used since this modality has a higher accuracy and reproducibility than echocardiography in evaluation of LV-mass.

Methods and results: Patients underwent cMRI before and 1 year after RDN. Body surface area-corrected myocardial mass was quantified by end-diastolic contour tracing on short axis balanced steady state free precession. Left ventricular trabeculae were included in myocardial mass. To assess the effect of RDN on blood pressure (BP), 24-h ambulatory blood pressure measurements (ABPM) at one-year follow-up were compared to baseline values. At moment of submission, 46 patients (23 male) were included with a mean age of 57 ± 11 yrs; using a median number of 4 different antihypertensive drugs. Mean ambulatory BP changed from $164\pm20/99\pm13$ mmHg to $155\pm22/92\pm12$ mmHg (P=0.001/ P<0.001). During follow-up, a $3.0\pm11.5\%$ decrease was observed. This corresponds to a median decrease of 2.5 (-100 - +43) g/m² (P=0.111). A trend was observed towards a relation between LV-mass reduction and change in BP (β: 0.443; P=0.061). In the subgroup of patients defined as responder based on ABPM (reduction 24-hr SBP ≥5 mmHg) a significant $6.2\pm11.7\%$ reduction in LV-mass was observed (median reduction: 5.5 (-100 - + 10) g/m²; P=0.033). Conclusions: The current study shows no prominent change in LV-mass, as assessed with MRI, one year after treatment with RDN. However, in the patients with a proven BP effect after RDN, the decrease in LV-mass is more prominent and comparable to the effect observed in studies with beta-blockers. Although a larger group of patients is needed before definite conclusions can be drawn, current results are promising.

The unique anatomy of renal arterial ostium may limit efficacy of endovascular radiofrequency ablation

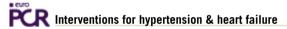
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Aims: Though sometimes difficult to treat due to catheter instability, the superior aspect of the renal artery ostium is held as an attractive nerve- and ganglion-rich target for endovascular ablation. We sought to provide a detailed morphometric characterisation of renal nerve and ganglion size and density within the renal ostium at three discrete distances from the aorta and to evaluate the efficacy of single-electrode endovascular radiofrequency (RF) ablation at the superior renal ostium in Yorkshire swine.

Methods and results: Nerve and ganglion distribution was characterised in 16 renal arteries (8 swine) at 3 discrete distances from the aorta (~0.3, ~3 and ~6 mm) as untreated controls. RF ablation was performed in the renal ostium of another 8 renal arteries (4 swine) using a prototype renal/crescent multi-electrode RF catheter (Biosense Webster, CA) by activating one or two RF electrodes at 15W/60 sec with 30 ml/min saline irrigation. Treatment locations were confirmed by angiography. Arteries and kidneys were harvested 7 days post denervation. Renal NEPI levels were correlated with ablation zone geometries and nerve and ganglia injury. Published data suggest that 50% of renal nerves in swine are located within 2.1-2.5 mm of the arterial lumen and 75% are within 4.5 mm. Our data show that while these estimates hold true sufficiently far from the aorta, nerve and ganglion location, size, and density differ within the renal ostium. Nerves and ganglia were more abundant and more distant from the lumen at locations closest to the aorta. At all three distances from the aorta nerves and ganglia were distributed randomly across all 4 quadrants. 75% of nerves were located within 9.9, 6.5, & 4.0 mm of the lumen at 0.3 mm, 3 mm, & 6 mm from the aorta. At these three locations, nerve counts (#) were 24.4±19.9, 8.9±7.7 (p=0.008 vs. 0.3 mm), & 5.8±4.3 (p=0.001), nerve distances (mm) 6.8±3.9, 5.0±2.8 (p=8e-8), & 3.4±3.2 (p=5e-18), ganglia counts(#) 1.2±1.4, 0.8±0.9 (p=NS), & 0.4±0.57 (p=0.001), and ganglia distances (mm) 8.3±3.6, 6.0±2.4 (p=0.034), & 5.9±3.0 (p=0.071). Efficacy was observed in 1 of 8 treated arteries where injury area was 99.1 mm² and involved all 4 quadrants at a maximal depth of 9.1 mm affecting 50% of nerves and reducing NEPI (37 ng/mg). In the other 7 arteries no efficacy was observed, fewer than 10% of the nerves were affected, the ablation areas were smaller (16.2±10.9 mm²) and present in only 1-2 quadrants at maximal depths of 3.8±2.7 mm, and renal NEPI levels remained at baseline (620-991 ng/g). Hal

Conclusions: Ganglia and nerves are more abundant in the renal ostium but are also located farther from the lumen and are present in all four quadrants not just in the superior aspect of the ostium. Therapies designed to treat the renal ostium in single ablation should deliver energy concomitantly deep and across multiple quadrants to injure a sufficient fraction of nerves (>50%) to achieve efficacy.



Euro14A-0P21

Renal arteries in resistant hypertension patients undergoing renal denervation display unusual accessory artery anatomy

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Aims: Device based renal artery denervation is emerging as a therapy for resistant hypertension. However, blood pressure reductions are markedly heterogeneous, with controversial efficacy results. Recent clinical trials have shown as many as 40% of patients exhibit marginal or no therapeutic response following renal denervation. Reasons for non-response are unclear, but an intriguing possibility may relate to unrecognised or untreated accessory renal arteries. This study retrospectively evaluated renal arteries using high-resolution 3-D computed tomography angiography to specifically determine accessory artery counts in patients from a clinical renal denervation trial.

Methods and results: Computed tomography scans from 33 patients representing a range of blood pressure response in the REDUCE-HTN trial were reconstructed and carefully examined for renal artery anatomy using commercial multiplanar/3-D software. Marked variability in renal blood supply was found, including presence, number, size and location of accessory renal arteries. Accessory renal arteries were found in 21 patients (67%). These vessels varied in number (minimum 1, maximum 5), size (0.5 mm-6 mm), location relative to principal artery ostium (up to 12 cm separation), and at all ostial axial angles around the abdominal aorta.

Conclusions: Accessory renal arteries in this study were markedly more prevalent (67%) than as reported in the general population (20-27%). This finding is consistent with large variability in blood supply to other abdominal viscera. Blood pressure response may relate to accessory artery size, prevalence or failure to intervene. Since even small accessory renal arteries commonly have sympathetic ganglia originating in the celiac plexus, failure to address these vessels may be key to understanding nonresponse to renal denervation.



Our aging cardiovascular population: preparing to care for the silver tsunami

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Aims: It is irrefutable that age is a major risk factor for cardiovascular (CV) disease. The World Health Organization statistics indicate that the number of people aged 60 and over has doubled since 1980, and the number of people >80 will quadruple to 396 million by 2050. CV morbidity and mortality rise rapidly after 65, and account for a significant mortality risk (>40% age 65-74 and >60% 85 & > respectively). Additionally our elderly patients tend to present with higher acuity conditions with multiple co-morbidities (inclusive of a combination of hypertension, diabetes, renal dysfunction, arrhythmias, bleeding risks, cognitive impairments and frailty concerns.) By definition this group is high risk and more complex. The prevalence of myocardial infarctions in this population is quite high, as is the predictor of adverse events after an acute coronary syndrome. The patients require more concentrated care by dedicated practitioners. Despite this impressive trend, the elderly population is poorly represented in clinical trials. Hence, there is a paucity of data to address this under-represented subset of patients that are referred for coronary evaluation and intervention. This begs the question: how do elderly patients fare in the invasive lab, and what can we do to maximise a successful outcome.

Methods and results: The scope is to address the care of our complex aging population with an overview of evidenced based medicine dedicated to guide interventional strategies and care of patients presenting for coronary evaluation. Review of published data evaluating outcomes of elderly patients undergoing coronary angiograms and angioplasty. Trends depict a population that was more likely to present as an urgent PCI and underwent more complex interventions. Mortality and post procedure MI were higher in the very elderly patients, as were renal, neurologic and access site complications. *(specific data pending)

Conclusions: By 2030, it has been predicted that more than 23 million people will die annually from cardiovascular disease. The vast majority of these will be >70 years old. This high risk subset (with projected increased morbidity and mortality) will account for a large contingency of our patient population and will have wide ranging implications for our cath labs and recovery floors. Patients with age associated impairments have multiple co-morbitdities, higher mortality, disability, extended health service usage and repeat admission rates. We must be prepared to provide optimal care for our elderly population and accommodate the changing needs, with a concerted effort on assessment, education and diligent outcome surveillance



Euro14A-0P221

Conscious sedation in the cathlab

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Aims: The number of minimally invasive cardiovascular procedures performed outside of the operating room has grown exponentially over the last several decades. Sedation, analgesia, or both may be needed for many of these interventional or diagnostic procedures performed in a non-anaesthetic environment. Concerns have been raised about the safety of these sedation and analgesic techniques by non-anaesthesiologists as the use of sedation and analgesia introduces an independent risk factor for morbidity and mortality in addition to the procedure itself.

Methods and results: Medications that bring out pharmacologic effects, such as anxiety release, amnesia, or analgesia, provide patient comfort during various cardiovascular procedures and have become common practice in the cath lab. Conscious sedation lets patients recover quickly and return to their everyday activities soon after the procedure. Understanding the efficacy and safe administration of these agents is there for essential to the cath lab team performing interventional procedures. The American Society of Anaesthesiologists (ASA) state that; Sedation and analgesia comprise a continuum of states ranging from minimal sedation through to general aesthesia (American Society of Anaesthesiologists. Practice guidelines for sedation and analgesia by non-anaesthesiologists. *Anaesthesiology*. 2002;96:1004-17) 1. fully awake; 2. drowsy; 3. asleep but rousable by normal speech; 4. asleep but responding to a physical stimulus; 5. asleep but not responding to physical stimuli (comatose). This state is similar to or synonymous with general anaesthesia. Most of the cardiovascular procedures in the cath-lab should be performed under sedation level 2 or 3. This is important not only for managing conscious sedation safely but also for the clinician who will require feedback from the patient during the procedure regarding chest pain, so high sedation levels are generally not recommended. Sedation level 4 or 5 should only be handled by a professional anaesthetic team.

Conclusions: All personnel managing patients under conscious sedation must have the necessary knowledge and skills to both recognise and manage adverse reactions safely. The cath lab environment must contain all the relevant critical care equipment, including oxygen, suction, and equipment for airway support and bag-mask ventilation. Emergency protocols and training for cardiopulmonary resuscitation in the event of cardiac arrest or anaphylaxis must also be integrated into the skillset of practitioners. All clinical staff will have proper training for administration of iv sedation and will be educated in the following: – medications, dosages and administration techniques for sedation; – pre, intra and post-procedure recognition of complications and interventions; – airway management and resuscitation; – ACLS trained; – equipment required in case of emergency



Furn144-NP222

The challenges and ethical dilemmas of caring for dementia patients during an ACS event requiring PCI

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Aims: The aim is to highlight and debate the unique challenges associated with delivering person centred care for dementia patients during an ACS event requiring PCI.

Methods and results: Dementia tends to affect the individual's cognitive abilities, memory, awareness, thought processes and behaviour (including distress and aggression), which are often exacerbated during episodes of acute illness such as ACS. This leads to significant challenges related to both establishing a diagnosis and managing the patients care during and after PCI, even for those displaying the early stages of dementia. These challenges may give rise to the potential for inadvertent discrimination, for example it has been reported that Dementia patients who experience STEMI are less likely to receive Primary PCI. As many as 35 million people are affected by Dementia worldwide and over the next 20 years this is likely grow by more than 50%; the prevalence ranges between 5 and 15% for those over 65 years of age. Likewise the age demographics are reciprocated by those experiencing ACS and requiring PCI. The use of person centred care has previously been shown to effectively reduce anxiety and distress and behavioural changes for Dementia patients in a non-acute setting. Adapting this approach for Cath Lab and nursing staff caring for this group of patients during an ACS event may help to ameliorate the patients anxiety and emotional distress and reduce the behavioural challenges.

Conclusions: The International agreement resulting from the G8 dementia summit held in December 2013 included a call upon "civil society to continue and to enhance global efforts to reduce stigma, exclusion and fear" and for "all sectors to treat people affected by dementia with dignity and respect". It is therefore imperative as practitioners that we innovate our care approach to meet these challenges.



Euro14A-0P223

CAG/PCI via arteria radialis - Which complications do the patients experience? What does it mean for the patients daily life?

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Aims: To investigate how many patients experience pain and/or neurological symptoms after the radial access CAG/PCI, and the importance of symptoms in patient's everyday life.

Methods and results: After a literature review, telephone interviews with themed structured questionnaire including some open questions were made. Patients were included consecutively from June 2012 and the interviews were conducted 7-9 months after discharge. SPSS was used for statistical analysis.

Conclusions: Sixty-six interviews were prepared, 3 patients had died and 15 patients could not be reached by telephone. Forty-eight patients, 41 men and 7 women, aged 42-84 years were interviewed, of which 3 experienced pain in the hand/arm up to 7 days. One patient had had neurological symptoms for 14 days. None of these patients indicated that it had influenced their everyday life. Five of the patients interviewed were not able to check the pulse in the wrist and had to be checked by Doppler ultrasound test in the hospital.



An evaluation of peripheral vascular access site complications following cardiac angiography and PCI

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Aims: To identify the prevalence of vascular access site complications following coronary angiography and PCI.

Methods and results: Prospective data collection from 2007 to 2012 following coronary angiography and PCI with patient follow-up at 1 week post procedure. Complications were defined as bruising, bleeding, haematoma. Less frequent complications included retroperitoneal bleeding, pseudoaneurysm, AV fistula, infection or requirement for vascular surgery. To determine predictors of complications separate models for were created for each complication using backwards conditional logistic regression techniques. 3793 patient procedures were analysed. Most participants were male (n=2408; 63.5%). The mean age was 65.8 years (SD 12.18) and average BMI was 29. 5 kg/m². A history of hypertension was reported for 72% (n=2855). 3058 procedures (80.6%) were for the purpose of diagnostic angiography and the remainder PCI. Vascular closure techniques included digital pressure (n=1402; 37%), femoral vascular closure devices (n=710; 18.7%), femoral mechanical compression device (n=990; 26.1%) or radial mechanical compression device (n=582; 15.3%), In 2007 most procedures performed used femoral access (n=273; 99.6%) and this decreased to 59.5% (n=304) in 2012. During this same period radial access increased from 0.4% (n=1) to 40.1% (n=205). Brachial access was used for 0.4% (n=2) of cases in 2012. Complications were experienced by 46.5% (n=1764); the most common was bruising (n=1690; 44.6%). Patients who had radial access procedures experienced fewer complications (n=164, 27.6%) compared to femoral (n=1585, 49.9%) or brachial access procedures (n=11, 64.7%). Females had a higher risk of bruising (OR 1.37, 95% CI 1.16-1.63), haematoma (OR 1.42, 95% CI 1.06-1.89) and rare complication (OR 2.49, 1.19-5.19). Risk of bruising (OR 0.60, 95% CI 0.49-0.75) or haematoma (OR 0.65, 95% CI 0.44-0.95) was lower for patients with diabetes. Administration of antiplatelet medication was associated with elevated risk of haematoma: Aspirin (OR 1.77, 95% CI 1.15-2.74) and Tirofiban (OR 5.75, 95% CI 1.50-22.12). PCI was associated with risk of bruising (OR 2.12, 95% CI 1.29-3.49) and bleeding (OR 3.54, 95% CI 2.02-6.20), compared to angiography alone. Radial access was associated with lower risk of bruising (OR 0.46, 95% CI 0.34-0.61). The use of radial compression devices was associated with lower risk of developing haematomas (OR 0.26, 95% CI 0.12-0.55) or bleeding (OR 0.10, 95% CI 0.02-0.42). More than 1 arterial puncture was associated with risk of both bruising (OR 1.75, 95% CI 1.36-2.25) and haematoma (OR 2.15 (95% CI 1.46-3.15). Pre procedure SBP of ≥140 mmHg was associated with bruising (OR 1.46, 95% CI 1.23-1.73), haematomas (OR 1.54, 95% CI 1.15-2.06) and rare access site complications: (OR 2.30, 95% CI 1.09-4.85) respectively.

Conclusions: Patients most at risk of developing peripheral vascular access site complications are females, patients with a SBP \ge 140 mmHg, multiple arterial punctures and patients having PCIs. Radial access procedures had significantly fewer post-procedure complications that decreased over the study period as the number of radial procedures increased. This data creates impetus for future research directed at lowering complication rates in those identified most at risk.



Euro14A-0P225

The use of a WHO derived safe surgery checklist to improve patient experience in the cardiac catheterisation laboratory

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Aims: To develop and implement a safe procedure checklist based on the WHO template, to improve patient experience, team work and efficiency in the Cardiac Catheterisation Laboratory.

Methods and results: Starting in March 2013, a WHO-derived checklist, specifically modified for the CCL, was introduced at the Royal Brompton Hospital. For three months, weekly PDSA cycles and staff feedback were used to optimise checklist design, followed by a full rollout. Patient experience (n=82, taken throughout the twelve-month period) and staff safety climate (taken 2 and 7 months after checklist introduction) surveys were undertaken to measure subjective impact. Clinical outcomes and efficiency data were obtained from in-house databases. The Safe Procedure Checklist has four components: - Team Briefing. The consultant runs through the patient list, alerting the team to the most important points. Typical examples are allergies which will affect the way the procedure is conducted (latex/shellfish), unusual equipment requirements, previous surgery etc. In addition, the consultant will explain how s/he would like the day to run (breaks, handovers etc). - Sign In. This is a series of checks, carried out by the nurses, in which the most important administrative points are confirmed. (The correct patient/procedure; consent has been signed; preprocedure test results are safe; pacemaker details are known (if applicable) etc. - Time Out. This is a briefing by the operator, given prior to the start of the procedure, in which s/he runs through the details of the case, highlighting the main points, confirming that (eg) equipment requests from the Team Brief have been carried out and talking through any contingency plans, in case of high risk patients. - Sign Out. This comprises a debrief from the operator, post procedure checks (dose levels/equipment etc) and recovery management - ensuring that the appropriate ward staff are briefed to expect the patient and know what care is required. The benefits of the checklist arise from two main mechanisms: 1. A structured framework to ensure that all essential procedural steps are carried out. 2. A leadership tool to create a sense of task and team focus and to empower all team members, regardless of role or seniority, to initiate the Time Out briefing and speak up if they notice anything untoward. Concrete results are hard to measure; anecdotal evidence indicates that patient lists run more smoothly; staff feel much more part of a team and more engaged in the procedure. Data on outcomes is still inconclusive, as improvements could be due to a number of factors and can't be attributed to the checklist alone. Nevertheless, when a full checklist is used, 65% of procedures are shorter than average duration and radiation exposure is reduced by a corresponding amount. (P<000.1) One emerging trend is that patients who are brought into the Time Out briefing, by a consultant who is confident in giving a briefing, felt far more confident in the team and less anxious than they were previously.

Conclusions: The checklist has been positively received by staff and patients, has improved efficiency and reduced screening time during cardiology procedures.



CR Nurses & Technicians Euro14A-0P226

Initial clinical experience of the use of OCT in coronary disease

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Aims: The evolution of intravascular imaging techniques has allowed a better characterisation of the arteries and mechanisms of coronary artery disease (CAD). Percutaneous coronary intervention (PCI) guided by these techniques has often been associated with improved outcomes. The quality of information provided by OCT may have clinical utility and complement validated methodologies. Analyze the initial experience in the clinical use of OCT.

Methods and results: Retrospective analysis of 74 patients who underwent OCT during coronary angiography, 53 (74%) men, 62±10 years, 28 (38%) diabetic patients, 24 (32%) prior history of MI and 42 (56.7%) with a history of ICP. Procedures were performed by radial approach 61 (82.4%), 62 (84%) were scheduled and 12 (16%) performed in the context of primary angioplasty. 101 pullbacks (P) of OCT were observed, with analysis of the right coronary artery in 37 (37%), left anterior descending 38 (38%), circumflex 22 (22%), left main 2 (2%) and aorto-coronary graft 2 (2%). The indication to use OCT was the evaluation of atherosclerotic lesions in 24 (24%), the immediate outcome of PCI in 30 (30%), late stent apposition 33 (33%), bioabsorbable scaffold in 6 (6%) and potential complication 8 (8%). The main findings observed were stent restenosis 20 (20%), dissection at stent edges 24 (24%), incomplete stent apposition 18 (18%), atherosclerotic plaque complicated by thrombosis 12 (12%), uncomplicated atherosclerotic plaque 11 (11%), stent thrombosis 10 (10%), calcified plaque 4 (4%) and coronary aneurysm 4 (4%). The conduct of the operator after the OCT findings observation was evaluated, the conduct change in 55 P (55%), led to the apposition of an additional stent 38 P (38%), led to post-dilatation with balloon 17 P (17%). There was a non-significant trend between observing a stent edge dissection and alteration of the conduct of the operator (p=0.051). Plaques without thrombus were associated significantly with the maintenance of the operator conduct (p=0.046).

Conclusions: The OCT has provided relevant information about the mechanisms of atherosclerosis. This mainly led to the change in the conduct of the operator. This might be related to the population bias, as well as, overestimation of the OCT findings, typical in the initial phase of a learning curve.



Euro14A-0P227

Stereoscopic three-dimensional imaging of metal stents and bioresorbable scaffolds in coronary bifurcation interventional strategies

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Aims: Benchtop studies have aided understanding of complex stenting strategies. Bifurcation stenting is a three-dimensional (3D) process undertaken with two-dimensional (2D) imaging. Understanding what is happening from 2D images can be confusing because of multiple overlying stent struts. A stereoscopic analyph 3D image viewed with dedicated spectacles provides depth perception by separating close and distant segments of the image. This study presents benchtop images of different bifurcation strategies in both 2D and stereoscopic 3D format, to demonstrate the additional insights provided by the stereoscopic images.

Methods and results: Images of six bifurcation strategies (provisional "T", "T" stenting, culotte, crush, mini crush, and "Y" stenting) from multiple deployment projects were analysed in 2D and stereoscopic 3D using anaglyph (red and cyan) 3D imaging software (CT Analyser and CT Vol, Skyscan, Belgium). The stent designs used with these strategies included Multilink 8, Vision, Driver, Liberte, Cypher Select, Co-star and the bioresorbable vascular scaffold Absorb. Using dedicated spectacles there was improved appreciation of bifurcation structures with stereoscopic 3D images compared with 2D images. Examples include: a) the separation of multiple overlying struts so the front and back of the stent are clearly visualised, b) the demonstration of stent distortion and strut free "holes" that sometimes occur after kissing balloon post-dilatation (not well seen on 2D images), c) the appreciation of the degree of side branch ostial obstruction especially at the carina, d) appreciating the extent of main vessel obstruction from protruding side branch stents, e) seeing fractured scaffold struts, and f) recognising when a wire has inadvertently passed outside a stent strut (with the potential for severe stent distortion with further balloon dilatation).

Conclusions: The novel analyph 3D imaging of bifurcation stenting bench deployments show the benefits of added depth perception not appreciated in 2D images. Overlying and multiple layers of stent struts are separated to reveal subtle but important aspects of stent deployment strategies in bifurcation lesions. Stereoscopic 3D imaging provides additional clinically-relevant insights. The 3D imaging technology warrants further development, and has the potential to be applied elsewhere.



New applications for the pressure wire (FFR) in the cathlab

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Aims: The invasive functional assessment of lesions with fractional flow reserve (FFR) has been available for more than a decade. However the trend to use this technology, increased only after publication of the DEFER and FAME studies. This technique is considered very useful, because it can discriminate with high power of spacial resolution, the extension of ischaemia. Furthermore, it is safe and cost-effective. The FFR is being used, more and more, in order to evaluate, bifurcation lesions, sequential lesion and even the microcirculation.

Methods and results: The functional evaluation of bifurcated lesions, allows us to optimise the result of angioplasty. For example, when stenting the main vessel compromises the side branch, it may transform a non ischaemic territory into an ischaemic one. But when the technique of kissing balloon is performed with the side branch, this jailing effect disappears, and the FFR might be normal. Another use that has been studied is the evaluation of sequential lesions, since the distal value of the FFR is the sum of all lesions in that vessel. So, the hyperaemic pullback of the pressure wire, can document the biggest gradient of pressure indicating the most functionally severe lesion. After treating that lesion, hyperaemia should be induced again. Since FFR result is flow dependent, relieving one obstruction, it will increase the flow to others, and so it can unmask lesions previously not associated with important pressure drop. It's not uncommon the association of angina, ischaemic positive tests, and "normal" epicardial arteries. It is been associated with endothelium dysfunction, which may affect the prognosis of patients. In that case, medical therapy must be optimised and risk factors controlled. The pressure wire is the easiest tool, when used routinely, to understand the microcirculation, since this represents almost 95% of the cardiac circulation, and can't be treated with stents or other devices.

Conclusions: Functional assessment of epicardial lesions with pressure-wire has better results, compared to visual (or QCA) estimation of lesions. Furthermore, new areas of interest using pressure-wire allow us to understand the cardiovascular disease from the functional point of view instead of just the angiographic anatomy.



Euro14A-0P229

Nursing needs for patients undergoing left atrial appendage occlusion

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Aims: Interventional occlusion of the left atrial appendage (LAAO) is an alternative to anticoagulation in patients with atrial fibrillation. The typical patient population and their needs of nursing on the ward are not well defined. The aim is to describe the patient population and their hospital course in order to find possible starting points for further improvement of the nursing to meet their needs.

Methods and results: A retrospective analysis of the nursing reports, patient files and hospital course of 32 patients referred to the hospital for LAAO between Nov. 2011 and Nov. 2013. Patient population: The mean age was 74.5 y±12.5 y, (19 male and 13 female). 7 of the patients were referred from cardiology, 22 from Neurology and 3 from other mepartments. 5 patients had a contraindication for Warfarin because of cerebral bleeding or stroke under anticoagulation. 11/19 patients (57.8%) had permanent sequelae from neurological event. Other comorbidities were Renal Insufficiency, (n=6 (18.7%) Diabetes (n=3 (9%), Coronary Heart Disease (n=8 (25%), Pacemaker implantation (n=5, 15.5%), Hypertension n=25 (78%), Heart Failure n=3 (9%), Lung Disease n=3 (9%). Patients were typically frail; 5 patients had help carrying out their Daily Life Activities, 10 patients were using walking-aids for short distances not only outside, 10 patients needed Primary Health Care to stay living alone. Relatives accompanied 15 patients to the outpatient clinic and at admission. Especially two kinds of expectations were presented. Patients who have had stroke were anxious and expressed concerns that a new stroke would occur whenever they sensed irregular heartbeat. Protection was their motivation. Patients with labile INR or who had experienced bleedings or stroke under anticoagulation were eager to undergo LAAO treatment in order to stop the therapy. Patients expressed fear of complications and discomforts towards TEE examination and general anaesthesia. Procedure and Complications: The procedures were performed in general anaesthesia and under TEE guidance. Patients came straight back to the ward after extubation in the Cath. Lab. Typical complications which needs to be monitored also on the ward are Pericardial Effusion, Device Embolization, Groin Bleeding, Stroke and other Bleedings. Hospital course: All patients were seen in the outpatient clinic prior to hospital admission. At these visits the indication was verified, the LAAO procedure was explained and after patients consent to undergo treatment pre examinations were planned. Patients were admitted 3 days (±1). Examinations pre-procedure were TEE or cardio CT plus blood work-up and ECG. Pre- discharge all patients had TTE and chest X-ray performed.

Conclusions: The patient population for LAAO is old and frail with several comorbidities needing attention on the ward. Not only awareness of possible symptoms of post procedural complications. The hospital stay is short and includes multiple Examinations and a procedure in general anaesthesia. The combination makes communication a keyword as well as cooperation with relatives. The findings show that the patient group is diverse and it seems beneficial to use an evident based frailty score to guide the nurses in planning the care. Developing a clinical nursing guideline seems mandatory in order to secure the above. This presentation will focus on the nursing for this complex patient population.



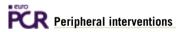
Nursing cares in mitral percutaneous valvuloplasty in pregnant patients guided by intracavitary echocardiography

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Aims: Describe nursing cares on two pregnant patients diagnosed of severe mitral stenosis who received a mitral valvuloplasty guided by Intracavitary Echocardiography taking place in a cathlab.

Methods and results: Patients firstly had the procedure explained to them. Afterwards they were placed in left lateral decubitus position to prevent inferior vena cava syndrome, improve safety measures, comfort and infection risk. The fetus and gonads were radiologically protected. During the procedure the fetus and patient were continuously monitored. Right and left diagnostic catherisation was performed by femoral access, then the transeptal puncture led by intracavitary echocardiography and the valvuloplasty of the mitral valve with INOUE balloon were performed. Finally the haemodynamical and fetal data were registered. As no unexpected event happened, the patients were moved to Coronary Unit for subsequent control.

Conclusions: The nursing care should focus on patient position, radiological specific protection and haemodynamic monitoring in both fetus and patient. The Intracavitary echocardiography protects against anaesthesia risks, high radiation rates and allows an early diagnose of complications.



Euro14A-MAO17

Setting-up a multidisciplinary program of carotid artery stenting in a community hospital

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Aims: Carotid artery stenting (CAS) compared to carotid endarterectomy (CEA) demonstrated controversial results but, the increase of the experience of the operators, the improvement of the stents and of the embolic protection devices and the high demand of a less invasive alternative has made CAS a highly competitive procedure. We sought to propose a multidisciplinary program of diagnosis, treatment and follow-up of all patients with carotid stenosis based on an in-hospital multidisciplinary task force.

Methods and results: We organized in our community hospital, a high volume catheterisation laboratory (>800 coronary angioplasties per year) without cardiac and vascular surgery, a management program for patients with carotid stenosis based on a task force composed of cardiologists and neurologists, and wecollected data about all consecutive patients with symptomatic or asymptomatic carotid artery stenosis who underwent CAS and analysed clinical and procedural characteristics as well as immediate and 30-day outcomes. From January 2008 and June 2013, 261 patients (mean age 72,1±7,1 years, 77,1% males) underwent CAS at our catheterisation laboratory by 2 operators. Of these 123 (47,1%) were symptomatic, whose 35 (13,4%) with acute symptoms (<48 hours). The procedures were performed after discussion of the cases and after reviewing imaging examination results with neurologists. Neurologic visits and duplex scans were scheduled 24 hours and 1 month after the procedure. The population was at high cardiovascular risk: 37,4% of the patients with known coronary artery disease, 12% with congestive heart failure, 41,4% aged ≥75 years. The degree of baseline stenosis was 83±7% with soft plaque in 26.4%, ulcerated plaque in 19.5% and thrombus in 2.7% of cases. All procedures were performed with embolic protection devices: 71.8% distal, 21.1% proximal and 7.1% both. The stent implanted were closed-cell in 64.2%, hybrid in 24% and open cell in 11.8%. The primary success was achieved in all but 1 patient (99.6%) who underwent CEA. The rate of major complications at 30 days was 4.6%: 2 deaths (0.8%), 5 major strokes (1.9%) and 5 minor strokes (1.9%). Five vascular complications at the access site (1.9%) also occurred.

Conclusions: Our multidisciplinary program allowed a reasonable and potentially successful approach of CAS in patients with carotid artery stenosis with a high rate of success and a low rate of major complications, in agreement with randomised trials and registries.



Long-term major cardiovascular adverse event in 3,106 carotid artery interventions: implications from national population-based cohort study in Taiwan

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Aims: Carotid artery stenosis is one of the major causes of ischaemia stroke. By analysing the Taiwan National Healthcare Insurance (NHI) database, we aimed to discover the efficacy and safety of carotid stenting program in a larger series of patients nationwide.

Methods and results: Through the NHI database from 2004 to 2010, we discovered 3106 patients that have ever received carotid artery stent. We analysed the patients' comorbidities with ICD-9 code and compared the patients major adverse cardiovascular events (MACE) including death, acute myocardial infarction and cerebral vascular accident. The periprocedure stroke rate was 2.7% and overall recurrent stroke rate was 20.3%. We found male sex, diabetes mellitus, and heart failure were significant risk factors for overall recurrent stroke (HR=1.36, P=0.005; HR=1.23, P=0.015; HR=1.49, P=0.003, respectively). The periprocedure acute myocardial infarction rate was 0.3%. Diabetes mellitus was the only significant factor for periprocedure myocardial infarction (HR=1.68, P<0.001; HR=1.76, P=0.004; HR=2.36, P=0.001, respectively). The periprocedure and overall mortality rate were 1.9% and 17.3%, respectively. The associated important risk factors were acute renal failure for periprocedure period. Age, diabetes mellitus, acute or chronic renal failure, heart failure, and malignancy were factors correlated to the overall period mortality.

Conclusions: Even carotid artery stent is conerstone of carotid artery stenosis. The major adverse cardiovascular event rate is very high in one year. Cardiologist shoult be aware of risk factors to result in mortality after carotid artery stenting.



Euro14A-MAO19

Safety and feasibility of carotid artery stenting using proximal protection method with a reversal flow of internal carotid artery

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Aims: There might to be some following ways in order to reduce the complications of carotid artery stenting (CAS). 1) To check the comorbid cardiovascular complications of the patient. 2) To check the vulnerability of the plaque. 3) To consider the protection method. 4) To consider which type of stent is better. 5) To avoid CAS for the patient with high risk of CAS. We thought proximal protection method with a reversal flow of ICA seems to be very promising way. So the aim of the present study is clarify the safety and feasibility of the proximal protection.

Methods and results: From July 2010 to December 2013, we performed CAS in 39 patients (41 cases). In this period, we used proximal protection method with a reversal flow of ICA if possible. So we excluded 3 patients with contralateral ICA occlusion, poor collateral, limit of occlusion of external carotid artery (ECA) and common carotid artery (CCA) due to stenotic lesion, limit of using 9 French sheath due to the problem of approach site. We could perform CAS in 36 patients (38 cases) with proximal protection method with a reversal flow of ICA. Average age was 72 and 8 patients (22.2%) were octogenarian. Thirty-four patients (94.4%) were male gender. The past history of coronary artery disease was seen in 16 patients (44.4%) and stroke/transient ischaemic attack (TIA) in 18 patients (50%). Nine cases (23.7%) were symptomatic lesion. We performed with 9 French sheath in 31 cases (81.6%). In these 31 cases, 29 cases were treated with OPTIMOTM and 2 cases with Mo.Ma. UltraTM. In 7 cases (18.4%), we used a sheathless type of OPTIMOTM. All cases were approached with femoral artery except one case with brachial artery using sheathless type of OPTMOTM. We could deliver the proximal occlusion catheter and stent successfully in all cases. Only one case became intolerant after the occlusion, we converted to distal protection method with filter device. Plaque protrusion was observed after stenting by intravascular ultrasound in 3 cases and an additional stent was needed in 2 cases. In 21 cases, debris was seen in the filter. There were no haemorrhagic complications including puncture related hematoma. Hyper-perfusion syndrome was seen in only one case, but intracranial haemorrhage was avoided. In 4 cases (10.5%), high intensity spot was observed in diffusion weighted magnetic resonance imaging after the procedure. But any stroke and TIA was not occurred.

Conclusions: In these our series of CAS using proximal protection method with a reversal flow of ICA, the rate of bleeding or distal embolic complications was very low and acceptable. Of course, proximal protection method is not adaptive and indispensable in all cases. But it might be promising way to reduce embolic complications for a certain group of the patient especially with vulnerable plaque.



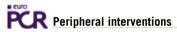
Black-blood magnetic resonance imaging could indicate the stability of the plaque and help us to perform carotid artery stenting more safely

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Aims: Distal embolism inducing stroke is the one of the most terrible complication during CAS. When we could know which plaque is vulnerable before the procedure, we can chooce the feasible protection method. So the aim of the present study is to elucidate whether BB-MRI of plaque could indicate the plaque stability.

Methods and results: We evaluated 25 consecutive patients (27 cases) who were underwent CAS from July 2010 to December 2013. In 23 patients (24 cases), BB-MRI with T1 weighted image (T1WI), T2 weighted image (T2WI) and time of flight (TOF) was taken prior to the CAS. Average age was 72 and 4 patients (14.8%) were octogenarian. Twenty-two patients (81.5%) were male gender. We perform CAS with distal protection using filter in 2 cases and with proximal protection in 22 cases. Precise stent was used in 4 cases, and Carotid wall stent in 20 cases. When debris was observed at the filter or stop/slow flow phenomenon occurred or plaque protrusion was seen by intravascular ultrasound after stenting in the course of CAS, the case was defined as unstable. Plaque protrusion was seen in 2 cases (18.5%) and additional stent was needed in 1 case. In 11 cases (40.7%), debris was trapped at the filter. We calculated the ratio of the intensity of the plaque and sternocleidomastoid muscle (P/S) in the same slice. We evaluated the value of P/S in the unstable cases (group U, n=15) and the stable cases (group S, n=9). The value of P/S in T1WI was significantly higher in the group U than group S (1.43±0.06 and 0.46±0.13, p value=0.0017).

Conclusions: The plaque with high P/S value in T1WI could be vulnerable and induce embolic complication. In these cases we should consider the proximal protection or consult a vascular surgeon for CEA.



Euro14A-MA021

OCT using saline infusion during percutaneous peripheral vascular intervention

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Aims: Angiography has been the keystone to assess vascular anatomy leading to a widespread development of percutaneous revascularisation techniques. Despite this, angiography alone can provide a limited analysis of lumen profile without the possibility to disclose vessel wall characteristics and with a relatively low-resolution rate compared with newer intravascular imaging modalities. Optical Coherence Tomography (OCT), a light-based technique able to provide information about intravascular anatomy that far exceeds the level of detail obtained from conventional angiography, has been mainly evaluated during coronary intervention. Unlike coronary, percutaneous transluminal angioplasty (PTA) of lower limb rarely sees the stent implantation as a final step. In so forth, we believe that an imaging modality able to precisely characterise the vessel wall response to interventional devices might provide useful information. Unfortunately, the significant amount of contrast required for OCT evaluation of large muscular arteries might expose this population to an increased risk of contrast-induced nephropathy. Aim of our study was to evaluate the usefulness and feasibility of OCT imaging using selective saline infusion instead of contrast agent during superficial femoral artery (SFA) intervention.

Methods and results: We evaluated so far 12 superficial femoral arteries (SFA) treated with rotational atherectomy (TurboHawk, Covidien, ev3 endovascular, Inc., Plymouth, MN). In the first 2 arteries the quality of the cross sections obtained after saline infusion were compared with conventional OCT acquisition performed according with international guidelines developed for intracoronary imaging. To this, we firstly performed an OCT acquisition with a motorized pull-back activated during injection of iodixanol 320 (Visipaque, GE Health Care, Cork, Ireland) at a flow rate sufficient to have full substitution of blood with contrast with no streaming. Subsequently we performed further OCT acquisition after a gentle and prolonged manual injection of a 50 ml of pure saline. Despite a certainly, improved OCT acquisition using contrast flush, pure saline was able to achieves a sufficient quality cross-section images to characterise vessel injuries and increase in mean luminal area (MLA) following atherectomy. The remaining 10 arteries were OCT-imaged using only saline infusion. In 3 cases OCT was able to detect diffuse vascular trauma following atherectomy despite normal control angiograms; the patients were treated with several additional balloon low-pressure inflations with final OCT evidence of significant reduction of vascular injuries. In 4 arteries OCT shows a significant residual plaque burden despite first atherectomy not detected by angiography alone that required further atherectomy-steps with a final OCT evidence of acceptable luminal gain.

Conclusions: We believe that our findings might enlarge the use of OCT during peripheral artery interventions where the use of a stent to seal angiographically silent vessel injuries after balloon inflation or plaque atherectomy is not as obvious as during PCI. The use of pure saline instead of contrast infusion improves the safety profile of OCT during guidance of peripheral artery intervention. A larger series of patients are expected to be enrolled and presented at the time of the EuroPCR congress.



Hypogastric stent-grafts for iliac side branched devices: long-term results of self-expanding versus ballon-expandable stent-grafts

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Aims: Current literature does not provide clear evidence regarding the role of different models of stent grafts for hypogastric arteries (HSG) in conjunction with the iliac branch devices (IBDs) in ensuring late patency. Aim of the present study is to evaluate perioperative and long term results of self expanding (SeSG-Group) vs. ballon-expandable (BeSG-Group) stent grafts used with IBDs in a consecutive series of patients with iliac aneurysms.

Methods and results: From 2006 to 2013, all consecutive patients treated with IBD were included in a prospective database. HSG selection was based on patient anatomy. Primary outcomes were: technical success at 30 days (successful implantation with patency of target vessels in absence of type I or III endoleak), five-year primary patency, and late clinical failure (need of iliac reintervention, conversion, iliac aneurysm growth >3 mm, rupture, aneurysm related death). Secondary outcomes were survival and symptoms of pelvic ischaemia. Five covariates (type of HSG, presence of iliac aneurysm >40 mm, presence of AAA >55 mm, presence of hypogastric aneurysm, isolated IBD repair) were evaluated for their possible influence on late clinical failure by multivariate analysis. A total of 123 patients were operated. In 76 patients (67%), 81 SeSGs (Fluency Plus, Bard USA) were deployed, in 38 cases (33%), 40 BeSGs (V12, Atrium USA.) were used. Nine (7%) patients using both kinds of HSG were excluded from this study. Preoperative data showed no significant differences regarding clinical risk factors. Patients treated with SeSG presented smaller iliac aneurysms compared to the counterpart (37.7 mm in SeSGgroup vs. 42.1 mm in BeSG group, p=0.004) and showed less frequently isolated iliac aneurysms (4 in SeSG group, 8 in BeSG group, 5% vs. 21%, p=0.014). No patient died in the peri-operative period. A total of 11 technical failures (8 occlusions and 3 endoleaks) occurred: 9 /76 (11.8%) with SeSGs vs. 2/38 (5.2%) with BeSGs (p=0.22). Median follow-up was 27.1 months (range 1-80). Patient survival at 5 years was similar in the groups: SeSGs 66.8%, BeSGs 67.2% (p=0.073). Actuarial hypogastric primary patency rate resulted 85% in SeSG-group and 97% in BeSG-group (p=0.08). Freedom from late failure was 93% inSeSG vs. 90% in BeSG-group (p=0.06). Freedom from hypogastric reintervention was 98% in SeSG-group and 93% in BeSG-group (p=0.22). At multivariate analysis none of the co-variates resulted predictive of late clinical failure

Conclusions: Our study did not find any significant difference in long term results of different models of HSG. SeSGs, used in hostile iliac arteries, presented slightly lower success rates reinforcing that adverse anatomy is the most important factor for failure of the endovascular procedure.



Euro14A-MA023

Safety and effectiveness of a balloon expandable stent system for the treatment of iliac occlusive disease: 9-month outcomes of the VISIBILITY iliac study

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Aims: Endovascular stents are an accepted treatment modality for iliac artery stenosis and occlusions. The VISIBILITY Iliac study evaluated the safety and effectiveness of primary stenting using the Visi-ProTM Balloon Expandable Stent for the treatment of lesions in the common and external iliac arteries.

Methods and results: Between 2011 and 2012, patients presenting with Rutherford Class 2-4 claudication and atherosclerotic lesions up to 10 cm in length were enrolled in the VISIBILITY Iliac study. Seventy-five patients underwent iliac artery stenting at 17 centres in the USA and Europe (mean age of 64 years, 61% male). The mean lesion length treated was 29.3±13.9 mm, including 54% moderate to severely calcified lesions. Eighty-one stents were implanted in 61 common iliacand 15 external iliac artery lesions. Device success, defined as the ability to deploy the stent as intended at the treatment site, was 100%. The major adverse event rate at 9 months occurred in 3 (4%) subjects (defined as a composite of periprocedural death, in hospital myocardial infraction, clinically-driven target lesion revascularisation, and amputation of treated limb). Primary patency and freedom from clinically-driven target lesion revascularisation at 9 months were 95.8% and 95.8% respectively. Between baseline, 1 and 9 month follow-up visits, ankle brachial indices (ABI) increased significantly from 0.67±0.14 to 0.94±0.14 and 0.96±0.16, respectively (p<0.0001 and p<0.0001).

Conclusions: Nine month results of the VISIBILITY Iliac study demonstrate safety and effectiveness for the treatment of lesions of the common and external iliac arteries with the Visi-ProTM stent.

One stage stenting of both iliac arteries for bilateral ostial-proximal common iliac arteries stenosis or occlusions

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Aims: We describe our experience in one stage treatment of both iliac arteries with contemporary placement of stents

Methods and results: As previously described in the region of Yambol (south-eastern Bulgaria) from the beginning of 2012 we organised an interdisciplinary team with participation of Italian specialists for early clinical and non-invasive diagnosis, hospitalisation for interventional or surgical treatment and consequence clinical follow-up of the patients at risk of PAD. The core of the team consists of interventional cardiologist, vascular surgeon and diabetologist. Any decision for treatment either surgical or interventional was done in complete consensus between the surgeon and the interventional cardiologist. From January 2012 to July 2013 we had 6 patients (4 males 66.7%, mean age 68.3 y) with bilateral ostial-proximal stenosis or ostial occlusions of both common iliac arteries. Two of them have had total ostial occlusions of both iliac arteries and the rest 4 (66%) have had severe ostial stenosis of both common iliac arteries (mean stenosis for the LCIA 86.7%, for the RCIA 85%). In all of them after consult with the members of the team we performed contemporarily one stage PTA with stenting of both iliac arteries. As a procedural standard in our cathlab the diagnostic procedure was performed via right radial artery with 5F long (21 cm) radial introducer. The contrast injection was applied or through the pigtail catheter or through the MP catheter. Once established the extension of the disease and its severity and after complete agreement with the vascular surgeon the PTA was performed. The radial pigtail catheter was left for dial injection during the procedure. The puncture of the both femoral arteries was performed under X-ray control and with small contrast injections from the pigtail catheter. In the both femoral arteries a 6F introducer was placed. Then in case of non total occlusions two long 0.35" wires were placed in the aorta. In case of the two patients with total bilateral ostial occlusion of the both common iliac arteries first we placed a 5F introducer and with the Terumo 0.35" wire with the support of 5F JR catheter we performed reopening of the artery. Pre-dilatation was performed in 4 LCIA (66%) and in 6 RCIA (66%). After achieving a sufficient lumen to pass through the lesion with the stent and under contrast injection from the radial pigtail catheter control contemporary in one moment the two stents were placed. In 5 patients 83% of the stents were balloon expandable ones. Post-dilatation kissing balloon for symmetric expansion of the stents was performed in all patients. The success rate was 100% and no complication was observed. No access site problems were noted. All patients were discharged with significant clinical improvement and at the one month follow-up all were free from claudication.

Conclusions: According to our experience bilateral ostial stenosis or occlusions of common iliac arteries can be considered a real bifurcation lesion and thus must be treated in one stage procedure with contemporary placing of both iliac stents. This will give an anatomic and homogeneous dilatation and apposition of the stents. Moreover the patients' satisfaction from one stage procedure and immediate resolution of their problem is another issue in favour of one stage procedure.



Euro14A-0P231

Drug-eluting balloons for the treatment of *de novo* lesions in the peripheral artery disease - First interim analysis of the Freeride study

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Aims: The use of paclitaxel-coated balloons during percutaneous transluminal angioplasty (PTA) for peripheral artery disease (PAD) might be associated with lower restenosis rates in comparison to PTA alone. The Freeride study investigates the inhibition of restenosis by the Paclitaxel-eluting balloon (DEB) Freeway PTA versus plain old balloon angioplasty (POBA) in the treatment of *de novo* occluded or stenotic lesions in the superficial femoral artery (SFA) and popliteal arteries (segment PI).

Methods and results: This study is a controlled multicentre trial conducted in 23 centres worldwide. 280 patients are randomised 1:1 either to Freeway arm or to POBA arm. The primary endpoint is the rate of clinically driven target lesion revascularisation (TLR) at 6 months. Further, several secondary endpoints like late lumen loss and patency rate at 6 months, TLR at 12, 24 months follow-up (FU), improvement in the Anklebraquial index (ABI) and in Rutherford classification at 6, 12, 24 months FU, and major adverse events (MAE) are investigated. Until the date 71 patients have been enrolled, 51 of them completed the 6 month FU, in 3 patients the FU was not available. The results show non statistical differences between Freeway and POBA arm at baseline except for residual stenosis in the lesion after the procedure, which was significant higher after POBA compared to Freeway PTA (20±18.7 vs. 10±14.3; p=0.01). After the procedure results there were also significant less clinical success and more bail out stenting in the POBA arm compared to Freeway arm (78.1% vs. 94.9%; p=0.03 and 28.1% vs. 10.3%; p=0.05). At 6 months there are positive trends for the FREEWAY arm in the TLR rate (6.6% vs. 9.5% after POBA), MAE (6.7% vs. 14.3% after POBA; p=0.36) and the clinical outcome in Rutherford Classification.

Conclusions: The first interim analysis indicates that the paclitaxel-eluting balloon Freeway might provide an advantage for peripheral artery interventions in the SFA and PI-segment. DEB might give better outcomes and could overcome the existing limitations encountered in the current treatments for the peripheral artery disease.



Investigation of inhibition of restenosis by drug-coated balloons in peripheral arteries: post dilatation of nitinol stents with drug-coated balloons versus plain balloon in the superficial femoral and popliteal arteries? Latest interim results of the Freeway Stent Study

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Aims: The restenosis rate of stents is a major limitation of peripheral arterial interventions. Drug-coated balloons potentially overcome the problem of restenosis when used for postdilatation after provisional nitinol stenting in the superficial femoral (SFA) or populated (PI) arteries.

Methods and results: The Freeway Stent Study is a prospective, randomised, international trial conducted in 15 centres in Germany and Austria. 200 patients with stenotic lesions or occlusions in the SFA or PI segment will be enrolled and randomised equally to nitinol stenting followed by either drug-coated balloon (DCB, FreewayTM) or plain old balloon (POBA) postdilatation. Primary endpoint is clinically driven target lesion revascularisation (TLR) at 6 months. Secondary endpoints include late lumen loss (LLL), patency rate, major adverse events (MAE) and change in Rutherford classification or ankle-brachial index (ABI). About 150 patients have been enrolled to date. The results at 6 and 12 months FU favour the use of FreewayTM DCB based on clinically driven target lesion revascularisation (TLR) (only 3.5% at 6 months and 8.9% at 12 months for DCB group vs. 7.8% at 6 months and 12.5% at 12 months for POBA group). Furthermore, favourable clinical results regarding patency rate (90.6% after DCB use vs. 75.0% after POBA use at 6 months; p=0.06) and significant better clinical results regarding shift in ABI (63.0% show ABI between 1.0 and 1.2 after DCB use vs. 39.1% after POBA use at 6 months; p=0.02) and shift in Rutherford classification (mean 0.21±0.59 after DCB use vs. 0.78±1.03 after POBA use at 6 months; p=0.0006) were obtained after stent postdilatation with the FreewayTM DCB.

Conclusions: The Freeway™ DCB is investigated in a new approach to decrease the restenosis rate in patients with stenting in the SFA or PI. The latest interim results of the Freeway Stent Study show that DCB might provide an advantage for the treatment of peripheral arterial disease (PAD) patients to overcome existing limitations.



Euro 14A-0P233

Twenty-four-month results with a new paclitaxel-coated balloon for treatment of femoropopliteal lesions: ILLUMENATE FIH Trial

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Aims: The aim of the ILLUMENATE FIH Study is to assess the safety and effectiveness of the StellarexTM drug-coated angioplasty balloon (Covidien, Mansfield, MA) to inhibit restenosis in the superficial femoral (SFA) and/or popliteal arteries.

Methods and results: This prospective, single arm, multicentre study enrolled 80 patients at three centres in Germany. Lesions in the first 50 patients were treated with traditional pre-dilatation with an uncoated angioplasty balloon prior to inflation of the drug-coated balloon (DCB). The subsequent 30 patients were enrolled in the direct DCB (e.g. no pre-dilation) cohort. Follow-up visits were conducted at pre-discharge, 1, 6, 12, and 24 months. Data pertaining to the pre-dilatation cohort are presented here. 50 patients with 58 lesions were enrolled in the pre-dilation cohort. Mean age was 69 years, 82% were classified as Rutherford Class 3, 52% were current smokers and 34% were diagnosed with diabetes mellitus. The mean target lesion length was 72.1±46.7 mm and baseline stenosis was 75.1±17.0%. Calcification was present in 62.1% (36/58) of lesions and 13.8% (7/58) were occluded. The post-DCB diameter stenosis was 21.1±11.4%, a mean reduction of 54.0±20.1%. As previously reported, late lumen loss was 0.44 mm at 6 months. Primary patency, per Kaplan-Meier analysis, was 91.7% at 6 months and the 12-month patency was 87% per Kaplan-Meier analysis. 24-month outcomes will be presented at EuroPCR 2014.

Conclusions: The Stellarex[™] DCB is safe with durable results throughout 12-months. Follow-up visits are in progress; 24-month outcomes will be presented at EuroPCR 2014.

Short-term clinical outcome of DES implantation for superficial femoral artery lesions as compared to BMS

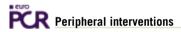
Mori S., Muramatsu T., Tsukahara R., Ito Y., Ishimori H., Hirano K., Nakano M., Yamawaki M., Araki M., Kato T., Kobayashi N., Inoue Y., Takimura H., Sakamoto Y., Tsutsumi M., Takama T., Takafuji H., Tokuda T., Makino K.

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Aims: Limited data exists on patients who have undergone drug-eluting stent (DES) implantation for superficial femoral artery lesions. We compared clinical outcomes of DES with bare metal stent (BMS).

Methods and results: This was a single-centre non-randomised retrospective study. From April 2007 to March 2013, 358 lesions (334 limbs) which underwent DES (Zilver PTX stent, Cook Co.Ltd) or BMS (S.M.A.R.T. stent, Cordis Co. Ltd) implantation for *de novo* superficial femoral artery lesion were included. Subjects were classified into two groups: the patients with Zilver PTX stent (Z group, 88 lesions, 78 limbs) and with S.M.A.R.T. stent (S group, 268 lesions, 255 limbs). We compared clinical outcomes at 9 months after stent implantation. For patients and lesion characteristics, there were no significant differences between two groups in age, female, diabetes mellitus, haemodialysis, critical limb ischaemia, lesion length >150 mm, and poor run-off. The rate of TransAtlantic Inter-Society Consensus (TASC) II classification C/D was lower in Z group (33.0% vs. 62.3%, p<0.05). The primary patency was higher in S group at 9 months estimated using the Kaplan-Meier methods compared to Z group (88.6% vs. 82.0%, Log rank p<0.05).

Conclusions: Short-term clinical outcome of DES implantation for superficial femoral artery was inferior to BMS.



Euro14A-0P235

Nitinol self-expanding paclitaxel-eluting stent was useful in endovascular therapy for in-stent restenosis after superficial femoral artery stenting

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Aims: In endovascular therapy (EVT) for superficial femoral artery (SFA), nitinol selfexpanding stent has been useful compared to only balloon angioplasty. However strategy for in-stent restenosis (ISR) after SFA stenting was unclear. Nitinol selfexpanding drug-eluting stent (DES) for SFA has been approved in our country. The primary patency of DES was higher than bare-metal stent (BMS). Our aim was to investigate clinical outcomes after endovascular therapy (EVT) for BMS-ISR in SFA.

Methods and results: In 710 consecutive cases which underwent EVT for SFA between April 2007 and August 2012, we analysed 68 consecutive cases (74 limbs) which underwent secondary EVT for SFA lesions of BMS-ISR. In secondary EVT, strategy was only balloon angioplasty (A group: 24 limbs, 37.5%), nitinol selfexpanding bare metal stenting (BMS group: 26 limbs, 40.6%) or nitinol selfexpanding pclitaxel-eluting stenting (Zilver PTX*) (DES group: 24 limbs, 21.9%). Either angiography (diameter stenosis>50%) or duplex ultrasoundgraphy (peak systolic velocity ratio >2.5) were used at six months follow-up to define restenosis. Mean age of patient was 67.6±9.6 years old; diabetic patient was 35 cases (51.5%). 21 limbs (28.4%) were over Rutherford category 4. In primary EVT, S.M.A.R.T Control stent or Zilver stent were deployed (mean diameter: 6.6±0.7 mm, total length 135.8±93.8 mm). In secondary EVT, cases of focal stenosis were 16 limbs (21.6%), diffuse stenosis were 34 limbs (46.0%), stent fracture were 3 limbs (4.1%) and 24 limbs (32.4%) were total occluded with thrombus. After secondary EVT, restenosis rate in DES group was the lowest (DES group: 0 limb vs. A group: 6 limbs, 25.0% vs. BMS group: 5 limbs, 19.2%; p<0.01).

Conclusions: In EVT for in-stent restenosis of SFA, nitinol selfexpanding paclitaxel-eluting stenting might be useful.

Belgian remedy registry: one-year results of bio-absorbable 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 commonly good. But problems such as in-stent stenosis or occlusion are now more and more apparent. 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: The Belgian multicentre prospective follow-up study used 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, 100 patients, with TASC II A & B lesions (20 c % occlusions) in the SFA region. Mean lesion length: 35 mm (2-80 mm). Technical success rate: 98%. There are no interventional related deaths. Follow-up is done by ulta-sound. Six months primary patency 70.2%, assisted patency: 88.5%. Target lesion revascularisation 17.9. At 12 months primary patency is around 65%.

Conclusions: Bioabsorbable stent technology might give an improvement in the mid & long-term durability of SFA endovascular treatment. The early results are encouraging, but 12-month results are rather disappointed. The combination of drug coated balloon and the Remedy stent are under investigation to see if this could improve the results. Better understanding and even adjustments of the kinetic and mechanical characteristics of the stent structure and design are nescessary and under investigation.



Euro14A-0P237

Synergistic strategy of laser atherectomy and drug-eluting balloon angioplasty for treatment of in-stent restenosis in the superficial femoral artery: a randomised study

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Aims: Femoral artery stenting is a good alternative to surgical bypass for treatment of superficial femoral artery disease. Several trials demonstrated that primary stenting may improve immediate angiographic results and long-term patency. Nonetheless improvements of device, neo-intimal hyperplasia still remain the biggest Achilles hell of this approach, resulting in a restenosis rate of 14-50% at one-year follow-up, of which 33% occluded. Even drug-eluting stents, recently introduced in the clinical practice for the treatment of femoral disease, have a rate of restenosis / occlusion of about 17%. Treatment of in-stent restenosis and occluded stent is a challenging condition for interventionist without clear guidelines. Debulking of the neo-intimal hyperplasia is a good option to a obtain a complete recanalisation reducing the risk of future recurrence reducing the disruptive stretching process of a redo percutaneous transluminal angioplasty. In particular laser ablation, using ultraviolet light emitted from catheter containing optical fibers, vaporizes different component of plaque without a inflammatory response. This approach may also improve the outcomes of an associated drug-eluting balloon angioplasty, increasing the amount of paclitaxel that reach the intimal layer, reducing the thickness of the wall. In this chapter a description of the synergistic effect of these techniques, focusing on literature experience.

Methods and results: From December 2009 to March 2013, 56 patients (of 558 CLI patients) underwent endovascular treatment of a SFA chronic stent occlusion. The patients were randomly subdivided in two groups: LD combined with DEB angioplasty was used in 28 patients (Group 1) and 28 patients were treated with DEB angioplasty alone (Group 2). The patency rate at 12-month follow-up was the primary endpoint. Secondary endpoints were target lesion revascularisation (TLR) and clinical success at 12-month follow-up. In Group 1, the patency rate was significantly higher than in Group 2 at 6- and 12-month follow-up (respectively 91.7% and 66.7% in group 1 and 58.3% and 37.5% in group 2, p=0.01). TLR at 12-month follow-up was 16.7% in group 1 and 50% in group 2 (p=0.01). Two patients (7.6%) needed major amputations in group 1 while 11 patients (42.3%) in group 2 at 12-month follow-up (p=0.003).

Conclusions: The combined treatment with LD and DEB angioplasty is correlated with better outcomes in CLI patients with SFA stent occlusions.

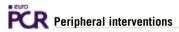
Long-term results of tapered stents in endovascular treatment of carotid stenosis - Single-centre experience

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Aims: To analyse the effect of stent configuration (cylindrical vs. tapered) on early and late outcomes of carotid stenting

Methods and results: Patients undergoing carotid stenting between 2005 and 2012 were reviewed. Primary endpoint was the composite of 30-day mortality and any neurological event. Secondary endpoints were any late (>30 days) neurological event and restenosis >50% at duplex scan. 1,368 procedures were included (68.7% males, age 71±7.4): in 485 a tapered stent (conic) and in 883 a cylindrical stent (straight) was deployed based on patient anatomy and operator choice. The 2 groups differed for preoperative neurological symptoms, 6.2% in conic group vs. 10.8% in straight group (p=0.004) and use of statin therapy, 64.9% in conic vs. 49.8% in straight (p<0.0001). At 30 days there was no mortality; neurological complications occurred in 5.5%, with similar rates between groups. The primary endpoint was reached in 99 cases (7.2%): 6% in conic and 7.9% in straight group. Age>80 years, contralateral occlusion, preoperative neurological symptoms and no statin therapy were significantly associated with the primary endpoint. At Cox regression analysis, independent association with the primary endpoint was confirmed for statin therapy (OR 0.49, CI 0.33-0.74) and contralateral occlusion (OR 2.2, CI 1.2-3.9) At a mean follow-up of 30.2± 24 months, late neurological events occurred in 27 cases (2%); conic stents resulted protective at univariate analysis (p=0.007), while there was borderline association at adjusted analysis. Restenosis occurred in 33 cases (2.4%): 1.2% in conic vs. 3.1% in straight groups (p=0.042). Difference in restenosis rates between groups was not statistically significant at 60 months Kaplan Meier analysis (Log Rank test p=0.2).

Conclusions: The use of conic stents appears to be associated with similar perioperative results if compared to straight stent configurations. Late outcomes suggest a lower risk of restenosis and late neurological events in patients with conical shape stents.



Euro14A-0P239

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 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 presentanalysis. 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 patient); 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.



Long-term results of drug-eluting balloon percutaneous transluminal angioplasty for treatment of refractory recurrent carotid in-stent restenosis

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Aims: Carotid artery stenting (CAS) is becoming a good alternative to endarterectomy particularly in high risk patients. ISR may occur with a variable incidence of 3 to 20% in literature. Several studies demonstrated the utility of DEB in coronary stent restenosis. Paclitaxel local delivery should play a potential role in carotid ISR. In this study we evaluated potential role, safety and efficacy of drug-eluting balloon for treatment of carotid in-stent restenosis (ISR)

Methods and results: 856 consecutive patients underwent carotid artery stenting from May 2002 to January 2008. In 41 patients a significant ISR (>80% stenosis) occurred. Nine of these were affected by the onset of recurrent restenosis in spite of multiple endovascular treatments (3.4±0.9 interventions) within a short period of time. These patients were treated with DEB angioplasty for neointimal hyperplasia. An ultrasound/Angio-CT control was performed at 1, 3, 6 and yearly after the procedure with mean follow-up time 36.6±2.7 months. A technical success was obtained in 100% of cases. A distal filter device was used in all cases. No major periprocedural neurological or myocardial events were recorded. Angiographic stenosis decreased from 87%±4% to 6±4%. Peak systolic velocity (PSV) decreased significantly after the procedure from 4.7±1.5 to 0.6.±0.3 m/s. PSV maintained under a significant values during the follow-up except in three patients, who developed a significant ISR at 18, 25 and 32 months after the procedure, respectively. TVR was 33.3% at 36 months follow-up. No neurological or myocardial events were recorded during the follow-up. 1 patient died at 3 months follow-up

Conclusions: DEB may have a potential role, improving outcomes of those patients treated for recurrent early carotid ISR.



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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 dlabetic 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), symptomatic COD 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 patient); 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 artery stenting with double cerebral embolic protection in symptomatic patients

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Aims: Stroke is the first cause of death in the industrialized countries and the first cause of permanent disability. The carotid endarterectomy (CEA) is at the moment the treatment of choice for both symptomatic and asymptomatic patients. Carotid artery stenting (CAS) has emerged in recent years as a viable alternative especially in surgical high risk patients and it was demonstrated to be the not inferior compared with CEA in this category of patients. The most serious complication for both CAS and CEA is represented by cerebral embolisation. To cope with this problem there are embolic protection systems. The distal filter protection systems have the advantage of preserving an anterograde flow and thus ensure a better tollerability and disadvantages in terms of ability to capture emboli and possible embolisation in positioning phase. The proximal protection system (MoMa) is a device which provides for the simultaneous inflation of a baloon in the external carotid artery and one in the common carotid artery with temporary exclusion of the anterograde flow. Expecially in symptomatic patients with soft carotid plaques there is a high risk of embolisation during CAS. Trying to minimise this complication we used in some of these high risk patients a double cerebral embolic protection, proximal and distal

Methods and results: From January 2008 to June 2013, 255 carotid angioplasty of both symptomatic and asymptomatic patients have been performed in our laboratory. Of these, 14 were treated with double embolic protection. All patients were symptomatic for minor stroke, with doppler demonstration of plaque >60% (NASCET) and neurological indication for percutaneous treatment. The average age of the patients was 72±7 years, men were 11. The procedure involved the placement of proximal embolic protection (MoMa) and the filter distal protection. There were no procedural complications and at follow-up (36±6 month), all patients were asymptomatic and had no recurrence of neurological symptoms.

Conclusions: In our experience the double cerebral embolic protection (proximal and distal) during CAS can be considered safe and effective in minimising the risk of cerebral embolisation in high risk patients. The arrest of carotid flow prior to the positioning of the distal filter can minimise the risk of embolisation associated with its positioning, particularly in case of soft plaques. Limits in using systems which stop the proximal flow are the potential poor tollerability of the patients and the controlndication in case of critical controlateral carotid disease.



Euro14A-0P243

Invasive treatment of critical limb ischaemia: long-term results

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Aims: Surgical tibial bypass for critical limb ischaemia is associated with significant morbidity, mortality, and graft failure, whereas percutaneous angioplasty and stenting has promising results. The objective of this prospective register was to investigate the long term outcomes of the below-knee percutaneous angioplasty in patients with critical limb ischaemia.

Methods and results: The clinical and angiographic data of 278 consecutive patients with critical limb ischaemia treated by angioplasty between 2009 and 2011 was evaluated in a prospective register. Patients received daily aspirin, and Heparin during the procedure. Clopidogrel was given in stented patients. Major adverse events were defined as death, myocardial infarction, major unplanned amputation, need for surgical revascularisation, or major bleeding. Clinical success was defined as relief of resting pain, healing of ulceration or amputation, and improvement of claudication. Mean age of patients was 72.5±36.5 years and the follow-up period was 900±120 days. Below-knee angioplasty was attempted in 278 patients with critical limb ischaemia. In 254 limbs (91.3%), straight inline flow was restored to at least one tibial vessel. Acute technical success was 91.3% for *de novo* lesions and the short and long term limb survival was 232 (83%) at one year and 221 (79%) at 3 years. Minor amputation (toe) was performed in 8 patients. Major adverse events occurred in 109 patients (39,2%) during the follow-up period. The long term mortality was after 3 years 44 (15,8%) and 2 (0,72%) successful and unsuccessful revascularisation (p<0.03).

Conclusions: Below-knee stent angioplasty for critical limb ischaemia is technically safe and effective procedure and the patients benefit long term on successful revascularisation.



The PES-BTK-70 study: interim results of the assessment of the first selfexpanding nitinol paclitaxel-eluting stent in below-the-knee lesions

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Aims: Previous studies have shown that treatment with drug-eluting stents is safe and effective in patients with critical limb ischaemia due to occlusive infrapopliteal disease. The results with currently available DES come from balloon-expandable stents. However, self-expanding nitinol stents traditionally yield better results in arterial anatomies which are prone to flexing, elongation, compression and bending. This study investigates primary stenting using the first self-expanding nitinol paclitaxel-coated DES (STENTYS, France) in below-the-knee lesions.

Methods and results: This study is a multicentre, single arm study, which prospectively evaluates the 6 and 12 months safety and effectiveness of the STENTYSDES in 70 patients with critical limb ischaemia. Inclusion criteria are evidence at screening of ≥50% *de novo* lesion, reference vessel diameter between 3.0 mm and 4.5 mm, lesion length shorter than 50 mm. Patients with previous bypass or major distal amputation in target limb, untreated flow limiting inflow lesions, in-stent restenosis, severe calcification were excluded. Predilatation of the target lesion was mandatory. Primary patency rate, defined by duplex ultrasound and no re-intervention of target lesion, was evaluated by a core laboratory at 6 months (primary endpoint). 70 patients were enrolled in 5 centres between Jan 2012 and May 2013.

Conclusions: Interim results on the 6 months follow-up data of the first 50 patients will be presented: in particular, the technical and procedure success rates, the primary patency rate at 6 months, as well as limb salvage rate, target lesion revascularisation, improvement in ankle-brachial index, Rutherford class and major adverse events.



Euro14A-0P245

BIOLUX P-II: a randomised clinical trial comparing a drug releasing balloon versus plain old balloon angioplasty for the treatment of infrapopiteal artery lesions

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Aims: Plain old balloon angioplasty of infrapopliteal arteries is associated with high restenosis rates. Recently, drug-releasing balloons have emerged as a viable treatment alternative. BIOLUX P-II assesses the safety and performance of the novel Passeo-18 Lux paclitaxel releasing balloon versus the uncoated Passeo-18 balloon for the treatment of stenosis, restenosis or occlusion of infrapopliteal arteries.

Methods and results: BIOLUX P-II is a prospective, international, multicentre, randomised, controlled, first-in-man clinical trial with follow-up investigations at 30 days, 6 and 12 months. Subjects with single or sequential, *de novo* or restenotic lesions in the infrapopliteal arteries (≥30 mm) were included in the study. Lesions should not have extended beyond the ankle joint and a maximum of two different vessels were treated. The safety and performance primary endpoints are major adverse events at 30 days and target lesion primary patency at 6 months (assessed by an independent angiographic core laboratory via quantitative vascular angiography), respectively. Secondary endpoints include binary restenosis at 6 months, and target lesion revascularisation, change in mean Ankle Brachial Index and Rutherford classification and major adverse events at 6 and 12 months. Seventy-two subjects, 79.2% men, mean age 71.3±9.7 years were randomised 1:1 at six sites in Austria, Belgium and Germany. At baseline, subjects presented with typical risk factors associated with peripheral artery disease: hypertension (86.1%), followed-by hyperlipidemia (68.1%) and diabetes (66.7%). The majority of subjects (77.8%) were classified as Rutherford 4 and 5 and 16.7% were Rutherford 3.

Conclusions: The primary endpoints for this study as well as 6-month secondary endpoints will be presented at EuroPCR 2014.

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Safety and efficacy of infrapopliteal endovascular therapy for haemodialysis patients with critical limb ischaemia according to the suggested objective performance goals

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Aims: The aim of this study is to investigate the clinical safety and efficacy of infrapopliteal endovascular therapy for haemodialysis (HD) patients with critical limb ischaemia (CLI) according to the objective performance goal (OPG) endpoints in catheter-based therapies for CLI suggested by the Society for Vascular Surgery.

Methods and results: This study used data obtained from a multicentre retrospective study conducted with the participation of 14 Japanese departments of cardiology or vascular surgery. Among 1,091 serial CLI patients with 1,310 limbs who underwent balloon angioplasty as primary treatment for isolated infrapopliteal artery disease from 2004 to 2012, subjects were 670 HD patients (mean 70±9 years) with 830 limbs. Outcome measures were freedom from any reintervention or above ankle amputation of the index limb (RAO), major adverse limb events with perioperative death (MALE+POD) and amputation-free survival (AFS) at 1 year estimated using the Kaplan-Meier method in the average follow-up period of 2.5±1.5 years. Independent predictors of AFS were examined using the Cox proportional hazards regression analysis. Freedom from RAO was 49.0±1.9%, MALE+POD was 78±2%, and AFS was 66±2% at 1 year. Freedom from MALE+POD surpassed the suggested OPG of 67%. Freedom from RAO however, was below the suggested OPG of RAO (51%) and AFS was below the OPG of AFS (68%) too. Independent predictors of AFS were non-ambulatory (HR2.9; p<.001), diabetes mellitus (HR2.2; p<.001), albumin <3.0 g/dl (HR1.9; p=0.02), ejection fraction 0.48 (HR1.7; p=0.02), and dorsalis pedis and plantar artery occlusion at baseline angiography (HR1.5; p=0.03). In the HD patients with more than two predictors, AFS at 1 year was below the suggested OPG. Conclusions: The clinical efficacy of limb salvage after infrapopliteal endovascular procedures for HD patients with CLI was acceptable using the OPG endpoints, but it did not achieve the treatment goal of survival with a functional limb. AFS is the most important clinical key point following EVT for HD patients with CLI, and preoperative risk stratification based on AFS predictors contribute to predicting life and limb prognosis after the procedure.



Euro14A-0P247

Percutaneous transluminal angioplasty of the infrapopliteal arteries for critical limb ischaemia in patients with indication of major amputation

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Aims: To analyse the limb salvage in critical limb ischaemia (CLI) treated by endovascular therapy in patients with the indication of infrapopliteal amputation

Methods and results: Between November 2011 to October 2013, a retrospective, descriptive and longitudinal study of 37 consecutive patients (37 limbs) with CLI, defined as rest pain or ulcer/gangrene, treated with endovascular technique in infrapopliteal territory, was developed. We analysed the clinical and angiography characteristics and the limb salvage rate. The decision regarding the type of treatment by a multidisciplinary team was made. The first option was to open at least one Tibial Artery (TA) to keep a straight-line outflow to the pedal arch. When it was no technically feasible, the option was to treat the Peroneal Artery (PA). Clinical success was defined as maintaining a viable extremity during the follow-up. The results were showed as mean±2 standard deviation for the continuous variables and percentage for categorical variables. 37 limbs were treated out of 37 patients; 12.8 months (range 2-18) was the clinical follow-up. Baseline characteristics were: 25 men (67.5%); mean age of 61.5 years (±22.6), diabetes mellitus 32 patients (89.5%), hypertension 22 patients (59.4%), dyslipemia 8 patients (21.6%) and 20 (54%) smokers patients. Five patients (5.2%) in Rutherford category 5 and 36 patients in category 6 (94.7%). Angiography characteristics: 27 patients (73%) with 3 vessels disease below the knee and 10 patients (27%) with 2 vessels disease. Arteries treated with three-vessel disease: 3 arteries 1 patient, 2 arteries 7 patients and 1 artery 19 patients. Arteries treated in two-vessel disease: 2 arteries 8 patients and 1 artery 2 patients. Treated arteries: 20 arteries (48.8%) were Anterior TA; 10 arteries (24.4%) were Posterior TA and 11 arteries (26.8%) were PA. There were concomitant angioplasties in popliteal artery in 3 patients and in Superficial Femoral Artery in 1 patient. Technical success was in 36 patient (97,3%). Clinical success: 31 patients (83.8%). Six patients (16.2%) needed below the knee amputation (one failure technical in Anterior TA and 5 with success technical in PA). Seven stents (18.9%) were implanted and drug-eluting balloon was used in 2 patients (5.4%). The limb salvage rate was 84%.

Conclusions: Percutaneous transluminal angioplasty of the infrapopliteal arteries appears to be an effective treatment to preserve the limb in patients with prior indication of amputation.



Covered endovascular reconstruction of aortic bifurcation, a heamodynamically proven technique for treating extensive aorto-iliac occlusive disease

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Aims: We developed and tested 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 then have a very tight combination with the aortic stent, as were they moulded together, simulating a new bifurcation. Two-centre physician-initiated, prospective, non-randomised, follow-up study. We have treated more than 80 patients with acute, chronic or recurrent aortoiliac occlusive disease. Technical success rate up till now was almost 95%. Follow-up 60-3 months. 5 patients died of non-interventional causes. Six 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. Further we tested this technique in a flow model, comparing it to both kissing bare and covered stent configurations and this showed that the CERAB technique is haemodynamically superior

Conclusions: CERAB is safe and feasible and can be performed completely percutaneously. A larger population and longer follow-up, 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. Haemodynamic *in vitro* investigation showed a superior outcome compared to other techniques.



Euro14A-0P250

Immediate and long-term results of stent repair in patients with complex coarctation of aorta - A twenty-year study

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Aims: Stent repair of coarctation of the aorta is an alternative to surgical correction. However, several anatomic or evolving characteristics of the coarctation throughout life may create challenging conditions for both, surgical or percutaneous treatment. We retrospectively analysed our 20-year experience in the percutaneous treatment of complex coarctation of aorta.

Methods and results: From November 1993 to July 2013 we have percutaneously treated 59 patients considered to have a complex coarctation of aorta. 15 of them had associated malformations (25%). 23 of them had one or more previous interventions on the coarctation, either surgical (n=8), percutaneous (n=14) or both (n=1). Time from first treatment was 9±9 years. 36 patients (61%), mean age 26±17 years, presented with a native coarctation of complex treatment. Adverse conditions for treatment were: 1) Complete interruption of the arch (n=10), 2) Associated aneurysm (n=17), 3) Complex stenosis (n=30) and 4) The need for re-expansion and/or re-stenting (n=21). 17 patients (29%) belonged to more than one group. Patients with interruption of the aortic arch presented with severe hypertension and 6 of them with heart failure; 2 had chronic atrial fibrillation. Following the classification of Celoria and Patton, 9 were type A and 1 was type B. The mean length of the interrupted aorta was 9±11 mm. Distortion of proximal and distal aortas was present in 5 patients, while they were well aligned in 5. In patients with associated aneurysm, the clinical condition was stable in all patients, with systemic hypertension and effort dyspnea in 10. The aneurysm was native in 7 patients, post surgery in 3 and post percutaneous intervention in 7. The aneurysm shape was fusiform in 8 and saccular in 9. Complex stenosis was defined as: a) a long diffuse stenosis (>45 mm) (n=12), b) a very tortuous coarctation, needing for repair an extremely acute remodeling (n=3), c) a stenosis involving a main branch (n=13), or d) a coarctation of unusual location (n=8). 6 of them had stenosis with more than one complex characteristics. Patients previously stented at early age (mean 3±3 years) as a palliative treatment, needed re-expansion and/or re-stenting when having 16±5 years of age. Re-expansion was performed at a mean of 13±4 years after first treatment, when there was a significant gradient across coarctation and a significant growing of the non-stented segments were demonstrated. Stent treatment and successful revascularisation was always achieved. One patient died suddenly 3 hours after treatment (1.7%). The remaining 58 patients did well and were followedup for a mean period of 10±6 years. Associated late surgery of the aortic valve was needed in 4 patients. Late adverse events (death, myocardial infarction or the need for new coarctation treatment) occurred in 3 patients (5%). The remaining 55 patients are sympthoms free and with normal baseline blood pressure. The last Doppler gradient across coarctation was 4±5 mmHg. Image techniques showed good patency of the aorta without associated aneurysm or restenosis. The actuarial survival free probability of all patients was 91% at 18 years after treatment.

Conclusions: Stent repair of complex coarctation of aorta is feasible and safe, despite the presence of adverse conditions for treatment. Initial results are maintained at late follow-up.

Mid-term results after thoracic endovascular aortic repair (TEVAR) with single branch Inoue stent graft of type-B thoracic aortic dissection

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Aims: The aim of present study is to investigate mid-term outcomes of single-branch Inoue stent graft implantation for thoracic aortic dissection with primary entry at distal aortic arch.

Methods and results: Among cumulative 504 patients who had stent graft implantation in our hospital from September 2004 to September 2013, 25 patients (7 women 18 men) had been performed TEVAR with single-branch stent graft for aortic dissection with primary entry at distal aortic arch. All patients had primary invasive treatment for aortic dissection. Primary endpoints were all cause death, aortic disease related death, clinical success. The mean aortic diameter at intervention was 59 ± 13 mm. Median follow-up interval was 39 ± 25 months. The technical deployment success to close the primary entry tear was 96%. 1 patient had failure to close the primary entry at the distal aortic arch. Hospital mortality was 0%. Cumulative incidence of all cause death was 0% at one-year and 12.6% at 3-year. Aortic related death was 0% at one-year and 0% at 3 year but only 1 case had aortic related death over 3-year after first TEVAR. Cumulative incidence of re-intervention was 8.7% at one-year and 51.3% at 3-year. The reason of re-intervention was non-coagulated false lumen because of remaining distal aortic tear or *de novo* tear at near the distal edge of stent graft. There were no surgical conversion cases in the present study.

Conclusions: TEVAR with single branch Inoue stent graft for type B aortic dissection was able to close the primary entry at the distal aortic arch with anatomical revascularisation. However the *de novo* tear at distal edge of stent graft might often become a problem, the mid-term results were favourable.



Euro14A-0P252

Endovascular treatment in patients with complicated type-B aortic dissection and malperfusion syndrome: mid-term results from a single-centre

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Aims: There were a few data with the safety and long term clinical outcome after endovascular treatment for complicated descending thoracic aortic dissection and malperfusion syndrome. The objective of this study is to investigate safety and mid-term clinical outcome after endovascular treatment for these pathologies.

Methods and results: The study included 11 cases of acute aortic dissection Standford type B, 3 cases of acute aortic dissection Standford type A, and 1 case of intramural hematoma Standford type B. A malperfusion syndrome involved 4 cases of celiac artery, 1 case of superior mesenteric artery, 6 cases of renal artery, 6 cases of iliac artery, 2 cases of common carotid artery, 1 case of left subclavian artery. 7 cases were also treated with aortic stent graft insertion along with treating a malperfusion syndrome. The number of treating lesions was 19, including 1 left subclavian a stenting, 3 celiac stenting, 6 renal stenting, 6 iliac stenting, 2 right common carotid a stenting, and 1 distal abdominal aorta stenting. The technical success was 100% (15/15). There was no death within the first 24 hrs or periprocedure events. However, 7 (45.7%, 7/16) cases of procedure related complications had occurred, including 4 cases of contrast induced nephropathy and 3 cases of anemia required transfusion. The mortality rate within index period was 6.6% (1/15), not related procedure itself nor disease entity. There was no major neurologic complication except 1 case of transient ischaemic attack during index period. The event rate during follow-up period was 0% (0/15). Mean follow-up duration was 17.2 (0.4-37.7) months. This was an observational retrospective study. 15 patients were managed with endovascular treatment from Dec. 2009 to Mar. 2013 at our hospital were enrolled. Mean age of patient was 54.3±14.2 years old. Male was 86.7% (13/15).

Conclusions: Endovascular treatment for complicated aortic dissection and malperfusion syndrome was a safe procedure with good mid-term clinical outcomes.



The AURORAA registry: two-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 vascular mimetic implant (Abbott Vascular, Santa Clara, Cal, US) we may have an answer in treating those problematic lesions.

Methods and results: Because of the Superas design; with 6 interwoven nitinol wires, it has extraordinary characteristics: very flexible, kink, fracture and crush resistant together with great radial force. This enables it to mimic the forces and movement of the native vessel. 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. Seven patients died of non-interventional causes. 9 patients had an occlusion due to progressive distal peripheral arterial disease. Six months primary patency was more then 90%. Twelve months primary patency was 80.3% and 24 months was more then 70%. We observed further more no stent fractures or flow limiting kinking. Average lesion length: 14 cm; average stent length: 18 cm. Technical success rate: 96%.

Conclusions: The Supera vascular mimetic implant 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 system can be a necessary complement in your tool box due to its special characteristics that truely mimics the native vessels movements and in-wotking forces.



Euro14A-0P254

Percutaneous treatment of stent-graft thrombosis employing a second stent-graft

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Aims: Thrombosed stent-grafts (Viabahn®) can accommodate large volumes of thrombus, up to 9 ml in a typical 6 mm×300 mm femoral-popliteal conduit. Due to the large thrombus burden, mechanical removal of clot from such conduits poses high risk of embolisation despite use of distal protection filters. On the other hand, thrombolysis is an overnight procedure fraught with logistic and bleeding issues. Therefore total exteriorisation of thrombus from the vascular lumen by relining the entire conduit with a second Viabahn® may be an option in management.

Methods and results: 10 consecutive cases that had previous Viabahn® placement in the superficial femoral artery and presenting with critical limb ischaemia from acute or subacute Viabahn® thrombosis were included. The mean time from initial Viabahn® placement to stent thrombosis was 11.2 months. The average age of the patients was 70.4 years. 90% of the patients had systemic hypertension and history of tobacco use. 60% of the patients had diabetes mellitus. All patients were treated percutaneously by relining the entire thrombosed conduit with a new Viabahn® via the femoral arterial approach. No distal embolic protection was used. Entry and exit disease was found in 9 cases and was addressed with angioplasty or stent placement as deemed appropriate. One case had no inflow or outflow issues and was started on long-term coumadin therapy. 50% of the patients required laser atherectomy. 100% of the patients had successful Viabahn® in Viabahn® placement with excellent angiographic results at the end of the procedure. The average length of the new Viabahn® was 111.2 mm. On an average, procedure time was 162 minutes with mean radiation time of 34.2 minutes. Average contrast used was 210 ml. All patients received statins and dual anti-platelet therapy with aspirin and clopidogrel. Patients were followed clinically at 1, 3 and 6 months and annually thereafter. Outcomes measured were recurrence of critical limb ischaemia, non-limiting claudication and ankle-brachial index suggestive of recurrence of disease. None of the patients had recurrence of critical limb ischaemia during one-year follow-up. 1 patient had non-limiting claudication reported at one month, 2 patients at 3 months and 1 patient at one year. Anklebrachial index measurements were available in 80% cumulatively and mean ankle-brachial index was 0.98.

Conclusions: Viabahn® in Viabahn® is a safe and simple therapeutic option for acute and sub-acute Viabahn® thrombosis. The procedure has low procedural complication rate and excellent short term clinical outcomes. There may be a role for this approach in surgical femoral-popliteal bypass graft malfunction as well. Larger studies with longer follow-up are needed to confirm our findings.

The novel sheathless method is useful and safety for retrograde approach for CTO of the superficial femoral artery

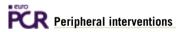
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Aims: Endovascular treatment (EVT) for superficial femoral artery (SFA) chronic total occlusion (CTO) typically involves attempting an antegrade approach. When this method is difficult, a wire lesion cross from a retrograde approach can be attempted. To date, there have been no reports on the success rate and safety using a microcatheter without a sheath. This study was conducted to investigate safety and success of wire lesion cross by retrograde approach with microcatheter.

Methods and results: We had performed EVT for 252 *de novo* SFA CTO lesions from April 2007 to December 2013. In these patients, the retrograde approach was used on 92 limbs in 70 patients. Of these cases, we divided these patients to two groups, which were the 4 Fr or 6 Fr sheath group and the microcatheter group. The sheath group was 37 limbs in 29 patients and the microcatheter group 50 limbs in 36 patients. We compared the success rates of popliteal artery (PA) puncture, wire lesion cross, haemostasis method, haemostasis time, and post-EVT as well as intrapostoperative, and a follow-up 30 days puncture site complications. We had excluded 5 patients (5 limbs) because they were switched from microcatheter group to sheath group during EVT procedure. There were no significant differences between two groups in patient's backgrounds and lesion characteristics. (N.S.) PA puncture was successful in all limbs. There was no significant difference in wire lesion cross between the two groups (sheath group: 91.9% vs. microcatheter group: 89.8%) (N.S.). Mean haemostasis time after completion of the procedure was 8.9±8.8 min in microcatheter group vs. 47.7±13 min in sheath group (p<0.0001). The rate of bleeding was higher in the sheath group (8.3% vs. 0%, p=0.02) and also, total intraoperative and postoperative complications were higher in the sheath group (22.2% vs. 2.0%, p=0.002).

Conclusions: The use of microcatheter for SFA CTO as a retrograde approach is superior to the use of 4 Fr or 6 Fr sheath in reduction of haemostasis time and complications.



Euro14A-0P256

Post-procedural intravascular ultrasound findings on short-term outcomes of DES implantation for superficial femoral artery lesions

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Aims: It has not been reported that Intravascular ultrasound (IVUS) findings correlate with drug-eluting stent (DES) restenosis after endovascular therapy for superficial femoral artery (SFA). So we investigated that in this study.

Methods and results: This was a single-centre non-randomised retrospective study. From April 2012 to March 2013, a total of 71 consecutive *de novo* SFA lesions in patients who underwent intravascular ultrasound (IVUS) after DES (Zilver PTX, Cook Co. Ltd) implantation were included. We excluded patients who underwent stenting for restenosis and those with acute limb ischaemia. The mean follow-up period was 9±4 months. In-stent restenosis (ISR) was defined as a peak systolic velocity ratio >2.4 on duplex ultrasonography or >75% stenosis on angiography. ISR were detected in 11 lesions (15.5%). Subjects were classified into two groups: the patients with ISR (ISR group, 11 lesions, 9 patients) and without ISR (non-ISR group, 60 lesions, 46 patients). We compared post-procedural IVUS findings between two groups. For baseline patients and lesion characteristics, the percentage of women and poor run-off were higher in ISR group than non-ISR group (77.8% vs. 25.0%, p<0.05, and 18.2% vs. 53%, p<0.05, respectively). There were no significant differences between two groups in diabetes mellitus (33.3% vs. 36.4%, p=0.86), haemodialysis (11.1% vs. 22.7%, p=0.43), TASC II C/D lesions (36.3% vs. 33.3%, p=0.85), and critical limb ischaemia (27.3% vs. 53.3%, p=0.11). For procedural characteristics, stent diameter, total stent length, and number of stents used were similar between the two groups (6.7±0.5 mm vs. 6.8±0.4 mm, p=0.14, 207±134 mm vs. 162±111 mm, p=0.23, and 2.3±1.3 vs.1.7±0.9, p=0.06, respectively). For post-procedural IVUS findings, there were no significant differences in minimum stent cross-sectional area (CSA), maximum stent CSA, radial stent symmetry index, and axial stent symmetry index (13.1±3.1 mm² vs. 14.7±4.5 mm², p=0.41, 15.1±4.9 mm² vs. 16.2±4.8 mm², p=0.48, 0.85±0.05 vs.0.79±0.14, p=0.15, and 0.59±0.12 vs.0.63±0.19, respectively). Distal lumen CSA was significantly smaller and the rate of tissue protrusion was higher in the ISR group (13.0±4.5 mm² vs. 19.9±7.2 mm², p<0.05, and 27.3% vs. 6.7%, p<0.05, re

Conclusions: DES implantation in small vessels and tissue protrusion were associated with ISR.



The late phase arterial healing evaluation after paclitaxel-coated nitinol DES implantation in the superficial femoral artery using endoscopy

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Aims: The late phase arterial healing after paclitaxel-coated nitinol drug-eluting stent (Zilver PTX) implantation in the superficial femoral artery (SFA) remains unclear. The aim of this study was to evaluate the atrial healing of Zilver PTX using endoscopy.

Methods and results: We performed endoscopic evaluation of 18 Zilver PTX stents (8 patients) implanted in the SFA. The follow-up period was 6 to 7 months after implantation. Neointimal coverage (NIC) was graded as 0, stent struts exposed; grade 1, struts bulging into the lumen, but still transparently visible although covered; grade 2, struts embedded in the neointima, but translucent; grade 3, struts fully embedded and invisible. The dominant, maximum, and minimal NIC was grade. The presence of yellow plaque and thrombus were evaluated. The dominant NIC was grade 3 in 17 stents (94%) and grade 1 in 1 stent (6%). The minimal NIC was grade 3 in 3 stents (18%), 2 in 2 stents (11%), and 1 in 12 stent (71%). Yellow plaque and thrombus were observed in 13 stents (76%). We performed the comparison of endoscopic evaluation of the stent body and stent edge. The dominant NIC grade was higher in the stent body (grade 3: 94%, grade 1: 6%) compared with the stent edge (grade 3: 65%, grade 2: 6%, grade 1: 29%; p=0.04). There were no difference in the presence of yellow plaque (body: 47%, edge: 59%, p=0.5) and thrombus (body: 47%, edge: 59%, p=0.5).

Conclusions: Ziver PTX stent attain good neointimal coverage in 6 months after implantation, however, uncovered struts, yellow plaque, and thrombus remains in the majority of stent. The poor arterial healing was frequently observed in the stent edge compared with stent body.



Euro 14A-MAOO9

Valve-in-valve implantation with a 23 mm auto-expandable transcatheter heart valve for the treatment of very small bioprosthesis: feasability, technique for implant and results

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Aims: Show the feasabibility of TAVI on degenerated smaller bioproshesis using a CoreValve 23 mm device.

Methods and results: Aortic bioprosthetic valves deteriorate with stenosis or regurgitation or both. Surgical reintervention is at high risk due to older age and redux; so in some patients TAVI procedures become an alternative even if the challenges are different from TAVI on native valve. At Arnault Tzanck institute in France, we describe 8 cases of the feasibility of TAVI in a very small bioprosthesis (19 and 21 mm Sorin Mitrowflow) with CoreValve 23 mm device with coronary occlusion risk, risk of mismatch and difficulties of implantation. 4 patients had severe aortic regurgitation before TAVI but none post TAVI. The higher level of implantation the lower the mean gradient. We had no complications during procedures. Although the mean gradient stayed high in some patients, all patients had a good functional status at median follow up of 6 months with a good quality of life.

Conclusions: TAVI in small aortic bioprosthesis is achievable with success using a CoreValve 23 mm device. Ensuring a high implantation reduces the residual gradient by favoring a suprannular "free" valve functioning.

PCR Interventions for structural heart disease

Euro14A-MA010

Cerebral white matter lesion volume is associated with cerebral embolism after

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Aims: Transcatheter aortic valve implantation (TAVI) is associated with silent and apparent cerebral embolism (CE). Since white matter lesion (WML) volume reflects pre-procedural brain injury, we hypothesised, that pre-existing cerebral lesions are associated with post-procedural events. Methods and results: A total of 119 patients were investigated with cerebral magnetic resonance imaging (MRI) before (E1) and within one week after TAVI (E2). All quantifications and segmentations were performed manually. Total brain volume (TBV) and WML, as well as baseline characteristics and procedural data were prospectively assessed. Post-procedural embolic events were obtained in 78 (65.5%) patients, predominantly located in the left hemisphere (57.5%; p=0.0045). WML volume was equally distributed without side predominance. Neither common clinical baseline characteristics, nor procedural characteristics demonstrated an association with silent cerebral embolic events. In subjects with and without CE, mean TBV was similar, namely 1184±121 ml and 1167±144 ml, respectively (p >0.05). Interestingly, mean WML volume was significantly higher in patients with as compared to patients without new CE after TAVI (16.1±14.5 ml vs. 11.2±13.0 ml, p=0.019).

Conclusions: The burden of pre-existing WML is related to post-procedural CE. Future studies need to investigate, whether pre-interventional MRI is a useful tool to estimate procedural stroke risk prior TAVI.



PCR Interventions for structural heart disease

Usefulness of a simple clinical risk prediction for TAVI by using the modified **ACEF** score

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Aims: We aimed to assess the predictive accuracy of a novel simple and user-friendly risk score, the modified ACEF (age, creatinine clearance, ejection fraction), in patients undergoing TAVI.

Methods and results: Between October 2006 and May 2013, 703 consecutive patients with severe aortic stenosis undergoing transcatheter aortic valve implantation (TAVI) were included in the current analysis. Society of thoracic surgeons predicted risk of mortality score (STS), Logistic EuroSCORE (LES), EuroSCORE II (ES II) and modified ACEF score were assessed. Modified ACEF score was calculated retrospectively using the following formula: age/ejection fraction +1 point for every 10 mL/min reduction in creatinine clearance below 60 mL/min per 1.73 m² (up to a maximum of 6 points). Patients were divided in low, medium and high modified ACEF terciles (236, 237 and 230 respectively). Increased modified ACEF score was associated with significantly higher one-year mortality rate (22%, 28% and 36%, p<0.01) and higher risk of acute kidney injury (AKI): 10%, 10% and 22%, p<0.01. The multivariate logistic regression analysis indicated highest modified ACEF score tertile as the only independent predictor of incidence of AKI. The multivariate COX regression model indicated increased modified ACEF score tertile and transapical approach as the independent predictors of one-year cumulative mortality. By using a receiver-operating characteristic analysis with the area under curve (AUC) as a measurement of accuracy, modified ACEF score better predicted the incidence of AKI compared to STS, LES and ES II (AUC=0.61, 0.55, 0.54, 0.57, respectively). Modified ACEF score had similar accuracy in predicting 30-day mortality (AUC=0.63, 0.59, 0.60, 0.64, respectively) and one-year mortality as the other risk scores (AUC=0.61, 0.61, 0.61, 0.61, respectively).

Conclusions: The simple and extremely user-friendly modified ACEF score can identify patients undergoing TAVI at high risk of AKI, as well as 30-day mortality and one-year mortality.

PCR Interventions for structural heart disease

Euro14A-MAO12

Prognostic impact of preoperative pro-BNP on outcomes in high-risk patients treated with MitraClip therapy for severe functional mitral regurgitation

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Aims: It has been recently shown that MitraClip treatment is not able to improve the clinical course in patients with end-stage heart failure and dramatically increased pro-BNP levels. The aim of this study is to investigate the prognostic role of a lower threshold of pro-BNP in high-risk patients undergoing MitraClip implantation for functional mitral regurgitation (FMR).

Methods and results: preoperative pro-BNP levels were collected in 75 high-risk patients undergoing MitraClip therapy for severe FMR. Patients were divided into 2 groups according to preoperative pro-BNP level; a threshold of 1,600 pg/ml for pre-operative pro-BNP levels was set according to the inclusion criteria of the ongoing COAPT trial. Preoperative features and clinical outcomes of 2 groups were then compared; 54 patients (72%) had pro-BNP ≥1,600 pg/ml and 21 patients (28%) had pro-BNP <1,600 pg/ml. Patients were comparable for age (p=0.6), Logistic EuroScore (p=0.9) and COPD (p=0.3). Prevalence of chronic renal failure was higher in patients with pro-BNP ≥1,600 pg/ml (p=0.01); 60% of patients with pro-BNP <1,600 pg/ml and 91% with pro-BNP ≥1,600 pg/ml were in NYHA class III-IV (p=0.003). LVEF was lower in patients with pro-BNP ≥1,600 pg/ml (25±9% vs. 33±10%; p=0.001), while no differences were observed in LVEDD (69±7 mm vs. 67±9 mm; p=0.8). In-hospital mortality was 0% and 3.7% in patients with pro-BNP <1,600 pg/ml and ≥1,600 pg/ml, respectively (p=0.3). Incidence of post-renal failure (p=0.02), need for blood transfusion (p=0.03) and need for high dose inotropic support (p=0.02) were higher in patients with pro-BNP≥1,600 pg/ml. Median postoperative LOS was longer in patients with pro-BNP≥1,600 pg/ml (6 and 4 days respectively; p=0.02). At discharge, 90% and 83% had residual MR ≤2+(p=0.4). At follow-up, actuarial survival was 100% and 84±5% at 1 year and 93±6% and 67±7% at 2 years for patients with pro-BNP <1,600 pg/ml and ≥1,600 pg/ml (p=0.01). Multivariable analysis identified preoperative pro-BNP ≥1,600 pg/ml as an independent predictor of mortality at follow-up (HR=3 CI 95%=1.2-5.5; p=0.005). No differences were observed in MR ≥3+ recurrence during follow-up (p=0.4).

Conclusions: Although patients treated in current practice are high-risk, MitraClip therapy for FMR remains safe and effective in selected patients. Patients with preoperative pro-BNP level ≥1600 pg/ml have a worse baseline clinical profile. Higher preoperative pro-BNP level is an independent risk factor for mortality at follow-up and should be considered when evaluating the postprocedural outcomes and deciding the appropriate timing for the procedure.



uro14A-MAO13

Comparison between transcatheter and minimally invasive surgical closure of secundum atrial septal defect in adults

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Aims: Recent studies have demonstrated the safety and efficacy of percutaneous atrial septal defect (ASD) occlusion, but there have been few reports of comparing percutaneous closure with minimally invasive surgical approaches. The goal of this study was to evaluate percutaneous interventional and minimally invasive surgical closure of secundum ASD in adults.

Methods and results: ASD closure via right minithoracotomy (mini-ASD) have been applied to repair ASDs to minimise surgical trauma and improve cosmetic results in our institution. Between December 2000 and January 2013, 210 patients underwent mini-ASD. Between March 2011 and January 2013, 84 patients underwent percutaneous ASD closure using the Amplatzer Septal Occluder under fluoroscopic and echocardiographic guidance. We reviewed the records of secundum ASD patients older than 10 years old at the time of the closure. In the device group, either transesophageal echocardiography or intracardiac echocardiography was used for guidance. In the mini-ASD group, a working port with 5 to 6 cm incision, a camera port, and a port were the only route to reach the heart and closure of the ASDs were performed either by direct closure or patch closure. A 5 cm right thoracotomy incision was made at the level of the fourth intercostal space. The size of the primary ASD was 17.5±6.3 mm for the device group and 21.2±7.7 mm for the mini-ASD group (p<0.001). Patients in the device group were older and had a higher incidence of hypertension. The procedure attempt success rate was 97.6% for the device group and 100% for the mini-ASD group (p=0.08). In the device closure group, there were 2 cases of failed deployment (in one case the ASD was too large for the available device and in the other case the atrial septal rim was insufficient). Device embolisation occurred in one case within one day of device implantation, but the device was percutaneously retrieved with a gooseneck snare. A slight residual shunt was observed in 2 patients in the device group at 24 hour follow-up transthoracic echocardiogram, but the residual shunt flow disappeared 3 months later. Residual shunt was not detected in the mini-ASD group. There was no device or surgical related death in either group. Major complications occurred in 2 patients (2.4%) in the device group and 8(%) in the mini-ASD group (p=0.730). The major complications in the mini-ASD group were; cardiac arrhythmias requiring major treatment in 3 patients, cerebral infarction in 3 patients, procedural myocardial infarction in one patient and repeat surgery for surgical wound complications in one patient. Minor complications occurred in 6 patients (7.1%) in the device group and 38 (18.1%) in the mini-ASD group (p=0.018). The most common minor complication was cardiac arrhythmias in the mini-ASD group (16 (7.6%)) and hematoma in the device group (4 (4.8%)). The mean length of hospital stay was 4.1±0.6 day for the device group and 7.2±0.5 days for the mini-ASD group (p<0.001).

Conclusions: The success rates and major complication rates were not statistically different between the two groups; however, the minor complication rate was lower and the length of hospital stay was shorter for the device closure group. The percutaneous closure and the mini-ASD can both be performed with acceptable clinical results. The percutaneous closure could be the first choice for the majority of secundum ASDs, but for those patients who have defects difficult to close percutaneously, mini-ASD should be considered.

Neurological events two years post TAVI in real world patients - The Advance study

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Aims: Evidence has suggested that compared to conventional surgery, transcatheter aortic valve implantation (TAVI) may have a unique spectrum of associated complications, including a higher rate of neurological events. The CoreValve ADVANCE study, which evaluated the clinical performance of the CoreValve system in a fully monitored, "real world" single-arm study in patients with aortic stenosis, has previously reported a low stroke rate at 1 year. The aim of the present analysis was to characterise the timing and predictors of neurological events which occurred out to 2 years after TAVI.

Methods and results: From March 2010 to July 2011, the ADVANCE study enrolled 1,015 patients (mean age 81±6 years, 51% female, mean Logistic EuroSCORE 19±12%, New York Heart Association class 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. All neurological events were adjudicated by an independent neurologist. The Kaplan-Meier rate of stroke at 2 years was 5.6%, while the rate of transient ischaemic attack was 1.9%. Two patients had both a major and a minor stroke during the study. The Kaplan-Meier rates of major and minor strokes were 2.9% and 3.0%, respectively. Time frames for the stroke events were defined as acute (0-48 hours), subacute (2-30 days), and late (>30 days), with the late strokes being subdivided into days 30-365, and day 366-730. A total of 14 strokes occurred in the acute phase, and 16 strokes occurred in the subacute phase. Twelve additional strokes occurred between days 31-365, and 9 occurred between days 366-730. No univariable baseline predictors of acute stroke could be identified. Additional procedural predictors and multivariable models will be explored and presented.

Conclusions: TAVI using the CoreValve system was associated with a low rate of stroke out to 2 years. Thirty strokes fell within the first month after TAVI, while 21 strokes occurred over the remaining 23 months of the 2 year study period. This distribution suggests that the post-TAVI stroke risk may peak within the first month. TAVI patients remain at risk for stroke out to 2 years, likely due to their age and baseline comorbidities.



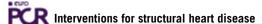
Euro14A-MA015

Numbers needed to treat patients and numbers needed to save money - The clinical and economic impact of TAVI and implantable cardioverter-defibrillator face to face

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Aims: Treating inoperable aortic stenosis patients with transcatheter aortic valve implantation (TAVI), as defined in the PARTNER trial, yields a Number Needed to Treat (NNT) to save 1 life at 1 year of 5 (and 3.7 at 3 years). Despite this formidable indicator, there have been concerns voiced on the cost implications of TAVI and impact on healthcare budgets, without comprehensive evaluation of the benefits brought by TAVI. Aim of this analysis is to compare clinical and economic benefits of two breakthrough innovations, such as TAVI in inoperable patients and Implantable Cardioverter Defibrillators (ICDs) in primary and secondary prevention, which both pose questions in terms ethics, equity of access, and budget allocation decisions. Methods and results: Hard-point clinical outcomes (i.e. mortality rate) are expressed in terms of NNT: a simple index commonly defined as a "therapeutic effort to clinical yield". The economic perspective chosen was the one of the Healthcare system, or payer. Costs of procedures are based on average funding and reimbursement tariffs recognised in the three Countries considered in the study (Germany, France, Italy). Results are expressed in "Cost per life saved". All clinical and economic data used are derived from publicly available sources, including peer-reviewed literature and national payment schedules (GHM for France, G-DRG for Germany, weighted National/Regional DRG tariffs and TAVI-specific reimbursements for Italy). One-way sensitivity analysis has been performed. Both TAVI and ICD already demonstrated in selected categories of patients high rates of clinical effectiveness, with excellent NNT, if compared to many other cardiovascular therapies. For ICD, a NNT between 15-20 patients has been observed after implantation for primary prevention, and 10-15 patients for secondary prevention. Treating surgically inoperable patients with aortic stenosis, as defined in the PARTNER trial, the NNT to save one life at one year is 5 and 3.7 at 3 years. For the example of ICDs used in secondary prevention, it was estimated that the mean cost to the payer per life saved at 1 year was €232,550, €197,098 and €215,449 for France, Germany and Italy respectively. For TAVI the corresponding cost per life saved was €161,170, €150,872 and €122.005. Results are still consistent even after sensitivity analysis.

Conclusions: Clinical data on TAVI is now unequivocal and it is calculated that these impressive results are matched by the economic performance when comparing against other technologies which are already often considered routine in their use. In fact, despite the "young age" and the still low adoption rate, TAVI already shows at least a comparable cost benefit ratio than established therapies such as ICDs. This result is highly consistent across biggest European Countries, despite wide differences in healthcare funding and reimbursement systems, and TAVI adoption rates. Limitations of such approach as quite clear, since only hard-point benefits are taken in consideration, longer term perspective is missing and cost assumptions may reflect opportunistic reimbursement-related policy decisions. Clinical evidence-based considerations in Hospital Budget allocation decision making are still critical for granting equity principles and achieving sustainability under Societal perspective.



RenalGuard system for the prevention of acute kidney injury in patients undergoing TAVI

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Aims: Acute kidney injury (AKI) is a frequent complication and significantly impacts on both early and long-term transcatheter aortic valve implantation (TAVI) survival. The use of the RenalGuard® System, to create high urine output and fluid balancing, may be beneficial in preventing

Methods and results: Thirty-three consecutive patients with an estimated glomerular filtration rate (eGFR) ≤60 ml/min/1.73 m² scheduled for TAVI through the femoral approach were assigned to 1) conventional hydration regimen and N-acetylcysteine (NAC) (Control group; n=25) or 2) the RenalGuard therapy, that is, hydration with saline and NAC controlled by the RenalGuard System andfurosemide (RenalGuard group; n=8). In all cases iodixanol was administered. The primary endpoint was an increase of 0.3 mg/dL in the serum creatinine concentration at 48 hours after the procedure. The secondary endpoints included serum cystatin C kinetics and rate of in-hospital dialysis. Although patients in the Renalguard group were at higher risk; AKI occurred in 10/25 (40%) patients in the Control group (20.5%) but in none of the 8 patients in the RenalGuard group (p=0.032). Serum cystatin C values (p=0.004; F=5.52 by ANOVA model) as well as the rate of in-hospital dialysis (8% versus 0%) were higher in the Control group.

Conclusions: Renal Guard therapy seems to be effective in preventing AKI in patients undergoing TAVI.



Euro14A-MA057

Impact of pre-procedural PCI on outcome of patients undergoing TAVI

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Aims: Coronary revascularisation impairs the peri-operative risk of patients undergoing surgical aortic valve replacement. The aim of the present study was to evaluate whether PCI affects the outcome of patients undergoing TAVI.

Methods and results: Between January 2008 and December 2013, 141 consecutive patients underwent a transferoral TAVI in our institution. A Sapien valve (Edwards Lifescience) was implanted in 126 cases, a CoreValve (Medtronic) among 8 patients and a Portico system (St Jude Medical) in 7 other patients. Patients undergoing a staged PCI before TAVI (Group 1, N=30) were compared with those with no need of revascularisation (Group 2, N=111). Baseline characteristics of patients were similar between Group 1 (84±5 yrs, 12 males, aortic valve area 0.5±0.1 cm², mean transvalvular gradient 48±17 mmHg, Euroscore 30±16%, frailty Sherpa score 6±2) and Group 2 (84±6 yrs, 60 males, aortic valve area 0.6±0.1 cm², mean transvalvular gradient 41±16 mmHg, Euroscore 32±16%, frailty Sherpa score 6±2; p=NS for the comparison between both groups). PCI was performed on the left main in 4 cases and in multivessels among 16 patients. Overall survival was not significantly different between Group 1 and Group 2, both at 30 days (90 vs. 98%, p=0.06) and at 1 year (81 vs. 85%, p=0.20). Major adverse events, according to VARC-2 criteria, were similar between both groups in terms of stroke (2.1 vs. 3.2%, p=NS), bleeding (4.3 vs. 3.2%, p=NS), myocardial infarction (0 vs. 0) and the VARC-2 combined safety end-point (26 vs. 37%, p=NS). With multivariate analysis, staged PCI prior to TAVI was not independent predictor of 30-d and 1-yr survival (hazard ratio: 1,028 and 0,665; 95% confidence interval: 0,401-1,839; p=0,69). There was no coronary stents thrombosis nor restenosis during follow-up (mean duration: 473±391 days).

Conclusions: Our study suggests that coronary revascularisation by staged PCI can be safely performed in patients undergoing transfermoral TAVI. Other larger trials are needed to confirm these data.

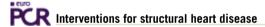
Incidence, feasibility and outcome of PCI after TAVI with a self-expandable prosthesis

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Aims: Aortic stenosis and coronary artery disease (CAD) commonly co-exist. In patients undergoing transcatheter aortic valve implantation (TAVI), percutaneous coronary intervention (PCI) prior to TAVI is not uniformly performed, and CAD is a progressive disease. Hence, PCI after TAVI becomes sometimes necessary, which could be limited and/or become technically challenging, especially after using the self-expanding Medtronic CoreValve (MCV) device, which completely covers the aortic root. Sporadic descriptions of PCI performed after MCV implantation have already been reported, but no formal analyses of the incidence, feasibility and outcome have been described.

Methods and results: Our prospective institutional TAVI-database currently includes 391 patients treated with TAVI between 2007 and 2013, of which 277 patients were treated with MCV. A strategy of pre-procedural PCI of all angiographically significant lesions in major epicardial coronary arteries (usually with DES) is adopted. All patients are clinically followed-up at regular time intervals (30 days, 6 months, 1 year and yearly thereafter). For the current analysis, all patients treated with PCI at any time point after MCV implantation were retrospectively identified, and clinical, angiographic and procedural characteristics were reviewed and analyzed. We identified a total of eleven patients (3.9%) treated with 14 PCI procedures for 16 lesions at a median of 73 weeks (range 1-234 weeks) after MCV implantation. The mean age at the time of TAVI was 81.7±5.8 years and the mean logistic EuroSCORE was 24.5±10.4%. Most patients (n=7) received the 29 mm MCV, and the mean depth of prosthesis implantation was 8.6±3.1 mm. Four patients (36.4%) had an acute coronary syndrome as an indication for PCI (3 patients with a non-ST segment elevation myocardial infarction and one patient with unstable angina). The mean SYNTAX score at the time of PCI was 10.9±4.9, but most lesions (n=13, 81.2%) were of type B or C. Most of the treated lesions (n=13) were de novo ones, and only 3 lesions were restenoses of previously implanted stents (two in bare-metal and one in drug-eluting stents). A median of one guiding catheter was necessary to successfully intubate the target coronary ostium (range 1-10). In 3 procedures (two on the right and one on the left coronary artery), the intubation of the coronary ostium was difficult and the stability of the guiding catheter was suboptimal. All lesions in the left coronary artery (n=12) were eventually treated through a left Judkins catheter. Mean procedural time was 60.4±34.1 minutes, but mean fluoroscopy time was high (22.3±11.1 minutes). All procedures were successfully performed through the transfemoral access route, and no peri-procedural complications (myocardial infarction, repeat revascularisation, stroke or death) were observed.

Conclusions: In an elderly population with a routine pre-TAVI revascularisation strategy using DES, the incidence of PCI after MCV implantation is low and mostly related to coronary artery disease progression. PCI in this setting is both feasible and safe, but requires careful planning and understanding of the three-dimensional geometry of the prosthetic valve and its relation to the coronary ostia.



Euro14A-MA059

The impact of acute and chronic troponin elevation after TAVI

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Aims: Myocardial injury occurs frequently following transcatheter aortic valve implantation (TAVI). The aim of this study was to assess timing, predictors, and prognostic value of peri-procedural myocardial injury and chronic troponin elevation after TAVI.

Methods and results: 276 patients (logistic EuroSCORE 26.6±17.1%) underwent transvascular TAVI. In all patients, troponin I, CK-MB, and NT-proBNP levels were measured before and after TAVI (1 h, 4 h, 24 h, 48 h, 72 h, 7 days, 3, and 6 months). Baseline troponin levels differed between survivors and non-survivors (<0.02 (IQR: <0.02 to 0.04) ng/mL vs. <0.02 (IQR: <0.02 to 0.09); p=0.04). In 13.5% of the patients, troponin was elevated above the URL (>0.10 ng/mL) before the procedure. Immediately after TAVI, peak troponin levels were significantly elevated in survivors (1.08 (IQR: 0.49 to 1.92) ng/mL vs. 0.63 (IQR: 0.30 to 1.50) ng/mL; p=0.009) but decreased after 4 h without any significant difference between survivors and non-survivors at 24 h after the procedure. Myocardial injury (defined as ΔTrop ≥15x URL) occurred in 143/276 patients (51.8%) during the first 72 hours following TAVI. Use of a self-expanding prosthesis (p=0.02), coronary artery disease (p=0.04), higher left-ventricular ejection fraction (LVEF) (p<0.001), and procedure time (p<0.001) were independent predictors for the development of myocardial injury after TAVI. 30-day (4.2% vs. 6.1%; p=0.48) and one-year mortality (19.4% vs. 26.5%; p=0.15) were not related to the incidence of peri-procedural myocardial injury. However, patients with chronic troponin elevation after TAVI had an increased one-year mortality risk (HR 4.5, 95%-CI: 2.0-10.0; p<0.001). In multivariate Cox regression analysis with adjustment for independent univariate predictors of outcome, the occurrence of more-than-mild paravalvular AR (Hazard ratio (HR) 4.4, 95%-confidence interval (CI): 1.6 to 11.7, p=0.003) and an elevated troponin after TAVI at follow-up (HR 4.5, 95%-CI: 2.0-10.0; p<0.001) were independently associated with outcome after one-year.

Conclusions: Acute troponin elevation in form of so-called myocardial injury (defined as $\Delta \text{Trop} \ge 15 \text{x URL}$) after TAVI seems to be a procedure-related issue but does not impact survival. However, a post-procedural troponin increase is independently associated with outcome might be useful for prognostication after TAVI.

PCR Interventions for structural heart disease

Euro14A-MA060

Platelet reactivity study in patients undergoing TAVI

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Aims: Transcatheter aortic-valve implantation (TAVI) has been associated with 2-5% risk of peri-procedural stroke. Several mechanisms were proposed for the stroke risk including a pro-thrombotic state and embolisation of calcified material from the aortic valve. Accordingly, it is common to administer dual anti-platelet treatment (DAPT) for 3-6 months following TAVI. The biologic response to aspirin and clopidogrel is heterogeneous, and low response, known as high on treatment platelet reactivity (HTPR) may be associated with adverse thrombotic events, including stroke. The prevalence of HTPR in patients undergoing TAVI has not been yet reported. Therefore, we aimed to assess the variability in response and rates of HTPR in patients undergoing TAVI.

Methods and results: We examined platelet reactivity and response to clopidogrel and aspirin using the VerifyNow P2Y12 assay and the multiple electrode aggregometry assay (Multiplate analyser) in response to ADP and arachidonic acid in patients who underwent TAVI at 3 different time points: baseline, 1-2 days following the procedure and 30 day follow-up. Our preliminary results include 22 consecutive high risk patients with severe aortic stenosis (mean age 81±5.7, 68.2% women) who underwent successful TAVI. Prior to the procedure 15 (68.2%) patients were chronically treated with aspirin and 8 (36.4%) with clopidogrel. HTPR rates for both aspirin and clopidogrel were high prior to TAVI and early after the procedure, but improved significantly 30 days after TAVI. According to the multiplate analyser, HTPR rates for aspirin were 20% at baseline, 12% 1 to 2 days after the procedure and none at 30 days (P=0.4).

Conclusions: Patients undergoing TAVI for severe aortic stenosis and treated with DAPT have high rates of HTPR during the peri-procedural period, which subside profoundly after 1 month. These novel findings should be confirmed and expanded but may have clinical implications for the anti-platelet management of these patients.



uro14A-MA061

The value of the German aortic valve score for the prediction of peri- and post-procedural mortality in TAVI patients

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Aims: Aortic stenosis is often seen at an older age and, as a consequence, there is a higher frequency of comorbidity and frailty, contributing to an increased peri-procedural and longterm risk. One year mortality rates still range inacceptably high at approximately 20-25%. To further improve post-procedural outcome, appropriate risk stratification is crucial to select the optimal treatment strategy for the individual patient. In this study, we validated the German Aortic Valve Score, which is the first attempt to develop a dedicated TAVI risk score, and compared it to established surgical risk scores.

Methods and results: The German Aortic Valve Score was calculated retrospectively in 410 consecutive patients undergoing TAVI and compared to the STS mortality score and the logistic EuroSCORE. Prognostic and discriminative power and calibration of each test was statistically evaluated. 410 patients (mean age 81.1±6.6 years, 49.5% male) at high surgical risk reflected by a mean German Aortic Valve Score 7.8±7.6%, STS score of 8.9±6.3%, and logistic EuroSCORE of 26.8±17.1%, underwent transvascular TAVI. 30-day and one-year mortality rates were 7.1% (29/410) and 24.4% (100/410), respectively. 30-day non-survivors had significantly higher risk scores than survivors: German Aortic Valve Score 11.5±8.4 vs. 7.5±7.5% (P=0.006), STS score of 13.3±10.6 vs. 8.6±5.7% (P<0.001), and logistic EuroSCORE of 43.6±19.9 vs. 25.5±16.2% (P<0.001). The German Aortic Valve Score showed a strong correlation to the logistic EuroSCORE (r=0.64; P<0.001) and the STS score (r=0.74; P<0.001). Although there was a significant overlap between risk groups, the expected (E) correlated well with the observed (O) 30-day mortality risk across increasing German Aortic Valve Score classes: <3: E=2.2% vs. O=1.7%; 3-6: E=4.1% vs. O=5.4%; 6-10: E=7.8% vs. O=8.3%; >10: E=19.7% vs. O=14.6%. For the prediction of 30-day mortality, the German Aortic Valve Score (AUC 0.69, 95%-CI: 0.64-0.73) was comparable to the STS score (AUC 0.67, 95%-CI: 0.62-0.71) (P=0.69) but inferior to the logistic EuroSCORE (AUC 0.77, 95%-CI: 0.73-0.81) (P=0.04) in ROC curve analysis. **Conclusions:** The German Aortic Valve Score fairly predicts the absolute risk of a TAVI procedure in a real life scenario. However, it does not provide additional prognostic information beyond the established imperfect surgical risk scores. We are still in need of a dedicated TAVI score to facilitate patient selection and to detect when the individual risk of the procedure outweighs the potential benefits for the patient.

Transfemoral transcatheter versus surgical aortic valve replacement in patients with intermediate surgical risk: six-month results of 650 matched pairs from the Italian OBSERVANT study

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Aims: Transcatheter Aortic Valve Replacement (TAVR) has being increasingly offered in low and intermediate surgical risk patients with severe aortic stenosis (AS). The OBSERVANT study aims to describe 6-month clinical outcomes of a large series of propensity-matched patients at low or intermediate risk undergoing transfemoral TAVR and surgical aortic valve replacement (SAVR).

Methods and results: OBSERVANT is an observational prospective multicentre cohort study, enrolling AS patients undergoing SAVR or TAVR. Data on mortality, hospitalisations at follow-up and major complications were derived from administrative reports. Propensity score method was applied to select two groups with similar baseline characteristics. The unadjusted enrolled population (N=7,618) comprises 5,707 SAVR patients and 1.911 TAVR patients. Matched population comprised a total of 1.300 patients (650 patients for each group). A relatively low risk population was selected (mean logistic EuroSCORE 10.2±9.2% vs. 9.5±7.1%, SAVR vs. transfemoral TAVR; p=0.104). Thirty-day mortality was 3.8% and 3.2% for SAVR and TAVR (p=0.546). The incidence of stroke and acute myocardial infarction was similar in the two groups, whereas a higher requirement for blood transfusion was reported across the surgical cohort (. 3.6±3.6 vs. 2.3±2.2 red blood cells units; p=0.002). A higher incidence of major access site complications (0.5% vs. 7.9%; p<0.001) and permanent pacemaker implantation (3.6% vs. 15.5%; p<0.001) were reported in the TAVR group. Six-month mortality was 10.4% and 8.8% for SAVR and TAVR (p=0.313). Data regarding re-hospitalisations and other major complications at 6 months will be available for the presentation of the abstract.

Conclusions: The results of this study show that transferoral TAVR and SAVR have comparable mortality outcomes at 6-month in patients with severe AS and at intermediate surgical risk. At 30-day SAVR was associated with a higher risk for blood transfusion, whereas TAVR showed a significantly increased rate of vascular damage, and permanent pacemaker requirement.

PCR Interventions for structural heart disease

Euro14A-MA063

EURyDICE Registry: EURopean Direct Aortic Corevalve 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. We report the results of the EURyDICE Registry: EURopean DIrect Aortic Corevalve Experience, a multicentre experience with the self-expanding CoreValve prosthesis implanted through a direct aortic approach (DA) in patients considered high risk surgical candidates.

Methods and results: This multicentre experience comprises patients treated in the 19 centres in 9 countries in Europe and in Israel, between June 2008 and October 2013. A standard dataset was circulated between centre, all definitions were collected according to VARC II. A total of 478 cases have been collected, 38 implant took place in the 54 months between the first implant and the end of 2010 and 96 patients were treated in 2011. Mean age of the population was 81,3±6.3 years, 48% were female, mean logistic EuroSCORE was 25.8±16.1; 387 patients were in NYHA class ≥III (81%). Peripheral vasculopathy was the principal exclusion criteria from trans-femoral TAVI and was present in 293 patients (61%); 280 patients had coronary artery disease (58%) and 101 patients had undergone previous coronary artery bypass surgery. TAVI procedure was performed in 220 of cases (46%) through a right anterior mini-thoracotomy in the 2nd intercostal space or via an upper hemisternotomy in the others 258 patients. A size 29 mm CoreValve was implanted in 200 patients (42%). Procedural success was achieved in 469 patients, 98% of cases. Three patients required a 2nd valve implanted and 2 patients had >moderate para-valvular regurgitation; 30-da mortality was 9%. Seven patients experience stroke (1.4%) and 67 patients (16%) required a new permanent pacemaker (67/415 without prior pace-maker), 90% of patients had aortic regurgitation <2+/4+. Median post-operative hospitalisation was 9 days.

Conclusions: Direct aortic access is a feasible approach for TAVI with the self-expanding CoreValve prosthesis. These initial results of the EURyDICE Registry are encouraging given the high risk patient cohort and evidence the fact that proximal approached should results higher valve deployment control and accurate implantation, translating into lower incidence of pace-maker implantation and para-valvular regurgitation.



Euro14A-MA064

Prosthetic valve associated infective endocarditis post-TAVI

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Aims: Prosthetic valve endocarditis is a rare but serious complication with high morbidity and mortality. Limited data are available regarding this complication after TAVI. We thus aimed to examine the epidemiology, management strategies and outcomes of post-TAVI prosthetic valve associated infective endocarditis (TAVI-PIE).

Methods and results: Between January 2008 and February 2013, 2572 consecutive patients underwent TAVI (1191 Edwards THV, 1343 CoreValve, 18 DirectFlow, Other 20) in 14 centres and were studied retrospectively. The diagnosis of PIE was defined according to the Valve Academic Research Consortium-2 criteria by applying the Duke definitions. Post TAVI–PIE was diagnosed in 29 patients with an overall incidence of 1.13%: 8 (28%) early (<60 days), intermediate 15 (52%) (60 days to one year), and 6 (20%) late (>one year). The index procedure was performed transfermorally in 79% and transapically in 21%. In majority of cases (n=23, 79%) the Edwards THV was implanted. Majority of patients presented with fever and heart failure symptoms while complications of infective endocarditis were common during the course of the disease. The predominant causative microorganisms were Staphylococci (31.5%), Enterococci (20%) and Streptococci (14.5%). Echocardiography was positive in 86% of patients with prosthetic vegetations the most common finding and mitral valve involvement in 4 patients. Overall mortality was high (62%) and chronic kidney disease was associated with adverse outcome on survival analysis.

Conclusions: TAVI-PIE is a rare but serious complication after TAVI and is most commonly caused by Staphylococcal and Streptococcal species. Despite early and aggressive therapy, TAVI-PIE is associated with a very high mortality.



Euro14A-0P258

The EVEREST II randomised controlled trial of percutaneous and surgical reduction of mitral regurgitation: five-year results stratified by degenerative or functional etiology

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Aims: EVEREST II is a prospective, multicentre, randomised controlled trial (RCT) to compare the safety and effectiveness of the MitraClip® System with mitral valve (MV) surgery in the treatment of patients with severe (≥3+) mitral regurgitation (MR) with follow-up through five years. Patients with symptoms, or if asymptomatic with left ventricular (LV) dysfunction, pulmonary hypertension or atrial fibrillation were included. All patients have completed final five-year follow-up as of December 31, 2013. Final EVEREST II RCT outcomes at five years will be presented to evaluate the durability of MR reduction, components of clinical endpoints, and LV volumes in MitraClip device and MV surgery patients by degenerative (DMR) or functional (FMR) etiology. Outcomes by type of intervention and predictors of late success are of continued interest. Methods and results: 279 patients, randomised 2:1 between MitraClip device (n=184) and MV surgery (n=95) were enrolled. The primary safety endpoint was the Major Adverse Event (MAE) rate at 30 days and the primary effectiveness endpoint was defined as freedom from the combined outcomes of death, MV surgery or re-operation for valve dysfunction, and MR >2+ at 12 months. Clinical outcomes of MR reduction, freedom from mortality, freedom from MV surgery or re-operation, LV volumes and NYHA Functional Class at five years will be summarized and presented by MR etiology. The mean age was 67 years; baseline ejection fraction was 60%. MR etiology was degenerative in 73%. The 30-day primary safety and 12-month primary effectiveness endpoints were previously reported. At six months, 22% of MitraClip DMR patients and 10% of MitraClip FMR patients underwent surgery. In surviving patients with paired data available at baseline and 3 years, MR severity was \leq 2+ in 85% of MitraClip DMR patients, 95% of MV surgery DMR patients, 82% of MitraClip FMR patients and 100% of MV surgery FMR patients. Corresponding Kaplan-Meier freedom from MV surgery or re-operation rates at 3 years in these etiology groups were 73%, 98%, 90% and 81% respectively. Few MitraClip patients converted to MV surgery after six months. Both MitraClip and MV surgery patients experienced significantly reduced LV end diastolic volumes and improved NYHA Functional Class from baseline, demonstrating durability of MR reduction and associated clinical benefit with the MitraClip device.

Conclusions: Final five-year results of the EVEREST II RCT will be presented by MR etiology to evaluate durability of outcomes post-treatment with both MitraClip and MV surgery.

Use of MitraClip in functional and degenerative mitral regurgitation: early outcomes from the Mitraclip Asia-Pacific Registry (MARS)

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Aims: In Europe, the MitraClip therapy has been used to treat both functional and degenerative mitral regurgitation (MR). However, there has been limited data from the Asia-Pacific. We aim to describe the impact of the etiology of MR on safety and efficacy outcomes with the MitraClip in the Asia-Pacific.

Methods and results: The MitraClip Asia-Pacific Registry (MARS) registry is a multicentre registry involving 8 different centres in the Asia-Pacific region (Singapore, Malaysia, Australia, Indonesia and China). The registry collects data on patients with ≥3+ MR who have undergone the MitraClip procedure. Primary efficacy outcome measured was a reduction in MR to ≤2+ at 30 days. The safety outcomes was 30-day freedom from major adverse events (MACE), including mortality, myocardial infarction, non-elective cardiac surgery for adverse events, renal failure, transfusion of ≥2 units of blood, ventilation for >48 h, septicaemia, and new onset of atrial fibrillation. A total of 141 patients (age 71.5±11.9 years, 90 males) were included. Seventy-six (53.9%) patients had functional MR and 65 (46.1%) had degenerative MR. Thirty four (44.7%) of functional MR patients had ≥2 clips inserted compared to 37 (57.8%) degenerative MR patients (p=0.123). Acute procedural success was similar in both functional and degenerative MR (96.1% (73/76) vs. 90.8% (59/65), p=0.201). 81.6% (62/76) of functional MR had a reduction in MR to ≤2+ at 30 days compared to 72.3% (47/65) of degenerative MR (p=0.176). There was no significant difference in the change in left ventricular ejection fraction post-clip between both groups. However, there was a greater reduction in left ventricular end diastolic and end systolic diameter in degenerative MR compared to functional MR (7.7% vs. 1.9%, p=0.001 and 6.2% vs. 0.6%, p=0.008 respectively). There was no significant difference in both 30-day MACE (9.3% (n=7) vs. 15.4% (n=10), p=0.274) as well as 30-day mortality rates (5.3% (n=4) vs. 6.2% (n=4), p=0.820) between functional and degenerative MR.

Conclusions: For both functional and degenerative MR, the MitraClip therapy has comparable good early efficacy and safety outcomes. However, there was a greater reduction in left ventricular end diastolic and end systolic diameter in degenerative MR.



Euro14A-0P260

Haemodynamic impact of intracardiac shunt in residual interatrial communication after MitraClip procedure

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Aims: Aim of our study was to assess the haemodynamic impact of the intracardiac shunt due to the residual interatrial communication (IAC) after MitraClip procedure.

Methods and results: From January 2012 to December 2013, 60 consecutive patients (70% males; mean age 73±9 y.o.; mean logistic EuroSCORE 22±18%), have been treated with MitraClip. Forty-seven patients (78%) had secondary mitral regurgitation (MR) with a mean left ventricle ejection fraction (LVEF) of 30±10%; 13 patients suffered from primary MR with a LVEF of 56±8% (p<0.00001). The residual IAC was immediately evaluated with transesophageal echo after the guiding-catheter was withdrawn; additionally the right cardiac catheterisation was performed before and after the procedure. The procedures were performed in deep-sedation and spontaneous breathing in 36 patients (60%), whereas 24 (40%) were intubated under general anaesthesia; one, two and three clips were implanted in 23 (38%), 36 (60%), 1 (2%) patients, respectively. The mean device time was 41±26 minutes and no intraprocedural deaths occurred. The IAC measured 0,6±0,4 cm and Qp/Qs was estimated 1,4±0,2. Six patients (10%) needed percutaneous closure of the residual defect, using devices for patent foramen ovale, because the shunt was judged to have significant haemodynamic impact. In 4 patients the closure was performed acutely during the same session. Among these the shunt was bidirectional in 3 cases, whereas one patient had acute right ventricle overload with severe acute cardiac failure. Sequentially two patients, who developed a chronic right cardiac failure, have been treated treated after one month and eight months, respectively. In addition another patient treated five years before for secondary MR and severe left ventricular failure in another institution developed a severe pulmonary hypertension, which improved after closure. **Conclusions:** In patients with very low LVEF and right ventricle dysfunction even small IAC with Qp/Qs <1,4 can cause signs of cardiac failure. A careful monitoring and haemodynamic assessment are mandatory to select patients who need percutaneous closure of the defect.

Impact of tricuspid regurgitation on outcome after percutaneous mitral valve repair

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Aims: Little is known of the prognostic significance of tricuspid regurgitation (TR) on percutaneous mitral valve repair (PMVR) with the MitraClip system and the impact of PMVR on TR severity. This study sought to evaluate the impact of moderate and severe TR on outcomes after PMVR with MitraClip system.

Methods and results: In a retrospective analysis of the prospectively maintained Getting Reduction of Mitral Insufficiency by Percutaneous Clip Implantation (GRASP) registry, 171 consecutive patients were divided into 2 groups according to the degree of preprocedural TR (moderate/severe vs. none/mild) and the results were compared. At baseline, moderate or severe TR was reported in 58 (33.9%) patients. These patients were older, more often were female, more likely to have atrial fibrillation. Patients with moderate/severe TRhad a larger pre-procedural right atrial area (21.6±7.8 vs. 18.0±5.5 mm, p=0.009), a larger right ventricle diameter (34.0±6.4 vs. 30.6±4.3 mm, p=0.001) and higher systolic pulmonary pressure (54.7±13.2 vs. 41.4±11.1 mmHg, p<0.001). The rates of acute device success were high and equivalent between the two groups (98.3% vs. 99.1%, respectively, p=0.629). The primary safety endpoint at 30-day was comparable between groups (6.9% vs. 3.5%, respectively, p=0.325). At 30 days, among survivors who had PMVR, moderate/severe TR had improved in 39 (69.6%) patients, was unchanged in 17 (30.4%) patients. New York Heart Association (NYHA) functional classat 30-day and one-year (NYHA >II 30-day 40.7% vs. 16.6%, p=0.033; one-year 32.4% vs. 13.6%, p=0.022) were significantly different among the two groups. TR severity at baseline did not affect mortality at 1 year in PMVR patients (15.0% vs. 8.2%, p=0.304). Kaplan-Meier freedom from death, surgery for mitral valve dysfunction, or grade ≥3+ MR at 12 months (primary efficacy endpoint) was demonstrated in 72.5% and 80%, respectively (log-rank: 0.017 p=0.389).

Conclusions: Patients treated with PMVR were associated with a significant early improvement in TR in survivors. Moderate or severe MR at baseline was not associated with increased one-year mortality after PMVR, however, the improvement of NYHA functional class was modest among them.



Euro14A-0P262

Anatomic predictors of procedural success in patients undergoing transcatheter mitral valve repair with the MitraClip system

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Aims: We sought to assess anatomic predictors of acute and midterm procedural success in patients with severe symptomatic mitral regurgitation (MR) at high surgical risk undergoing transcatheter mitral valve repair (TMVR) with the MitraClip (MC) system.

Methods and results: 123 consecutive patients (age 77.5±8.0 years) at high surgical risk (EuroScore 29.8±21.5%) underwent TMVR with the MC system and completed 6 months follow- up (FU). Structural parameters of the mitral valve (MV) were assessed with 3D echocardiography using a dedicated MV analysis software. MC failure was defined as: MR grade >2+ after the procedure, inability to reduce MR, re-clip or MV surgery, aborted procedure, partial clip detachment. MC failure was observed in 21 patients (16.8%). Reasons for acute procedural failure were the occurrence pericardial tamponade (n=3, 2.4%), or relevant MV stenosis (n=3, 2.4%). In 8 patients (6.5%) MR could not be reduced relevantly after clip deployment. During FU 7 patients (5.6%) needed re-intervention, including 6 patients (4.8%) with relapse of more than moderate MR. Multivariable logistic regression identified coaptation length (CL) (OR 0.56, 95% CI 0.3-1.04, p=0.02), coaptation depth (CD) (OR 2.22, 95% CI 0.87-5.7, p=0.01) and distance between the papillary muscles (DPM)(OR 1.07, 95% CI 1.0-1.1, p=0.02) as independent predictors of MC failure. Receiver operating characteristic (ROC) curve analysis identified an optimal cut-off for CL <2.7 mm, for CD >6.3 mm and for DPM >32 mm for the identification of MC failure. A combined variable including these cut-off values had a specificity of 95.05%, a sensitivity of 10%, a positive predictive value of 28.6% and a negative predictive value of 84.2% for MC failure.

Conclusions: Using 3D echocardiography MV anatomy can be assessed prior to TMVR with determination of anatomic landmarks. Awareness of MV anatomy characteristics is important for planning of the procedure. In our study, we found patients undergoing TMVR with the MC having a CD > 6.3 mm, CL < 2.7 mm and DPM > 32 mm to be at increased risk for procedural failure. Incorporation of these cut-off values for the prediction of procedural success had an specificity of 95.05%, a sensitivity of 10%.

Haemodynamic effects of the MitraClip system. Focusing v-wave, left atrial- and pulmonary artery pressure, grade of mitral regurgitation and cardiac output. Analysing 393 patients from the AK St. Georg, Hamburg, Germany

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Aims: Haemodynamic changes after MitraClip® procedure are rarely described. Most experience results from the Everest Trials including patients with organic mitral regurgitation (MR). In Europe and especially Germany nearly 2/3 of the patients treated with the MitraClip® System suffer from functional MR. Aim of this work was to improve the understanding of the acute haemodynamic effects in these patients.

Methods and results: From September 2009 till December 2013, 393 patients have been treated with the MitraClip® System at the AK St. Georg in Hamburg. Haemodynamics have been evaluated via Swan Ganz catheterisation and thermodilution method directly before and after Clip deployment. The functional result was assessed 6 weeks, 6 months and 12 months after the MitraClip® procedure. Nearly 95% (374/393) of the patients could be treated successfully (Clip implanted, MR post \leq 2). 30 day mortality was less than 7%. Systolic pulmonary artery pressure (PAPs) increased slightly from 39.6 mmHg (\pm 12.1) to 42.1 mmHg (\pm 11.9) (p<0.05). Left atrial pressure (LA, mean) was reduced significantly (p<0.001) from 15.37 mmHg (\pm 6.3) to 12.7 mmHg (\pm 6.0). V-wave measured continuously in the left atrium by a seperate 4F Pigtail catheter fell from 26,5 mmHg (\pm 11.9) to 19,5 mmHg (\pm 9.51). Cardiac output (CO) increased from 3.9 l/min (\pm 1.2) to 4.9 l/min (\pm 1.5) directly after the procedure (p<0.001). The average amount of Clips used was 1,4(\pm 0.3). Grade of MR assessed by echo was reduced stable and significantly from 3.1 (\pm 0.3) before to 1.1(\pm 0.6) directly after and 1.8 (\pm 0.7) after 6 months, p<0.001. This result remained stable after 1 year though the the number of patients lost to follow-up was high.

Conclusions: The MitraClip® is a safe and effective treatment of MR in patients being decided tob e too sick for surgical treatment. This procedure also shows a stable reduction of MR combined with a stable improvement of the clinical symptom dyspnoea. We've shown that this non open chest treatment of MR improves the CO up to 25% while reducing LA pressure and v-wave significantly.



Euro14A-0P264

Evolution of mitral valve procedural volumes in Germany in the advent of endovascular treatments: national utilisation volumes 2006-2012 and experiences at an early-adopting University Heart Centre

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Aims: Endovascular mitral valve therapy using the MitraClipTM system has been adopted in Germany since 2008 as a complementary treatment option for mitral valve regurgitation, primarily for high-risk patients who are not eligible for open heart surgery. Our objectives were to assess mitral valve procedural utilisation in Germany over the seven year period 2006-2012 to analyse the overall evolution of surgical and endovascular procedural volumes, and to study utilisation and reimbursement effects of growing endovascular therapy use at our centre offering both surgical and endovascular treatment.

Methods and results: Relevant procedure codes were identified for the period 2006-2012 and yearly utilisation volumes obtained from inpatient statistics of the German Federal Statistics Office and from our centre. Volumes were analysed in total, stratified by age and surgical versus endovascular approach. In addition, the heart centre's total mitral valve procedure reimbursement was estimated for years 2006-2012. Nationwide, overall mitral valve procedural volumes grew by 56.1% from 2006 to 2012, with endovascular mitral valve repair constituting 9.1% of a total of 20,328 procedures in 2012. During the same period overall volumes grew by 96.0% at our centre with 19.7% of all procedures being endovascular. Since the introduction of endovascular MitraClip™ therapy in 2008, nationwide surgical procedural volumes grew at an average of 6.3% per year (14,477 in 2008; 18,478 in 2012; 27.6% total growth rate). At our centre a total of 378 endovascular MitraClip™ procedures were performed in the period 2008-2012. During this period, surgical volumes grew at an average of 10.6% annually (262 in 2008; 392 in 2012; 49.6% total growth rate). Estimated total surgical and endovascular mitral valve reimbursement increased from EUR 3.8 million in 2007 to EUR 7.9 million in 2012. This increase was more pronounced since the introduction of endovascular clipping in 2008. Total average per-case reimbursement increased from EUR 18,863 in 2007 to EUR 22,566 in 2012.

Conclusions: The observed growth in procedural volumes in the studied period 2006-2012 suggests a growing mitral valve disease burden in Germany as well as expanded therapy access. The introduction of endovascular procedures has contributed to this overall growth, but at the same time seems to not have reduced continued growth in surgical volumes. Our centre-specific analysis suggests addition of endovascular therapies as an integrated approach to mitral valve disease contributes to additional growth in surgical and overall reimbursement volumes.

PCR Interventions for structural heart disease

Euro14A-0P265

Impact of femoral artery puncture using digital subtraction angiography and road mapping on vascular and bleeding complications after TAVI

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Aims: The use of large-diameter sheaths in an elderly patient population carries the risk for significant vascular and bleeding complications after transcatheter aortic valve implantation (TAVI). An appropriate vascular access with a true anterior puncture in a disease-free segment of the common femoral artery is essential for limiting these complications and could potentially improve overall clinical outcomes. In this analysis, we sought to assess the impact of a modified femoral artery puncture technique using digital subtraction angiography (DSA) and road mapping during transfemoral TAVI on peri-procedural vascular and bleeding events.

Methods and results: This is a retrospective analysis of transfemoral TAVI patients included in our prospective institutional TAVI-database which currently comprises 391 patients. The modified femoral artery puncture techniqueusing the road mapping guidance was introduced in October 2012. Briefly; a fluoroscopic sequence is acquired during contrast injection from a contralaterally inserted pigtail catheter positioned at the aortic bifurcation. This "road map mask" is then subtracted to produce a real-time fluoroscopic image overlaid on a static image of the ilio-femoral vessels. Before introduction of this technique, vascular puncture was acquired based on an integration of angiographic data, the bony ilio-femoral landmarks and a radiopaque object. Consecutive patients who underwent TAVI with implementation of the road mapping technique (RM group, n=137) were compared with consecutive patients who underwent TAVI without the road mapping technique (control group, n=137) prior to its introduction. Patients performed earlier (n=117) were excluded from this analysis in an attempt to reduce the impact of the learning curve on measured outcomes. A standardised strategy of periprocedural anticoagulation was adopted in both groups (unfractionated heparin according to activated clotting time) as well as use of a single suture-based closure device (ProGlide®, Abbott Vascular). All endpoints were defined according to the Valve Academic Research Consortium (VARC) 2 criteria for event definition. The mean age in the RM group was 81±6 years compared to 79±8 years in the control group, and females were equally distributed among both groups (61.3% vs. 59.1%, respectively). The baseline logistic EuroSCORE was 21.2±14.8% vs. 25.0±15.7% in the RM and control group, respectively (p=0.04). The prevalence of hypertension, diabetes mellitus, coronary and peripheral arterial disease was similar in both groups. Laboratory parameters such as baseline haemoglobin level, platelet count and prothrombin time were also similar in both groups. Notably, sheath size was significantly larger in the RM compared to the control group (18.3±0.9 vs. 17.9±0.5 French, p<0.001) owing to the more frequent use of the 29 mm Edwards Sapien XT valve in the RM group (19.7% vs. 2.2%, respectively, p<0.001). Despite the latter finding, major vascular complications and major bleeding at 30 days were both significantly lower in the RM group compared to the control group (5.1% vs. 11.7%, p=0.047, and 15.3% vs. 26.3%, p=0.026, respectively). Other forms of vascular and bleeding complications as well as all-cause mortality were comparable in both groups.

Conclusions: A modified femoral artery puncture technique using DSA and road mapping reduces major vascular and bleeding complications after transfermoral TAVI, and provides a simple and effective strategy to potentially improve patient outcomes.



Euro14A-0P266

Vascular stenting with a self-expanding stent graft for vascular complications after percutaneous TAVI

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Aims: The vascular complications (VC) after percutaneous transcatheter aortic valve replacement (TAVR) are independent predictors of post-operative mortality and are associated with sheath size, vessel diameter and female gender. For the acute treatment of VC different interventional approaches have been reported including the implantation self-expanding stent grafts into the "no stent zone" AFC.

Methods and results: Retrospective analysis of patients undergoing TAVR between 2010 and 2013 in which a covered Fluency Plus® stent graft (Bard Peripheral Vascular Inc., USA) was placed due to vascular access site complications. Patients were evaluated for in-stent restenosis (ISR) and vascular graft complications (restenosis, obstruction) by doppler-sonography after 3, 6, 9 and 12 months. We identified 58 patients in whom a self-expanding Fluency® stent graft was implanted (by a cross-over technique via contralateral approach). Of these, 39 (67%) had a routine angiological follow-up (median 91 days). Of these, 36 patients (92%) had undergone transfemoral TAVR, whereas three patients were treated by transsubclavian access (8%) Stent graft placement was necessary due to minor vascular complications (failure of access site closure/ paravasation) in 90% and major vascular complications (iliac artery dissection) in 10%. Technical success of the procedure was achieved in 100% leading to primary angiographic haemostasis. Angiologic follow-up revealed only one case of in-stent restenosis in a subclavian stent and no incidence of stent fracture. I year mortality was 5.1% (2/39).

Conclusions: In this observational study, the routine implantation of a self-expanding stent graft for vascular complications proved safe and feasible. Incidence of ISR, relevant vascular complications and mortality after mid-term follow in patients, who have received such a stent, is low.

Direct aortic vs. transfemoral TAVI: comparison of one-year outcome

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Aims: For patients with severe, symptomatic calcified aortic stenosis and high risk for open surgery, transcatheter aortic valve implantation (TAVI) is a good alternative to conservative treatment. Besides the established transfemoral access, there is also the possibility of a surgical approach through the ascending aorta using minithoracotomy or ministernotomy (direct aortic). In this study we analyse the two methods in terms of success, intraprocedural complications and survival over one year.

Methods and results: Between 2010 and 2012, 138 consecutive patients underwent TAVI (Medtronic CoreValve prothesis) at the Heart Centre Halle, Germany, using either the transfemoral (69 patients, 54% male, age 80±5 years, EuroScore 25±18%) or the direct aortic (69 patients, 49% male, age 79±6 years, EuroScore 24±14%) access. All patients were enrolled in our registry and retrospective analysis after one-year follow-up was performed. Successful implantation was mainly achieved in both collectives, completing 94% in the transfemoral (65 patients, 4 conversions) and 96% in the direct aortic group (66 patients, 2 conversions, 1 re-implantation). Complications were documented reffering to VARC-2 criteria comparing transfemoral to direct aortic access: vascular complications - 25% vs. 3%, stroke – 1% vs. 1%, new pacemaker in consequence of AV-Block – 23% vs. 26%. Observed thirty-day and one-year mortality was 10% (7 patients) resp. 33% (23 patients) in the transfemoral and 16% (11 patients) resp. 29% (20 patients) in the direct aortic group. Logistic regression analysis adjusted for age and sex did not show a significant difference for thirty-day (OR=0.51, CI [95%]=0.18-1.39, p=0.19) or one-year mortality (OR=1.25, CI [95%]=0.57-2.49, p=0.55).

Conclusions: In our TAVI collective both access ways showed comparable success and complication rates with the direct aortic access having notable less vascular complications. Furthermore, there was no significant difference in thirty-day or one-year survival. Based on these results we suggest a prospective, randomised study with the aim to show the equivalence of both approaches and to define suitable patient collectives for each method.



Euro14A-0P268

Clinical outcomes one-year post transapical and transaortic TAVI in patients with severe aortic stenosis from the SOURCE XT Registry

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Aims: Transcatheter aortic valve implantation (TAVI) has been established as a treatment of choice for inoperable patients with severe symptomatic aortic stenosis and a viable alternative to surgical valve replacement for patients at high risk. Patients who are not suitable for transfemoral approach can undergo TAVI using a surgical approach – transapical (TA) or transaortic (TAo). However, the differences in patient characteristics and clinical outcomes between the two surgical approaches are not well understood.

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post approval study, which consecutively enrolled 2,688 patients at 99 sites in 17 countries. A total of 995 patients were treated with the SAPIENT XT valve using the Ascendra+ delivery system by either the TA (n=894) or TAo (n=101) approach. Baseline characteristics and early and late clinical outcomes were compared between the two groups. Two-year follow-up had been completed and preliminary data were analysed. Final data will be available at the time of the PCR. There were no significant differences between the 2 groups in terms of gender, Logistic EuroSCORE, congestive heart failure, severe pulmonary hypertension, moderate/severe mitral regurgitation, pulmonary disease, previous stroke, diabetes or liver disease. Compared to the TA patients, the TAo patients were significantly older (82.2±7.4 years vs. 80.1±6.4 years, p=0.0021), but were less likely to have angina (30.7% vs. 50.3%, p=0.002), previous myocardial infarction (9.9% vs. 20.9%, p=0.008), PCI (23.8% vs. 37.0%, p=0.0084), CABG (7.9% vs. 24.4%, p<0.0001), atrial fibrillation (17.8% vs. 30.5%, p=0.0077), moderate/severe tricuspid regurgitation (2.2% vs. 13.2%, p=0.006) or porcelain aorta (5.0% vs. 11.0%, p=0.0592). Effective orifice area, annulus size, pressure gradient and ejection fraction were comparable between the two groups. At 30 day follow-up, overall mortality was similar for the TAo and TA patients (6.9% vs. 10.1%, p=0.3441) but cardiac mortality was lower in the TAo group (1.0% vs. 5.7%, p=0.0521). The incidence of stroke (3.1% vs. 4.2%, p=0.6066), and life-threatening bleeding (11.0% vs. 8.3%, p=0.3396) were also similar between TAo and TA patients but the need for permanent pacemakers was significantly less for the TAo patients (4.1% vs. 11.6%, p=0.0252). The overall mortality at 1 year was almost identical for the TAo and TA patients (26.9% vs. 27.2%, p=0.9354), and remained so at two-year follow-up (35.2% vs. 35.6%, p=0.9999).

Conclusions: Patients undergoing transaortic and transapical TAVI are relatively similar at baseline, and present comparable short term clinical outcomes and identical survival. Both TAo and TA are viable alternatives for patients who are not suitable for transfemoral approach and should be considered as variations of surgical access for TAVI rather than distinct TAVI approaches.



Alternative access in TAVI

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Aims: The most common approach in transcatheter aortic valve implantation (TAVI) is no doubt the transfemoral access. However, in case of atherosclerosis, small vessel size or previous peripheral arterial surgery, transfemoral access is not an option. Multiple alternative approaches have been described. In patients not suitable for transfemoral TAVI, we opt for an open approach through either the brachiocephalic artery or the ascending aorta.

Methods and results: Pre-procedural computed tomography scan of the aorta is used to determine the ideal patient-tailored access. In deploying the Medtronic CoreValve*, the minimally required distance between the point of vascular access and the aortic valve annulus is 6 cm. In patients with poor iliofemoral access or with patent mammary artery graft after previous CABG, the open brachiocephalic artery access is our preferred approach. The access can be either suprasternal or through upper ministernotomy. The ascending aorta may be the preferred access site in case of calcification or small caliber of the brachiocephalic artery. In our series of 179 consecutive TAVI procedures (Medtronic CoreValve*), 148 patients were treated transfemorally. No major vascular complications were seen. However, in 36 patients (24.3%) minor access related vascular injury necessitated further intervention (surgical repair (4.05%), femoral artery stenting (11.49%), femoral artery dilatation (4.05%), thrombin injection for pseudoaneurysm (4.73%)). Thirty-one valves were implanted trough non-femoral access because of severe femoroiliac disease. In our early experience, 9 patients were treated by trans-subclavian access. In one of these cases, periprocedural occlusion of a patent mammary artery graft caused transient myocardial ischaemia, so this approach is no longer our primary choice. As an alternative to the subclavian artery, we opted for a direct approach trough the ascending aorta. Seven valves were implanted by direct aortic access after partial sternotomy in patients with both patent left mammary artery graft after previous CABG and severe peripheral atherosclerosis. More recently, the open brachiocephalic approach was added to our access options and successfully used in 15 patients. Eight had previous CABG with patent left mammary artery grafts, and 14 patients had severe femoroiliac atherosclerosis. In 11 of these patients, the brachiocephalic artery could be accessed without ministernotomy. No procedural or vascular complic

Conclusions: TAVI is an accepted alternative to surgical aortic valve replacement in high risk patients. Vascular access and access related complications remain a key point of concern. Brachiocephalic and transaortic access are safe and feasible if transfemoral TAVI is contra-indicated, and are valid alternatives for transapical approach. The distance from the brachiocephalic artery or ascending aorta to the aortic valve annulus is short, hereby increasing delivery catheter stability and accurate valve positioning. Up to now, we did not decline any patient for TAVI treatment based exclusively on the lack of suitable access.



Euro14A-0P270

Von Willebrand factor (vWF) and ADAMTS-13 changes induced by TAVI: insights from Heyde's syndrome pathogenesis

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Aims: In patients with severe aortic valve stenosis, von Willebrand factor (vWF) degradation triggered by high shear-stress forces is a frequent phenomenon and surgical aortic valve replacement (SAVR) has been associated with improved post-operative vWF values. Aim of this study is to verify whether transcatheter aortic valve implantation (TAVI) has an analogue benefit. Furthermore, we sought to address the pathogenesis of possible vWF variations by assessing its cleavage protein (ADAMTS-13), the latter strongly associated to shear stress variations.

Methods and results: We enrolled 40 consecutive patients with severe aortic stenosis undergoing TAVI. Measurements of vWF multimers, ADAMTS-13 activity, vWF antigen (vWF:Ag) and vWF collagen binding activity (vWF:CB) were obtained immediately prior to TAVI, 24 hours after and at hospital discharge. Repeated measures ANOVA showed a significant variation for high molecular weight vWF (26±4% vs. 29±4% vs. 28±4%, at baseline, 24 h and pre-discharge, respectively; p<0.001) and vWF: CB (222±81 vs. 255±111 vs. 282±122 U/dl, at baseline, 24 h and pre-discharge, respectively; p=0.001), but not for ADAMTS-13 (94±32 vs. 84±34 vs. 91±31 ng/ml, at baseline, 24 h and pre-discharge, respectively; p=0.101).

Conclusions: We confirm a benefit in terms of post-procedural vWF increase in patients undergoing TAVI, however not significant variations in ADAMTS-13 show that vWF variations are only partially driven by shear-stress changes, suggesting of the existence different pathways for the onset of Heyde's syndrome.

Predictors of all cause death after TAVI: a gender based analysis

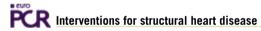
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Aims: The impact of gender related pathophyisiological features of severe aortic stenosis on the outcome of TAVI patients remains to be determined, as is the consistency of predictors of mortality among the genders.

Methods and results: All consecutive patients who underwent TAVI at 6 institutions were enrolled, and stratified according to gender. The primary end-point was all-cause mortality at midterm follow-up and all events were adjudicated according to VARC definitions. 836 patients were enrolled and 464 (55.5%) of them were female. At midterm follow-up (median 365 days IQR 100-516) women had comparable rates of all-cause mortality compared to men (18.1% vs. 22.6% p=0.11) and similar incidence of myocardial infarction and cerebrovascular accident. Gender did not affect mortality also at multivariate analysis. Among clinical and procedural features, Glomerular Filtration Rate <30 mL/min/1.73 m² (HR 2.55, CI 1.36 to 4.79) and Systolic Pulmonary Arterial Pressure more than 50 mmHg (HR 2.26, 95% CI 1.26 to 4.02) independently predicted mortality in females, while insulin treated diabetes (HR 3.45 95% CI 1.47 to 8.09), previous stroke (HR 3.42 95% CI 1.43 to 8.18), ejection fraction <30% (HR 3.82 95% CI 1.41 to 10.37) were related to mortality in males. Post procedural moderate to severe aortic regurgitation was independently related to midterm mortality in both groups. (HR 11.19, 95% CI 3.3 to 37.9).

Conclusions: Women and men share the same life expectancy after TAVI, but different predictors of adverse events stratified by gender were demonstrated. These findings underline the importance of a gender tailored clinical risk assessment in TAVI patients.



Euro14A-0P272

Structural valve deterioration after TAVI with a balloon-expandable prosthesis due to possible valve thrombosis

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Aims: Despite the lack of evidence, the combination of low dose aspirin and clopidogrel is used early after transcatheter aortic valve implantation (TAVI). We report on 5 cases of early structural deterioration of the Edwards Sapien XT valve (ESV) secondary to possible valve thrombosis despite appropriate antiplatelet therapy.

Methods and results: Our prospective institutional TAVI-database currently includes 391 patients treated with TAVI between 2007 and 2013 (277 patients treated with the Medtronic CoreValve and 112 patients treated with the ESV). All patients are clinically followed-up at regular time intervals (30 days, 6 months, 1 year and yearly thereafter), and an echocardiographic evaluation is performed at hospital discharge, 30 days, 6 months, 1 year and 5 years. Patients are routinely prescribed aspirin and clopidogrel for 3 months followed by lifelong aspirin therapy. Patients with an indication for oral anticoagulation are treated with a combination of phenoprocoumon and clopidogrel for 3 months followed by lifelong anticoagulation. During this period, we observed 5 cases of early structural deterioration after TAVI, all with the ESV (mean follow-up period of ESV patients=8 months). Structural deterioration was observed 7 days (1 case), 6 months (3 cases) and 17 months (1 case) after TAVI. The mode of valve failure was severe stenosis with mild transvalvular regurgitation in 4 cases, and severe transvalvular regurgitation with mild stenosis in 1 case. In 4 cases, mobile masses were observed on the valve leaflets on transoesophageal echocardiography with no signs of infection. These patients were treated with intravenous heparin followed by oral anticoagulation, and subsequent echocardiography showed a rapid restoration of normal valve function suggesting a thrombotic etiology of valve failure. The fifth patient was successfully treated with a valve-in-valve procedure due to haemodynamic instability. All cases of structural deterioration were observed in patients discharged on dual antiplatelet therapy (n=67), while no cases were seen in patients discharged on oral anticoagulation (n=41), yielding an overall incidence of 4.4% in all ESV patients and 7.5% in ESV patients treated with dual antiplatelet therapy.

Conclusions: Early structural deterioration is an uncommon but clinically significant complication after TAVI that is probably caused by valve thrombosis and seems to be reversible with a short course of oral anticoagulation. The optimal antithrombotic therapy after TAVI remains to be determined.



Impact of pulmonary hypertension on early and late outcomes after TAVI in patients with severe aortic stenosis from the SOURCE XT Registry

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Aims: Pulmonary hypertension (PHT) can occur as a complication of severe left-sided heart disease, and increases the surgical risk for patients undergoing aortic valve replacement (AVR). The effect of PHT in patients undergoing TAVI is not well understood. We sought to examine the clinical outcome after TAVI with the SAPIEN XT valve (Edwards Lifesciences, LLC) in patients with PHT.

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post approval study, which consecutively enrolled 2688 patients at 99 sites in 17 countries. The PHT group included 644 patients (24.0%) and the control group included 2043 patients, all with no evidence of PHT. One patient with no information provided was excluded from this analysis. All patients were treated with the Edwards SAPIEN XT valve. Two-year follow-up had been completed and preliminary data were analysed. Final data will be available by the time of the PCR. Compared to the controls, patients in the PHT group were more likely to be female (63.8% vs. 55.7%, p=0.0003), and had a higher Logistic EuroSCORE (26.6±13.7% vs. 18.5±11.4%, p<0.0001) as to expect. PHT patients had significantly higher incidence of congestive heart failure, atrial fibrillation, permanent pacemakers, diabetes and renal insufficiency. Significantly more patients in the PHT group were in NYHA class III/IV (80.6% vs. 75.7%, p=0.0116), had moderate/severe tricuspid regurgitation (25.2% vs. 14.2%, p<0.0001), or moderate or severe mitral regurgitation (29.4% vs. 16.8%, p<0.0001). Compared to the controls, patients with PHT had a significantly smaller effective orifice area (0.6±0.2 cm² vs. 0.7±0.2 cm², p=0.0003); lower left ventricular ejection fraction (52.8±13.8% vs. 54.9±12.1%, p=0.0003) but similar mean gradient (48.2±16.1 mmHg vs. 47.5±16.3 mmHg, p=0.3502). At 30-day follow-up, there was no significant difference between the two groups in terms of overall mortality (6.4% vs. 6.2%, p=0.9101), cardiac death (3.8% vs. 2.8%, p=0.2368), stroke (3.6% vs. 3.6%, p=0.9662) or other complications. However, one-year all-cause mortality was significantly higher in the PHT group as compared with the controls (22.3% vs. 18.6%, p=0.0417) and so was the cardiac mortality (12.7% vs. 8.5%, p=0.0019). Although, the two-year mortality was similar between the two groups (28.3% vs. 25.8%, p=0.2385) cardiac mortality remained significantly higher in the PHT group (14.0% vs. 10.7

Conclusions: Approximately 25% of patients with severe aortic stenosis undergoing TAVI have PHT. Despite a worse risk profile, these patients had a similar early mortality compared to patients without PHT. The observed worse late cardiac mortality warrants further study.



Euro14A-0P274

Treatment and clinical outcomes of transcatheter heart valve thrombosis: multicentre registry

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Aims: Valve thrombosis after surgical bioprosthetic aortic valve replacement is uncommon. This has yet to be evaluated in the context of transcatheter aortic valve implantation (TAVI). This study aimed to report the incidence, timing and management of transcatheter heart valve (THV) thrombosis. Methods and results: Between January 2008 and September 2013, 4143 patients underwent TAVI in 11 centres in Europe. THV dysfunction was defined as aortic valve area <1.2 cm² and mean aortic valve gradient ≥20 mmHg or peak velocity ≥3 m/s, or moderate or severe prosthetic valve regurgitation. THV thrombosis was defined as THV dysfunction secondary to thrombosis, which was diagnosed based on the timing post-TAVI, response to anticoagulation therapy, echo findings or histopathology. At a median follow-up period of 181 (IQR 45-313) days after TAVI, valve thrombosis was observed in 26/4143 (0.63%) patients: 20/2766 (0.72%) in Edwards Sapien/Sapien XT, 6/1308 (0.46%) in Medtronic CoreValve and 0/69 (0%) in other valves. The most common clinical presentation was dyspnea on exertion (n=17, 65.4%) whereas 8 (30.8%) patients had no worsened symptom. Of note, only 1 patient had stopped any anti-thrombotic agents. Mean aortic valve gradient was found to be markedly elevated (40.5±14.0 mmHg). However, 2 patients had normal gradient: 1 had pure severe AR and another already had taken warfarin. Regarding echo findings, thickened leaflets or thrombotic apposition of leaflets were observed in 20 (76.9%) patients, whereas thrombotic mass on leaflets in the remaining 6 (23.1%) patients. In 23 (88.4%) patients, anticoagulation resulted in significant decrease of aortic valve gradient within 3 months. Two (7.7%) patients underwent valve-in-valve, while the remaining 1 (3.8%) underwent surgical aortic valve replacement. Regarding clinical outcomes after diagnosis of THV thrombosis, 2 patients who were effectively treated with anti-coagulation died due to pneumonia and acute heart failure (left ventricular ejection fraction: 30%), respectivel

Conclusions: Although a rare phenomenon, THV thrombosis may occur within the first 2 years following TAVI despite continuing anti-platelet agents. This usually presents with dyspnea with an increased gradient. It would appear that anticoagulation is very effective in decreasing the gradient and should be considered even in patients without visible thrombotic mass on echo.

Multicentre evaluation of transcatheter aortic valve replacement according to computed tomographic annular size: improved clinical outcomes with an individualised device approach

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Aims: The degree of device oversizing associated with optimal clinical outcomes differs between current transcatheter heart valve devices. We sought to determine whether individualised-device-approach, in which a specific device is selected for a specific aortic annulus, as determined by computed tomography, may improve clinical outcomes.

Methods and results: We analysed a multicentre database of consecutive transfemoral aortic valve replacement (TAVR) procedures using either SAPIEN XT (Edwards Lifesciences, CA) and CoreValve (Medtronic, MN). Favorable oversizing was defined for SAPIEN XT (5-20% area oversizing or 2.5-9.5% perimeter oversizing) and for CoreValve (20-35% area oversizing or 9.5-16.2% perimeter oversizing). Separate "SAPIEN XT-zones" and "CoreValve-zones" were defined, which included annular sizes for which implantation of only a SAPIEN XT or a CoreValve, respectively, allowed for optimal oversizing. A total of 368 patients were included in the study (age 81.5±6.7, 42.1% men): 190 patients in the "SAPIEN XT-zone" (treated by either SAPIEN XT, n=78, or CoreValve, n=112) and 178 patients in the "CoreValve-zone" (treated by either CoreValve, n=90 or SAPIEN XT, n=88). The majority of the spectrum of annular sizes (68%) between areas of 250-650 mm² was favourable for one device only. In "SAPIEN XT-zone" annuli, those treated by CoreValve had more post dilatation and 30-day major stroke in comparison with those treated by SAPIEN XT (16.1% vs. 7.7%, p=0.04 and 8% vs. 1.3%, p=0.02, respectively). In "CoreValve-zone" annuli, those treated by SAPIEN XT had more annular rupture and conversion to cardiac surgery in comparison with those treated by CoreValve (3.4% vs. 0, p=0.04 and 4.5% vs. 0, p=0.02, respectively).

Conclusions: Most of the aortic annulus spectrum could be defined as either favourable for SAPIEN XT or for CoreValve implantation, but not for both. An individualised-device-approach utilising a specific THV (CoreValve or SAPIEN XT), enabling optimal degree of device oversizing, may improve clinical outcomes after TAVR.



Euro14A-0P276

Routine screening of associated coronary artery disease with coronary multidetector computed tomography scan in place of coronary angiography in patients with severe aortic stenosis undergoing TAVI

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Aims: The aim of this study was to evaluate the use of routine coronary artery disease (CAD) screening using coronary multi-detector computed tomography (MDCT) scan rather than invasive coronary angiography (CA) in patients with severe aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI).

Methods and results: From November 2007 to May 2013 all patients treated with TAVI procedure in our institution were included in this analysis. Coronary MDCT scan was used as first-line imaging tool in order to assess preoperatively CAD. Invasive CA was only performed when any of the following were present: presence of extensive coronary calcifications or calcifications rendering impossible assessment of lesion severity at MDCT scan, presence of significant CAD at MDCT scan, arrhythmias not allowing gating and late stage chronic kidney disease (CKD). Outcomes were assessed according to valvular academic research consortium (VARC-2) criteria at 30 days and 1 year. Out of 525 patients that underwent TAVI in our institution, 482 (91.8%) underwent cardiac MDCT scan. Among those, 112 (21.3%) underwent also CA. Only 46 (8.7%) performed CA alone. Of those patients, 2 (0.5%) in the MDCT scan, 12 (10.6%) in the CA and cardiac MDCT scan and 2 (4.6%) in the CA-only group, underwent concomitant percutaneous coronary intervention (PCI) for critical coronary lesions. In the MDCT scan-only group, at 30 days, total and cardiovascular mortality was 4.7% and 3.3%, respectively. The incidence of cardiac tamponade (CT) was 3.9%, peri-procedural myocardial infarction (MI) 0.8%, aortic dissection (AD) 0.5%, whereas no coronary obstruction (CO) events occurred. Incidence of life-threatening and major bleeding was 16.1% and 21.3% respectively. In the group where both MDCT scan and CA were performed, total and cardiovascular mortality at 30 days was the same at 3.1%. The incidence of CT was 2.8%, peri-procedural MI 1.7%, CO 0.9% whereas no AD occurred. Incidence of lifethreatening and major bleeding was 19.8% and 28.4% respectively. In the CA-only group total and cardiovascular mortality at 30 days was 4.8% and 3.3% respectively. Incidence of CT was 4.7%, AD 2.3%, CO 2.3%, while no cases of peri-procedural MI occurred. Incidence of life-threatening and major bleeding was 30.2% and 35% respectively. At a median follow-up period of 387 days (IQR 236-517) total mortality in groups was of 7.1%, 10.3% and 16.3%, in the MDCT scan-only, MDCT scan and CA and CA-only group respectively, while cardiovascular mortality was of 4.9%, 6.8% and 9.3% respectively.

Conclusions: Cardiac MDCT scan performed as a routine non-invasive diagnostic screening in patients with AS undergoing TAVI is safe and effective allowing, with a single test, acquisition of information on aortic annulus anatomy, peripheral access sites as well as coronary anatomy evaluation.

PCR Interventions for structural heart disease

Euro14A-0P277

Computer simulation predicts displacement of native leaflet calcification after TAVI

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Aims: Coronary obstruction is a rare but potentially life-threatening complication after transcatheter aortic valve implantation (TAVI). Coronary height has been identified as an important determinant, but other factors may be involved and better methods to forecast coronary obstruction are required. We, therefore, evaluated a computer model predicting the displacement of native leaflet calcification.

Methods and results: Seventeen patients who received a 26 or 29 mm Medtronic CoreValve prosthesis and in whom MSCT before and after TAVI was available were included. Pre-operative MSCT was used to generate patient-specific three-dimensional models of the native aortic root using image segmentation techniques. Implantation of virtual CoreValve models in these patient-specific aortic root models was then simulated using finite element computer modelling, resulting in a prediction of frame deformation and native leaflet displacement. In each computer-simulated implantation, all steps of the clinical implantation were respected (i.e. predilatation, valve size, depth of implantation and postdilatation if applied). Post-operative MSCT was used to evaluate the accuracy of the predicted displacement of the native leaflet calcifications. In particular, the smallest distance between a calcification nodule and the coronary ostia was measured. Data are given as means and standard deviations (SD). Correlation and agreement was tested using Pearson's correlation and Bland Altman analysis. A paired comparison between the dimensions measured on the clinical MSCT post TAVI and those derived from the computer simulation was done using Student's t-test. Visual assessment revealed a good agreement between the predicted (computer model) and the observed (MSCT post) displacement of native leaflet calcification. The distance measurements obtained from the model were strongly correlated with those from the post-operative MSCT (r=0.75). There was a small overestimation of this distance in the model as compared to the MSCT-based measurements (respectively mean±SD: 9.2±2.7 mmvs. 7.8±2.4 mm; difference mean±SD: 1.4±1.8 mm, p<0.001).

Conclusions: The computer generated model accurately predicted the displacement of native leaflet calcification. Such a model may be helpful in clinical practice to predict the interaction between valve frame and native leaflets, thereby, preventing complications such as coronary obstruction.



Euro14A-0P278

Unexpected extracardiac findings by multidetector computed tomography before TAVI

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Aims: In the transcather aortic valve implantation (TAVI) era, pre-procedural systemic evaluation including aortic root complex, coronary arteries and vascular access by systemic multidetector computed tomography (MDCT) is essential for selection of appropriate approach site and bioprosthesis sizing. Despite the incidental detection of extracardiac findings noted during this MDCT study before TAVI, the incidence of these findings remain unclear. The purpose of this study was to clarify the incidence and clinical impact of unexpected extracardiac findings by MDCT before TAVI. **Methods and results:** Forty-five consecutive patients underwent systemic MDCT evaluation before TAVI procedure under the variable pitch helical scan protocol (an ECG-gated cardiac and subsequent non-gated whole body MDCT, total examination time of 14 sec. and total contrast amount of 49 ml) using 256-slice machine between March and Docember 2013. An experienced radiologist examined all cases. In our cohort of elderly patients (83.5±5.9 years old), logistic EuroSCORE was 12.28% (9.78-21.71) and STS score was 3.22% (2.42-5.82). Twenty patients (44.4%) were male gender. Unexpected extracardiac findings were identified in 32 patients (71.1%). Out of these patients, 4 had definitive malignant tumors

male gender. Unexpected extracardiac findings were identified in 32 patients (71.1%). Out of these patients, 4 had definitive malignant tumors (8.9%) (renal cell carcinoma, recurrence of prostate cancer, pancreas cancer, colon cancer). Five had possible malignant tumors (11.1%). The other 3 patients had important findings; perforation of the small intestine, ventricular septal aneurysm and common bile duct stones. TAVI procedure was postponed in two patients and aborted in one due to the newly identified findings.

Conclusions: The incidence of unexpected extracardiac findings by systemic MDCT study was high in this very high-risk cohort of TAVI candidates. Notably, malignant tumor were highly prevalent in these elderly patients. These extracardiac findings may change the indication of TAVI procedure and thus should be evaluated with utmost cautionas well as cardiovascular findings.

Contrast-induced acute kidney injury after computed tomography prior to TAVI

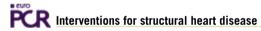
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Aims: Contrast-induced acute kidney injury is still a severe clinical complication and associated with high incidence of in-hospital mortality and poor long-term outcome. In addition, the impact of enhanced MDCT in high-risk patients with severe, symptomatic aortic stenosis who undergo TAVI is still unclear. The aim of this study is to identify independent predictors of contrast-induced acute kidney injury after enhanced multi-detector-row computed tomography prior to transcatheter aortic valve implantation (TAVI) in high-risk patients.

Methods and results: In this single-centre study we analysed retrospectively 361 patients who were assessed by MDCT prior to TAVI. CI-AKI was defined as an increase in serum creatinine (SCr) of \geq 25% or \geq 0.5 mg/dl over baseline measured 24, 48 and 72 hours after MDCT. A total of 38 patients (10.5%) experienced CI-AKI. As compared to patients without CI-AKI, they presented more frequently with estimated glomerular filtration rate (eGFR) <60 ml/min/1.73 m², (81.6% vs. 64.4%, p=0.045) and tended to receive higher volumes of iodinated contrast media (ICM) (55.3% vs. 39%, p=0.057). There was a significant interaction between baseline eGFR and the amount of intravenous ICM administered (Pfor interaction \leq 0.001) identifying the amount of ICM >90 mlas independent predictive factor of CI-AKI only in patients with baseline eGFR <60 ml/min/1.73 m² (OR 2.615 [95% CI, 1.213-5.640]).

Conclusions: High volumes of ICM increase the risk of CI-AKI in patients undergoing MDCT prior to TAVI with impaired baseline renal function, whilst they do not play a significant role in patients with normal renal function.



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Impact of periprocedural stroke on mid-term mortality after TAVI

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Aims: Stroke occurrence in patients undergoing transcatheter aortic valve implantation (TAVI) has been reported among complications in several studies. The aim of this study was to assess the impact of periprocedural stroke on mortality at mid-term follow-up after TAVI.

Methods and results: Six-hundred-fifty-six patients with aortic stenosis underwent TAV1 with the CoreValve system (92.8%) or the Edwards SAPIEN valve system (7.2%), using the trans-femoral or trans-subclavian approach. Stroke and transient ischaemic attack were defined according to the Valve Academic Research Consortium-2 consensus document. A cerebrovascular accident (CVA) was defined as any stroke or transient ischaemic attack. Periprocedural stroke or CVA were defined as stroke or CVA occurring within 72 hours from the index procedure. Separate multivariable cox regression analyses were performed to calculate hazard ratio (HR) with 95% confidence intervals (CI) of mortality for periprocedural stroke and periprocedural CVA, respectively. Procedural success occurred in 97.4% of patients. The incidence of any stroke and of CVA after the index procedure was 2.4% and 2.7%, respectively. Periprocedural strokes accounted for 56.2% of all strokes and occurred in 1.4% of patients included in the study. Periprocedural CVA accounted for 55.6% of all CVA and occurred in 1.5% of patients. After a median follow-up of 434 days, all-cause mortality was significantly higher in patients with periprocedural stroke as compared to those without (66.7% vs. 22.9%, log-rank p=0.001), and in patients with periprocedural CVA as compared to those without (70.0% vs. 22.8%, log-rank p <0.001). At multivariable cox regression, periprocedural stroke (HR 4.66, 95% CI 1.95-11.1, p=0.001) and periprocedural CVA (HR 4.64, 95% CI 2.06-10.5, p<0.001) were significant predictors of all-cause mortality.

Conclusions: More than half of strokes and CVA following TAVI occur within the periprocedural period. Periprocedural stroke and CVA are independent predictors of all-cause mortality at mid-term follow-up. Strategies for periprocedural cerebrovascular events prevention are needed.

Safety and performance of the Keystone Heart Triguard™ embolic deflection device in patients undergoing TAVI: first report of the DEFLECT II trial

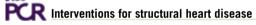
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Aims: To demonstrate the safety and performance of the cerebral embolic deflection device (TriGuardTMHD) in patients undergoing transcatheter aortic valve implantation (TAVI).

Methods and results: Prospective, single-centre, single arm pilot study enrolling up to 12 patients undergoing TAVI. Patients meeting eligibility criteria for TAVI and none of the exclusion criteria will be enrolled to receive the embolic deflection device (TriGuardTMHD) throughout the duration of the TAVI procedure. This filter consists of a nitinol mesh filter that is advanced through a guide catheter, positioned in the aortic arch over all major cerebral vessels. The filter is intended to reduce cerebral embolisation by deflecting debris into the descending aorta. TriGuardTMHD is similar to the one investigated in the DEFLECT-I study, however with smaller pore size, improved visibility and maneuverability. In all patients neurological examinations and cerebral diffusion-weighted magnetic resonance imaging (DWI) will be performed at baseline and at 4(+2) days post procedure. The primary endpoints of this trial are device performance and safety during and immediately post TAVI procedure. The secondary endpoints are the number and volume of new cerebral lesions by cerebral DWI and change in neurological status. We will report our results at the EuroPCR congress in May 2014.

Conclusions: In regard to the performance of the TriGuardTMHD embolic deflection device it is expected that a smaller pore size of this device will provide added brain protection during TAVI. We will report our results at the EuroPCR congress in May 2014.



Euro 14A-0P282

Embrella embolic deflection device for cerebral protection during transcatheter aortic valve replacement

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Aims: To compare the extent of cerebral ischaemic injury, detected by cerebral diffusion weighted magnetic resonance imaging (DWI), after transcatheter aortic valve replacement (TAVR) with the use of an Embrella Embolic Deflector System versus TAVR procedures without the use of an embolic protection device.

Methods and results: Fifteen patients with severe symptomatic aortic stenosis underwent TAVR with usage of Embrella Embolic Deflector System. This self-expandable embolic protection device was placed in the transverse aortic arch through a sheath inserted in arterial vasculature of the right arm. Cerebral DWI was obtained in all patients at day 4 after the procedure and retrospectively compared to 37 patients previously undergoing TAVR without a protection device (TAVR-only group). The primary endpoint was the number of new ischaemic lesions on cerebral DWI and secondary endpoints included volume and distribution of DWI lesions and periprocedural cerebrovascular events. Successful placement of the Embrella device was achieved in all patients. DWI revealed an increase in the number of ischaemic lesions in the Embrella group as compared to the TAVR-only group (9.0 vs. 5.0, p=0.044). The use of the Embrella device was however associated with a significant reduction in single lesion volume, 9.7 μ l [5.8, 18.4] versus 17.8 μ l [9.5, 38.7] (p <0.001). Moreover, total infarct volumes of more than 1000 μ l were only seen in the TAVR-only group. More lesions occurred in the right side of the brain in the Embrella group, whereas in the TAVR-only group lesions were distributed equally between left and right. One patient in the TAVR-only group suffered from a transient ischaemic attack. Postoperative evaluation was clinically uneventful in the Embrella group.

Conclusions: In the present study the use of the Embrella device was associated with a higher number of post-procedural cerebral DWI lesions compared to unprotected TAVR. This increase in number was however accompanied by a significant reduction in single lesion volume and a trend towards lower total infarct volumes as compared to TAVR-only procedures.

Lesion distribution of brain ischaemic lesions after percutaneous aortic valve implantations

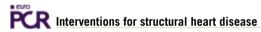
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Aims: Silent brain infarction and stroke are complications of transcatheter aortic valve replacement (TAVR). The present study aims to investigate the occurrence and distribution of TAVR-related silent cerebral infarctions using diffusion-weighted magnetic resonance imaging (DWI).

Methods and results: Consecutive patients with severe aortic valve stenosis treated with percutaneous implantation of Edwards SAPIEN XT or Medtronic CoreValve prostheses, underwent cerebral DWI within 5 days after the index procedure. DWI scans were analysed for occurrence and distribution of new ischaemic lesions post-TAVR. Forty-two patients were enrolled in this study. An Edwards SAPIEN bioprosthesis was deployed in 26 (62%) patients and a Medtronic CoreValve in the remaining 16 (38%) patients. After TAVR, a total of 276 new ischaemic lesions were detected in 38 (90%) patients, with a median of 4.5 [2.0-7.0] lesions per patient. The majority of the lesions were located in the left brain (left 57%, right 43%, p=0.02). A total of 129 (47%) lesions were detected in the cerebral cortex, 97 (35%) lesions were detected in the subcortical region, and 50 (18%) lesions were located in the cerebellum and brainstem. Median lesion volume was 20.2 μl [10.0, 42.7] and total ischaemic volume was 132.3 μl [42.8, 336.9]. Only one patient was diagnosed with transient ischaemic attack during index hospitalisation, whereas the new infarctions were clinically silent in the remaining 37 (97%) patients.

Conclusions: Multiple small brain infarcts occurred in 90% of patients following TAVR, with the majority located in the left brain and especially in the cerebral cortex. The small size and the cortical localisation (associated with a milder clinical course) of DWI lesions might explain their short-term benign character.



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Long-term cognitive trajectory after TAVI

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Aims: Transcatheter aortic valve implantation (TAVI) is known to be associated with "silent" cerebral injury, which could contribute to cognitive impairment. Considering its increasing use, thorough longitudinal investigation of cognitive trajectory after TAVI is pivotal.

Methods and results: Repeatable neuropsychological testing (RBANS) was performed before (E1), three days (E2), three months (E3), one (E4) and two years (E5) 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. Cognitive performance was investigated in 111 patients (mean log. EuroSCORE: 30±13%). Global cognitive function (RBANS total score) increased transiently at E2 (p=0.02) and was comparable to baseline levels at E3, E4 and E5. Six patients (5.4%) demonstrated early cognitive decline (CD). Persistence and late onset were seen infrequently (n=3, 2.7% and n=4, 3.6%, respectively). Hence, early CD was ruled out in 105 patients (94.6%), the great majority of patients (91%) demonstrated sustained cognitive performance throughout all investigated time points. Interestingly, only patient age, but neither prior cerebrovascular events, cognitive status, "direct" TAVI, cerebral embolism in DW-MRI, nor the use of a cerebral embolic protection device was found to be independently associated with cognitive decline (p=0.012), linking higher age to cognitive impairment along the first two years after TAVI.

Conclusions: Long-term cognitive performance was preserved in the great majority of patients throughout the first two years after TAVI despite the high intrinsic risk for cognitive deterioration.

Multicentre clinical study evaluating a novel re-sheathable self-expanding TAVI system using the transfemoral approach

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Aims: Transcutaneous aortic valve implantation (TAVI) significantly improves the prognosis of patients; however limitations with repositioning and optimisation of placement can result in complications. This investigation evaluates the resheathable and repositionable St Jude Medical Portico self-expanding TAVI system.

Methods and results: The study is a prospective, single arm, multicentre study evaluating the safety and efficacy. Between March 2012 and September 2013, 93 TAVI patients were enrolled and treated at 6 sites in the UK and Germany using the 18F Portico system with either a 23 mm (50) or 25 mm valve (43). Patients were followed post procedure at 30, 90, 180 days and 1 year. Adverse events were categorised by VARC definitions and adjudicated by an independent events committee. Echocardiography was evaluated by an independent laboratory. The Portico TAVI system was successfully implanted in 93 patients (94% Female: Mean Age=83.8; Euroscore=16.3), Resheathing (23%) was successful in all instances, VARC related outcomes were measured at 30 days and through one year regardless of relationship to the device or procedure. Paravalvular Leak at 30 days, as assessed by core lab (available in 60 patients thus far): 29.8% absent/trace, 64.9% mild, 5.3% moderate and 0% severe. Average implant depth was 6.6 mm. The proportion of NYHA Class 1 was 0% at baseline, 32.8% at 1 month, 32.3% at 3 months, 48.8% at 6 months and 39.5% at 12 months. At 30 days, 70% of patients had improved at least 1 class, 27% remained in the same class as baseline, and 3% had worsened one class. Haemodynamic performance was significantly improved at all followups. Mean Aortic Valve Area (AVA) was improved from 0.6 cm² to 1.7, 1.6, 1.5 and 1.5 cm² at 30 days, 3, 6 and 12 months, respectively. Mean gradient improved from 45.6 mmHg, to 8.7, 9.3, 9.7, 10.1 mmHg over the same follow-up intervals. Peak velocity was reduced from 421.3 cm/s to 199.5, 207.6, 209.6 and 213.9 cm/s at 30 days, 3, 6, and 12 months respectively. VARC defined event rates observed in the trial were generally low. Mortality at 30 days was 3.5%, all due to cardiovascular causes. Mortality increased to 8.2% through all follow-up, with 4.7% due to cardiovascular causes. Disabling stroke was observed in 2.4% of patients through 30 days, and 3.5% through follow-up. Non-disabling stroke occurred in 1.2% and 2.4% respectively. Ten patients (10.8%) have had new pacemaker implantation. Stage 3 acute kidney injury was observed in 2.4% of patients and 3.5% at 30 days and through all followup, respectively. Bleeding events at 30 days included life threatening (3.5%), major (11.8%) and minor (17.6%), remaining relatively stable throughout follow-up (3.5%, 15.3%, 17.6%). Vascular complications were low at 30 days, with 3.5% of patients experiencing major vascular complications, and 3.5% with minor complications. One additional patient had a major vascular complication after 30 days.

Conclusions: The novel Portico TAVI system allows for safe repositioning and optimisation of the device position. The functional and symptomatic outcomes appear to support the efficacy of the device.



Euro14A-0P287

Six-month outcomes with a fully repositionable and retrievable transcatheter aortic replacement valve in 120 high-risk surgical patients with severe aortic stenosis: results from the REPRISE II CE-Mark study

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Aims: Early transcatheter aortic valve implantation (TAVI) devices have established the feasibility of TAVI in patients who are unsuitable for surgical valve replacement, but these devices may face challenges with precise valve positioning, paravalvular leakage, and undesirable rates of stroke, bleeding, or vascular complications. The repositionable and fully retrievable LotusTM Valve was designed to facilitate accurate positioning and minimise paravalvular leakage in patients with severe aortic stenosis who are at high or extreme risk for surgery. The device demonstrated favourable efficacy and safety primary outcomes at 30 days in the REPRISE II CE-Mark trial. This analysis will present the first report of 6-month outcomes in the full cohort of patients in REPRISE II.

Methods and results: The prospective, single-arm, multicentre REPRISE II study was designed to assess the safety and performance of the Lotus Valve System in symptomatic patients aged ≥70 years with severe calcific aortic stenosis who are at high or extreme surgical risk. The primary device performance endpoint was the mean aortic valve pressure gradient at 30 days post-procedure, as assessed by an independent core laboratory. The primary safety endpoint was 30-day all-cause mortality. Among 120 enrolled patients, the mean age of 84.4±5.3 years, 57% (68/120) were female, mean STS Score was 7.1±4.6, mean euroSCORE II was 6.9±5.8, and 26% had medically treated diabetes. The mean baseline aortic valve area was 0.7±0.2 cm², and the mean aortic valve pressure gradient was 46.4±15.0 mmHg. All patients (100%) were successfully implanted with a Lotus valve. A total of 28.6% (34/119) patients had a permanent pacemaker implanted within 30 days post-procedure. The primary device performance endpoint of 30-day mean aortic valve pressure gradient was 11.5±5.2 mmHg, which was significantly less than the performance goal of 18 mmHg (P<0.001). All-cause mortality at 30 days was 4.2% and disabling stroke was 1.7%. A total of 84% of patients had no or trace paravalvular regurgitation by independent core lab evaluation at 30 days.

Conclusions: The LOTUS Valve has demonstrated minimal paravalvular regurgitation and low rates of death and stroke at 30 days. Six-month results for the full 120 patients in the REPRISE II trial will be available for the first time at the time of the meeting.

Initial German experience with transapical implantation of a second-generation transcatheter heart valve for the treatment of aortic regurgitation

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Aims: Experience with transcatheter aortic valve implantation (TAVI) for isolated aortic regurgitation is limited due to the risk of insufficient anchoring of the valve stent within the non-calcified aortic annulus. We report on the initial German multicentre experience using the JenaValve (JenaValve Technology GmbH, Munich, Germany) transcatheter heart valve for the treatment of aortic regurgitation.

Methods and results: Transapical implantation of a JenaValve prosthesis was performed in 31 patients (age 73.8±9.1 years) with severe aortic regurgitation in 9 German centres from 04/2012 to 10/2013. All patients were considered high risk for surgical aortic valve replacement (logistic EuroSCORE 23.6±14.5%). Aortic annulus diameters were 24.7±1.5 mm. Implantation was successful in 30/31 cases. Due to dislodgement of the device in one patient, valve-in-valve implantation with an Edwards Sapien XT (Edwards Lifesciences, Irvine, CA) was performed. Postprocedural aortic regurgitation was none or trace in 28/31 and mild in 3/31 patients. During 30-day follow-up, 4 patients died (cardiac n=1, non-cardiac n=3). One patient underwent valve-in-valve implantation 3 months after initial implantation due to increasing paravalvular regurgitation and transvalvular gradients and one patient underwent surgical aortic valve replacement for endocarditis 6 months after TAVI. Both patients exhibited good valve function afterwards. The remaining patients had an uneventful follow-up.

Conclusions: Aortic regurgitation continues to be a challenging pathology for TAVI. After initial demonstration of feasibility, this multicentre study revealed the JenaValve transcatheter heart valve as a reasonable option in this subset of patients. Short-term follow-up was promising with regard to valve function. However, a significant early non-cardiac mortality related to the high-risk population emphasizes the need for careful patient selection.



Euro14A-0P289

The JUPITER registry: thirty-day primary endpoint results of a second generation transapical TAVI system

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Aims: Transcatheter aortic valve implantation (TAVI) has emerged as an accepted treatment option for high-risk patients with severe aortic stenosis (AS). The JUPITER post market registry evaluates long-term safety and efficacy of the second TAVI generation transapical JenaValve™ (JenaValve Technology GmbH, Munich, Germany) in high-risk patients with AS in a real world setting.

Methods and results: Until November 2013, 126 of 180 patients with AS (63.2% male, logistic EuroSCORE I 23.3±13.0%, STS score 7.1±6.2%, NYHA functional class ≥III 84.0%) were enrolled in the JUPITER Registry in 11 European sites. In total 118 of 126 patients underwent successful JenaValve™ implantation, resulting in a procedural success (defined as successful delivery and deployment of JenaValve™) of 93.7%. In the remaining 8 patients (6.3%), Valve-in-Valve (ViV: n=3/2.4%) or conversion to surgical AVR (sAVR: n=5/3.9%) was required. Indications for ViV were: supraannular dislocation (n=2) and moderate paravalvular leakage (PVL: n=1). Indications for conversion to sAVR were: severe PVL (n=3), annular dissection (n=1) and apical bleeding (n=1). Peak and mean aortic transvalvular gradients decreased from 66.8±23.8 mmHg and 39.6±13 mmHg pre implantation to 17.3±9.4 and 8.3±5 mmHg post implantation, respectively (p<0.0001). Effective orifice area increased from 0.6±0.2 cm² to 1.7±0.5 cm² at 30d follow-up (p<0.0001). In this interim analysis 91.3% of patients (115/126) have reached 30-day follow-up. Thirty-day Kaplan-Meier all-cause and cardiovascular mortality were 12.7% and 5.8%, respectively. Thirty-day clinical outcome according to VARC I was: acute kidney injury: 13.0% (15/115), permanent pacemaker implantation for new onset conduction disorders: 13.0% (15/115; of which 9/15 developed new onset AVB 3°), major vascular/ access site complications: 7.8% (9/115) and acute myocardial infarction: 0.9% (1/115). None of the patients suffered from major stroke. Discharge echocardiography revealed none of the patients with a PVL >mild. Patients were discharged from hospital after 10.5±5.5 days. At 30-day follow-up, 72.8% of patients improved to NYHA functional class ≤II. Data of the complete cohort will be available at time of presentation.

Conclusions: Interim results of the JUPITER registry demonstrate that transapical TAVI using the JenaValveTM results in high procedural success with acceptable safety and efficacy outcomes. Implantation of the JenaValveTM guarantees a low incidence of PVL and coronary obstruction, which may be attributed to the native valve cusp clipping mechanism and the device-specific anatomical positioning.



Long-term clinical outcomes after TAVI in patients with severe aortic stenosis and moderate or severe paravalvular leak from the SOURCE XT Registry

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Aims: Transcatheter aortic valve implantation (TAVI) improves survival and quality of life compared with medical therapy in inoperable patients with severe degenerative aortic stenosis, and is as effective as surgery in high risk patients. However, post-implantation paravalvular leak (PVL) remains a significant complication specifically associated with TAVI, which may be linked to higher mortality. We sought to investigate the long term outcomes of PVL after the implantation of the Edwards SAPIEN XT valve.

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post approval study, which consecutively enrolled 2688 patients at 99 sites in 17 countries. A total of 103 patients (4.4%) developed moderate or severe PVL at discharge and 2255 patients with none/trace or mild PVL served as Controls. Patients with missing echocardiographic assessment of the PVL were excluded from this analysis. All patients were treated with the Edwards SAPIEN XT valve (Edwards Lifesciences, LLC). Two-year follow-up had been completed and preliminary data were analysed. Final data will be available by the time of the PCR. Most of the baseline characteristics were very similar for the two groups. Compared to the Controls, patients in the PVL group were more likely to be male (59.2% vs. 31.4%, p=0.0005), and had a higher prevalence of diabetes (29.8% vs. 20.4%, p=0.0460). Significantly more patients in the PVL group were with moderate or severe aortic regurgitation (24.2% vs. 14.5%, p=0.0131), moderate or severe mitral regurgitation (34.3% vs. 19.2%, p=0.0005), or moderate or severe tricuspid regurgitation (22.3% vs. 13.6%, p=0.0220). Annulus size, mean gradient and effective orifice area were well matched between the two groups. A larger proportion of PVL patients underwent TAVI with the transferoral approach (78.36% vs. 64.7%, p=0.0278) and received the 26 mm valve (56.3% vs. 48.8%) as opposed to the larger 29 mm valve (1.9% vs. 8.7%, p=0.0384), which was available for transapical delivery only. More predilations were done in the PVL group as compared to the controls (1.4±1.0 vs. 1.1±0.5, p<0.0001) but the number of post dilations were similar. All-cause mortality was only slightly increased at 30 day post-TAVI for the PVL group as compared to the Controls (4.9% vs. 2.2%, p=0.0780) but was significantly higher at 1 year (25.8% vs. 15.1%, p=0.0024) and two-year follow-up (36.9% vs. 22.2%, p=0.0011). Cardiac mortality was consistently higher at all follow-up visits for the PVL group (30 day: 3.9% vs. 1.5%, p=0.0491; 1 year: 15.5% vs. 7.3%, p=0.0019; 2 years: 17.5% vs. 9.7%, p=0.0171). Moderate or severe PVL was found to be a significant multivariate predictor of mortality (HR 2.15, p=0.0056).

Conclusions: TAVI is an efficient treatment for patients with severe degenerative aortic stenosis but may cause moderate or severe PVL in a small portion of patients treated with the SAPIEN XT valve. Given the adverse effect of moderate or severe PVL on late survival, any action to reduce paraprosthetical regurgitation, whether through improved technology or optimised sizing, is highly recommended.



Euro14A-0P291

Identification of parameters contributing to the variability of the aortic regurgitation index in a two-centre TAVI cohort

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Aims: For precise quantification of paravalvular aortic regurgitation (AR) in patients undergoing transcatheter aortic valve implantation (TAVI), the assessment of haemodynamics with the AR Index as part of a multimodal approach helps to identify patients, who will benefit from corrective measures such as post-dilation or valve-in-valve implantation. However, a significant part of patients has a false positive AR Index below the cut-off 25, although they do not suffer from more than mild paravalvular AR. In this study, we assess parameters, which impact the AR Index.

Methods and results: Pre- and post-procedural AR Indices were calculated in 524 patients before and after TAVI. The AR Index was calculated as ratio of the trans-valvular gradient between diastolic blood pressure (DBP) in the aorta and left-ventricular end-diastolic pressure (LVEDP) to the systolic blood pressure (SBP) according to the formula: [(DBP-LVEDP)/SBP] x 100. Multivariate regression analysis was used to identify pre- and peri-procedural parameters, which contribute to the variability of the AR Index. 524 patients (age 81.2±6.5 years, 51.1% male, left-ventricular ejection fraction 50.0±14.0%, STS score 8.5±5.9%) underwent TAVI in two independent institutions. 30-day, one-year, and two-year mortality were 6.3%, 23.3%, and 26.3%, respectively. The post-procedural AR Index was significantly associated with two-year mortality (survivors: 28.2±7.8 vs. non-survivors: 24.5±8.7; P<0.001). In multivariate regression analysis, the AR Index was independently associated with the degree of paravalvular AR following TAVI and the pre-procedural AR Index (P<0.001) but not with heart rate (P=0.21) or the prosthesis type (P=0.77). In patients with an AR index ≥25 after TAVI, outcome was independent from the pre-procedural AR Index. However, patients with an AR Index below 25 could be further stratified by the pre-procedural AR Index: while patients with high pre-procedural AR Index (below 35 as optimum cut-off in ROC curve analysis) had an only 2.9-fold higher risk (P<0.001), a pre-procedural high AR Index ≥35 was associated with a 4.5-fold higher two-year mortality risk (P=0.008).

Conclusions: Patients with an AR Index below 25 have a significantly impaired prognosis after TAVI. This predictive value of the AR Index is less pronounced in patients who displayed a low AR Index already before TAVI and was more accentuated in patients with normal pre-procedural AR Index.

Quantification by cardiac magnetic resonance imaging of peri-prosthetic aortic regurgitation after TAVI

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Aims: Peri-prosthetic aortic regurgitation (Peri-AR) after transcatheter aortic valve implantation (TAVI) has been associated with increased mortality. Quantification of Peri-AR is difficult after TAVI and needs the combination of haemodynamic, angiographic and echocardiographic parameters. The aim of this study is to assess the value of cardiovascular magnetic resonance (CMR) with the technique of phase contrast velocity mapping for the quantification of Peri-AR.

Methods and results: 30 patients underwent TAVI (COREVALVE (CV), n=10; or EDWARDS SAPIEN XT (EDXT), n=20) in our centre between November 2012 and august 2013 and could have CMR. Peri-AR severity was assessed using both transthoracic echocardiography (TTE) following the VARC criteria, and CMR. Both CMR and TTE were performed 5 days after TAVI. Invasively measured Aortic Regurgitation index (AR index) was obtained during TAVI in 26 patients. These 30 patients were included, 20 with ED XT and 10 with CV. Peri-AR were graded by TTE as mild in 22, moderate in 3 and severe in 5 patients. The mean regurgitant volume and the mean regurgitant fraction (RF) by CMR were 5.5 ml and 9.2% for mild Peri-AR, 16.7 ml and 20.3% for moderate and 34.6 ml and 46.8% for severe Peri-AR, respectively, with significant differences between the three groups (p <0.005). A regurgitant fraction <14%, discriminates mild from moderate/severe peri-AR with a 100% sensivity and 82% specificity (AUC 0.95). The reproducibility of CMR was excellent, with a coefficient of correlation at 0.99 for the intra and inter-operators variability. The mean AR index was 29.4 for mild Peri-AR and 13.8 for moderate/severe Peri-AR. Three patients were classified as mild Peri-AR by TTE but moderate/severe Peri-AR by AR index. For these 3 patients, FR by CMR was >14%, suggesting a possible underestimation of Peri-AR severity by TTE in some cases.

Conclusions: CMR is a reliable method for assessing the severity of peri-AR using RF determination. In some cases CMR can correct an underestimation by TTE. A future prospective study should assess the RF as a predictor of morbidity and mortality in the follow-up after TAVI.



Euro14A-0P293

Prothesis-specific predictors of paravalvular regurgitation after TAVI: impact of calcification and sizing on balloon-expandable versus self-expandable transcatheter heart valves

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Aims: Paravalvular aortic regurgitation is frequently observed after transcatheter aortic valve implantation (TAVI), as self-expandable and balloonexpandable transcatheter heart valves engage differently with the native aortic valve structures, factors that impact paravalvular aortic regurgitation may differ between prosthesis types. Hence, the aim of this study was to investigate prosthesis specific predictors for paravalvular aortic regurgitation in self-expandable versus balloon-expandable transcatheter heart valves.

Methods and results: 137 TAVI patients with pre-procedural multi-slice computed tomography and post-procedural transthoracic echocardiography were studied. Predictors for paravalvular aortic regurgitation including annulus area and perimeter oversizing as well as aortic valve calcification mass and volume were analysed in a multivariate model. The Medtronic CoreValve prosthesis was utilised in 68 (50%) patients, the Edwards SAPIEN prosthesis in 69 (50%) patients, respectively. More than mild paravalvular aortic regurgitation was observed in 43 (32%) patients. In Medtronic CoreValve patients, aortic valve calcification volume and mass were higher in patients with more than mild paravalvular aortic regurgitation compared to those with none or mild paravalvular aortic regurgitation (p=0.04 and p=0.03). In Edwards SAPIEN patients, annulus area and perimeter undersizing was higher in patients with more than mild paravalvular aortic regurgitation compared to those with none or mild paravalvular aortic regurgitation (p=0.001). By multivariate logistic regression analysis, aortic valve calcification mass was the only independent predictor for more than mild paravalvular aortic regurgitation in Medtronic CoreValve patients (p=0.02), while in Edwards SAPIEN patients the only independent predictor was transcatheter heart valve undersizing (p=0.001) irrespective of calcific burden.

Conclusions: For self-expandable transcatheter heart valves, aortic valve calcification mass was the strongest predictor for paravalvular aortic regurgitation, while in balloon-expandable transcatheter heart valves, it was prosthesis undersizing. Hence, in patients evaluated for TAVI, these parameters should guide selection of the prosthesis type.



The aortic regurgitation index to assess the success of post-dilatation on the reduction of paravalvular aortic regurgitation

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Aims: Significant paravalvular aortic regurgitation (AR) is associated with worse outcome in patients undergoing transcatheter aortic valve implantation (TAVI). Balloon post-dilation is an option to reduce the degree of paravalvular AR by obtaining a better expansion of the prosthesis stent frame and a better sealing of the paravalvular space. This study investigates whether the periprocedural measurement of haemodynamic parameters is useful to assess the success of post-dilation on the reduction of paravalvular AR.

Methods and results: In this prospective study, 223 patients underwent TAVI at our institution after introduction of a multimodal algorithm considering haemodynamics in addition to imaging modalities to identify patients with significant paravalvular AR after TAVI. In patients with more than mild aortic regurgitation after initial valve deployment, balloon post-dilation was used to reduce the procedure-related rate of paravalvular leakage. In these patients, haemodynamics were measured before and after post-dilation with a balloon aortic valvuloplasty catheter. 223 patients (age 81.3±6.3 years, 54.3% male, left-ventricular ejection fraction 52.2±14.4%, STS score 8.4±5.6%) underwent transvascular TAVI with use of the self-expanding CoreValve (79.4%) and the balloon-expandable Edwards-SAPIEN XT prosthesis (20.6%). After deployment of the prosthesis, moderate and severe paravalvular AR was present in 54 (24.7%) and 26 (11.9%) of the patients, respectively. 78 patients (35.0%) underwent post-dilation due to suboptimal prosthesis expansion. In patients with moderate AR, the AR Index increased significantly from 20.3±11.5 to 26.4±5.2, and in patients with severe AR from 15.4±6.2 to 26.1±7.7. Due to misplacement of the prosthesis, 11 (4.9%) patients had to undergo valve-in-valve implantation. After corrective measures, 17/223 (7.6%) still suffered from moderate AR. 30-day and one-year mortality rates were 4.0% and 18.4%, respectively. The necessity for post-dilation was higher in patients without pre-dilation (44.1% vs. 25.0%; P=0.003). Annular rupture with fatal outcome occurred in one patient (1.3%). However, performing post-dilation after TAVI was not associated with an increased one-year mortality (17.5% vs. 18.9%; P=0.87), pacemaker implantation rate (16.2% vs. 14.3%; P=0.73), or stroke rate (1.3% vs. 1.4%; P=0.94).

Conclusions: Post-dilation is a safe treatment option to reduce the severity of paravalvular AR in patients with suboptimal prosthesis expansion. The success of this measure can be precisely assessed by the evaluation of haemodynamics in addition to imaging modalities.



Euro14A-0P295

Percutaneous closure of patent foramen ovale and atrial septal defect

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Aims: This study aims to evaluate the "real life" safety and efficacy of percutaneous closure of patent foramen ovale (PFO) or atrial septal defect (ASD) in the prevention of subsequent cerebrovascular accident, in patients with history of cryptogenic stroke.

Methods and results: Prospective, non-randomised study that included 191 patients with cryptogenic stroke (48.4±10.1 years, 62.3% female) from January 2005, with a mean follow-up of 1086±772 days corresponding to 830 patient/years. Our sample showed low prevalence of risk factors for cardioembolic events (hypertension 34%, age>65 y 6.8%, diabetes 4.7%, heart failure 3.1%, vascular disease 1.0%). Predisposing conditions were present: venous disease of lower limbs/pelvis (12.0%), history of pulmonary embolism (3.7%), thrombophilia (2.6%), history of cancer (1.6%). Closure of PFO (N=139, 72.8%) and ASD (N=52, 27.2%) were performed using the following devices: Amplatzer (53.9%), Premere (31.4%), Occlutech (11%), Solysafe (2.6%), Helex Gore (0.5%). Average size of the device was 24 mm (9-35). Regarding the anatomical high risk features of PFO we found: long tunnel [>12 mm] (60.7%), septal aneurysm (46.1%), Eustachian valve (33.5%), spontaneous R-L shunt (22.3%). Procedure was unsuccessful in 3 cases (1.6%) due to inappropriate ASD size. Periprocedural complications (<7 days) were only seen once (0.5%) - femoral pseudoaneurysm. Residual shunt (>1 month) was found in 2 patients (1.1%). The antithrombotic therapy after the first month of the procedure was as follows: device+single antiplatelet therapy (76.0%), device only (16.2%), device+oral anticoagulation (4.7%). Cardiovascular or non-cardiovascular mortality in the follow-up was not found (0%). The expected rate of recurrent cryptogenic stroke in the literature is about 2%/year in the case of PFO, and possibly even higher in the presence of anatomical PFO high-risk features or ASD. This would make an expected stroke incidence of 30 ischaemic events in our sample (for the 830 patient/years). We found 2 cerebral ischaemic events in the follow-up (1.05%) corresponding to a 93% reduction in stroke (considering the expected stroke incidence in our sample).

Conclusions: This "real life" registry consisted in a young population with prior cryptogenic stroke, and low prevalence of cardioembolic risk factors. The study achieved a long follow-up, with a very relevant event-exposure (830 patient -years). We found a high rate of success in percutaneous closure of PFO / ASD, with a favourable safety profile. Our results showed a highly significant reduction in the rate of cerebral embolic events compared to the estimated risk observed in previous clinical trials/registries.

Severe disabling migraine with aura and a high grade contrast transcranial doppler shunt predicts symptom relief from transcatheter patent foramen ovale closure

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Aims: Closure of patent foramen ovale (PFO) for the indication of severe disabling migraine with aura remains controversial. To date randomised trials have not shown definitive benefit. The PREMIUM trial (St Jude Medical) yet to be reported closely aligns to our Centre's migraine program. This abstract reports initial 3 month and late outcomesfollowing transcatheter patent foramen ovale closure, using contrast transcranial Doppler as a guide.

Methods and results: A single-centre cohort of 71 patients (69% female; mean age 47, range 14-73) of severe migraine with aura patients defined by migraine disability assessment score (MIDAS) grade 3 and 4 were considered for diagnosis of patent foramen ovale. These patients underwent contrast transcranial Doppler pre-operatively. Only Valsalva Spencer grade 3-6 (mean grade 4.85) proceeded to closure. (St Jude Amplatz: 46, St Jude Premere: 27, Occlutech Figulla: 1). At 3 months contrast transcranial Doppler (Valsalva) was performed to confirm closure (mean Valsalva 1.2, range 0-5) and repeated at 6 or 9 months if a residual shunt was present (defined as ≥grade 3). 3 patients who had a persistent ≥grade 3 shunt went on to have successful secondary closure. At 3 month follow-up, complete migraine with aura resolution was reported in 83% and a >50% reduction in frequency and severity was reported in a further 14%; (response rate of 97%). 2 patients reporting less than 50% symptom reduction responded to changing from aspirin to clopidogrel. There was no residual shunt present in the low responders. These outcomes persisted with a mean follow-up for 1.75 years (range 121-1,576 days).

Conclusions: Our single-centre study suggests that there can be successful treatment of severe disabling migraine with aura by transcatheter patent foramen ovale closure, using contrast transcranial Doppler as both the primary screening tool and to confirm closure. By selecting only high grade shunts, a significant and lasting efficacious response rate is possible. We await the results of the PREMIUM trial that is using a similar cohort and methodology.



Euro14A-0P297

Feasibility of transcatheter closure of sinus venosus atrial septal defect and large secundum atrial septal defect(s) with absent superior or inferior rim

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Aims: These procedures have been challenging and are usually not recommended. Therefore our goal was to assess the feasibility of transcatheter closure of such defects.

Methods and results: To provide a stable rim to device anchorage, we have used a covered & uncovered CP-stent in the superior & inferior vena cava respectively, part of the stent or a fold which is created after balloon inflation of the stent at the site of superior or inferior rim, would be the future rims. From July 2011 to Sept. 2013, Seven patients under went such trial in Ibn-Albitar Center For Cardiac Surgery, their age ranged from 14-31 years. Three patients had large secundum atrial septal defect, two of them had absent superior rim & one with no inferior rim. All those patients underwent successful transcather closure of their defects using atrial septal occluder size 30, 40, & 34 mm with covered & uncovered CP-stents in the superior & inferior vena cava respectively with no residual shunt immediately after closure. Four patients have large sinus venosus atrial septal defect with anomalous right upper pulmonary venous drainage which is overriding interatrial septum, two of them had superior vena cava-type underwent catheter closure using covered CP – stents with no need for septal occluder. One of them had no residual shunt immediately after the procedure while the other one had mild residual shunt which was becoming trivial six months later. The other two patients had large sinus venosus atrial septal defect (right atrial-type) underwent catheter closure using two covered CP-stents. One of them had trivial residual shunt six months after the procedure. The second patient (23 years old girl) had significant residual shunt 4 months after the deployment of two overlapping covered CP-stents in the superior vena cava inoreder to do septation between the superior vena cava and right upper pulmonary vein so we decided to close the posterosuperior residual shunt near the entrance of the right upper pulmonary vein to the left atrium using patent foramena ovale device where control angiogram revealed no residual shunt one year later. All patients had been followed up to 9-27 months and all had been given aspiri

Conclusions: Long term follow-up data are still needed to assess long term safety and efficacy of this technique.

Comparison of conventional surgery and transapical transcatheter approach for paravalvular leak closure in high risk patients: acute results from a single-centre experience

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Aims: Paravalvular leaks (PVL) affect up to 17% of all surgically implanted prosthetic valves. Reoperation is associated with high morbidity and mortality. Transcatheter transapical (TA) closure is an emerging alternative for selected high-risk patients with PVL. The aim of this study is to compare the in-hospital outcomes of patients who underwent surgery and TA-closure for PVL in our single-centre experience.

Methods and results: From October 2000 and June 2013, 139 patients with PVL were treated in our Institution: 122 patients (87.3%) underwent surgery (68% mitral-PVL; 32% aortic-PVL) and 17 patients (12.2%) underwent TA closure (all the patients had mitral PVL; 1 case had combined mitral and aortic PVLs). All the TA procedures were performed under general anaesthesia in a hybrid operative room: in all but 1 case an Amplatzer Vascular Plug III device was utilised. Baseline features of the patients were comparable in terms of age (p=0.9), chronic renal failure (p=0.2), previous endocarditis (p=0.08), concomitant atrial fibrillation (p=0.2), while COPD was more prevalent in TA group (p=0.02). Log-EuroScore was 15±11% and 18±8% in surgical and TA group respectively (p=0.1). Most of the patients were in NYHA class III-IV (57% vs. 59%; p=0.2); 41% of surgical patients and 82% of TA patients were at their second of more reoperation (p=0.01). Procedural success in TA group was 93% (1 conversion to surgery because of the dislocation of the device). In-hospital mortality was 10.6% in surgical group and 0% in TA group (p=0.05). Median LOS was 19 days for surgery and 9 days for TA (p=0.08). All the patients had less than moderate residual valve regurgitation after the procedure. Surgical treatment was identified as risk factor for in-hospital death at univariate analysis (OR 8 – CI 95%=1.8-13.4; p=0.05).

Conclusions: Transcatheter TA approach is a safe and effective therapeutic option in selected high-risk patients with PVL and it is associated with reduced risk of hospital mortality than surgical treatment, in spite of higher predicted risk. Further studies are needed to determine the long-term results of the two procedures.



Euro14A-0P300

Percutaneous closure of paravalvular leak: the acute, 30-day and one-year results from single-centre

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Aims: The treatment of paravalvular leak traditionally has been repeat open surgery, which may be challenging because of technical factors and operative risk greadually increases. Because of frequent patient morbidity and increased risk of reoperation, percutaneous closure of leaks by devices has been performed in recents reports. We aimed to present the our first results with high success rate from a single-centre on this issue.

Methods and results: Eighteen patients (67% female) were enrolled the study. The mean age was 57±14 years-old. Paravalvular mitral regurgitation was found in 13(72%) and aortic paravalvular regurgitation in the remainder. The clininal indications for the percutaneous closure were heart failure in 8 patients, severe regurgitation in 5 (mitral in four, aortic in 1) and haemolytic anemia in 5. Two patients had history of endocarditis. The mean number of open surgery operation was 2.2. One patient had history of five cardiac operations and transapical approach was used because of unusual cardiac anatomy. The degree of regurgitation was grade 3 in 12(67%) and grade 4 in the remainder. Acute Outcomes. The mean procedure time was 96±43 minutes in paravalvular mitral defects and 108±56 minutes in paravalvular aortic defetcs. Device placement was seccessful in 16(88%) patients. Device was not placed successful in two patients (one in mitral, one in aortic group). Device was deployed at the second attempt in two patients. In one patient, the procedure ended because of cardiac asystole during procedure. Percutaneous closure was performed successfully two months later. Another patient had grade 3 paravalvular aortic regurgitation and defect could not be crossed by guidewire due to unusual position of aorta. However, device was deployed successfully at second attempt. Complications. No device embolisation occurred. Cardiac asystole occurred in one patient and resuscitation was successful. Major bleeding requiring blood transfusion at the access site (femoral artery) was seen in one patient. Thirty-day Outcomes. All patients were contacted to our clinic at 30th-day and evaluated by transthoracic echocardiography (TTE) and transoesophageal echocardiography (TOE). Functional status class was 2 in all patients except one. The mean improvement in functional satatus was 1.1 at 30-day follow-up. Significant residual regurgitation was detected in one patient. Three-months Outcomes. Recurrent haemolysis was detected in one patient at third month follow-up. On TOE, grade 2 residual regurgitation was detected at third-month follow-up. who had recurrent haemolysis not requiring transfusion was recorded 3 months later. One-year follow-up. Transthoracic echocardiograppy revealed grade 1 mitral regurgitation in only one patient at one-year follow-up. However, grade 3 mitral regurgitation was detected on transthoracic echocardiography at 15th month in one patient. When we evaluated by TOE and fluoroscopy, we also found prosthesis dehiscence and re-operation was recommended to patient. In the remainder, no more than grade 1 regurgitation or haemolysis requiring blood transfusion were recorded. No cardiac related death occurred during follow-up period.

Conclusions: Percutaneous closure of paravalvular leak may be performed with high procedural success and acceptable complication rates in patients with high risk although cardiac surgery is the gold standart in current guidelines on this issue.

Conduction disturbances after perimembranous ventricular septal defect device closure in young children with significant left to right shunt: a prospective study

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Aims: The study aims to assess and evaluate the conduction disturbances after transcatheter device closure of perimembranous ventricular septal defect device (PMVSD) using different occluders at mid-term follow-up.

Methods and results: We studied 297 patients having PMVSD with clinical and/or echocardiographic evidence of a significant left-to-right shunt. All patients were screened by conventional two dimensional (2-D) and colour doppler transthoracic echocardiography (TTE). Catheterization procedure was performed under local or general anaesthesia. All subjects underwent clinical examination, electrocardiogram (ECG), chest X-rays and TTE before discharge and at 1, 6 and 12-months after the procedure and yearly thereafter. Platelet anti-aggregation therapy with aspirin 5 mg/kg/day p/o and endocarditis prophylaxis was prescribed for 6-months. Holter monitoring was done at a lag period of 6-months or earlier if required. Oral steroids (tablet prednisolone 1-2 mg/kg) were given to all patients and dose was tapered over 2-3 week period. Treatment with steroid was extended in patients developing post procedure conduction disturbances if required. Transcatheter closure of PMVSD was attempted in 297 patients with male to female ratio of 1.33:1. The mean age of the patients was 8.64±3.14 years (range 3-17.2 years). Most of the patients did not have a ortic regurgitation (AR) with mild AR being present only in 14.5% of the patients. Majority (86.2%) had no residual shunt at follow-up. None of the patient had more than mild residual shunt. Total rhythm disturbances were seen in about 6% (18/297) of patients with transient complete atrioventricular block (CAVB) occurring in 3 patients. Conduction disturbances were transient in most of the patients. Overall, most common conduction disturbances encountered in decreasing order of frequency were junctional rhythm (6 patients), right bundle branch block (RBBB) complete and incomplete (3 patients each), incomplete left bundle branch block (LBBB) (1 patient), complete LBBB with first degree AV block (1 patient) and bifascicular block in one patient. There was no association between the conduction disturbances and VSD device to defect ratio in our study. In our study, the total complication rate was 19.5% (most of them minor) with majority of the patients having transient loss of peripheral pulses, hematoma etc. There was no mortality in our study which compares well with the surgical results in which it is between 0-3 percent.

Conclusions: This study showed that transcatheter closure of PMVSD using symmetric PMVSD occluders and duct occluders is a safe and effective alternative to surgery. It has excellent results in experienced hands with minimum morbidity and almost no mortality. Oversizing of devices should be minimised and low profile devices appropriate to specific morphology of VSD should be used. Onsets of AV conduction disturbances are rare and unpredictable and patients should be followed up carefully till the post procedure ECG returns to normal. The decision to implant a permanent pacemaker in the absence of guidelines should only be done only after optimised anti-inflammatory regime for 3-4 weeks. Newer hardware design or modifications like steroid eluting devices may reduce the incidence of conduction disturbances.



Euro14A-0P302

Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the Amplatzer cardiac plug

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Aims: Left atrial appendage occlusion (LAAO) with the Amplatzer Cardiac Plug (ACP) has shown favourable results in single-centre studies. This study aimed to investigate the safety, feasibility, and efficacy of LAAO with the ACP for stroke prevention in patients with atrial fibrillation (AF). **Methods and results:** Data from consecutive patients treated in 22 centres were collected in a specially designed database. One thousand forty four patients (mean age 75±8 years, 62% males) with a CHA₂DS₂-Vasc score of 4.5±1.6 and a HASBLED score of 3.1±1.2 were included in the study. The predicted annual rates of systemic thromboembolism and major bleeding were 5.65% and 5.35%, respectively. Procedural success was 97.3% (1016/1044 patients). In 272 patients (26.1%), LAAO was combined with another procedure: coronary angiography 107 (10.2), patent foramen ovale closure 61 (5.8%), percutaneous coronary intervention 54 (5.2%), AF ablation 18 (1.7%). There were 44 (4.2%) peri-procedural major adverse events: death 8 (0.7%), stroke 9 (0.9%), myocardial infarction 1 (0.1%), cardiac tamponade 12 (1.2%), major bleeding 13 (1.3%), and device embolisation needing major intervention 1 (0.1%). Follow-up was complete in 998/1016 (98.2%) of successfully implanted patients. Average follow-up was 13 months (IQ range 6-25 months), a total of 1345 patient-years. Aspirin monotherapy increased from 31% to 64% and warfarin monotherapy decreased from 16% to 1.6% between admission and last follow-up. One-year all-cause mortality was 4.2%. A total of 63 deaths were reported at follow-up (17 due to cardiovascular causes). None was related to the device. There were 9 (0.9%) strokes, and 9 (0.9%) transient ischaemic attacks at follow-up. The annual rate of systemic thromboembolism (peri-procedural + follow-up) was 2.3% (31/1,345 patient-years), which translates into a 59.3% risk reduction. There were 16 (1.6%) major bleedings at follow-up. The annual rate of major bleeding (peri-procedural + follow-up) was 2.2% (29/1,345 patient-years), whic

Conclusions: In this multicentre real-world study, LAAO with the ACP had a high procedural success and a moderate amount of peri-procedural complications. LAAO with the ACP showed a favourable outcome regarding efficacy for the prevention of AF-related thromboembolism. Modification in antithrombotic therapy after LAAO resulted in fewer than expected bleeding events.

Long-term follow-up from a left atrial appendage occlusion European multicentre post market observational study

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Aims: The AMPLATZER™ Cardiac Plug (ACP) (St. Jude Medical, Plymouth, MN) is a percutaneous transcatheter device intended to prevent thrombus embolisations from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (AF). The objective of this prospective, open-labelstudy is to evaluate safety and performance of the ACP device in occlusion of the LAA and report the initial long-term follow-up results out to two years.

Methods and results: We report preliminary results on a total of 76 patients who have been followed for two years post ACP implantation at ten investigative centres in Germany, Spain, United Kingdom, Ireland and the Czech Republic. This data represents 76 patients out of the original 201 that agreed to be re-consented out to at least two years. Others were unreachable or did not provide their consent to reenter the study. Study follow-up included rigorous neurological and echocardiographic assessments at baseline, 1, 6, 12 months and 2 or more years post implant, as well as after a suspected stroke, TIA or systemic embolism. The study is being 100% monitored. An independent Data Monitoring Board is utilised and adjudicates seriousness and relatedness of all the safety events. In comparison to previously presented studies on ACP and other percutaneous LAA closure devices, this cohort was older and had a higher incidence of comorbidities. The majority of reconsented patients (57.9%) had a history of permanent AF, mean age was 73.48±7.1, mean CHA₂DS₂-VASc score 3.9±1.6, and mean HAS-BLED score 2.7±1.1. Seventy-six (76) subjects completed up to four-year follow-up. One ischaemic stroke occurred at 256 days post implant in a patient with a risk factor of CHA₂DS₂-VASc score of 6 including a prior ischaemic stroke and one TIA occurred at 559 day post implant in a subject who had a CHA₂DS₂-VASc score of 2. There have been no reported haemorrhagic strokes, thrombi on the device, or device embolisations reported in the long-term follow-up cohort. At 211 patient years of follow-up, the actual stroke rate in this cohort of patients is 0.94%. This compares to an expected stroke rate of 4.89% based on CHA₂DS₂-VASc score.

Conclusions: With 211 patient years of follow-up, a high risk patient cohort implanted with the AMPLATZERTM Cardiac Plug for left atrial appendage occlusion exhibited an 80% stroke risk reduction versus the expected stroke rate. These results show benefit over a longer follow-up period than previously reported with the ACP device, and compare favourably with other LAA occlusion devices.



Euro14A-0P304

Early results of first versus second-generation Amplatzer occluders for left atrial appendage occlusion in patients with atrial fibrillation

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Aims: Transcatheter left atrial appendage (LAA) occlusion has been proven to be an effective treatment for stroke prophylaxis in patients with atrial fibrillation. The aim of the present study was to investigate the safety and efficacy of first-generation (Amplatzer Cardiac Plug, ACP) versus second-generation Amplatzer occluders (Amulet) for LAA occlusion.

Methods and results: Retrospective analysis of prospectively collected data from the Bern and Zurich university hospitals LAA occlusion registries. Comparison of the first consecutive 50 Amulet cases versus the last consecutive 50 ACP cases. For safety, a periprocedural combined endpoint, which is composed of death, stroke, cardiac tamponade, and bailout by surgery was predefined. For efficacy the endpoint was procedural success, which was defined as successful implantation of a device at its intended position by end of the procedure. There were no differences between the two groups in baseline characteristics. The percentage of associated interventions during LAA occlusion was high in both groups (78% vs. 70%, p=ns). Procedural success was similar in both groups (98% vs. 94%, p=0.61). The combined safety endpoint for severe adverse events was reached by a similar rate of patients in both groups (6% vs. 8%, p=0.7). Overall complication rate was insignificantly higher in the ACP group, which was mainly driven by clinically irrelevant pericardial effusions (24% vs. 14%, p=0.31). Death, stroke, or tamponade were similar between the groups (0% vs. 2%, 0% vs. 0%, or 6% vs. 6%, p=ns).

Conclusions: Transcatheter occlusion of the LAA for stroke prophylaxis in patients with atrial fibrillation can be performed with similarly high success rates with first and second generations of Amplatzer occluders. According to this early experience, the Amulet has failed to improve results of LAA occlusion. The risk for major procedural adverse events is acceptable but has to be taken into account when selecting patients for the procedure.

Preclinical evaluation of a novel left atrial appendage occluder in a pig model

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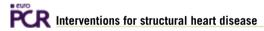
property of the device results in secondary complete LAA occlusion even in cases with leaks at the implantation.

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Aims: Transcatheter left atrial appendage occlusion is comparable to warfarin in preventing atrial fibrillation-related strokes. The study evaluated the feasibility and safety of a novel left atrial appendage occluder (Occlutech LAA OccluderTM, Occlutech GmbH, Jena, Germany) in pigs.

Methods and results: The transcatheter implantation of Occlutech LAA Occluder was attempted in 12 young adult pigs (species: sus scrofa, strain: DanBred Hybrid) with a body weight of 40-45 kg. The implantation failed in 2 pigs, in 1 due to transseptal puncture related tamponade, in 1 due to device embolisation during device release. In 10 pigs 11 LAA occluders (3 size 15 mm, 6 size 18 mm, 2 size 21 mm devices) could be successfully implanted. One pig with bilobular LAA received 2 implants. The device consists of a self-expanding, flexible nitinol mesh. It has a tapered cylindrical shape that adapts to the shape of the LAA. The proximal part has a larger diameter to seal the orifice. The loops at the distal rim aid to keep the implanted device in position. The outside of the occluder is covered with a non-woven, Poly(carbonate)urethane layer called bio-stable. Due to the softness of the device with low radial force the deployment, repositioning, and retrieval of the device was found to be easy, atraumatic, and controlled. The TEE investigation revealed complete LAA closure in 8 out of 10 pigs during implantation and in all 10 pigs at 6 weeks control. Until the sacrification of the pigs after 6 weeks all 10 pigs remained clinically healthy with normal weight gain. In the necropsy findings the complete closure of the LAA in all pigs could be confirmed. With the exception of mild pericarditis without macroscopical signs of inflammation on the device surrounding endocardium in 1 pig, no signs of bleeding, pericardial effusion, thrombus formation on the device, device dislocation or embolisation were found. The immuno-histological examination demonstrated that all devices were more or less inhabitated by endothelial cells.

Conclusion



Euro14A-0P306

Long-term follow-up after interventional left atrial appendage occlusion in a real world collective: data from the ALSTER-LAA registry

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Aims: Interventional left atrial appendage (LAA) occlusion for stroke prevention in atrial fibrillation has been proven to be non-inferior to oral anticoagulation with warfarin in terms of safety and efficacy. Based on these data, european guidelines recommend LAA occlusion in patient ineligible for warfarin therapy while the FDA recently voted in favour of this therapy for the "PROTECT" patients, namely patients eligible for warfarin. Patient selection therefore varies widely and postprocedural anticoagulation differs greatly between implanting centres. Clinical data are available mainly for low risk patients with a CHADs score of around 2 (2.1 in PROTECT-AF). Here, we present follow-up data after WATCHMAN® implantation in a high-risk population in terms of safety and efficacy from our all-comers ALSTER-LAA registry.

Methods and results: Patients with atrial fibrillation admitted to our departmen w/o oral anticoagulation were screened for interventional LAA occlusion. Postinterventional anticoagulation was chosen according to the individual bleeding risk and conducted either with warfarin, dual antiplatelet therapy or low-dose novel anti-coagulants (NOACS). Follow-up TEE was performed after three months with regular clinical follow-ups thereafter. Between 2010 and October 2013, 113 patients were treated with WATCHMAN® devices in our centre. Mean follow-up duration was 396 (±33) days. Mean age was 75.9 years (±0.9), the CHA₂DS₂-VASc-Score 4.5 (±0.2) and the HAS-BLED score 3.5 (±0.1). 102 patients (90%) had relative or absolute contraindications to oral anticoagulation with warfarin, in most cases due to prior bleeding events. Periprocedural mortality was 0%. Periprocedural, two strokes occurred (1.7%) as well as one device embolisation (0.9%) and three relevant pericardial effusions (2.6%). For a combined safety endpoint of procedure-related stroke, bleeding, pericardial effusion, device embolisation and major bleeding during follow-up this results in 7 events (6.2/100 patient years compared to 5.5 in PROTECT-AF). For a combined efficacy endpoint consisting of stroke (ischaemic or haemorrhagic) and systemic embolism 4 events occurred (3.6/100 patient years compared to 2.0 in PROTECT-AF). For a combined endpoint of stroke and major bleeding we observed 5 events (4.6/100 patient years) compared to an expected rate according to CHA₂DS₂-VASc and HAS-BLED-Score of 11.6/100 patient years (5.4/100 patient years for stroke and 6.2/100 patient years for major bleeding). 22 patients of our cohort were treated whith low-dose dabigatran (75 mg twice daily) for three months after implantation followed by aspirin monotherapy after follow-up TEE. None of these patients developed a thrombus on the device (compared to 4 patients from the overall collective) neither did we observe any bleeding events in these patients. Conclusions: Interventional left atrial appendage occlusion is a valid alternative to oral anticoagulation especially in patients at high risk for both bleeding and thromboembolic events. Our data suggests that this also the case in a patient collective that does not meet the strict inclusion criteria of the PROTECT-AF trial and that thereby inhabits a significant increased risk for adverse events during implantation and follow-up. As the optimal postinterventional anticoagulation regime is still a matter of debate, we present data suggesting that dual-anti-platelet therapy as well as low-dose NOACs may be a valid option in this setting.



Outcome of patients with coronary artery disease and atrial fibrillation undergoing concomitant PCI and left atrial appendage occlusion

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Aims: To investigate feasibility and safety of concomitant PCI and left atrial appendage occlusion (LAAO) as compared to PCI in combination with antithrombotic treatment in patients with coronary artery disease and non-valvular atrial fibrillation (AF).

Methods and results: Patients with AF undergoing concomitant PCI with DES and LAAO with dedicated devices have been consecutively entered into a prospective single-centre registry and have been compared to AF patients from the Bern DES registry treated with different antithrombotic strategies. Among 379 patients with AF, 56 patients were treated with concomitant PCI and LAAO, 268 patients were treated with PCI and dual therapy (DT), and 55 patients were started on triple antithrombotic therapy (TT). Clinical follow-up was assessed by standardised telephone interviews. Patients with PCI+LAAO were older (76±7 years) as compared to patients with PCI+DT (72±9 years) or PCI+TT (73±8 years) (p=0.01), respectively, and more commonly had a history of cerebrovascular events (31% vs. 10% vs. 16%, p<0.001). CHA₂DS₂-Vasc Scores amounted to 3.5±2.2, 3.6±1.3, and 4.2±1.3 among patients with PCI+LAAO, PCI+DT, and PCI+TT, respectively. At 30 days, the composite of all-cause death, myocardial infarction, ischaemic stroke, or bleeding type 3-5 according to the BARC definition was documented in 12.5% of patients undergoing PCI+LAAO, 9.0% in patients with PCI+DT, and 10.9% in patients with PCI+TT, with no significant differences between groups in an age-adjusted analysis (PCI+DT being the reference; PCI+LAAO: HR 1.29 (95% CI 0.55-3.02), p=0.56; PCI+TT (1.20 (95% CI 0.49-2.93), p=0.69). Two patients (3.6%) with PCI and LAAO suffered a periprocedural stroke, and 5 patients (8.9%) were recorded to have bleeding BARC type 3 or 3b. At one year, all-cause mortality in patients with PCI+LAAO, PCI+DT, and PCI+TT amounted to 6.3% (HR 0.51, 95% CI 0.12-2.23, p=0.37), 6.7% (reference), and 18.2% (HR 2.89, 95% CI 1.33-6.26, p<0.01), respectively. There was no difference with regards to the composite of all-cause death, myocardial infarction, ischaemic stroke, or bleeding (BARC type 3-5) (PCI+DT being the reference; PCI+LAAO: HR 1.20 (95% CI 0.58-2.50), p=0.63; PCI+TT (HR 1.69 (95% CI 0.90-3.17), p=0.10)

Conclusions: PCI with concomitant LAAO appears to be a safe alternative to combined antiplatelet and antithrombotic management in patients with CAD and AF. Longer term follow-up will be needed to demonstrate efficacy.



Euro14A-0P308

Outcome after anticoagulant versus double antiplatelet therapy after left atrial appendage closure

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Aims: Left atrial appendage (LAA) closure is increasingly used for the prevention of stroke in patients with atrial fibrillation who are not suitable for anticoagulant therapy. While anticoagulant therapy was initially encouraged for the first 4-8 weeks after the implantation, more recent data suggest that a double antiplatelet therapy might be a viable alternative. No direct comparison data are available.

Methods and results: We report on the 1-month TEE and clinical outcome of consecutive patients treated with LAA closure in our centre between March 2011 and November 2013. Patients were divided in two groups based on the therapy received during the first 4 weeks after implantation: anticoagulant (aspirin + one among vitamin K antagonist, a novel anticoagulant, or low-molecular weight heparin in full anticoagulant dosis) or double antiplatelet (aspirin and clopidogrel) therapy. A total of 54 patients received successful LAA closure. After the procedure, 28 patients (age 76±10, CHADS2VASC score 3.5±1.5, HAS-BLED score 2.9±1.6) were treated with double antiplatelet therapy and 26 (age 79±5, CHADS2VASC score 3.5±1.9, HAS-BLED score 3.9±1.7) with anticoagulant therapy + aspirin. There were 3 cases of device thromboses (one associated with transient ischaemic attack) in those treated with double antiplatelet therapy and none in the group of patients that received anticoagulant therapy. 3 patients died before the 1-month follow-up in the dual antiplatelet group, none in the anticoagulant group. There was no difference in the incidence of bleedings.

Conclusions: In a single-centre experience, double antiplatelet therapy after LAA closure was associated with a higher incidence of device thrombosis and unexplained death without differences in that of bleeding.

Mitral valvuloplasty with Balt single balloon - Long-term follow-up of 25 years

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Aims: To evaluate the long-term follow-up (FU) of mitral balloon valvuloplasty (MBV) with Balt single balloon (BSB) technique and to determine independent predictors of survival and event-free survival (EFS).

Methods and results: From 1987 to 2012, 526 procedures of MBV were performed, 404 (77.1%) with BSB. There were 256 procedures with long-term FU. The balloon diameter was 25 mm in 5 procedures and 30 mm in 251, mean dilatation area was 7.02 ± 0.30 cm². The FU was 54.6 ± 32.8 (1 to 174) months. The multivariate Cox analysis was used to determine IPS and EFS. Mean age was 38.0 ± 12.6 (13 to 83) years, 222 (86.7%) female gender, 215 (84.0%) in sinus rhythm, echo score (ES) 7.2 ± 1.5 (4 to 14) points and echo mitral valve area (MVA) pre-MBV 0.93 ± 0.21 cm². Mean pre and post-MVA (Gorlin) were 0.90 ± 0.20 and 2.02 ± 0.37 cm², respectively (p<0.001). There were successful (MVA ≥1.5 cm²) in 241 (94.1%) procedures. Mean pulmonary artery pressure pre and post-MBV were 27 ± 10 and 20 ± 7 mmHg, respectively. Three (1.2%) patients began the FU with severe mitral regurgitation (SMR). At the end of FU 119 (46.5%) patients were in NYHA funcional class (FC), I I, 70 (27.3%) in FC II, 53 (20.7%) in FC III, 3 (1.2%) in FC IV and there were 11 (4,3%) deaths. At the end of the FU there were: 17 (8.2%) patients with SMR; 20 (4.7%) were submitted to a new MBV; 27 (10.5%) to mitral valve surgery and 70 (26.3%) without any medicine. Independent predictors of survival were: ES ≤8 points (p<0.001, HR0.116, 95% IC 0.035-0.384), age ≤50 years old (p=0.011, HR 0.203, 95% IC 0.059-0.693) and absence of mitral valve surgery in the FU (p=0.004, HR 0.170, 95% IC 0.050-0.571). Independents of EFS were: absence of prior commissurotomy (p<0.002, HR 0.318, 95% IC 0.151-0.667), female gender (p=0.036, HR 0.466, 95% IC 0.229-0.951) and MVA post-MBV ≥1.50 cm² (p<0.001, HR 0.466, 95% IC 4.884-28.457).

Conclusions: It was observed 94% of procedure success (MVA \ge 1.5 cm²). At the end of follow-up (25 years) 4,3% of mortality. The independent predictors of survival were: ES \le 8 points, age \le 50 years old and absence of mitral valve surgery in the FU. Independent predictors of EFS were: absence of prior commissurotomy, female gender and MVA post-MBV \ge 1.50 cm².



Euro14A-0P310

Transesophageal echocardiographic evaluation of atrial septal defect after percutaneous transvenous mitral commissurotomy

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Aims: Rheumatic fever and rheumatic heart disease continue to be the major health problem in all developing countries including Bangladesh. Iatrogenic atrial septal defects during percutaneous transvenous mitral commissurotomy (PTMC) are usually of no clinical consequence. We aimed to evaluate atrial septal defect after PTMC.

Methods and results: A prospective study was done in NICVD, Dhaka, during the period of August 2005 to May 2010. Two hundred thirty five (235) patients with rheumatic mitral stenosis who underwent PTMC were evaluated by transthoracic (TTE) and transesophageal echocardiography (TOE) with color doppler before and within 48 hours after procedure. Most of the population are female (79%). Post PTMC TOE demonstrated ASD in 128 (54.46%) of 235 patients. But only 73 (31.1%) of these defects were detected by TTE. The mean di ameter of the interatrial septal defect detected by TOE was 3.89±1.3 mm. The most common site of septal puncture was the inferior vena caval side of the interatrial septum followed by fossa ovalis. We examined the relationship of different variables including the duration of the procedure from atrial septal puncture to balloon inflation between both groups and found that none of these factors except the duration of the procedure from atrial septal puncture to balloon inflation predicted the development of ASD.

Conclusions: ASD shunt in these patients was clinically insignificant and data suggest that residual ASD may depend on the duration of the procedure.

Interventions for structural heart disease

Euro14A-0P311

Acute reduction of the mitral valve diameters impact on functional outcomes after interventional edge-to-edge repair of mitral regurgitation with the MitraClip system

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Aims: To assess the immediate effect of transcatheter mitral valve repair (TMVR) with the MitraClip system (MC) on mitral valve annular (MV) geometry with 3D transesophageal echocardiography (TOE) and to evaluate the impact of MV diameter reduction on clinical outcomes after 6 months.

Methods and results: 111 consecutive patients (age 78.3 ± 8.1 years) at high risk for surgical mitral valve surgery (logistic EuroSCORE $29.8\pm21.5\%$) underwent TMVR with the MC. The procedure was completed successfully in 107 patients (96%) under 3D TOE guidance with reconstruction of MV annular geometry immediately before and after clip implantation. Concerning the underlying MV disease, only patients with FMR (n=71) experienced an acute reduction of anterior-posterior-MV diameters (4.0 ± 0.6 cm- 3.6 ± 0.6 cm, p<0.0001), MV annulus areas (2D- annulus area: 13.9 ± 3.8 cm² - 12.9 ± 3.4 cm², p<0.0001; 3D annulus area: 14.4 ± 0.5 cm²- 12.9 ± 3.4 cm², p<0.0001) and changes in MV annular geometry (MV sphericity- index: 0.94 ± 0.1 - 0.82 ± 0.1 , p<0.0001); the lateral-medial-MV diameters remained unchanged after MC (4.3 ± 0.7 cm- 4.4 ± 0.6 cm, p=0.13). In subjects with DMR all MV annular geometry-defining parameters were not relevantly altered after TMVR (n=36, p>0.05). Acute AP-diameter reduction was significantly associated with the clinical response to TMVR after 6 months of FU (cut-off value $\ge6.4\%$, AUC=0.81, p=0.002; sensitivity=81.6%, specificity=81.8%), which was confirmed by logistic regression analysis (hazard ratio [HR] 6.3, confidence interval 0.59-0.79, p=0.0106).

Conclusions: 3D TOE enables the assessment of acute changes of MV annular geometry in patients undergoing interventional edge-to-edge-repair with the MC system. Only patients with functional MR experienced a significant reduction of MV annular dimensions, which was independently associated with clinical response to TMVR.



Euro14A-0P312

Stratification of priority among candidates to percutaneous mitral repair with the Mitraclip system according to their risk of mortality

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Aims: Percutaneous mitral valve repair with the Mitraclip system is an alternative to surgical correction of mitral regurgitation (MR) in inoperable or high-risk patients. The advanced cardiac heart failure (CHF) status of this population often results a high mortality within one-year when medical treatment alone is employed. Mitraclip therapy may interrupt the negative evolution of the disease, however, the access to Mitraclip therapy is still restricted in most centres. Objective: To determine the rationale in candidates to Mitraclip based on early mortality predictors.

Methods and results: Single-centre study including 86 patients derived from cardiac imaging department/outpatient clinic to CHF consultation as potential candidates for Mitraclip. All baseline characteristics were prospectively recorded at the time of first evaluation and all patients were later on followed by same experts in CHF. Until December 2013, 9 patients were excluded due to clinical (2) or imaging criteria (7) and 14 patients underwent Mitraclip implantation. The rest (63 patients) were considered the pool of good candidates for Mitraclip and constituted our study population. Mean age was 71±10 years and 47 patients (75%) were males. Main baseline characteristics included: Congestive heart failure in 63 patients (100%), previous surgical revascularisation in 4 patients (6.3%), and percutaneous revascularisation in 27 (42.9%), chronic pulmonary disease in 9 patients (14.3%), and 2-3 NYHA functional class in 41 patients (65.1%). MR was of moderate degree in 27 patients (42.9) and severe in 36 (57.1%). The etiology was mainly functional in 34 patients (54.0%) and degenerative in 29 patients (46.0%). Twenty patients (31.7%) died due to cardiac causes within the first year of inclusion in the pool of candidates to Mitraclip. Main predictors of mortality included: Female gender (50% vs. 19.1%, p=0.024); non-revascularizable coronary artery disease (45% vs. 19.3%, p=0.050); severe MR (30.9% vs. 0%, p=0.095), NYHA class 4 requiring inclusion in list of trasplant (80% vs. 22.4%, p=0.016); and higher pulmonary pressure (52±6 vs. 46±14, p=0.034), specially if under pulmonary vasodilator drugs (75% vs. 23.7%, p=0.057). Independent predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality included female gender (males' OR=0.241 [95% or personal predictors of mortality includ CI:0.059-0.980], p=0.047) and severe pulmonary hypertension (>45 mmHg) with OR=6.091 [95% CI:1.371-27.058], p=0.018. Comparatively, at a mean follow-up of almost one-year, only one of the patients treated with Mitraclip died several months after the implantation (mortality rate of 7.1% vs. 31.7% in the other group, p=0.096). No differences were found in terms of risk between patients who underwent Mitraclip implantation (LogEuroSCORE=24.5±16.4%) and the rest of candidates (19.8±12.7%, p=0.239).

Conclusions: Between candidates for Mitraclip, females and patients with severe pulmonary hypertension (specially if requiring pulmonary vasodilators), presented higher risk of mortality within the first year after initial evaluation for Mitraclip. Therefore, if other therapies have been dismissed, Mitraclip should be promptly performed in this subgroup.

Percutaneous versus surgical repair for degenerative mitral regurgitation in octogenarians

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Aims: To compare the results of MitraClip and surgical mitral valve repair in octogenarian patients with isolated degenerative mitral regurgitation (DMR).

Methods and results: From October 2008 to June 2013, 40 octogenarians underwent isolated mitral repair for DMR at our Institution using MitraClip or standard surgery. A retrospective comparison was conducted. Patients with associated tricuspid regurgitation >2+ were excluded. MitraClip was performed in 18 (45.0%) and surgery in 22 (55.0%) cases. At baseline, MitraClip patients were older (84.9±3.5 vs. 81.8±1.7 years, p=0.0003) and more symptomatic (NYHA class >II in 72% vs. 40% of patients, p=0.04). MitraClip patients were also affected by a heavier burden of comorbidities: median STS mortality 9.1 vs. 5.7, p=0.02; mean creatinine 1.25±0.3 vs. 0.9±0.3 mg/dL, p=0.01; chronic obstructive pulmonary disease 33% vs. 9% (p=0.04). No statistically significant difference was observed regarding EDD, EF and sPAP (all p>0.05). The mitral valve prolapsing target lesion was posterior in 72% vs. 77.3%, anterior in 22.2% vs. 4.5% and bileaflet in 5.6% vs. 18.2% of MitraClip and surgical patients respectively (p=0.15). Two MitraClip and 4 surgical patients had mitral annular calcifications (p=0.53). MitraClip was successful in all but 1 early patient whereas surgery was successfully conducted using standard leaflet techniques and annular ring implantation in all cases. One singlein-hospital death occurred in the MitraClip group (p=0.3). Major postoperative complications were less frequent for MitraClip as compared with surgery: low cardiac output syndrome 5.5% vs. 36.4% (p=0.02), acute kidney disease 16.7% vs. 45.5% (p=0.04), need for transfusions 11.1% vs. 40.9% (p=0.03). Median length of stay was 4 vs. 8 days (p=0.001) and home-discharge was 94.1% vs. 0% (p<0.0001) respectively. No acute residual MR>2 was observed in either group, although MR≤1+ was present in 61.1% of MitraClip vs. 100% of surgical patients (p=0.0003). Median follow-up was 1.6 (interquartile range 0.6-2.1) vs. 2.8 (interquartile range 1.4-3.8) years for MitraClip and surgery respectively (p=0.002). At last clinical follow-up, NYHA was still >2 in 11.7% in MitraClip (p=0.0006) and 5.3% of surgical (p=0.01) patients, although similar between the groups (p=0.4). No differences were observed in the Minnesota Living with Heart Failure, SF-36 physical and the SF-36 mental questionnaries between MitraClip and surgery (all p>0.05). No statistically significant difference was observed regarding EDD, EF and sPAP (all p>0.05). Actuarial 1.5 years survival for MitraClip and surgery was 94.4% vs. 100% (p=0.06), whereas actuarial freedom from MR>2 was 83% vs. 100% respectively (p=0.1).

Conclusions: In octagenarians undergoing mitral valve repair for DMR, those treated with MitraClip are older, have more comorbidities, and higher surgical risk scores. Despite this, MitraClip patients have less periprocedural complications and are discharged home sooner than surgical patients. MitraClip and surgery appeared also clinically equivalent at short term follow-up, although surgery more effectively reduces MR grade.



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Predictors of permanent pacemaker implantation after TAVI: a meta-analysis

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Aims: Several patient and procedure related characteristics have been evaluated and proposed as potential predictors of permanent pacemaker (PPM) implantation after transcatheter aortic valve implantation (TAVI); however, the available evidence is sparse and inconsistent, mainly derived from small studies. Therefore, we aimed to provide summary effect estimates for clinically useful risk predictors.

Methods and results: We performed a systematic search for studies of original design reporting the incidence of PPM implantation after TAVI. We deemed eligible any study that provided quantitative raw data that enabled the calculation of crude risk ratios for each predictor of interest. When overlapping populations (according to participating institution(s) and recruitment period) were documented in different reports, we included the one with the most recent results and available data of interest. Patients with prior PPM were excluded from the analysis. For our purpose, we focused on previously proposed and clinically meaningful predictors, which could be plausibly related to the intervention owing to direct injury to the aortic root. Data on study design, patients, and procedural characteristics were abstracted. Crude risk ratios (RR) and 95% confidence intervals (CI) were obtained for each predictor and combined by using random effects models, while stratified analyses by the type of valve was also performed. Heterogeneity across the studies was quantified with I² index. Data were obtained from 41 studies including 11,210 TAVI patients of whom 1,917 (17%) required PPM implantation after intervention. Studies were mainly performed in Europe (93%) and published between 2009-2013; while patients' recruitment occurred between 2005-2011. The self-expandable Medtronic CoreValve Revalving System (MCRS) and the Edwards Sapine Valve (ESV) were equally used; and the valve implantation was performed via femoral (73%), apical (23%), or other route (4%) (aortic or subclavian access). The rate of PPM ranged from 2% to 51% in individual studies (with a median of 28% for MCRS (interquartile range, 24% to 35%) and 6% for ESV (5% to 7%)). Fourteen predictors of interest were identified, while two or more non-overlapping datasets were available for 11 of them. The summary estimate indicated increased risk of PPM after TAVI for men (RR 1.23, 95% CI 1.10-1.38); for patients with first degree AV block (RR 1.52, 95% CI 1.15-2.01), left anterior hemiblock (RR 1.62, 95% CI 1.17-2.25), or RBBB (RR 2.89, 95% CI 2.36-3.54) at baseline and for patients with intraprocedural AV block (RR 3.49,95% CI 2.49-4.89) (p-value < 0.01 for all estimates). There was no significant heterogeneity for any of the above predictors and the I² point estimate was 0% to 44%. The aforementioned variables remained significant predictors when only patients treated with the MCRS were considered; conversely, the data for ESV were limited. Unadjusted estimate indicated a 2.5-fold higher risk of PPM for patients who received MCRS compared to ESV.

Conclusions: Conduction disturbances at baseline and intraprocedural AV block emerged as predictors of PPM implantation after TAVI in high-risk patients receiving one of the two most widely used bioprostheses. Given the clinical and economic impact of such interventions, clinicians should appropriately stratify patients. This study provides useful tools to help clinicians to identify high-risk patients and to guide clinical decision-making before and after TAVI.



Predictors of permanent pacemaker implantation after TAVI

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Aims: High-grade conduction disturbances requiring permanent pacemaker (PPM) implantation occur in up to 34% of patients following transcatheter aortic valve implantation (TAVI). The aim of this study was to asses the anatomical and electrocardiographical (ECG) predictors of postoperative permanent pacemaker (PPM) implantation in patients undergoing the Medtronic CoreValve (MCV) implantation

Methods and results: From July 2010 until June 2012 in total 198 inoperable patients or patients with high surgical risk underwent transfemoral TAVI using the CoreValve Revalving system (26/29/31 mm). Patients (23) with pre-existing pacemaker or bifascicular block were excluded from the study leaving 175 patients for retrospectively evaluation for preoperative clinical, electrocardiographic, anatomical, and procedural predictors for PPM implantation after TAVI. To evaluate procedural data, device position was measured on fluoroscopy as distance between the proximal aspect of the CoreValve stent frame below the native aortic annulus. Optimal high device position was defined on fluoroscopy as final position of the proximal aspect of the MCV stent frame 8-16 mm between the native aortic annulus. We analysed 175 patients (mean age 79.8±0.65 years, log Euroscore 24.2±0.81%, mean pressure gradient 44.2±1.04 mmHg, AVA 0.65±0.01 cm², left ventricular ejection fraction 50.6±0.8%). A total of 42 (24%) patients underwent PPM-implantation post TAVI during the same hospital admission. Before TAVI 19 (10.9%) of patient showed preoperative abnormal conduction abnormalities, including first degree AV block, right (RBBB) and left bundle branch block (LBBB). Patients with PPM implantation showed a significant longer pre-procedural PQ interval versus patients without PPM-implantation (201.3±8.9 ms versus 175.7±4.3 ms, p=0.04). Pre-existing LBBB seems not to be associated with permanent PM implantation because in our PPM group there was was no patient with a pre-existing LBBB (PMM group versus no-PMM group: 0 versus 9.8%; p=0.026). Pre existing RBBB showed a slightly enhanced trend in the PPM group but did not reach statistical significance (16.7% versus 5.2%; p=0.05). The depth of the device implantation showed also no significant difference between patients with and patients without PPM (12.2±0.38 mm versus 11.6±0.21 mm; p=0.177), only the incidence of post-interventional new left bundle-branch block was associated with a deeper implantation of the prosthesis: LBBB group versus non-LBBB group: 12.05±0.307 mm versus 11.15±0.316 mm; p=0.05. The overall rate of new post procedural LBBB) was 38,9%. In a multivariate logistic regression analysis for predictors of post-interventional PPM implantation analysis for prediction of post TAVI including pre-PQ time, pre-existing LBBB, pre-existing RBBB, pre existing atrial fibrillation and depth of implantation, only pre-PQ time interval turned as independent predictor for PMM implantation.

Conclusions: Only a prolonged pre-PQ time interval turned out as independent predictor for PMM implantation after TAVI. The implantation depth of the CoreValve system does not predict the need for PMM implantation, but is associated with a new-onset LBBB after TAVI with the MCV.



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Prognostic significance and predictors of left bundle branch block after transcatheter aortic valve implantation. Single centre follow-up results of 1,000 patients

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Aims: Transcatheter aortic valve implantation (TAVI) is a gold-standard for inoperable patients with severe aortic stenosis and has progressive importance in high-risk patients. Compared to surgical aortic valve replacement, the risk of conduction disorders is higher and affects primarily the left ventricular function (left bundle branch block-LBBB) as well as the atrioventricular conduction (AV-Block). The aim of the following analysis is to assess the prognostic significance and the risk factors of a new LBBB in patients who underwent TAVI.

Methods and results: Single centre study of 1000 TAVI-patients treated with Edwards SAPIEN (ESV) (N=467) or Medtronic CoreValve (MCV) (N=96) by an interdisciplinary heart-team (enrolment period 05/2008 until 04/2012). Patients with a prior pacemaker or QRS complex >120 ms (n=298; 29.8%) were excluded from this analysis. In 139 (13.9%) patients a new permanent pacemaker implantation was necessary. The remaining 563 patients were evaluated for LBBB and were divided in two groups. Survival in the first year was compared. New LBBB was manifested in 167 (29.66%) patients. Age (81.92 vs. 82.27 years; p=0.48), EF (59.15% vs. 59.0%; p=0.90), mean log EuroSCORE (21.1 vs. 23.22; p=0.15) and risk factors were comparable in both groups. The mean survival in the patients without LBBB was 343±3.69 days (mean±SD), 95% CI336-351 days and in the group with new LBBB 316±8.58 days, 95% CI; 300-334 days, Log-rank p=0.004. The Hazard Ratio (HR) was 1.81, 95% CI; 1.20-2.7, p=0.004). A new-onset LBBB has a higher incidence with the MCV than with the ESV (HR 2.02, 95% CI; 1.28-3.18, p=0.003).

Conclusions: A new-onset LBBB after TAVI is associated with higher mortality in the first year. The incidence of a new LBBB is higher with the MCV.

Rhythm changes and pacemaker incidence associated with a novel resheathable self-expanding TAVI system: a prospective multicentre analysis

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Aims: Self-expanding transcatheter aortic valve implantation (TAVI) valves have been associated with high rates of permanent pacemaker implantation when compared to balloon expandable TAVI valves. This report evaluates the incidence and associated circumstances of the rhythm disturbances observed with the St Jude Medical Portico Self Expanding TAVI system.

Methods and results: Rhythm information was collected as part of a prospective, single arm, multicentre study. Between March 2012 and September 2013, 93 TAVI patients were enrolled and treated at 6 sites in the UK and Germany using the 18F Portico system with either a 23 mm (50) or 25 mm valve (43). Native rhythms were collected with strips at baseline and at key steps during the implant procedure. Rhythms were gathered prior to wire passage through the valve, prior to pre-dilatation, immediately post-dilatation, prior to valve crossing, post valve deployment and at the end of the procedure. Strips were taken during recovery and at all follow-up intervals. The Portico TAVI system was successfully implanted in 93 patients with 10 receiving a permanent pacemaker (PPM) after TAVI implantation. One additional patient experienced sinus arrest with bradycardia leading to PPM implant at 1 year. At baseline, there was a higher presence of right bundle branch block (RBBB) in the pacemaker group. The most common rhythm disturbances were left bundle branch block (LBBB), RBBB, ventricular tachycardia (VT), and ectopic beats. Excluding those with only ectopic beats, there were 25 patients with rhythm disturbances during the procedure; 14 with LBBB, 2 with RBBB and 9 with VT. Fourteen of the 25 patients had the rhythm observed during wire placement or after balloon valvuloplasty. Of those receiving a PPM, one patient had Mobitz II heart block pre-procedure. Four patients with intra-operative rhythm disturbances had heart block leading to PPM observed during the procedure. All four patients were free of rhythm disturbances during wire placement and valvuloplasty. Five additional patients received PPM prior to discharge unrelated to intra-operative rhythm, caused by sinus arrest (1), sick sinus (1) or heart block (3) prior to discharge. Implant depth showed a trend towards pacemaker implant, but depth of implant was not statistically significant between those who did and did not receive a pacemaker after TAVI valve implantatio

Conclusions: The Portico TAVI system demonstrated a low rate of PPM implantation. There does not appear to be a consistent cause intraoperatively and further analysis is necessary to understand this phenomenon.



Euro14A-0P318

Trends in the occurrence of new left bundle branch block after TAVI

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Aims: The aim of the study was to investigate the changes in occurrence of new left bundle branch block after transcatheter aortic valve implantation (TAVI) in both the Medtronic CoreValve System and Edwards SAPIEN Valve over time.

Methods and results: Electrocardiograms at multiple time points in 476 patients without pre-procedural left bundle branch block and/or pacemaker were assessed to determine the frequency of new left bundle branch block and the transient or permanent nature. To study the effect of experience, patients were subdivided per participating centre into equal tertiles based on the number of procedures. Univariate and multivariate logistic regression was used to study the independent predictors of permanent left bundle branch block after TAVI. Left bundle branch block occurred in 175 patients (36.8%) and was transient in 64 (36.6%) and persistent in 111(63.4%) patients. The frequency significantly decreased over time; from 47.2% in cohort 1 to 28.5% in cohort 3 (p=0.002). This effect was dependent on the valve type implanted and was only significant after implantation with the Medtronic CoreValve System (68.3% versus. 53.2% versus. 35.5%, p<0.001). The same holds for the depth of implantation (Medtronic CoreValve System (in millimetres): 10.6 [3.4–17.8] versus. 8.0 [5.1–11.0] versus. 6.9 [4.4–9.5], p<0.001 – Edwards SAPIEN Valve (in millimeters): 4.1 [2.4–5.9] versus. 3.3 [2.0–4.6] versus. 2.2 [0.1–4.3], p=0.21). Multivariate analysis stratified for valve type revealed that cohort was the only significant predictor of permanent left bundle branch block in patients undergoing TAVI with the Medtronic CoreValve System (Odds Ratio [95% confidence interval] 0.12 [0.02-0.58], p=0.009).

Conclusions: Over time the frequency of left bundle branch block after TAVI decreased significantly. This effect was mainly seen in patients undergoing TAVI with the Medtronic CoreValve System in parallel to a reduction in the depth of implantation. Patients with Edwards SAPIEN Valve had significantly less left bundle branch block of which its frequency showed a trend of further reduction over time.



The impact of TAVI related permanent pacemaker implantation on the German healthcare system

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Aims: The need for permanent pacemaker implantation (PPI) following transcatheter aortic valve implantation (TAVI) appears to be strongly influenced by the design of the percutaneous valve. The economic impact of TAVI related PPI on health care systems has, however, not been fully elucidated. We addressed this question to estimate the impact for the German healthcare system.

Methods and results: Data from published literature were used to obtain TAVI frequency, incidence of PPI after TAVI and the incidence and type of additional complications associated with PPI. A simple decision tree model was constructed to project incidence of PPI and associated complications. Since the data on other recent devices are still limited, we restricted this analysis to those TAVI systems which are currently predominantly used: the Edwards Sapien XT (EW) and the Medtronic Corevalve (MDT). In 2012 about 7,500 TAVI procedures were performed in Germany. The expected TAVI-related PPI rates were 7.6% (EW) and 25.7% (MDT), resulting in 314 (EW) and 867 (MDT) PPIs. Using published data on mortality and complication rates associated with TAVI-related PPI, we estimated additional 103 complications necessitating hospital admission for EW and 285 for MDT patients. Thus, the estimated annual incidence of complications due to PPI for EW and MDT is 2.50% and 8.45%, respectively. The resulting total cost to the healthcare system, if conservatively estimated, is €2.2 (EW) and £6.2 (MDT) million per year. **Conclusions:** PPI following TAVI not only has significant impact on patient's health and well being but confers significant additional costs. Our model shows a significant cost impact of TAVI-related PPI on the German healthcare system which should be considered when assessing overall cost implications of TAVI.



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Long-term clinical outcomes after TAVI in patients with severe aortic stenosis and low pressure gradient from the SOURCE XT registry

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Aims: Low gradient in severe aortic stenosis is often associated with worse outcomes following surgical aortic valve replacement. However, little information is available on the impact of low gradient on outcomes following TAVI, as this treatment is not studied and indicated in this patient population. We sought to evaluate the clinical impact of TAVI in patients with low gradient severe aortic stenosis (LG-AS), who are at high operative risk for surgical valve replacement.

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post approval study, which consecutively enrolled 2,688 patients at 99 sites in 17 countries. A total of 782 patients (29.1%) were presented with LG-AS (<40 mmHg) and the remaining 1,721 patients with pressure gradient ≥40 mmHg served as Controls. A total of 185 patients with missing echocardiographic assessment of the transvalvular pressure gradient were excluded from this analysis. All patients were treated with the Edwards SAPIEN XT valve (Edwards Lifesciences, LLC). Two-year follow-up had been completed and preliminary data were analysed. Final data will be available by the time of the PCR. Compared to the Controls, patients in the LG-AS group were more likely to be male (49.7% vs. 38.8%, p<0.0001), were younger (80.7±6.7 years vs. 81.8±6.5 years, p<0.0001), and had a higher Logistic EuroSCORE (22.8±13.8% vs. 19.4±11.5%, p<0.0001). LG-AS patients had significantly higher incidence of congestive heart failure, coronary artery disease including history of myocardial infarction, PCI or CABG, as well as atrial fibrillation, and renal insufficiency. Compared to the Controls, patients with LG-AS had a significantly lower mean gradient (30.4±6.2 mmHg vs. 55.5±13.0 mmHg, p<0.0001); larger effective orifice area (0.8±0.2 cm² vs. 0.6±0.2 cm², p<0.0001), and significantly lower left ventricle ejection fraction (49.8±14.2% vs. 56.7±11.0%, p<0.0001). At 30-day follow-up, there were no significant differences between the LG-AS patients and the Controls in terms of all-cause mortality (7.2% vs. 5.8%, p=0.1851), stroke (4.5% vs. 3.4%, 0.1979), major vascular complications (5.5% vs. 7.1%, p=0.1350), major or life-threatening bleedings (14.5% vs. 15.6%, p=0.4075) and new pacemaker implantations (9.4% vs. 9.6%, p=0.8714); however, cardiac mortality was significantly higher for the LG-AS group (4.3% vs. 2.4%, p=0.0099). At 1 year, all-cause mortality was significantly higher for the LG-AS group (26.6% vs. 16.2%, p<0.0001) and so was the cardiac mortality (15.0% vs. 7.0%, p<0.0001). At 2 year, both all cause-mortality (33.6% vs. 23.0%, p<0.0001) and cardiac mortality (16.4% vs. 9.4%, p<0.0001) remained higher in the LG-AS group.

Conclusions: Approximately 1/3 of patients with severe aortic stenosis undergoing TAVI have a transvalvular pressure gradient <40 mmHg. Low gradient in severe aortic stenosis, as assessed by valve area, is associated with worse long term survival even after treatment, and represents a more advanced state of aortic stenosis. These data suggest that an earlier TAVI procedure rather than deferred treatment needs to be considered for LG-AS patients and warrant further study.

Paradoxical low-flow, low-gradient aortic stenosis is a good option for TAVI

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Aims: Previous studies showed that the paradoxical low-flow, low-gradient (PLFLG) aortic stenosis (AS) is a highly challenging condition in terms of diagnostics and therapy. Moreover, this subgroup demonstrates an increased all-cause mortality if treated medically compared to surgically treated patients. The aim of this study was to investigate the clinical outcome and mortality in patients with PLFLG AS after transcatheter aortic valve implantation (TAVI).

Methods and results: 580 consecutive patients in high operative risk underwent TAVI with the Medtronic Corevalve (Medtronic, Minneapolis, MN, USA) or Edwards Sapien (Edwards Lifesience, Irvine, CA, USA) prostheses at our institutionbetween June 2008 and October 2012. Full data of 469 patients was collected. Of these, 258 patients presented with normal-flow, high gradient (NFHG) AS (aortic surface area (ASA) <1.0 cm², mean gradient (ΔPmean) >30 mmHg, left ventricular ejection fraction (LVEF) >50%) and 39 patients with PLFLG AS (ASA <1.0 cm², ΔPmean <30 mmHg, LVEF >50%, stroke volume index (SVI) <35 ml/m²). Clinical follow-up, echocardiography and measurements of NT-pro-BNP levels were analysed at 10 days, 4 weeks, 6 month and 1 year after TAVI. Patients with PLFLG AS had a similar survival at 12 month after TAVI compared to patients with NFHG AS (85% vs. 86%, p=0.771). The LVEF decreased slightly but significant after 4 weeks (before 60.2±1.7% vs. 4 weeks 57.7±5.3%, p=0.049), but remained stable after 6 month (57.8±5.0%) and 1 year (57.0±5.6%). Furthermore, patients with PLFLG AS showed slightly high values of NT-proBNP at baseline but a similar reduction over time (PLFLG: before 3860±2960 ng/L vs. 1 year 2264±1810 ng/L, p=0.079) in conjunction to reduced symptoms of heart failure. NYHA functional capacity improved similar between both groups (PLFLG vs. NFHG: Δ4 weeks: -1±0.6 vs. -1.3±0.7; p=n.s.; Δ6 month: -0.8±0.6 vs. -1.3±0.8; p=n.s.; Δ12 month: -1.3±0.9 vs. -1.2±0.7; p=n.s.).

Conclusions: This study shows that patients with PLFLG AS have a similar benefit after TAVI as patients with NFHG AS and should no longer be withheld from TAVI procedures.



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Impact of reduced left ventricular ejection fraction on mid-term mortality after transcatheter aortic valve implantation

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Aims: Whether patients with reduced left ventricular function present worse outcome after transcatheter aortic valve implantation (TAVI) is controversial. The aim of this study was assess the impact of baseline severe impairment of left ventricular function on mortality after TAVI. Methods and results: Six-hundred-forty-nine patients with aortic stenosis underwent TAVI with the CoreValve system (92.8%) or the Edwards SAPIEN valve system (7.2%). Patients were classified as those with baseline left ventricular ejection fraction (LVEF) ≤30% (N=63) and those with LVEF >30% (N=586). Cox regression analysis with calculation of hazard ratio (HR) with 95% confidence interval (CI) was performed to assess the impact of LVEF ≤30% on mortality. Patients with LVEF ≤30%, as compared to those with LVEF >30%, had a higher prevalence of previous myocardial infarction (33.3% vs. 13.9%, p<0.001), of NHYA class >2 (93.6% vs. 73.8%, p<0.001) and presented with higher Euroscore (median 37 vs. 19.5, p<0.001). Procedural success was similar in patients with LVEF <30% as compared to those with LVEF >30% (98.4% vs. 97.2%, p=1). After a median follow-up of 436 days, all-cause mortality (23.8% vs. 23.7%, logrank p=0.87, HR 0.96, 95% CI 0.56-1.63) and cardiac mortality (19.1% vs. 17.6%, logrank p=0.89, HR 1.04, 95% CI 0.57-1.90) were similar in patients with LVEF ≤30% as compared to those with LVEF >30%. At 30 days no significant difference in all-cause mortality was found between the two groups (11.1% in patients with LVEF \le 30\% vs. 6.3\% in patients with LVEF >30%, logrank p=0.14, HR 1.81, 95% CI 0.81-4.06). The risk of 30-day cardiac mortality tended to be higher in patients with LVEF ≤30% as compared to those with LVEF >30% (11.1% vs. 5.3%, logrank p=0.06, HR 2.16, 95% CI 0.95-4.90, simple cox regression). However after multivariable adjustment, LVEF ≤30% was not associated with 30-day cardiac mortality (HR 1.82, 95% CI 0.70-4.71, p=0.22). Conclusions: Baseline severe impairment of left ventricular function is not a predictor of increased short-term and mid-term mortality after TAVI. Selected patients with severe impairment of left ventricular function should not be denied TAVI.

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Long-term clinical 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 very low EF.

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post-approval study, which enrolled >2,688 consecutive patients at 99 sites in 17 countries. A total of 274 patients (mean age 80.7±6.3 years), were identified with low EF≤35% (LowEF group), and 2,262 patients (mean age 81.4±6.6 years) with EF>35% served as Controls. Patients with missing assessment of EF were excluded from this analysis. All patients were treated with the SAPIEN XT valve. Two-year follow-up had been completed and preliminary data were analysed. Final data will be available by the time of the PCR. Compared to the controls, LowEF patients were more likely to be male (65.3% vs. 40.1%, p<0.0001), had more severe symptoms (NYHA III/IV; 87.6% vs. 76.0%, p<0.0001) and a greater Logistic EuroSCORE (31.1±15.3% vs. 19.2±11.4%, p<0.0001). Low EF patients had significantly higher incidence of congestive heart failure, previous myocardial infarction (MI), previous CABG, moderate or severe mitral regurgitation or pulmonary hypertension. Effective orifice area was similar for LowEF and Controls (0.6±0.2 cm² vs. 0.7±0.2 cm², p=0.1181); however, mean gradient was significantly lower (37.1±14.0 mmHg vs. 48.9±15.9 mmHg, p<0.0001) and pulmonary pressure was significantly higher (50.8±14.5 mmHg vs. 44.2±14.8 mmHg, p<0.0001) in the LowEF group. At 30-day follow-up, overall mortality (9.9% vs. 5.6%, p=0.0055), cardiac death (7.5% vs. 2.5%, p<0.0001) were significantly higher in the LowEF group as compared to the Controls. There were no significant differences between the two groups in terms of stroke (3.8% vs. 3.5%, p=0.8067), major vascular complications (6.3% vs. 6.2%, p=0.9797), major/ life-threatening bleeding (12.6% vs. 15.0%, p=0.2962) or new permanent pacemaker implantations (9.3% vs. 9.3%, p=0.9784). All-cause mortality remained significantly higher for the LowEF group at 1 year (28.6% vs. 18.2%, p<0.0001) and two-year follow-up (33.2% vs. 25.3%, p=0.0070) and so did the cardiac mortality (17.9% vs. 8.5%, p<0.0001 at 1 year and 19.7% vs. 10.6%, p<0.0001 at two-year follow-up). Among patients with LowEF at baseline, 30 day cardiac mortality was significantly different between the subset with early EF improvement ≥5% and those without improvement (11.8% vs. 1.4%, p=0.0006) and this difference remained significant at 1 year (20.5% vs. 11.5%, p=0.0414) and two-year follow-up (24.7%% vs. 12.8%, p=0.0295).

Conclusions: Low EF in patients undergoing TAVI was associated with significant co-morbidity at baseline and increased mortality over the two-year follow-up. Specifically patients with low EF at baseline, which did not improve early after TAVI, are at increased risk of death.



Euro14A-0P325

Impact of left ventricular mass index on the outcome of transcatheter aortic valve implantation

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Aims: More severe left ventricle (LV) concentric remodeling or hypertrophy has been linked to increased risk of cardiovascular events, increased operative and late mortality after aortic valve replacement in patients with severe aortic stenosis. However, whether the degree of left ventricle hypertrophy impacts the outcome after transcatheter aortic valve implantation (TAVI) has not been thoroughly evaluated. We sought to assess the relation of left ventricle hypertrophy with outcomes following TAVI.

Methods and results: In a retrospective analysis of the prospectively maintained registry, we divided 353 consecutive patients into 2 groups according to the degree of left ventricle hypertrophy which we used left ventricular mass index (LVMI) as a parameter. We compared patients with LVMI ?140 (n=179) to those with LVMI >140 (n=174). Baseline characteristics, procedural and outcome variables were compared. Patients with higher LVMI had a smaller body surface area (BSA) (1.67±0.17 m² vs. 1.73±0.21 m², p=0.02). Patients with higher LVMI had lower ejection fractions (48.9±11.8%vs. 54.7±9.6%, p<0.001) and larger LV chamber size (left ventricle end diastolic volume (LVEDV) 112.6±44.5 ml vs. 90.2±31.6 ml, left ventricle end systolic volume (LVESV) 59.7±35.0 ml vs. 41.8±22.1 ml, p<0.001 respectively). Otherwise baseline characteristics were similar. The device success rate according to the Valve Academic Research Consortium (VARC)-2 criteria was comparable between the two groups (94.4%vs. 93.1%, p=0.626). The 30-day all-cause and cardiovascular mortality were comparable between the two groups, however, one-year rehospitalisation rate for heart failure, all-cause and cardiovascular mortality were significantly higher for patients with higher LVMI group (rehospitalisation 18.2% vs. 7.1%, p=0.015, all-cause 21.2% vs. 10.0%, p=0.008, cardiovascular mortality 12.3% vs. 5.3%, p=0.034). Kaplan-Meier survival curves at one-year follow-up demonstrated the one-year survival rate significantly lower in highter LVMI group (log-rank: 0.017) Multivariate logistic regression analysis showed LVMI >140 to be an independent predictor of death at one-year (OR 2.5, 95% CI 1.1–6.4, p=0.046).

Conclusions: Compared with patients undergoing TAVI with lower LVMI, those with higher LVMI >140 had worse one-year outcome and rehospitalisation rate. Advanced LV hypertrophic patients undergoing TAVI should be carefully managed.

Clinical outcomes of patients with low-flow, low-gradient severe aortic stenosis according to treatment modality

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Aims: We aimed to compare clinical outcomes among patients presenting with "classical" low-flow, low-gradient severe aortic stenosis according to the assigned treatment modality.

Methods and results: Between April 2005 and December 2012, 210 patients with low-flow, low-gradient severe AS (indexed aortic valve area [AVA] \le 0.6 cm².m⁻², left ventricular ejection fraction [LVEF] <50% and mean gradient (MG) <40 mmHg) underwent treatment allocation to either medical therapy (MT) (n=47) surgical aortic valve replacement (SAVR) (n=52) or transcatheter aortic valve implantation (TAVI) (n=111). Preprocedural non-invasive and invasive haemodynamic indices, coronary artery disease (CAD) complexity and procedural characteristics were compared between groups. Primary end-point was all-cause mortality at one-year. Baseline characteristics were similar between patients allocated to MT and TAVI, whereas SAVR patients were younger (MT 82.47±5.03 vs. SAVR 78.43±54.10 vs. TAVI 82.04±5.08 years, p<0.0001) and lower risk (STS score MT 10.82±7.25 vs. SAVR 4.85±2.95 vs. TAVI 7.88±4.80%, p<0.001). CAD complexity was significantly greater among MT patients (SYNTAX score MT 29.18±17.89 vs. SAVR 20.38±12.54 vs. TAVI 21.58±14.09, p=0.036). Pre-procedural AVA (MT 0.69±022, SAVR 0.73±0.23, TAVI 0.74±0.21 cm², p=0.40) and MG (MT 25.23±9.33 vs. SAVR 29.26±9.54 vs. TAVI 28.54±10.30 mmHg, p=0.09) were similar between groups, but patients undergoing SAVR had a higher baseline LVEF (MT 30.28±9.72 vs. SAVR 38.90±11.94 vs. TAVI 34.35±11.32%, p=0.001) and lower prevalence of moderate/severe mitral regurgitation (MT 52.3% vs. SAVR 30.0% vs. TAVI 52.8%, p=0.02). SAVR patients also had lower pulmonary artery systolic pressures (MT: 59.71±15.29 vs. SAVR 50.63±16.15 vs. TAVI 58.17±14.72 mmHg, p=0.023) on pre-procedural right heart catheterisation. Contractile reserve was present in 68.8% of patients undergoing dobutamine stress echocardiography. At 12-months, the primary endpoint was significantly lower among both SAVR (13.5% vs. 57.4%, HR 0.17, 95% confidence interval [CI] 0.076-0.40, p<0.001) and TAVI (20.7% vs. 57.4%, HR 0.28, 95% CI 0.16-0.49, p<0.001) as compared with MT patients. No significant differences in the primary endpoint were observed between SAVR and TAVI patients (p=0.27).

Conclusions: Among patients with low-flow, low-gradient severe AS, SAVR and TAVI improved survival compared with MT. Clinical outcomes of TAVI and SAVR appeared similar among appropriately selected patients with low-flow, low-gradient severe AS.



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Aortic valve-in-valve implantation inside stented versus stentless bioprostheses: insights from the Global Valve-in-Valve registry

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Aims: Transcatheter aortic valve-in-valve (VinV) implantation inside failed bioprostheses is increasingly being performed. Stentless surgical valves lack fluoroscopic markers and may pose unique challenges during the procedure. We aimed to evaluate clinical outcomes following aortic VinV procedures in stentless bioprostheses, using a large global registry.

Methods and results: Aortic VinV procedures included in the Global Valve-in-Valve Registry were investigated (553 procedures: 441 in stented bioprostheses, 112 stentless). Patients with failed stentless bioprostheses were younger and had similar STS score in comparison with those with failed stented bioprostheses (73.4±13.9 vs. 78.6±8, p<0.001; 10.7±8.3 vs. 12.1±10.6, p=0.20, respectively). Stentless bioprostheses failed more commonly with isolated regurgitation (58.9% vs. 21.8% in stented, p<0.001) and had lower degree of stenosis in comparison with stented: valve area 1.28±0.62 cm² vs. 0.88±0.43, mean gradient 48±28.6 mmHg vs. 64.7±26.8, respectively; p<0.001 for both). Stentless bioprostheses were more commonly treated by a CoreValve device (65.1% vs. 34.7% SAPIEN, p<0.001). Device malposition was more common in procedures performed in stentless and Mosaic stented valves (16.1%, 14.0% vs. 9.0% in non-Mosaic stented valves, p=0.03). Coronary occlusion was more common in stentless bioprostheses (5.4% vs. 1.4% in stented, respectively, p=0.01). Post procedural mean aortic valve gradient was lower post stentless VinV procedures (11.7±7.2 vs. 16.9±9.1 in stented, p<0.001). Thirty-day and one-year mortality rates were similar, when comparing patients undergoing VinV procedures for stented and stentless aortic bioprostheses: 8.9% vs.6.6% (p=0.39), 17.9% vs. 16.6% (p=0.68), respectively.

Conclusions: Aortic VinV implantation inside stentless bioprosthesis is challenging and associated with more device malposition and coronary occlusion events. Nevertheless, VinV procedures performed in stentless bioprostheses resulted better valve haemodynamics than in stented surgical valves and patient survival was similar.

Transcatheter aortic valve-in-valve implantation for failing surgical aortic bioprosthetic valves; short- and long-term outcome

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Aims: Conventional redo cardiac surgery for failing aortic valve replacement (AVR) is associated with high mortality and morbidity rates in elderly patients, particularly those with comorbidities. Transcatheter aortic valve implantation (TAVI) is a less invasive and potentially lower-risk therapeutic option. Our centre has an historical record of performing surgical homograft aortic valve replacement, and according to the most recently published global v-i-v series, approximately 16% of worldwide v-i-v procedures for stentless AVR has been performed at our centre. We therefore sought to assess the outcome of v-i-v procedures, particularly in failing stentless AVR, performed at our institution.

Methods and results: A total of 27 v-i-v procedures for failing AVR have been performed at our centre. All were included in this study. From the total of 27 patients, 18 had a failing stentless AVR (of which 15 patient had a failing homograft) and 9 had a failing stented AVR. Overall mean age was 73±14 years and logistic Euroscore was 38±10%. Thirteen patients had calcification of the ascending aorta, 10 patients had patent coronary bypass grafts, 9 had renal impairment stage III, 9 had undergone previous PCI, 3 had severe pulmonary disease (TLCO <30%), 2 had previous stroke, and 1 had abnormal platelet function. Original implant dates ranged from 1981 to 2008. Twenty patients were in NYHA Class III and 7 patients were NYHA Class IV. One patient had significant in-valve aortic stenosis (presure drop 88 mmHg), and the remaining had at least moderate-severe aortic regurgitation (AR). Mean left ventricular ejection fraction was 54±18%. All patients recieved a v-i-v CoreValve; 20 patients received a 26 mm device, 2 a 23 mm device, 3 a 29 mm device, and 2 a 31 mm device. Access route was transfemoral in 23 patients, subclavian in 3, and direct aortic in 1. Device implantation was successful in all cases. Peak aortic pressure drop post-procedure was 24±14 mmHg, and AR was reported as absent in 9 patients, mild in 15 cases, and mild-moderate in 3 cases. There was no intra-procedural death, no peri-procedural myocardial infarction, and no patient converted to cardiac surgery. Within 30 days of the procedure, only 1 patient died (a 34 year old man with multi-organ failure in whom TAVI had been performed as a salvage case 24 hours after cardiac arrest). This patient's death increased the 30-day mortlaity from 0.0% to 3.7%. Based on VARC-II definitions, the rate of major stroke was 0.0%, acute kidney injury 0.0%, and of pacemaker implantation 26%. Device embolisation was 0.0%. Average length of hospital stay was 15±11 days, all remaining patients were discharged home, and 25 patients were alive at long-term (range 3 to

Conclusions: Valve-in-valve TAVI may be performed in patients with high risk for conventional aortic redo surgery using a range of CoreValve size and a variety of access routes, with very low morbidity and mortality in both short- and long-term follow-up. Deployment of valve-in-valve TAVI was successful even in degenerative stentless AVR which lack fluroscopic landmarks, with no case of valve embolisation and with resolution of AR from severe to mild in the majority of cases. Valve-in-valve TAVI is therefore a safe and attractive alternative to conventional redo AVR when operative risks are deemed preventatively high, even in failing stentless AVR.



Euro14A-0P329

Transcatheter mitral valve-in-valve implantation in fourteen high risk patients: gradient, symptoms and functional status at up to 4 years

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Aims: The recourse to transcatheter mitral valve-in-valve is expected to rise consistently, due to the increasing use of bioprostheses, and to the risks related to redo mitral valve replacement. However, there is concern that the excellent early haemodynamic results of mitral valve-in-valve could be nullified by the development of significant transvalvular gradients. We describe our experience with transapical transcatheter mitral valve-in-valve in fourteen consecutive high risk patients, with particular emphasis on the gradient, symptoms and functional status at up to four years postoperatively. Methods and results: Fourteen patients underwent mitral valve-in-valve at our institution. The mean STS score was 10.1. All patients were heavily symptomatic. The mechanism of bioprosthesis failure was stenosis (3) regurgitation (2) or mixed (9). The mean transprosthetic gradient was 13.5±3.6 mmHg. All the procedures were transapical, and balloon predilatation was never used. Two patients underwent concomitant paravalvular leak occlusion. In the first patient the transcatheter valve splayed the prosthesis struts and embolised in the ventricle. The patient died two days later for multi-organ failure. There were no other hospital deaths. Two patients died for pneumonia and endocarditis at 1 and 8 months. The mean gradient at discharge was 4.4±1.4. At follow-up (median 376 days), all patients were alive and well in NYHA class ≤2. The mean transprosthetic gradient was 6.4±2.2 and 2 patients had a gradient >10 mmHg. In both these patients, the valve had been significantly oversized compared to the surgical bioprosthesis. A non-enhanced, ECG-gated control CT scan was performed in 9 out of 11 survived patients during the follow-up period, to analyse the spatial relationships between the surgical prosthesis and the transcatheter valve, and to examine the final geometry of the latter. In most patients, the valve was not perfectly cylindrical after deployment: in 5 patients it had the shape of a truncated cone with the base on the ventricular side, in 4 patients it was hourglass-shaped, and in 2 it was asymmetrically flattened on one side. This latter appearance was particularly pronounced in one of the patients that developed a high gradient at follow-up.

Conclusions: Mitral valve-in-valve represents a safe and effective alternative to conventional surgery, especially for elderly patients with multiple comorbidities. Limited data exist, however, on the intermediate and long-term results of this procedure. In particular, there is concern that the incomplete expansion of the transcatheter valve, due to the constraint exerted by the rigid surgical prosthesis' sewing ring, could result in poor valve function, high gradients and early structural deterioration. Our data indicate that excessive oversizing and asymmetric expansion of the transcatheter valve could be associated with the development of high gradients during follow-up period. Further studies are needed to confirm this finding.

Valve-in-valve implantation for failed bioprosthetic valves: experience of a single-centre

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Aims: It is well known that currently implanted bioprosthetic heart valves are prone to degenerate with time. Repeat cardiac surgery to replace these valves is associated with significant morbidity and mortality. In this setting, transcatheter valve-in-valve implantation represents an emerging treatment option for high-risk patients with failing bioprostheses.

Methods and results: From March 2010 to December 2013, twenty-four high-risk patients underwent to valve-in valve procedures in our Centre. The procedures were performed in fourteen patients in mitral position through a transapical approach, eight in aortic position through transapical (N=3) or transfemoral (N=5) approach, one patient in a pulmonary bioprosthesis through transfemoral vein approach and one in tricuspid position through transjugular approach. All patients received Edwards Sapien XT Valve. Overall thirty-day mortality was 10% with a predicted Euroscore of 30.9%. Mean age was 76.2 years and thirteen patients were female. Implantation was successful in 95,8% of cases. One patient (mitral valve in valve) died the day after the procedure because the device embolised in the left ventricular outflow tract after the deployment. We had no periprocedural stroke cases and two patients had an acute kidney injury that required haemodyalisis. At a median follow-up of ten months, nineteen patients are alive (79%). One patient died one month after the procedure for pneumonia and one patient after eight months for endocarditis. One patient died after one year for ischaemic stroke and one after two years for non cardiac disease.

Conclusions: With growing need for reoperative valve replacement in elderly patients with high surgical risk, transcatheter valve-in-valve implantation is an acceptable option for the management of bioprosthetic valve failure.



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Is TAVI the solution for patient-prosthesis mismatch?

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Aims: Patient-prosthesis mismatch has been reported in up to 70% of patients after aortic valve replacement and may be associated with unfavourable haemodynamics and increased morbidity and mortality. Stent valves used for transcatheter aortic valve implantation (TAVI) do not require a sewing ring and therefore have a larger effective aortic valve area. The aim of this study was to determine the incidence and haemodynamic significance of patient-prosthesis mismatch after TAVI.

Methods and results: We studied 98 consecutive patients (82±6 y, 40 males) who had TAVI for native valve aortic stenosis (CoreValve 76, Sapien XT 22) and had transthoracic echocardiography before and after TAVI. Aortic valve area was determined using the continuity equation. Patient-prosthesis mismatch was defined as aortic valve area index ≤0.85 cm²/m² and severe patient-prosthesis mismatch as aortic valve area index ≤0.65 cm²/m². Pre TAVI aortic valve area was 0.76±0.14 cm² and aortic valve area index 0.43±0.08 cm²/m², increasing to 2.1±0.46 cm² and 1.2±0.29 cm² /m² after TAVI. Post TAVI peak aortic gradient was 16±6 mmHg. Patient-prosthesis mismatch occurred in 16 patients (16%), 2 (2%) of which had severe Patient-prosthesis mismatch. Peak aortic gradient in the patients with patient-prosthesis mismatch was only 20±6 mmHg (range 12-32 mmHg), compared to 15±6 mmHg in those without patient-prosthesis mismatch (p=0.0006). Patient-prosthesis mismatch occurred in only 2/21 patients (10%) with a small left ventricular outflow tract (≤2.0 cm), and was no more frequent than in patients with a large left ventricular outflow tract (14/77 (18%), p=0.5). Patient-prosthesis mismatch was not related to valve type or size, age or gender. Peak aortic gradient after TAVI was similar in patients with small as compared to large left ventricular outflow tract (16±7 vs. 15±6 mmHg, p=0.7). Post TAVI aortic valve area index inversely correlated with weight (r=0.54) and body surface area (r=0.51).

Conclusions: Patient-prosthesis mismatch after TAVI, unlike post aortic valve replacement, is: 1) Uncommon and usually non-severe, even in patients with a small left ventricular outflow tract 2) Associated with low trans-aortic gradients.

Euro14A-0P332

Multicentre registry of TAVI for bicuspid aortic valve stenosis

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Aims: Bicuspid aortic valve (BAV) stenosis is considered a relative contraindication to TAVI. We evaluated the TAVI outcomes in patients with BAV stenosis in a multinational registry.

Methods and results: Clinical characteristics, procedural data and outcomes were analysed in all patients with BAV stenosis at 12 international high-volume TAVI centres. Outcomes were assessed according to the Valve Academic Research Consortium criteria. The BAV registry includes 141 patients undergoing TAVI for BAV stenosis (64.3%), regurgitation (0.7%), or mixed stenosis/regurgitation (34.3%). The mean age was 77.7±9.1 years, 66% were male, and the mean logistic EuroSCORE and STS mortality risk score were 14.6±10.6% and 4.9±3.4%, respectively. BAVs were classified as Type 0 (24.4%); Type 1 (65.6%); and Type 2 (4.6%). The Edwards SAPIEN (n=51) and Medtronic CoreValve (n=91) were both implanted. The implanted THV diameters were: 23 mm (7.0%), 26 mm (36.4%), 29 mm (42.7%), and 31 mm (14.0%). Major vascular complications were noted in 6.3%, device malposition in 6.3%, and 3.5% required implantation of a second THV during the index procedure. Overall procedural success was determined in 89.5% of patients. The mean post procedural transvalvular gradient was 11.5±9.8 mmHg and aortic regurgitation ≥grade 2 occurred in 28.3% of cases. At 30-day follow-up, all-cause mortality or stroke occurred in 7.7% and 1.4%, respectively. A VARC device safety endpoint occurred in 22.4% and VARC efficacy was adjudicated in 83.9%.

Conclusions: TAVI for BAV disease is both feasible and safe, though post-implantation aortic regurgitation ≥grade 2 occurs more frequently than reported with tricuspid aortic valve stenosis. Further follow-up is required to determine the clinical efficacy in these patients.



Euro14A-0P333

Long-term outcomes after TAVI in patients with severe aortic stenosis and coexisting moderate or severe mitral regurgitation

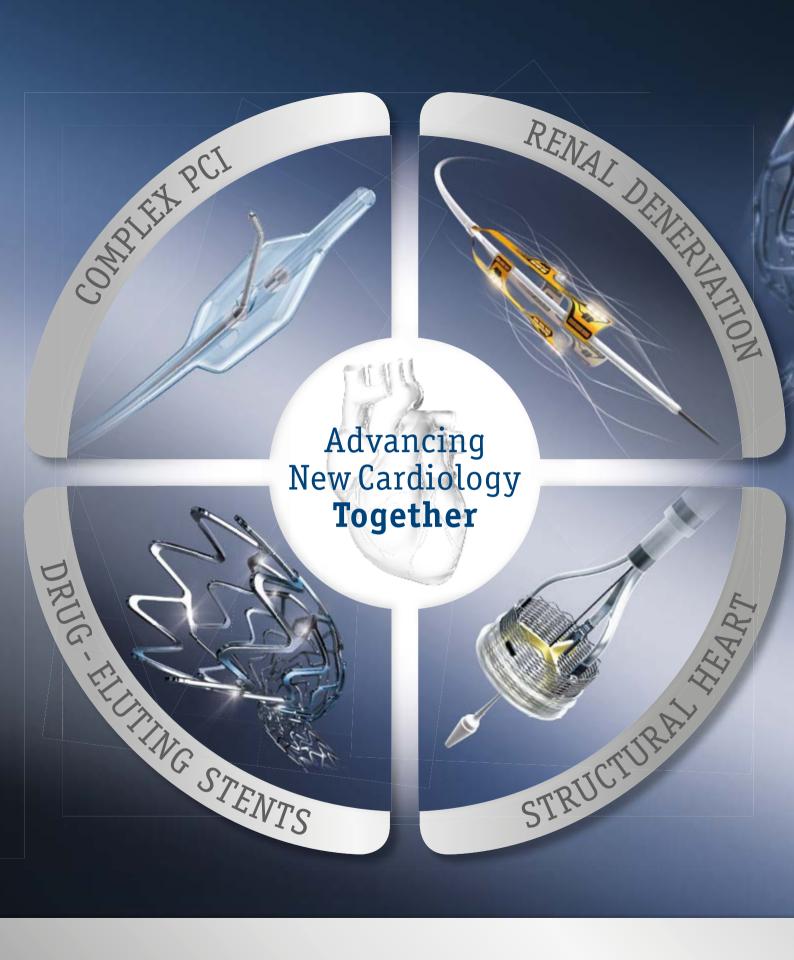
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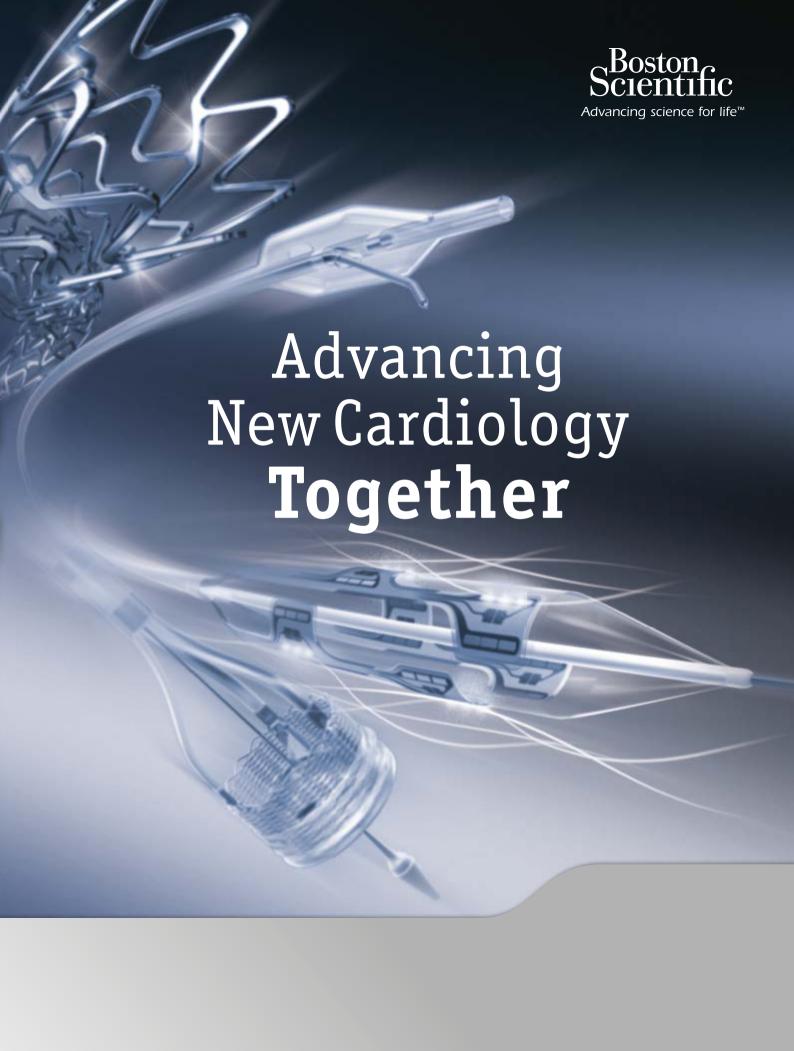
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Aims: Moderate and severe mitral regurgitation (MR) is associated with a higher mortality in patients with congestive heart failure (CHF) but little is known about its impact on outcomes in patients with severe aortic stenosis undergoing transcatheter aortic valve implantation (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 long term effect of MR on clinical outcomes after TAVI.

Methods and results: The SOURCE XT Registry is a multicentre, prospective, post approval study, which enrolled 2,688 consecutive patients at 99 sites in 17 countries. Patients with moderate or severe MR were included in the MR group (MR, n=519) and those with none or mild MR were included in the control group (Controls, n=2,096). Patients with missing assessment of MR at baseline were excluded. All patients were treated with the SAPIEN XT valve (Edwards Lifesciences, LLC). Two-year follow-up had been completed and preliminary data were analysed. Final data will be available by the time of the PCR meeting. Compared to the controls, patients in the MR group were more likely to be female (62.0% vs. 56.6%, p=0.0256), had more severe symptoms (NYHA class III/IV - 81.3% vs. 75.9%, p=0.0087) and a higher Logistic EuroSCORE (22.9±13.2% vs. 19.8±12.2%, p<0.0001). The prevalence of moderate or severe aortic regurgitation was 3 times higher in the MR group (32.3% vs. 11.5%, p<0.0001) and that of moderate or severe tricuspid regurgitation was 4.5 times higher (37.2% vs. 8.4%, p<0.0001). MR patients had a significantly higher incidence of CHF, atrial fibrillation, diabetes or renal insufficiency. Mean gradient was similar for the two groups (48.0±16.5 mmHg vs. 47.6±16.2 mmHg, p=0.6068); however ejection fraction was significantly lower (51.5±12.9% vs. 55.1±12.3%, p<0.0001) and pulmonary pressure was significantly higher (50.7±16.1 mmHg vs. 43.2±14.1 mmHg, p<0.0001) in the MR group vs. Controls. Following TAVI, MR improved by at least 1 degree in 65% of patients. At 30-day follow-up, there were no significant differences between the two groups in terms of all-cause mortality (7.0% vs. 5.9%, p=0.3557) and cardiac death (3.5% vs. 2.9%, p=0.4222). At one-year follow-up, all-cause mortality was significantly higher for the MR group as compared to the controls (23.1% vs. 18.4%, p=0.0161) and so was the cardiac mortality (12.4% vs. 8.7%, p=0.0111); however, the difference in all-cause mortality (28.9% vs. 25.7%, p=0.1476) and cardiac mortality (13.3% vs. 10.9%, p=0.1226) decreased at two-year followup. Importantly, patients with residual MR post TAVI had significantly higher mid-term (1 year: 22.4% vs. 14.2%, p=0.0002) and long-term mortality (2-year: 30.9% vs. 21.3%, p=0.0006) as compared to those with no residual MR.

Conclusions: Patients undergoing TAVI with severe aortic stenosis and coexisting moderate or severe MR have a worse risk profile than those with none or mild MR and an increased mid-term but not long-term mortality. Residual rather than baseline MR has a persistent adverse impact on survival over 2 years post TAVI. MR improvement after TAVI should be considered an additional clinical benefit of TAVI.





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