PCR webinars

How Should We Treat Low Risk Patients With Aortic Stenosis?

Sabine Bleiziffer

Nicolas Dumonteil

Thomas Modine

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Learning objectives

To review the design, results, and limitations of the low risk TAVI trials

To outline how the heart team should individualize treatment for low risk patients

To discuss which low risk patients should continue to be offered surgery

Case example

Mrs J.E. 79 years old,

Severe AS (0.45 cm2/m2, PMG 50 mmHg, LV EF 63 %)

NYHA 2 shortness of breath

Lives independantly at home with her husband

No cognitive impairment, no frailty

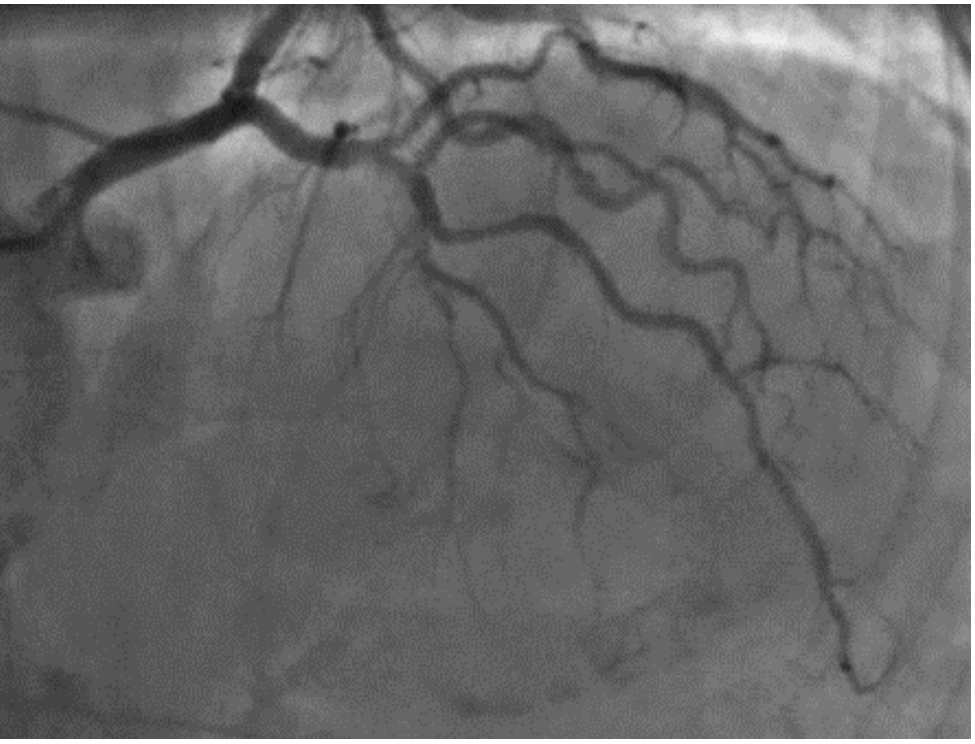
Past Medical History:

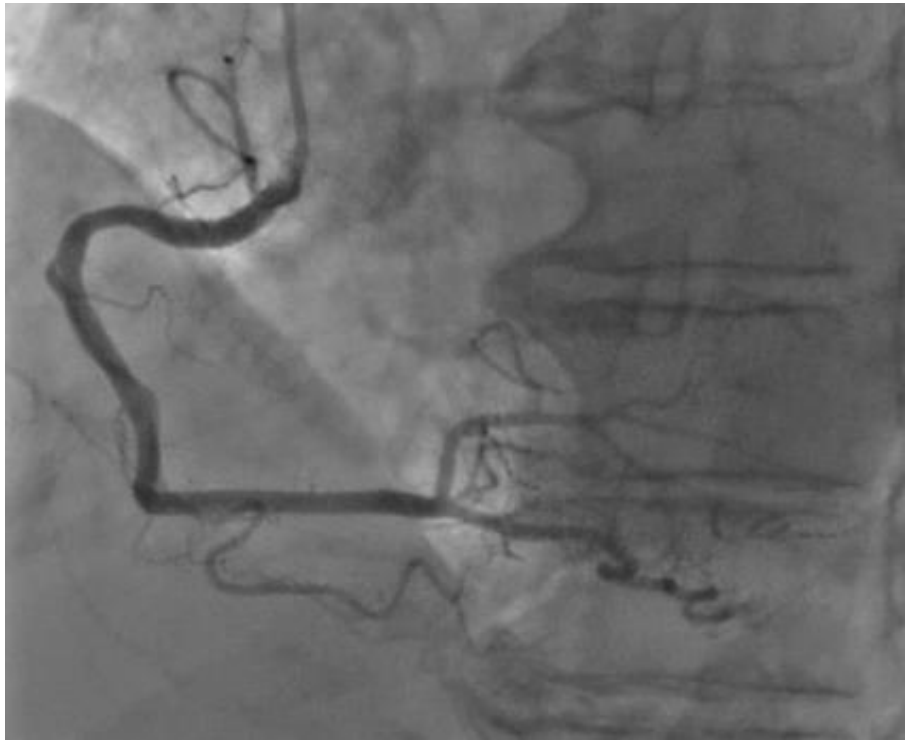
- Hypertension
- Arthrosis

Case example

PRE-OP ASSESSMENT:

- eGFR : 76 ml/min, Hb 12,7 g/dl





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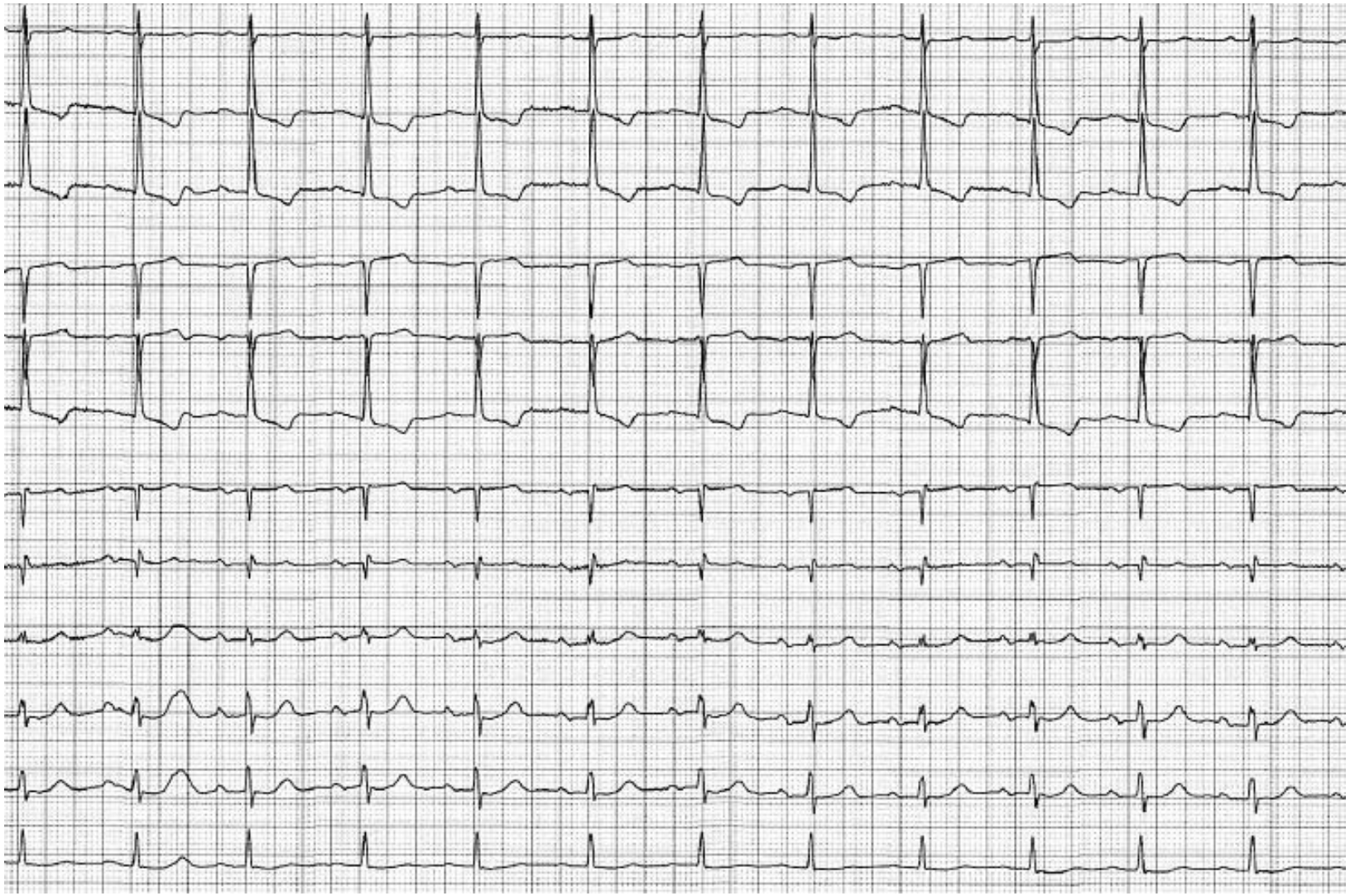
Case example



Case example

COMPREHENSIVE CT SCAN ASSESSMENT

22,8 mm area-derived ⦸
23,5 mm perimter-derived ⦸

Case example

COMPREHENSIVE CT SCAN ASSESSMENT

- Global evaluation of aortic root : No risk of coronary artery obstruction
- 3 leaflet aortic valve
- Moderate Ca++

FAVORABLE ANATOMY
FOR TRANSFEMORAL TAVI
WITH ANY COMMERCIALLY AVAILABLE DEVICE

AGE

vs

LIFE EXPECTANCY ?

Heart Team discussion

FRAILTY

ASSESSMENT ?

COMORBIDITIES ?

COMPREHENSIVE CT Scan assessment before any decision ?

SURGICAL RISK SCORES ?

Heart Team discussion

SUMMARY

Rather than surgical risk score assessment,

Focus on :

- life-expectancy / age balance
- comorbidities / frailty potentially impairing quality of life despite AS treatment
- anatomical assessment of TAVI procedural risk (CT Scan +++)

PCR webinars

CRITICAL REVIEW OF TAVI LOW RISK TRIALS

The New York Times

Tens of Thousands of Heart Patients May Not Need Open-Heart Surgery

Replacement of the aortic valve with a minimally invasive procedure called TAVR proved effective in younger, healthier patients.

SURGEON'S POINT OF VIEW

- Doubt
- Limitations
- Concerns

LIMITATIONS

AGE

SCREENING

CONCOMITANT PROCEDURES

Only 1.3 % of patients were less than 60 years old in the Evolut LR

Only 7% of patients were less than 65 years old in PARTNER 3

SCREENING PROCESS IN THE US

520/1,520 (34%) in the balloon-expandable trial were deemed inappropriate for TAVR

255/1,723 (14.8%) in the self-expanding valve trial were deemed inappropriate for TAVR

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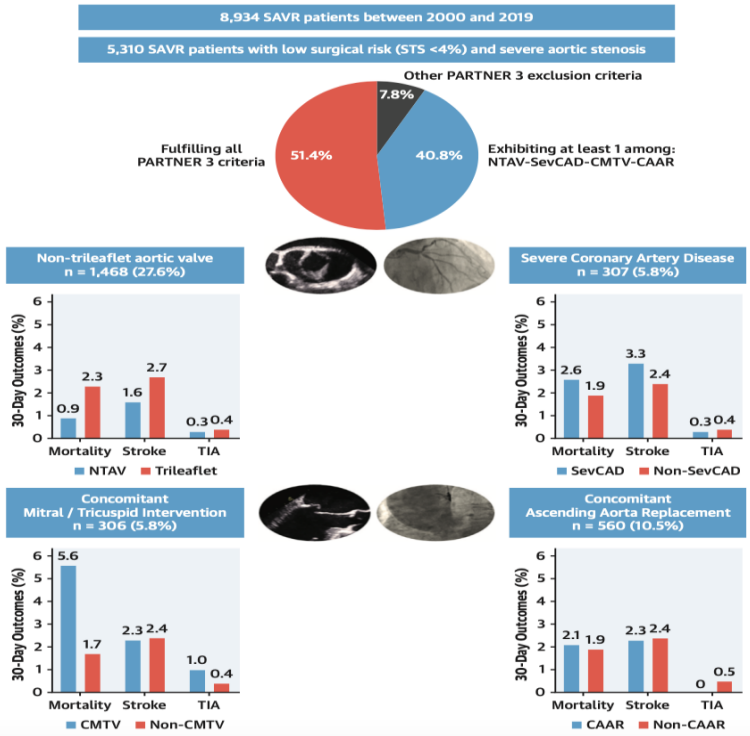
VOL. 77, NO. 2, 2021

ORIGINAL INVESTIGATIONS

Aortic Valve Replacement in Low-Risk Patients With Severe Aortic Stenosis Outside Randomized Trials

Alberto Alperi, MD, Pierre Voisine, MD, Dimitri Kalavrouziotis, MD, Eric Dumont, MD, François Dagenais, MD, Jean Perron, MD, Iria Silva, MD, Fernando Bernardi, MD, Siamak Mohammadi, MD, Josep Rodés-Cabau, MD, PhD

CENTRAL ILLUSTRATION Clinical Outcomes Following Surgical Aortic Valve Replacement in Low-Risk Patients Ineligible for Randomized Trials of Transcatheter Aortic Valve Replacement Versus Surgical Aortic Valve Replacement



Alperi, A. et al. J Am Coll Cardiol. 2021;77(2):111-23.

FIGURE 3 Kaplan-Meier Estimates for 30-Day Mortality

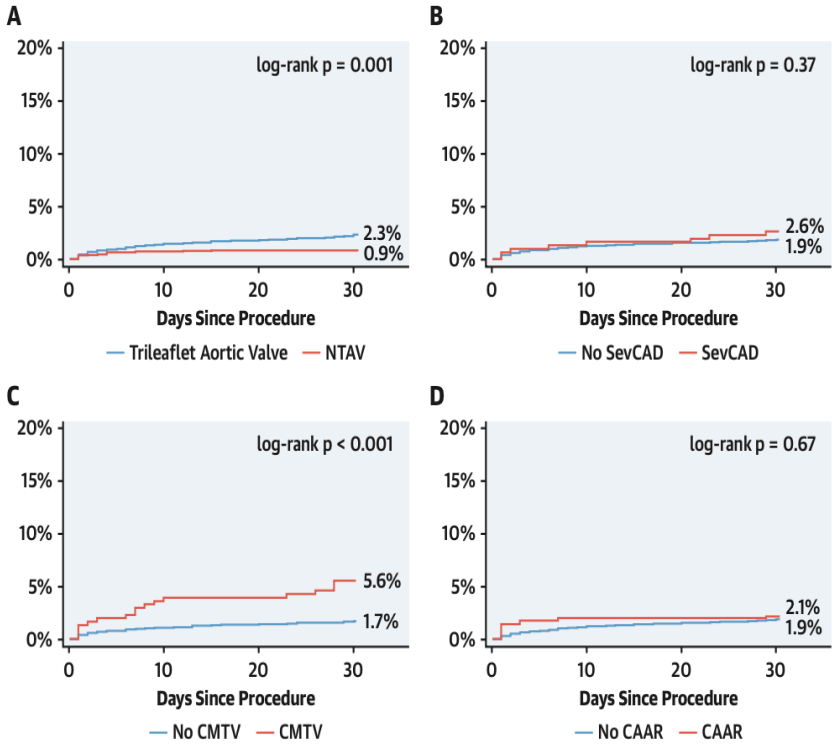


Table S2. Concomitant Procedures (TAVR & Surgery)

TAVR	n/N (%)
PCI*	32/496 (6.5)
Pacemaker or ICD	5/496 (1.0)
Other†	2/496 (0.4)

*includes stenting and balloon angioplasty
†includes 1 patient who was converted to surgery and received an aortic root enlargement

Surgery	n/N (%)
CABG	58/454 (12.8)
MAZE*	22/454 (4.8)
LAA ligation	43/454 (9.5)
Root enlargement	21/454 (4.6)
Ascending aorta replacement	1/454 (0.2)
Aortic endarterectomy	4/454 (0.9)
Septal myomectomy	4/454 (0.9)
MVR (replacement or repair)	6/454 (1.3)
TVR (replacement or repair)	4/454 (0.9)
Other	1/454 (0.2)

*includes MAZE, Extended L atrial maze, Extended L + R atrial maze, Pulmonary vein isolation

8%

CONCOMITANT PROCEDURES
PARTNER3

35%

Concomitant Surgical Procedures	Surgery (N=678)
Number of Index Procedures	678
None – no. (%)	500 (73.7)
Aortic root enlargement – no. (%)	11 (1.6)
Coronary artery bypass grafting– no. (%)	92 (13.6)
Permanent pacemaker implantation – no. (%)	0 (0.0)
Surgical treatment of atrial fibrillation – no. (%)	24 (3.5)
Automatic cardioverter defibrillator implantation – no. (%)	0 (0.0)
Left atrial appendage closure – no. (%)	42 (6.2)
Patent foramen ovale closure – no. (%)	5 (0.7)
Mitral valve repair – no. (%)	4 (0.6)
Mitral valve replacement – no. (%)	0 (0.0)
Other – no. (%)	34 (5.0)

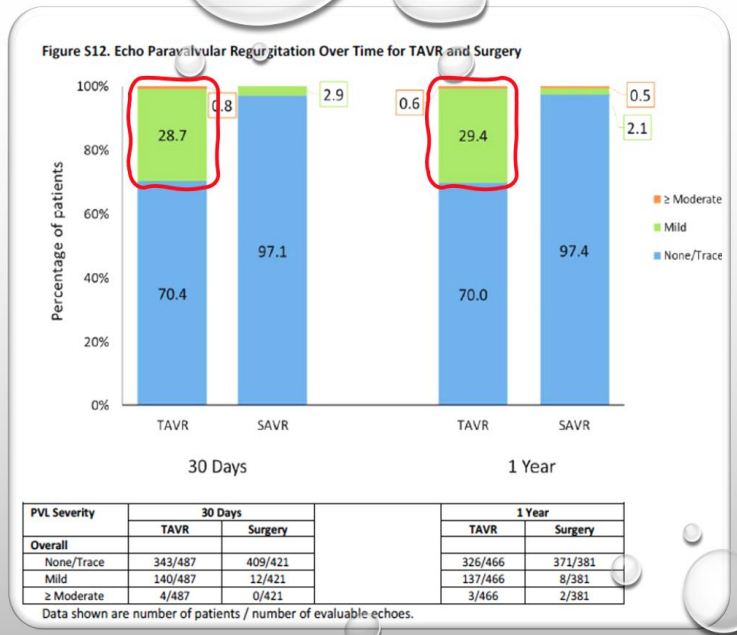
Patients may have had more than one concomitant procedure.

CONCOMITANT PROCEDURES
EVOLUT LR

7% Vs 26%

CONCERNS

- Paravalvular leak
- Pacemaker
- Patient-prothesis mismatch
- Subclinical valve thrombosis
- Bicuspid aortic valve
- And long-term durability



PVL Severity	30 Days		1 Year	
	TAVR	Surgery	TAVR	Surgery
Overall				
None/Trace	343/487	409/421	326/466	371/381
Mild	140/487	12/421	137/466	8/381
≥ Moderate	4/487	0/421	3/466	2/381

Data shown are number of patients / number of evaluable echoes.

PVL
PARTNER3

Paravalvular leak	N=703	N=608		N=407	N=326		N=70	N=61	
None – no. (%)	146 (20.8)	544 (89.5)	(-71.9, -64.2)	168 (41.3)	299 (91.7)	(-55.2, 43.8)	39 (55.7)	59 (96.7)	(-50.5, -24.2)
Trace – no. (%)	280 (39.8)	44 (7.2)	(28.2, 36.5)	86 (21.1)	17 (5.2)	(11.1, 20.4)	9 (12.9)	1 (1.6)	(2.0, 19.4)
Mild – no. (%)	253 (36.0)	18 (3.0)	(29.0, 36.6)	138 (33.9)	8 (2.5)	(26.2, 35.9)	18 (25.7)	1 (1.6)	(12.1, 33.3)
Moderate – no. (%)	22 (3.1)	1 (0.2)	(1.6, 4.4)	14 (3.4)	2 (0.6)	(0.7, 4.9)	4 (5.7)	0 (0.0)	(-0.7, 12.1)
Severe – no. (%)	2 (0.3)	1 (0.2)	(-0.6, 0.8)	1 (0.2)	0 (0.0)	(-0.8, 1.1)	0 (0.0)	0 (0.0)	(-4.6, 3.9)

PVL
EVOLUT LR

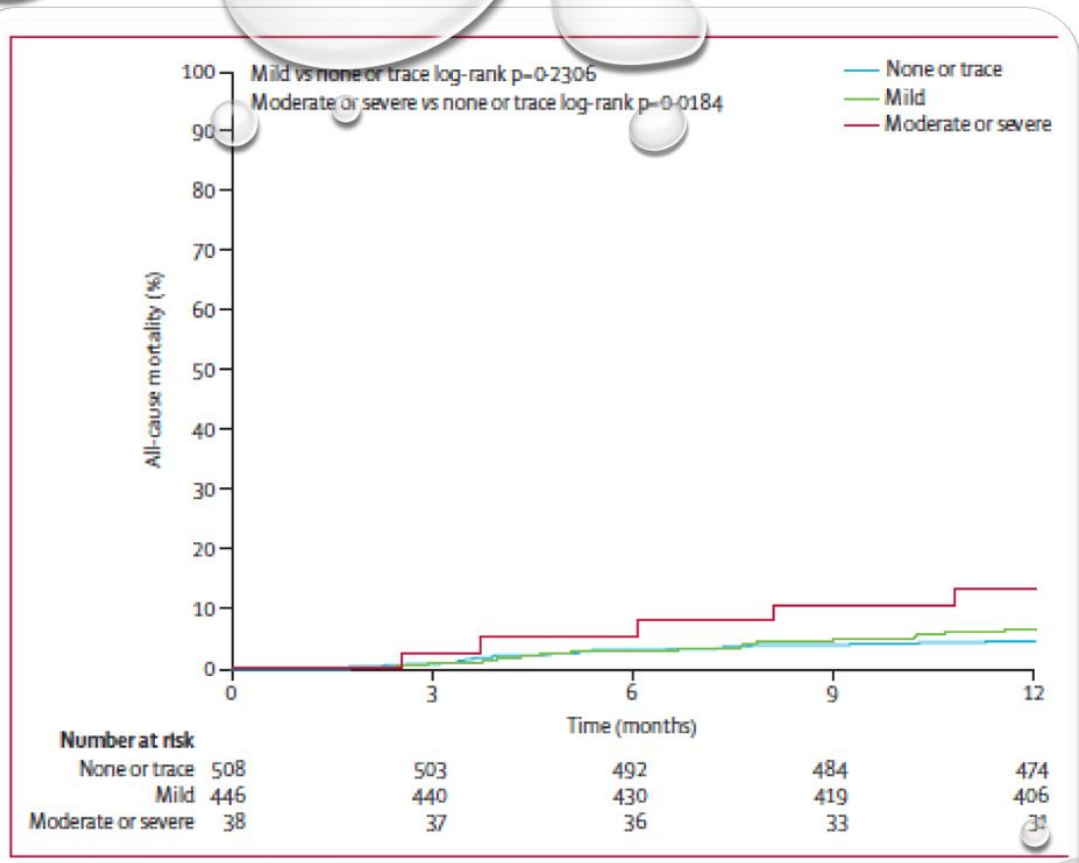


Figure 2: All-cause mortality stratified by severity of paravalvular aortic regurgitation after transcatheter aortic valve replacement

Patients were classified into groups based on their 30 day echocardiogram (or discharge echocardiogram if 30 day was not available).

IMPACT PVL ON MORTALITY

PARTNER 2A

PACEMAKER
PARTNER3

New permanent pacemaker	6.5% (32)	4.0% (18)	1.66 [0.93, 2.96]	7.3% (36)	5.4% (24)	1.39 [0.83, 2.33]
New permanent pacemaker (Baseline pacemaker excluded)	6.6% (32)	4.1% (18)	1.65 [0.92, 2.95]	7.5% (36)	5.5% (24)	1.38 [0.82, 2.32]
New LBBB	22.0% (106)	8.0% (35)	3.17 [2.13, 4.72]	23.7% (114)	8.0% (35)	3.43 [2.32, 5.08]

PACEMAKER
EVOLUT LR

Table 2. Clinical End Points at 30 Days and at 12 Months.*

End Point	30 Days			12 Months		
	TAVR	Surgery	Difference, TAVR–Surgery (95% BCI)	TAVR	Surgery	Difference, TAVR–Surgery (95% BCI)
	% of patients		*percentage points*	*% of patients*		*percentage points*
Permanent pacemaker implantation	17.4	6.1	11.3 (8.0 to 14.7)	19.4	6.7	12.6 (9.2 to 16.2)

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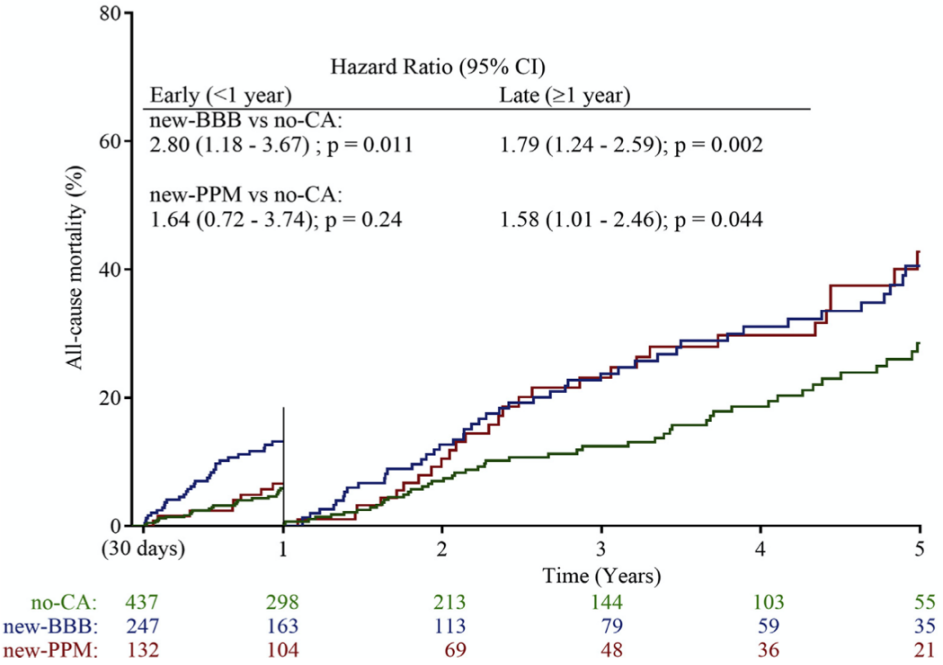
Mortality and Heart Failure Hospitalization in Patients With Conduction Abnormalities After Transcatheter Aortic Valve Replacement

Troels H. Jørgensen, MD,[a] Ole De Backer, MD, PhD,[a] Thomas A. Gerds, DrRerNat,[b] Gintautas Bieliauskas, MD,[a] Jesper H. Svendsen, MD, DMSc,[a,c] Lars Søndergaard, MD, DMSc[a,c]

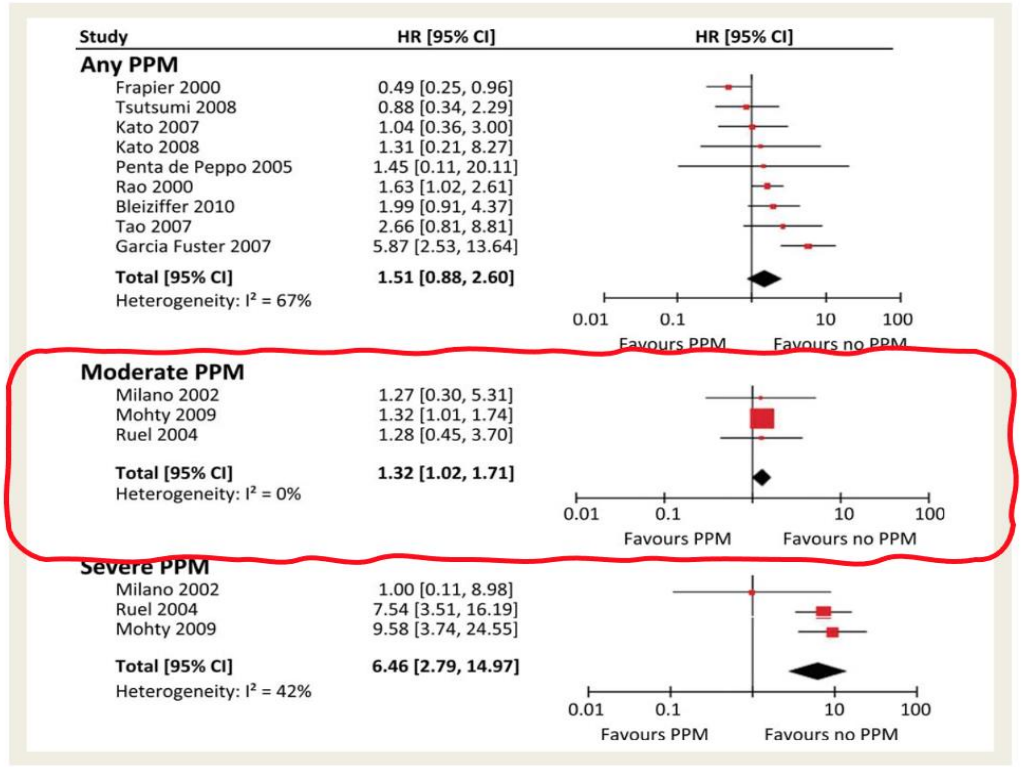


European Heart Journal (2012) **33**, 1518–1529
doi:10.1093/eurheartj/ehs003

CLINICAL RESEARCH
Cardiac surgery

The impact of prosthesis–patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years

Stuart J. Head[1]*, Mostafa M. Mokhles[1], Ruben L.J. Osnabrugge[1,2], Philippe Pibarot[3], Michael J. Mack[4], Johanna J.M. Takkenberg[1], Ad J.J.C. Bogers[1], and Arie Pieter Kappetein[1]



JACC: CARDIOVASCULAR INTERVENTIONS VOL. 12,
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Temporal Trends and Outcomes of Transcatheter Versus Surgical Aortic Valve Replacement for Bicuspid Aortic Valve Stenosis

Ayman Elbadawi, MD,[a,b] Marwan Saad, MD, PhD,[b,c] Islam Y. Elgendy, MD,[d] Kirolos Barssoum, MD,[e] Mohamed A. Omer, MD,[f] Ahmed Soliman, MD,[g] Mohamed F. Almahmoud, MD,[a] Gbolahan O. Ogunbayo, Amgad Mentias, MD,[i] Syed Gilani, MD,[a] Hani Jneid, MD,[j] Herbert D. Aronow, MD, MPH,[c] Neil Kleiman, M J. Dawn Abbott, MD[c]

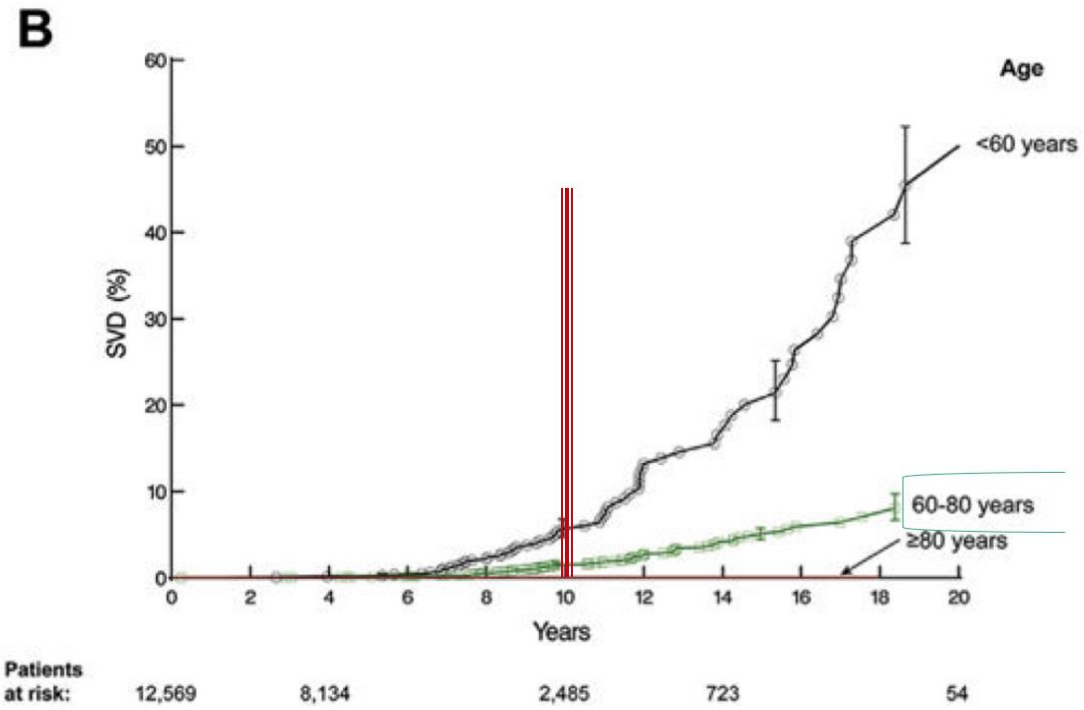
TABLE 2 Comparative Outcomes for TAVR and SAVR for Bicuspid AS in the Matched Cohort

	TAVR (n = 975)	SAVR (n = 975)	OR	Lower CI	Upper CI	p Value
In-hospital mortality	30 (3.1)	30 (3.1)	1.000	0.598	1.672	>0.999
Cardiac arrest	40 (4.1)	30 (3.1)	1.348	0.832	2.182	0.273
Cardiogenic shock	55 (5.6)	45 (4.6)	1.236	0.825	1.851	0.356
MCS	30 (3.1)	26 (2.6)	1.129	0.684	1.472	0.585
AKI	141 (14.4)	145 (14.9)	0.942	0.779	1.283	0.789
AKI hemodialysis	NR	NR	1.000	0.414	2.413	>0.999
AMI	NR	30 (3.1)	0.326	0.159	0.671	0.002
Hemopericardium	NR	NR	1.000	0.289	3.465	>0.999
Cardiac tamponade	NR	15 (1.5)	0.663	0.296	1.484	0.421
Respiratory complications	20 (2.1)	35 (3.6)	0.562	0.322	0.981	0.055
Post-operative bleeding	230 (23.6)	435 (44.6)	0.383	0.316	0.465	<0.001
Blood transfusions	70 (7.2)	265 (27.2)	0.207	0.156	0.275	<0.001
Acute stroke	20 (2.1)	25 (2.6)	0.796	0.439	1.443	0.547
Ventricular arrhythmias	40 (4.1)	45 (4.6)	0.884	0.572	1.367	0.658
Complete heart block	145 (14.9)	60 (6.2)	2.664	1.944	3.651	<0.001
PPM	135 (13.8)	45 (4.6)	3.321	2.340	4.713	<0.001
Vascular complications	NR	25 (2.6)	0.196	0.073	0.514	<0.001
Facility discharge	140 (14.4)	175 (17.9)	0.766	0.601	0.977	0.036
Length of stay, days	4 (2-7)	7 (5-9)				0.001

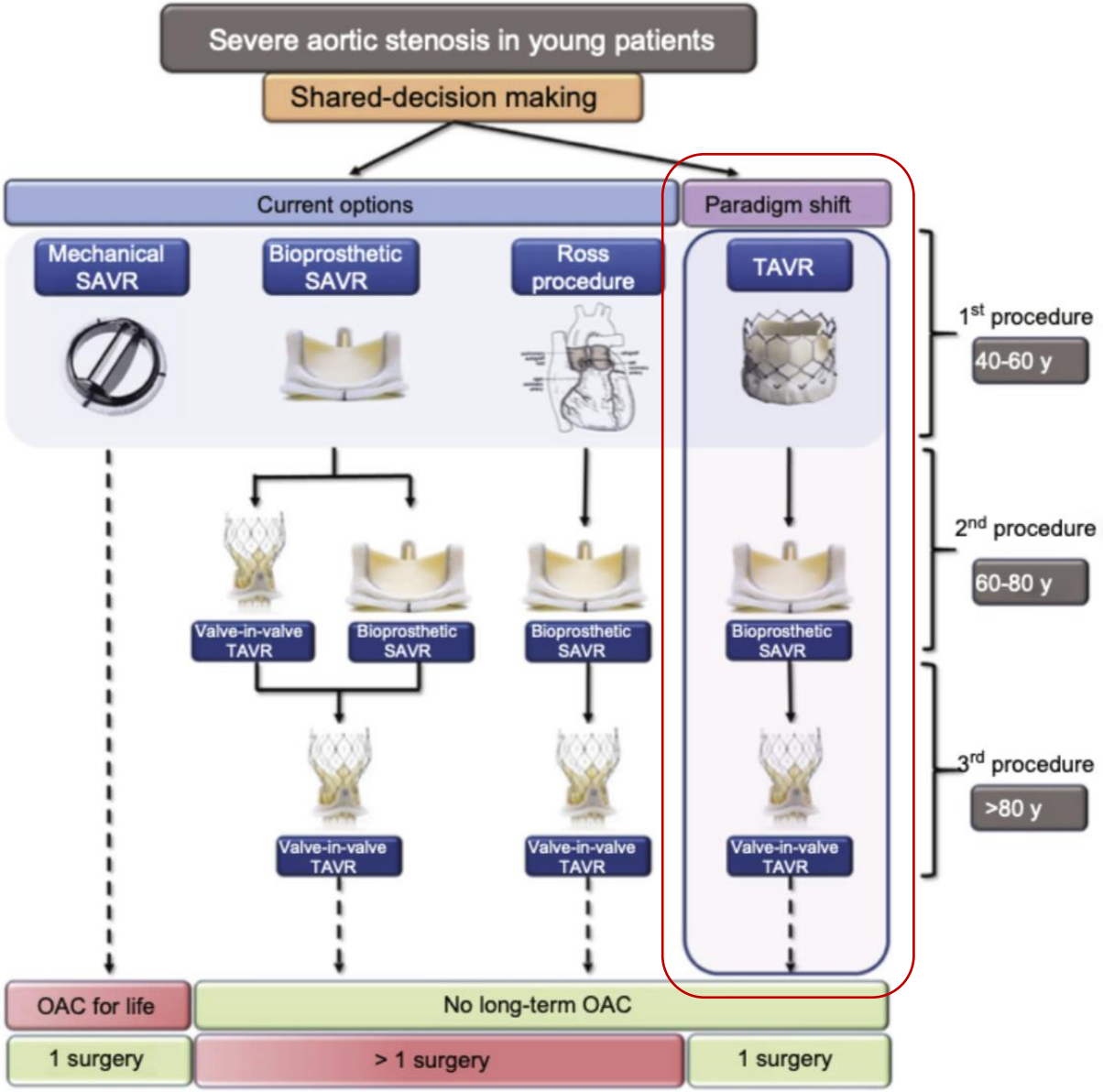
Ann Thorac Surg. 2015 April ; 99(4): 1239–1247. doi:10.1016/j.athoracsur.2014.10.070.

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, **Edward G. Soltesz, MD**, **Nakul Vakil, MD**, **Jeevanantham Rajeswaran, PhD**, **Eric E. Roselli, MD**, **Joseph F. Sabik III, MD**, **Nicholas G. Smedira, MD**, **Lars G. Svensson, MD, PhD**, **Bruce W. Lytle, MD**, and **Eugene H. Blackstone, MD**
Department of Thoracic and Cardiovascular Surgery, Heart and Vascular Institute, and Department of Quantitative Health Sciences, Research Institute, Cleveland Clinic, Cleveland, Ohio



Is this the future ?

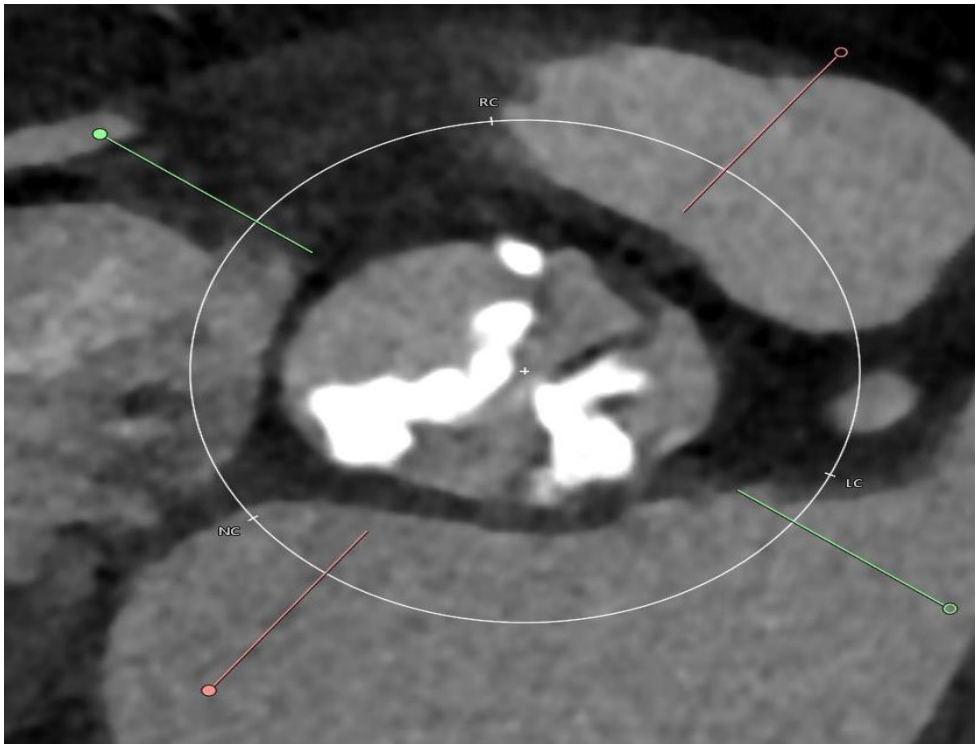


Conclusion

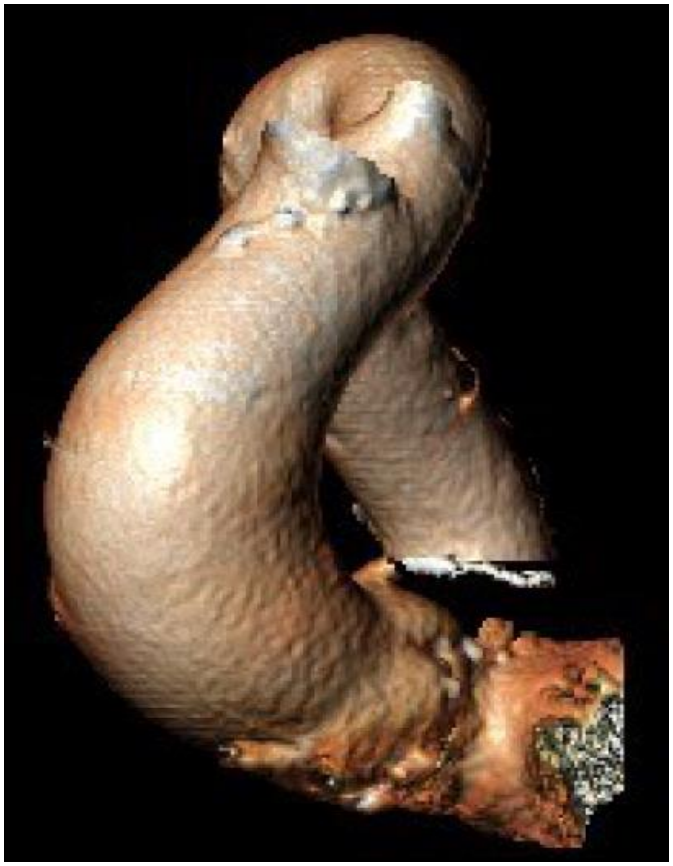
LOADING YOUR NOT SO Perfect

Which low risk patients should still be referred to surgery ?

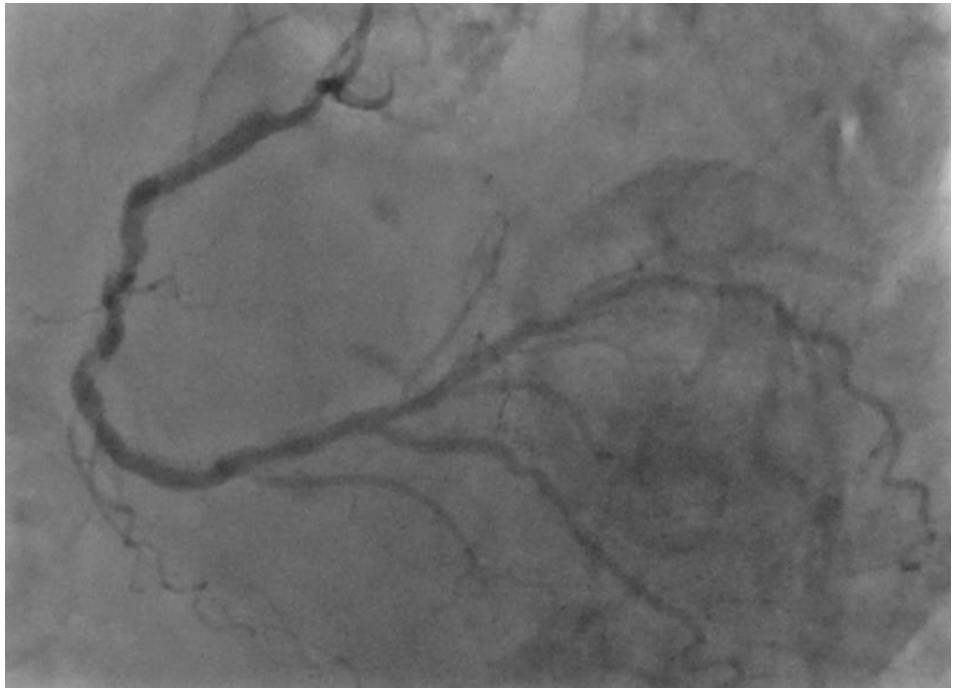
BICUSPID AORTIC VALVES



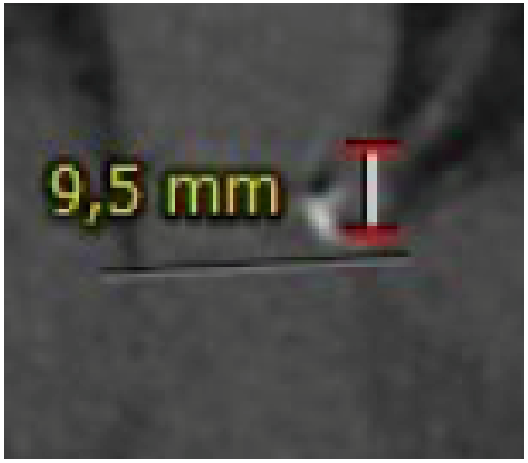
ASSOCIATED AORTOPATHY

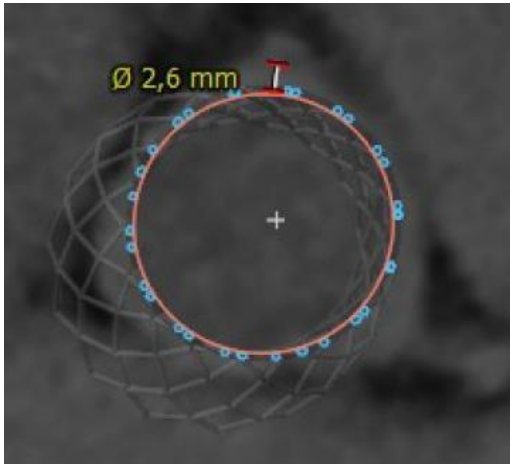


COMPLEX CORONARY ARTERY DISEASE



RISK OF PERIPROCEDURAL CORONARY ARTERY OCCLUSION





Virtual Tanscatheter heart valve to Coronary distance
At risk if VTC < 4 mm

COMPLEX ILIO FEMORAL ANATOMY PRECLUDING SAFE TF TAVI

PCR webinars

Main informations to extract from recent ACC/AHA VHD guidelines update

Herz- und Diabeteszentrum NRW
Bad Oeynhausen
Sabine Bleiziffer

HDZ NRW
UKRUB UNIVERSITÄTSKLINIKUM DER RUHR-UNIVERSITÄT BOCHUM

PCR webinars

ACC/AHA CLINICAL PRACTICE GUIDELINE

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Otto CM, et al. Circulation. 2021. PMID: 33332150
Writing Committee Members, et al. J Am Coll Cardiol. 2021. PMID: 33342586

HDZ NRW
UK RUB UNIVERSITÄTSKLINIKUM DER RUHR-UNIVERSITÄT BOCHUM

TOP 10 TAKE-HOME MESSAGES

4

All patients with severe valvular heart disease being considered for valve intervention should be evaluated by a multidisciplinary team, with either referral to or consultation with a Primary or Comprehensive Valve Center.

1. Assess the risk

Indications for transcatheter aortic valve implantation are expanding as a result of multiple randomized trials of transcatheter aortic valve implantation versus surgical aortic valve replacement. The choice of type of intervention for a patient with severe aortic stenosis should be a shared decision-making process that considers the lifetime risks and benefits associated with type of valve (mechanical versus bioprosthetic) and type of approach (transcatheter versus surgical).

Recommendation for Evaluation of Surgical and Interventional Risk		
COR	**LOE**	**Recommendation**
1	C-EO	1. For patients with VHD for whom intervention is contemplated, individual risks should be calculated for specific surgical and/or transcatheter procedures, using online tools when available, and discussed before the procedure as a part of a shared decision-making process.

Definition of Low risk

Table 8. Risk Assessment for Surgical Valve Procedures

Criteria	Low-Risk SAVR (Must Meet ALL Criteria in This Column)
STS-predicted risk of death*	<3% AND
Frailty†	None AND
Cardiac or other major organ system compromise not to be improved postoperatively‡	None AND
Procedure-specific impediment§	None

- Cardiac dysfunction
- Kidney dysfunction
- Pulmonary dysfunction
- Central nervous system dysfunction
- Cancer
- Liver dysfunction

- Tracheostomy
- Porcelain aorta
- Chest malformation
- Arterial coronary graft adherent to posterior chest wall
- Radiation damage

Procedure specific risk

Table 9. Examples of Procedure-Specific Risk Factors for Interventions Not Incorporated Into Existing Risk Scores

SAVR	TAVI
Technical or anatomic	
Prior mediastinal radiation	Aorto-iliac occlusive disease precluding transfemoral approach
Ascending aortic calcification (porcelain aorta may be prohibitive)	Aortic arch atherosclerosis (protuberant lesions) Severe MR or TR Low-lying coronary arteries Basal septal hypertrophy Valve morphology (eg, bicuspid or unicuspid valve) Extensive LV outflow tract calcification

2. TAVI or SAVR?

(if risk is low)

Recommendations for Choice of SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR Is Appropriate Referenced studies that support the recommendations are summarized in Online Data Supplement 11 to 13.		
COR	**LOE**	**Recommendations**
1	A	1. For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended.[1–3]
1	A	2. For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability.[1,4–8]
1	A	3. For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR.[1,4–10]

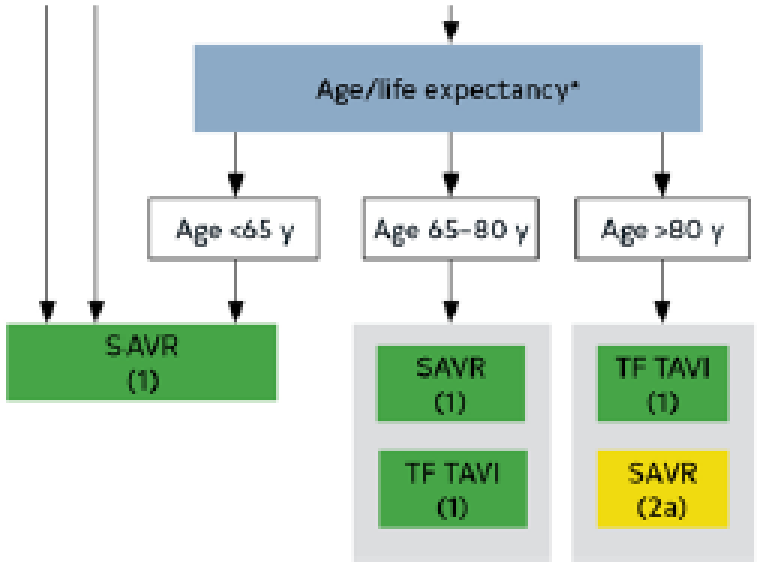


Table 14. A Simplified Framework With Examples of Factors Favoring SAVR, TAVI, or Palliation Instead of Aortic Valve Intervention

	Favors SAVR	Favors TAVI	Favors Palliation
Age/life expectancy*	Younger age/longer life expectancy	Older age/fewer expected remaining years of life	Limited life expectancy
Valve anatomy	BAV Subaortic (LV outflow tract) calcification Rheumatic valve disease	Calcific AS of a trileaflet valve	
Prosthetic valve preference	Mechanical or surgical bioprosthetic valve preferred Concern for patient–prosthesis mismatch (annular enlargement might be considered)	Bioprosthetic valve preferred Favorable ratio of life expectancy to valve durability TAVI provides larger valve area than same size SAVR	
	Severe CAD requiring bypass grafting Septal hypertrophy requiring myectomy AF		Severe MR attributable to annular calcification
Noncardiac conditions		Severe lung, liver, or renal disease Mobility issues (high procedural risk with sternotomy)	Symptoms likely attributable to noncardiac conditions Severe dementia Moderate to severe involvement of ≥2 other organ systems
Frailty	Not frail or few frailty measures	Frailty likely to improve after TAVI	Severe frailty unlikely to improve after TAVI
Estimated procedural or surgical risk of SAVR or TAVI	SAVR risk low TAVI risk high	TAVI risk low to medium SAVR risk high to prohibitive	Prohibitive SAVR risk (>15%) or post-TAVI life expectancy <1 y
Goals of Care and patient preferences and values	Less uncertainty about valve durability Avoid repeat intervention Lower risk of permanent pacer Life prolongation Symptom relief Improved long-term exercise capacity and QOL Avoid vascular complications Accepts longer hospital stay, pain in recovery period	Accepts uncertainty about valve durability and possible repeat intervention Higher risk of permanent pacer Life prolongation Symptom relief Improved exercise capacity and QOL Prefers shorter hospital stay, less postprocedural pain	Life prolongation not an important goal Avoid futile or unnecessary diagnostic or therapeutic procedures Avoid procedural stroke risk Avoid possibility of cardiac pacer

Essentials from the new ACC/AHA guidelines

1. TAVI for all > 80 years

2. Heart Team discussion for all

3. Multifactorial decision

   (based on age expectancy, comorbidities and anatomical characteristics)

Discussion

TAVI in young patients

with long life-expectancy :

be prepared for the re-intervention

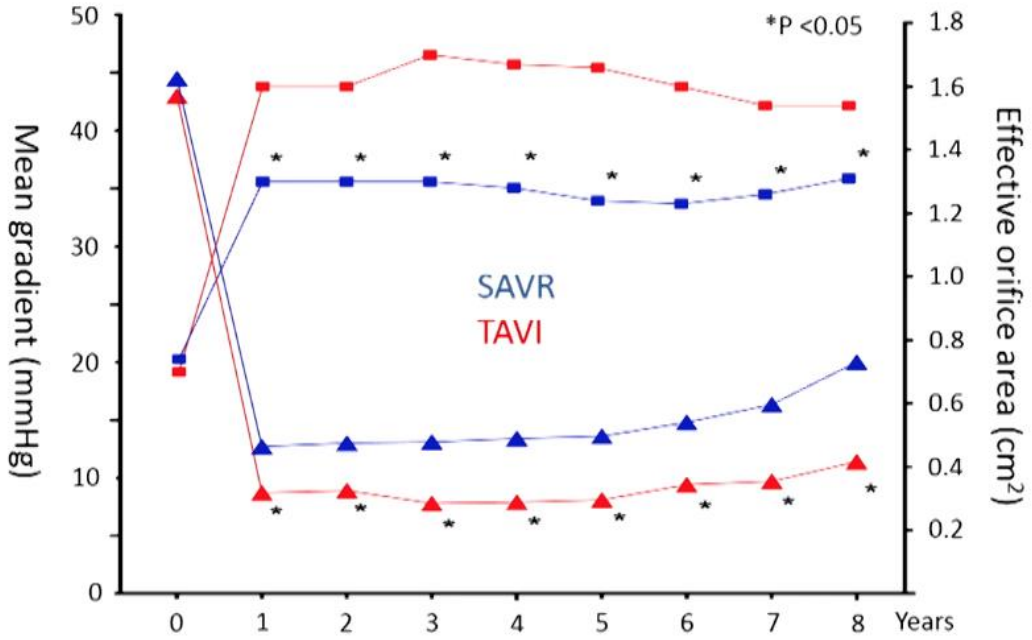
SVD ?

2020 PCR VALVES e-Course

Lars Søndergaard
Copenhagen - Denmark

2020 PCR VALVES e-Course

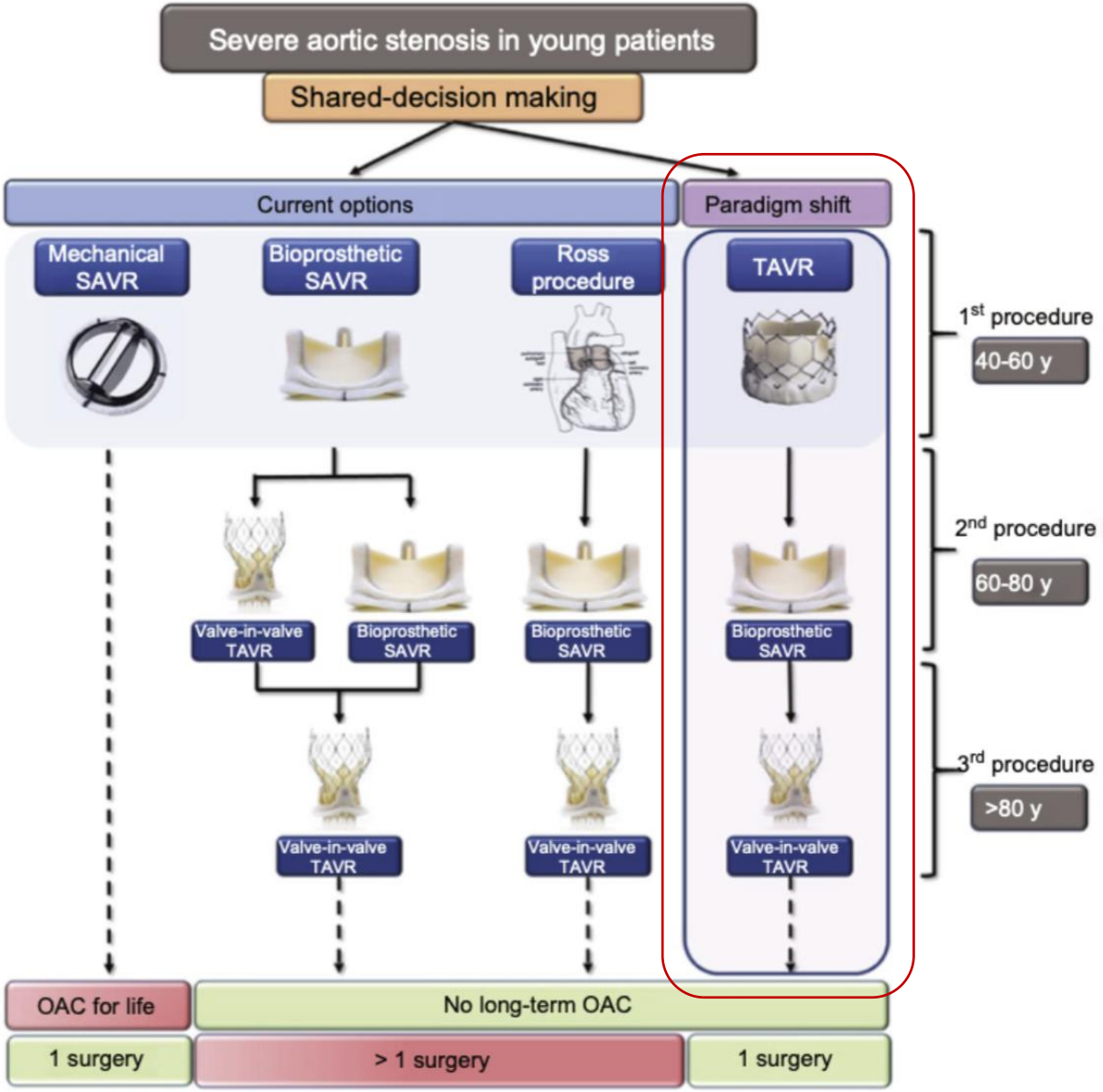
Aortic valve performance



NOTION trial long term F-Up

Which procedure first ?

Is this the future ?



TAVI in TAVI / ViV procedural issues ?

RISK OF SEVERE RESIDUAL STENOSIS

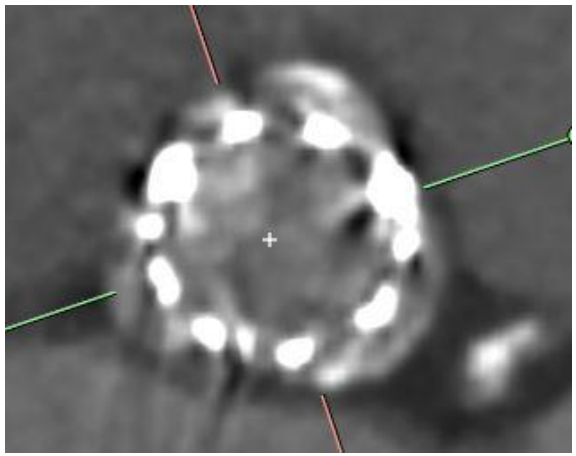
17 mm prothesis inner ⦸

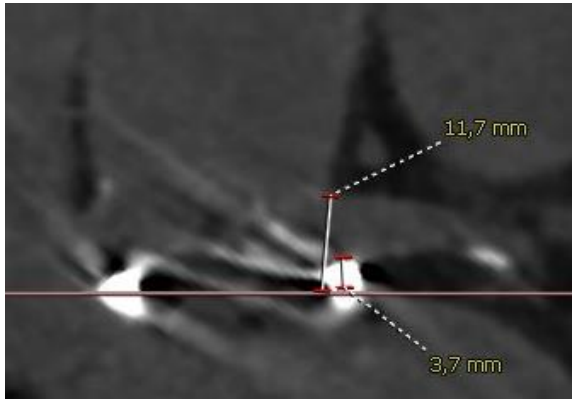
1.To be anticipated at the time of 1st prosthetic implant

2.BVF feasible for surgical valves

TAVI in TAVI / ViV procedural issues ?

RISK OF CORONARY OBSTRUCTION

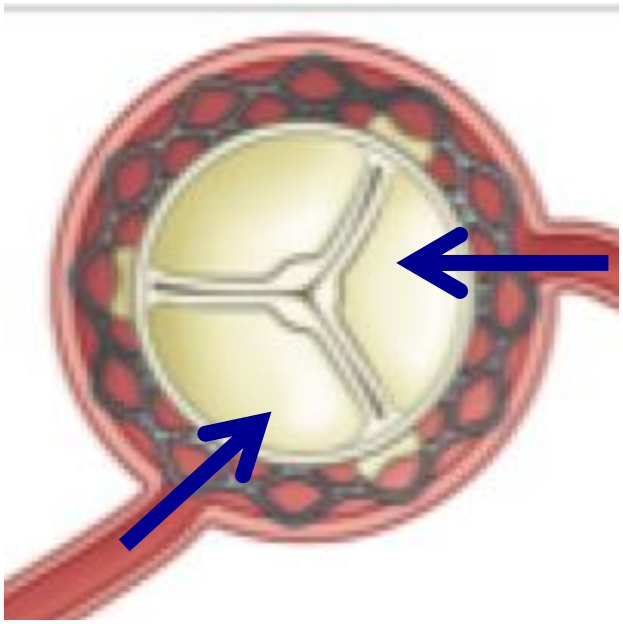




1.To be anticipated at the time of 1st prosthetic implant

TAVI in TAVI / ViV procedural issues ?

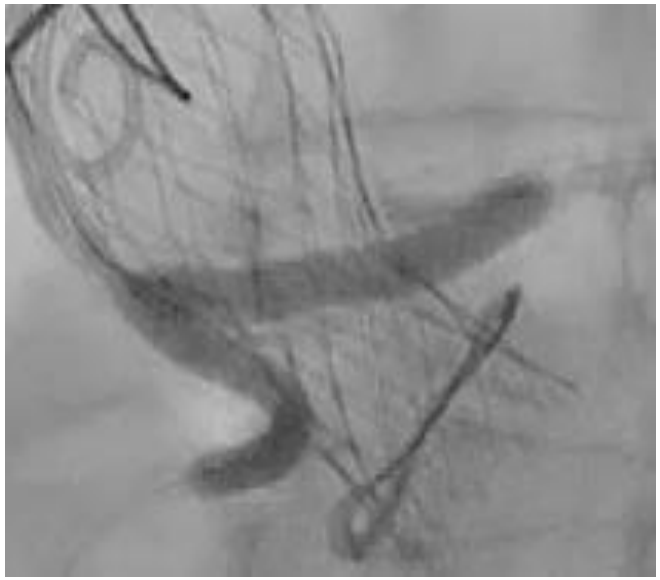
RISK OF CORONARY OBSTRUCTION



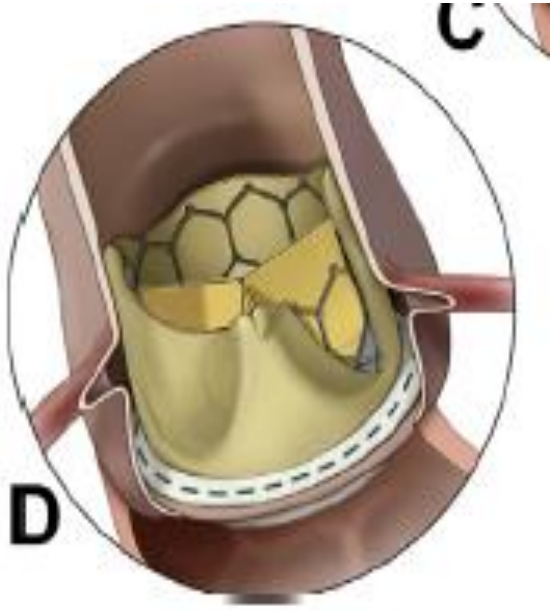
THV implantation
with commissural alignement

TAVI in TAVI / ViV procedural issues ?

RISK OF CORONARY OBSTRUCTION



Chimney stenting technique



Basilica technique

Khan et al. ***JACC Cardiovasc Interv*** 2018

Conclusion

KEY MESSAGES

TAVI low risk trials positive outcomes do not mean TAVI for all

HEART team to tailor therapy based on individual clinical and ANATOMICAL risk assessment

Needs to schedule lifelong treatment of AS, thinking from 1st prosthesis implant to reintervention and related issues

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