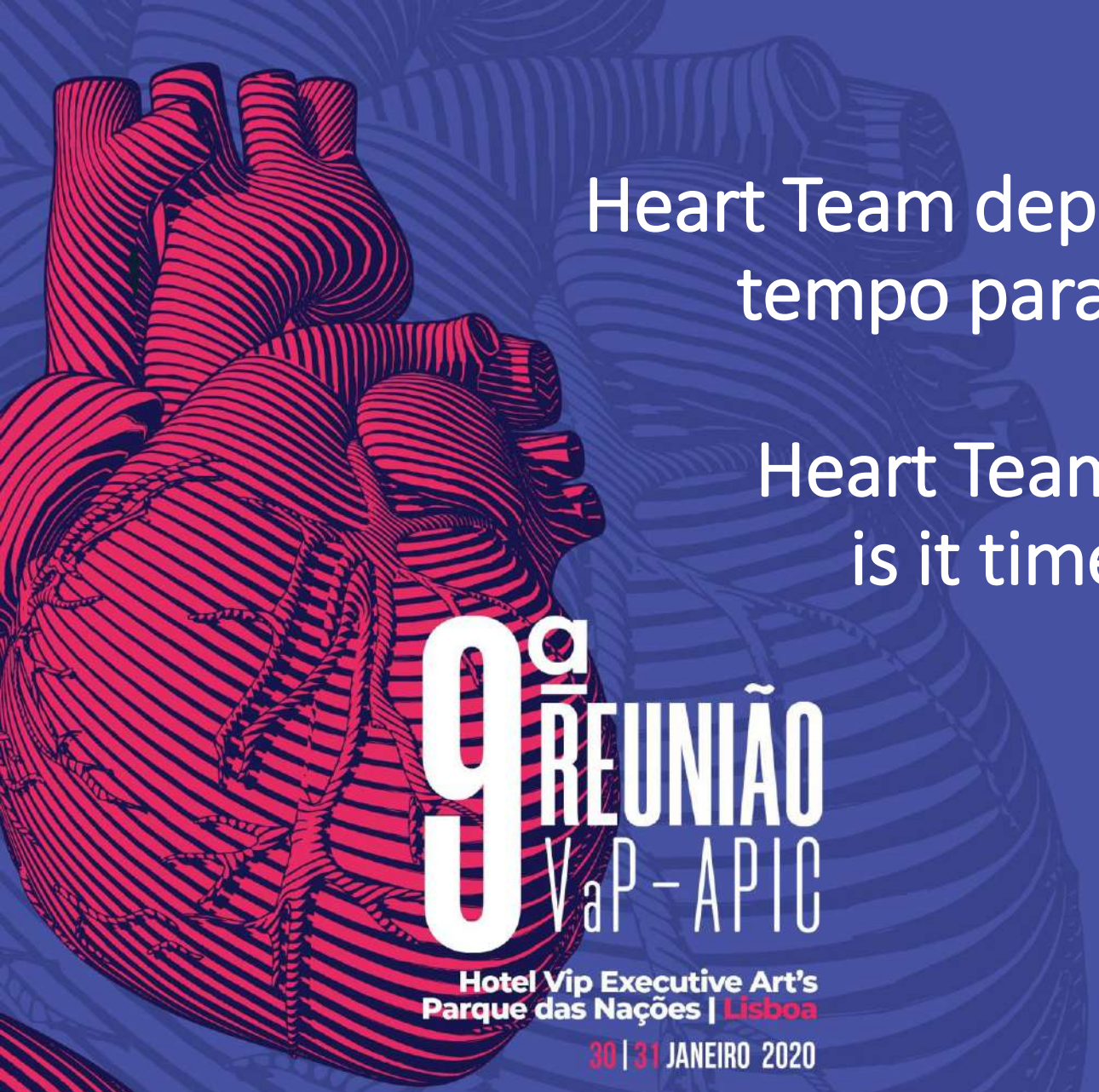


Heart Team depois dos ensaios de baixo risco: tempo para mudança de paradigma?

Heart Team after the low risk trials: is it time for a paradigm shift?

Bruno Melica
CHVNG

9ª REUNIÃO VaP-APIC

Hotel Vip Executive Art's Parque das Nações | Lisboa

30 | 31 JANEIRO 2020

apic Associação Portuguesa de Intervenção Cardiovascular sociedade portuguesa de cardiologia

cardiologiadegaia | UDIC Unidade de Diagnóstico e Intervenção Cardiovascular | Porto Heart Center | CAS MITRAL TRICUSPID CERTIFICATE OF ADVANCED STUDIES STRUCTURAL INTERVENTIONS

I have nothing to disclose about this presentation

Cambridge Dictionary

paradigm shift

noun [C] • formal

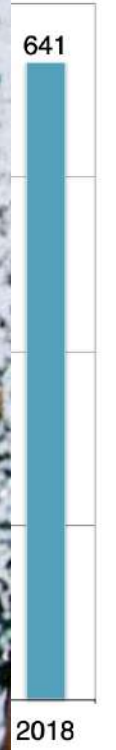
UK /ˈpær.ə.daɪm ˌʃɪft/ **US** /ˈper.ə.daɪm ˌʃɪft/

a time when the usual and accepted way of doing or thinking about something changes completely


PARTNER 1A
PARTNER 1B
CoreValve ER
CoreValve HR
PARTNER 2A
NOTION I
SURTAVI
2011
2012
2014
2016
2017
ESC
European Society of Cardiology
EACTS
Extreme risk I B
High-risk IIa B
Extreme risk I B
Increased risk I B
American Heart Association
AMERICAN COLLEGE of CARDIOLOGY
Prohibitive risk I B
High-risk IIa B
Prohibitive risk I A
High- risk I A
Intermediate risk IIa B-R

TAVI pe AP registry

2430 pro



1. NOTION trial

Circulation

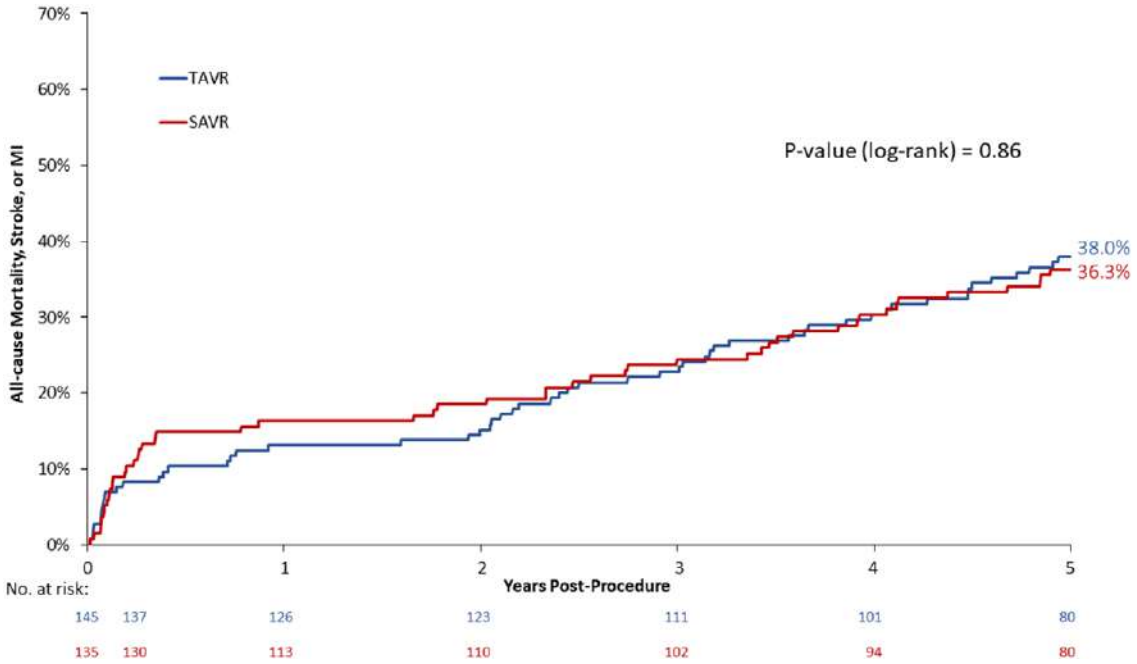
ORIGINAL RESEARCH ARTICLE

Five-Year Clinical and Echocardiographic Outcomes From the NOTION Randomized Clinical Trial in Patients at Lower Surgical Risk

Circulation. 2019;139:2714–2723. DOI: 10.1161/CIRCULATIONAHA.118.036606

- Randomized, investigator initiated
- 3 centres in northern Europe
- 280 pts, no prespecified surgical risk
- Self-expandable TAVI vs any stented SAVR
- Primary EP: all cause mortality + stroke + myocardial infarction at 1 year
- 5 years FU

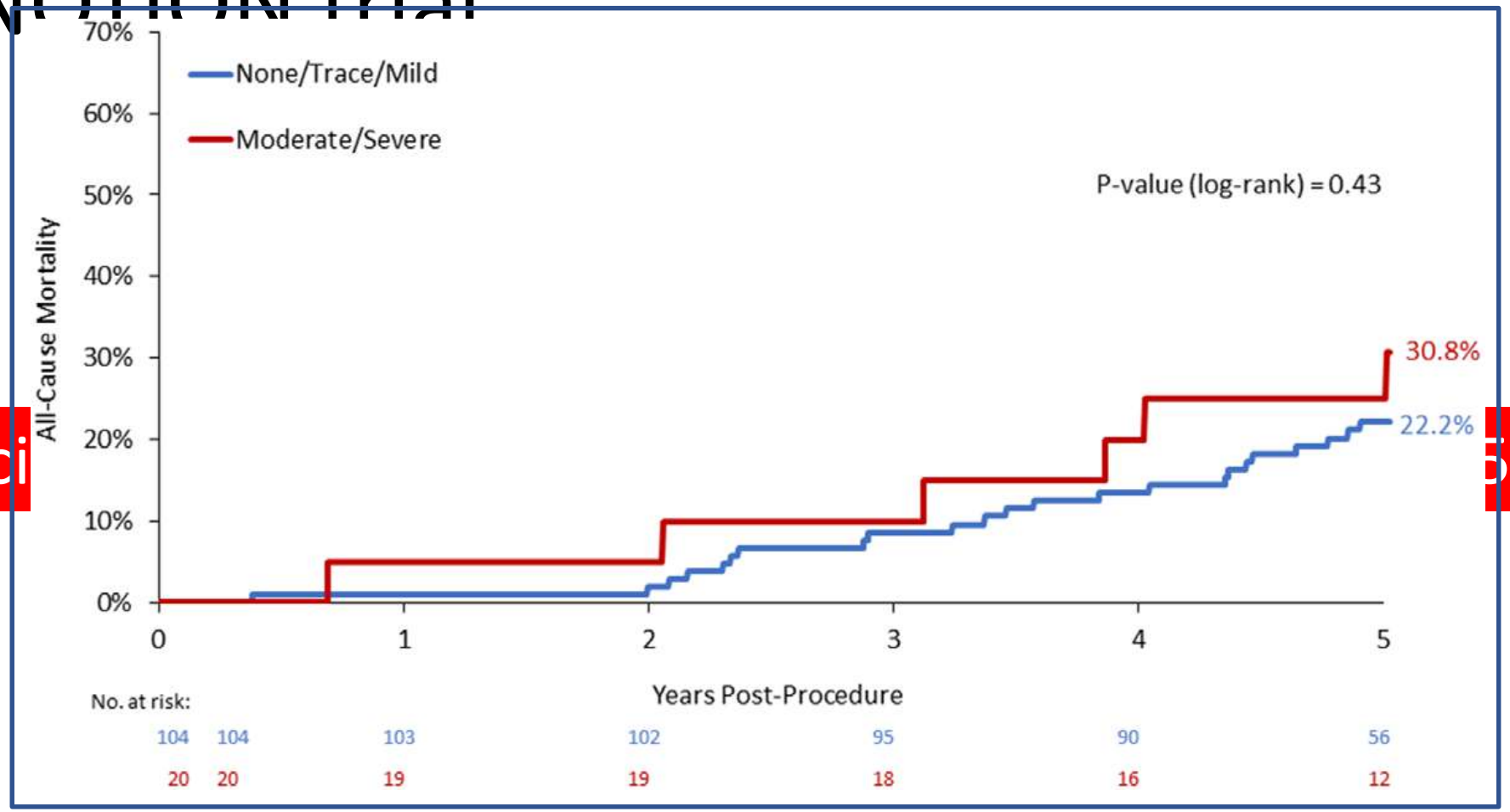
1. NOTION trial



Outcome (%)	TAVR (n=145)	SAVR (n=135)	*P* Value
All-cause mortality, stroke, or MI*	55 (38.0)	49 (36.3)	0.86
All-cause mortality*	40 (27.6)	39 (28.9)	0.75
Cardiovascular mortality	30 (20.8)	31 (23.0)	0.62
Stroke	13 (9.0)	10 (7.4)	0.65
TIA	9 (6.2)	5 (3.7)	0.33
MI	11 (7.7)	10 (7.4)	0.96
Atrial fibrillation	34 (23.4)	82 (60.8)	<0.0001
Pacemaker†	58 (41.7)	10 (7.8)	<0.0001
Aortic valve reintervention	3 (2.1)	1 (0.7)	0.35
Valve endocarditis‡	9 (6.2)	6 (4.4)	0.51

No difference in primary EP @ 5 years FU

1. NOTION trial



Higher inci … 5 years FU

2. PARTNER 3 trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

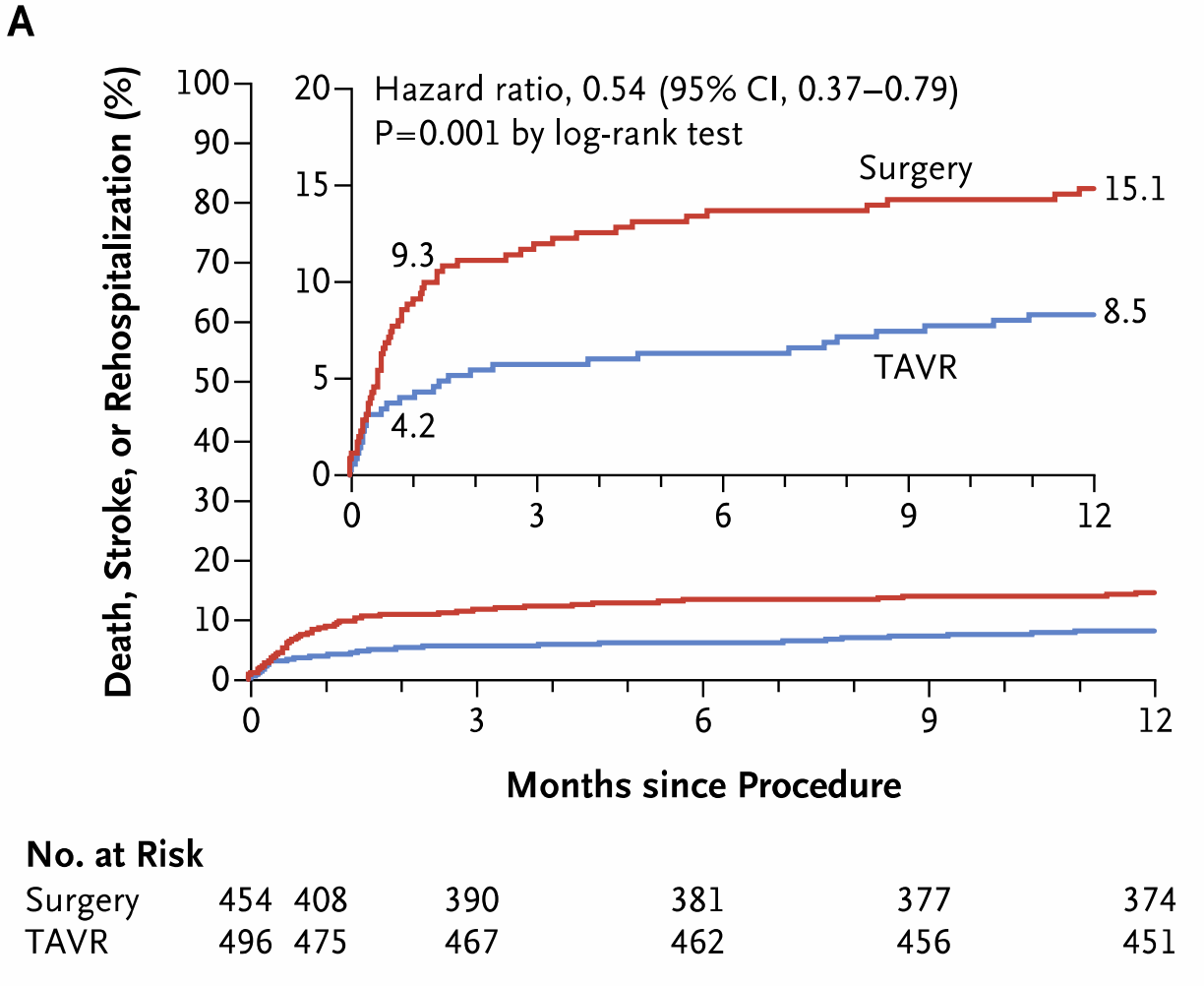
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*

- Randomized, industry sponsored
- Multicentre (mainly US)
- 1000 pts, low surgical risk
- Balloon-expandable TAVI vs SAVR
- Primary EP: all cause mortality + stroke + HF admission at 1 year

2. PARTNER 3 trial

Primary EP:
TAVI better than SAVR
@ 1 year FU



2. PARTNER 3 trial

End Point	TAVR (N = 496)	Surgery (N = 454)	TAVR vs. Surgery (95% CI)†	P Value‡
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Death or stroke at 30 days — no. (%)§	5 (1.0)	15 (3.3)	0.30 (0.11 to 0.83)	0.01
Stroke at 30 days — no. (%)§	3 (0.6)	11 (2.4)	0.25 (0.07 to 0.88)	0.02

No difference in moderate/severe paravalvular regurgitation

No difference in new permanent PM implantation

TAVI better than SAVR in all secondary endpoints

3. Evolut low risk trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

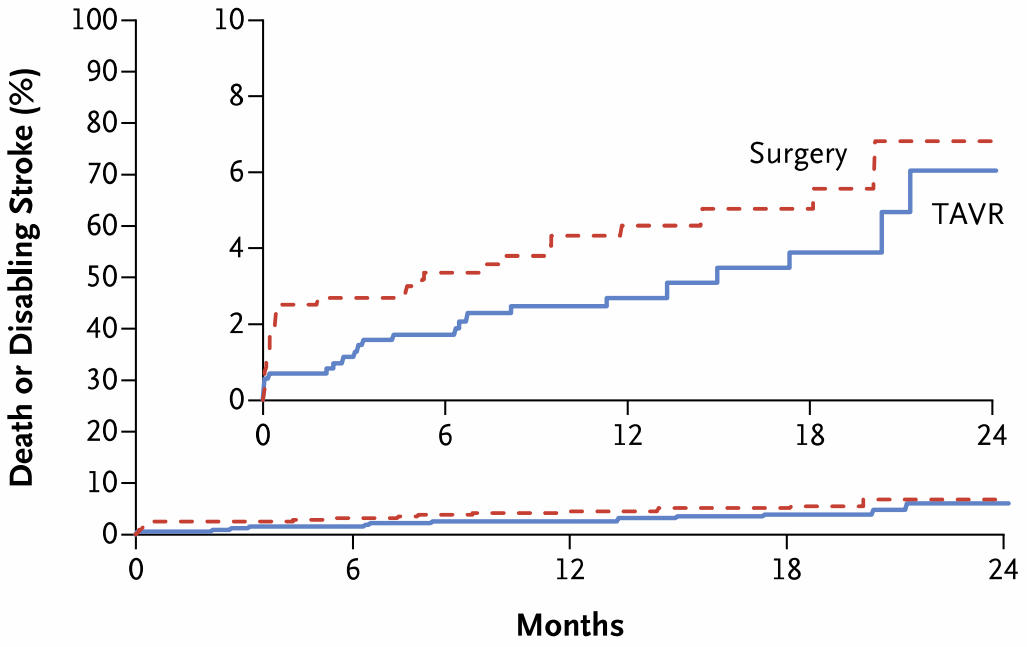
Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*

- Randomized, industry sponsored
- Multicentre (US, Europe, Japan, Australia, New Zeaaland)
- ~1400 pts, low surgical risk
- Self-expandable TAVI vs SAVR
- Primary EP: all cause mortality + disabling stroke @ 2 years

3. Evolut low risk trial

Primary EP:
TAVI non-inferior to SAVR
@ 2 year FU

B Incidence of Primary End Point



No. at Risk					
Surgery	678	576	366	195	69
TAVR	725	648	435	233	80

3. Evolut low risk trial

Clinical Outcomes at 30 Days

Evolut™ Low Risk Trial

Bayesian rates as %	TAVR (N=725)	SAVR (N=678)	(95% BCI for Difference)
30-Day composite safety endpoint*	5.3	10.7	(-8.3, -2.6)
All-cause mortality	0.5	1.3	(-1.9, 0.2)
Disabling stroke*	0.5	1.7	(-2.4, -0.2)
Life-threatening or disabling bleeding*	2.4	7.5	(-7.5, -2.9)
Acute kidney injury, stage 2-3*	0.9	2.8	(-3.4, -0.5)
Major vascular complication	3.8	3.2	(-1.4, 2.5)
Atrial fibrillation*	7.7	35.4	(-31.8, -23.6)
Permanent pacemaker implant*	17.4	6.1	(8.0, 14.7)
All-cause mortality or disabling stroke*	0.8	2.6	(-3.2, -0.5)
All stroke	3.4	3.4	(-1.9, 1.9)
Aortic valve reintervention	0.4	0.4	(-0.8, 0.7)

* Significantly favors TAVR; * Significantly favors SAVR

BCI = Bayesian credible interval

3. Evolut low risk trial

Clinical Outcomes at 1 Year

Evolut™ Low Risk Trial

Bayesian rates as %	TAVR (N=725)	SAVR (N=678)	(95% BCI for Difference)
All-cause mortality or disabling stroke	2.9	4.6	(-4.0, 0.4)
All-cause mortality	2.4	3.0	(-2.6, 1.3)
Cardiovascular mortality	1.7	2.6	(-2.7, 0.7)
All stroke	4.1	4.3	(-2.4, 1.9)
Disabling stroke*	0.8	2.4	(-3.1, -0.3)
Transient ischemia attack	1.7	1.8	(-1.6, 1.3)
Myocardial infarction	1.7	1.6	(-1.3, 1.5)
Endocarditis	0.2	0.4	(-0.9, 0.5)
Valve thrombosis	0.2	0.3	(-0.9, 0.5)
Aortic valve reintervention	0.7	0.6	(-1.0, 0.9)
Heart failure hospitalization*	3.2	6.5	(-5.9, -1.0)

* Significantly favors TAVR

BCI = Bayesian credible interval

NEWS • INTERVENTIONAL

FDA Expands TAVR Indication to Low-Risk Patients

Both Evolut R and Evolut PRO, as well Sapien 3, received the expanded indication in today's eagerly awaited announcement.

ESC
European Society of Cardiology

Guidelines Planned for 2021

- **Cardiac Pacing**

Chairpersons: Jens Cosedis Nielsen and Michael Glikson

- **Valvular Heart Disease**

Chairpersons: Alec Vahanian and Friedhelm Beyersdorf

- **CVD Prevention**

Chairpersons: François Mach and Frank Visseren

- **Heart Failure**

Chairpersons: Theresa McDonagh and Marco Metra

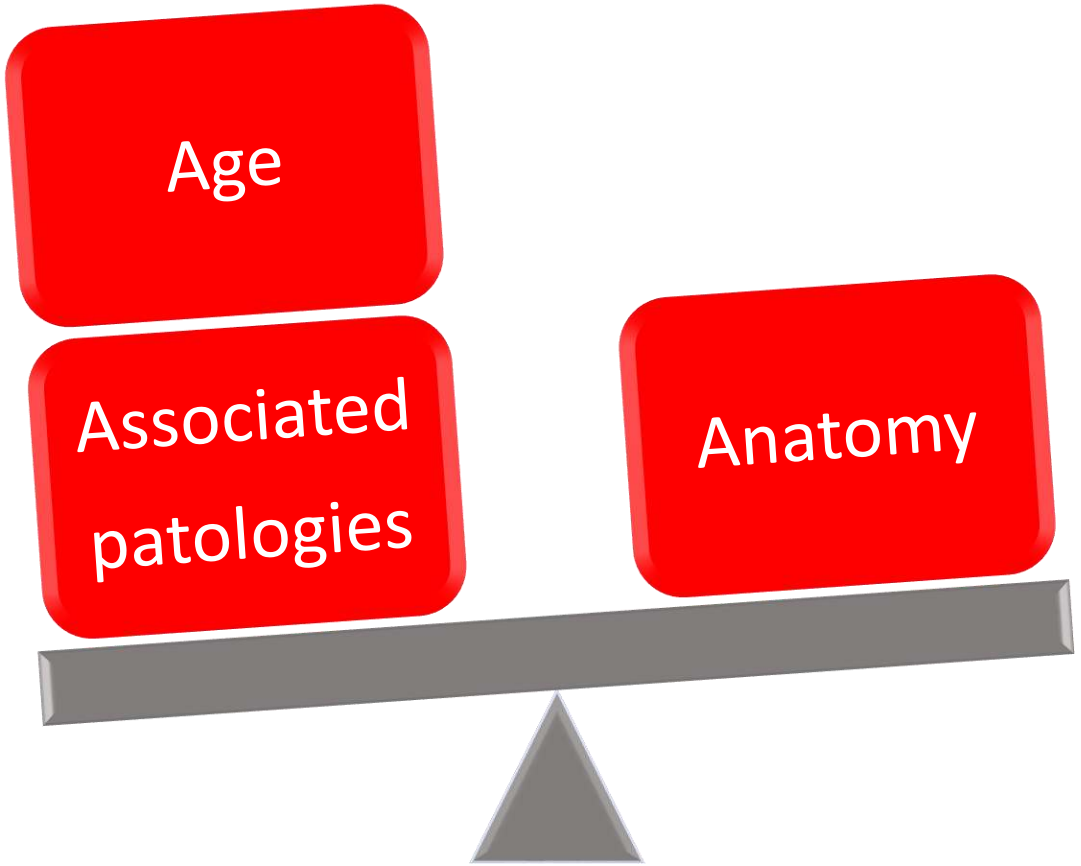
AMERICAN COLLEGE of CARDIOLOGY

Document Topic	Estimated Release Date
Practice Guidelines	
Valvular Heart Disease (Revision)	2020 Quarter 3
Hypertrophic Cardiomyopathy	2020 Quarter 4
Evaluation and Diagnosis of Chest Pain	2021 Quarter 1
Coronary Revascularization	2021 Quarter 1

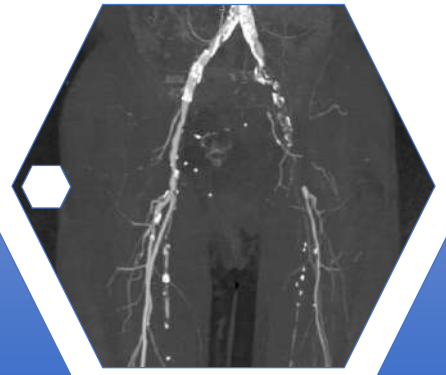
Scenarios for the heart team 2.0

1. TAVI first

TAVI or SAVR: tailoring the benefit

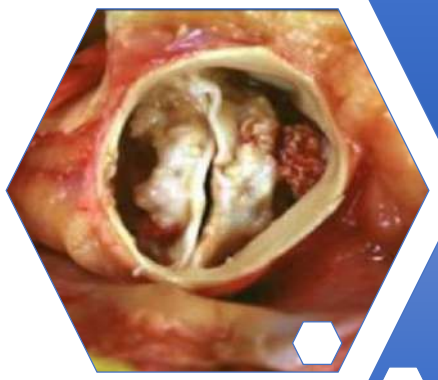


SAVR better- anatomic issues

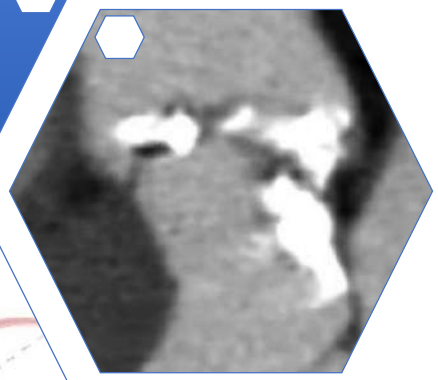


Severe PAD

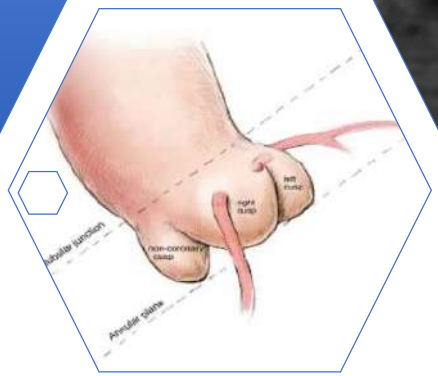
Severe Annulus/LVOT calcification



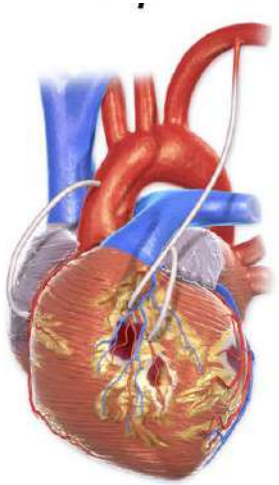
Low coronary take off



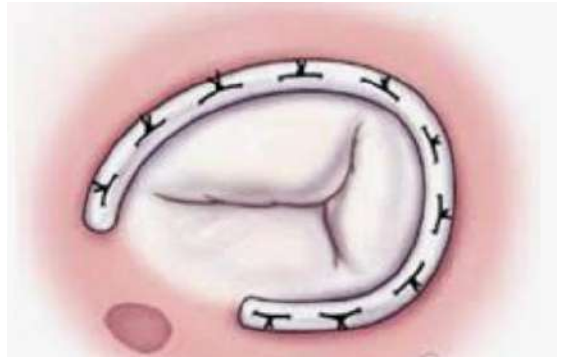
Bicuspid valve

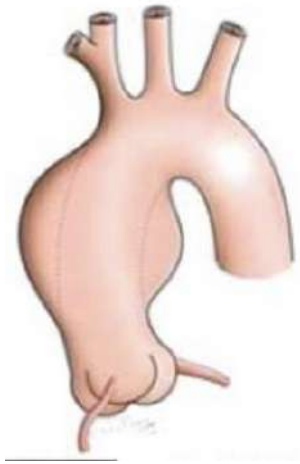


SAVR better- asssociated patologies



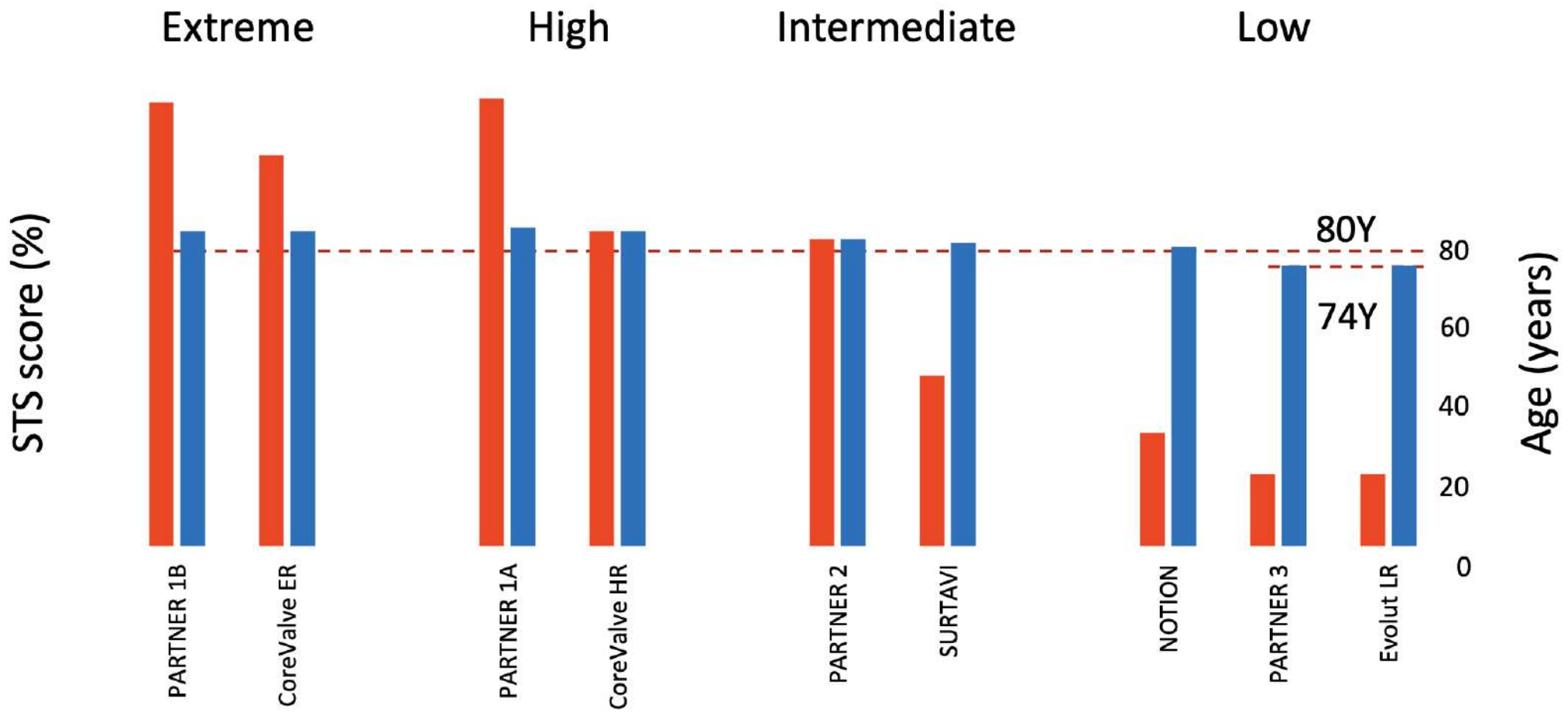
- Severe CAD
- Severe IT
- Aorta disease
- Suspect endocarditis
- Severe IM



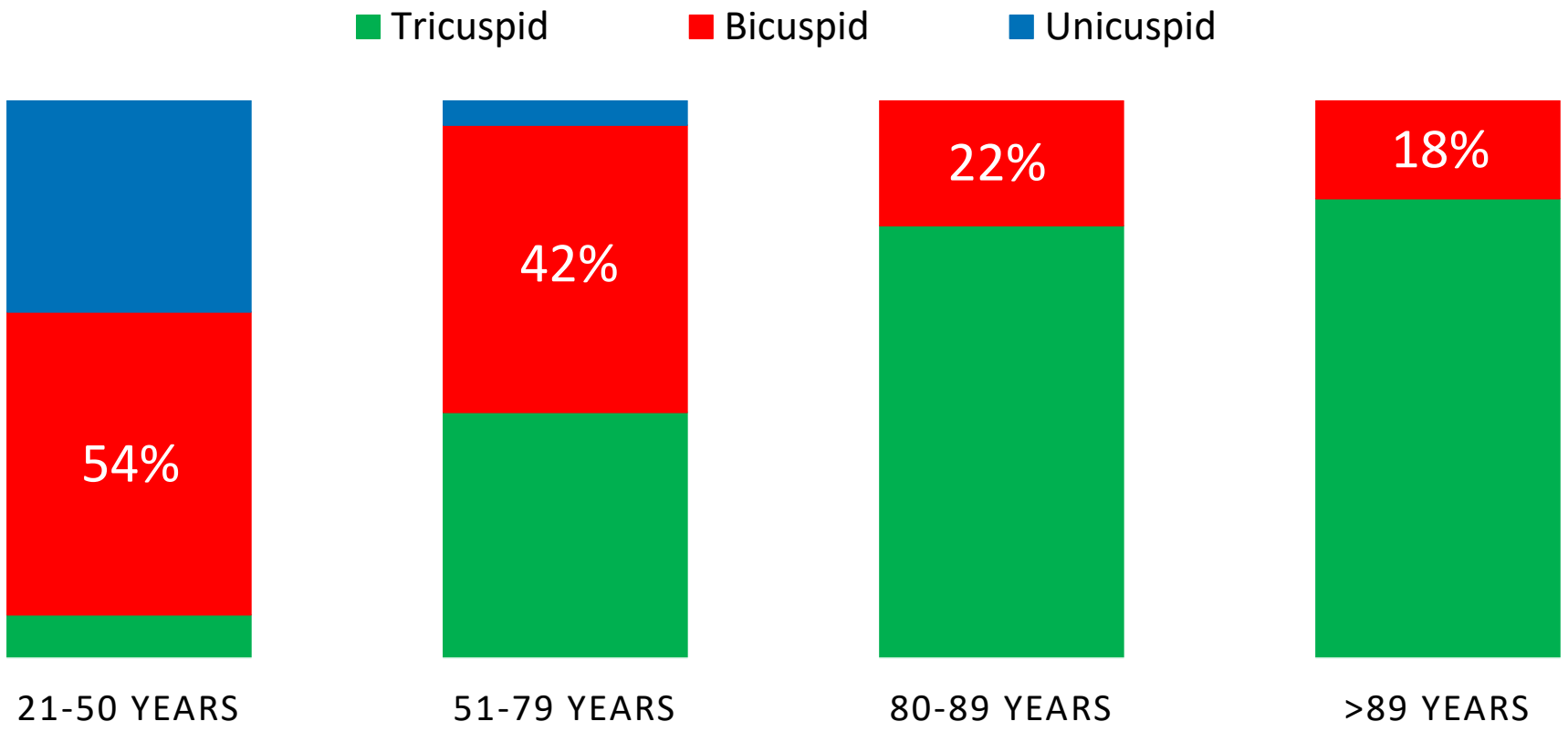


Low risk: just a matter of age?

Tavi trials: lower risk, (almost) same age



Age -related issues: BAV



Roberts et al, AJC 2012

TAVI durability: what do we know?

Common language

ESC European Society of Cardiology

European Heart Journal (2017) **38**, 3382–3390
doi:10.1093/eurheartj/ehx303

SPECIAL ARTICLE
Valvular heart disease

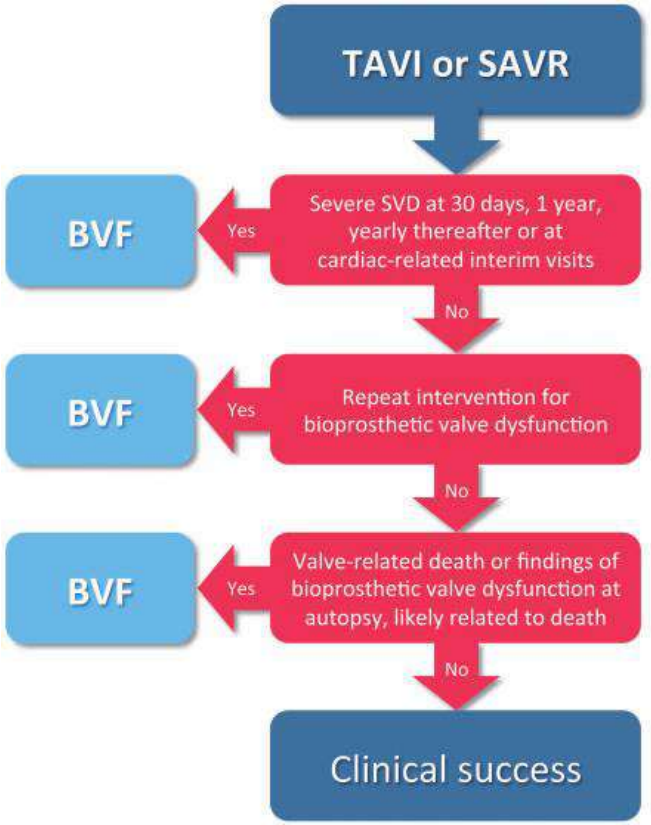
Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

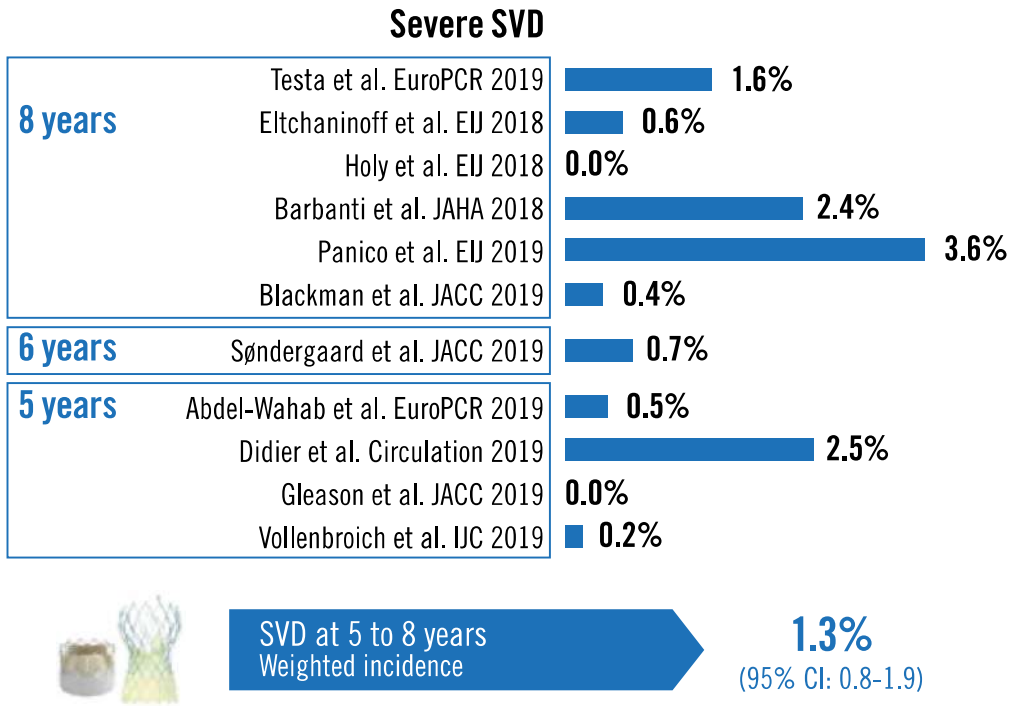
Structural valve deterioration & bioprosthetic valve failure

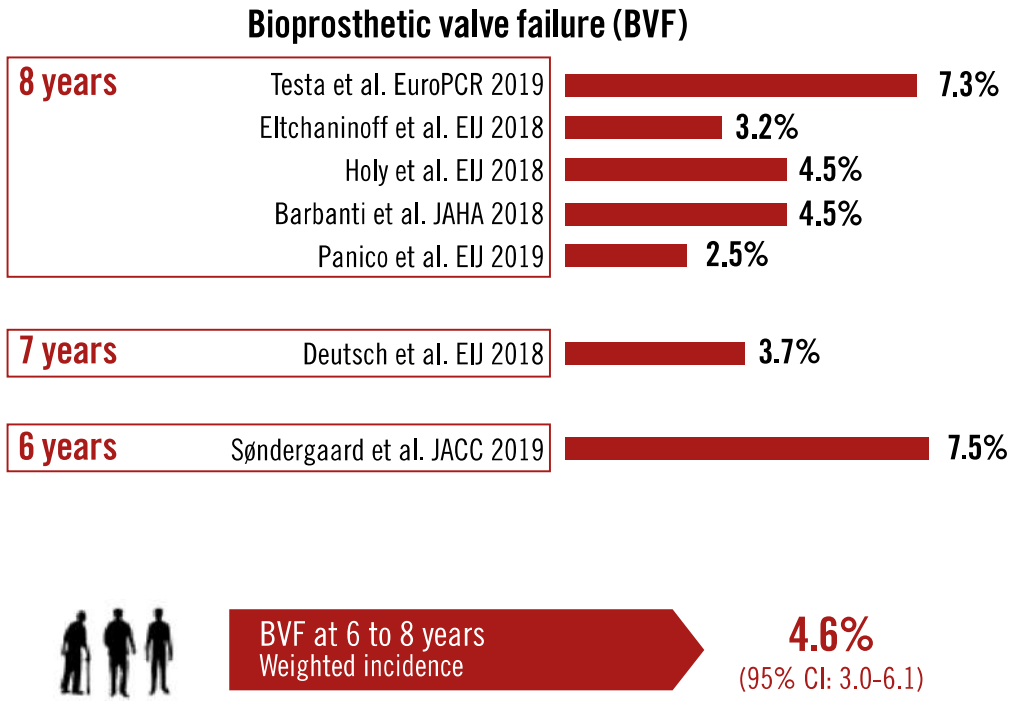
Table 3 Structural valve deterioration

Moderate haemodynamic SVD (any of the following)
Mean transprosthetic gradient ≥20 mmHg and <40 mmHg
Mean transprosthetic gradient ≥10 and <20 mmHg change from baseline
Moderate intra-prosthetic aortic regurgitation, new or worsening (>1+/4+) from baseline
Severe haemodynamic SVD (any of the following)
Mean transprosthetic gradient ≥40 mmHg
Mean transprosthetic gradient ≥20 mmHg change from baseline
Severe intra-prosthetic aortic regurgitation, new or worsening (>2+/4+) from baseline
Morphological SVD (any of the following)
Leaflet integrity abnormality (i.e. torn or flail causing intra-frame regurgitation)
Leaflet structure abnormality (i.e. pathological thickening and/or calcification causing valvular stenosis or central regurgitation)
Leaflet function abnormality (i.e. impaired mobility resulting in stenosis and/or central regurgitation)
Strut/frame abnormality (i.e. fracture)
Haemodynamic and morphological SVD

SVD, structural valve deterioration.



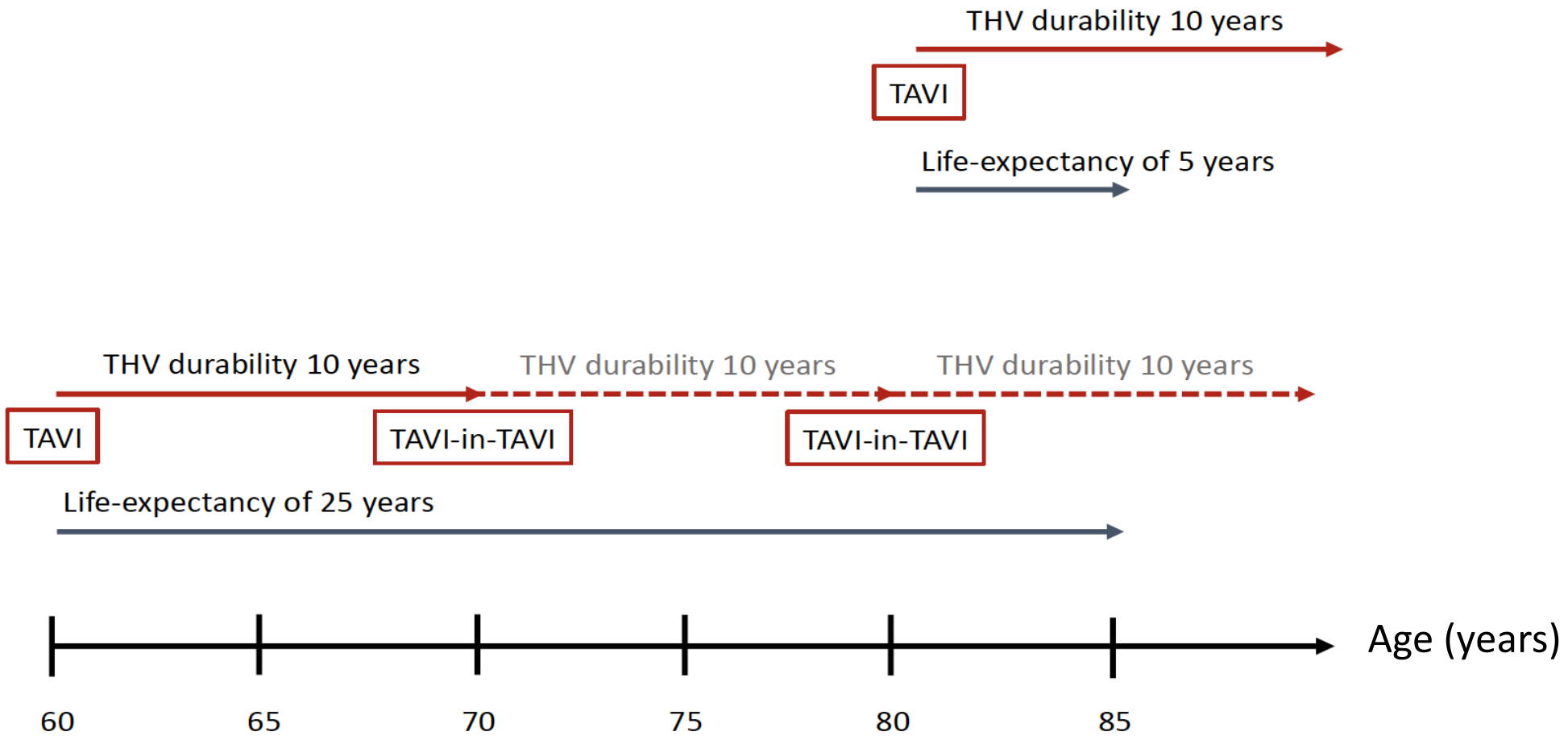




"… time will tell, but so far, so good"

Capodanno et al, EI 2019

TAVI & patient life-expectancy



Sondergaard. Eur Heart J. 2019;40:1331-3

TAVI-in-TAVI: what do we know?

Structural Heart Disease

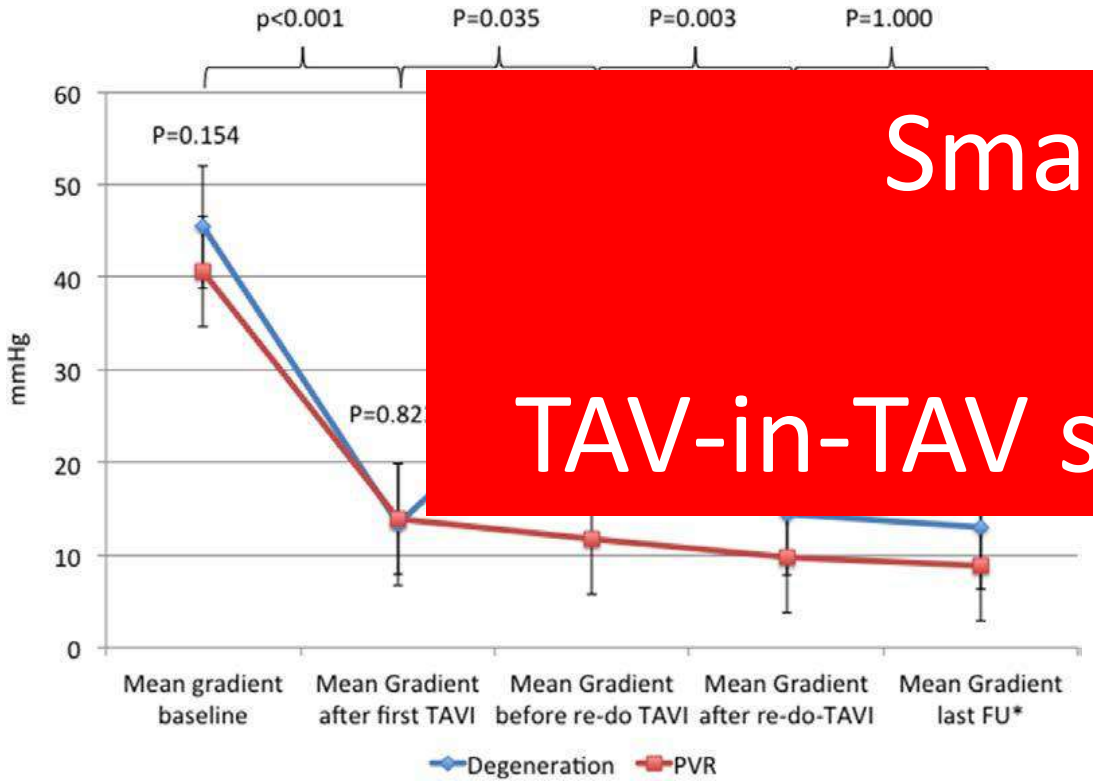
Outcomes of Redo Transcatheter Aortic Valve Replacement for the Treatment of Postprocedural and Late Occurrence of Paravalvular Regurgitation and Transcatheter Valve Failure

Marco Barbanti, MD; John G. Webb, MD; Claudia Tamburino, MD; Nicolas M. Van Mieghem, MD, PhD; Raj R. Makkar, MD; Nicolò Piazza, MD; Azeem Latib, MD; Jan-Malte Sinning, MD; Kim Won-Keun, MD; Sabine Bleiziffer, MD; Francesco Bedogni, MD; Samir Kapadia, MD; Didier Tchetche, MD; Josep Rodés-Cabau, MD; Claudia Fiorina, MD; Luis Nombela-Franco, MD; Federico De Marco, MD; Peter P. de Jaegere, MD, PhD; Tarun Chakravarty, MD; Beatriz Vaquerizo, MD; Antonio Colombo, MD; Lars Svensson, MD; Rüdiger Lange, MD; Georg Nickenig, MD; Helge Möllmann, MD; Thomas Walther, MD; Francesco Della Rosa, MD; Yacine Elhmidi, MD; Danny Dvir, MD; Nedy Brambilla, MD; Sebastiano Immè, MD; Carmelo Sgroi, MD; Simona Gulino, MD; Denise Todaro, MD; Gerlando Pilato, MD; Anna Sonia Petronio, MD; Corrado Tamburino, MD, PhD

Circulation Cardiovascular Interventions 2016

- Multicentric registry (~14000 pts)
- 50 pts with TAVI failure
- 50% SVD, 50% PVL
- At least 2 weeks after implant
- TAVI: 75% self-expandable

TAVI-in-TAVI: what do we know?



Small cohort

TAV-in-TAV safe and feasible

- RE-DO: same device in 80% of cases
- n 80% of cases
- rast media
- in hospital: no death, no stroke
- One case of coronary occlusion
- One case of TAVI embolization

Estimated annual numbers of TAVI candidates in different countries

- Currently,approximately **115,000 patients** can be considered potential TAVI candidates Europe.

- This number might increase up to over **175,000 patients** if indications for TAVI expand to low- risk patients.

These findings have a major impact on health care resource planning. Knowing the number of potential candidates aid health care systems preparing for the future needs. Human resource and hospital volume requirements can be forecasted, along with the expected budgetary requirements.[24] Moreover, these numbers help the indus-

Under current indications
TAVI indicated for following patients:

- ☑ Inoperable
- ☑ High risk
- ☑ Intermedidate risk
- ❑ Low risk

- ☑ Inoperable
- ☑ High risk
- ☑ Intermedidate risk
- ☑ Low risk

Durko A. P. et al. Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections. Eur Heart J 2018; 0, 1–8

3.6 Concept of the Heart Team and heart valve centres

- Multidisciplinary teams
- Expertise in all surgical/percutaneous valve procedures
- High volume
- Competence in complex valve procedures
- Advenced imaging capability
- Results accountability

CENTROS DE REFERÊNCIA
PORTUGAL

ESC VHD guidelines, 2017

Conclusions

- TAVI first
- Caution with younger patients (?)
- TAVI durability: so far, so good
- System capacitation