

TAVI - Update

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Disclosure

Speaker name: Matthias Thielmann

.....

I have the following potential conflicts of interest to report:

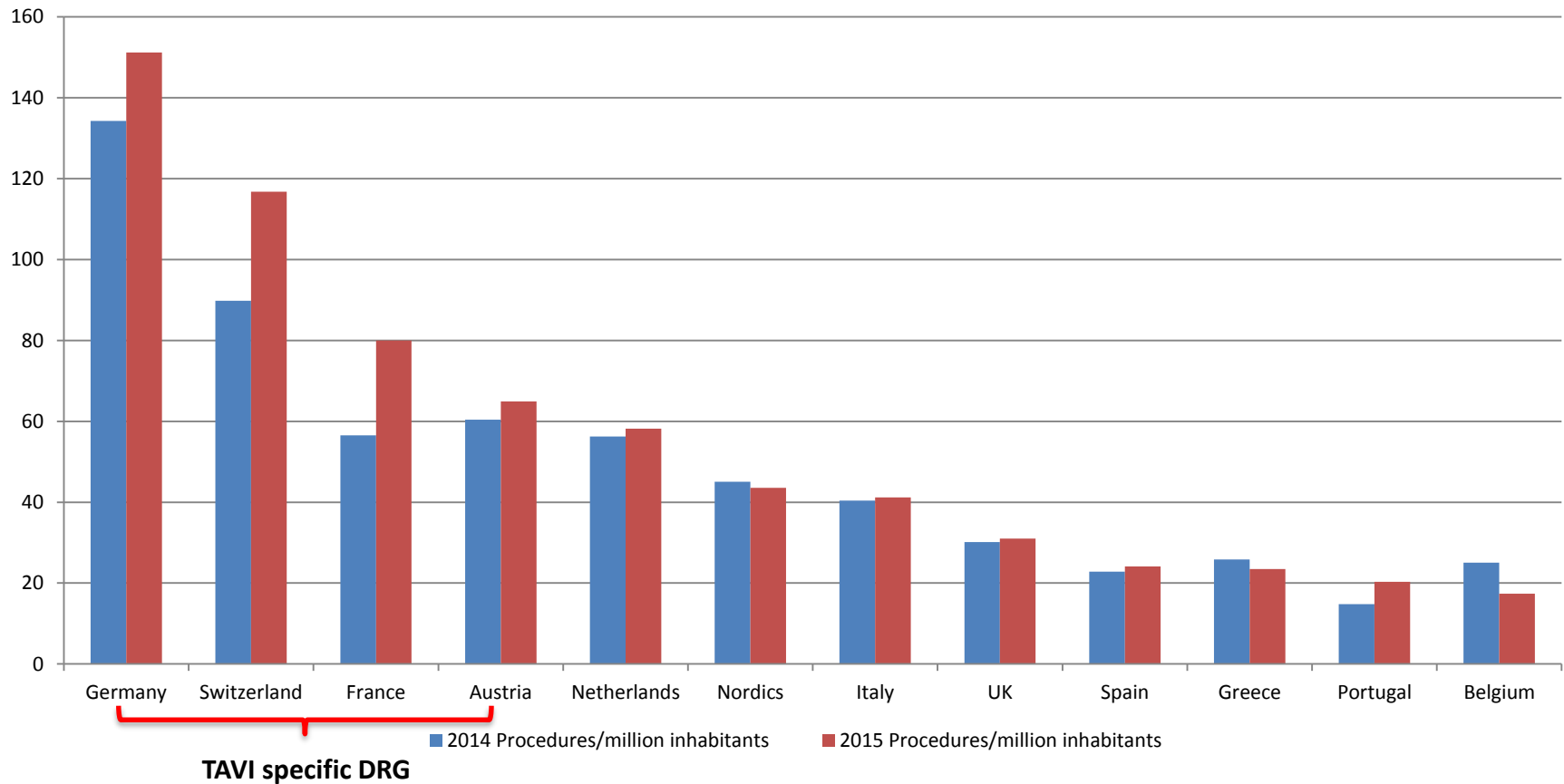
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☒ I do not have any potential conflict of interest

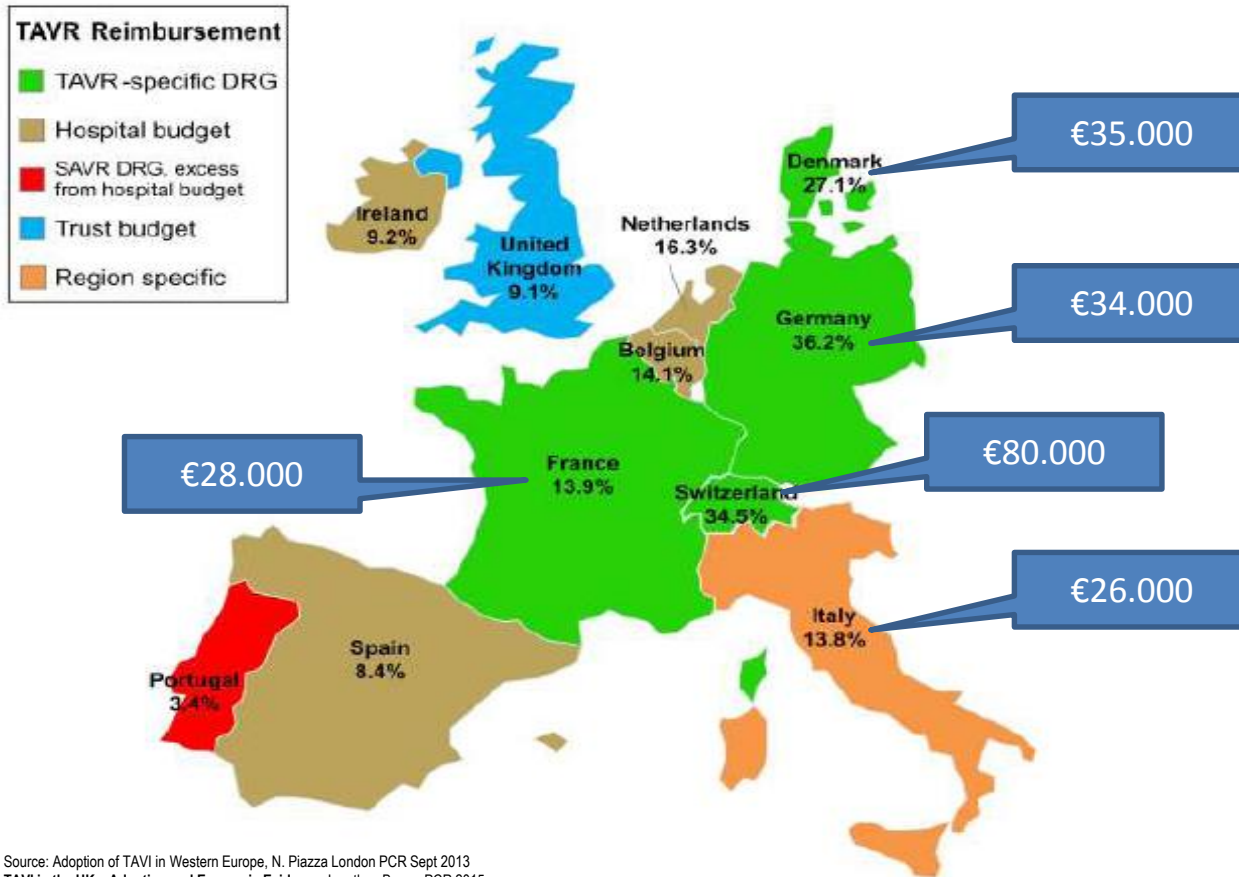
...except that fact that I am a CV surgeon, experienced in TAVI (~500) as well as sAVR (>1000)

2014 and 2015 TAVI Penetration In Europe

TAVI Procedures/million inhabitants



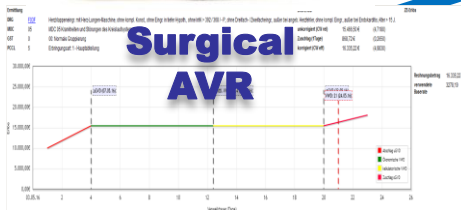
TAVI Reimbursement In EU-Countries



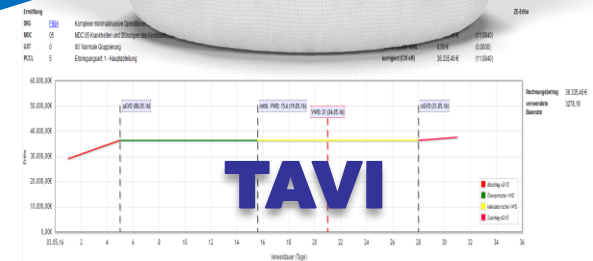
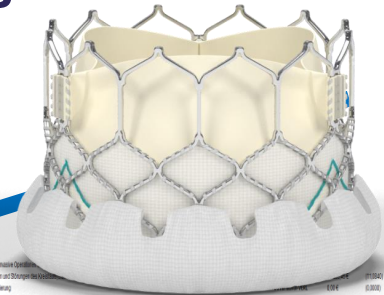
Source: Adoption of TAVI in Western Europe, N. Piazza London PCR Sept 2013
TAVI in the UK – Adoption and Economic Evidence Jonathan Byrne, PCR 2015

Current TAVI Reimbursement in Germany

DRG for TAVI is currently ~2-3-fold higher
in the same AS candidate!



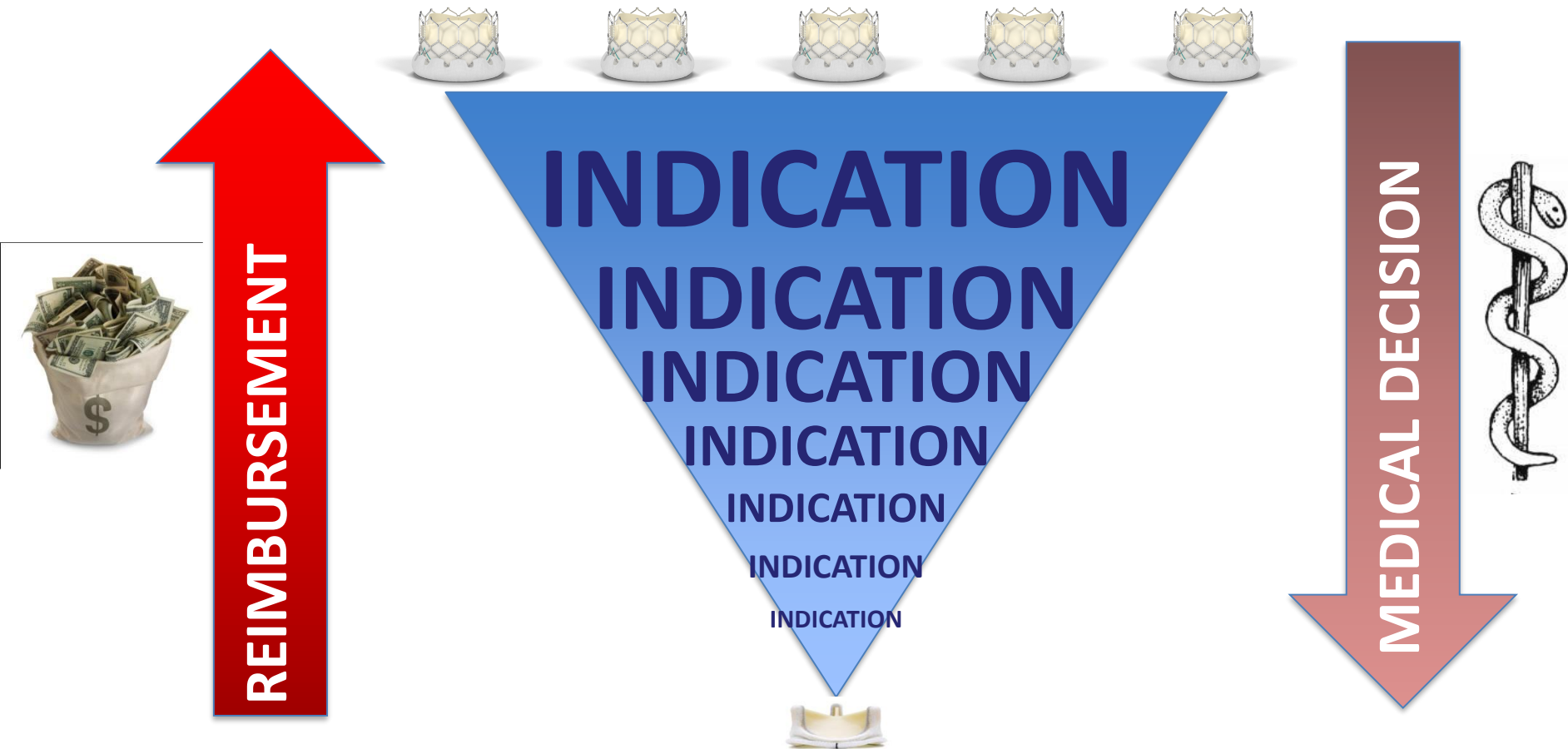
~15.000 Euro



~35.000 Euro



The Dilemma: 'Indication follows Reimbursement'



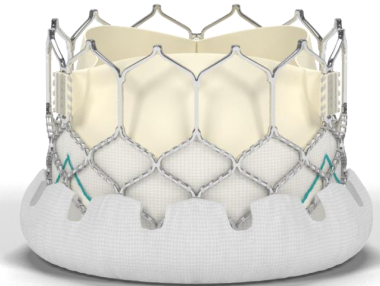
Hospital management and physicians are not rewarded for best treatment but rather for best DRG!

Current & Future Indications?

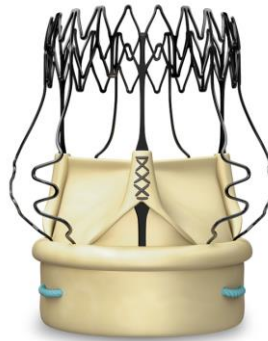
Multidisciplinary 'Heart Team'



sAVR



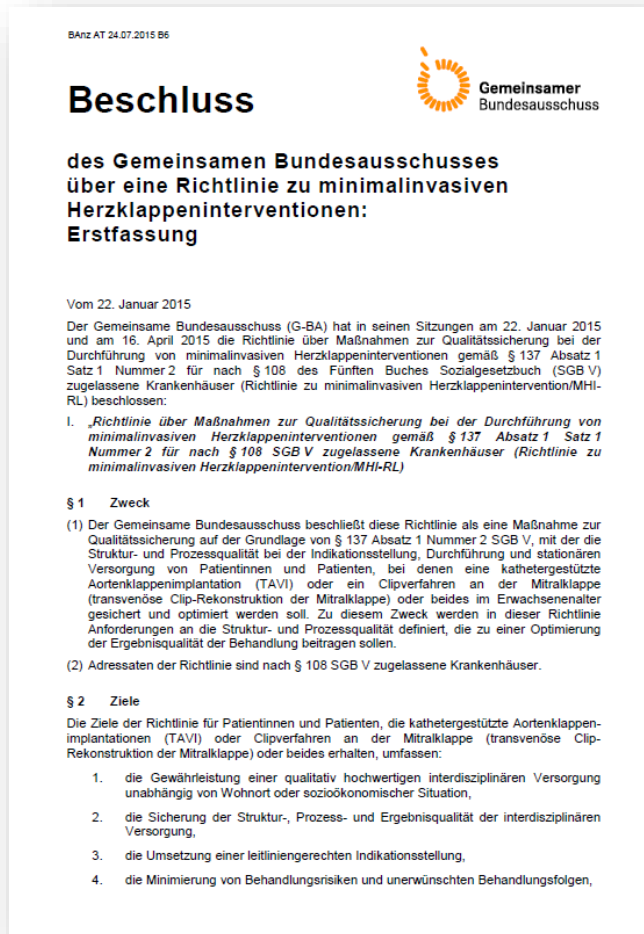
TAVI



sutureless AVR

„Guideline For Minimal-invasive Heart Valve Interventions“

Mutual Resolution By The German Federal Government Commission (G-BA)



TAVI & MitraClip in Germany



Quality guidelines:

- Indication & decision-making
- Institutional treatment

Legal prerequisites:

- structural (heart team)
- institutional (IVC + CVS)
- professionally qualified & skilled
- certified by review committee

State Of The Art In TAVI



Two Different Concepts

balloonexpandable



**bovine pericardial tissue +
cobalt-chromium stent**

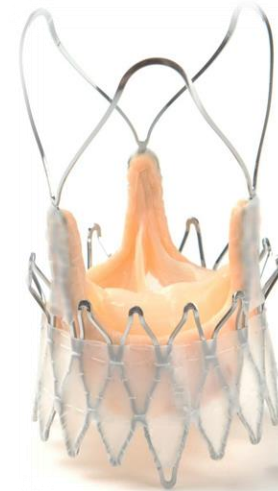
selfexpandable



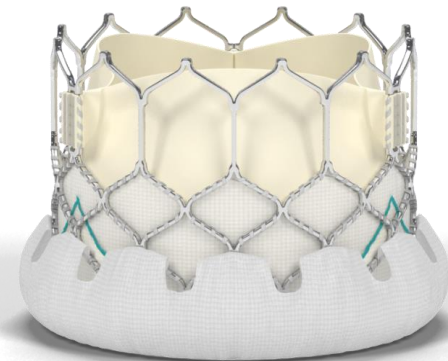
Porcine tissue + nitinol stent

2nd & 3rd THV-Generation - Reduction of PVLs

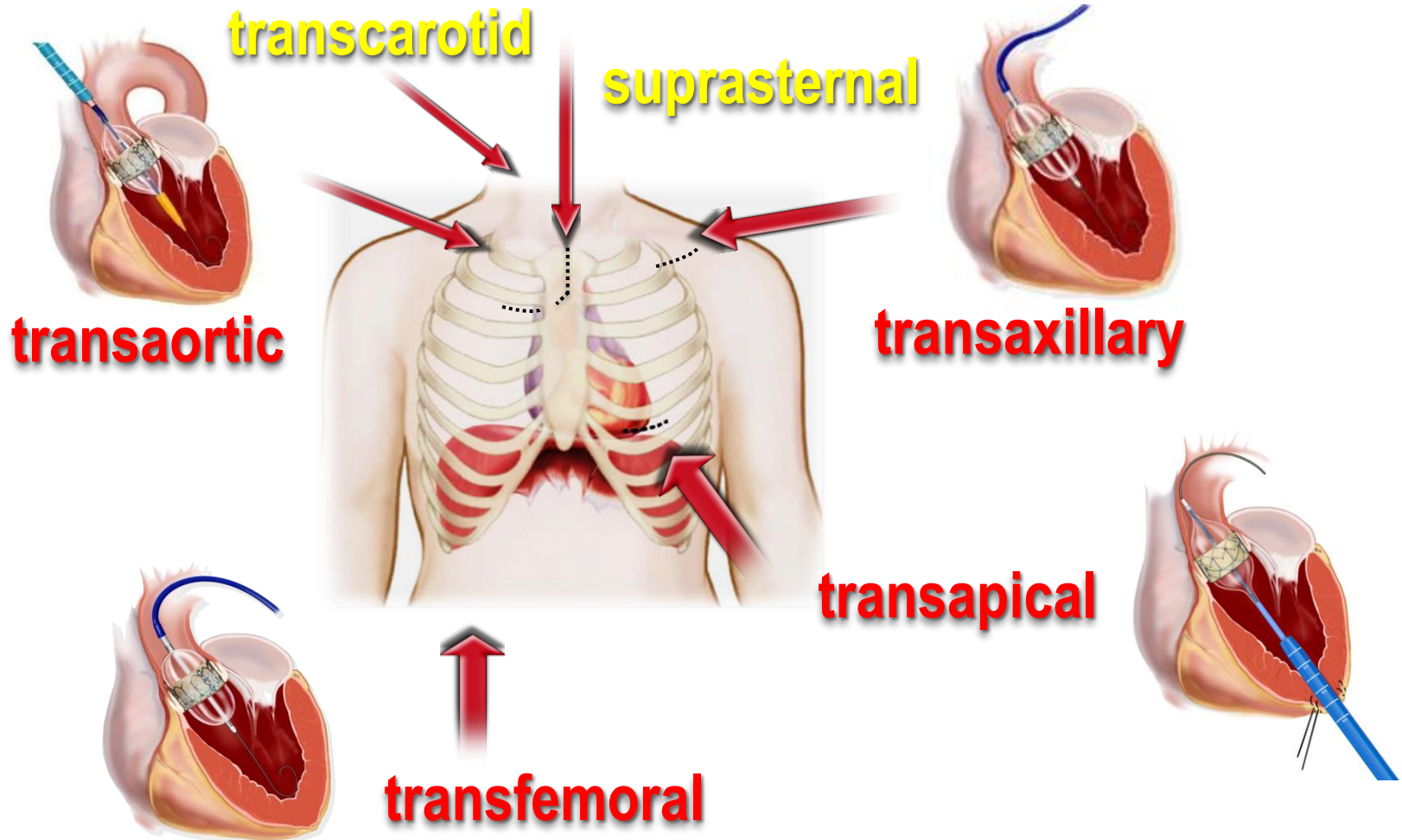
“subannular fixation”



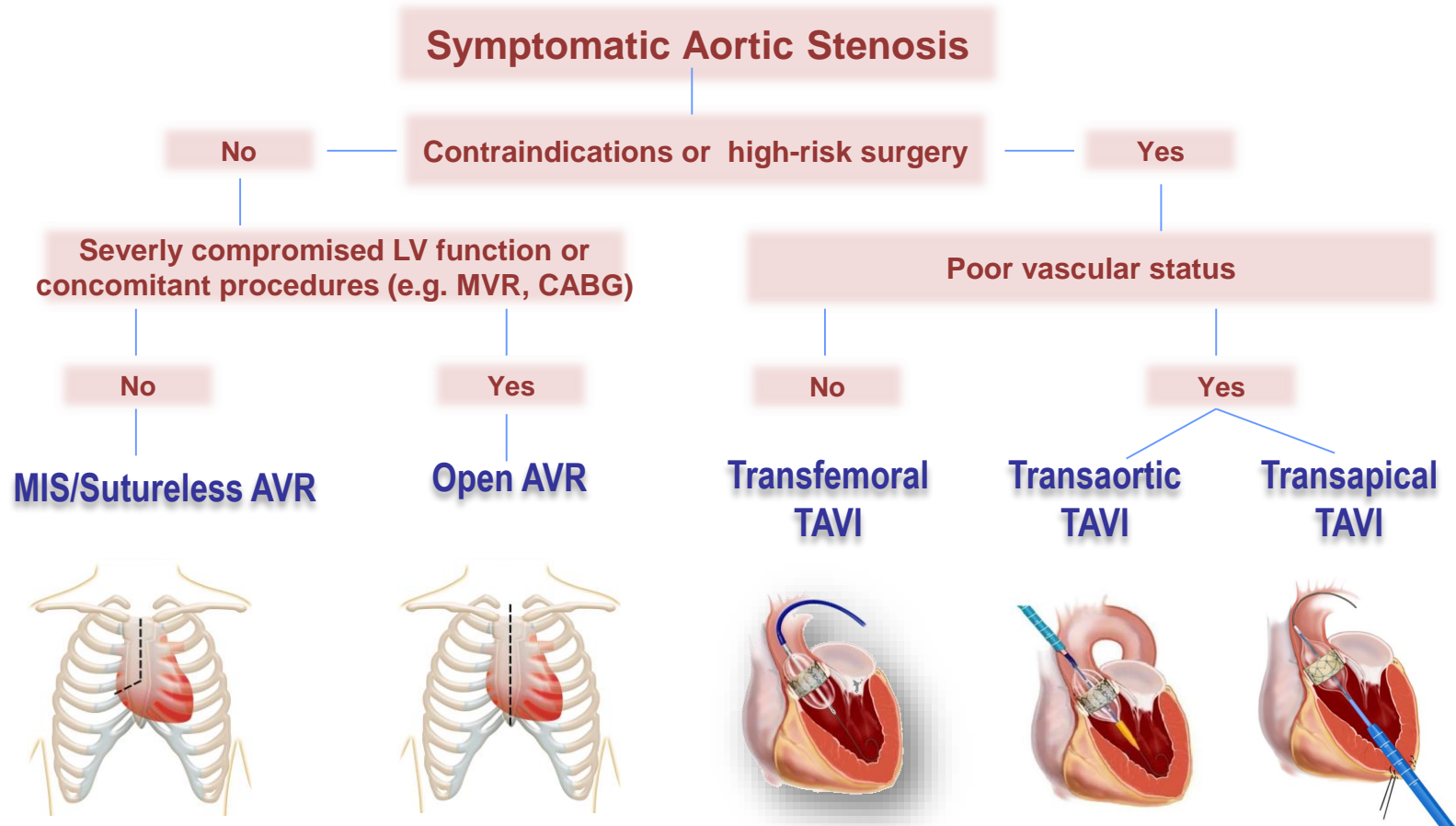
“space filler”



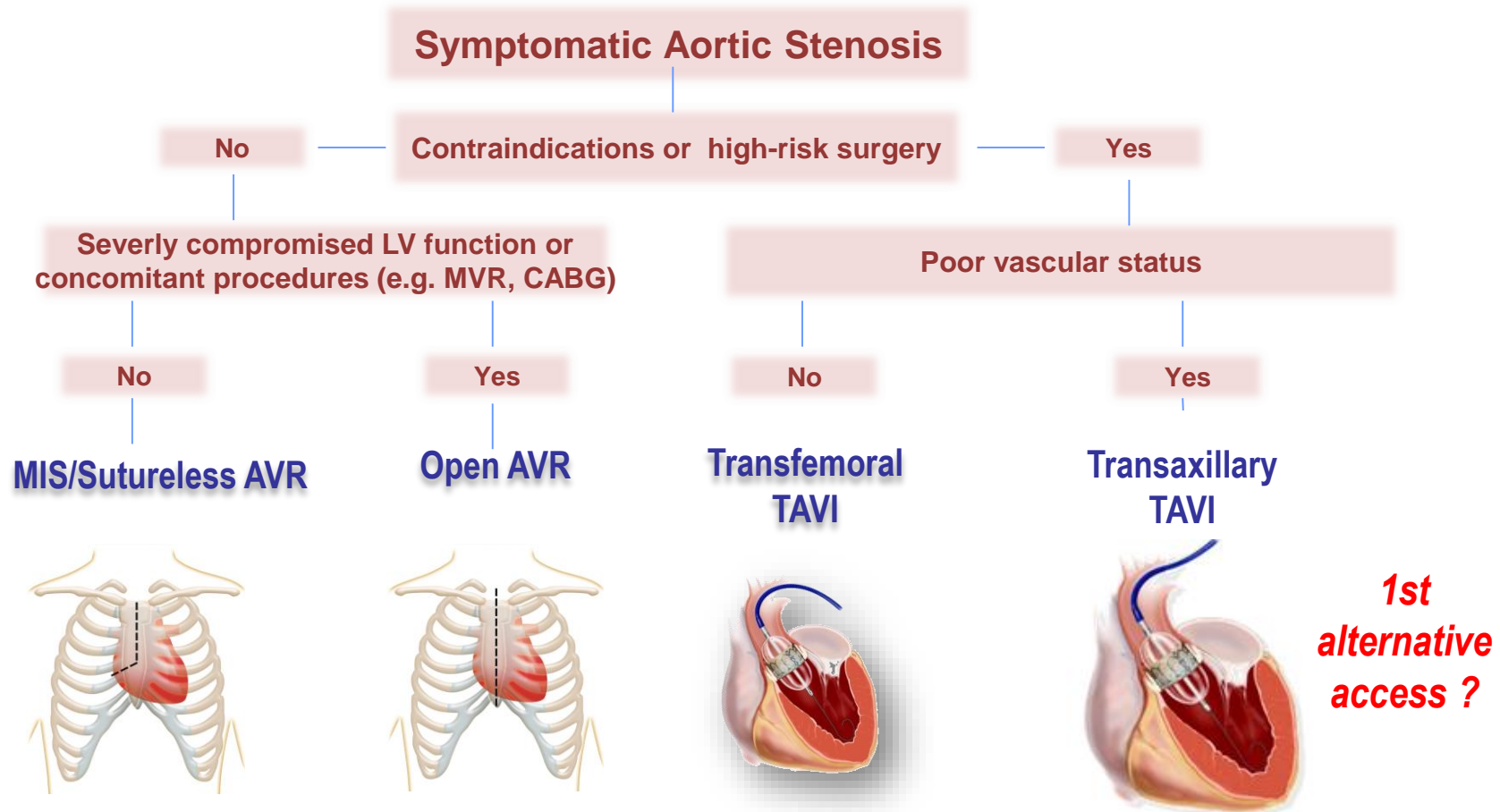
...Via Different Approaches!



West-German Heart Center Strategy...so far



West-German Heart Center Strategy...*in near future* ?



West-German Heart Center TAVI SOP

“Standard Operating Procedure” for TAVI practice



**West-German Heart Center TAVI Team
(2 Senior Cardiologists, 2 Senior Surgeons)**



1
Transkatheter-Aortenklappenimplantationen (TAVI)
am Westdeutschen Herz- und Gefäßzentrum (WHGZ) Essen:

Standard Operating Procedure
bezüglich Struktur, Indikationsstellung und Durchführung
gemäß aktueller Qualitätsstandards

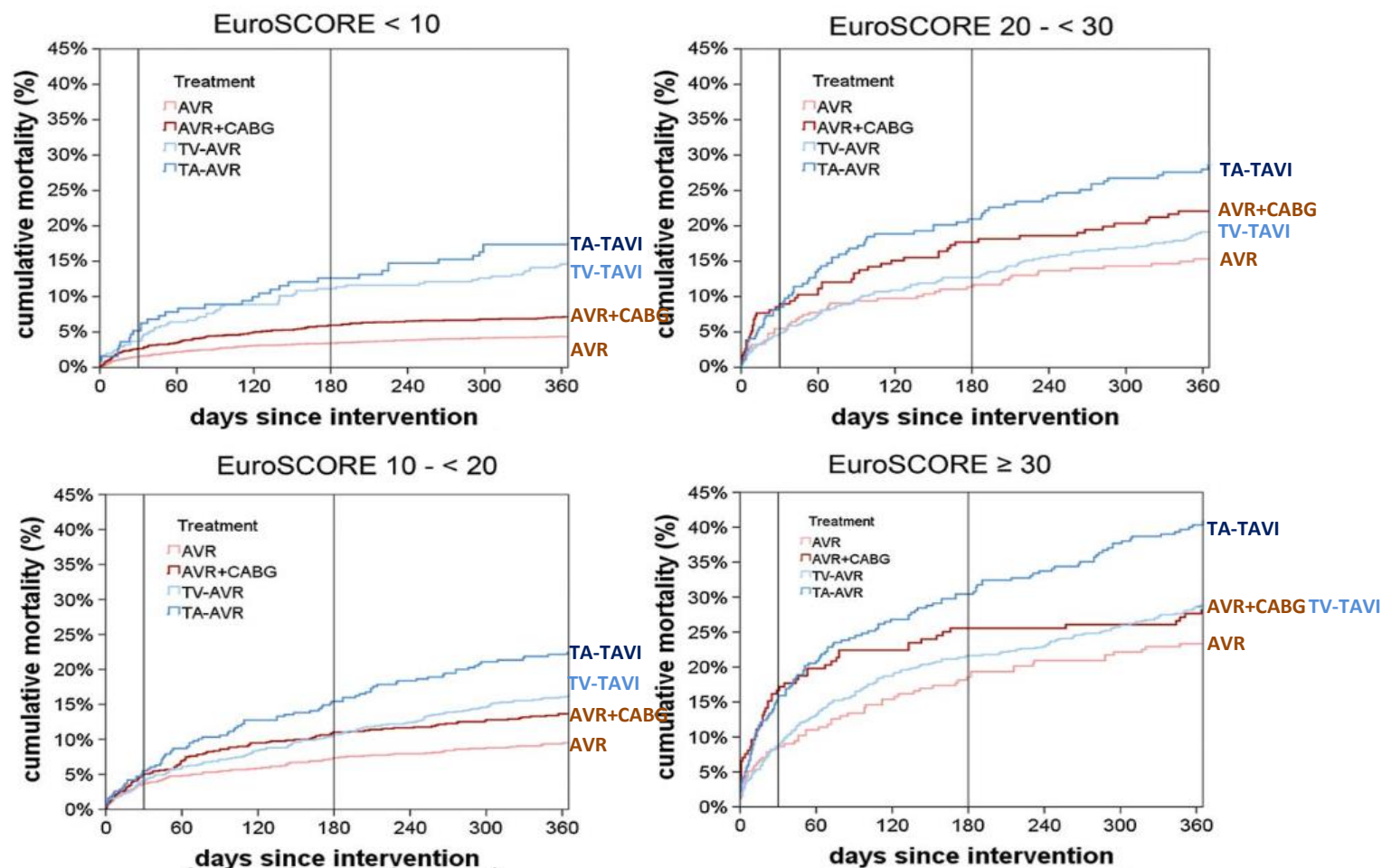
am 26.11.2014 vom Direktorium des WHGZ einstimmig verabschiedete Version

Gliederung

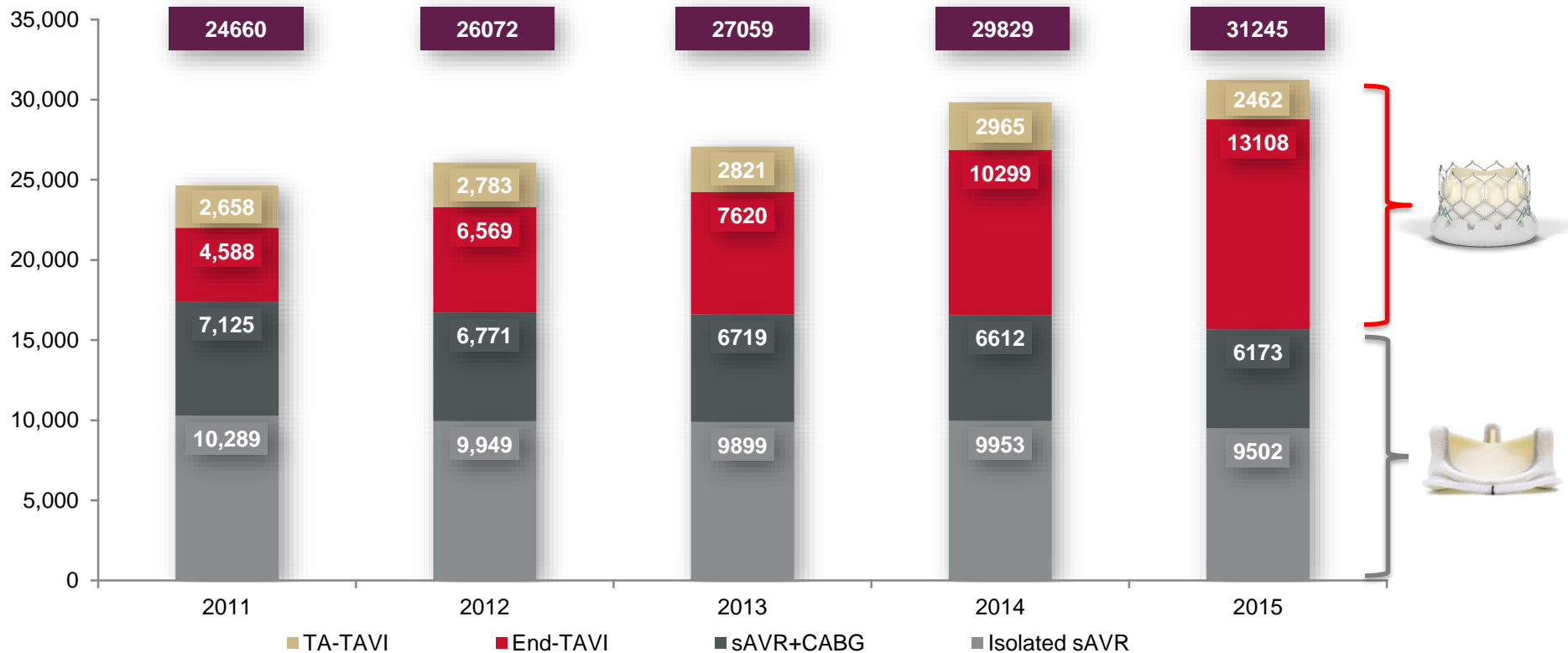
1. Strukturqualität	2
1.1 Infrastruktur	2
1.2 Personal	2
1.3 Mitwirkung externer Kollegen	3
2. Indikationsqualität	3
3. Prozessqualität	4
3.1 stationäre Aufnahme	4
3.2 vorbereitende Diagnostik	6
3.3 Aufklärung	6
3.4 Komplikationsmanagement	6
3.5 postinterventionelle Nachbetreuung	7
3.6 Verlaufskontrollen	7
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The German Aortic Valve Registry – GARY

Time-to-event curves for death stratified by the logistic EuroSCORE (n=13639)

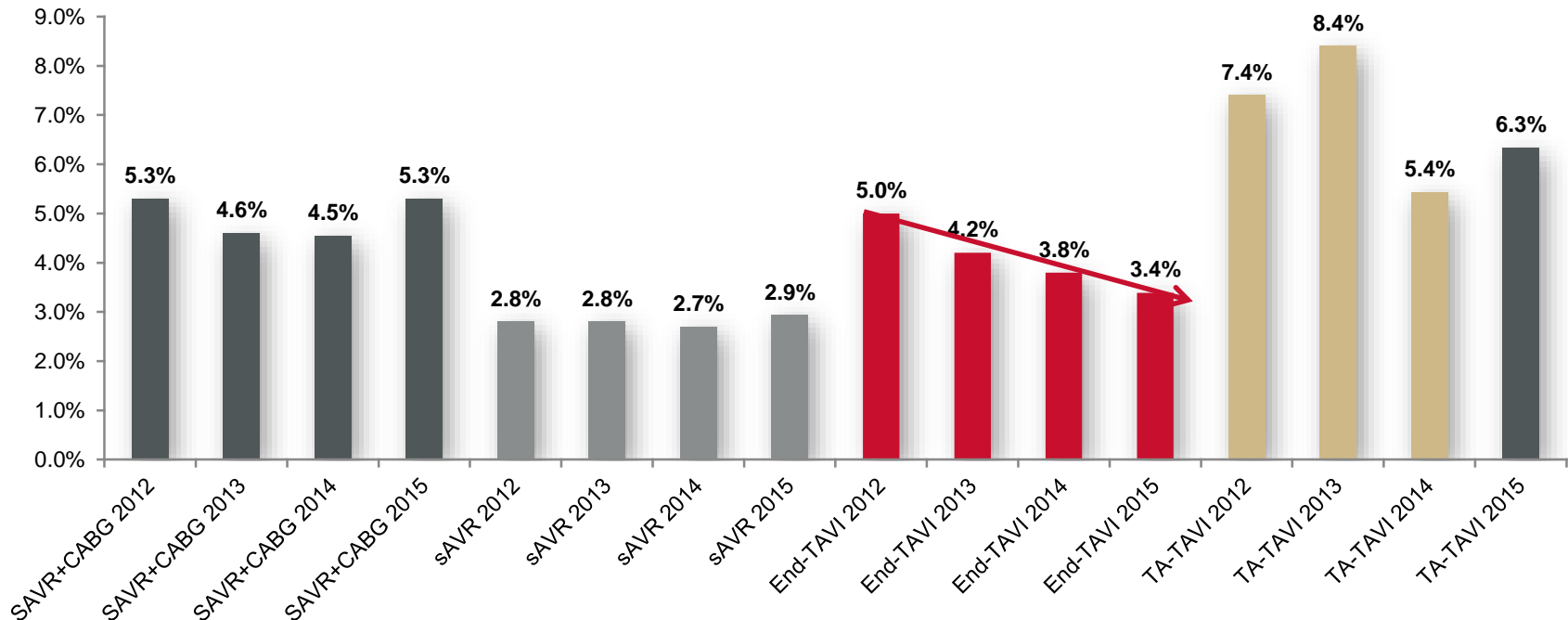


Evolution Of Aortic Valve Procedures In Germany



- Since 2014 TAVI > sAVR
- Strong increase in endovasc TAVI, decrease in transapical TAVI
- Decrease in sAVR both isolated and combined with CABG

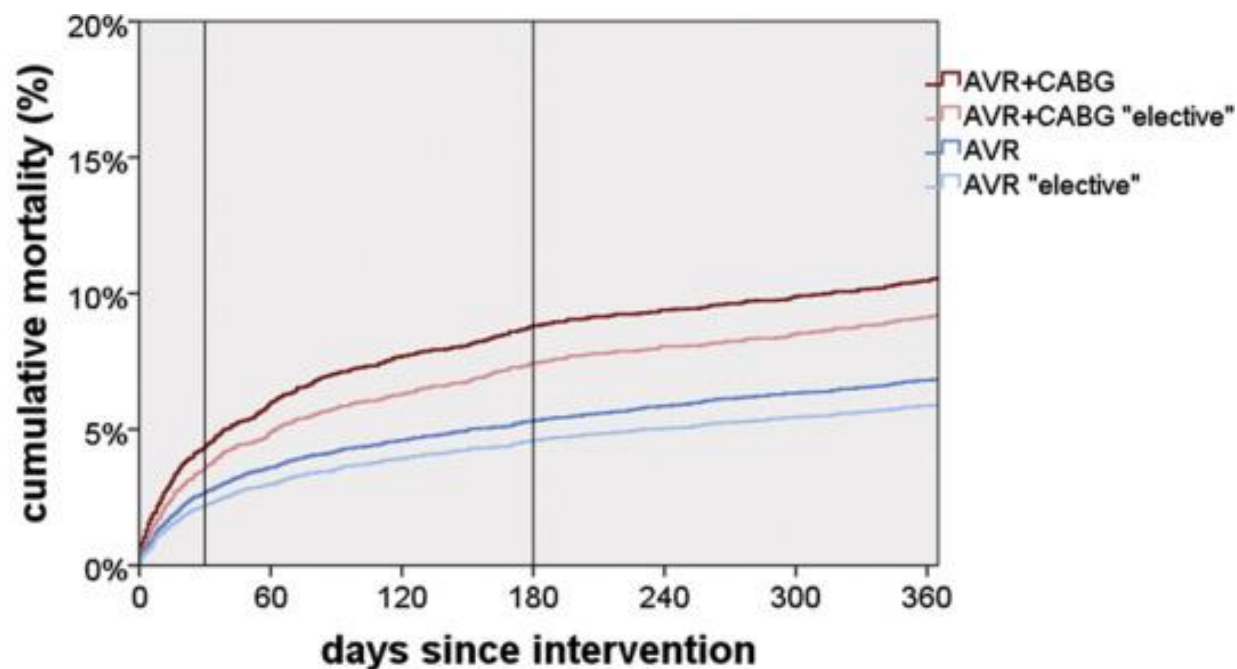
In-hospital mortality evolution in Germany



- Overall decrease in mortality in endovascular TAVI. It is the only access route with a decrease in mortality
- Mortality in endovascular TAVI is getting close to SAVR in-hospital mortality

The German Aortic Valve Registry (GARY)

Mortality of patients undergoing AVR for all four subgroups (n=34063)



Death	sAVR (el.)	sAVR	sAVR+CABG (el.)	sAVR+CABG
In-hospital	1.9%	2.3%	3.5%	4.4%
180 Days	4.6%	5.3%	7.4%	8.8%
365 Days	5.9%	6.8%	9.2%	10.6%

‘Minimalist’ Approach: Optimizing Without Compromizing!

Minimalist transcatheter aortic valve replacement: The new standard for surgeons and cardiologists using transfemoral access?

Hanna A. Jensen, MD, PhD,^a Jose F. Condado, MD,^b Chandan Devireddy, MD,^b Jose Binongo, PhD,^c Bradley G. Leshnower, MD,^a Vasilis Babaliaros, MD,^b Eric L. Sarin, MD,^a Stamatios Lerakis, MD,^b Robert A. Guyton, MD,^a James P. Stewart, MD,^b Amjadullah Q. Syed, MD,^a Kretan Mavromatis, MD,^b Brian Kaebnick, MD,^b Mohammad Hossein Rajaei, MD,^a Lillian L. Tsai, AB,^a Ayaz Rahman, MD,^b Amy Simone, PA,^a Patricia Keegan, NP,^b Peter C. Block, MD,^b and Vinod H. Thourani, MD^a

Jensen et al. JTCVS 2015;150:833-9.

JACC: CARDIOVASCULAR INTERVENTIONS
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<http://dx.doi.org/10.1016/j.jcin.2014.04.005>

Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) Versus Hybrid Operating Room (Standard Approach) Outcomes and Cost Analysis

Vasilis Babaliaros, MD,* Chandan Devireddy, MD,* Stamatios Lerakis, MD,* Robert Leonardi, MD,* Sebastian A. Ijuma, MD,† Kretan Mavromatis, MD,* Bradley G. Leshnower, MD,† Robert A. Guyton, MD,† Mihir Kanikar, MD,* Patricia Keegan, NP,* Amy Simone, PA,† James P. Stewart, MD,* Nima Ghasemzadeh, MD,* Peter Block, MD,* Vinod H. Thourani, MD†

Babaliaros et al. JACC Cardiovasc Int 2014;7:898-904.

Sedation or general anesthesia for patients undergoing transcatheter aortic valve implantation—does it affect outcome? An observational single-center study ☆,☆☆

Or Goren MD^{a,*}, Ariel Finkelstein MD^b, Andrei Gluch MD^a, Nechama Sheinberg MD^a, Elia Dery MSc^a, Idit Matot MD^a

^aDivision of Anesthesiology, Pain, and Intensive Care, Tel Aviv Medical Center, Tel Aviv University, Tel Aviv, Israel

^bDepartment of Cardiology, Tel Aviv Medical Center, Tel Aviv University, Tel Aviv, Israel

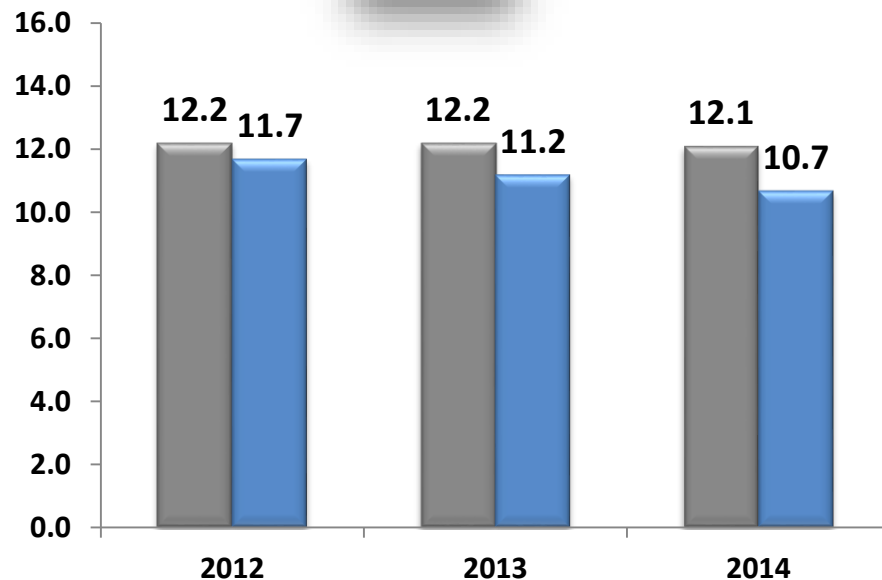
Or Goren et al. Journal of Clinical Anesthesia 2015;5385–90.

- Acquiring experience and “mastering” the TAVI procedure
- Local anesthesia as the preferred approach
- Simplifying TAVI procedure
- Standardized care
- Avoiding complications
- Limiting ICU stay
- Optimizing the length of stay
- Understanding optimal reimbursement conditions

Evolution of Length of Stay - sAVR vs. TAVI



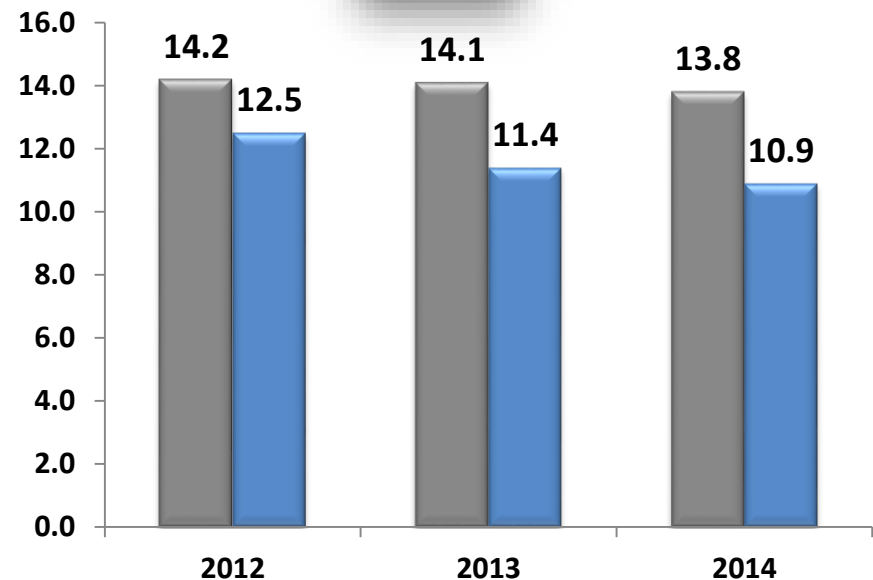
Germany



Source: AQUA – quality report



France



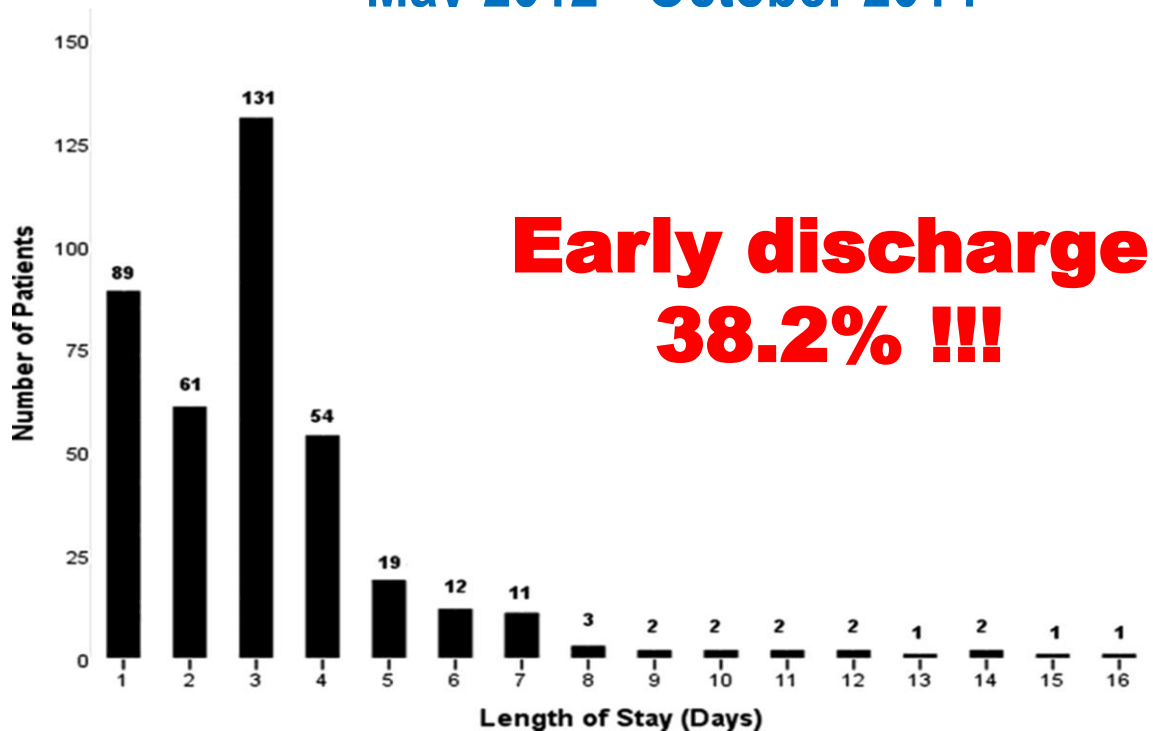
Source: PMSI-database

Mean length of stay (days)



Vancouver ,Minimalist' Approach in TAVI

Length of stay in 393 consecutive patients discharged after TAVI
May 2012 - October 2014

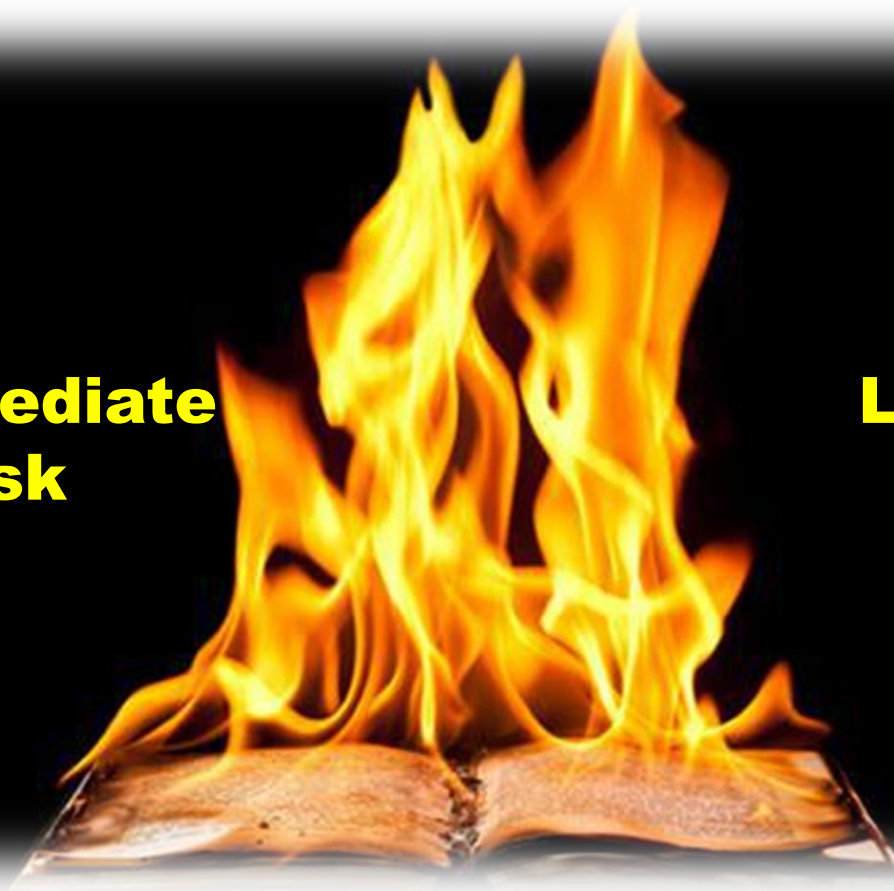


Lauck et al. Circ Cardiovasc Qual Outcomes. 2016;9:312-321

Hottest Current TAVI Data!

**Intermediate
risk**

**Lower
risk**



PARTNER II Cohort A - Intermediate risk

Methods

2,032 patients with severe symptomatic AS and **intermediate surgical risk** from 55 sites in the US and Canada were included.

Criteria for inclusion

- Severe AS (aortic valve area <0.8 cm or AVA index <0.5 cm/m²)
- Signs of heart failure (NYHA class \geq II)
- Intermediate risk (STS score ≥ 4 % and decision by a heart team)

Primary endpoint

- Combination of all-cause mortality or disabling stroke at two years

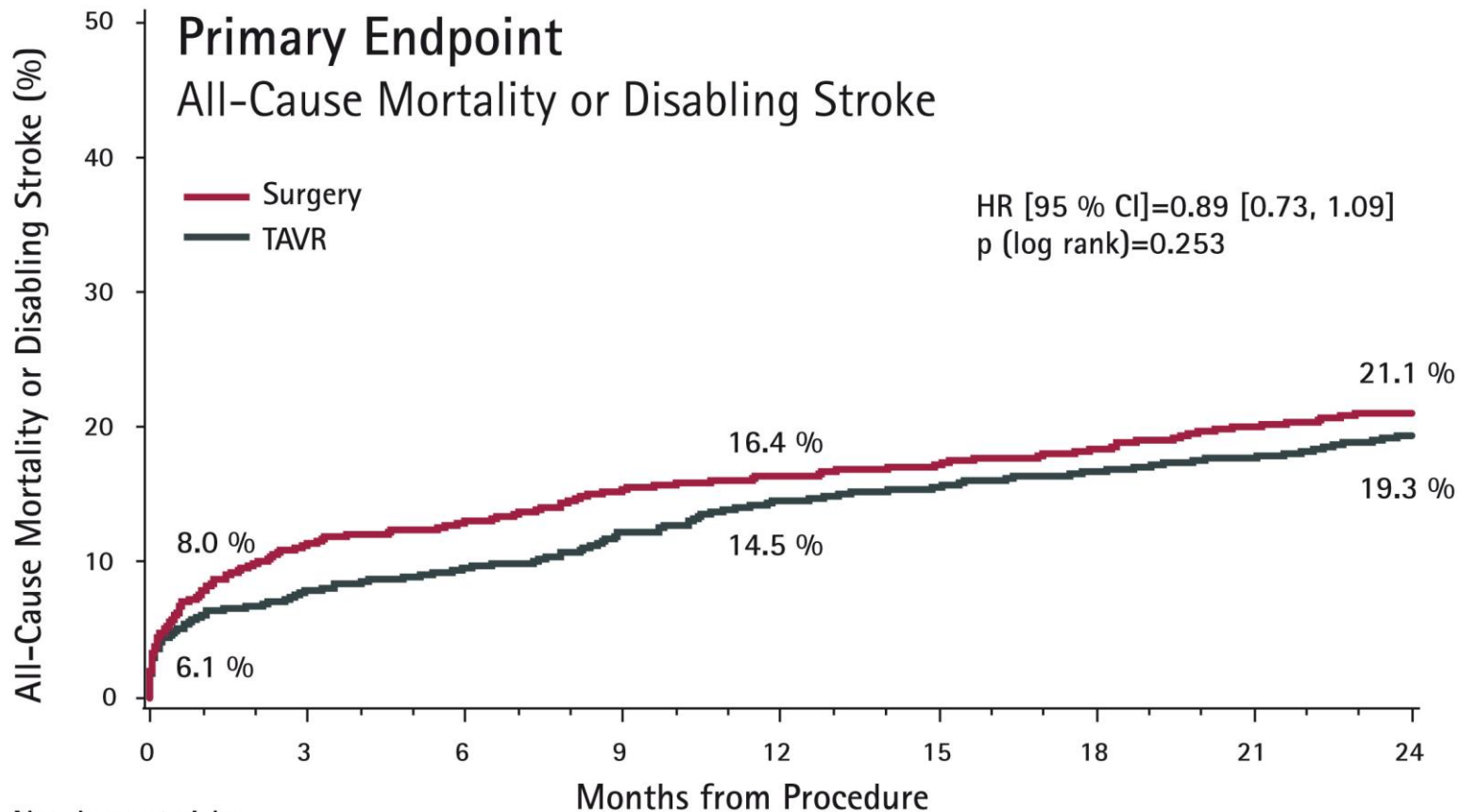
Study design and patient characteristics

Both groups were randomized 1:1 to receive either TAVI or sAVR.

775 patients received transfemoral TAVI and 236 transapical/transaortic TAVI with the SAPIEN XT, while 1,021 received sAVR.

- **Mean age: 81.5y (TAVI) vs. 81.7y (sAVR)**
- **Mean STS score: 5.8 vs. 5.8 %**
- NYHA class III or IV: 77.3 vs. 76.1 %

PARTNER II Cohort A - Intermediate risk



Numbers at risk:

Surgery	1,021	838	812	783	770	747	735	717	695
TAVR	1,011	918	901	870	842	825	811	801	774

Conclusions & Limitations - PARTNER II Cohort A

CONCLUSIONS

- The PARTNER II A study shows the non-inferiority of the TAVI procedure with a second-generation prosthesis as compared to surgical valve replacement.
- This cohort demonstrates for the first time that transfemoral TAVI is to be actually superior to surgical AVR.

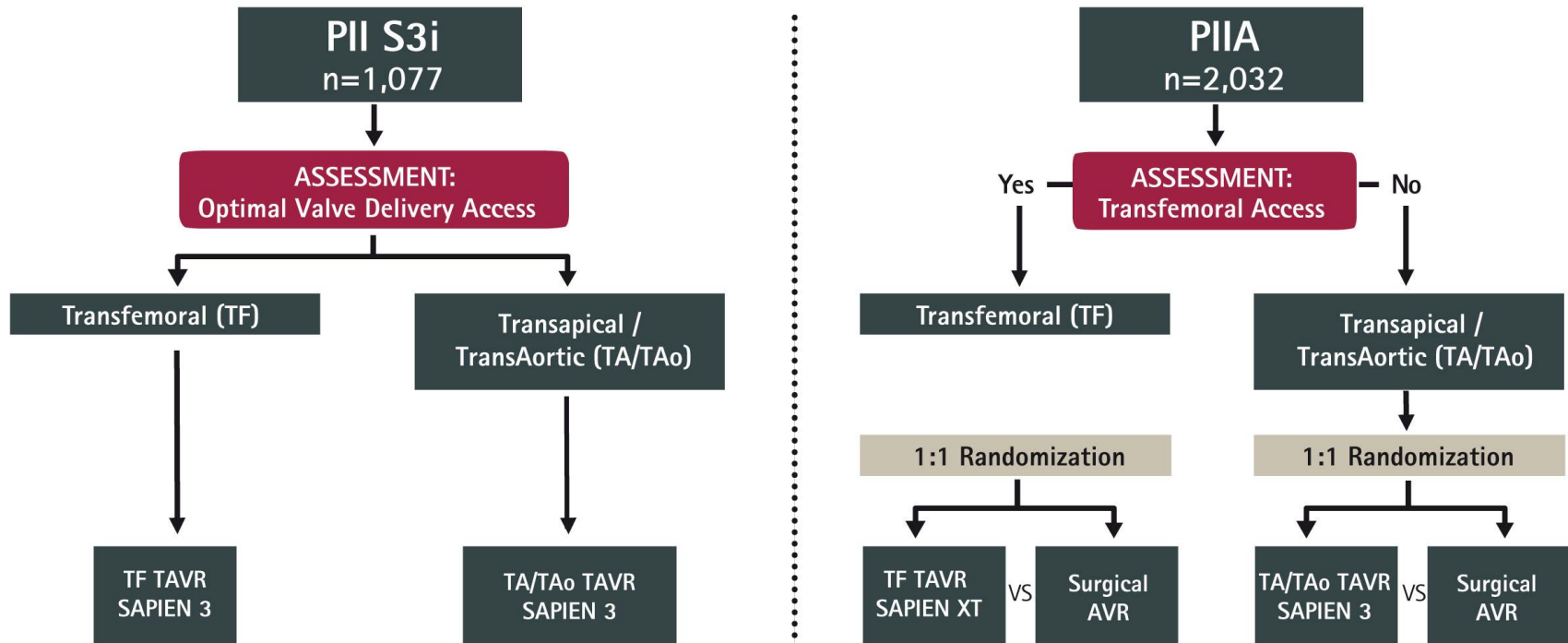
...but

- Not really intermediate risk patients!
- *"...patients are still among the high risk quintile of AS who are candidates for surgery in the US and elsewhere"...*
- 26% had previous CABG (redo!), 14% sAVR had concomitant CABG
- 9% sAVR had other concomitant procedures (aortic endarterectomy, aortic root replacement, MVR or tricuspid).

PARTNER II S3i - Intermediate risk

Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team



PARTNER II S3i - Intermediate risk

Methods

1,077 patients with severe symptomatic AS and **intermediate surgical risk** from 51 US sites were included.

Criteria for inclusion

- Severe AS
(aortic valve area <0.8 cm or aortic valve index <0.5 cm²/m² and aortic valve gradient >40 mmHg or peak velocity >4.0 m/s)
- **Intermediate surgical risk (STS score 4-8 or decision by a heart team)**

Patient characteristics

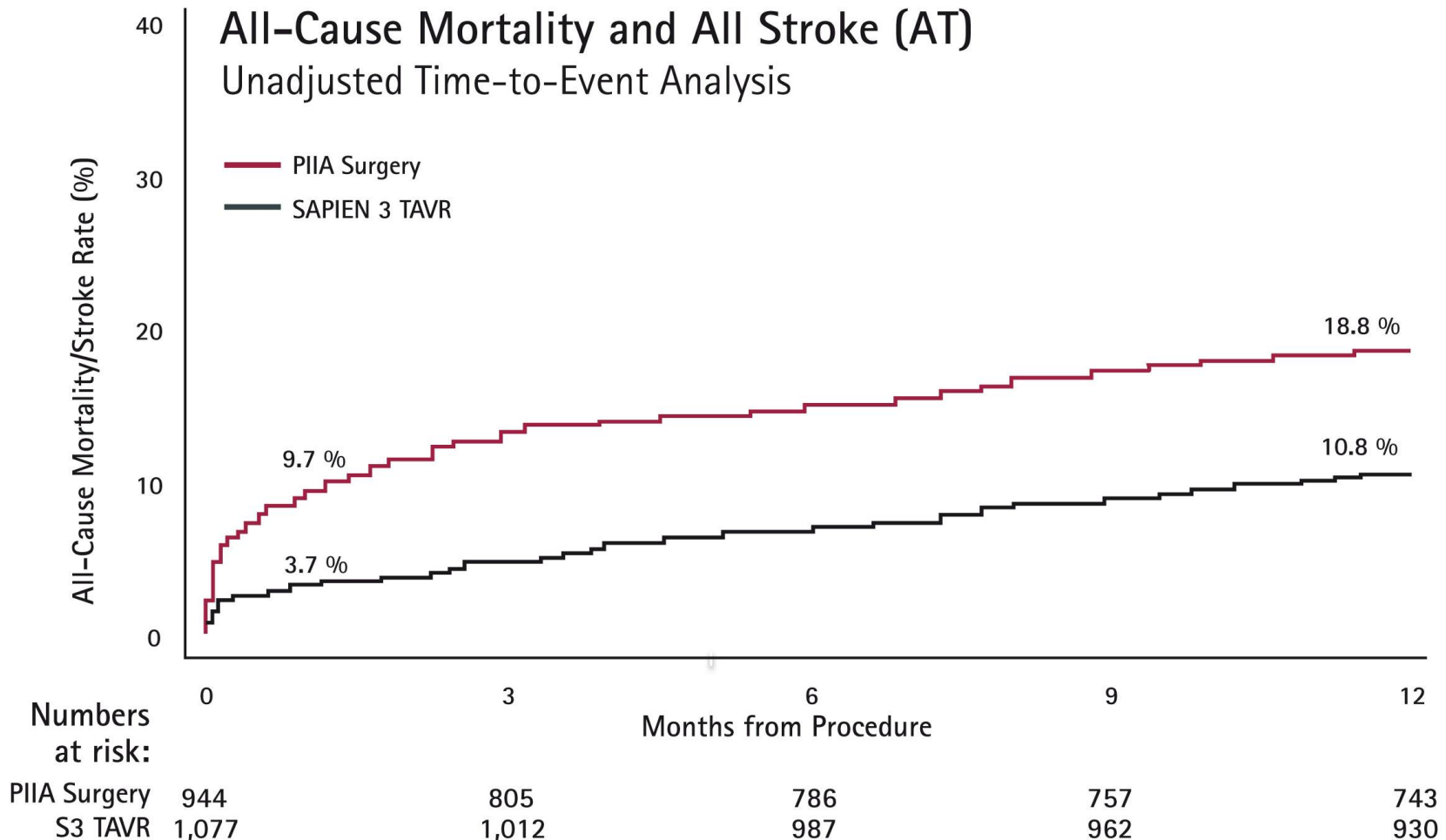
The patients received either transfemoral TAVI (89 %), transapical TAVI (7 %) or transaortic TAVI (0.4 %).

- Mean age: 81.9 years
- Mean STS score: 5.2 %
- NYHA class III/IV: 72.6 %

Primary endpoints

- Mortality and stroke rate at 30 days
- Combined endpoint of overall survival, stroke rate and severe/moderate paravalvular regurgitation at one year (Non-inferiority in the propensity score analysis)

PARTNER II S3i - Intermediate risk



PARTNER II S3i - Intermediate risk

CONCLUSIONS

- In patients with severe AS and intermediate risk, TAVI with the SAPIEN 3 achieves very good 30-day results with low mortality and stroke rates.
- At one year, TAVI proves to be superior to sAVR in this cohort as shown by propensity score analysis regarding the combined endpoint of mortality, stroke rate and paravalvular regurgitation^{1,2}.

Kodali S et al. EHJ 2016;pii: ehw112. [Epub ahead of print].

Thourani et al. Lancet 2016;387;2218-2225.

Limitations of PARTNER II S3i Trial

...but – *first issue on adjustment!*

- Big selection bias of this observational study
- Propensity has to be adjusted at least for MR and LVEF

Variable	TAVR Sapien 3 <small>Lancet 2016; 387: 2218–25</small>	TAVR PARTNER 2A <small>N Engl J Med 2016; 374:1609–20.</small>	
	(n=1077)	(n=1011)	
LVEF (%)	58.5 ± 13.4	56.2 ± 10.8	P < 0.0001
Moderate-severe MR (%)	91/1033 (9%)	151/899 (16.8%)	P < 0.0001
STS score	5.2% (4.3% - 6.3%)	5.8 ± 2.1	DATA NOT COMPARABLE
Mean gradient (mmHg)	46.1 ± 12.6	44.9 ± 13.4	P = 0.035
Gender (%)	665 (62%)	548 (54.2%)	P = 0.0005

Comparing apples and oranges

Eugene H. Blackstone, MD

.....in whatever way they arise,
they invalidate direct comparison

Limitations of PARTNER II S3i Trial

...but – second issue on adjustment!

- No data on concomittant procedures (9.1% in sAVR group)
- No adjustment for concomittant procedures (14.5% sAVR+CABG)
- No data on the number of concomittant procedures

STS score

Version 2.81

RISK SCORES

About the STS Risk Calculator

Procedure: **AV Replacement**

Risk of Mortality: **0.945%**

Version 2.81

RISK SCORES

About the STS Risk Calculator

Procedure: **AV Replacement + CAB**

Risk of Mortality: **1.347%**



Different Algorithms

EuroSCORE

Operation related factors		
Urgency ¹¹	elective	0
Weight of the intervention ¹²	isolated CABG	.0062118
	✓ single non CABG	
	2 procedures	
	3 procedures	0
Surgery on thoracic aorta		

Operation related factors		
Urgency ¹¹	elective	0
Weight of the intervention ¹²	2 procedures	.5521478
Surgery on thoracic aorta	no	0



Same algorithm, different weights

Limitations of PARTNER II S3i Trial

...but – *third issue on adjustment!*

- Kaplan-Meier survival is non-parametric
- For proper adjustment a propensity score matching, stratification and weighting with regression modeling is necessary
- This appears to be a countersense and these curves are NOT interpretable, as they are simply a first-step evaluation before adjustment.
- Stating the “important differences between TAVR and surgery for each endpoint are observed” is inappropriate until data are confirmed by adjusted results.

Quality Criteria for Performing TAVI in Germany

Positionspapier

Kardiologie 2016 · 10:282–300
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Qualitätskriterien zur Durchführung der kathetergestützten Aortenklappenimplantation (TAVI)

Aktualisierung des Positionspapiers der
Deutschen Gesellschaft für Kardiologie

TF-TAVI as 1st choice in all pts (Class-I) with:

- *STS $\geq 4\%$ or*
- *logES $\geq 10\%$ or*
- *age $> 85y$*

TA-TAVI as 2nd choice in all pts (Class-I) with:

- *STS $\geq 4\%$ or*
- *logES $\geq 10\%$ or*
- *age $> 85y$*

sAVR is only recommended in:

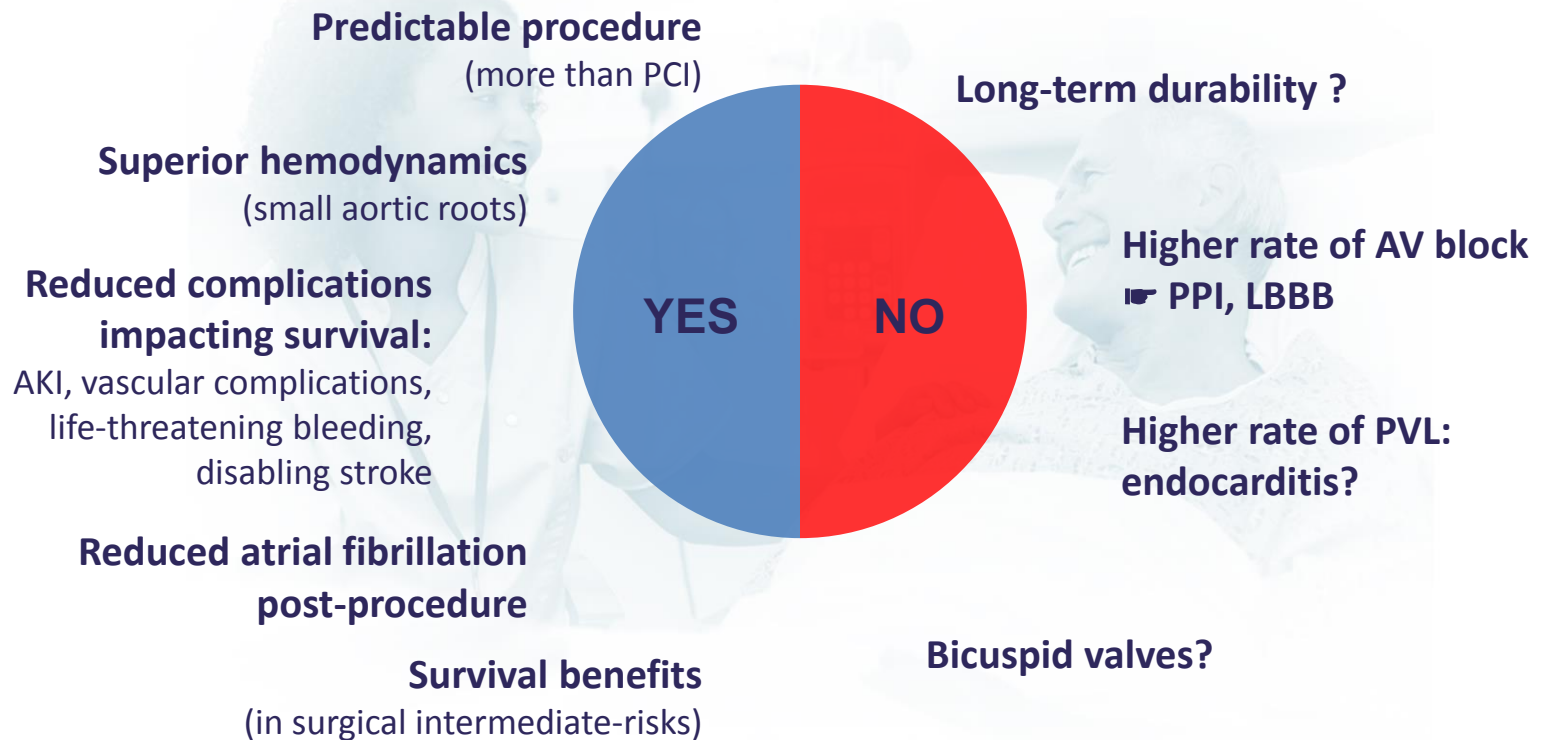
- *low risk patients (Class-IIb)*
- *as 3rd choice in intermediate risk*
(STS $\geq 4\%$ or logES $\geq 10\%$)
- *only in reasoned cases of high risk*
(STS $> 8\%$ oder logES $> 20\%$)
- *only in reasoned cases $> 85y$*



DGK.

Leitlinien
der Deutschen Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V.

Is TAVI Legitimate in Lower risk Patients?

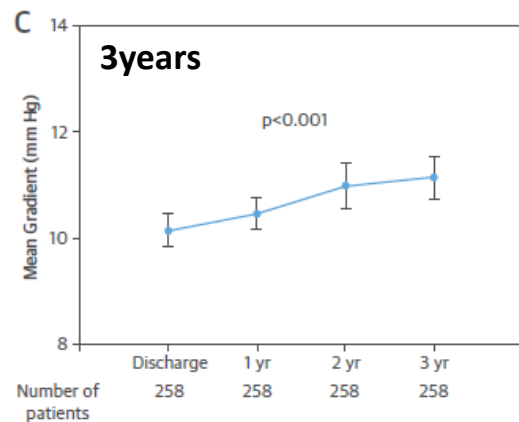
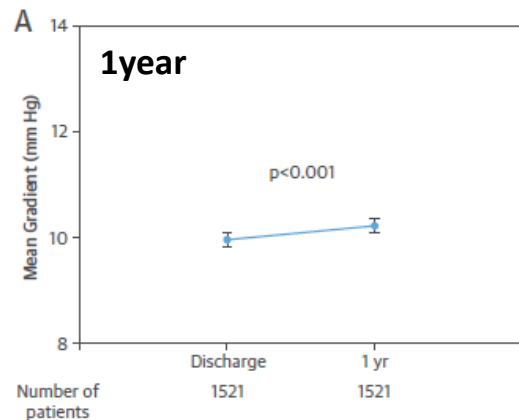


Long-term THV Durability?

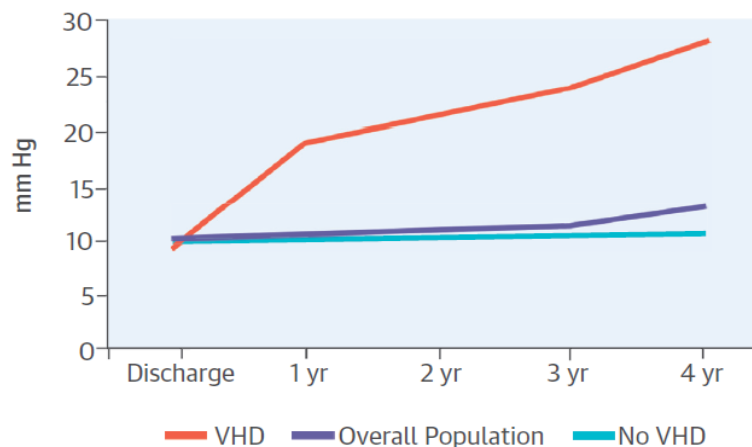


Ferrari 250 GTO 1962; sold in 2014 for 38 Mio US\$

Progression of Mean Gradients 4 years after TAVI; n=1521



Progression of Transvalvular Mean Gradients Following TAVR



Predictors of Transcatheter Valve Hemodynamic Deterioration Post-TAVR

- Absence of Anticoagulation Therapy at Discharge
- Valve-in-Valve Procedure (TAVR in a Surgical Valve)
- ≤ 23 mm Transcatheter Heart Valve
- Greater Body Mass Index

Long-term Durability of TAVI Valves?



Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

2016 | euro
PCR

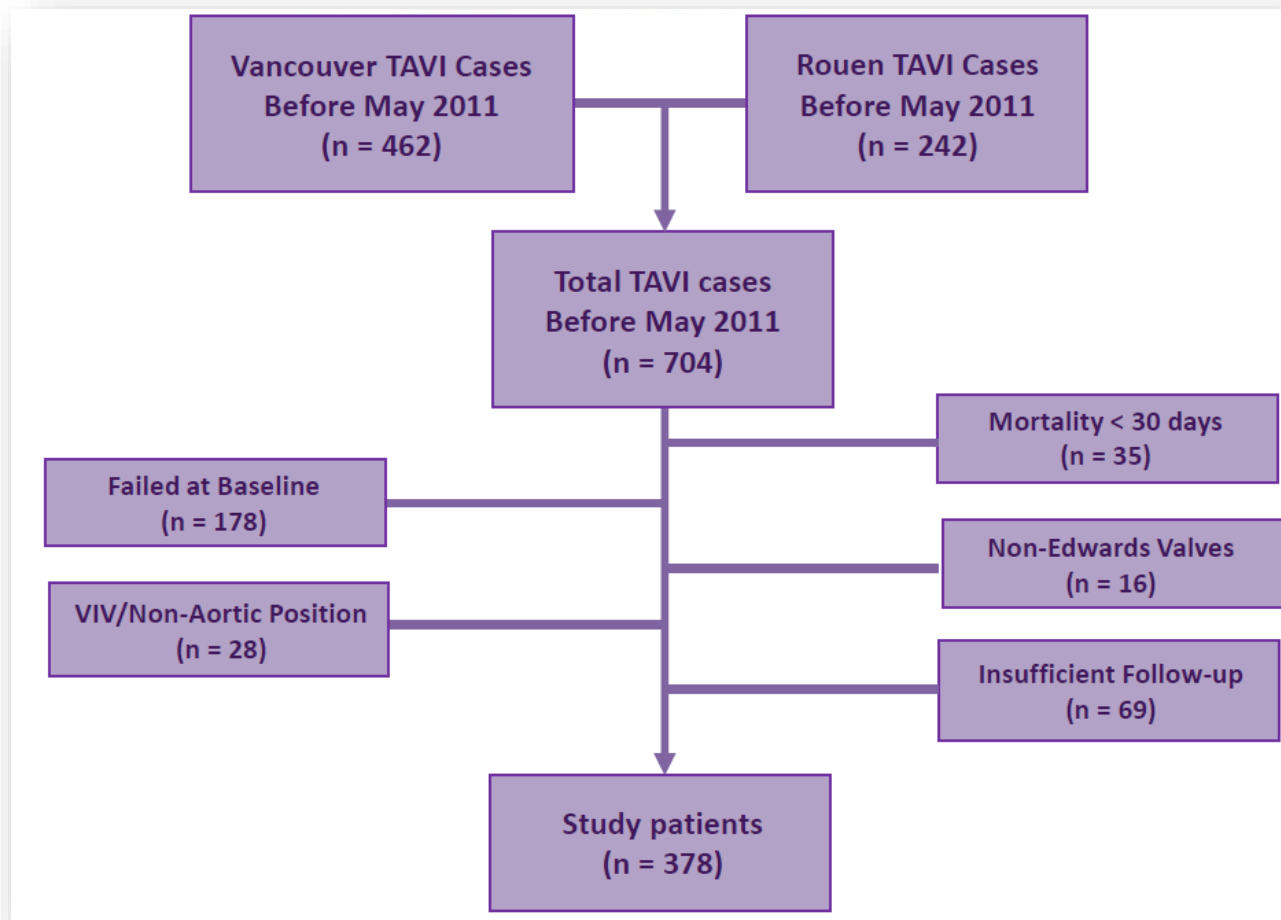
First look at long-term durability of transcatheter heart valves: Assessment of valve function up to 10-years after implantation

Danny Dvir, St. Paul's Hospital, Vancouver, Canada.

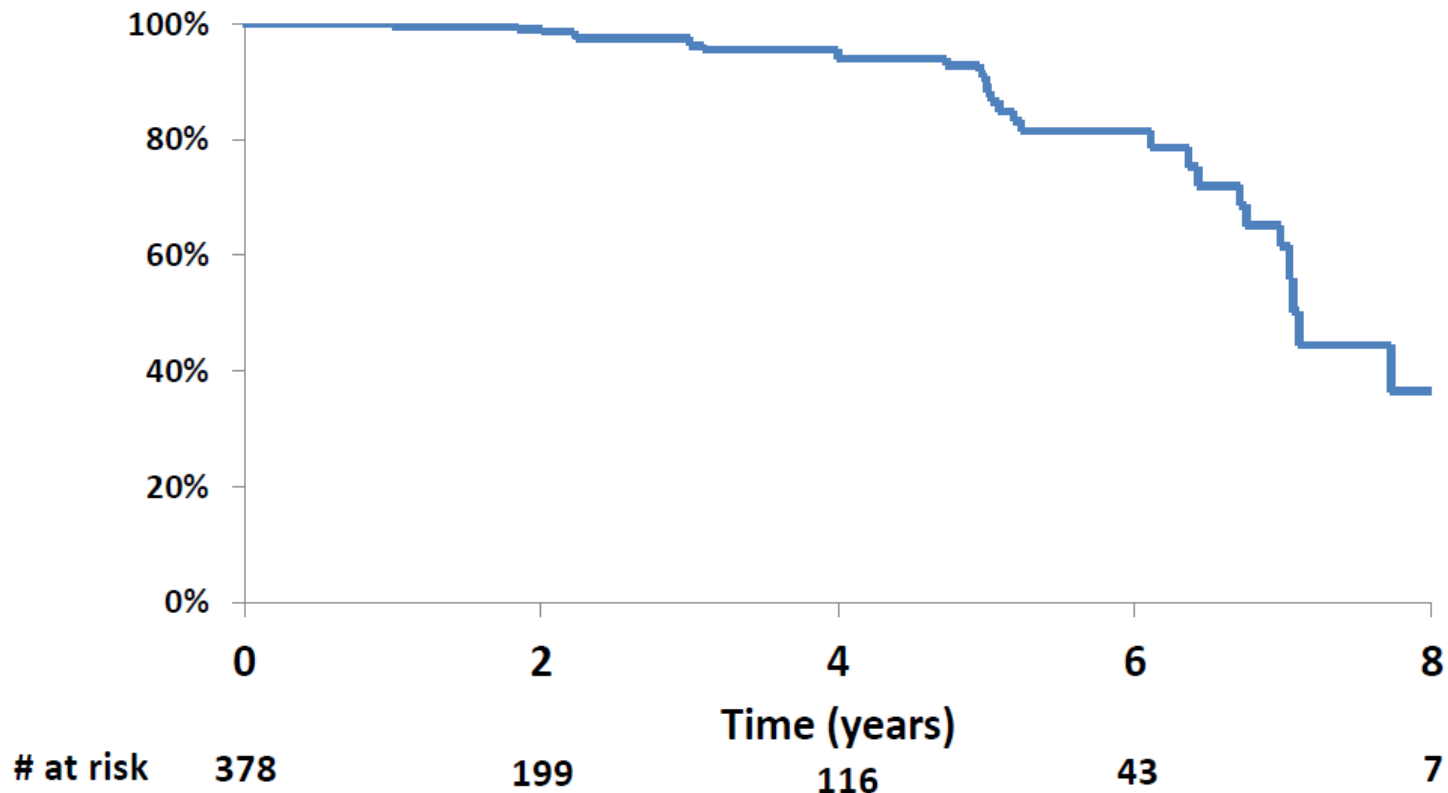
On behalf of coauthors: Helene Eltchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Matheus Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone, Sandra Lauck, Sam Lichtenstein, David Wood, Alain Cribier, John Webb



Long-term Durability of TAVI Valves?

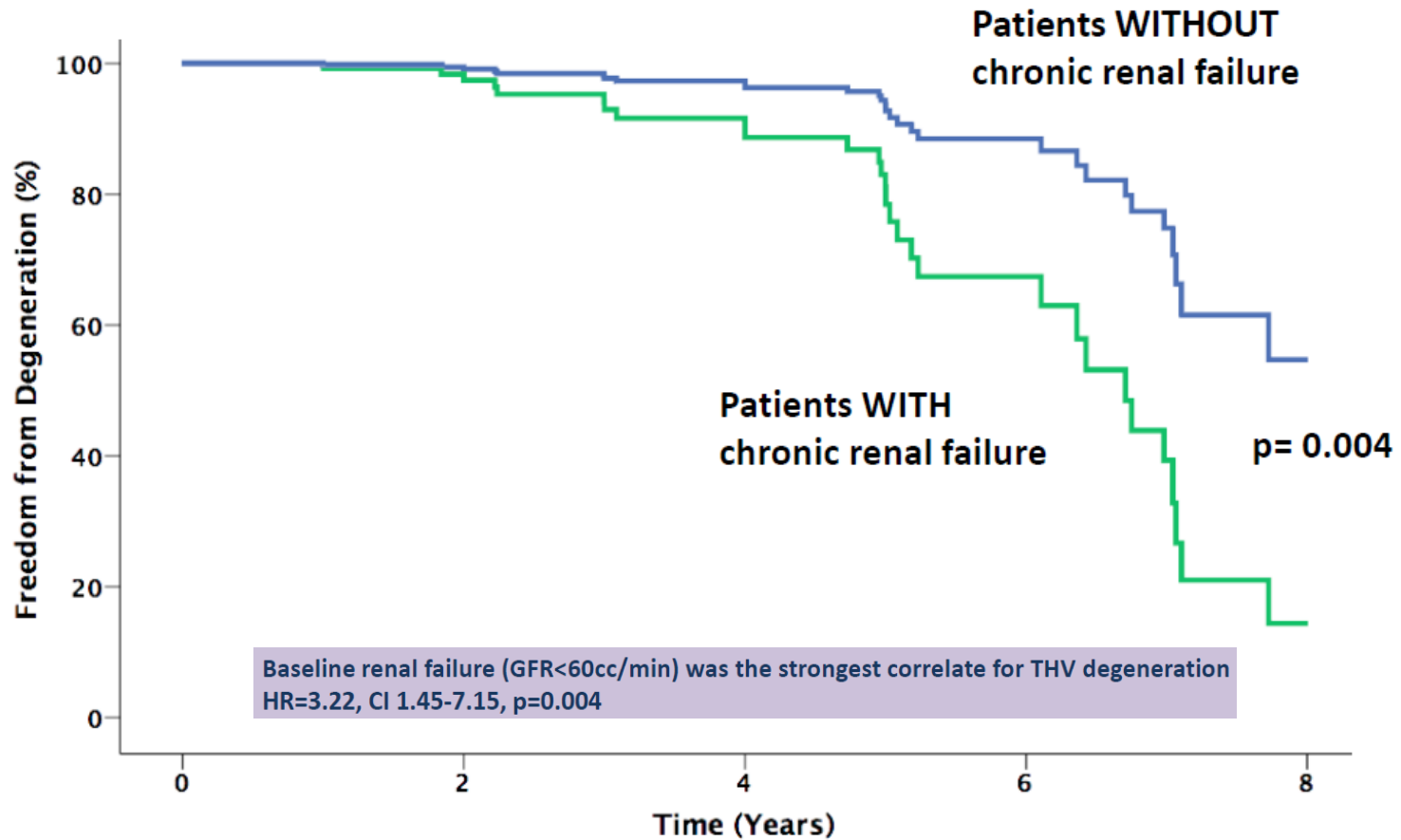


Freedom from THV Degeneration (n=378)



THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20 mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

Freedom from THV Degeneration (n=378)



Conclusions

- **Dramatic continued growth in TAVI worldwide!**
- **Currently major indication is high-risk or inoperable AS**
- **TAVI indication is and will be expanded (intermediate/lower risk)**
- **Current RCTs for intermediate/low-risk pts are biased & most initiated/funded by industry**
- **Physician-initiated RCTs are necessary – isolated TAVI vs. sAVR**
- **The TAVI ‘heart-team’ plays a key role in clinical practice**

Conclusions II

- TAVI can be performed with high procedural success rates
- There is a (substantial) institutional learning curve
- There are valve-specific complications & limitations
- Long-term durability data are still rare
- *Will CV surgeons play a key role in TAVI ?*

Westdeutsches
Herzzentrum
Essen

Westdeutsches
Herzzentrum
Essen

Klinik für Kardiologie
Klinik für Herz- und Lungentransplantation
Klinik für Herz- und Thoraxchirurgie
Klinik für Herz- und Thoraxradiologie
Klinik für Herz- und Thoraxphysiologie
Klinik für Herz- und Thoraxnachsorge

Herz- und Thoraxklinik
Herz- und Thoraxklinik
Herz- und Thoraxklinik