STS/EACTS Latin America Cardiovascular Surgery Conference

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TAVR for low-risk patients in 2017: not so fast.

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The Society of Thoracic Surgeons

EACTS
European Association For Cardio-Thoracic Surgery

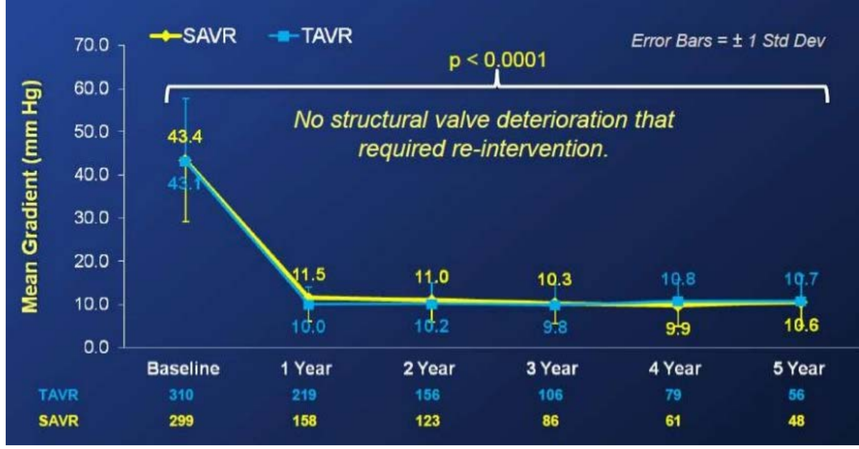
Conflicts of Interest

- Consultant and proctor for Edwards Lifesciences (Irvine, CA, US)
- Consultant for Comed (Bolsward, The Netherlands)

TAVR

- Transcatheter Aortic Valve Replacement
- Balloon-expandable or self-expandable valves
- Indication: severe AS, failed bioprosthesis (VinV)
- Available accesses: TF, TA, TAO, trans-subclavian, trans-carotid
- EVOLVING TECHNOLOGY: repositionable/retrievable valves, low-profile delivery systems, new valve design to prevent PVL

TAVR in 2017



- Proven efficacy in inoperable and high-risk patients
- Proven efficacy in failed bioprosthesis (VinV)
- Incoming data are showing good results in moderate-risk patients
- Proven hemodynamics over the years

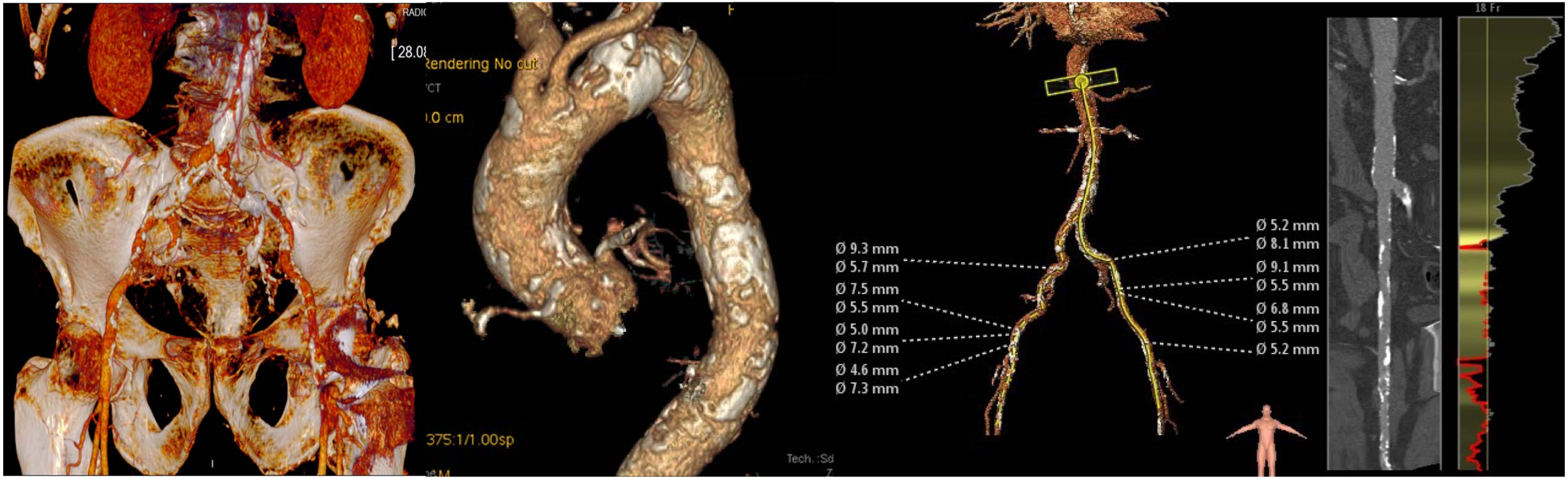
WHY NOT PERFORMING TAVR IN LOW-RISK PATIENTS AS WELL?

Agenda

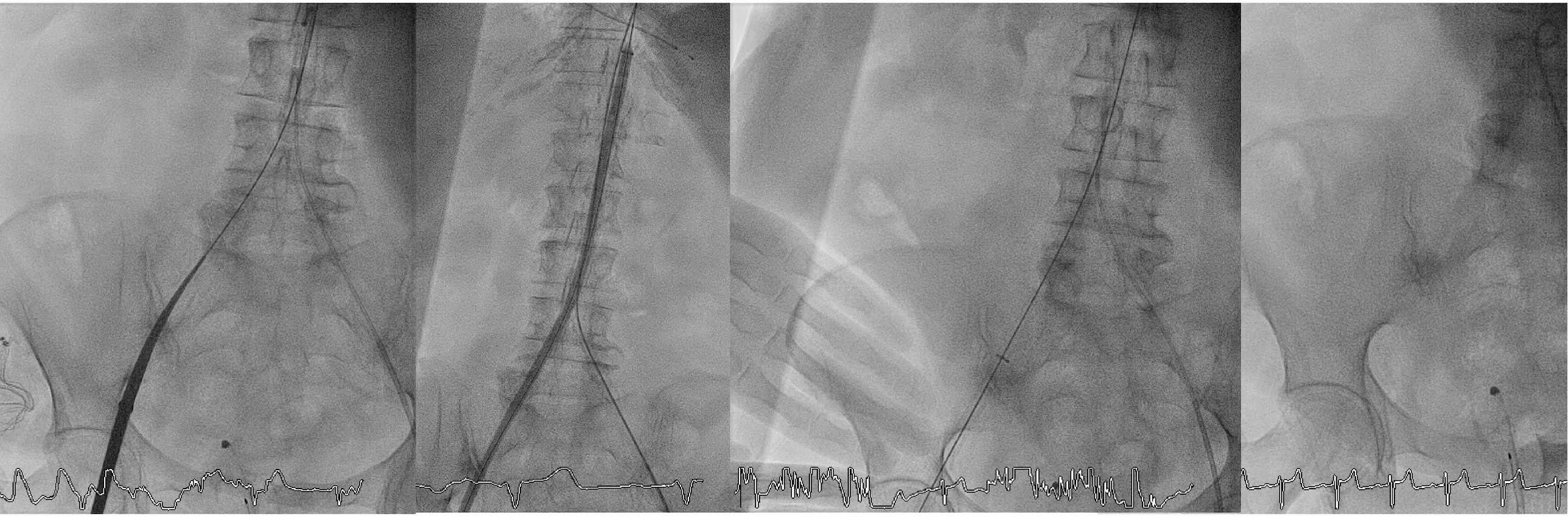
1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability

1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability

Preoperative vascular assessment



Vascular complications



Never force the indication for TF

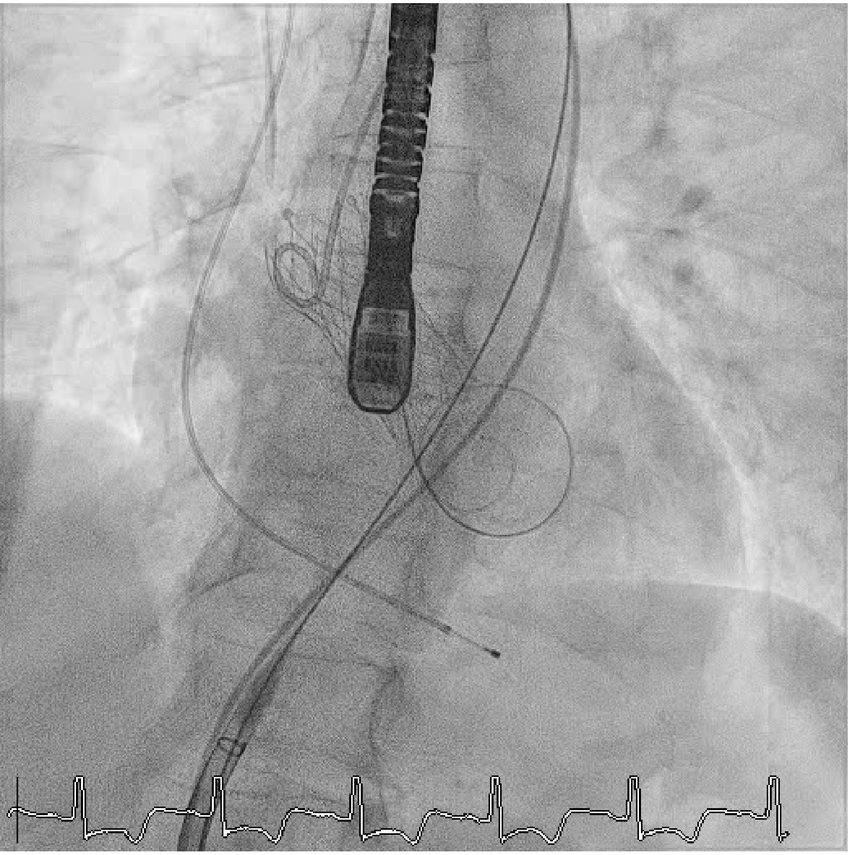
Vascular complications in TAVR

- Drop in access-site related major/life-threatening vascular complication rate with “low-profile” devices (32Fr ⟷ 14Fr sheath)
- Vascular complications: 5-11% (dissection, rupture)
- (SAVR: <2%)
- TF >> TA = TAO
- New devices will further decrease the risk
- Choice of the right TAVR access-site is the key factor to further decrease vascular complications (Heart-Team)

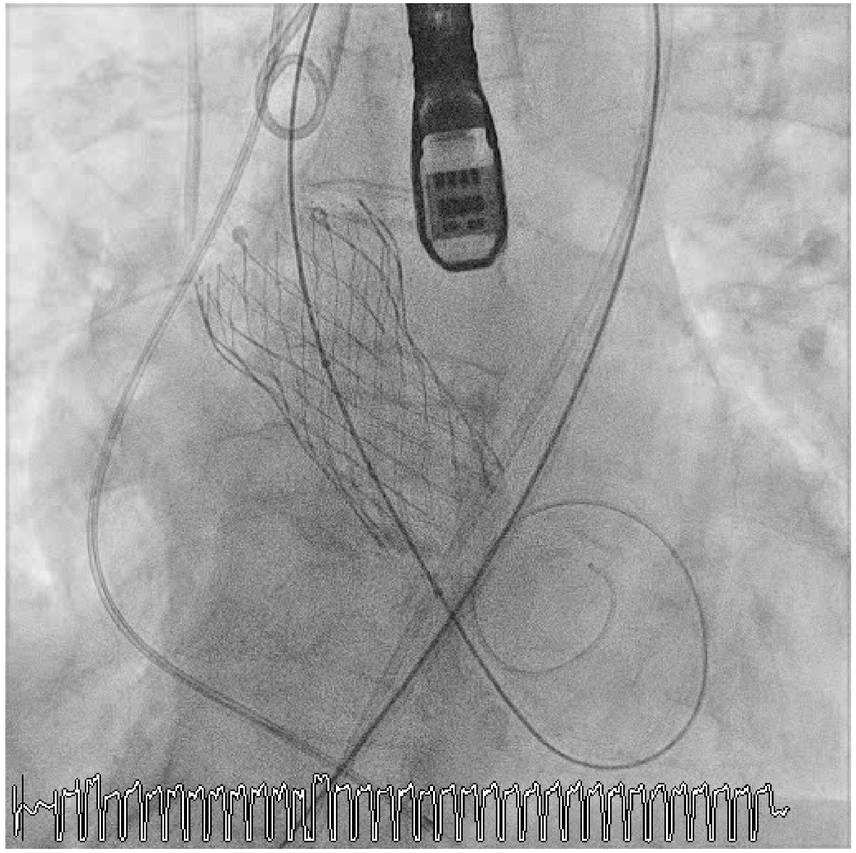
1. Ferrari et al. Transfemoral versus transapical approach for transcatheter aortic valve implantation: hospital outcome and risk factor analysis. J Cardiothorac Surg. 2017 Sep 6;12(1):78. doi: 10.1186/s13019-017-0638-9
2. Wendler et al. SOURCE 3: 1-year outcomes post-transcatheter aortic valve implantation using the latest generation of the balloon-expandable transcatheter heart valve. Eur Heart J. 2017 Jun 12. doi: 10.1093/eurheartj/ehx294
3. Romano et al. Transaortic transcatheter aortic valve implantation using SAPIEN XT or SAPIEN 3 valves in the ROUTE registry†. Interact Cardiovasc Thorac Surg. 2017 Jun 5. doi: 10.1093/icvts/ivx159.
4. Ando et al. Comparison of In-Hospital Outcomes of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Obese (Body Mass Index ≥ 30 Kg/M2) Patients. Am J Cardiol. 2017 Aug 7. pii: S0002-9149(17)31304-8.
5. Bapat et al. Transcatheter Aortic Valve Replacement Using Transaortic Access: Experience From the Multicenter, Multinational, Prospective ROUTE Registry. JACC Cardiovasc Interv. 2016 Sep 12;9(17):1815-22.

1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability

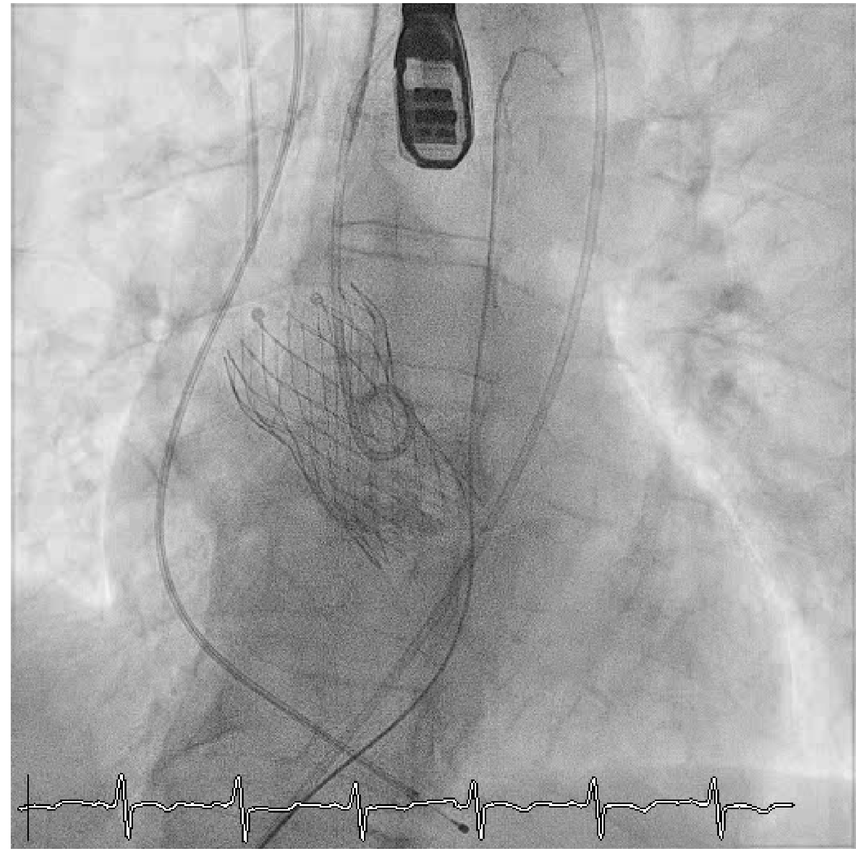
PLV



PVL ++

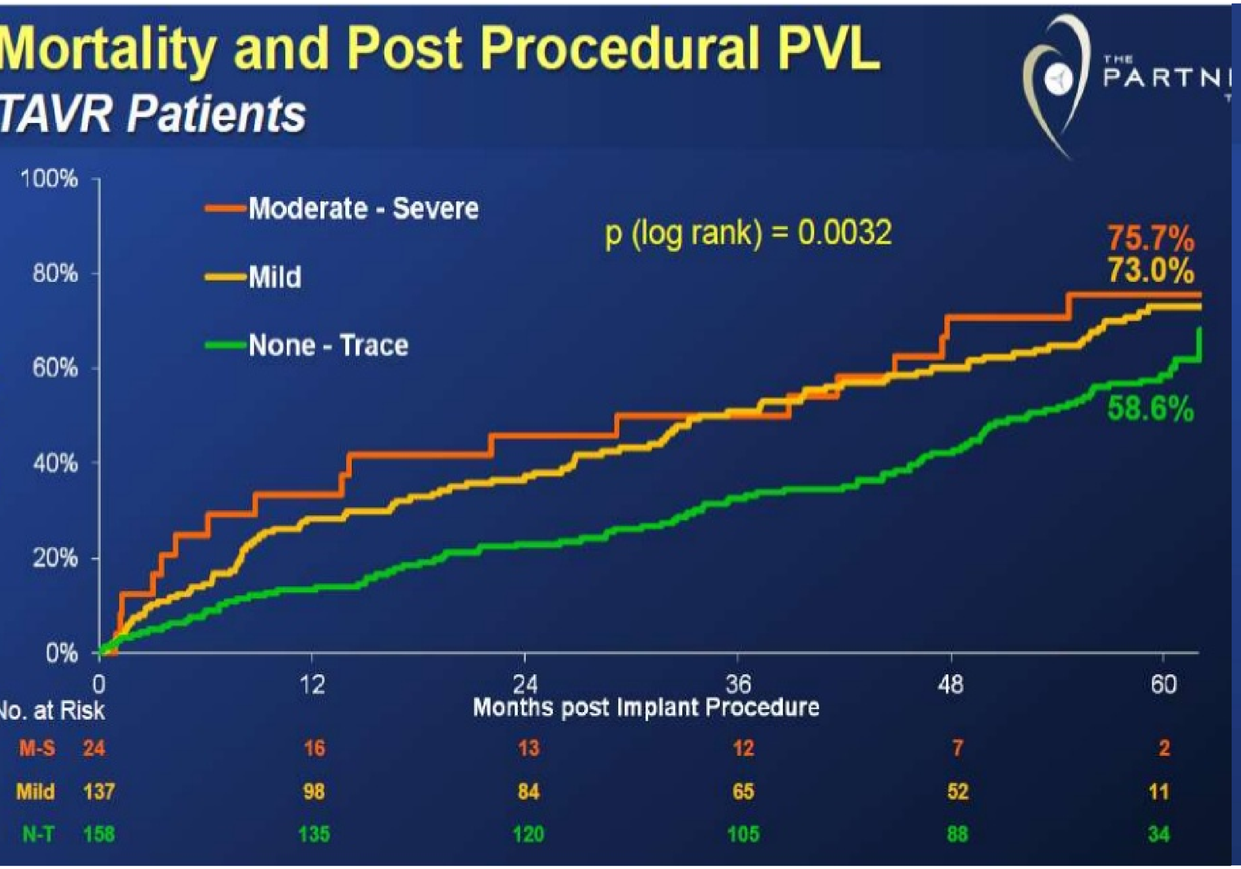


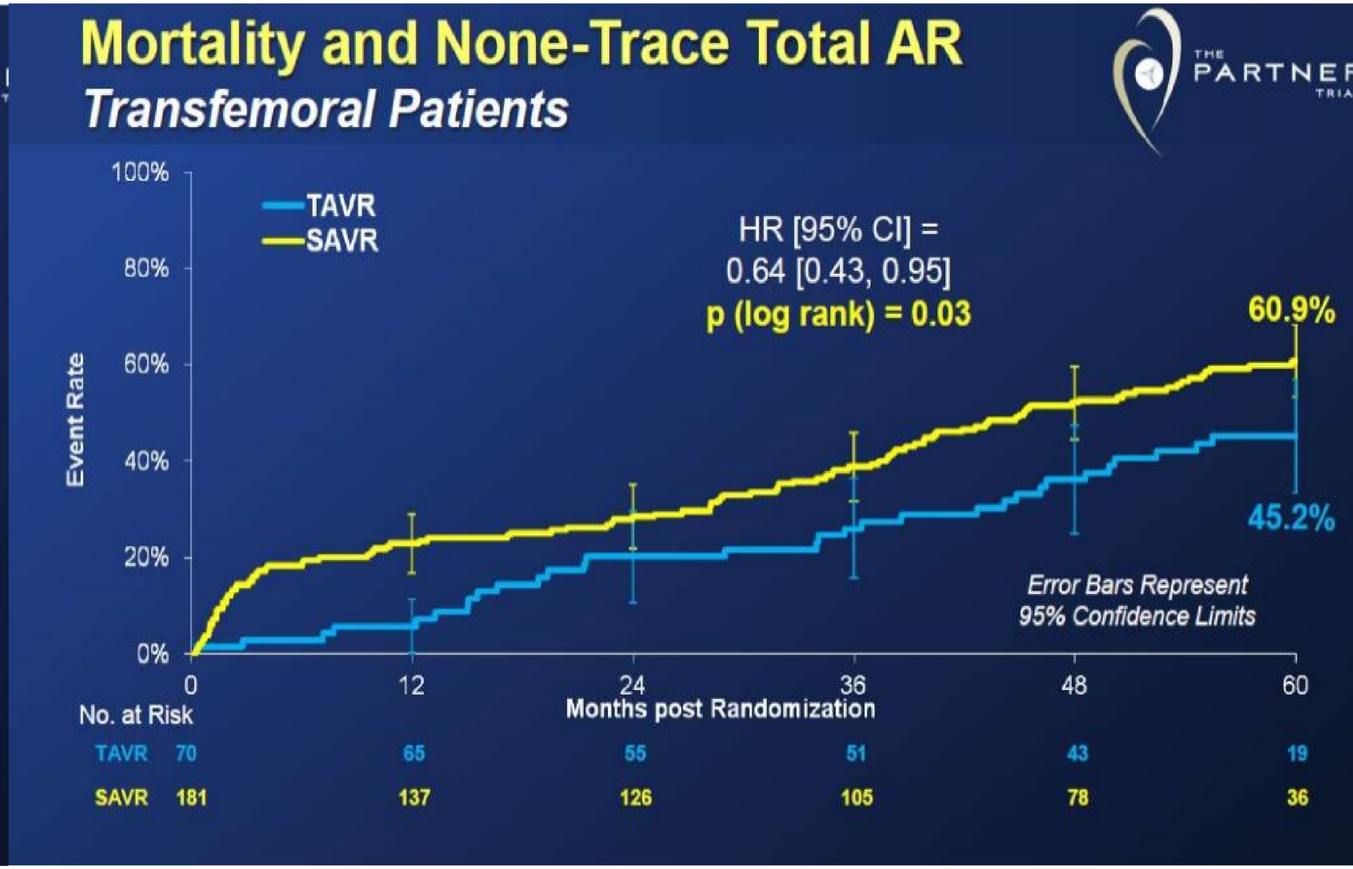
Re-ballooning



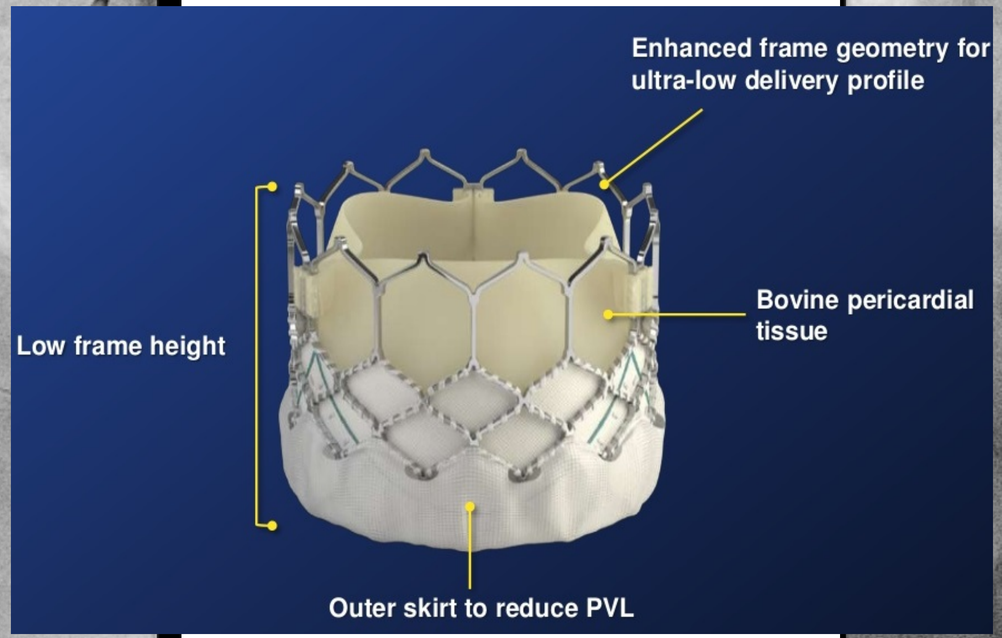
PVL +

PVL and mortality

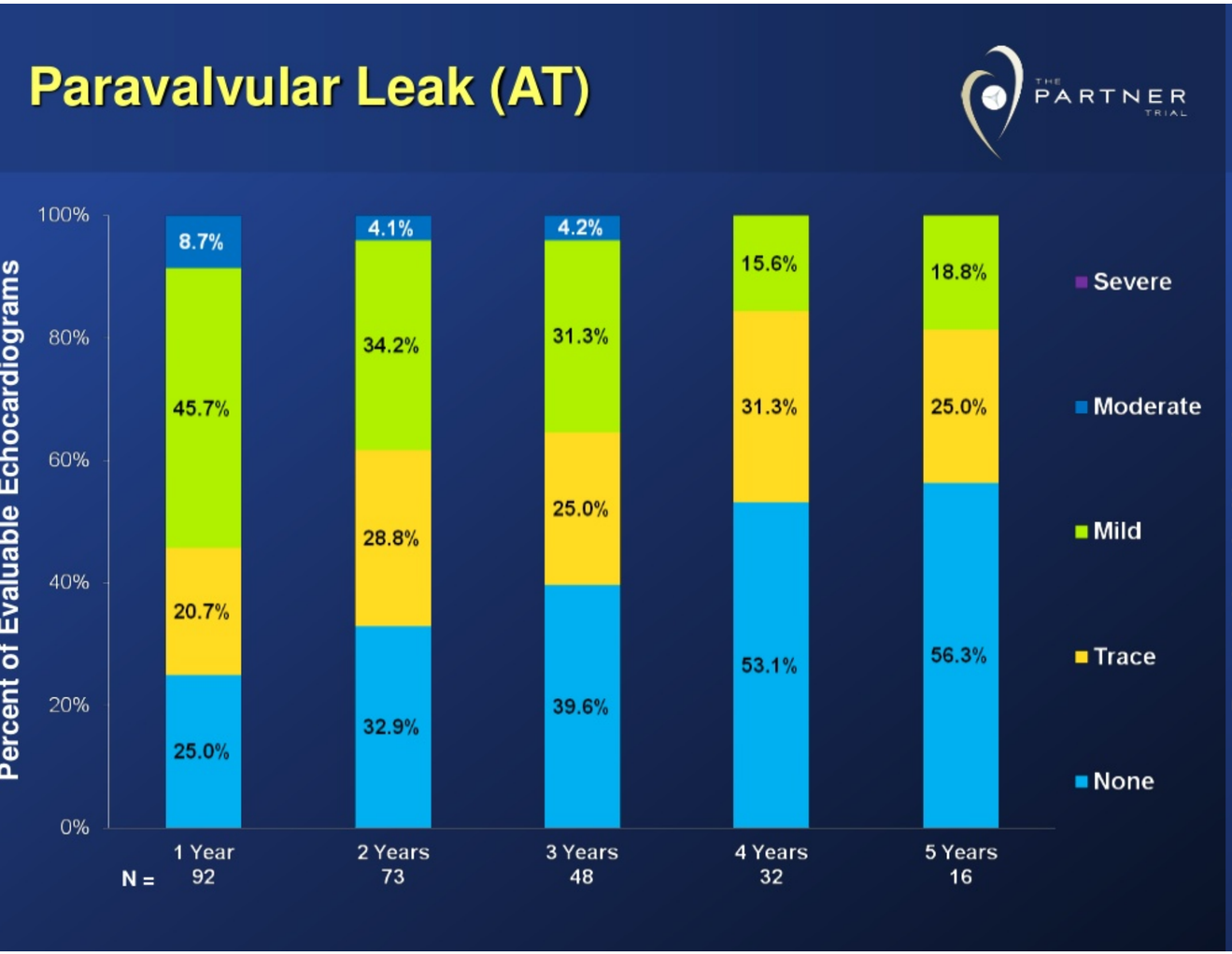


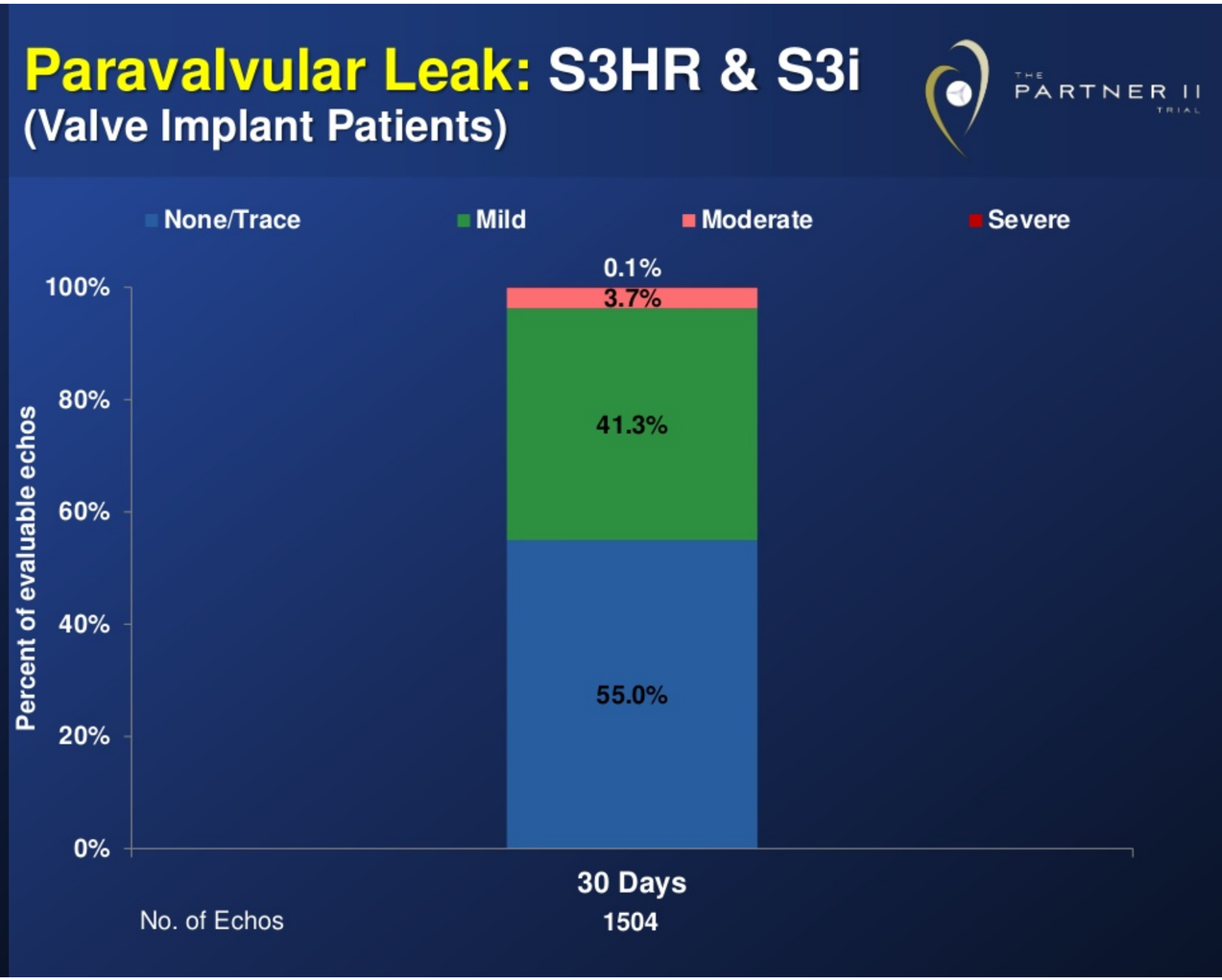


SAPIEN 3

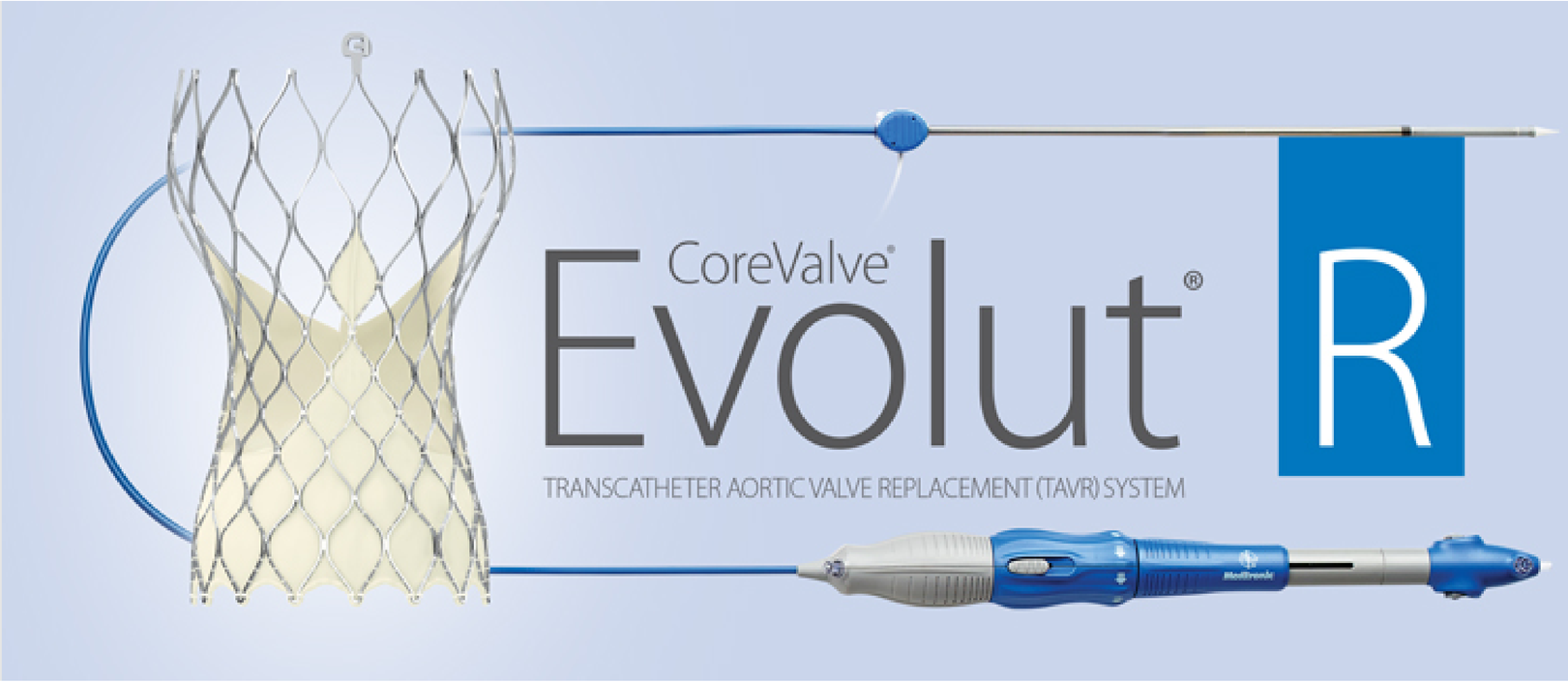

Enhanced frame geometry for ultra-low delivery profile
Low frame height
Bovine pericardial tissue
Outer skirt to reduce PVL

SAPIEN 3


Paravalvular Leak (AT)
THE PARTNER TRIAL
Percent of Evaluable Echocardiograms
100%
80%
60%
40%
20%
0%
8.7%
45.7%
20.7%
25.0%
4.1%
34.2%
28.8%
32.9%
4.2%
31.3%
25.0%
39.6%
15.6%
31.3%
53.1%
18.8%
25.0%
56.3%
Severe
Moderate
Mild
Trace
None
N =
1 Year
92
2 Years
73
3 Years
48
4 Years
32
5 Years
16


Paravalvular Leak: S3HR & S3i
(Valve Implant Patients)
THE PARTNER II TRIAL
None/Trace
Mild
Moderate
Severe
Percent of evaluable echos
100%
80%
60%
40%
20%
0%
0.1%
3.7%
41.3%
55.0%
30 Days
1504
No. of Echos

Repositionable valves



LOTUS Valve (996pts)
- repositioned: 29.2%
- Severe PVL: 0%
- Moderate PVL: 0.3%

Evolut R (151pts, 317pts)
- repositioned: 22.1%
- Moderate to Severe PVL: 0-8%

1. Falk et al. Safety and efficacy of a repositionable and fully retrievable aortic valve used in routine clinical practice: the RESPOND Study. Eur Heart J. 2017 Jun 22. doi: 10.1093/eurheartj/ehx297.
2. Schulz et al. Transcatheter aortic valve implantation with the new-generation Evolut R™: Comparison with CoreValve® in a single center cohort. Int J Cardiol Heart Vasc. 2016 Jul 5;12:52-56.
3. Noble et al. Comparison of procedural and clinical outcomes with Evolut R versus Medtronic CoreValve: a Swiss TAVI registry analysis. Eurointervention. 2017 Apr 7;12(18):e2170-e2176.

PVL after TAVR

- Moderate to severe PVL rate after TAVR: 0.3-11% (SAVR: 0-2%; sutureless valves: 0.4-2.5%)
- Moderate PVL > severe PVL
- New valve design to decrease the risk of PVL
- Balloon pre-dilation increases the risk of PVL (RR:0.59)
- No BAV, choice of the right TAVR-valve, Positioning, sizing, post-TAVR re-ballooning and bailout VinV are key factors to further decrease the risk of PVL post-TAVR

1. Falk et al. Safety and efficacy of a repositionable and fully retrievable aortic valve used in routine clinical practice: the RESPOND Study. Eur Heart J. 2017 Jun 22. doi: 10.1093/eurheartj/ehx297.
2. Wendler et al. SOURCE 3: 1-year outcomes post-transcatheter aortic valve implantation using the latest generation of the balloon-expandable transcatheter heart valve. Eur Heart J. 2017 Jun 12. doi: 10.1093/eurheartj/ehx294
3. Waterbury et al. Techniques and outcomes of paravalvular leak repair after transcatheter aortic valve replacement. Catheter Cardiovasc Interv. 2017 Aug 2. doi: 10.1002/ccd.27224
4. Ferrari et al. Transfemoral versus transapical approach for transcatheter aortic valve implantation: hospital outcome and risk factor analysis. J Cardiothorac Surg. 2017 Sep 6;12(1):78. doi: 10.1186/s13019-017-0638-9
5. Kleczynski et al. Impact of post-dilatation on the reduction of paravalvular leak and mortality after transcatheter aortic valve implantation. Kardiol Pol. 2017;75(8):742-748.
6. Möllmann et al. Implantation and 30-Day Follow-Up on All 4 Valve Sizes Within the Portico Transcatheter Aortic Bioprosthetic Family. JACC Cardiovasc Interv. 2017 Aug 14;10(15):1538-1547
7. Auffrel et al. Feasibility, safety, and efficacy of transcatheter aortic valve replacement without balloon predilation: A systematic review and meta-analysis. Catheter Cardiovasc Interv. 2017 Apr 12. doi: 10.1002/ccd.27040

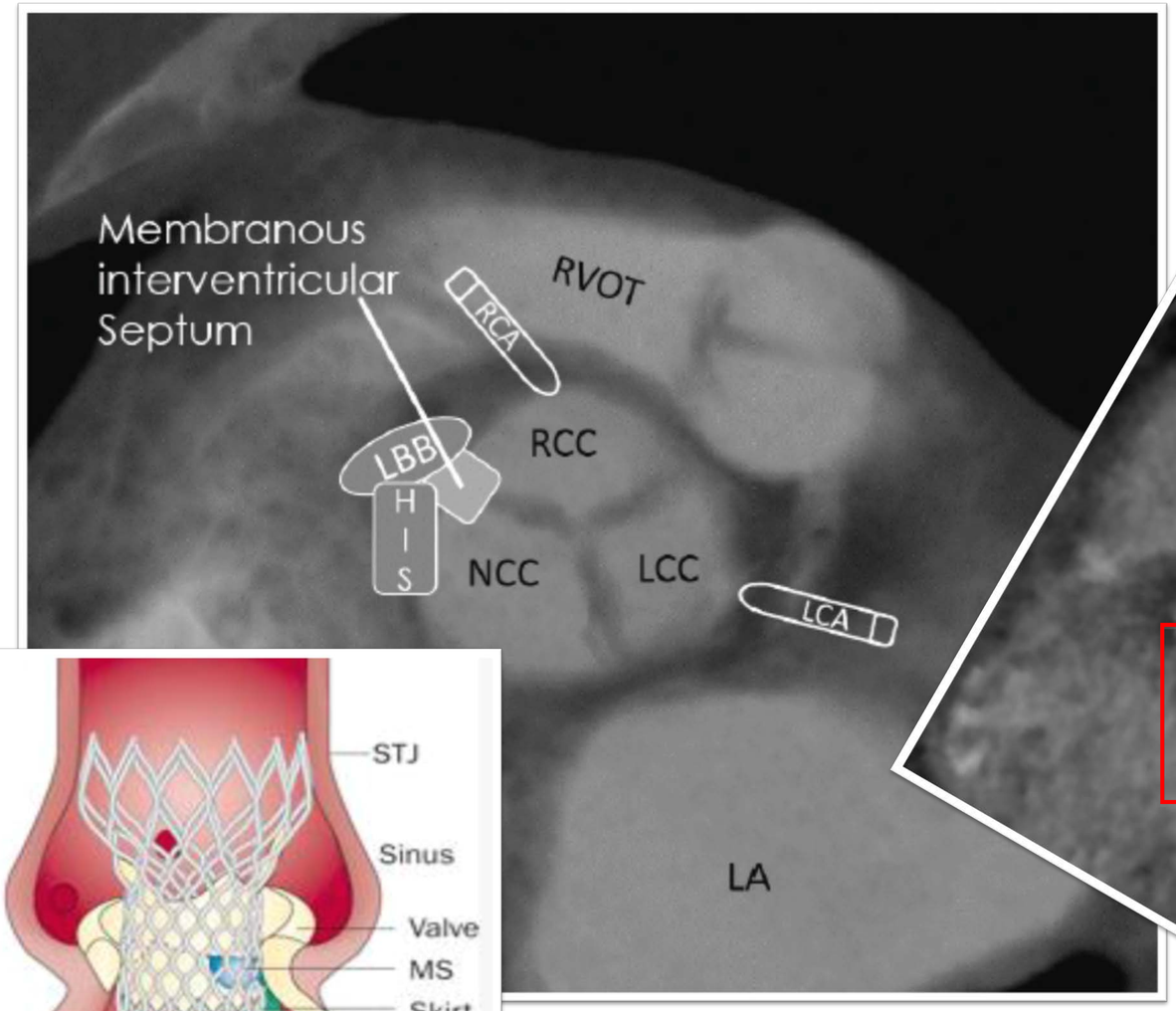
1. Vascular and access-site related complications

2. Paravalvular leak

3. PM implantation

3. Valve durability

PM after TAVR



Pacing after cardiac surgery, transcatheter aortic valve implantation and heart transplantation

Recommendations	Class [a]	Level [b]
1) High degree or complete AV block after cardiac surgery and TAVI. A period of clinical observation up to 7 days is indicated in order to assess whether the rhythm disturbance is transient and resolves. However, in case of complete AV block with low rate of escape rhythm this observation period can be shortened since resolution is unlikely.	I	C
Sinus node dysfunction after cardiac y and heart transplantation. clinical observation from weeks is indicated in order disturbance resolves.	I	C
etence after Cardiac pacing should otropic the quality of life l period.	IIa	C

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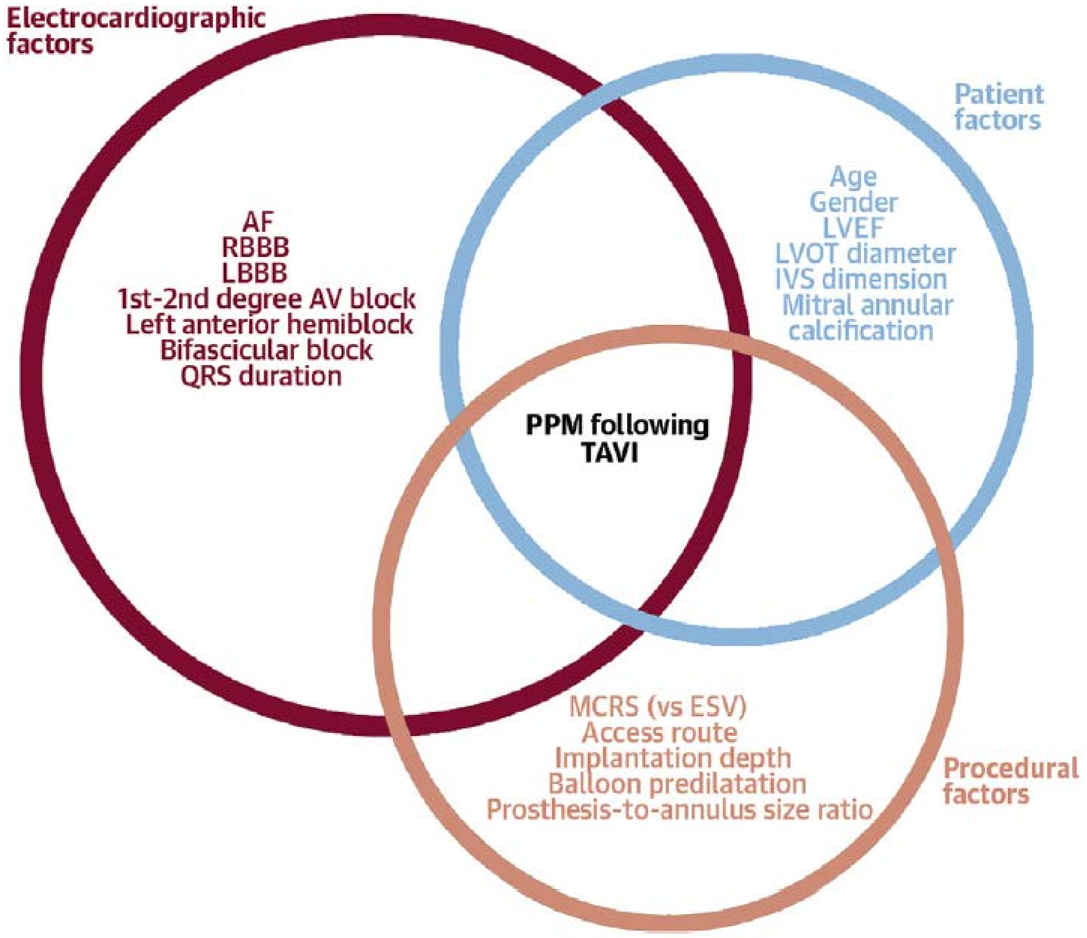
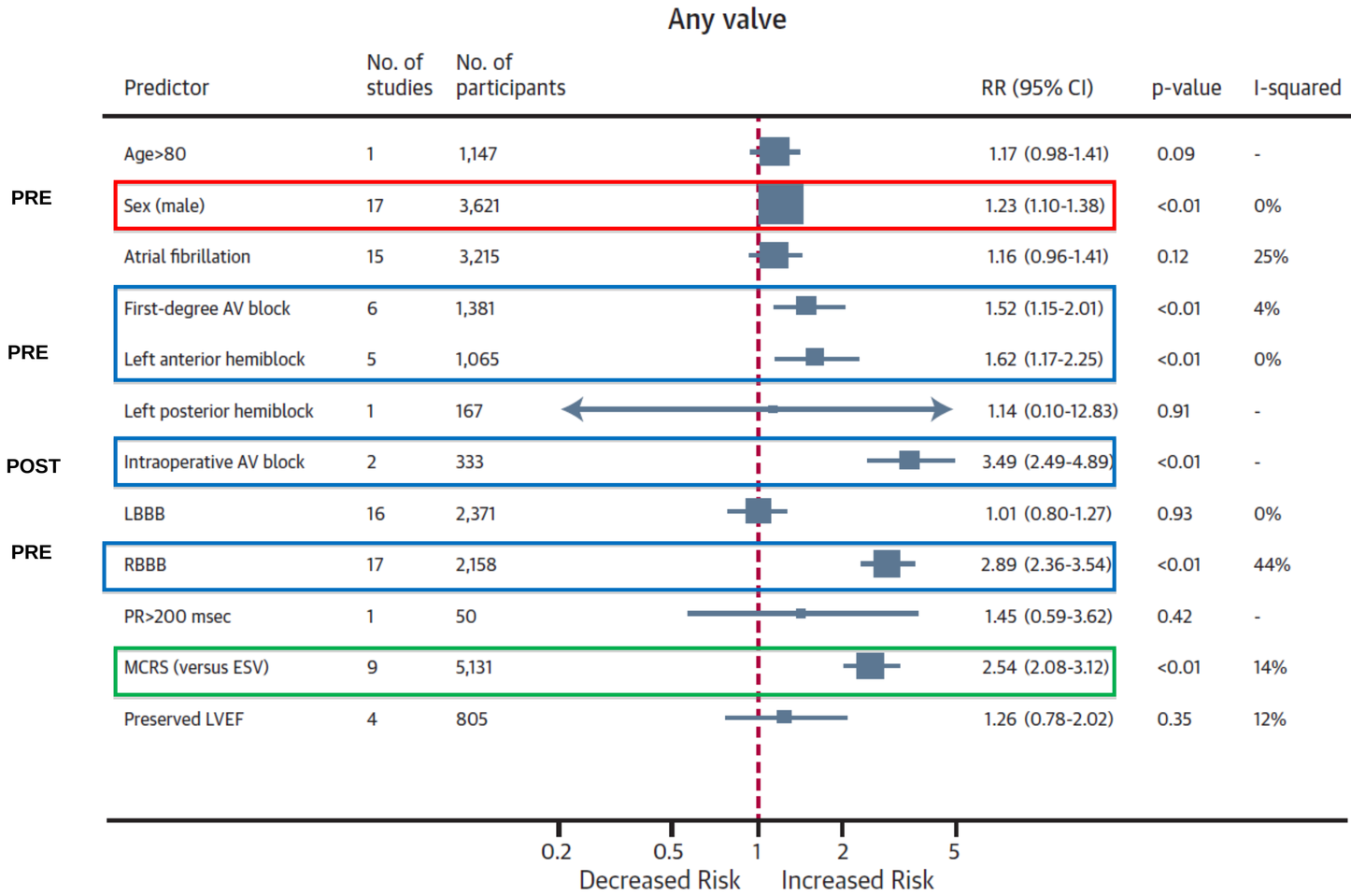
Predictors for new PM after TAVR



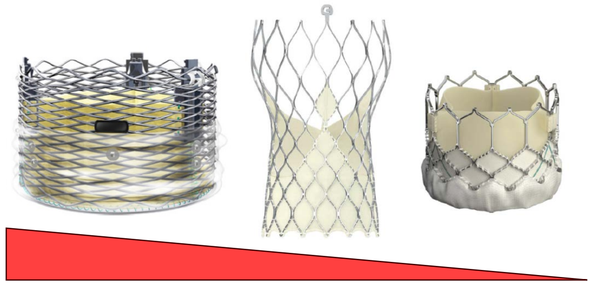


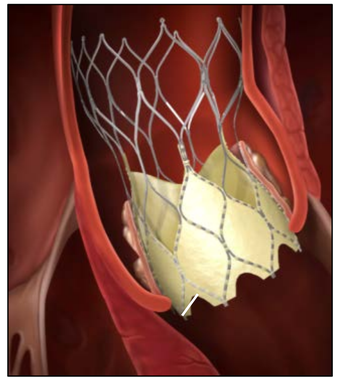
1. Siontis et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. J Am Coll Cardiol. 2014 Jul 15;64(2):129-40

PM after TAVR

Source	Patients per each cohort	Perceval PM (%)	Traditional PM (%)	P value
Pollari. et al.	82	6.1	8.5	0.36
Gilmanov et al.	133	4.4	2.3	0.5
Laborde et al.	65	7.7	10.8	na
Meuris et al.	53	1.8	3.7	na

- New PM after TAVR: 6-30%
  (SAVR: 2.3-8.5%; sutureless valves: 1.8-7.7%)
- Lotus > CoreValve > Sapien
- Balloon pre-dilation seems not to increase the risk of PM
- Positioning, sizing, and choice of the right TAVR-valve, are key factors to decrease the risk of new PM implantation
  (less oversizing, better re-positioning: “not-too-low”)





1. Noble et al. Comparison of procedural and clinical outcomes with Evolut R versus Medtronic CoreValve: a Swiss TAVI registry analysis. Eurointervention. 2017 Apr 7;12(18):e2170-e2176
2. Falk et al. Safety and efficacy of a repositionable and fully retrievable aortic valve used in routine clinical practice: the RESPOND Study. Eur Heart J. 2017 Jun 22. doi: 10.1093/eurheartj/ehx297.
3. Möllmann et al. Implantation and 30-Day Follow-Up on All 4 Valve Sizes Within the Portico Transcatheter Aortic Bioprosthetic Family. JACC Cardiovasc Interv. 2017 Aug 14;10(15):1538-1547
4. Ferrari et al. Transfemoral versus transapical approach for transcatheter aortic valve implantation: hospital outcome and risk factor analysis. J Cardiothorac Surg. 2017 Sep 6;12(1):78. doi: 10.1186/s13019-017-0638-9
5. Auffrel et al. Feasibility, safety, and efficacy of transcatheter aortic valve replacement without balloon predilation: A systematic review and meta-analysis. Catheter Cardiovasc Interv. 2017 Apr 12. doi: 10.1002/ccd.27040

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SAVR bioprosthesis

- FU > 20 years
- Proven age-related durability

ADULT CARDIAC

Hancock II Bioprosthesis for Aortic Valve Replacement: The Gold Standard of Bioprosthetic Valves Durability?

Tirone E. David, MD, Susan Armstrong, MS, and Manjula Maganti, MS

Division of Cardiovascular Surgery of Peter Munk Cardiac Centre, Toronto General Hospital and University of Toronto, Toronto, Ontario, Canada

Background. This study examined the long-term durability of the Hancock II bioprosthesis (Medtronic, Minneapolis, MN) in the aortic position.

Methods. From 1982 to 2004, 1134 patients underwent aortic valve replacement (AVR) with Hancock II bioprosthesis and were prospectively monitored. Mean patient age was 67 ± 11 years; 202 patients were younger than 60, 402 were 60 to 70, and 526 were older than 70. Median follow-up was 12.2 years and 99.2% complete. Valve function was assessed in 94% of patients. Freedom from adverse events was estimated by the Kaplan-Meier method.

Results. Survival at 20 and 25 years was 19.2% ± 2% and 6.7% ± 2.8%, respectively, with only 34 and 3 patients at risk. Survival at 20 years was 54.9% ± 6.4% in patients younger than 60 years, 22.7% ± 3.3% in those 60 to 70, and 2.4% ± 1.9% in those older than 70 ($p = 0.01$). Structural valve deterioration developed in 67 patients aged younger than 60, in 18 patients aged 60 to 70, and in 2 patients older than 70. The freedom from structural valve deterioration at 20 years was 63.4% ± 4.2% in the entire cohort, 29.2% ± 5.7% in patients younger than 60 years, 85.2% ± 3.7% in patients aged 60 to 70, and 99.8% ± 0.2% in patients older than 70 (truncated at 18 years). Repeat AVR was performed in 104 patients (74 for structural valve failure, 16 for endocarditis, and 14 for other reasons). At 20 years, the overall freedom from AVR was 65.1% ± 4% for any reason, 29.8% ± 5.4% in patients younger than 60 years, 86.8% ± 3.3% in patients 60 to 70, and 98.3% ± 0.6% in patients older than 70.

Conclusions: Hancock II bioprosthesis is a very durable valve in patients 60 years and older and is probably the gold standard of bioprosthetic valve durability in this patient population.

(Ann Thorac Surg 2010;90:775–81)

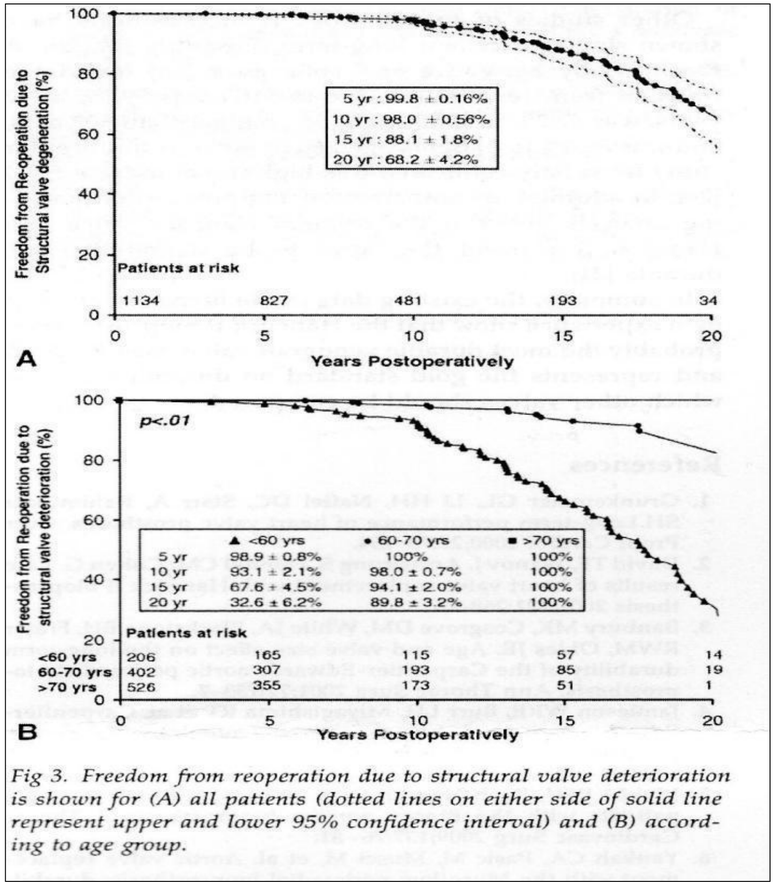
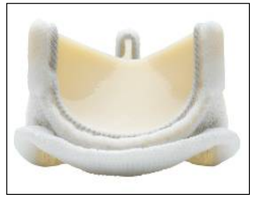


Fig 3. Freedom from reoperation due to structural valve deterioration is shown for (A) all patients (dotted lines on either side of solid line represent upper and lower 95% confidence interval) and (B) according to age group.

SAVR bioprosthesis

- FU > 20 years
- Proven age-related durability



Late Outcomes for Aortic Valve Replace the Carpentier-Edwards Pericardial Biop Up to 17-Year Follow-Up in 1,000 Patien

R. Scott McClure, MD, SM, Narendren Narayanasamy, MD, Esther
Stuart Lipsitz, ScD, Ann Maloney, BA, John G. Byrne, MD, Sary F.
Gregory S. Couper, MD, and Lawrence H. Cohn, MD

Division of Cardiac Surgery, Brigham and Women's Hospital, and Center for Surgery and Public H
Boston, Massachusetts

Background. This study reviews a single institution experience with the Carpentier-Edwards pericardial aortic valve bioprosthesis, concentrating on late outcomes.

Methods. From December 1991 to June 2002, 1,000 patients underwent aortic valve replacement with the Carpentier-Edwards pericardial valve (mean follow-up 6.01 ± 3.56 years). The institutional database was reviewed. Follow-up data were acquired through telephone interviews and mail-in questionnaires. Time-to-event analyses were performed by the Kaplan-Meier method. Mean age was 74.1 years; 545 patients (54.5%) were male. Mean preoperative ejection fraction was 52.5%. Isolated aortic valve replacement occurred in 372 cases (37.2%). Combined aortic valve replacement with coronary artery bypass grafting occurred in 443 cases (44.3%). The remaining 185 patients (18.5%) underwent complex procedures with concomitant mitral, tricuspid, or arch repair. One hundred forty patients (14.0%) had prior aortic valve surgery. Follow-up was 99.4% complete.

Results. Overall operative
1,000). There were 503 late d
survival at 15 years was 43.
years of age; 18.2% for patien
patients aged more than 75
bioprostheses (2.6%) requi
valve deterioration was the
endocarditis in 11 of 26 (42%
of 26 (7.6%). Age-stratified
due to structural valve de
34.7% for patients less thar
patients aged 65 to 75; an
more than 75 years.

Conclusions. The Carpent
prosthesis shows long-term
structural failure.

(Ann

Table 3. Long-Term Outcomes Assessment for Structural Valve Deterioration With Various Aortic Valve Replacement Options

Valve Type	Model	Author [Ref], Year	Follow-Up Maximum, Mean (Years)	Time of SVD Estimate (Years)	Age (Years)	Freedom From SVD (%)
Stented bioprostheses						
Bovine pericardium	Carpentier-Edwards	Biglioli [3], 2004	18, 6.0	18	67 (mean)	52.9 ± 9.9
					<65	35.8 ± 10.7
					≥65	83.7 ± 8.9
					65 (mean)	77 (CI: 74–82)
	Carpentier-Edwards	Banbury [4], 2001	17, 12	15	<50	48
					50–70	80
					≥70	90
	Carpentier-Edwards	McClure, current study	17, 6.0	15	74 (mean)	82.3 (CI: 67–91)
					<65	34.7 (CI: 6–67)
					65–75	89.4 (CI: 63–97)
					≥75	99.5 (CI: 97–99.9)
	Carpentier-Edwards	Poirier [6], 1998	15, 4.8	14	NR (mean)	79.9 ± 5.0
					<60	84.7
				10	60–69	87.9
					≥70	100
	Carpentier-Edwards	Dellgren [5], 2002	14, 5	12	71 (mean)	86 ± 9.0
					>65	100
	Carpentier-Edwards	Neville [7], 1998	12, 4.7	12	68 (mean)	94 (CI: 90–98)
					<60	89 (CI: 80–98)
					≥60	98 (CI: 96–100)
	Sorin Mitroflow	Yankah [11], 2008	21, 4.1	20	73 (mean)	62.3 ± 5.0
					≥65	71.8 ± 6.0
					≥70	84.8 ± 0.7
Porcine	St. Jude Biocor	Myken [12], 2009	20, 6.0	20	71 (mean)	61.1 ± 8.5
					≤50	37.7 ± 8.6
					51–60	60.7 ± 10.3
					61–70	81.0 ± 5.1
					71–80	97.8 ± 1.2
					>80	100
Stentless bioprostheses	St. Jude Toronto SPV	David [13], 2008	15, 7.7	12	65 (mean)	69 ± 4.0
					≤65	52 ± 8.0
					>65	85 ± 4.0
	Medtronic Freestyle	Ennker [14], 2009	9.8, 2.9	9	73 (mean)	92.4 ± 7.4
Mechanical prostheses	Medtronic-Hall	Svennevig [19], 2007	25, NR	25	56 (mean)	100
	St. Jude Mechanical	Ikonomidis [17], 2003	21, 7	20	56 (mean)	100
	Sorin Bicarbon Bileaflet	Spiliopoulos [18], 2008	10, NR	10	62 (mean)	100
Aortic homograft	Cryopreserved	Lund [20], 1999	27, 10	20	51 (mean)	18 ± 3
Pulmonary autograft	Ross procedure	Chambers [21], 1997	26, 20	20	32 (mean)	75
	Ross procedure	deKerchove [22], 2009	16, 7.8	12	40 (mean)	82 ± 8

TAVR valve durability

- 5 year follow-up shows good results with low degeneration rate
- Limited number of “survivors” from first cohorts of patients.
- Long-term durability can be limited by:
  - Underexpansion
  - Crimping
  - Calcium in native leaflets

1. Gerkens et al. Final 5-year clinical and echocardiographic results for treatment of severe aortic stenosis with a self-expanding bioprosthesis from the ADVANCE Study. Eur Heart J. 2017 Jun 13. doi: 10.1093/eurheartj/ehx295.
2. Sondergaard. Time to Explore Transcatheter Aortic Valve Replacement in Younger, Low-Risk Patients. JACC Cardiovasc Interv. 2016 Nov 14;9(21):2183-2185
3. Martin et al. Transcatheter Valve Underexpansion Limits Leaflet Durability: Implications for Valve-in-Valve Procedures. Ann Biomed Eng. 2017 Feb;45(2):394-404
4. Abdelghani et al. Patient selection for TAVI in 2016: should we break through the low-risk barrier? EuroIntervention. 2016 Sep 18;12(Y):Y46-50.
5. Kovac et al. Four-year experience with the CoreValve transcatheter heart valve. EuroIntervention. 2016 Oct 10;12(8):e1039-e1046.

Discussion

- In TAVR, incidence of PVL, vascular complications and new PM implantation is still high compared to SAVR
- Long-term TAVR valve durability is still not yet proven

- Hospital mortality and stroke after TAVR are low and more related to the patients' comorbidities than to the procedure itself
- Next generation TAVR devices will overcome the limits of the available valves.

Conclusion

- In 2017, TAVR has higher risks of PVL, vascular complications and new PM implantation compared to SAVR.
- While waiting for next-generation devices and long-term results, TAVR in low-risk patients should only be considered in selected cases.

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The Society of Thoracic Surgeons

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