Αντιστέκεται επαρκώς η «κλασσική» αντικατάσταση της αορτικής βαλβίδος στο TAVI-tsunami ;

Π. Δεδεηλίας, MD, PhD, FECTS

Διευθυντής ΕΣΥ, Τμήμα Χειρουργικής Καρδιάς Θώρακος και Αγγείων, ΓΝΑ «Ο ΕΥΑΓΓΕΛΙΣΜΟΣ»

Δεν υπάρχει σύγκρουση συμφερόντων με τις Χορηγούς Εταιρείες:

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

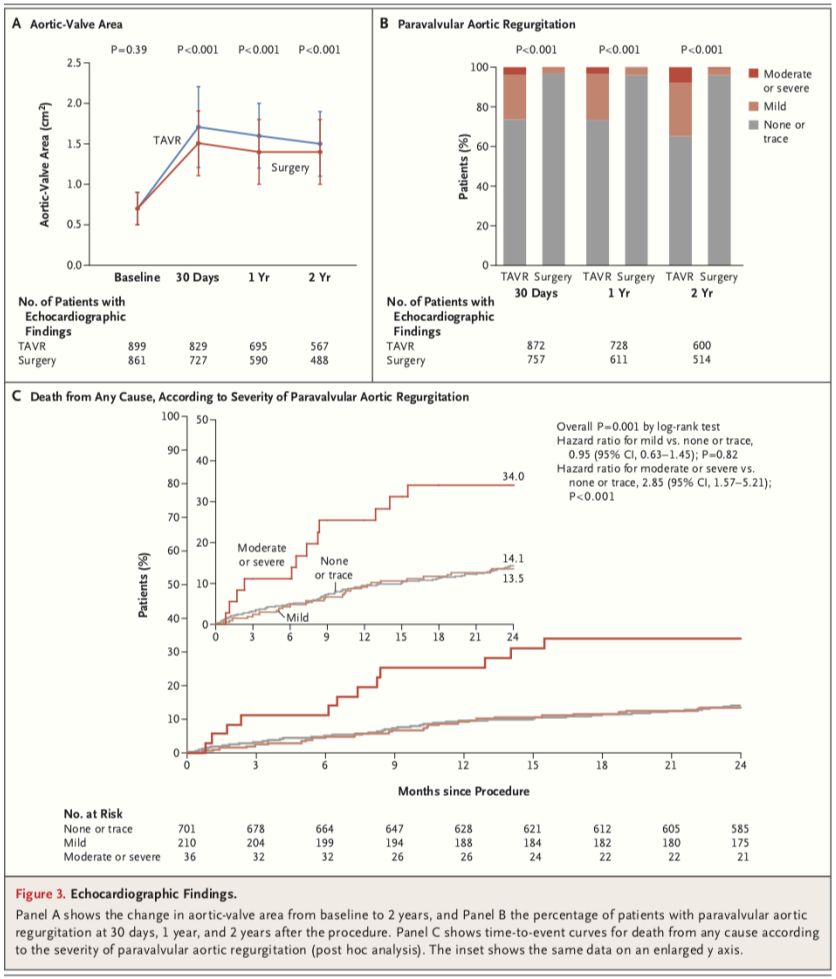


Figure 3. Echocardiographic Findings.
Panel A shows the change in aortic-valve area from baseline to 2 years, and Panel B the percentage of patients with paravalvular aortic regurgitation at 30 days, 1 year, and 2 years after the procedure. Panel C shows time-to-event curves for death from any cause according to the severity of paravalvular aortic regurgitation (post hoc analysis). The inset shows the same data on an enlarged y axis.

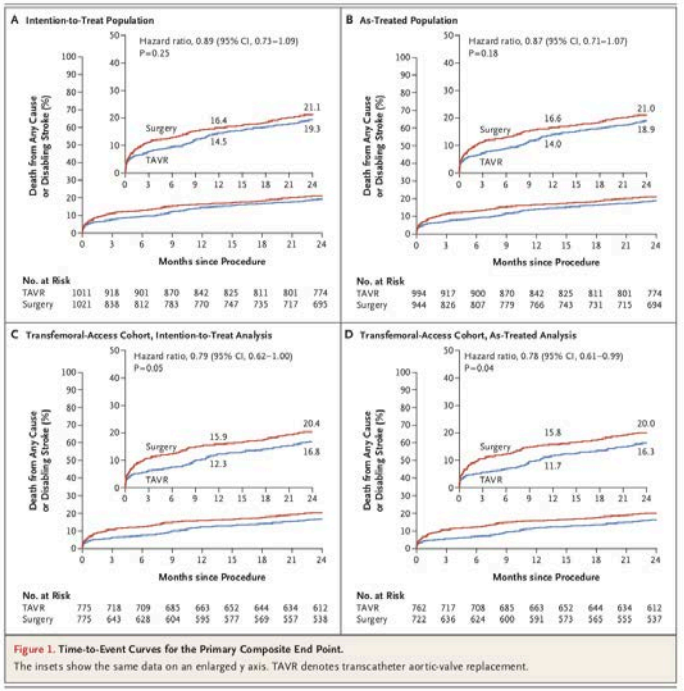


Figure 1. Time-to-Event Curves for the Primary Composite End Point.
The insets show the same data on an enlarged y axis. TAVR denotes transcatheter aortic-valve replacement.

CONCLUSIONS

In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. (Funded by Edwards Lifesciences; PARTNER 2 ClinicalTrials.gov number, NCT01314313.)

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 2, 2019 VOL. 380 NO. 18

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*

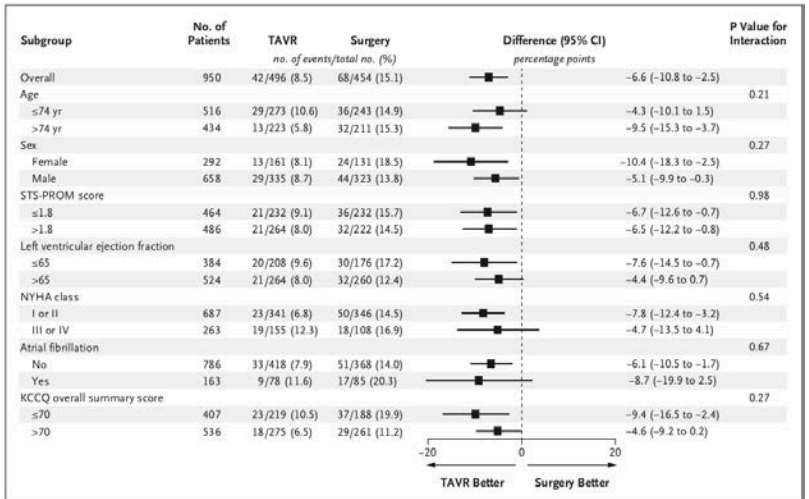


Figure 2. Subgroup Analyses of the Primary Composite End Point of Death from Any Cause, Stroke, or Rehospitalization.

All percentages are Kaplan–Meier estimates. Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) scores range from 0 to 100%, with higher scores indicating a greater risk of death within 30 days after the procedure. Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores range from 0 to 100, with higher scores indicating fewer physical limitations and a greater feeling of well-being. NYHA denotes New York Heart Association.

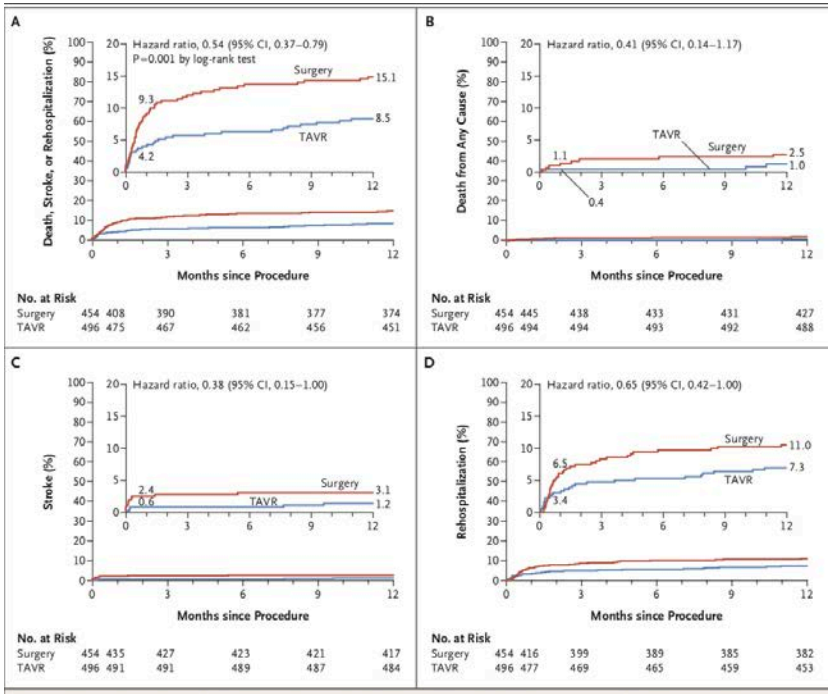


Figure 1. Time-to-Event Curves for the Primary Composite End Point and the Individual Components of the Primary End Point.

Shown are Kaplan–Meier estimates of the rate of the primary composite end point (Panel A) and the individual components of the primary end point, which are death from any cause (Panel B), stroke (Panel C), and rehospitalization (Panel D), in patients who underwent transcatheter aortic-valve replacement (TAVR) and those who underwent surgical aortic-valve replacement. The insets show the same data on an enlarged y axis.

CONCLUSIONS

Among patients with severe aortic stenosis who were at low surgical risk, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVR than with surgery. (Funded by Edwards Lifesciences; PARTNER 3 ClinicalTrials.gov number, NCT02675114.)

European Journal of Cardio-Thoracic Surgery 0 (2019) 1–9
doi:10.1093/ejcts/ezz245

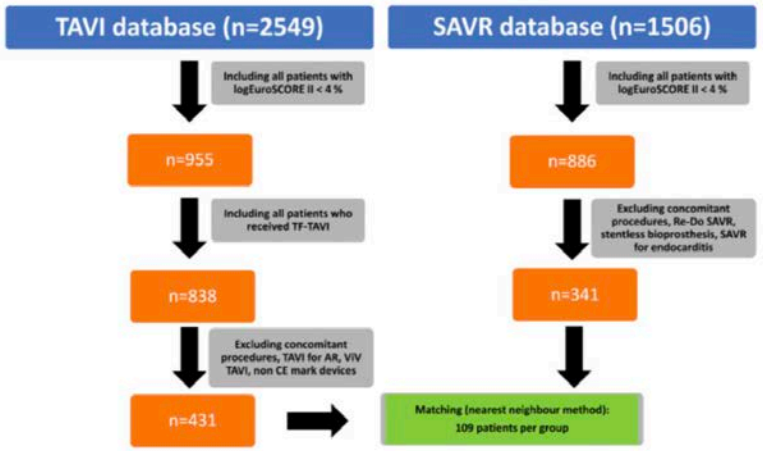
ORIGINAL ARTICLE

Cite this article as: Schaefer A, Schofer N, Goßling A, Seiffert M, Schirmer J, Deuschl F *et al.* Transcatheter aortic valve implantation versus surgical aortic valve replacement in low-risk patients: a propensity score-matched analysis. Eur J Cardiothorac Surg 2019; doi:10.1093/ejcts/ezz245.

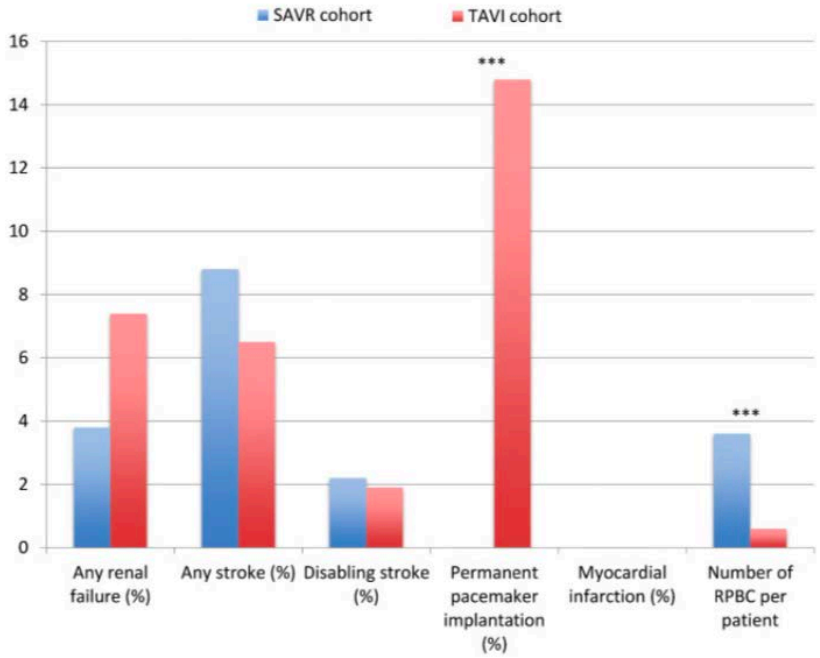
Transcatheter aortic valve implantation versus surgical aortic valve replacement in low-risk patients: a propensity score-matched analysis

Andreas Schaefer [a,*,†], Niklas Schofer[b,†], Alina Goßling [b], Moritz Seiffert[b], Johannes Schirmer [a], Florian Deuschl [b], Yvonne Schneeberger[a], Lisa Voigtländer[b], Christian Detter[a], Ulrich Schaefer[b], Stefan Blankenberg[b], Hermann Reichenspurner[a], Lenard Conradi[a,†] and Dirk Westermann[b,†]

A. Schaefer *et al.* / European Journal of Cardio-Thoracic Surgery



A. Schaefer *et al.* / European Journal of Cardio-Thoracic Surgery



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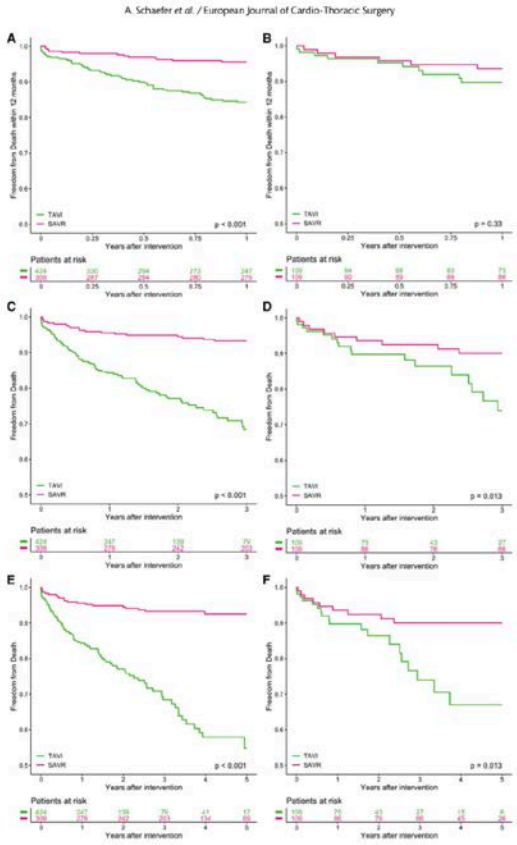


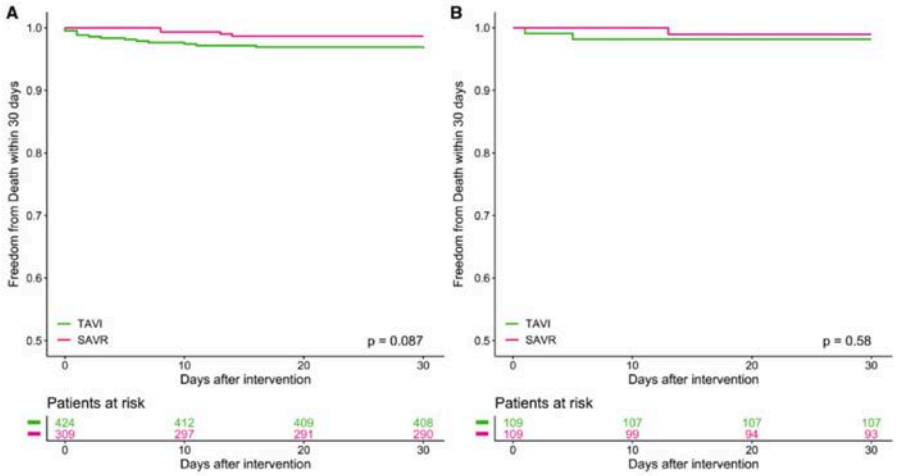
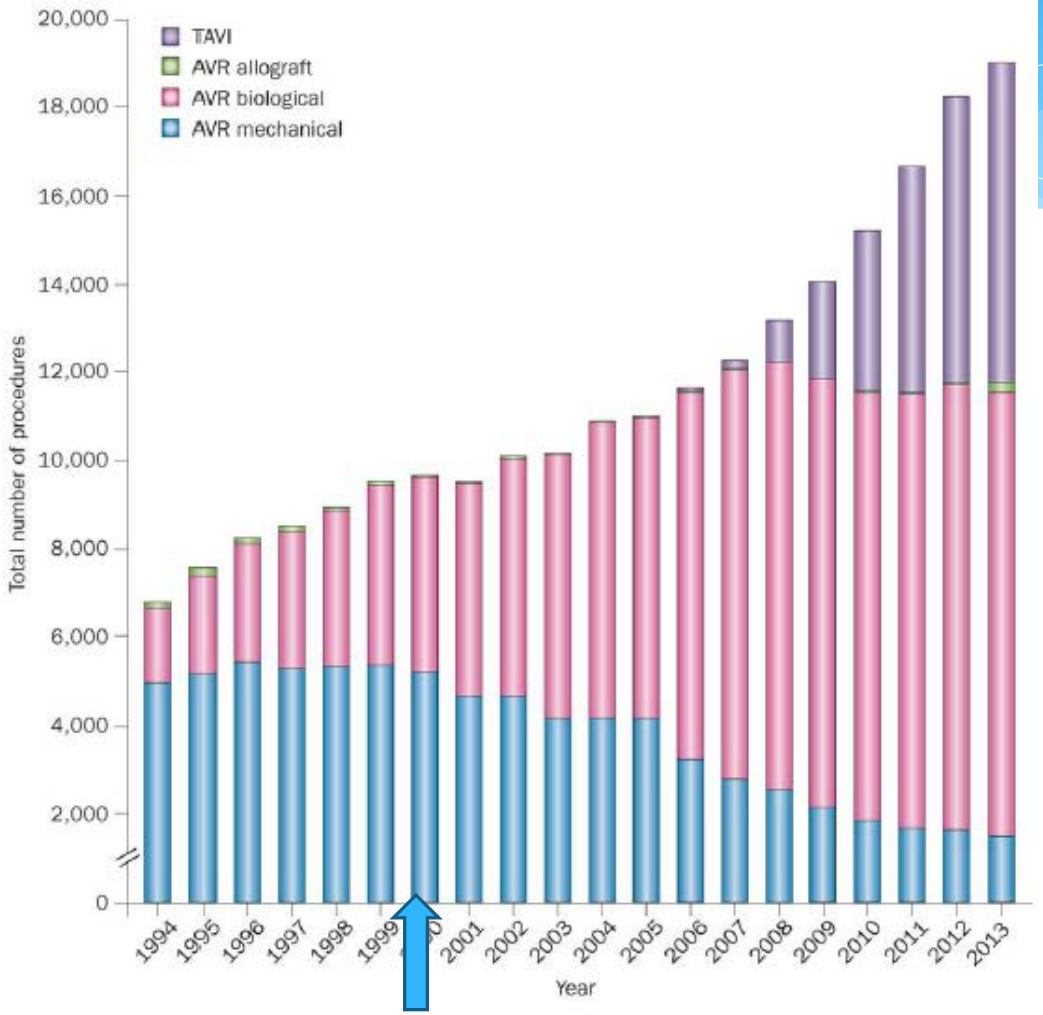


Figure 2: Kaplan–Meier analysis of 30-day survival in unmatched (**A**) and matched (**B**) patient cohorts. SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

ΕΠΙΔΗΜΙΟΛΟΓΙΚΑ ΔΕΔΟΜΕΝΑ

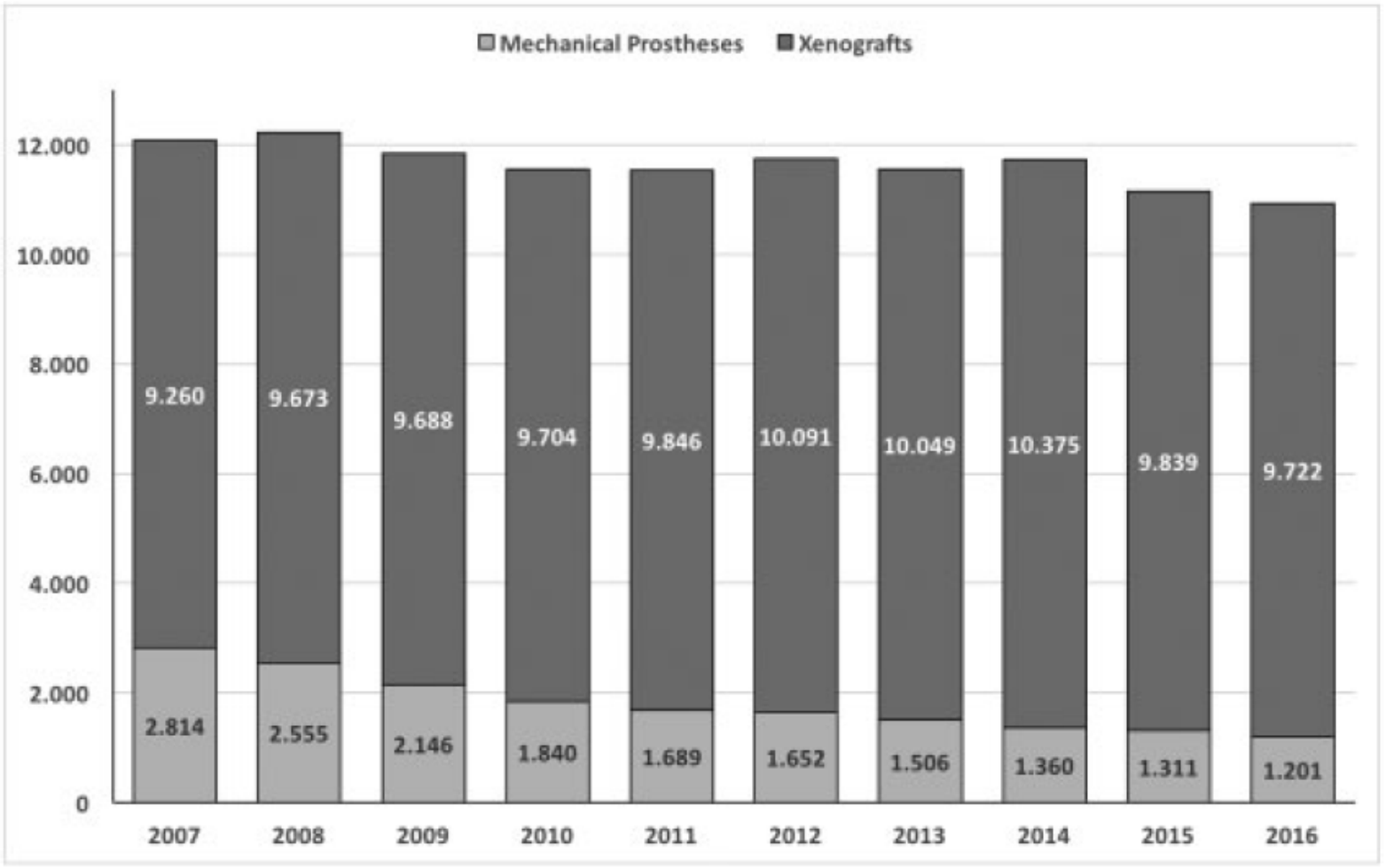
* ΕΥΡΩΠΗ: 520 εκ.(-RUS,TR,CIS)
* Αύξηση ΚΡΧ επεμβάσεων κατά 101%
* Αύξηση επεμβάσεων βαλβίδων: 62%
* Επεμβ.καρδιάς/πληθυσμό:80/100.000
* Επεμβ. Βαλβίδων/πληθ.:16.4/100.000
* % αντικατάσταση βαλβ./επ.καρδιάς: 25.95%~21%
* Μηχανικές:57% του συνόλου βαλβίδων
* Περίπου 85.000 αντ.βαλβίδος/έτος

Increasing Use of Bioprostheses
Data from German Registry



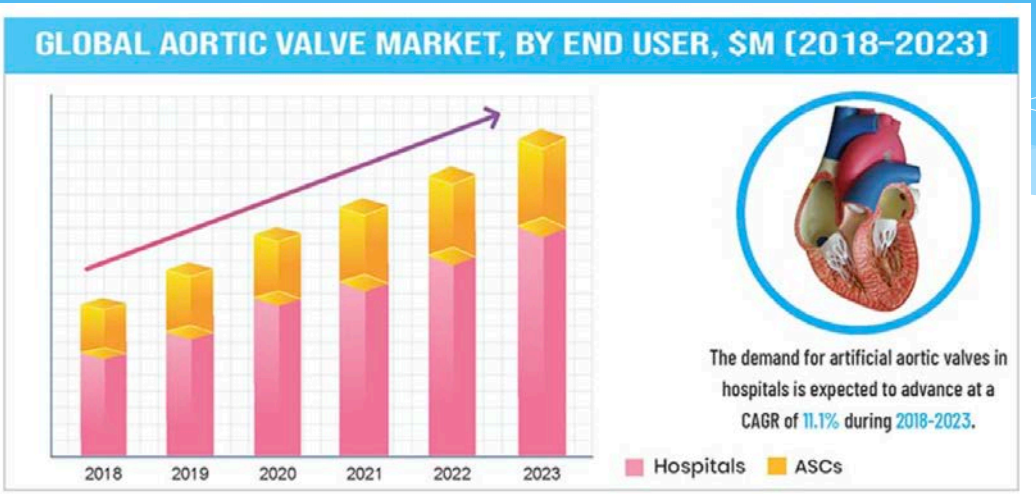
SOURCE: Mohr, Nat Rev, 2014

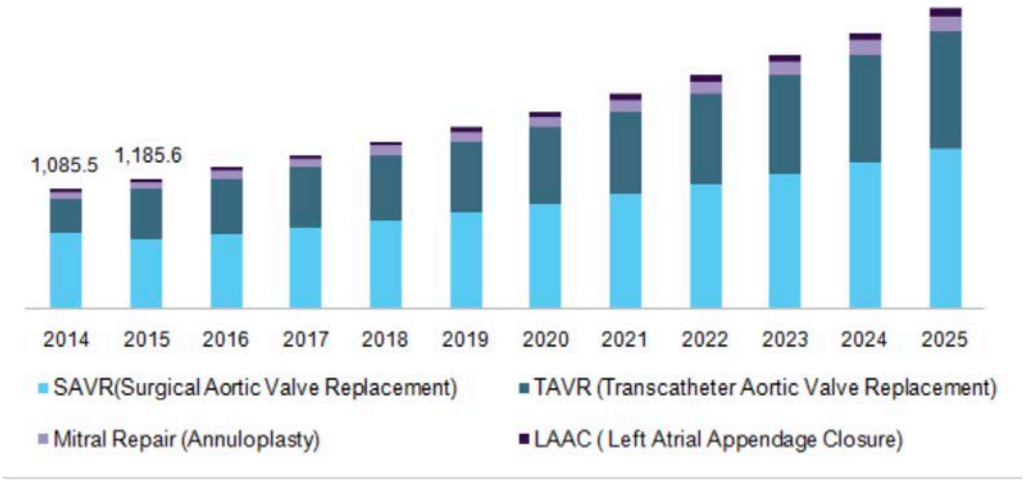
Isolated aortic valve replacement (2007–2016)



German Heart Surgery Report 2016: The Annual Updated Registry of the German Society for Thoracic and Cardiovascular Surgery

AORTIC VALVE MARKET



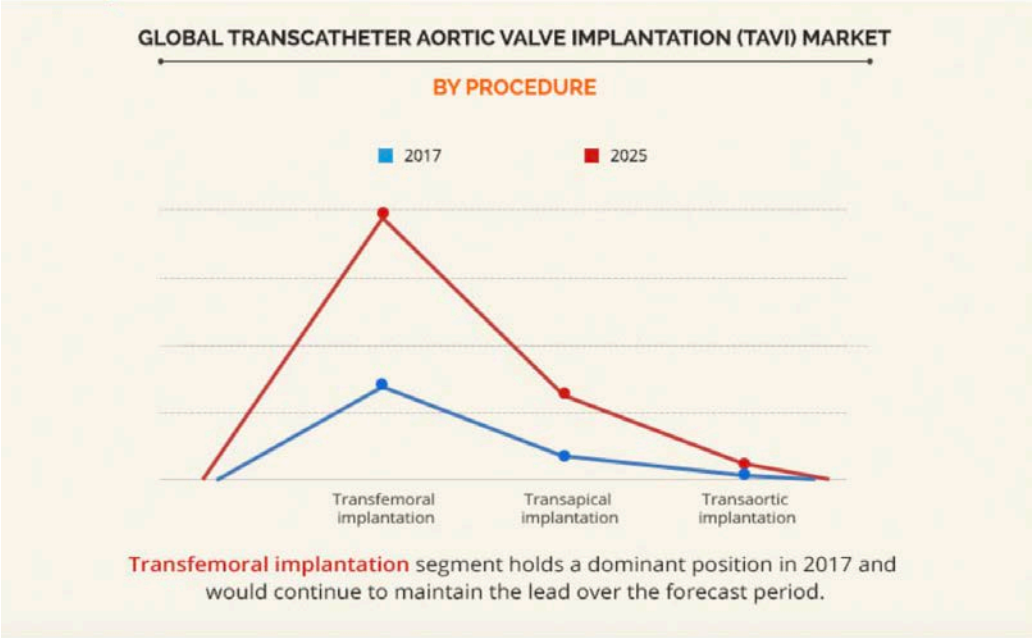


TAVI MARKET OVERVIEW

Transcatheter Aortic Valve Implantation (TAVI) Market Overview:

The **Global Transcatheter Aortic Valve Implantation (TAVI) Market** revenue was valued at $2,761 million in 2017 and is expected to reach $8,138 million by 2025, growing at a CAGR of 13.8% from 2018 to 2025. The volume market was valued at 107,011 units in 2017 and is expected to reach 337,778 units by 2025, growing at a CAGR of 14.8% from 2018 to 2025.

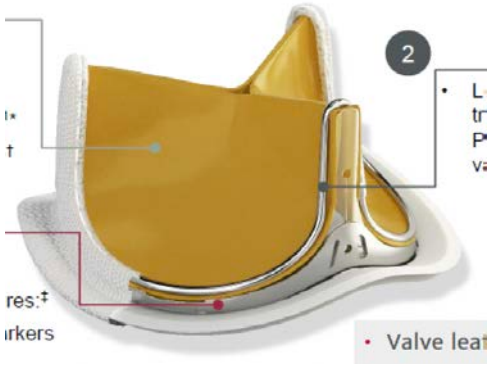
Transcatheter aortic valve implantation (TAVI), also called as transcatheter aortic valve replacement (TAVR), is a minimally invasive surgical procedure, which is performed to treat high-risk patients from aortic stenosis. These high-risk patients refer to the patient population that are inoperable and cannot undergo surgical aortic valve replacement (SAVR) procedure. Older population (above 75 years of age) falls under the high-risk category, as the open-heart procedure is too risky for them. TAVR involves implantation of transcatheter aortic valves to regenerate the blood circulation ability of the aortic valve. The need of transcatheter aortic valve implantation is on the rise due to the increase in prevalence of aortic stenosis.

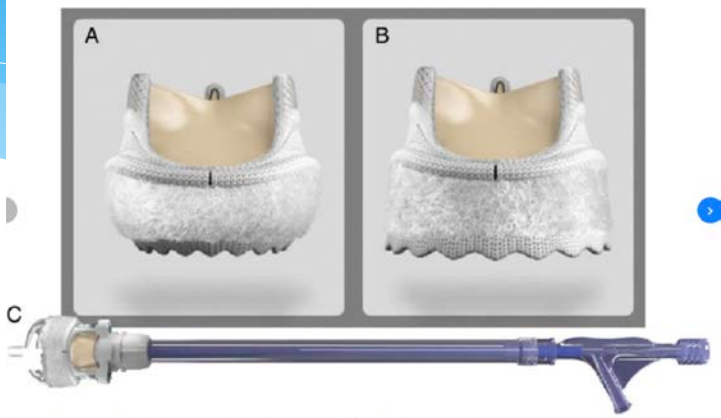


What is the role of the new generation surgical aortic valves?

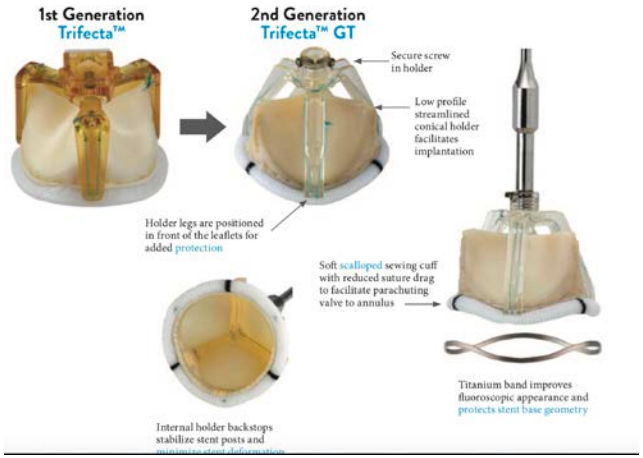
* 1) Minimalization of the ischemia time, CPB time, operation time.
* 2)Compatibility with Minimally Invasive Approches
* 3)Provide improved haemodynamic performance (EOA)
* 4)Competitive with TAVI (Cost Effectiveness)
* 5)Durability – less degenerative disease
* 6)Friendly with future TAVI in valve
* 7)Become the first choice in AVR

New Generation Surgical Aortic Valves

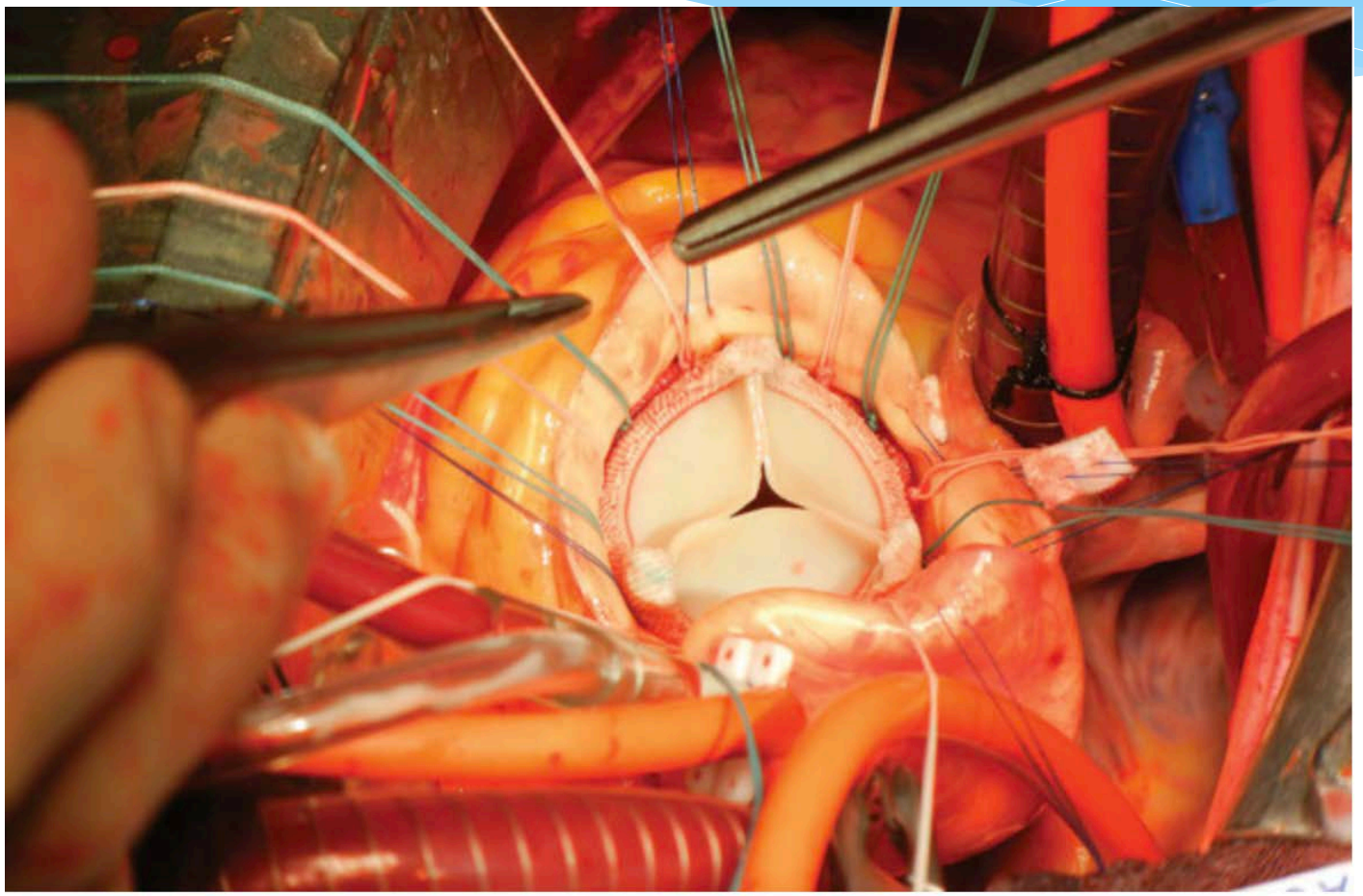




The EDWARDS INTUITY valve. The subannular skirt frame in the (A) precrimped and (B) deployed configuration. (C) Complete valve deployment system.



1) Minimalization of the ischemia time, CPB time, operation time.



Shrestha M,Fischlein T,Meuris B,Flameng W,Carrel T,Madonna F,Martin Misfeldf, **Thierry Folliguet**, Axel Haverich, **Francois Laborde**. European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up **to 5 years in over 700 patients**. **Eur J Cardiothorac Surg 2016**;49:234–41.

* This European multicentre experience, with the **largest cohort of patients** with **Perceval S** valves to date, shows **excellent clinical and haemodynamic results** that remain stable even up to the 5-year follow-up.
* Even in this elderly patient cohort with 40% octogenarians, both early and late mortality rates were very low.
* There were no valve migrations, structural valve degeneration or valve thrombosis in the follow-up.
* The sutureless technique is a promising alternative to biological aortic valve replacement.

Shrestha M, Fischlein T, Meuris B, Flameng W, Carrel T, Madonna F , Martin Misfeldf, **Thierry Folliguet**, Axel Haverich and **Francois Laborde**. European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up **to 5 years in over 700 patients**. Eur J Cardiothorac Surg 2016;49:234–41.

* **From April 2007 to August 2012, 731 consecutive patients (mean age: 78.5 years; 68.1% females; mean logistic EuroSCORE 10.9%) underwent AVR with the Perceval valve in 25 European centres.**
* **Isolated AVR was performed in 498 (68.1%) patients.**
* A minimally invasive approach was performed in 189 (**25.9%)** cases.
* **The cumulative follow-up was 729 patients-years.**

Shrestha M, Fischlein T, Meuris B, Flameng W, Carrel T, Madonna F , Martin Misfeldf, **Thierry Folliguet**, Axel Haverich and **Francois Laborde**. European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up **to 5 years in over 700 patients**. Eur J Cardiothorac Surg 2016;49:234–41.

* **mean cross-clamp and CPB times were 30.8 and 50.8 min in FS**
* **37.6 and 64.4 min in the MIAVR , respectively**
* **Early cardiac-related deaths occurred in 1.9%**
* **Overall survival rates at 1 and 5 years were 92.1 and 74.7%, respectively**
* **Major paravalvular leak occurred in 1.4% and 1% at early and late follow-up, respectively**
* **Significant improvement in clinical status was observed postoperatively in the majority of patients**
* **Mean and peak gradients decreased from 42.9 and 74.0 mmHg preoperatively, to 7.8 and 16 mmHg at the 3-year follow-up**
* **LV mass decreased from 254.5 to 177.4 g at 3 years**

Dedeilias et al. Journal of Cardiothoracic Surgery (2016) 11:54
DOI 10.1186/s13019-016-0438-7

Journal of Cardiothoracic Surgery

STUDY PROTOCOL Open Access

Aortic valve replacement in elderly with small aortic root and low body surface area; the Perceval S valve and its impact in effective orifice area

Panagiotis Dedeilias[1], Nikolaos G. Baikoussis[1*], Efstathia Prappa[2], Dimitrios Asvestas[2], Michalis Argiriou[1] and Christos Charitos[1]

Conclusions: Aortic valve replacement with Perceval aortic valves in geriatric patients with comorbidities and small aortic annulus seems to be an alternative, safe and "fast" intervention with excellent short and mid-term results which provides a better effective orifice area.

Patient Characteristics

	SVP (25) *Sutureless valve*	**BVP (25)** *Classic* (SOPRANO)
Number of patients	25	25
Age (mean)	80 ± 3.3	79 ± 4.1
Sex (♀/total)	18/25	17/25
Euro Score II	9.5 ± 3.5	9.9 ± 3.6
BSA (m^2)	1.45 ± 1.2	1.78 ± 1,1
Stroke history	3/25 (12%)	2/25(8%)
Preop rhythm	2/25 rbbb, 1/25 lbbb, 16/25 NSR , 1/20 A-F	3/25 rbbb, 2/25 A-F, 15/25 NSR
Concomitant CAD requiring CABG	3/25 (2-3grafts)	2/25 (1graft each)

Table 1. Patient characteristics and results of our initial experience.

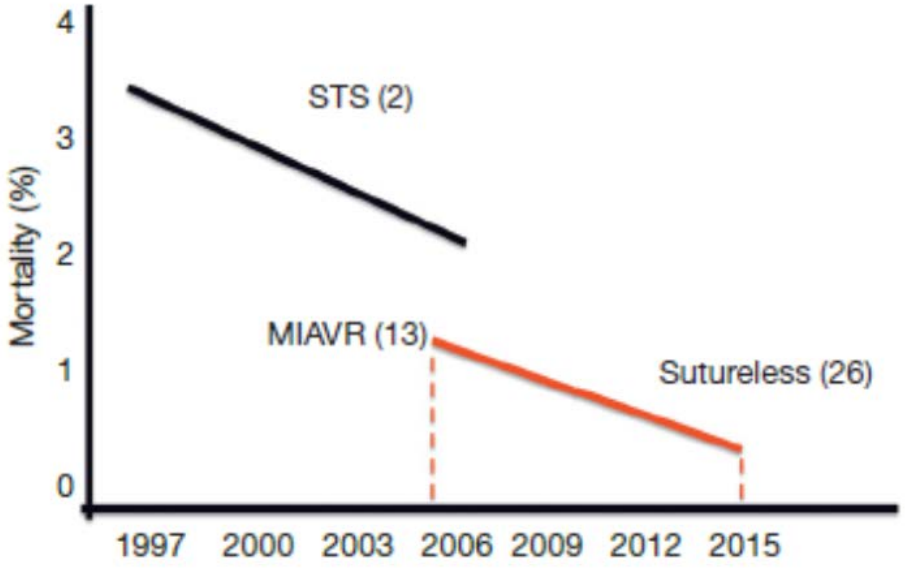
	SVP (25) *Sutureless valve*	BVP (25) *Classic biological valve* (SOPRANO)	P
Number of patients	25	25	
Preop. max gradient	88±10.5	89±12.5	
Postop. max gradient	**23.5±19.20 mmHg**	**24.5±19.90 mmHg**	0.670
Preop EOA	0.45 ± 0.19	0.47 ± 2.1	
Postop EOA	1.5±0.3 cm2	1.1±0.5 cm2	0.002
Operation time	149.38±15.22 min	**206.64±42.85 min**	p<0.001
CPB time	73.75±8.12 min	120.36±28.31 min	p<0.001
Ischemia time	40±5.50 min	86±15.86 min	p<0.001
Temporary postop pacing, permanent	**15/20-3/20**	**2/20- 0/15**	
Death	0/25	**1/25 arrhythmia**	

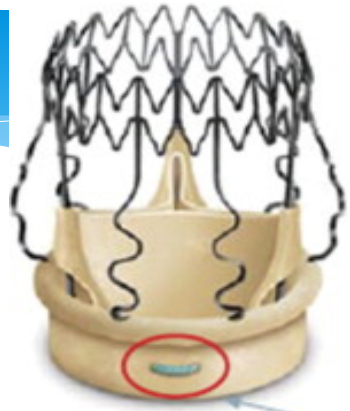
2)The combination of MIAVR using sutureless/fast deployment valves has improved postoperative mortality

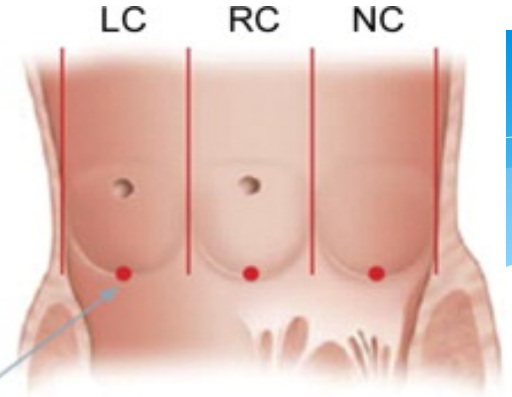
Black line: in-hospital mortality reduction from 3.4% in 1997 to 2.6% in 2006 for isolated AVR according to STS data (2).

Red line: the introduction of **sutureless valves** associated with **MIAVR** has decreased the in-hospital mortality from *1.6% in 2005* to **0.7% in 2013**.

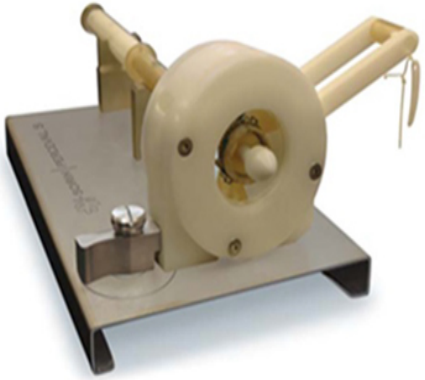
Ann Cardiothorac Surg 2015;4(1):26-32

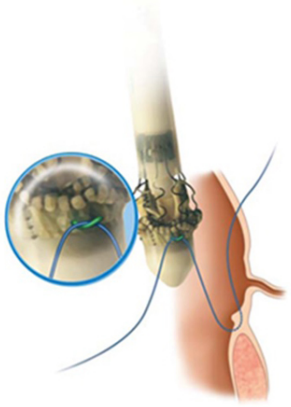


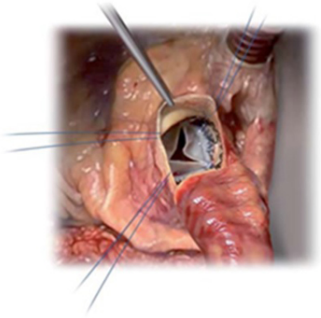


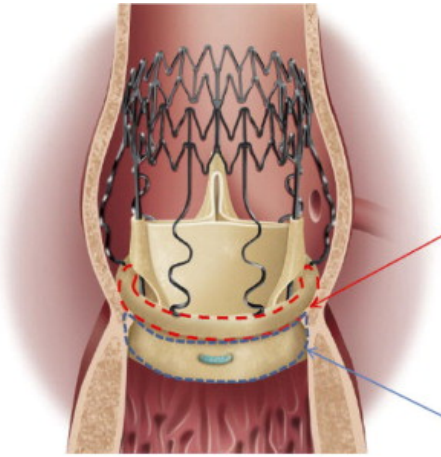


Button hole



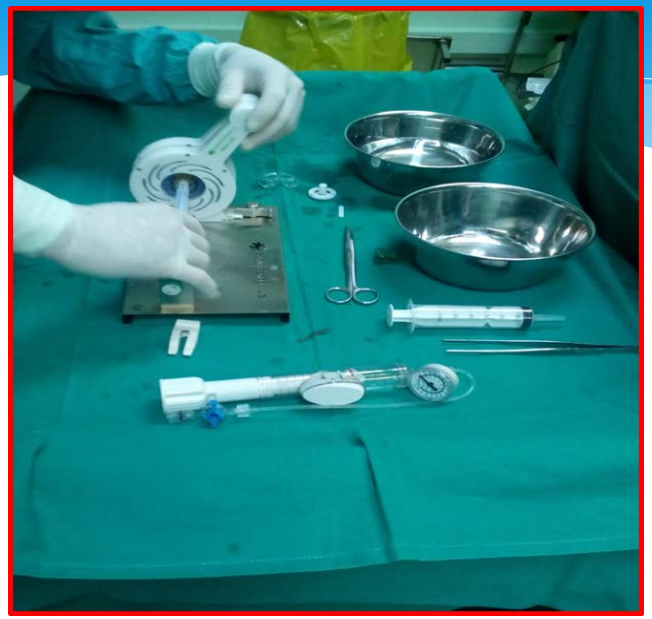


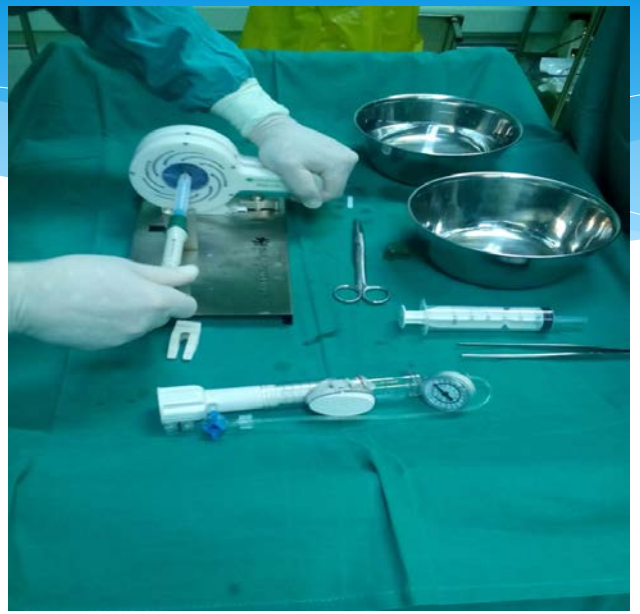


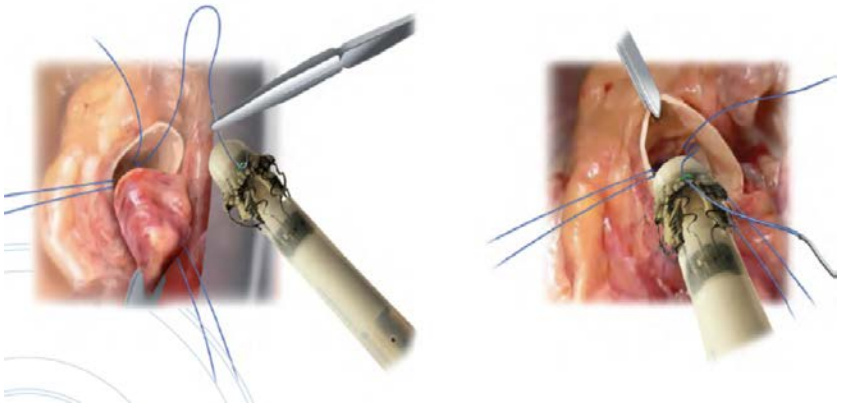


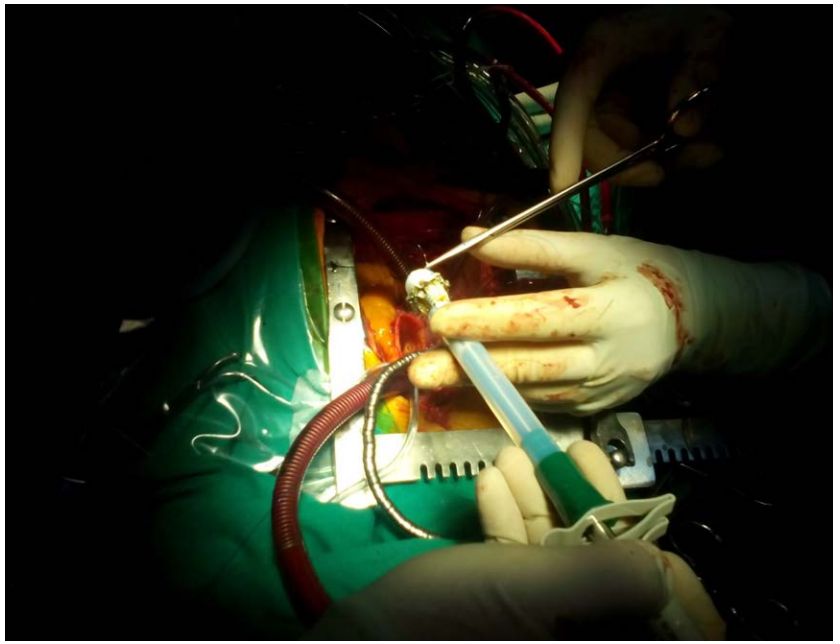
Supra-annular sealing collar

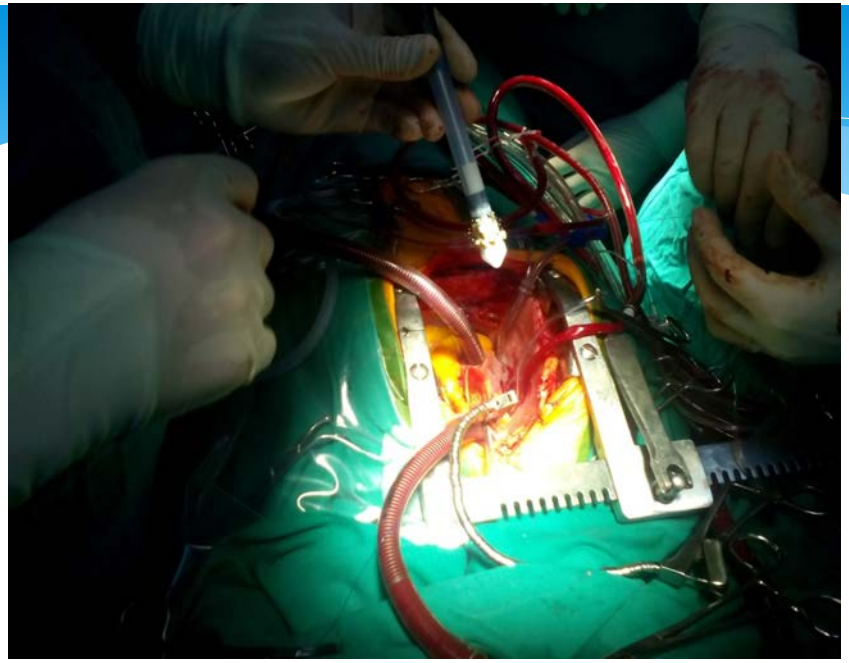
Intra-annular sealing collar

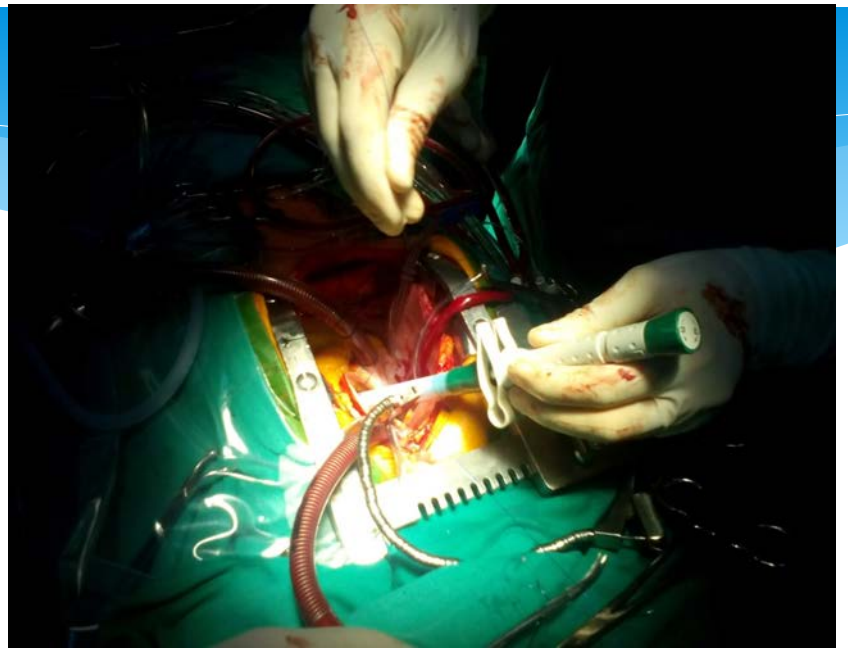


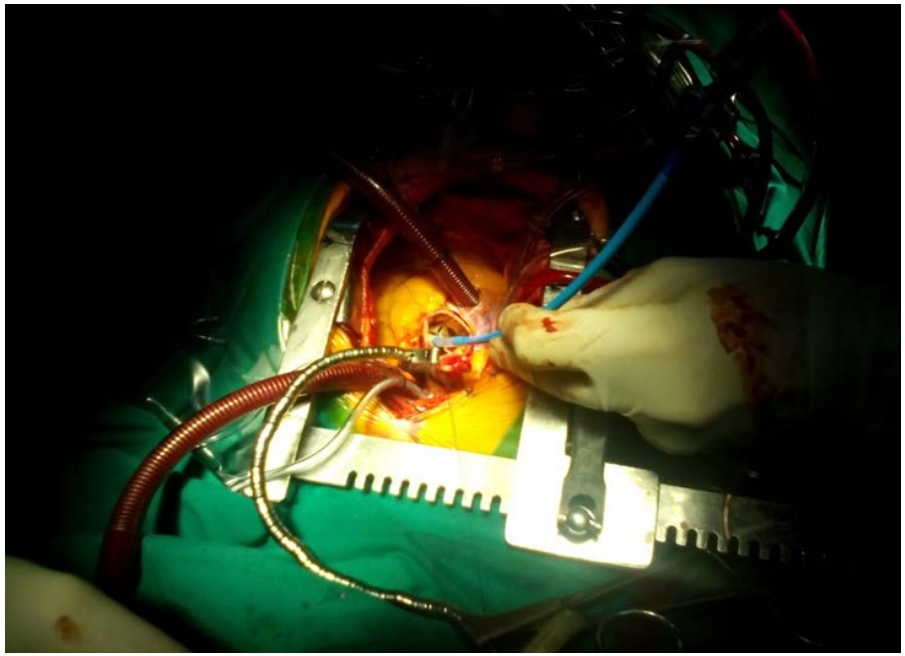


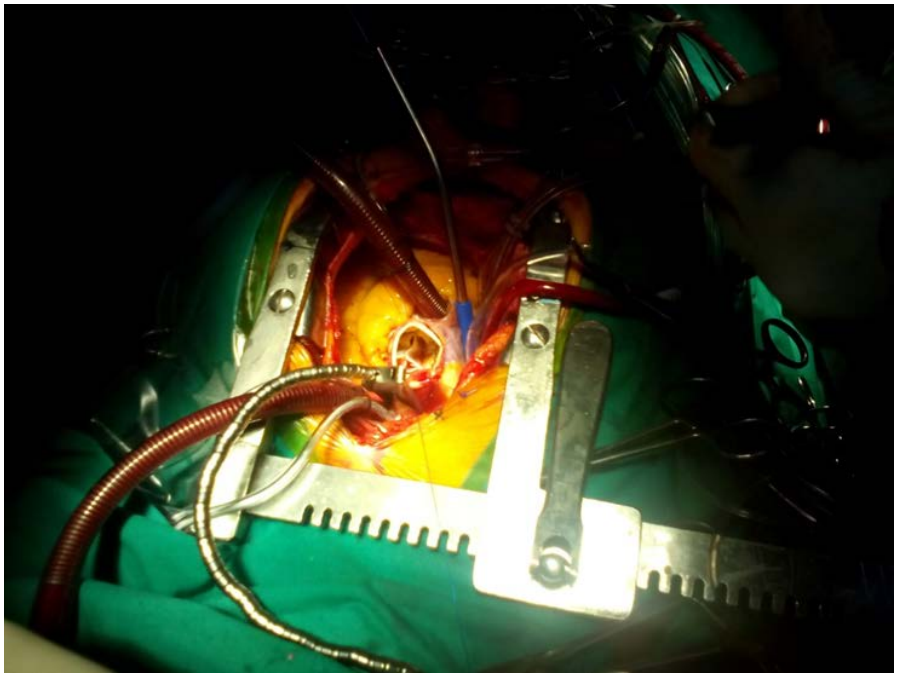


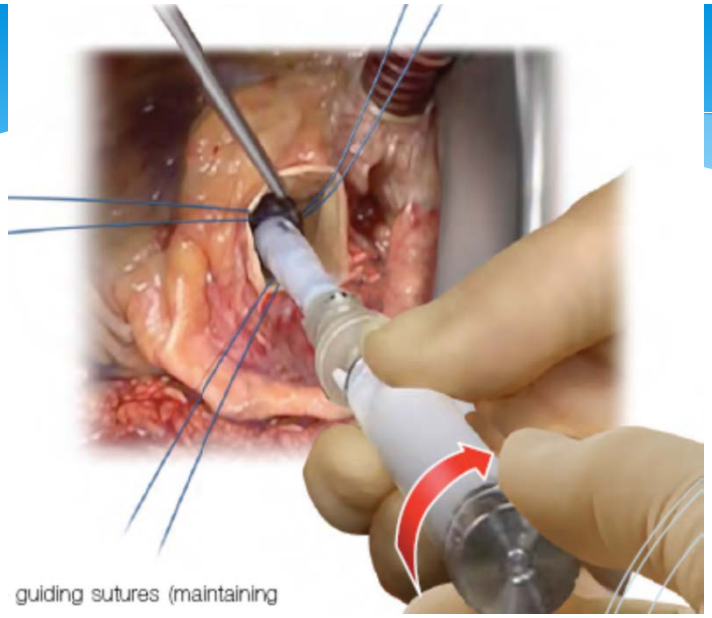




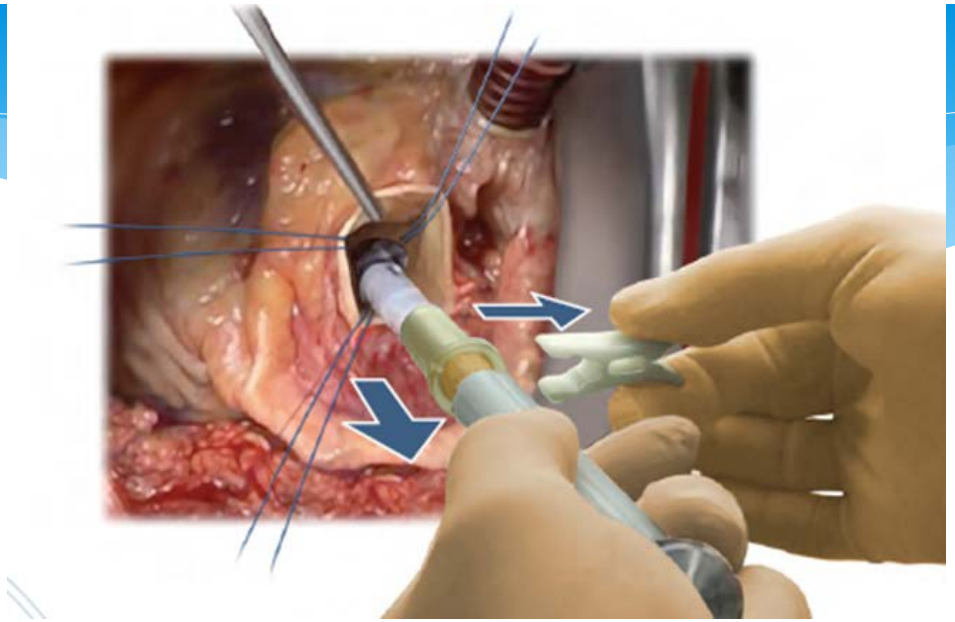


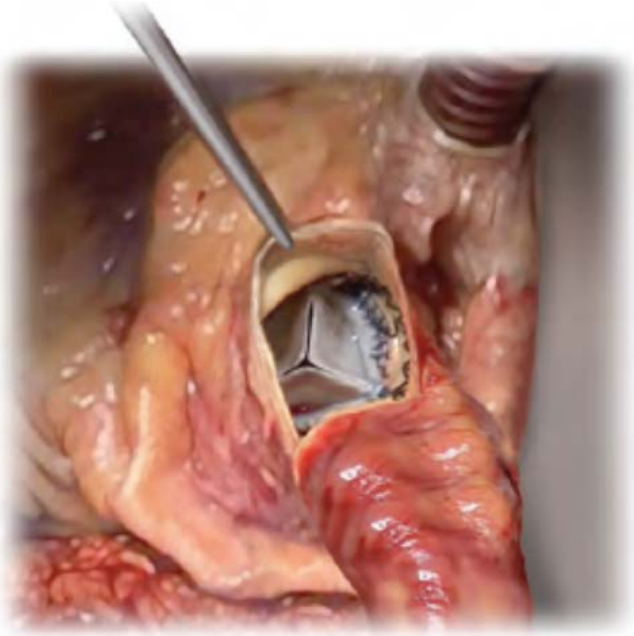


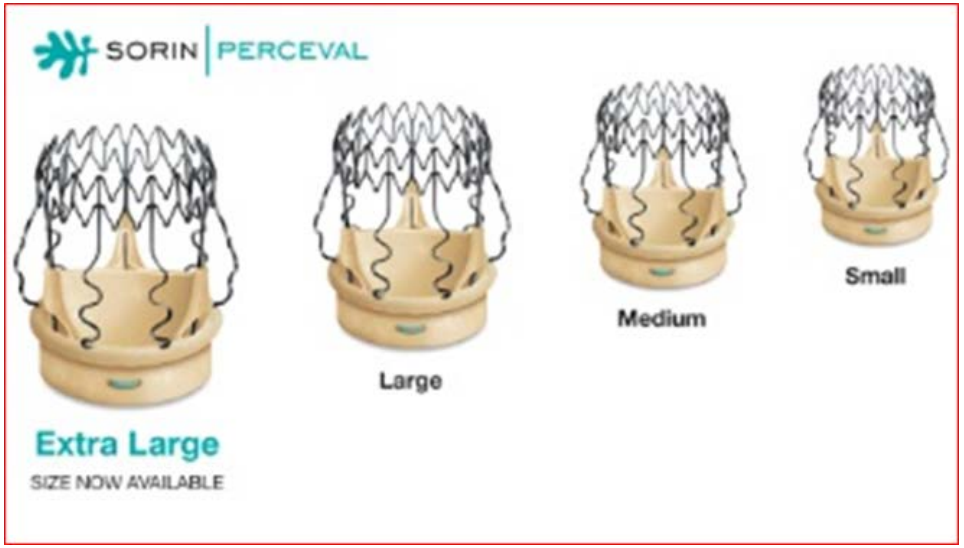


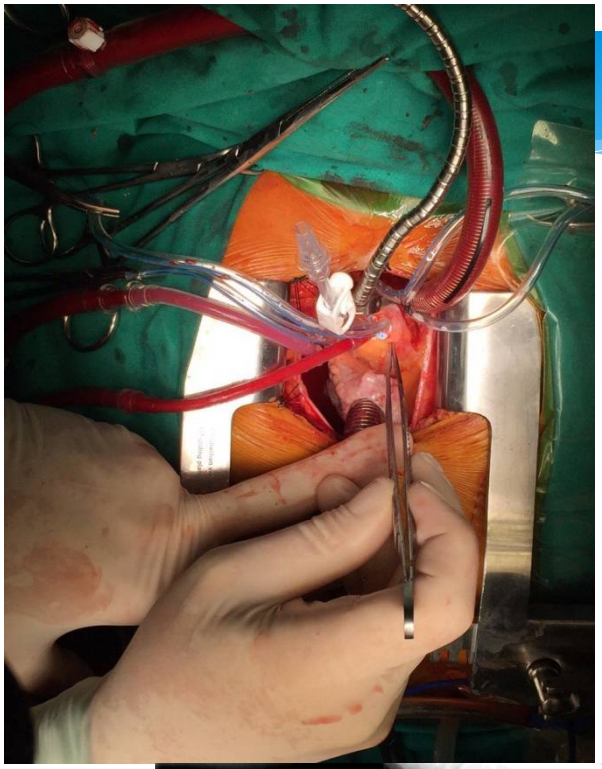


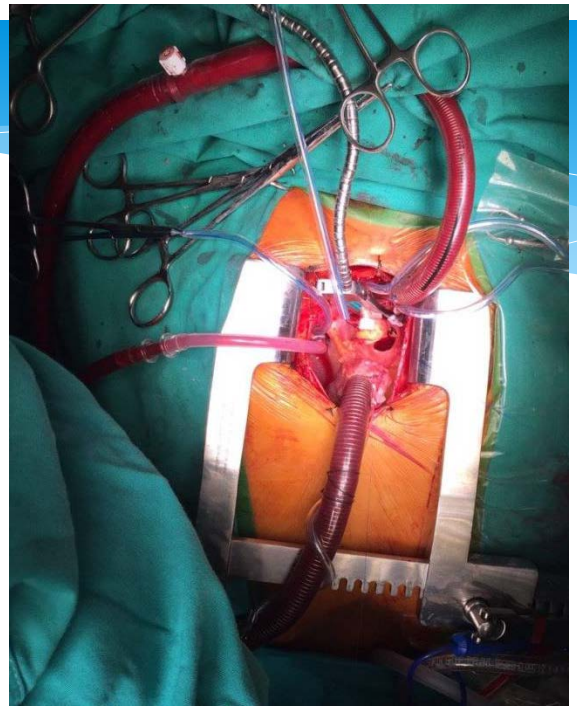
guiding sutures (maintaining

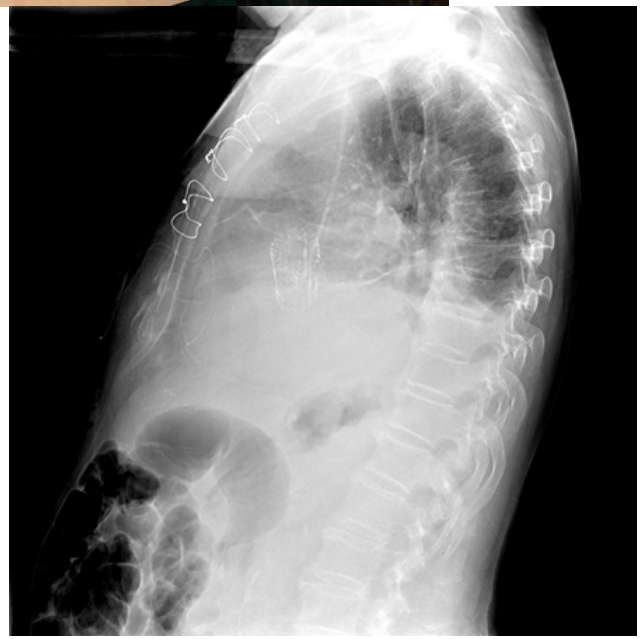


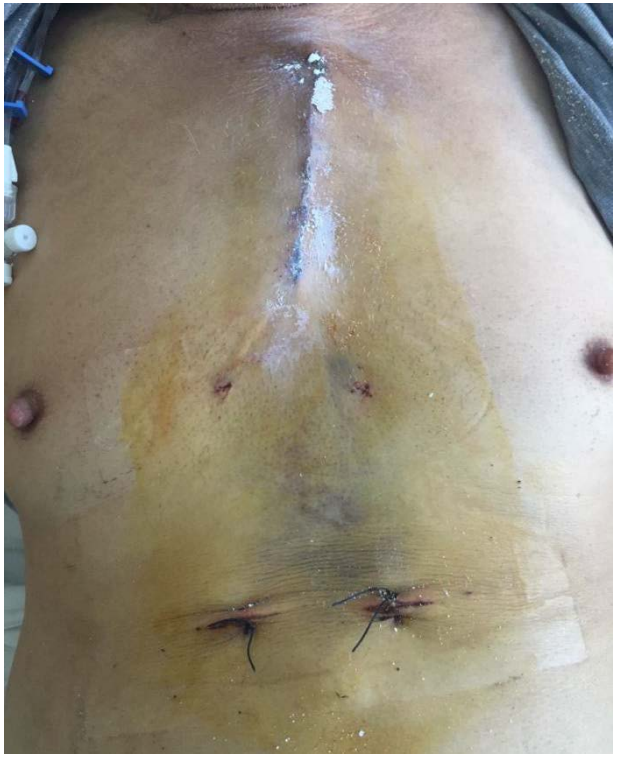




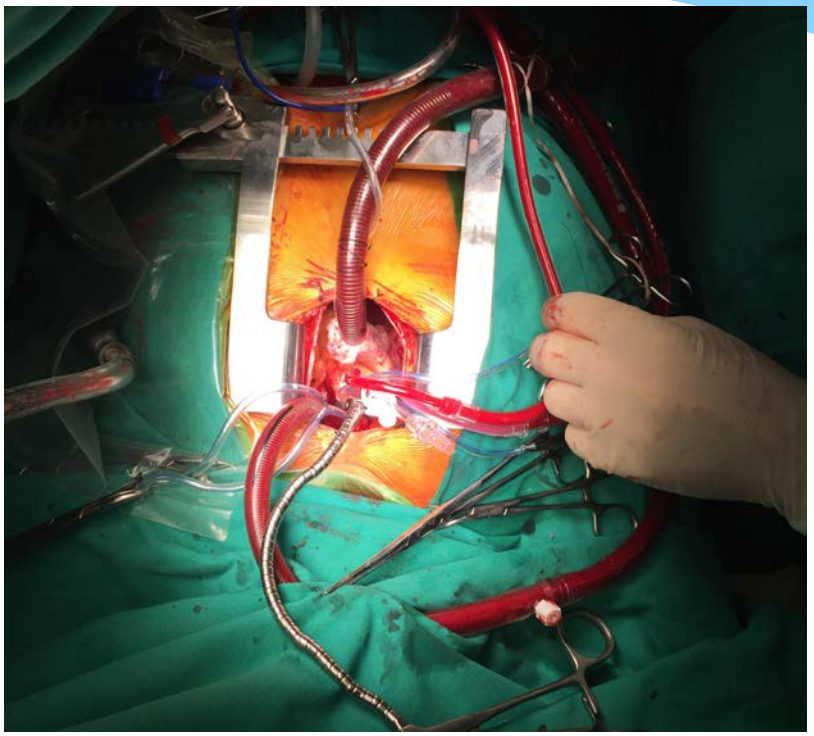


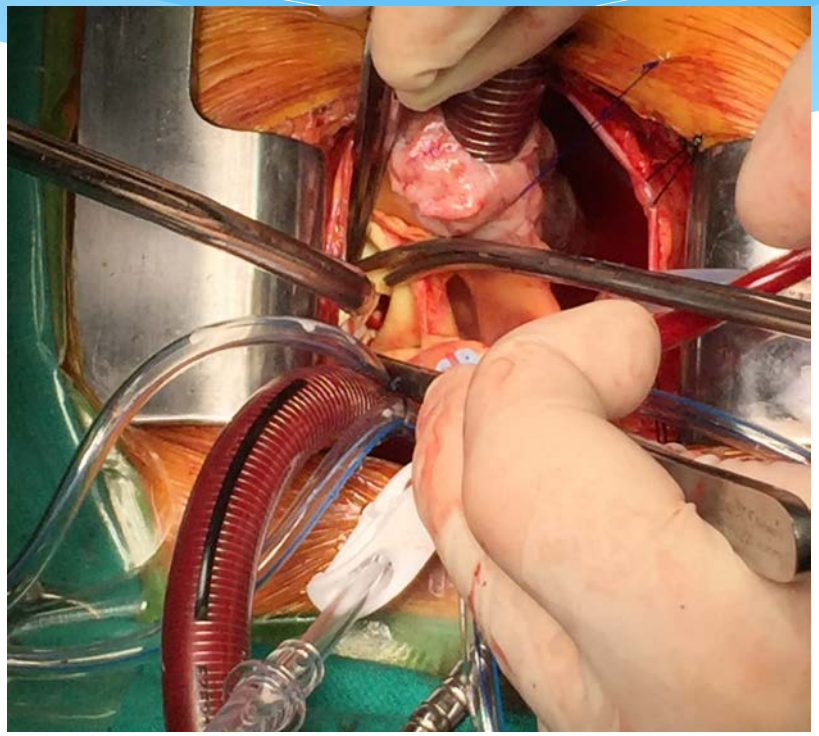




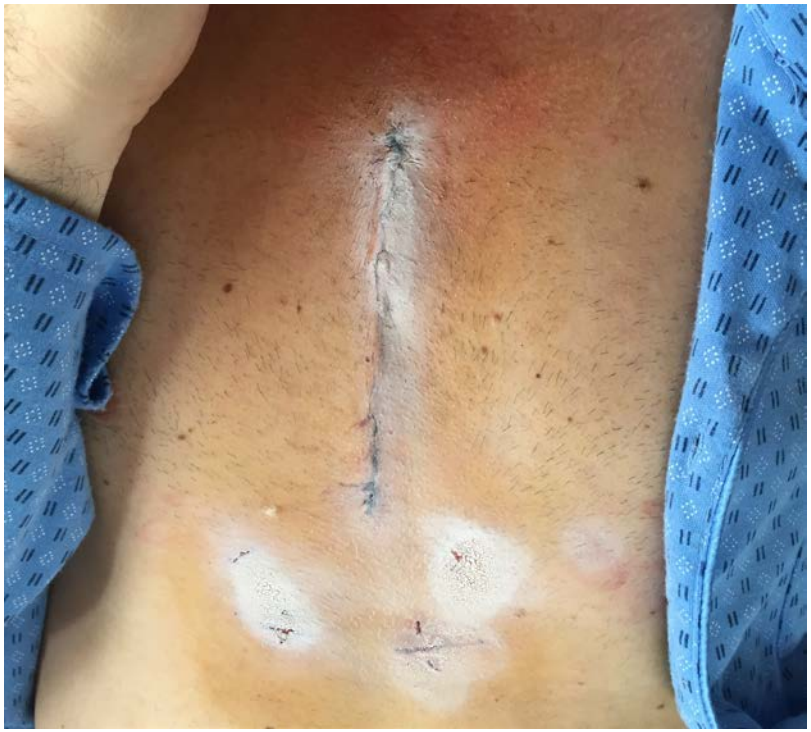


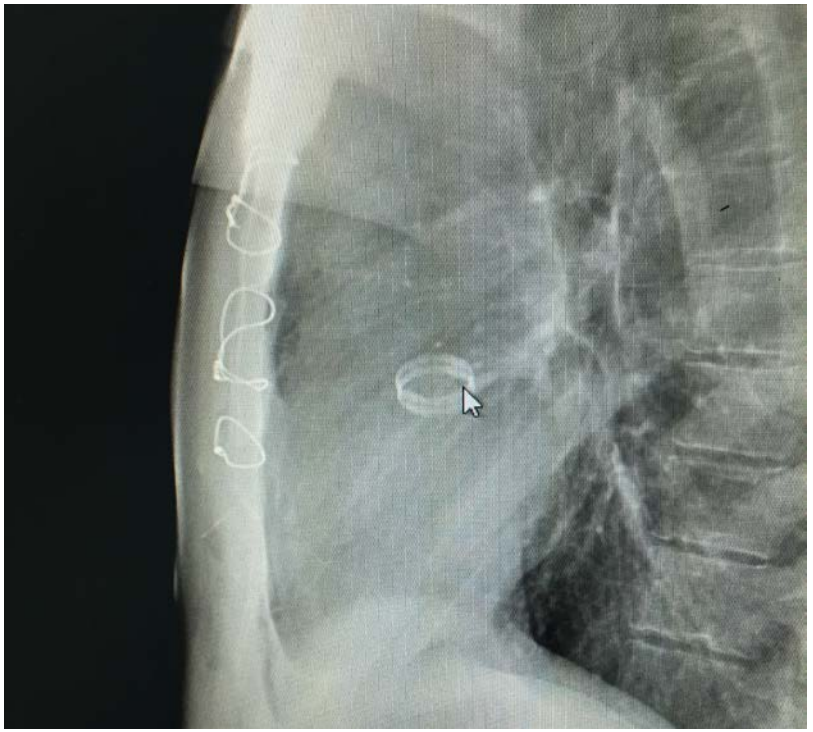
MISAVR- Evangelismos





MISAVR- Evangelismos





Only 3 staying stitches to hold the valve in place and balloon expansion for the final result

Secure assembly

Engineered to ensure only the correct size valve and delivery system are connected for procedural confidence.

Rapid valve preparation

No collapsing or folding of the valve leaflets during preparation or implantation.

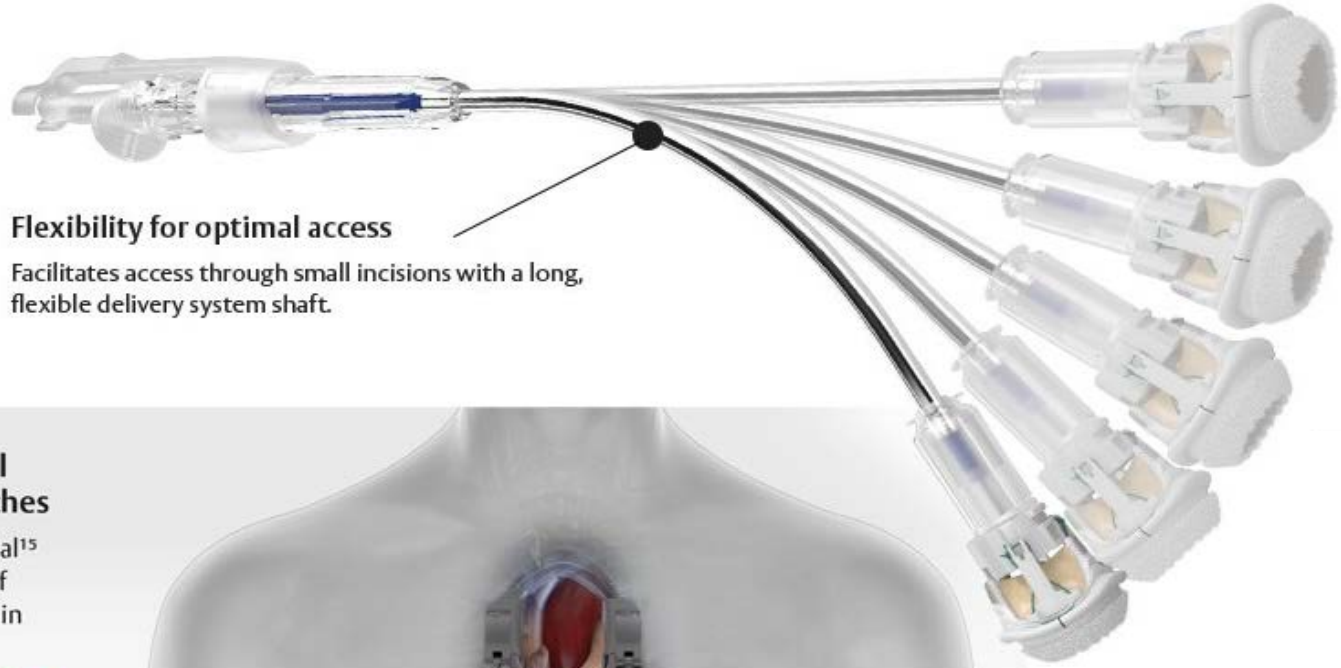
Innovative balloon design

Incorporated within the delivery system for reliable balloon positioning and inflation, as well as simplified device preparation.

Balloon expanded delivery for efficient procedures

The EDWARDS INTUITY Elite valve system utilizes three guiding sutures in conjunction with the expanded frame for secure annular placement, helping reduce procedural steps.

Compatibility with minimally invasive technics



Flexibility for optimal access

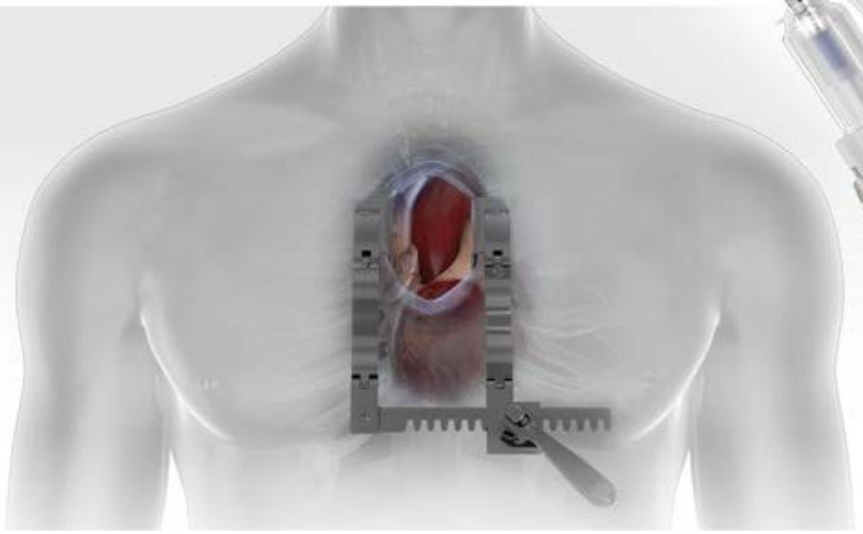
Facilitates access through small incisions with a long, flexible delivery system shaft.

High use of small incision approaches

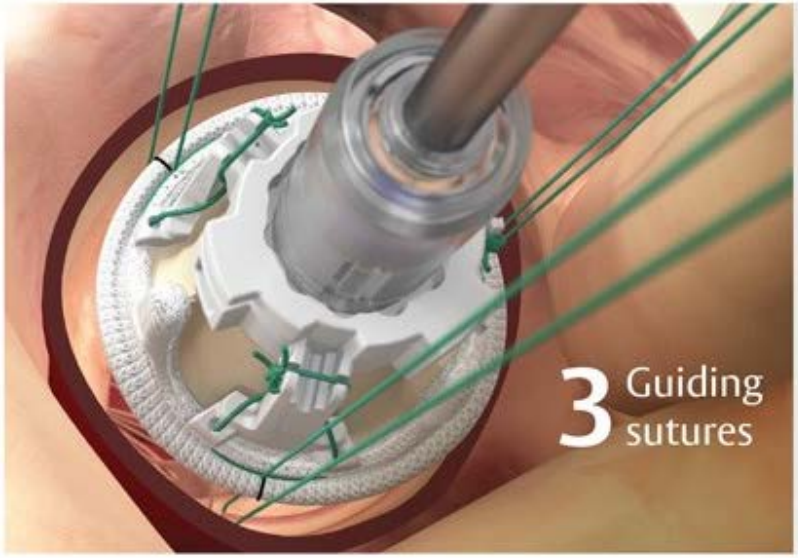
The TRANSFORM Trial[15] showed high rates of small incision usage in isolated AVR.

60%

(n=327/548)

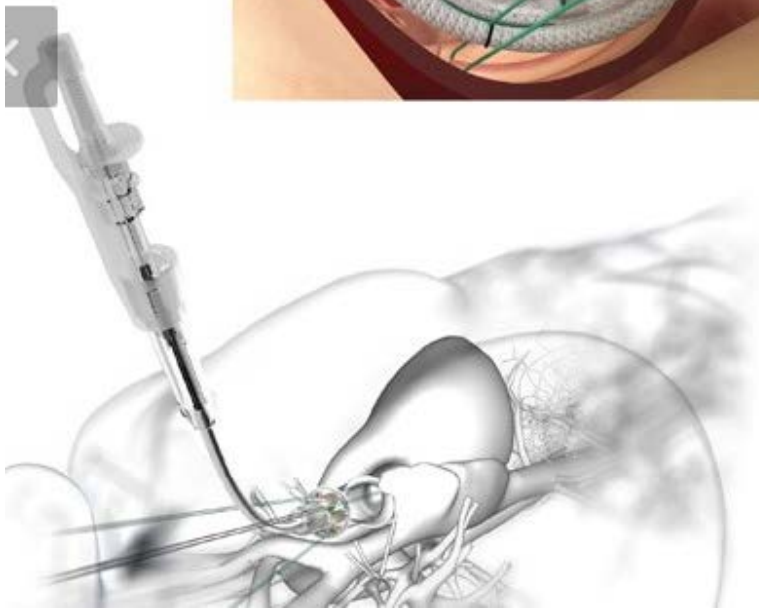


Compatibility with minimally invasive technics



Streamlined delivery

Utilizes a balloon expanded frame and 3 guiding sutures to provide ease of implantation and excellent visualization.



Traditional surgical valves

Require 12–15 sutures, making implantation difficult through smaller incisions.

TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve

Glenn R. Barnhart, MD,[a] Kevin D. Accola, MD,[b] Eugene A. Grossi, MD,[c] Y. Joseph Woo, MD,[d] Mubashir A. Mumtaz, MD,[e] Joseph F. Sabik, MD,[f] Frank N. Slachman, MD,[g] Himanshu J. Patel, MD,[h] Michael A. Borger, MD, PhD,[i] H. Edward Garrett, Jr, MD,[j] Evelio Rodriguez, MD,[k] Patrick M. McCarthy, MD,[l] William H. Ryan, MD,[m] Francis G. Duhay, MD, MBA,[n] Michael J. Mack, MD,[m] and W. Randolph Chitwood, Jr, MD,[o] on behalf of the TRANSFORM Trial Investigators

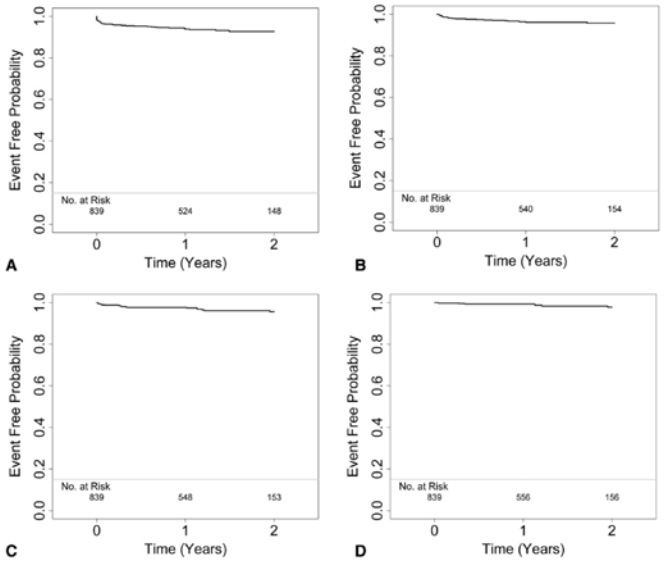


FIGURE 4. Kaplan-Meier Freedom from thromboembolism (A), bleeding (B), PVL (C), Major PVL (D).

TABLE 5. Primary effectiveness endpoints (EOA, mean gradients) at 1 year

	EOA and mean gradients at 1 y					
	19 mm, n mean (min, max)	21 mm, n mean (min, max)	23 mm, n mean (min, max)	25 mm, n mean (min, max)	27 mm, n mean (min, max)	Total, n mean (min, max)
EOA, cm^2	36, 1.1 ± 0.1 (1.0, 1.3)	113, 1.3 ± 0.1 (1.0, 1.8)	157, 1.7 ± 0.2 (1.2, 2.1)	127, 1.9 ± 0.2 (1.4, 2.9)	58, 2.2 ±0.2 (1.3, 2.5)	491, 1.7 ± 0.3 (1.0, 2.9)
Mean gradient, mm Hg	36, 13.9 ± 3.9 (7.2, 25.1)	15, 11.6 ± 3.6 (5.5, 23.5)	165, 10.4 ± 3.5 (3.6, 24.6)	132, 9.1 ± 3.2 (3.1, 19.6)	61, 8.3 ± 3.7 (3.6, 28.7)	509, 10.3 ± 3.8 (3.1, 28.7)

EOA, Effective orifice area.

ABSTRACT

Background: The TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) trial (NCT01700439) evaluated the performance of the INTUITY rapid deployment aortic valve replacement (RDAVR) system in patients with severe aortic stenosis.

Methods: TRANSFORM was a prospective, nonrandomized, multicenter (n = 29), single-arm trial. INTUITY is comprised of a cloth-covered balloon-expandable frame attached to a Carpentier-Edwards PERIMOUNT Magna Ease aortic valve. Primary and effectiveness endpoints were evaluated at 1 year.

Results: Between 2012 and 2015, 839 patients underwent RDAVR. Mean age was 73.5 ± 8.3 years. Full sternotomy (FS) was used in 59% and minimally invasive surgical incisions in 41%. Technical success rate was 95%. For isolated RDAVR, mean crossclamp and cardiopulmonary bypass times for FS were 49.3 ± 26.9 minutes and 69.2 ± 34.7 minutes, respectively, and for minimally invasive surgical 63.1 ± 25.4 minutes and 84.6 ± 33.5 minutes, respectively. These times were favorable compared with Society of Thoracic Surgeons database comparators for FS: 76.3 minutes and 104.2 minutes, respectively, and for minimally invasive surgical, 82.9 minutes and 111.4 minutes, respectively ($P < .001$). At 30 days, all-cause mortality was 0.8%; valve explant, 0.1%; thromboembolism, 3.5%; and major bleeding, 1.3%. In patients with isolated aortic valve replacement, the rate of permanent pacemaker implantation was 11.9%. At 1 year, mean effective orifice area was 1.7 cm^2; mean gradient, 10.3 mm Hg; and moderate and severe paravalvular leak, 1.2% and 0.4%, respectively.

(J Thorac Cardiovasc Surg 2017;153:241-51)

Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial†

Michael A. Borger[a,*], Pascal M. Dohmen[b], Christoph Knosalla[c], Robert Hammerschmidt[c], Denis R. Merk[b], Markus Richter[d], Torsten Doenst[d], Lenard Conradi[e], Hendrik Treede[e], Vadim Moustafine[f], David M. Holzhey[b], Francis Duhay[g] and Justus Strauch[f]

OBJECTIVES: Aortic valve replacement (AVR) via minimally invasive surgery (MIS) may provide clinical benefits in patients with aortic valve disease. A new class of bioprosthetic valves that enable rapid deployment AVR (RDAVR) may facilitate MIS. We here report the 1-year results of a randomized, multicentre trial comparing the outcomes for MIS-RDAVR with those for conventional AVR via full sternotomy (FS) with a commercially available stented aortic bioprosthesis.

METHODS: A total of 100 patients with aortic stenosis were enrolled in a prospective, multicentre, randomized comparison trial (CADENCE-MIS). Key exclusion criteria included AVR requiring concomitant procedures, ejection fraction of <25% and recent myocardial infarction or stroke. Patients were randomized to undergo MIS-RDAVR via upper hemisternotomy (EDWARDS INTUITY) or AVR via FS with a commercially available stented valve. Procedural, early and late clinical outcomes were assessed for both groups. Haemodynamic performance was evaluated by an echocardiography CoreLaboratory.

RESULTS: Technical success was achieved in 94% of MIS-RDAVR patients. MIS-RDAVR was associated with significantly reduced cross-clamp times compared with FS (41.3 ± 20.3 vs 54.0 ± 20.3 min, $P < 0.001$). Clinical and functional outcomes were similar at 30 days and 1 year postoperatively for both groups. While both groups received a similarly sized implanted valve (22.9 ± 2.1 mm MIS-RDAVR vs 23.0 ± 2.1 mm FS-AVR; $P = 0.91$), MIS-RDAVR patients had significantly lower peak gradients 1 year postoperatively (16.9 ± 5.3 vs 21.9 ± 8.6 mmHg; $P = 0.033$) and a trend towards lower mean gradients (9.1 ± 2.9 vs 11.5 ± 4.3 mmHg; $P = 0.082$). In addition, MIS-RDAVR patients had a significantly larger effective orifice area 1 year postoperatively (1.9 ± 0.5 vs 1.7 ± 0.4 cm^2; $P = 0.047$). Paravalvular leaks, however, were significantly more common in the MIS-RDAVR group ($P = 0.027$).

CONCLUSIONS: MIS-RDAVR is associated with a significantly reduced cross-clamp time and better valvular haemodynamic function than FS-AVR. However, paravalvular leak rates are higher with MIS-RDAVR.

M.A. Borger *et al.* / European Journal of Cardio-Thoracic Surgery

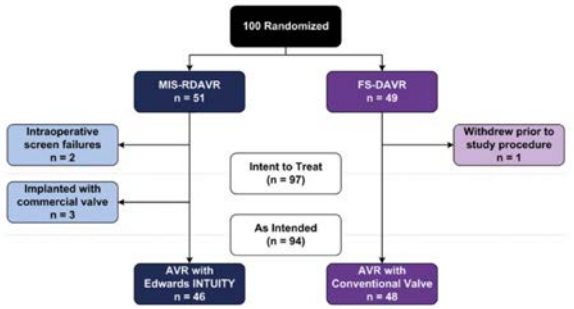


Table 2: Clinical outcomes

Outcome	30 days			1 year		
	EDWARDS INTUITY % (n/N)	Control % (n/N)	*P*-value	EDWARDS INTUITY % (n/N)	Control % (n/N)	*P*-value
Mortality	4% (2/46)	2% (1/48)	0.53	6% (3/46)	6% (3/48)	0.96
Cardiac reoperation for any reason (including explant)	13% (6/46)	10% (5/48)	0.69	15% (7/46)	13% (6/48)	0.70
Resternotomy	13% (6/46)	10% (5/48)	0.69	15% (7/46)	10% (5/48)	0.49
New permanent pacemaker	4% (2/46)	2% (1/48)	0.53	4% (2/46)	2% (1/48)	0.53
Thromboembolism	7% (3/46)	6% (3/48)	0.96	8% (4/46)	8% (4/48)	0.95
Major bleeding event	17% (8/46)	8% (4/48)	0.19	17% (8/46)	10% (5/48)	0.33
Cardiac tamponade	4% (2/46)	6% (3/48)	0.68	4% (2/46)	6% (3/48)	0.68
CVA or permanent stroke	4% (2/46)	4% (2/48)	0.97	4% (2/46)	4% (2/48)	0.97
Endocarditis	0% (0/46)	0% (0/48)	–	0% (0/46)	0% (0/48)	–
Myocardial infarction	0% (0/46)	2% (1/48)	0.33	0% (0/46)	4% (2/48)	0.16
Deep sternal wound infection	2% (1/46)	2% (1/48)	0.98	2% (1/46)	2% (1/48)	0.98
Respiratory failure	4% (2/46)	0% (0/48)	0.14	4% (2/46)	4% (2/48)	0.97
Renal failure	7% (3/46)	0% (0/48)	0.072	7% (3/46)	2% (1/48)	0.29

P-values comparing the rates of events between EDWARDS INTUITY and control group are based on Pearson's χ^2 tests.
CVA: cerebrovascular accident.

Table 4: Haemodynamic outcomes

Parameter	Trial arm	Baseline *n*: mean ± SD	Discharge *n*: mean ± SD	30 days *n*: mean ± SD	3 months *n*: mean ± SD	1 year *n*: mean ± SD	*P*-value
BSA-corrected LV mass (g)	Control	38: 135.2 ± 37.9	N/A	31: 115.4 ± 30.5	37: 105.3 ± 31.8	29: 102.1 ± 28.9	0.33
	EDWARDS INTUITY	33: 123.9 ± 35.4	N/A	26: 118.2 ± 33.2	35: 104.1 ± 26.7	24: 108.5 ± 31.0	
EOA (cm^2)	Control	43: 0.7 ± 0.2	36: 1.9 ± 0.7	31: 2.0 ± 0.7	39: 1.8 ± 0.6	29: 1.7 ± 0.4	0.047
	EDWARDS INTUITY	38: 0.7 ± 0.2	38: 1.9 ± 0.6	30: 1.9 ± 0.5	36: 1.9 ± 0.5	27: 1.9 ± 0.5	
Mean gradient (mmHg)	Control	45: 45.4 ± 20.0	44: 10.8 ± 3.4	37: 9.7 ± 3.9	40: 10.3 ± 4.8	40: 11.5 ± 4.3	0.082
	EDWARDS INTUITY	42: 44.0 ± 15.9	40: 10.3 ± 5.4	33: 8.8 ± 4.2	39: 9.1 ± 4.2	40: 9.1 ± 2.9	
Peak gradient (mmHg)	Control	45: 75.4 ± 27.9	44: 21.0 ± 6.9	37: 17.8 ± 6.5	40: 18.9 ± 8.2	40: 21.9 ± 8.6	0.033
	EDWARDS INTUITY	42: 69.6 ± 23.7	40: 19.0 ± 9.5	33: 16.5 ± 7.8	39: 17.0 ± 7.6	40: 16.9 ± 5.3	

BSA-corrected LV mass (per CoreLaboratory) is used in place of LV mass index.
SD: standard deviation; LV: left ventricular; EOA: effective orifice area.

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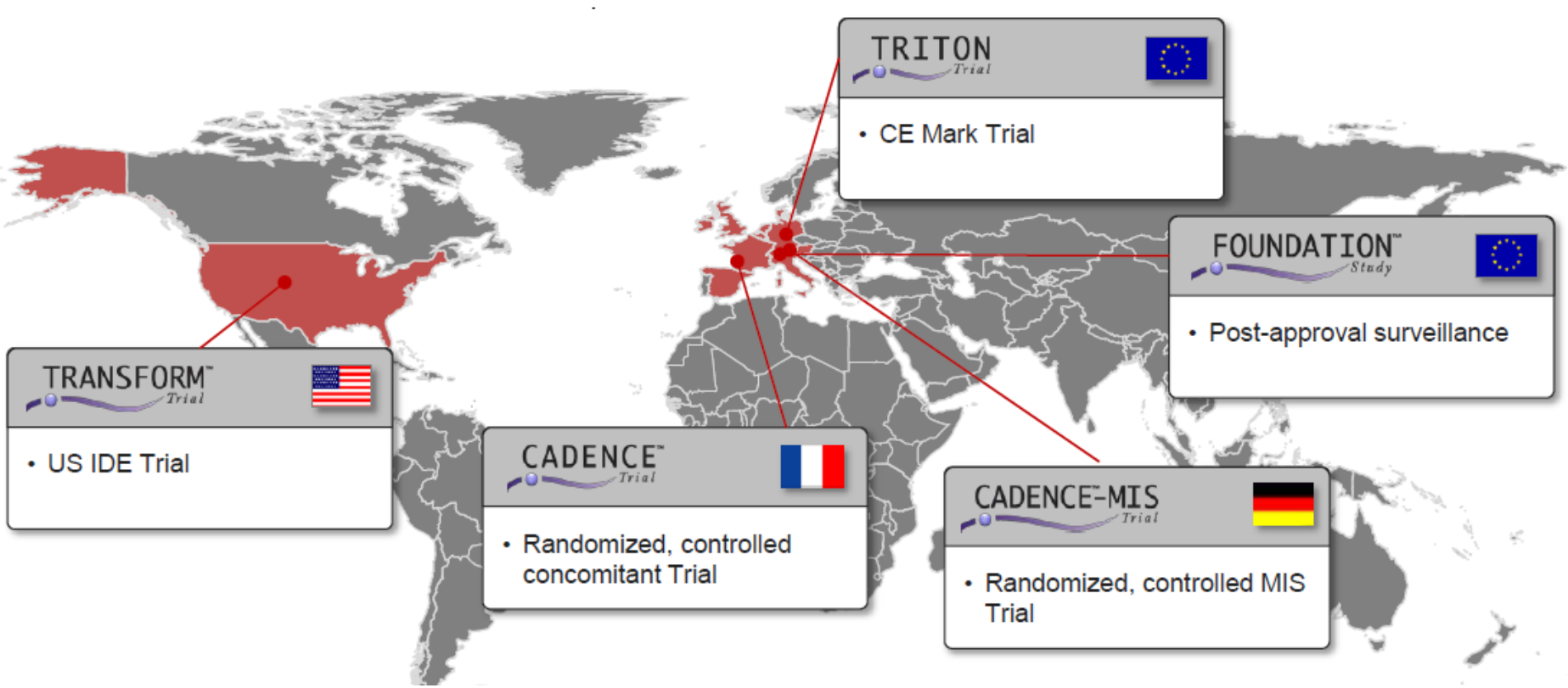
EDWARDS INTUITY ELITE



3) Sutureless valve vs TAVI

Santarpino et al 2014; J Thorac Cardiovasc Surg

- **High risk pt**
- **No difference in:**
- **in-hospital mortality**
- **Permanent pacemaker**
- **Neurological events**
- Higher paravalvular leak in TAVI (13.5% vs 0% p=0.027)
- At 19 months follow up: higher survival (97.3% vs86.5%)
- Conclusion: sutureless valves may be the ideal treatment for pt in ''gray zone'' between conventional AVR and TAVI

D'Onofrio et al 2013; J Thorac Cardiovasc Surg

- **Multicenter analysis**
- **349 conventional**
- **38 sutureless**
- **566 TAVI**
- **Similar results between sutureless and TAVI**

Muneretto et al 2015; Interact Cardiovasc and Thorac Surg

- TAVI:Higher pacemaker (25.5%vs2%)
- Peripheral vascular complications (14.5 vs 0%)
- 24 months survival: 91.6% vs 70.5%)

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doi:10.1093/ejcts/ezv210

ORIGINAL ARTICLE

Cite this article as: Miceli A, Gilmanov D, Murzi M, Marchi F, Ferrarini M, Cerillo AG *et al*. Minimally invasive aortic valve replacement with a sutureless valve through a right anterior mini-thoracotomy versus transcatheter aortic valve implantation in high-risk patients. Eur J Cardiothorac Surg 2015; doi:10.1093/ejcts/ezv210.

Minimally invasive aortic valve replacement with a sutureless valve through a right anterior mini-thoracotomy versus transcatheter aortic valve implantation in high-risk patients

Antonio Miceli[†]*, Daniyar Gilmanov, Michele Murzi, Federica Marchi, Matteo Ferrarini, Alfredo G. Cerillo, Eugenio Quaini, Marco Solinas, Sergio Berti and Mattia Glauber[†]

OBJECTIVES: The aim of this study was to compare early outcomes and mid-term survival of high-risk patients undergoing minimally invasive aortic valve replacement through right anterior mini-thoracotomy (RT) with sutureless valves versus patients undergoing transcatheter aortic valve implantation (TAVI) for severe aortic stenosis.

METHODS: From October 2008 to March 2013, 269 patients with severe aortic stenosis underwent either RT with perceval S sutureless valves ($n = 178$ patients, 66.2%) or TAVI ($n = 91$, 33.8%: 44 transapical and 47 trans-femoral). Of these, 37 patients undergoing RT with the perceval S valve were matched to a TAVI group by the propensity score.

RESULTS: Baseline characteristics were similar in both groups (mean age 79 ± 6 years) and the median logistic EuroSCORE was 14% (range 9–20%). In the matched group, the in-hospital mortality rate was 8.1% ($n = 3$) in the TAVI group and 0% in the RT group ($P = 0.25$). The incidence rate of stroke was 5.4% ($n = 2$) versus 0% in the TAVI and RT groups ($P = 0.3$). In the TAVI group, 37.8% ($n = 14$) had mild paravalvular leakage (PVL) and 27% ($n = 10$) had moderate PVL, whereas 2.7% ($n = 1$) had mild PVL in the RT group ($P < 0.001$). One- and 2-year survival rates were 91.6 vs 78.6% and 91.6 vs 66.2% in patients undergoing RT with the perceval S sutureless valve compared with those undergoing TAVI, respectively ($P = 0.1$).

CONCLUSIONS: Minimally invasive aortic valve replacement with perceval S sutureless valves through an RT is associated with a trend of better early outcomes and mid-term survival compared with TAVI.

Minimally invasive aortic valve replacement with a sutureless valve through a right anterior mini-thoracotomy versus transcatheter aortic valve implantation in high-risk patients

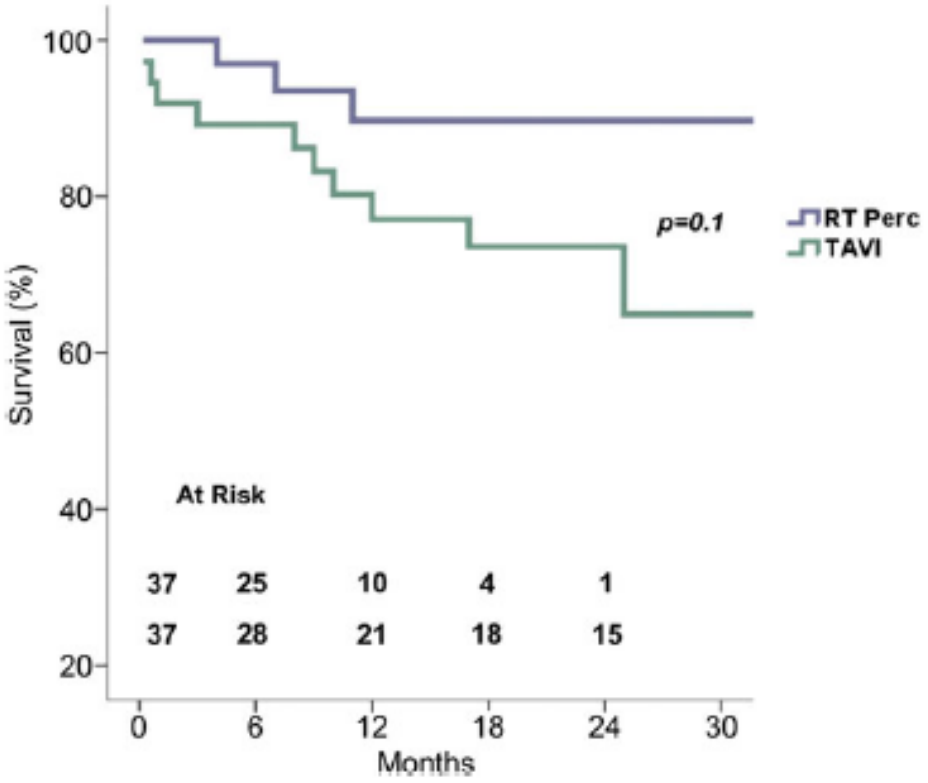
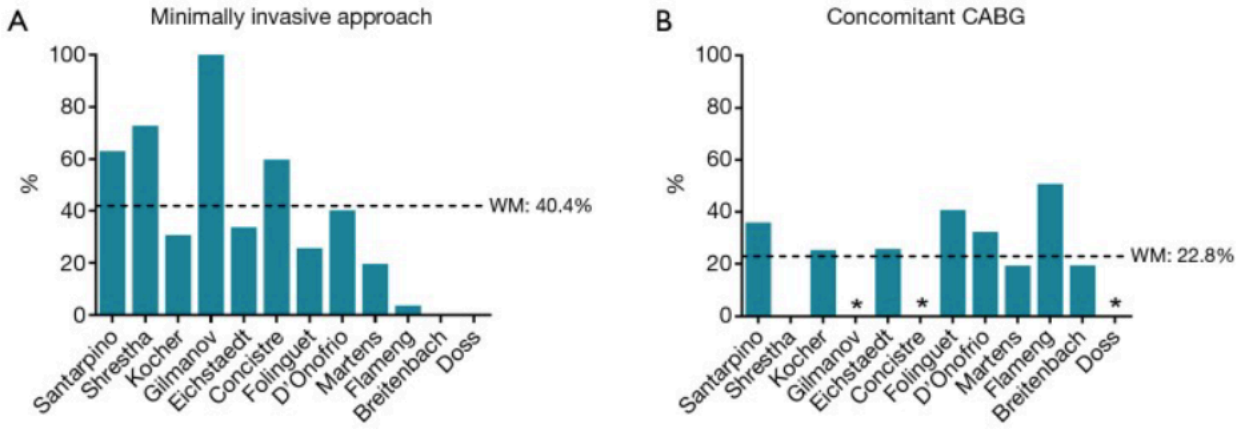


Figure 1: Survival between two matched groups. TAVI: transcatheter aortic valve implantation; RT: right anterior minithoracomy.

4). EOA. Phan K, Tsai Y-C, Niranjan N, et al. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Annals of Cardiothoracic Surgery*. 2015;4(2):100-111. doi:10.3978/j.issn.2225-319X.2014.06.01.

Hemodynamic outcome	n	N	Weighted pooled proportion or estimate (95% CI)	Heterogeneity	
				I^2 (%)	P value
Mean gradient					
Mean gradient (discharge)	654	8	11.128 (9.831,12.425)	94	<0.001
Mean gradient (6 mo)	529	5	9.004 (8.697,9.311)	0	0.663
Mean gradient (12 mo)	579	6	9.644 (8.703,10.586)	86	<0.001
Peak gradient					
Peak gradient (discharge)	529	5	19.61 (16.54,22.681)	95	<0.001
Peak gradient (6 mo)	529	5	17.797 (16.046,19.547)	86	<0.001
Peak gradient (12 mo)	528	5	17.286 (16.136,18.436)	69	0.007
Effective orifice area					
Effective orifice area (discharge)	579	6	1.772 (1.554,1.990)	98	<0.001
Effective orifice area (6 mo)	529	5	1.745 (1.499,1.991)	97	<0.001
Effective orifice area (12 mo)	577	6	1.731 (1.548,1.914)	97	<0.001

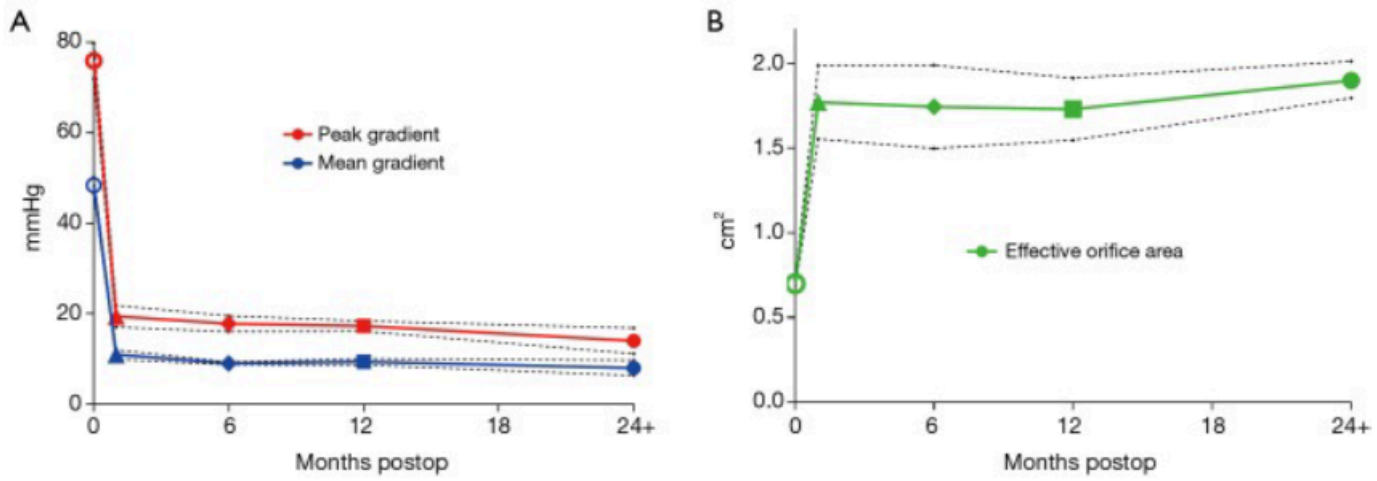
Phan K, Tsai Y-C, Niranjan N, et al. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Annals of Cardiothoracic Surgery*. 2015;4(2):100-111. doi:10.3978/j.issn.2225-319X.2014.06.01.



Operation characteristics for SU-AVR, including: (A) minimally invasive approach; (B) concomitant coronary artery bypass graft (CABG) performed. SU-AVR, sutureless AVR; WM, weighted mean; *, not reported.

Phan K, Tsai Y-C, Niranjan N, et al. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Annals of Cardiothoracic Surgery*. 2015;4(2):100-111. doi:10.3978/j.issn.2225-319X.2014.06.01.

Figure 6



Hemodynamic outcomes of SU-AVR at up to 12-month follow-up. (A) Change in mean gradient and peak gradient after SU-AVR; (B) change in effective orifice area after SU-AVR. The solid line indicates the pooled results of the meta-analysis while the dashed lines represent 95% CI. Open circle, preoperative; closed triangle, discharge; closed diamond, 6-month follow-up; closed square, 12-month follow-up; closed circle, 2-year follow-up. SU-AVR, sutureless AVR; CI, confidence interval.

Interactive CardioVascular and Thoracic Surgery 26 (2018) 202–209
doi:10.1093/icvts/ivx294 Advance Access publication 11 September 2017

ORIGINAL ARTICLE

Cite this article as: Meco M, Miceli A, Montisci A, Donatelli F, Cirri S, Ferrarini M *et al.* Sutureless aortic valve replacement versus transcatheter aortic valve implantation: a meta-analysis of comparative matched studies using propensity score matching. Interact CardioVasc Thorac Surg 2018;26:202–9.

Sutureless aortic valve replacement versus transcatheter aortic valve implantation: a meta-analysis of comparative matched studies using propensity score matching

Massimo Meco[a,†], Antonio Miceli[b,c,†], Andrea Montisci[b,*,†], Francesco Donatelli[b,d], Silvia Cirri[b], Matteo Ferrarini[b], Antonio Lio[b] and Mattia Glauber[b]

Abstract

OBJECTIVES: The aim of this meta-analysis was to compare outcomes of patients undergoing transcatheter aortic valve implantation (TAVI) with those undergoing surgical aortic valve replacement using sutureless valves.

METHODS: A systematic review and meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was performed.

RESULTS: No randomized controlled trials were identified. Six comparative studies using propensity score matching met the inclusion criteria. This meta-analysis identified 1462 patients in that 731 patients underwent surgical aortic valve replacement using sutureless valves (SU) and 731 patients underwent a TAVI. The 30-day or in-hospital mortality was lower in the SU group [odds ratio (OR) 0.54, 95% confidence interval (CI) 0.36–0.80; $P = 0.003$]. In the TAVI group, the incidence of postoperative stroke was higher (OR 0.36, 95% CI 0.17–0.79; $P = 0.01$). The incidence of moderate or severe paravalvular regurgitation was higher in the TAVI group (OR 0.22, 95% CI 0.14–0.35; $P = 0.001$). There were neither differences in the postoperative renal failure (OR 1.44, 95% CI 0.46–4.58; $P = 0.53$) nor in the number of patients requiring postoperative pacemaker implantation (OR 1.06, 95% CI 0.54–2.08; $P = 0.86$). Patients in the SU group required more transfusions (OR 4.47, 95% CI 2.77–7.21; $P = 0.0001$), whereas those in the TAVI group had higher major vascular complications (OR 0.06, 95% CI 0.01–0.25; $P = 0.0001$). Intensive care unit stay was not different (mean difference 0.99, 95% CI - 1.22 to 1.40; $P = 0.53$). One-year survival was better in the SU group (Peto OR 0.35, 95% CI 0.18–0.67; $P = 0.001$), as was the 2-year survival (Peto OR 0.38, 95% CI 0.17–0.86; $P = 0.001$).

CONCLUSIONS: Surgical aortic valve replacement using sutureless valves is associated with better early and mid-term outcomes compared with TAVI in high- or intermediate-risk patients.

Keywords: Aortic valve surgery • Sutureless bioprosthesis • Transcatheter aortic valve implantation • Minimally invasive cardiac surgery • Meta-analysis

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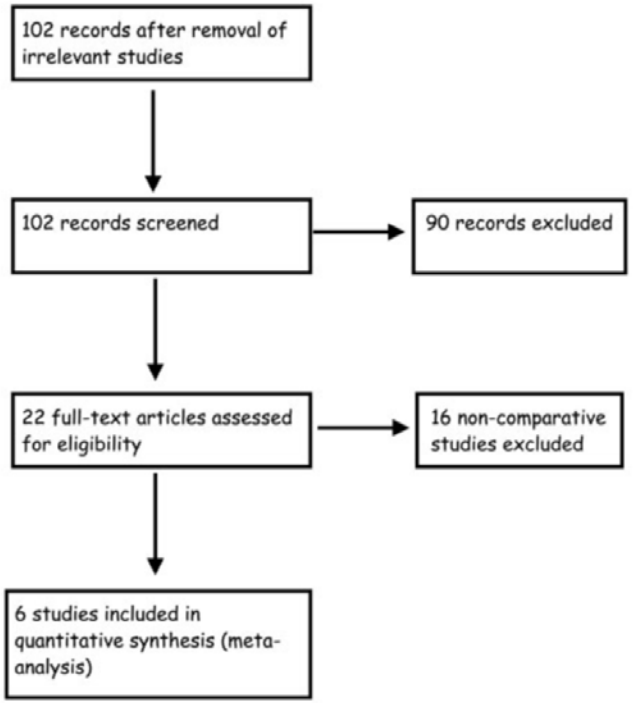

Table 1: List of included studies

First author	Year	Institution	Study period	Type of study	Number of sutureless valves	Number of TAVI	Mean follow-up SU (months)	Mean follow-up TAVI (months)
Muneretto	2014	University of Brescia, Italy	Oct 2010–Feb 2013	PSM	204	204	1.9 ± 0.6	2 ± 0.8
Biancari	2015	6 European centres	Jun 2007–Apr 2014	PSM	144	144	None	None
Miceli	2015	Fondazione Monasterio, Massa Italy	Oct 2004–Mar 2013	PSM	37	37	Not indicated	Not indicated
Kamperidis	2015	Leiden University Medical Center, Netherlands	Nov 2007–Feb 2013	PSM	40	40	1.5 ± 0.9	1.5 ± 0.8
D'Onofrio	2016	6 European centres/Italian Registry of TAVI	2010–2014	PSM	206	206	None	None
Santarpino	2015	Paracelsus Medical University, Nuremberg, Germany	2010–2014	PSM	102	102	23 ± 14	24 ± 13

PSM: propensity score matching; SU: surgical aortic valve replacement using sutureless valves; TAVI: transcatheter aortic valve implantation.

Table 2: Patient preoperative characteristics

	Sutureless	TAVI	OR (95% CI)/(WMD)	*P*-value
Female gender (%)	48.25	50	0.93 (0.75 to 1.15)	0.48
Preoperative renal insufficiency (%)	26.6	29.2	0.88 (0.69 to 1.129)	0.29
Hypertension (%)	80	73.6	1.29 (0.60 to 2.78)	0.51
Redo (%)	9.48	12	0.77 (0.54 to 1.09)	0.13
Diabetes	20.63	20.70	0.99 (0.75 to 1.30)	0.94
CAD (%)	9	10.2	0.86 (0.58 to 1.26)	0.43
Extracardiac arteriopathy (%)	19.4	18.4	1.07 (0.82 to 1.4)	0.63
NYHA Class III–IV (%)	68.6	68.6	1 (0.78 to 1.28)	1
LVEF (%), mean ± SD	55.2 ± 8.6	54.7 ± 6.8	0.78 (-1.07 to 2.62)	0.41
Age (years), mean ± SD	78.96 ± 4.6	78.91 ± 6	-0.16 (-0.90 to 0.57)	0.66
EuroSCORE, mean ± SD	15.45 ± 9	15.58 ± 8.1	-0.36 (-1.11 to 0.40)	0.35

CAD: coronary artery disease; CI: confidence interval; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; OR: odds ratio; TAVI: transcatheter aortic valve implantation; WMD: weighted mean difference.

Table 3: Postoperative data

	SU-AVR	TAVI	*P*-value
30-days mortality (%)	24/741 (3.23)	44/741 (5.93)	0.01
Postoperative stroke (%)	12/741 (1.61)	27/741 (3.64)	0.01
Postoperative aortic regurgitation (%)	21/731 (2.8)	133/731 (18.19)	0.001
Postoperative AKI (%)	35/527 (6.51)	37/527 (6.89)	0.8
Pacemaker implantation (%)	69/741 (9.31)	70/741 (9.44)	0.9
Transfused patients (%)	88/426 (20.6)	26/424 (6.1)	0.001
Vascular complications (%)	0/490 (0)	41/490 (8.36)	0.001

AKI: acute kidney injury.

Transcatheter aortic valve implantation (TAVI) versus sutureless aortic valve replacement (SUAVR) for aortic stenosis: a systematic review and meta-analysis of matched studies

Nelson Wang[1], Yi-Chin Tsai[2], Natasha Niles[2], Vakhtang Tchantchaleishvili[3], Marco Di Eusanio[4], Tristan D. Yan[2], Kevin Phan[1,2]

Journal of Thoracic Disease, Vol 8, No 11 November 2016

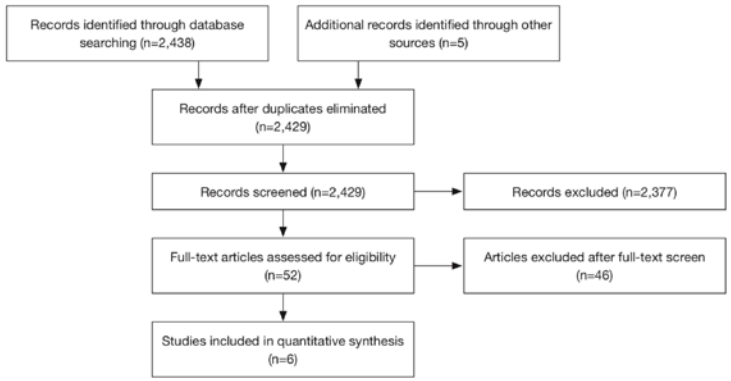

Figure 1 PRISMA flowchart diagram for systematic review from literature search to final analysis.

Table 1 Study characteristics

First author	Year	Country	Study period	Design	n (SUAVR)	n (TAVI)	Type of SUAV	Type of TAV	Predominant incision	Notes
Biancari	2016	Italy	2007–2014	PSM	144	144	Perceval	Sapien, CoreValve, Portico, Lotus	Mini sternotomy	High risk patients received TAVI
D'Onofrio	2016	Italy	2007–2014	PSM	214	214	Perceval	Sapien or Sapien XT	NR	High risk patients received TAVI; Aortic annulus size between 19 and 27 mm sinotubular: aortic annulus ratio <1.3
Kamperidis	2015	Netherlands	2007–2013	PSM	40	40	3F Enable	Sapien XT or CoreValve	Medial sternotomy	High risk patients
Miceli	2016	Italy	2008–2013	PSM	37	37	Perceval	Sapien	Right mini-thoracotomy	High risk patients considered for TAVI
Muneretto	2015	Italy	2007–2014	PSM	204	204	Perceval	Stented/stentless bioprosthesis	Mini J-sternotomy	Intermediate-high risk patients only
Santarpino	2015	Germany	2010–2015	PSM	102	102	Perceval	Sapien, Sapien XT or Sapien 3	NR	High frailty and euroSCORE >20% underwent TAVI

MI, minimal incision; NR, not recorded; PC, prospective cohort; PSM, propensity score matched, SUAVR, sutureless aortic valve replacement; TAVI, transcatheter aortic valve implantation

Table 2 Quality assessment of included studies

Assessment	Biancari	D'Onofrio	Kamperidis	Miceli	Muneretto	Santarpino
Clear definition of study population	Yes	Yes	Yes	Yes	Yes	Yes
Clear definition of outcomes and outcome assessment	Yes	Yes	Yes	Yes	Yes	Yes
Independent assessment of outcome parameters	No[a]	No[a]	No[a]	No[a]	No[a]	No[a]
Sufficient duration of follow-up	No	Yes	Yes	Yes	Yes	Yes
No selective loss during follow-up	Yes	Unclear	Unclear	Unclear	Unclear	Unclear
Important confounders and prognostic factors identified	Yes	Yes	Yes	Yes	Yes	Yes

[a], lack of blinding during outcome assessment, not independently assessed by multiple investigators.

Transcatheter aortic valve implantation (TAVI) versus sutureless aortic valve replacement (SUAVR) for aortic stenosis: a systematic review and meta-analysis of matched studies

Nelson Wang[1], Yi-Chin Tsai[2], Natasha Niles[2], Vakhtang Tchantchaleishvili[3], Marco Di Eusanio[4], Tristan D. Yan[2], Kevin Phan[1,2]

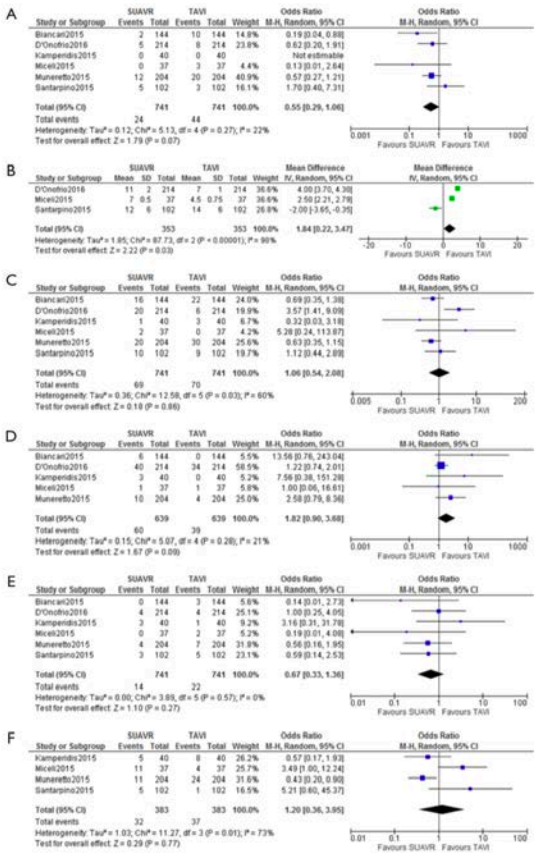

Figure 2 Short-term outcomes of patients undergoing SUAVR and TAVI. A comparison of patients undergoing SUAVR and TAVI in terms of (A) perioperative mortality; (B) length of hospital stay; (C) need for pacemaker implantation; (D) re-exploration for bleeding; (E) incidence of stroke/TIA and (F) incidence of acute kidney injury.

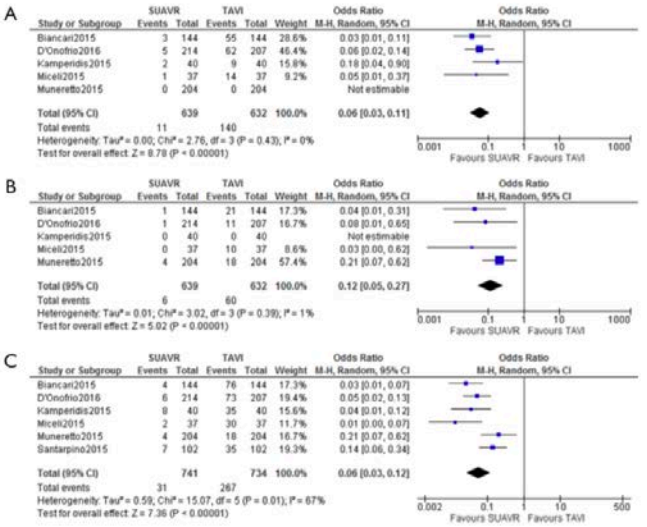

Figure 3 The incidence of paravalvular regurgitation for patients undergoing SUAVR and TAVI. Rates of paravalvular leak were stratified into (A) mild paravalvular leak; (B) moderate-severe paravalvular leak and (C) any paravalvular leak.

Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

Giuseppe Santarpino, MD,[a] Steffen Pfeiffer, MD,[a] Jürgen Jessl, MD,[b] Angelo Maria Dell'Aquila, MD,[c] Francesco Pollari, MD,[a] Matthias Pauschinger, MD,[b] and Theodor Fischlein, MD[a]

Objective: This propensity-matched study compared clinical and echocardiographic outcomes between patients undergoing transcatheter aortic valve implantation (TAVI) and sutureless aortic valve replacement.

Methods: From January 2010 to March 2012, 122 patients (age 79.4 ± 5.3 years, logistic euroSCORE 12% ± 8.4%) underwent minimally invasive sutureless aortic valve replacement, and 122 (age 84.6 ± 6.2 years, logistic euroSCORE 20.9% ± 2.5%) underwent TAVI. After propensity matching, 37 matched pairs were available for analysis.

Results: Preoperative characteristics and risk scores of matched groups were comparable. In-hospital mortalities were 0% in the sutureless group and 8.1% (n = 3) in the TAVI group ($P = .24$). Permanent pacemaker implantation was required in 4 patients in the sutureless group and 1 patient in the TAVI group (10.8% vs 2.7%; $P = .18$). A neurologic event was recorded in 2 patients of each group. Predischarge echocardiographic data showed higher paravalvular leak rate in the TAVI group (13.5% vs 0%; $P = .027$). At mean follow-up of 18.9 ± 10.1 months, overall cumulative survival was 91.9% and significantly differed between groups (sutureless 97.3% vs TAVI 86.5%; $P = .015$). In the TAVI group, a significant difference in mortality was observed between patients with (n = 20) and without (n = 17) paravalvular leak (25% vs 0%; $P = .036$).

Conclusions: Combining the advantage of standard diseased valve removal with shorter procedural times, minimally invasive sutureless aortic valve replacement may be the first-line treatment for high-risk patients considered in the "gray zone" between TAVI and conventional surgery. (J Thorac Cardiovasc Surg 2014;147:561-7)

Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

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TABLE 3. Postoperative outcomes of the matched sutureless and transcatheter aortic valve implantation groups

Variable	Sutureless AVR (n = 37)	TAVI (n = 37)	*P* value
In-hospital mortality	0	3 (8.1%)	.24
ARF requiring CVVH	0	2 (5.4%)	.25
Stroke	2 (5.4%)	2 (5.4%)	>.999
Permanent PM implantation	4 (10.8%)	1 (2.7%)	.18
Mean transaortic gradient (mm Hg)	13.3 ± 3.9	14.2 ± 5.8	.564
AR at discharge (at least mild)	0	5 (13.5%)	.027

AVR, Aortic valve replacement; *TAVI*, transcatheter aortic valve implantation; *ARF*, acute renal failure; *CVVH*, continuous venovenous hemofiltration; *PM*, pacemaker; *AR*, aortic regurgitation.

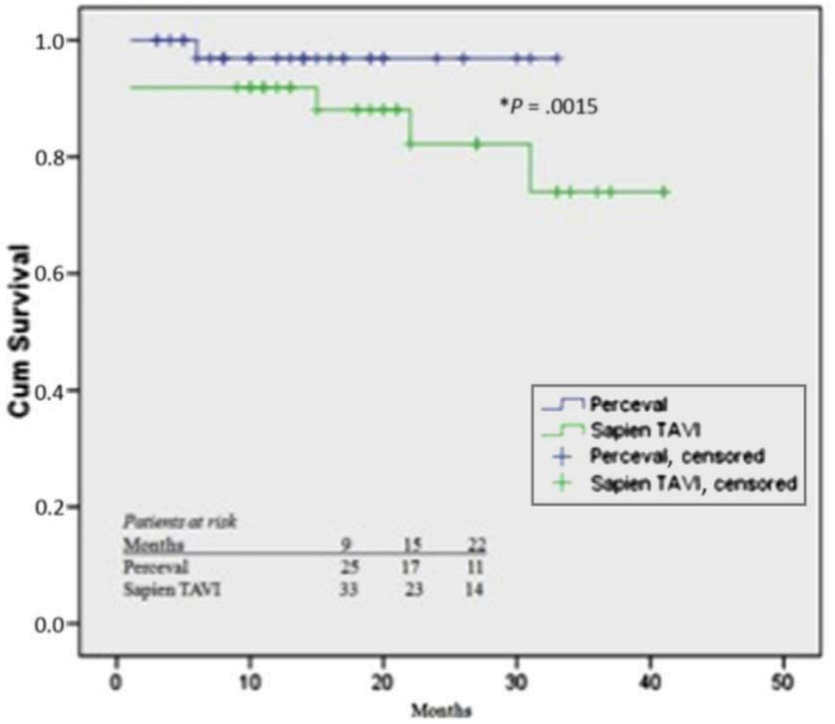

FIGURE 2. Kaplan-Meier survival curve. *TAVI*, Transcatheter aortic valve implantation; *Cum*, cumulative.

4)

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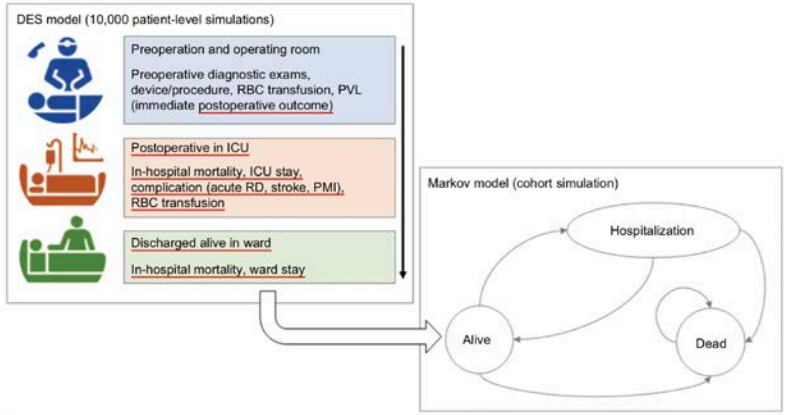

Figure 1 DES model for the in-hospital phase (top-left box) and lifetime Markov model (bottom-right box) for SU-AVR vs TAVIs comparison.
Abbreviations: DES, discrete event simulation; ICU, intensive care unit; PMI, pacemaker implantation; PVL, paravalvular leak; RBC, red blood cell; RD, renal dysfunction; SU-AVR, sutureless aortic valve replacement; TAVIs, transcatheter aortic valve implants.

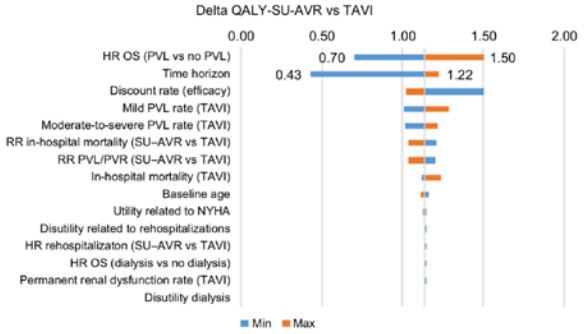

Figure 7 Tornado diagram of QALY gain (SU-AVR vs TAVIs): Blue bars (min) represent QALY gain for the minimum value of each parameter, and orange bars (max) represent QALY gain for the maximum value of each parameter.
Abbreviations: NYHA, New York Heart Association; OS, overall survival; PVL, paravalvular leak; QALY, quality-adjusted life-year; RR, relative risk; SU-AVR, sutureless aortic valve replacement; TAVIs, transcatheter aortic valve implants.

Table 1 List of unit/annual/per episode costs used in the model for each country considered in the analysis

	US $		Germany €		France €		Italy €		UK £		Australia AUD	
In-hospital costs												
Operating room												
TAVI	6,641.92	7	4,522.77	13	3,363.70	37	5,401.22[a]		5,586.81[a]		1,204.80	38
SU-AVR	7,818.74[a]		5,324.11	13	7,120.36[b]		6,358.20[b]		6,576.68[b]		6,917.00	38
Diagnostic												
TAVI	4,831.32	40	4,339.22	13	4,633.46[c]		4,927.70[d]		1,706.91	41,42	2,731.98	43
SU-AVR	2,199.03[d]		1,975.04	13	2,108.97[c]		2,242.89	44	776.92[d]		1,243.49[c]	
Device												
TAVI	32,000.00	7	11,000.00[e]						14,500.00[e]		22,932.00	45
SU-AVR	12,220.46	46	6,000.00[e]						6,000.00[e]		8,977.00	
Reoperation[f]												
TAVI	6,544.97		4,526.83		3,519.83		5,318.93		5,107.67		1,634.47	
SU-AVR	7,207.58		5,193.18		7,260.40		6,125.62		5,796.47		7,101.56	
ICU (daily cost)	1,303.45	50	1,196.46	51	1,578.41	52	1,469.90	53	1,360.00	54	4,877.46	55
Ward (daily cost)	779.98	50	469.88	51	443.15	51	484.20	53	280.00	54	789.80	56
RBC (cost per unit)	295.94	50	105.53	51	108.45	37	153.00	51	127.70	57	231.26	58
RRT (daily cost)	978.10	50	76.26	51	152.74	51	284.81	51	159.81	57	160.46	59
In-hospital stroke	16,732.36	60	4,854.25	49	5,860.67[c]		6,867.10	61	3,479.00	54	11,126.72	62
In-hospital PMI	5,974.25	48	4,507.15	49	3,242.59	37	3,265.73	63	2,886.00	54	4,692.00	38
Long-term costs												
Dialysis (annual cost)	67,497.35	64	60,732.30	65	53,047.50	66	42,815.78	67	23,713.95	68	111,618.17	69
Rehospitalization (cost per episode)												
Stroke (cost per episode)	47,896.34	70	23,385.34	66	11,457.14	66	13,967.46	66	19,063.18	71	41,008.49	66
PMI (cost per episode)	48,211.79	72	8,945.02	73	11,938.56	74	12,133.59	63	10,256.07	75	14,208.18	38
Others (cost per episode)	27,249.08	64	11,921.67	66	9,905.65	66	11,399.58	66	7,168.98	76,77	18,046.01	66

Notes: [a]Estimated by applying the ratio between TAVIs and Perceval operating room costs reported in Santarpino et al[13] as it is the only analysis that reported both costs in the same structure. [b]Calculated as the mean of full-sternotomy (FS), minimally invasive (MiS), and concomitant (CONC) procedures estimated in Pradelli et al[8] weighted for the frequencies of FS (41%), MiS (26%), and CONC (33%) reported in Shrestha et al.[19] [c]Estimated as the mean between Germany and Italy. [d]Estimated by applying the ratio between TAVIs and Perceval diagnostic costs reported in Santarpino et al[13] as it is the only analysis that reported both costs in the same structure. [e]Market values. [f]Calculated as the cost of operating room plus the cost of device for the 2.0% of patients who need a second valve implant.[47–49] The superscript numbers represent reference citations.
Abbreviations: ICU, intensive care unit; PMI, pacemaker implantation; RBC, red blood cell; RRT, renal replacement therapy; SU-AVR, sutureless aortic valve replacement; TAVIs, transcatheter aortic valve implants.

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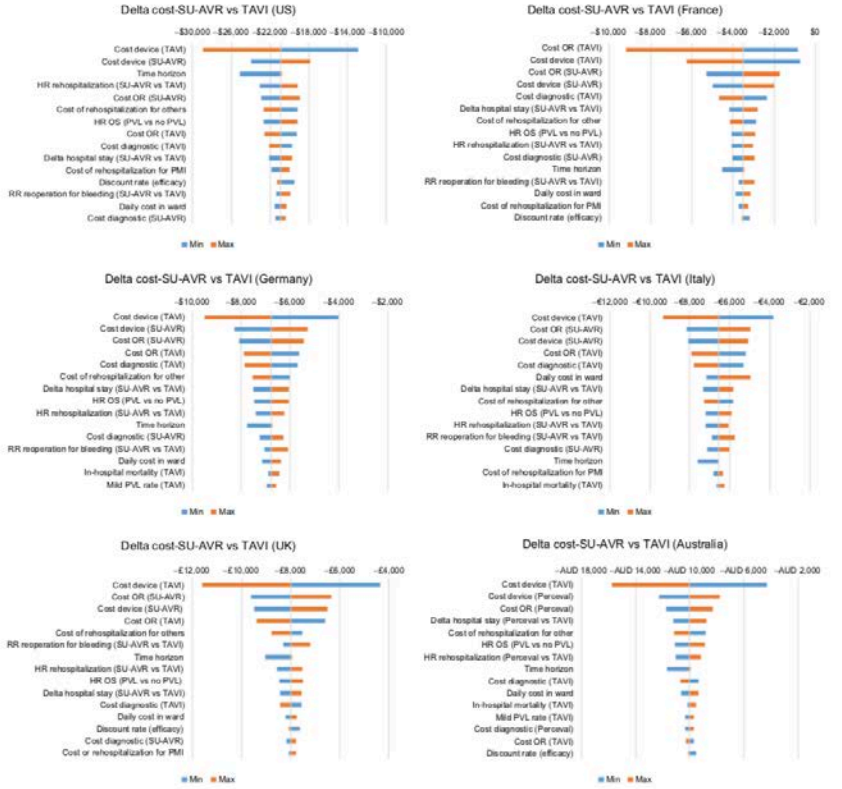

Figure 8 Tornado diagram of cost differences (SU-AVR vs TAVIs) for the six countries considered in the analysis: Blue bars (min) represent cost differences for the minimum value of each parameter and orange bars (max) represent delta cost for the maximum value of each parameter.
Abbreviations: OR, operating room; OS, overall survival; PVL, paravalvular leak; PMI, pacemaker implantation; RR, relative risk; SU-AVR, sutureless aortic valve replacement; TAVIs, transcatheter aortic valve implants.

Table 3 Economic results: values expressed as mean and interquartile range

	TAVIs	SU-AVR	Delta (SU-AVR vs TAVIs)
Total costs (US $)	**69,389 (67,459; 75,965)**	**48,459 (45,647; 53,536)**	**−20,930 (−26,084; −17,671)**
Hospital costs	52,727 (51,518; 53,806)	34,375 (33,724; 35,089)	−18,351 (−19,556; −16,951)
Operating room	6,642 (6,545; 6,742)	7,819 (7,690; 7,936)	1,177 (1,015; 1,320)
Device cost	32,000 (30,857; 32,985)	12,220 (11,833; 12,616)	−19,780 (−20,863; −18,539)
Diagnostics	4,831 (4,668; 4,990)	2,199 (2,123; 2,270)	−2,632 (−2,800; −2,449)
Hospital stay[a]	6,234 (5,949; 6,504)	8,753 (8,285; 9,241)	2,519 (2,140; 2,958)
Complications[b]	3,020 (2,813; 3,186)	3,384 (3,126; 3,716)	365 (163; 627)
Long-term costs	16,663 (15,102; 22,791)	14,084 (11,297; 18,978)	−2,579 (−8,020; 423)
Dialysis	278 (231; 309)	408 (351; 445)	130 (103; 148)
Rehospitalization	16,385 (14,802; 22,498)	13,676 (10,916; 18,573)	−2,709 (−8,124; 300)
Total costs (Germany €)	**31,722 (30,704; 33,580)**	**24,951 (24,273; 26,668)**	**−6,772 (−8,203; −5,109)**
Hospital costs	25,355 (24,893; 25,807)	20,598 (20,259; 21,128)	−4,757 (−5,307; −4,065)
Operating room	4,523 (4,421; 4,611)	5,324 (5,211; 5,416)	801 (653; 934)
Device cost	11,000 (10,626; 11,364)	6,000 (5,801; 6,231)	−5,000 (−5,445; −4,563)
Diagnostics	4,339 (4,124; 4,589)	1,975 (1,843; 2,107)	−2,364 (−2,634; −2,114)
Hospital stay[a]	4,159 (4,003; 4,326)	5,677 (5,375; 6,010)	1,518 (1,279; 1,787)
Complications[b]	1,334 (1,191; 1,472)	1,622 (1,444; 1,854)	288 (165; 455)
Long-term costs	6,367 (5,500; 7,976)	4,353 (3,566; 5,974)	−2,014 (−3,341; −579)
Dialysis	250 (210; 282)	367 (318; 402)	117 (92; 135)
Rehospitalization	6,117 (5,270; 7,717)	3,986 (3,218; 5,596)	−2,131 (−3,428; −697)
Total costs (UK £)	**30,511 (29,886; 32,308)**	**22,520 (21,751; 23,930)**	**−7,991 (−9,664; −6,889)**
Hospital costs	26,032 (25,437; 26,515)	18,846 (18,473; 19,290)	−7,186 (−7,794; −6,481)
Operating room	5,587 (5,348; 5,794)	6,577 (6,300; 6,849)	990 (641; 1,375)
Device cost	14,500 (13,979; 14,973)	6,000 (5,779; 6,192)	−8,500 (−9,041; −7,976)
Diagnostics	1,707 (1,649; 1,767)	777 (751; 804)	−930 (−997; −867)
Hospital stay[a]	3,113 (3,000; 3,225)	4,018 (3,817; 4,220)	904 (764; 1,064)
Complications[b]	1,125 (1,033; 1,212)	1,475 (1,303; 1,680)	349 (196; 528)
Long-term costs	4,479 (3,939; 6,285)	3,674 (2,981; 4,892)	−805 (−2,295; −4)
Dialysis	98 (82; 109)	143 (124; 155)	46 (36; 51)
Rehospitalization	4,381 (3,839; 6,190)	3,531 (2,831; 4,748)	−850 (−2,337; −45)
Total costs (France €)	**29,870 (29,092; 31,339)**	**26,365 (25,553; 27,638)**	**−3,504 (−4,949; −2,376)**
Hospital costs	24,510 (24,064; 24,941)	22,385 (21,872; 22,884)	−2,125 (−2,765; −1,486)
Operating room	3,364 (3,322; 3,405)	7,120 (6,805; 7,410)	3,757 (3,418; 4,050)
Device cost	11,000 (10,588; 11,373)	6,000 (5,781; 6,200)	−5,000 (−5,418; −4,581)
Diagnostics	4,633 (4,484; 4,789)	2,109 (2,042; 2,181)	−2,524 (−2,690; −2,369)
Hospital stay[a]	4,364 (4,203; 4,507)	5,795 (5,471; 6,095)	1,431 (1,173; 1,676)
Complications[b]	1,149 (1,043; 1,246)	1,360 (1,229; 1,529)	211 (102; 331)
Long-term costs	5,359 (4,738; 6,714)	3,980 (3,261; 5,068)	−1,379 (−2,581; −530)
Dialysis	219 (184; 243)	320 (278; 350)	102 (80; 115)
Rehospitalization	5,141 (4,513; 6,487)	3,660 (2,958; 4,763)	−1,481 (−2,661; −632)
Total costs (Italy €)	**33,250 (32,384; 35,038)**	**26,679 (25,833; 28,206)**	**−6,570 (−7,989; −5,314)**
Hospital costs	27,275 (26,691; 27,884)	22,447 (21,862; 23,232)	−4,827 (−5,439; −3,973)
Operating room	5,401 (5,187; 5,620)	6,358 (6,080; 6,627)	957 (590; 1,294)
Device cost	11,000 (10,623; 11,351)	6,000 (5,797; 6,205)	−5,000 (−5,413; −4,553)
Diagnostics	4,928 (4,756; 5,073)	2,243 (2,172; 2,323)	−2,685 (−2,847; −2,476)
Hospital stay[a]	4,518 (4,212; 4,851)	6,082 (5,615; 6,619)	1,564 (1,298; 1,874)
Complications[b]	1,427 (1,328; 1,531)	1,764 (1,595; 2,014)	336 (176; 539)
Long-term costs	5,975 (5,305; 7,497)	4,232 (3,493; 5,474)	−1,743 (−2,946; −853)
Dialysis	176 (148; 197)	259 (225; 281)	82 (66; 93)
Rehospitalization	5,799 (5,137; 7,323)	3,973 (3,255; 5,226)	−1,825 (−3,018; −944)
Total costs (Australia AUD)	**48,285 (47,135; 51,267)**	**38,269 (36,821; 40,985)**	**−10,016 (−12,819; −7,568)**
Hospital costs	38,238 (37,446; 39,130)	31,132 (30,514; 31,838)	−7,106 (−8,137; −6,156)
Operating room	1,205 (1,167; 1,249)	6,917 (6,682; 7,135)	5,712 (5,451; 5,922)
Device cost	22,932 (22,205; 23,778)	8,977 (8,658; 9,247)	−13,955 (−14,883; −13,168)
Diagnostics	2,732 (2,685; 2,781)	1,243 (1,224; 1,265)	−1,488 (−1,540; −1,437)
Hospital stay[a]	9,804 (9,467; 10,137)	12,355 (11,841; 12,983)	2,551 (2,194; 3,008)
Complications[b]	1,566 (1,412; 1,719)	1,640 (1,484; 1,818)	74 (7; 149)
Long-term costs	10,047 (8,767; 12,854)	7,137 (5,828; 9,607)	−2,910 (−5,546; −684)
Dialysis	460 (384; 510)	674 (587; 729)	214 (170; 239)
Rehospitalization	9,587 (8,294; 12,372)	6,463 (5,176; 8,950)	−3,124 (−5,738; −890)

Notes: Interquartile ranges are provided in parentheses. [a]Including intensive care unit stay. [b]Reoperation, renal replacement therapy, transfusion of red blood cell units, stroke, pacemaker implantation.
Abbreviations: TAVIs, transcatheter aortic valve implants; SU-AVR, sutureless aortic valve replacement.

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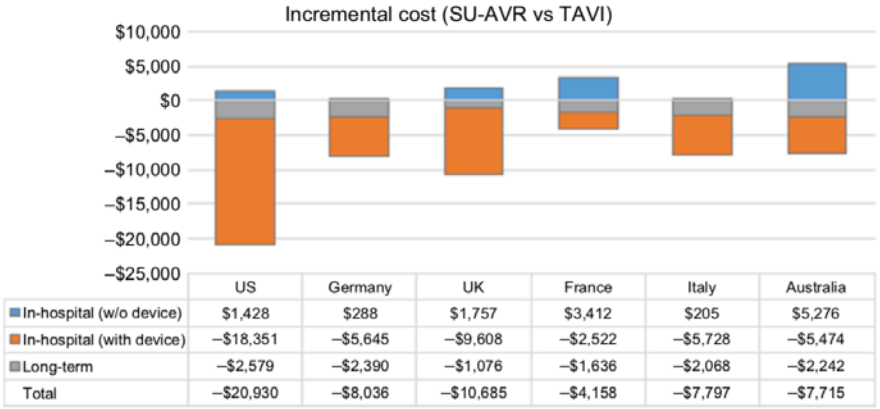
ORIGINAL RESEARCH

Cost-utility of surgical sutureless bioprostheses vs TAVI in aortic valve replacement for patients at intermediate and high surgical risk

Table 2 Effectiveness results: values expressed as mean and interquartile range

	TAVIs	SU-AVR	Delta (SU-AVR vs TAVIs)
In-hospital outcomes			
30-day mortality	7.0% (6.1%; 8.1%)	4.1% (3.2%; 4.8%)	−2.9% (−3.7%; −2.1%)
Renal dysfunction	2.6% (2.0%; 3.1%)	2.6% (2.0%; 3.1%)	0%
Reoperation	4.7% (4.5%; 4.7%)	11.3% (8.4%; 14.9%)	6.7% (3.9%; 10.3%)
Stroke	2.3% (1.8%; 2.8%)	1.2% (0.8%; 1.5%)	−1.1% (−1.4%; −0.8%)
PMI	18.8% (15.7%; 21.1%)	18.8% (15.7%; 21.1%)	0%
PVL	54.4% (51.5%; 58.8%)	8.9% (7.6%; 10.5%)	−45.5% (−49.1%; −42.5%)
POVC (major)	7.7% (5.7%; 10.1%)	0.4% (0.1%; 0.8%)	−7.3% (−9.3%; −5.3%)
RBC units	0.85 (0.82; 0.88)	1.21 (1.17; 1.25)	0.36 (0.31; 0.41)
Hospital stay (days)	7.33 (7.09; 7.58)	10.56 (10.00; 11.17)	3.23 (2.73; 3.77)
Long-term outcomes			
LY	4.26 (3.98; 4.52)	5.51 (5.25; 5.75)	1.25 (1.03; 1.44)
QALY	3.44 (3.15; 3.60)	4.58 (4.31; 4.72)	1.14 (0.98; 1.31)
Dialysis	5.6% (4.7%; 6.3%)	8.4% (7.3%; 9.2%)	2.8% (2.2%; 3.2%)
Rehospitalization	44.2% (39.5%; 48.3%)	32.5% (26.8%; 38.6%)	−11.7% (−14.1%; −8.2%)

Note: Interquartile ranges are provided in parentheses.
Abbreviations: LY, life-year; PMI, pacemaker implantation; POVC, postoperative vascular complication; PVL, paravalvular leak; QALY, quality-adjusted life-year; RBC, red blood cell; SU-AVR, sutureless aortic valve replacement; TAVIs, transcatheter aortic valve implants.



	US	Germany	UK	France	Italy	Australia
In-hospital (w/o device)	$1,428	$288	$1,757	$3,412	$205	$5,276
In-hospital (with device)	−$18,351	−$5,645	−$9,608	−$2,522	−$5,728	−$5,474
Long-term	−$2,579	−$2,390	−$1,076	−$1,636	−$2,068	−$2,242
Total	−$20,930	−$8,036	−$10,685	−$4,158	−$7,797	−$7,715

Figure 5 Comparison between incremental cost items for the six analyzed countries.
Notes: All values are expressed in 2017 US$ (negative increments favor SU-AVR, while positive increments favor TAVIs). €1= €1.1870, £1=$1.3372, AU$1=$0.7704.
Abbreviations: SU-AVR, sutureless aortic valve replacement; TAVIs, transcatheter aortic valve implants; w/o, without.

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ORIGINAL RESEARCH

Cost-utility of surgical sutureless bioprostheses vs TAVI in aortic valve replacement for patients at intermediate and high surgical risk

Massimiliano Povero[1]
Antonio Miceli[2,3]
Lorenzo Pradelli[1]
Matteo Ferrarini[2]
Matteo Pinciroli[4]
Mattia Glauber[2]

[1]AdRes Health Economics and Outcomes Research, Turin, Italy; [2]Minimally Invasive Cardiothoracic Department, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Milan, Italy; [3]Bristol Heart Institute, University of Bristol, Bristol, UK; [4]LivaNova, Milan, Italy

Background: Meta-analyses of studies comparing transcatheter aortic valve implants (TAVIs) and sutureless aortic valve replacement (SU-AVR) show differing effectiveness and safety profiles. The approaches also differ in their surgical cost (including operating room and device).

Objective: The objective of this study was to assess the incremental cost-utility of SU-AVR vs TAVIs for the treatment of intermediate- to high-risk patients in the US, Germany, France, Italy, UK, and Australia.

Methods: A patient-level simulation compares in-hospital pathways of patients undergoing SU-AVR or TAVIs; later, patient history is modeled at the cohort level. Hospital outcomes for TAVIs reproduce data from recent series; in SU-AVR patients, outcomes are obtained by applying relative efficacy estimates in a recent meta-analysis on 1,462 patients. After discharge, survival depends on the development of paravalvular leak and the need for dialysis. A comprehensive third-party payer perspective encompassing both in-hospital and long-term costs was adopted.

Results: Due to lower in-hospital (4.1% vs 7.0%) and overall mortality, patients treated with SU-AVR are expected to live an average of 1.25 years more compared with those undergoing TAVIs, with a mean gain of 1.14 quality-adjusted life-years. Both in-hospital and long-term costs were lower for SU-AVR than for TAVIs with total savings ranging from $4,158 (France) to $20,930 (US).

Conclusion: SU-AVR results dominant when compared to TAVIs in intermediate- to high-risk patients. Both in-hospital and long-term costs are lower for SU-AVR than for TAVI patients, with concomitant significant gains in life expectancy, both raw and adjusted for the quality of life.

Keywords: sutureless valve, aortic valve replacement, TAVI, DES model, cost-utility

5) Αντοχή στο χρόνο

Five-year results of the pilot trial of a sutureless valve

Bart Meuris, MD, PhD,[a] Willem J. Flameng, MD, PhD,[a] François Laborde, MD,[b] Thierry A. Folliguet, MD,[b] Axel Haverich, MD,[c] and Malakh Shrestha, MD, PhD[c]

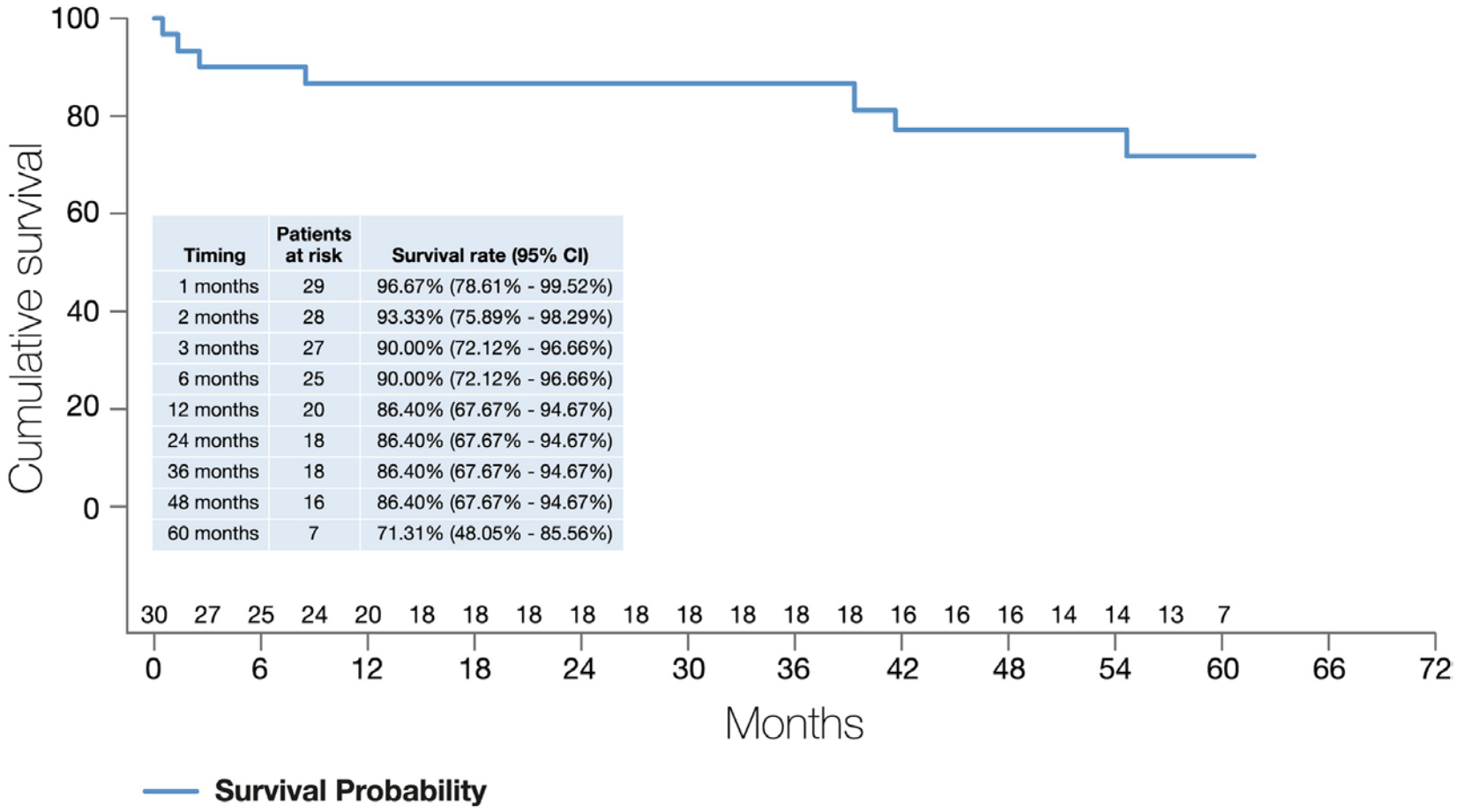
Central Message

Five-year outcomes of a sutureless aortic valve in 30 elderly patients showed survival at 71.3%, and a mean gradient of 9.3 mm Hg. Effective orifice area was 1.7 cm^2, without dislodgement, structural valve deterioration, hemolysis, or valve thrombosis.

Perspective

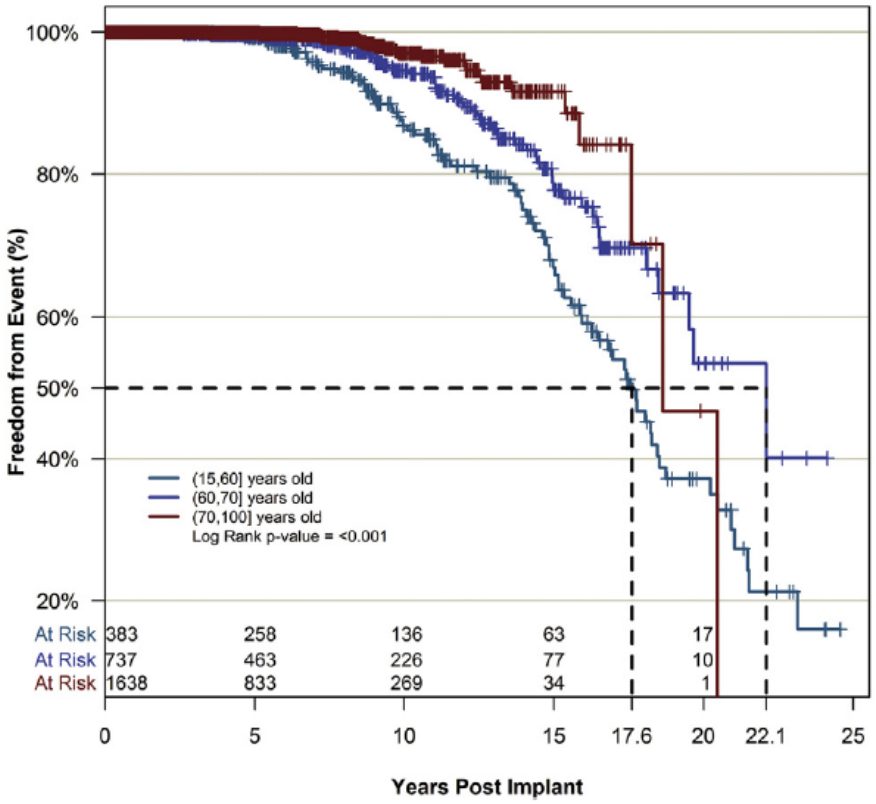
The current article summarizes the 5-year follow-up data of the 30 first Perceval valves that were implanted. This experience is the first and longest with humans, with a truly sutureless valve, to evaluate implantation feasibility and valve safety. Results for up to 5 years of follow up confirmed the performance and safety of this device, even in a medium- to high-risk patient population. The valve did not reveal any dislodgement, structural valve deterioration, hemolysis, or thrombosis.

J Thorac Cardiovasc Surg 2015;150:84-8



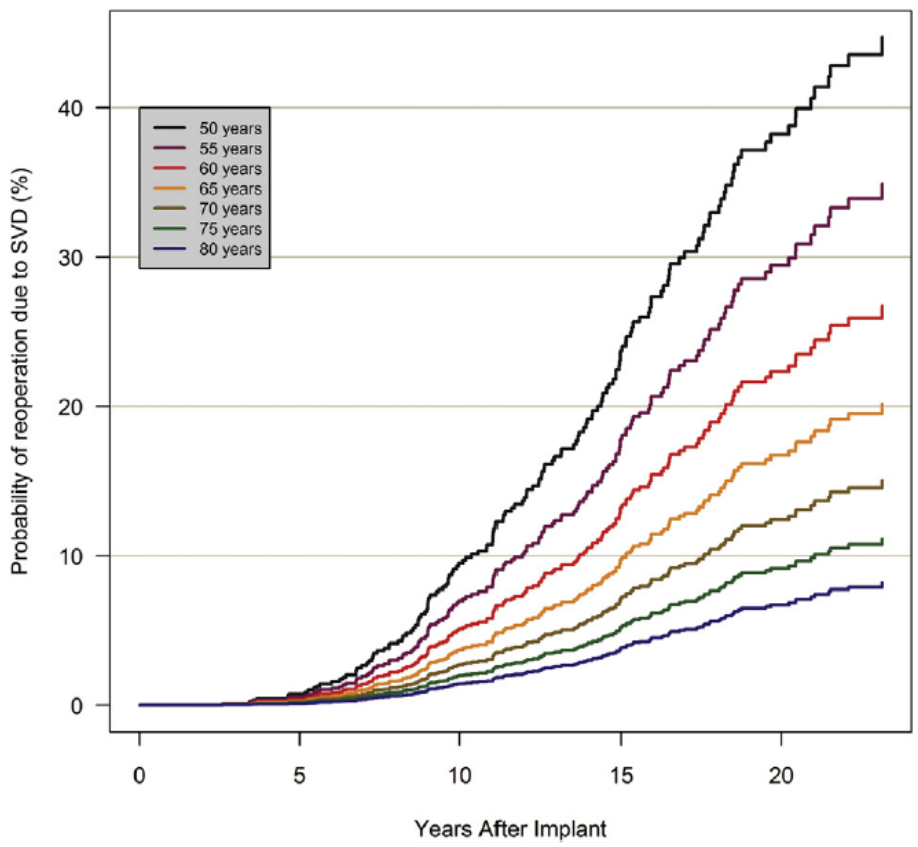
Timing	Patients at risk	Survival rate (95% CI)
1 months	29	96.67% (78.61% - 99.52%)
2 months	28	93.33% (75.89% - 98.29%)
3 months	27	90.00% (72.12% - 96.66%)
6 months	25	90.00% (72.12% - 96.66%)
12 months	20	86.40% (67.67% - 94.67%)
24 months	18	86.40% (67.67% - 94.67%)
36 months	18	86.40% (67.67% - 94.67%)
48 months	16	86.40% (67.67% - 94.67%)
60 months	7	71.31% (48.05% - 85.56%)

Freedom from SVD/age



Kaplan-Meier freedom from structural valve deterioration (SVD) by age groups. The expected valve durability (median survival time without SVD) was 17.6 and 22.1 years for the younger (≤ 60) and the 60 to 70 years group, respectively.

Reoperation/age



Competing risk regression evaluating the cumulative risk of reoperation due to structural valve deterioration (SVD) with age at surgery as the unique covariate.

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position (Ann Thorac Surg 2015;99:831–7)

Age-stratified **freedom from reoperation** due to structural valve deterioration at 15 and 20 years (Edwards Perimount Aortic)

* **age ≤ 60**: 70.8% (15y) and 38.1% (20y)
* **age 60 – 70**: 82.7% (15y) and 59.6% (20y)
* **age > 70**: 98.1% (15y)

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

2017 ESC/EACTS Guidelines for the management of valvular heart disease

* Expected valve durability: 19.7 years (2659pts)

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position (Ann Thorac Surg 2015;99:831–7)

Evaluation and Selection of Prosthetic Valves

IIa / B-NR See Online Data Supplement 20 (Updated From 2014 VHD Guideline)	An aortic or mitral mechanical prosthesis is reasonable for patients less than 50 years of age who do not have a contraindication to anticoagulation	MODIFIED: LOE updated from B to B-NR. The age limit for mechanical prosthesis was lowered from 60 to 50 years of age.
IIa / B-NR See Online Data Supplement 20 (Updated From 2014 VHD Guideline)	For patients between 50 and 70 years of age, it is reasonable to individualize the choice of either a mechanical or bioprosthetic valve prosthesis on the basis of individual patient factors and preferences, after full discussion of the trade-offs involved (141–145,157–160).	MODIFIED: Uncertainty exists about the optimum type of prosthesis (mechanical or bioprosthetic) for patients 50 to 70 years of age. There are conflicting data on survival benefit of mechanical versus bioprosthetic valves in this age group, with equivalent stroke and thromboembolic outcomes. Patients receiving a mechanical valve incur greater risk of bleeding, and those undergoing bioprosthetic valve replacement more often require repeat valve surgery.
IIa / B	A bioprosthesis is reasonable for patients more than 70 years of age (163–166).	2014 recommendation remains current.

Grey zone: 50-70yo

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

Choice of the aortic/mitral prosthesis in favour of a mechanical prosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class[a]	Level[b]
A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindications to long-term anticoagulation.[c]	I	C
A mechanical prosthesis is recommended in patients at risk of accelerated structural valve deterioration.[d]	I	C
A mechanical prosthesis should be considered in patients already on anticoagulation because of a mechanical prosthesis in another valve position.	IIa	C
A mechanical prosthesis should be considered in patients <60 years of age for prostheses in the aortic position and <65 years of age for prostheses in the mitral position.[e]	IIa	C
A mechanical prosthesis should be considered in patients with a reasonable life expectancy[f] for whom future redo valve surgery would be at high risk.	IIa	C
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to the high risk for thromboembolism.[g]	IIb	C

2017 ESC/EACTS Guidelines for the management of valvular heart disease

Choice of the aortic/mitral prosthesis in favour of a bioprosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class[a]	Level[b]
A bioprosthesis is recommended according to the desire of the informed patient.	I	C
A bioprosthesis is recommended when good-quality anticoagulation is unlikely (compliance problems, not readily available) or contraindicated because of high bleeding risk (previous major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom there is a low likelihood and/or a low operative risk of future redo valve surgery.	IIa	C
A bioprosthesis should be considered in young women contemplating pregnancy.	IIa	C
A bioprosthesis should be considered in patients >65 years of age for a prosthesis in the aortic position or > 70 years of age in a mitral position or those with a life expectancy[c] lower than the presumed durability of the bioprosthesis.[d]	IIa	C

2017 ESC/EACTS Guidelines for the management of valvular heart disease

Mechanical vs bioprosthetic AVR: grey zones

50(!) – 70 years

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

60-65 years

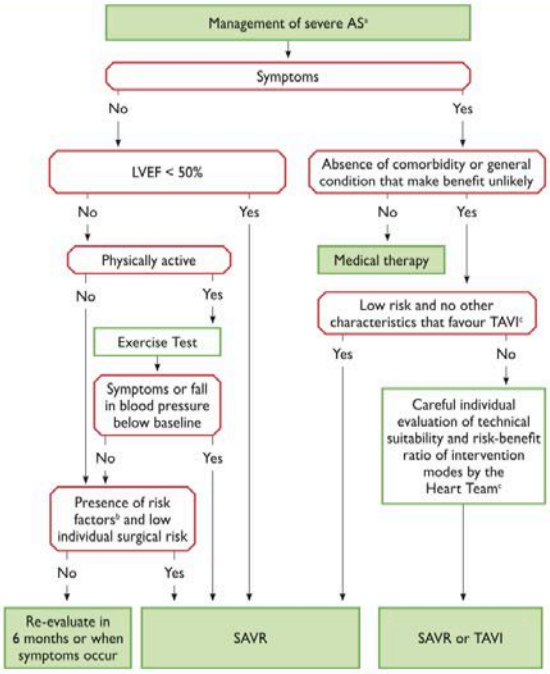
2017 ESC/EACTS Guidelines for the management of valvular heart disease

ESC European Society of Cardiology
European Heart Journal (2017) **38**, 2739–2791
doi:10.1093/eurheartj/ehx391

ESC/EACTS GUIDELINES

2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)



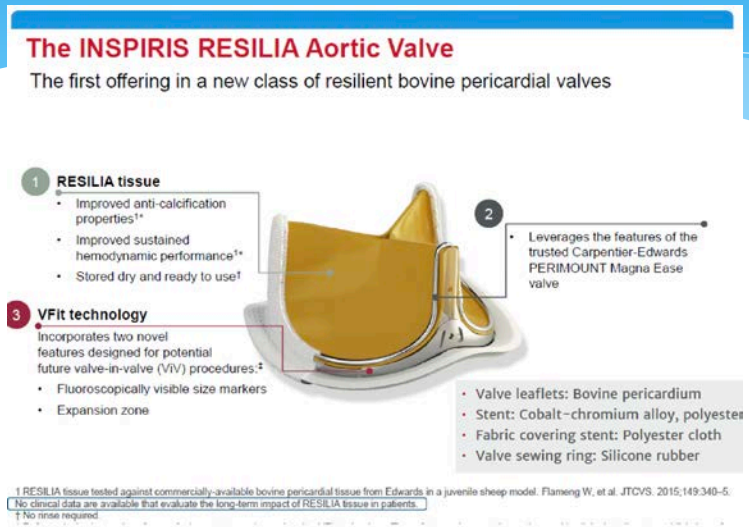
Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode

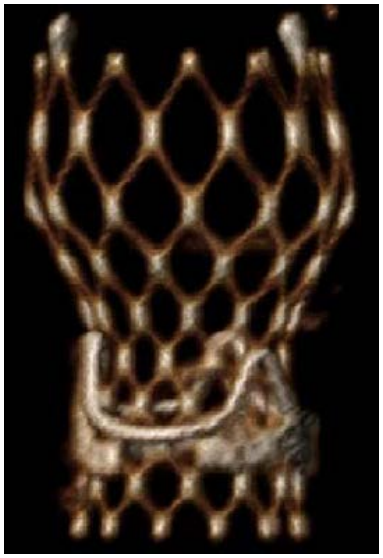
	Class[a]	Level[b]
A) Symptomatic aortic stenosis		
Intervention is indicated in symptomatic patients with severe, high-gradient aortic stenosis (mean gradient ≥40 mmHg or peak velocity ≥4.0 m/s).[91–93]	I	B
Intervention is indicated in symptomatic patients with severe low-flow, low-gradient (<40 mmHg) aortic stenosis with reduced ejection fraction and evidence of flow (contractile) reserve excluding pseudosevere aortic stenosis.	I	C
Intervention should be considered in symptomatic patients with low-flow, low-gradient (<40 mmHg) aortic stenosis with normal ejection fraction after careful confirmation of severe aortic stenosis[c] (see *Figure 2* and *Table 6*).	IIa	C
Intervention should be considered in symptomatic patients with low-flow, low-gradient aortic stenosis and reduced ejection fraction without flow (contractile) reserve, particularly when CT calcium scoring confirms severe aortic stenosis.	IIa	C
Intervention should not be performed in patients with severe comorbidities when the intervention is unlikely to improve quality of life or survival.	III	C
B) Choice of intervention in symptomatic aortic stenosis		
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on site and with structured collaboration between the two, including a Heart Team (heart valve centres).	I	C
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in *Table 7*). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.	IIb	C
Balloon aortic valvotomy may be considered as a diagnostic means in patients with severe aortic stenosis or other potential causes for symptoms (i.e. lung disease) and in patients with severe myocardial dysfunction, pre-renal insufficiency or other organ dysfunction that may be reversible with balloon aortic valvotomy when performed in centres that can escalate to TAVI.	IIb	C
C) Asymptomatic patients with severe aortic stenosis (refers only to patients eligible for surgical valve replacement)		
SAVR is indicated in asymptomatic patients with severe aortic stenosis and systolic LV dysfunction (LVEF <50%) not due to another cause.	I	C
SAVR is indicated in asymptomatic patients with severe aortic stenosis and an abnormal exercise test showing symptoms on exercise clearly related to aortic stenosis.	I	C
SAVR should be considered in asymptomatic patients with severe aortic stenosis and an abnormal exercise test showing a decrease in blood pressure below baseline.	IIa	C
SAVR should be considered in asymptomatic patients with normal ejection fraction and none of the above-mentioned exercise test abnormalities if the surgical risk is low and one of the following findings is present: • Very severe aortic stenosis defined by a V_{max} >5.5 m/s • Severe valve calcification and a rate of V_{max} progression ≥0.3 m/s/year • Markedly elevated BNP levels (>threefold age- and sex-corrected normal range) confirmed by repeated measurements without other explanations • Severe pulmonary hypertension (systolic pulmonary artery pressure at rest >60 mmHg confirmed by invasive measurement) without other explanation.	IIa	C
D) Concomitant aortic valve surgery at the time of other cardiac/ascending aorta surgery		
SAVR is indicated in patients with severe aortic stenosis undergoing CABG or surgery of the ascending aorta or of another valve.	I	C

Continued

SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B

6)Friendly with future TAVI in valve





CT reconstruction VIV:
23-mm CoreValve Evolut R in a 19-mm Edwards Magna, followed by bioprosthetic valve fracture (BVF).

The INSPIRIS RESILIA Aortic Valve

The first offering in a new class of resilient bovine pericardial valves

1 RESILIA tissue

- Improved anti-calcification properties[1*]
- Improved sustained hemodynamic performance[1*]
- Stored dry and ready to use[†]

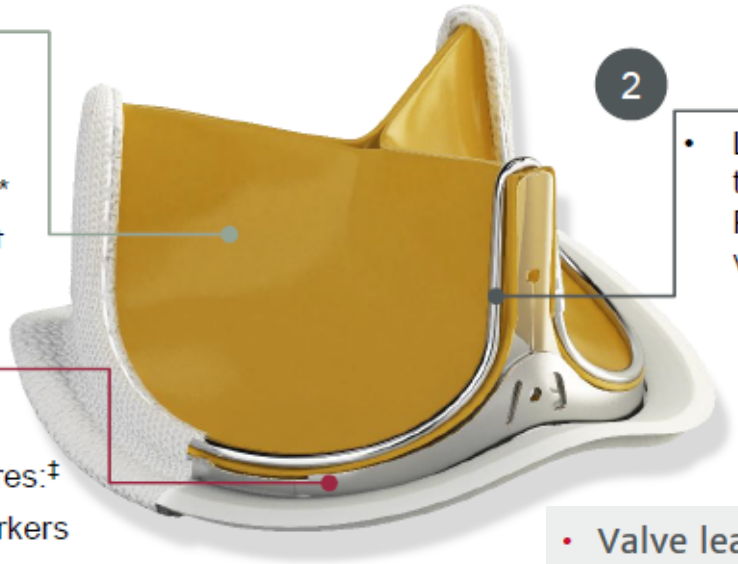
2

- Leverages the features of the trusted Carpentier-Edwards PERIMOUNT Magna Ease valve

3 VFit technology

Incorporates two novel features designed for potential future valve-in-valve (ViV) procedures:[‡]

- Fluoroscopically visible size markers
- Expansion zone



- Valve leaflets: Bovine pericardium
- Stent: Cobalt–chromium alloy, polyester
- Fabric covering stent: Polyester cloth
- Valve sewing ring: Silicone rubber

1 RESILIA tissue tested against commercially-available bovine pericardial tissue from Edwards in a juvenile sheep model. Flameng W, et al. JTCVS. 2015;149:340–5.
No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
† No rinse required.

7) Μελλοντικές προοπτικές

REVIEW ARTICLE

The Perceval Sutureless Aortic Valve

Review of Outcomes, Complications, and Future Direction

Ramsey Powell, BEng, Marc P. Pelletier, MD,† Michael W. A. Chu, MD,‡ Denis Bouchard, MD,§ Kevin N. Melvin, MD,// and Corey Adams, MD//*

Abstract: Surgical aortic valve replacement with a stented prosthesis has been the standard of care procedure for aortic stenosis. The Perceval (LivaNova, London, United Kingdom) is a sutureless aortic valve bioprosthesis currently implanted in more than 20,000 patients. The purpose of this article was to review the literature available after 9 years of clinical experience of the Perceval aortic valve. PubMED, Embase, and the Cochrane Library databases were searched. A meta-analysis of summary statistics from individual studies was conducted. A total of 333 studies were identified and 84 studies were included. Thirty-day mortality and 5-year survival ranged from 0% to 4.9% and 71.3% to 85.5%, respectively. Compared with stented prosthesis, pooled analysis demonstrated a statistically significant reduction in aortic cross-clamp and cardiopulmonary bypass times (minutes) with Perceval (38.6 vs 63.3 and 61.4 vs 84.9, $P < 0.00001$, respectively). Compared with transcatheter aortic valve implantation, pooled analysis demonstrated a statistically significant reduction with Perceval in paravalvular leakage (1.26% vs 14.31%) and early mortality (2.3% vs 6.9%). Favorable hemodynamics, acceptable valve durability, and ease of implantation in minimally invasive cases were reported as benefits. A trend toward increased rates of permanent pacemaker implantation and low postoperative platelet count were identified. Special use and off-label procedures described included bicuspid aortic valves, valve-in-valve for homograft and stentless prosthesis failure, concomitant valvular procedures, porcelain aorta, and endocarditis. The Perceval valve has shown safe clinical and hemodynamic outcomes. Outcomes support its continued usage and potential expansion.

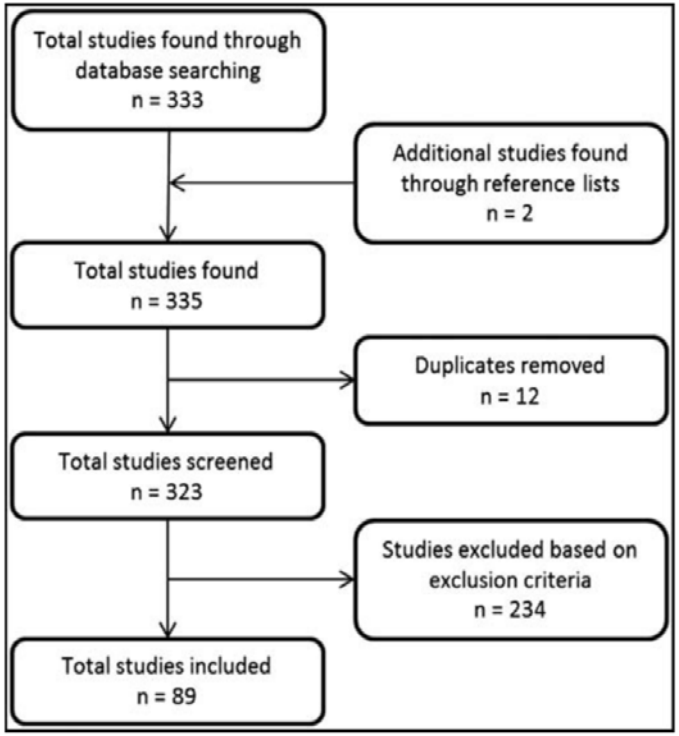


FIGURE 1. Study selection process

(*Innovations* 2017;12:155–173)

Evangelismos Hospital Experience with sutureless & rapid deployment AVRs

- 192 AVRs with Perceval S sutureless (2013-2019)
- (30 S, 75 M, 56 L, 31 XL Total: 192)
- 12 AVRs with Intuity - Edwards
- 164 scheduled procedures : 24 with CABG, 3 on REDO AVR, 2 with concomitant MVR
- 14 Postop Pacemaker implantations (7.2%)
- In 4 cases the valve had to be repositioned.
- 6 non valve related in hospital deaths (3.1%)
- 1 acute MI 4 months postop without clinical effect and clean angiography.
- 1 late endocarditis following hip replacement (died without surgery)

Συμπέρασμα

Η τεχνολογία σήμερα προσφέρει πολλές επιλογές στη χειρουργική των καρδιακών βαλβίδων.
Στους γιατρούς όμως εναπόκειται να προσφέρουν στον ασθενή την καταλληλότερη γι αυτόν επιλογή που με τη συγκατάθεσή του θα του προσφέρει και την καλύτερη θεραπεία.
Τα περισσότερα σύγχρονα δεδομένα και οι κατευθυντήριες οδηγίες συνιστούν την αντικατάσταση αορτικής βαλβίδας με συμβατικό τρόπο σε χαμηλού κινδύνου ασθενείς.

Ευχαριστώ