6ο ΠΑΝΕΛΛΗΝΙΟ ΣΥΝΕΔΡΙΟ ΕΝΩΣΗΣ ΕΛΕΥΘΕΡΟΕΠΑΓΓΕΛΜΑΤΙΩΝ ΚΑΡΔΙΟΛΟΓΩΝ ΕΛΛΑΔΟΣ

05.4 - 07.4 2019
ΞΕΝΟΔΟΧΕΙΟ
ΛΙΜΝΕΟΝ ΚΑΣΤΟΡΙΑ

TAVI VS SAVR.
ΝΈΑ ΔΕΔΟΜΈΝΑ

Χριστόφορος Σ. Κωτούλας **MD, MSc, PhD, FETCS, FCCP**

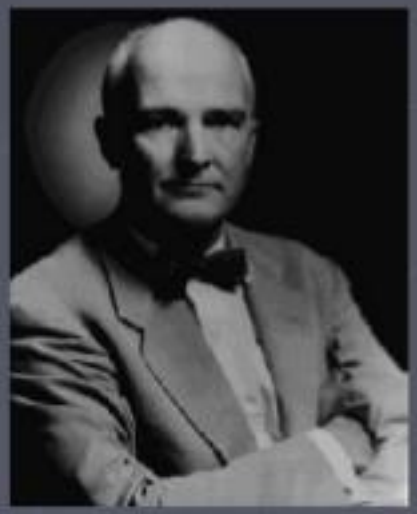
401ΓΣΝΑ – METROPOLITAN General

DISCLOSURES

I have nothing to declare.

I am just a Cardiac Surgeon.

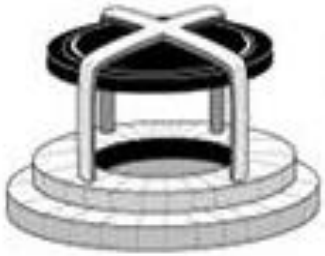
JOHN GIBBON
1953



CHARLES A. HUFNAGEL
1952

Caged ball valve

Tilting disc valve



Single leaflet valve

Bi-leaflet valve

A

CE Perimount

CE Perimount Magna

CE Perimount Magna Ease

Sorin Mitroflow

B

Medtronic Hancock II

Medtronic Mosaic

CE Porcine SAV

Biocor

C

Edwards Prima Plus

Medtronic Freestyle

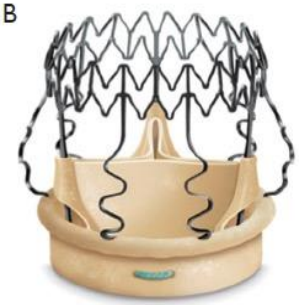
St. Jude Toronto SPV

Sorin Freedom

Medtronic Mosaic valve

A

B



C

Dr. Alain Cribier
First-in-Man PIONEER

April 16, 2002

Circulation

American Heart Association. Learn and Live.

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

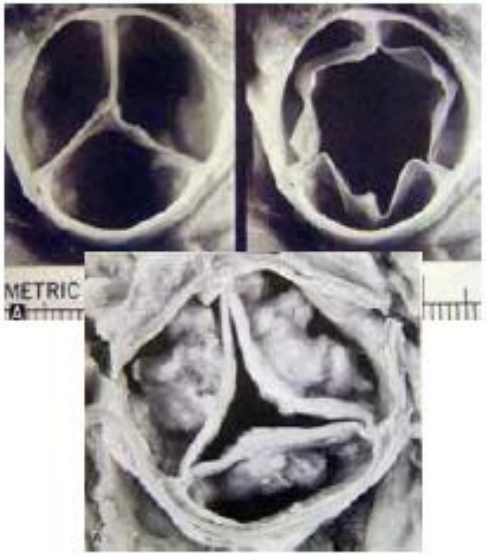
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

AHA; Nov, 2002


Poland Spring
CONSULTING
State Farm

The *Standard* therapy for critical AS is *Surgical Aortic Valve Replacement*

(30day Mortality 3%)



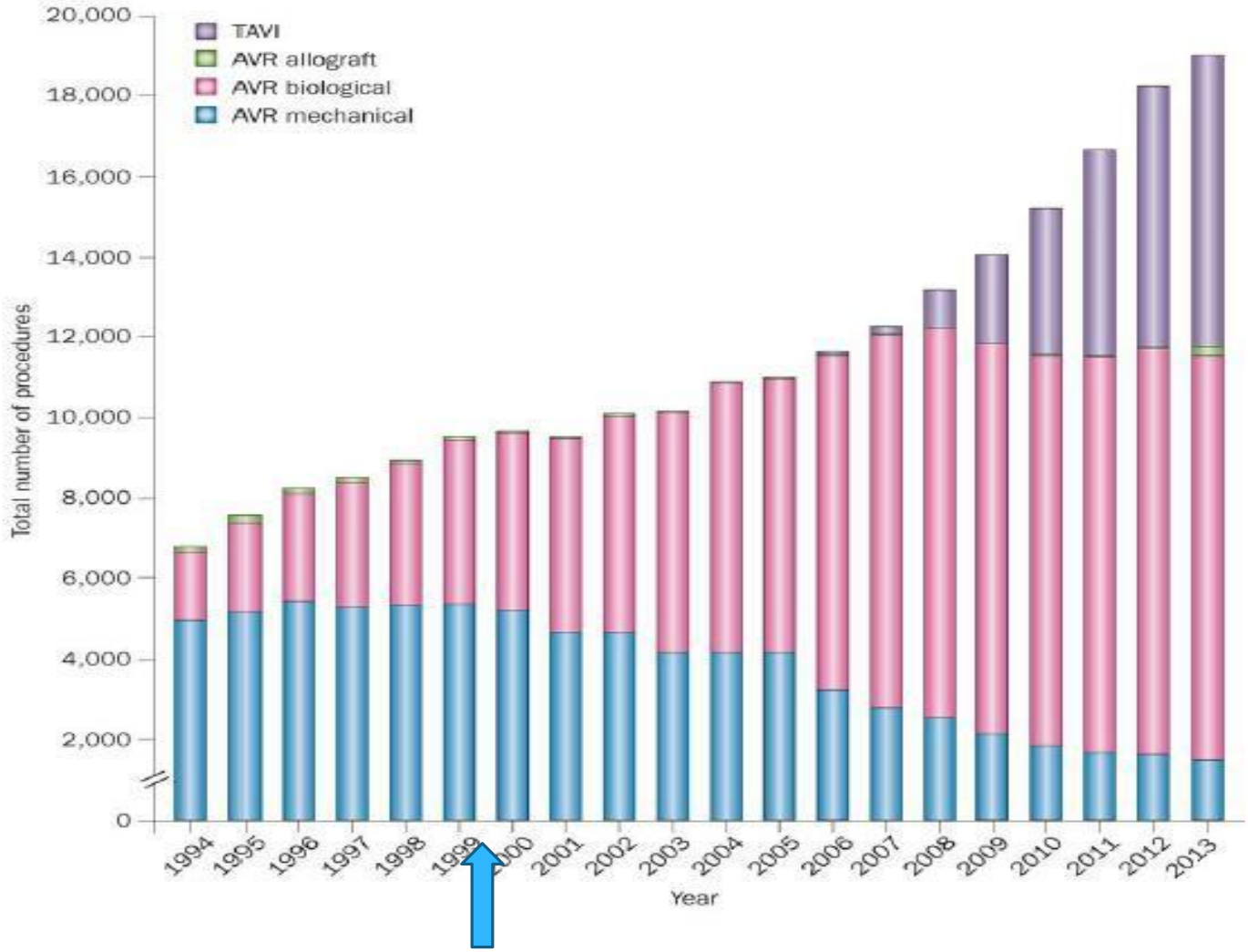
Options for sAVR:

Mechanical

Tissue

Stentless

Increasing Use of Bioprostheses
Data from German Registry



SOURCE: Mohr, Nat Rev, 2014

The Current (surgical) Market

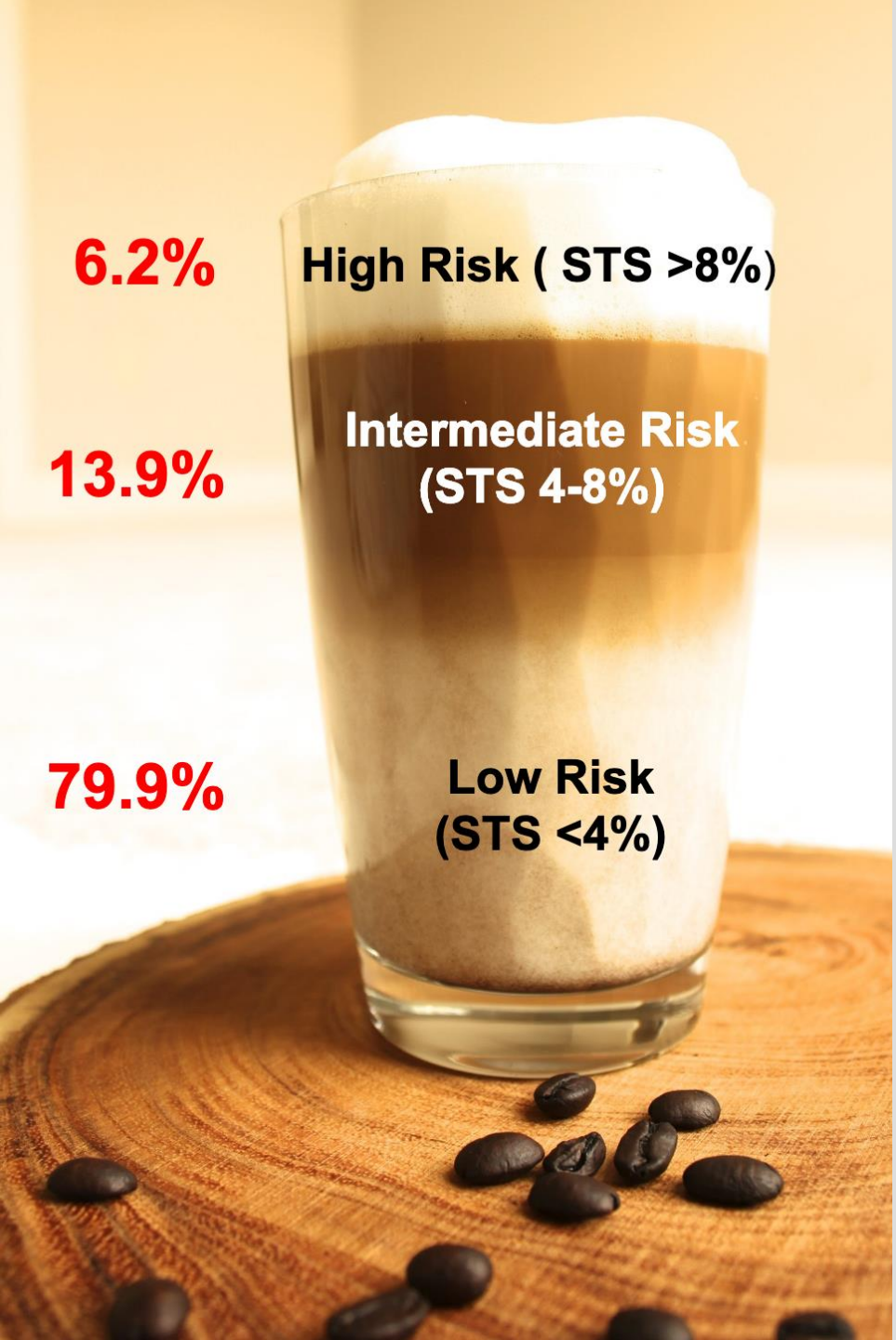
(≈ 200‘000 pts per year)

78-85%
(43% in 1997)

15-22%
(55% in 1997)

2018

- **8500** επεμβάσεις καρδιάς
- 1500 επεμβάσεις στην αορτική βαλβίδα
  - 70% βιολογικές βαλβίδες
  - 30% μηχανικές βαλβίδες



TAVI ΣΤΗΝ ΕΛΛΑΔΑ

- EUROSCORE >20%
- EUROSCORE II >8% - >5%

- Υψηλού – ενδιαμέσου κινδύνου ασθενείς

How do you define debility or frailty ?

- Same age and predicted risk
- One passes the "eyeball test"; one doesn't
- Frailty Index

Patient related factors			Cardiac related factors		
Age [1] (years)	75	0.46	NYHA	II	.1070545
Gender	female	.2196434	CCS class 4 angina [8]	no	0
Renal impairment [2] *See calculator below for creatinine clearance*	normal (CC >85ml/min)	0	LV function	good (LVEF > 50%)	0
Extracardiac arteriopathy [3]	yes	.5360268	Recent MI [9]	no	0
Poor mobility [4]	no	0	Pulmonary hypertension [10]	no	0
Previous cardiac surgery	no	0	**Operation related factors**		
Chronic lung disease [5]	no	0	Urgency [11]	elective	0
Active endocarditis [6]	no	0	Weight of the intervention [12]	single non CABG	.0062118
Critical preoperative state [7]	no	0	Surgery on thoracic aorta	no	0
Diabetes on insulin	no	0			

EuroSCORE II — *EuroSCORE* II: 1.80 %

Note: This is the 2011 EuroSCORE II

Calculate Clear

Patient-related factors			Cardiac-related factors		
Age (years)	75	0	Unstable angina[6]	No	0
Gender	Female	.3304052	LV function	Good	0
Chronic pulmonary disease[1]	No	0	Recent MI[7]	No	0
Extracardiac arteriopathy[2]	Yes	.6558917	Pulmonary hypertension[8]	No	0
Neurological dysfunction[3]	No	0	**Operation-related factors**		
Previous Cardiac Surgery	No	0	Emergency[9]	No	0
Creatinine > 200 µmol/ L	No	0	Other than isolated CABG	Yes	.5420364
Active endocarditis[4]	No	0	Surgery on thoracic aorta	No	0
Critical preoperative state[5]	No	0	Post infarct septal rupture	No	0

Logistic *EuroSCORE*: 10.64 %

Note: Logistic is now default calculator

Calculate Clear

Σύγκριση με TAVI

Τι δεν προσμετρούν τα χειρουργικά συστήματα βαθμονόμησης κινδύνου

LVEF??!! (STS)

Frailty (STS , Euroscore II, logistic Euroscore)

Porcelain aorta (STS , Euroscore II, logistic Euroscore)

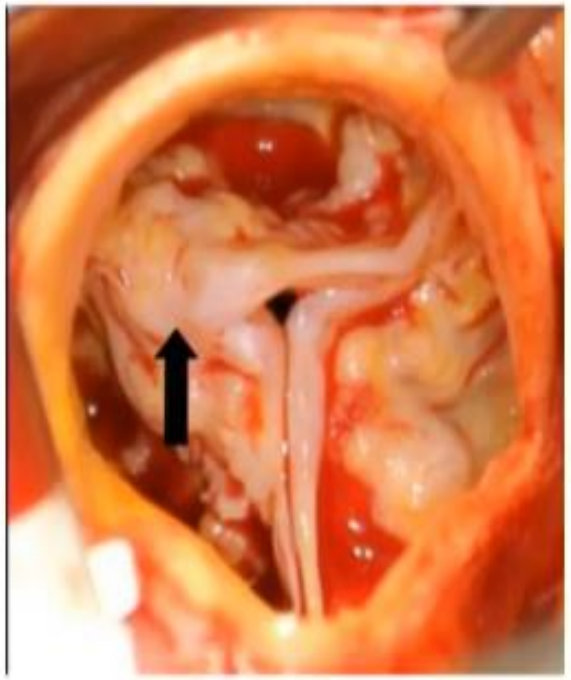
Liver disease (STS , Euroscore II, logistic Euroscore)

RV function (STS , Euroscore II, logistic Euroscore)

PA (STS , logistic Euroscore)

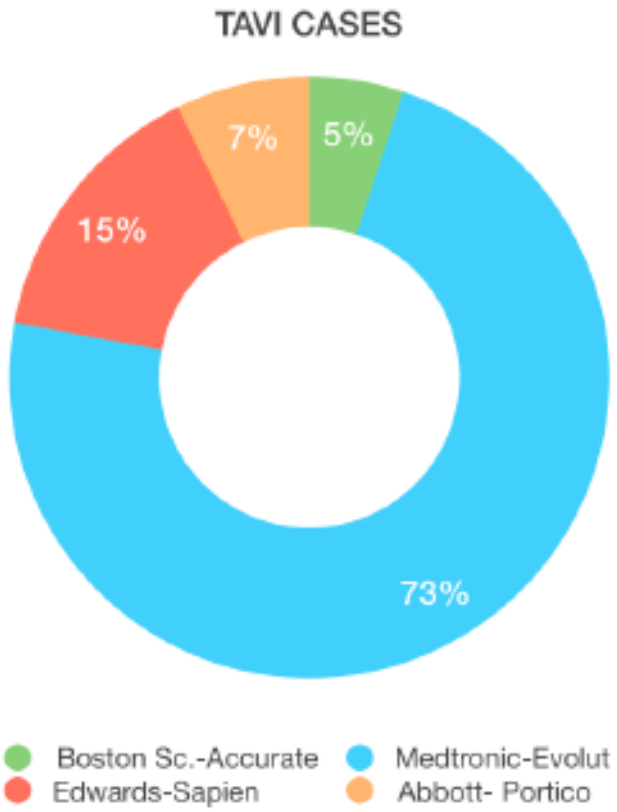
BMI (Logistic Euroscore, Euroscore II

Poor mobility (Logistic Euroscore, STS)



TAVI GREECE 2018

TAVI CASES 2018 CY	
Boston Sc.-Accurate	26
Medtronic-Evolut	373
Edwards-Sapien	76
Abbott- Portico	37
TOTAL	512



MEDTRONIC

HOSPITAL	UNITS
IPPOKRATEIO	65
ONASEIO	80
HYGEIA	36
METROPOLITAN	57
AGIOS LUKAS	25
CRETE	16
IOANNINA	12
PAPANIKOLAOU THES.	7
PAPAGEORGIOU THES.	13
MEDITERRANEO	14
IATRIKO ATH.	13
DIAVALKANIKO THES.	4
NNA	12
401	8
EVAGGELISMOS	2
ERRIKOS NTYNANT	5
EUROCLINIC ATH.	2
IASSO GENERAL	1
GENIKI THES.	1

EDWARDS

HOSPITAL	UNITS
IPPOKRATEIO	2
ONASEIO	9
HYGEIA	54
AGIOS LUKAS	5
CRETE	3
IOANNINA	1
DIAVALKANIKO THES.	1
NNA	1

ABBOTT

HOSPITAL	UNITS
IPPOKRATEIO	5
ERRIKOS NTYNANT	3
AGIOS LOUKAS	1
AHEPA	6
IOANNINA	7
PAPANIKOLAOU THES.	2
CRETE	7
EVAGGELISMOS	6

BOSTON

HOSPITAL	UNITS
IPPOKRATEIO	4
ERRIKOS NTYNANT	4
HYGEIA	2
GENIKI CLINIC THES.	5
IASSO GENERAL	3
NNA	5

Σύγκριση με TAVI

Τυχαιοποιημένες μελέτες

1. PARTNER 2, CoreValve US Pivotal , NOTION, and SURTAVI

2. Σχεδόν όλες οι ως τώρα μελέτες έχουν εξαιρέσει ασθενείς με προηγηθείσα ΚΡΧ επέμβαση, νεφρική ανεπάρκεια, πρόσφατη νευρολογική συνδρομή κ α

3. Συμπερήφθηκαν σε πολύ μικρό βαθμό ασθενείς με συνοδό στεφανιαία νόσο, μειωμένο κλάσμα εξώθησης αριστερής, και καθόλου ασθενείς με άλλες συνοδές βλάβες (πχ TVR, MR, ανεύρυσμα ανιούσης αορτής)

3. Όπως σε όλες τις τυχαιοποιημένες μελέτες ένα μόνο ποσοστό των ελεγχθέντων ασθενών συμπεριελήφθησαν. Πχ 18% στην 'all comers' (!)NOTION, 20% στην PARTNER 1 .

4. Όλες οι τυχαιοποιημένες μελέτες έδειξαν non-inferiority ή δεν έδειξαν διαφορά στα πρώιμα καταληκτικά σημεία ενώ λίγες έχουν μακροπρόθεσμα αποτελέσματα.

5.Ο μέσος όρος ηλικίας των RCTs ήταν 80+.

TAVI

ΜΕΛΕΤΕΣ ΣΕ ΑΣΘΕΝΕΙΣ ΕΝΔΙΑΜΕΣΟΥ ΚΙΝΔΥΝΟΥ

ΙΣΟΔΥΝΑΜΗ ΘΝΗΤΟΤΗΤΑ
(ΥΠΕΡΟΧΗ TAVI ΣΕ ΔΙΑΜΗΡΙΑΙΑ ΠΡΟΣΠΕΛΑΣΗ)

ΤΑΧΥΤΕΡΗ ΑΝΑΡΡΩΣΗ, ΚΑΛΥΤΕΡΗ ΠΟΙΟΤΗΤΑ ΖΩΗΣ, ΛΙΓΟΤΕΡΗ ΝΟΣΗΡΟΤΗΤΑ, ΒΕΛΤΙΩΜΕΝΗ ΑΙΜΟΔΥΝΑΜΙΚΗ ΣΥΜΠΕΡΙΦΟΡΑ

Η ΑΝΑΓΚΗ ΓΙΑ ΒΗΜΑΤΟΔΟΤΗΣΗ, ΚΑΙ ΟΙ ΠΑΡΑΒΑΛΒΙΔΚΗ ΔΙΑΦΥΓΗ (ΜΕΤΡΙΟΥ ΒΑΘΜΟΥ ΚΑΙ ΑΝΩ) ΕΊΝΑΙ ΘΕΜΑΤΑ ΠΟΥ ΧΡΗΖΟΥΝ ΒΕΛΤΙΩΣΗΣ ΚΑΤΙ ΠΟΥ ΗΔΗ ΣΥΜΒΑΙΝΕΙ ΜΕ ΤΟΥΣ ΚΑΙΝΟΥΡΓΙΟΥΣ ΤΥΠΟΥΣ ΤΩΝ TAVI.

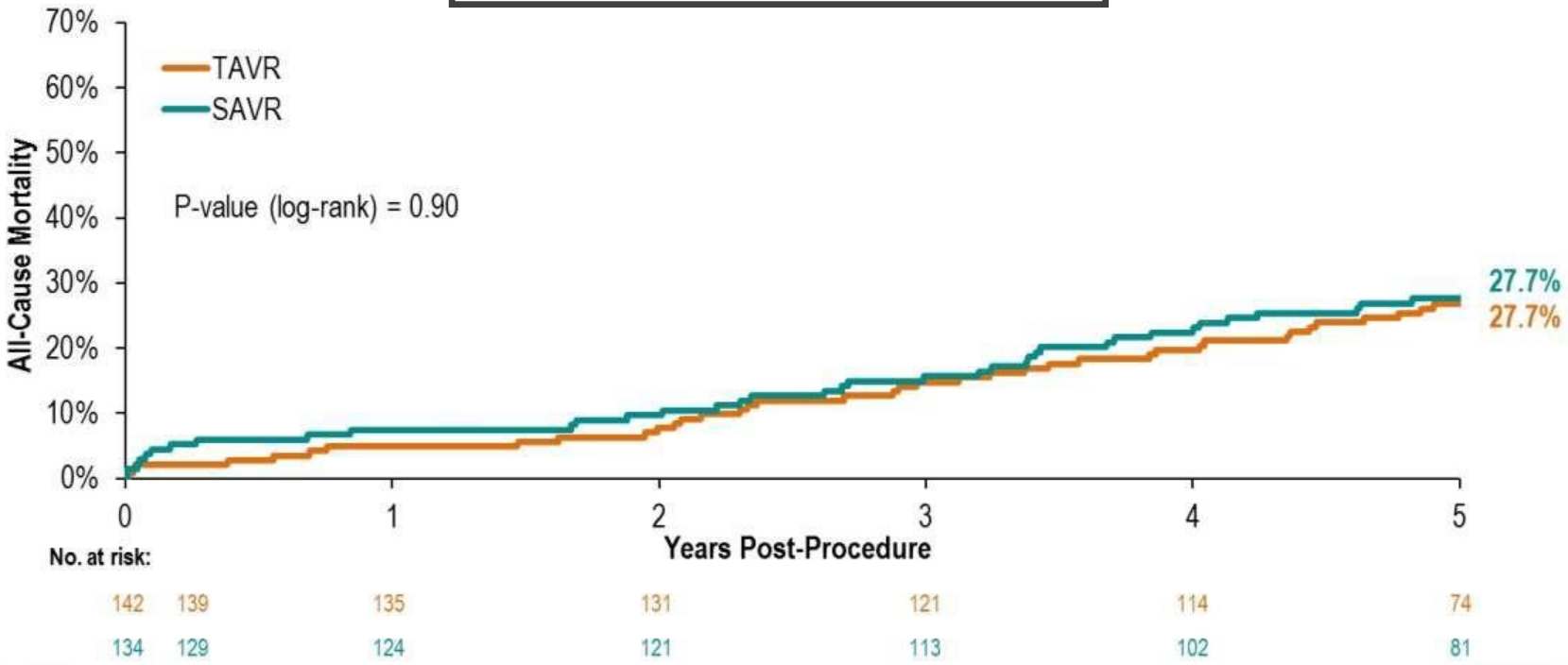
TAVI IN LOW - RISK PATIENTS : ONGOING TRIALS

PARTNER 3 *NCT02675114*	CoreValve *NCT02701283*	NOTION-2 *NCT02825134*
Low surgical risk as assessed by Heart Team		
STS < 4%	*STS < 3%*	*STS < 4%*
Sample Size		
N=1,228	*N=1,200*	*N=992*
1:1 Randomization TAVI Vs. SAVR		
SAPIEN 3	*Evolut R*	*Any CE-approved device*
Primary Endpoint		
All-cause mortality, Any strokes, or re-hospitalization at 1 year	*All-cause mortality, any stroke, life-threatening bleeding, major vascular complications, or AKI at 30-day*	*All-cause mortality, myocardial infarction, or any stroke at 1-year*

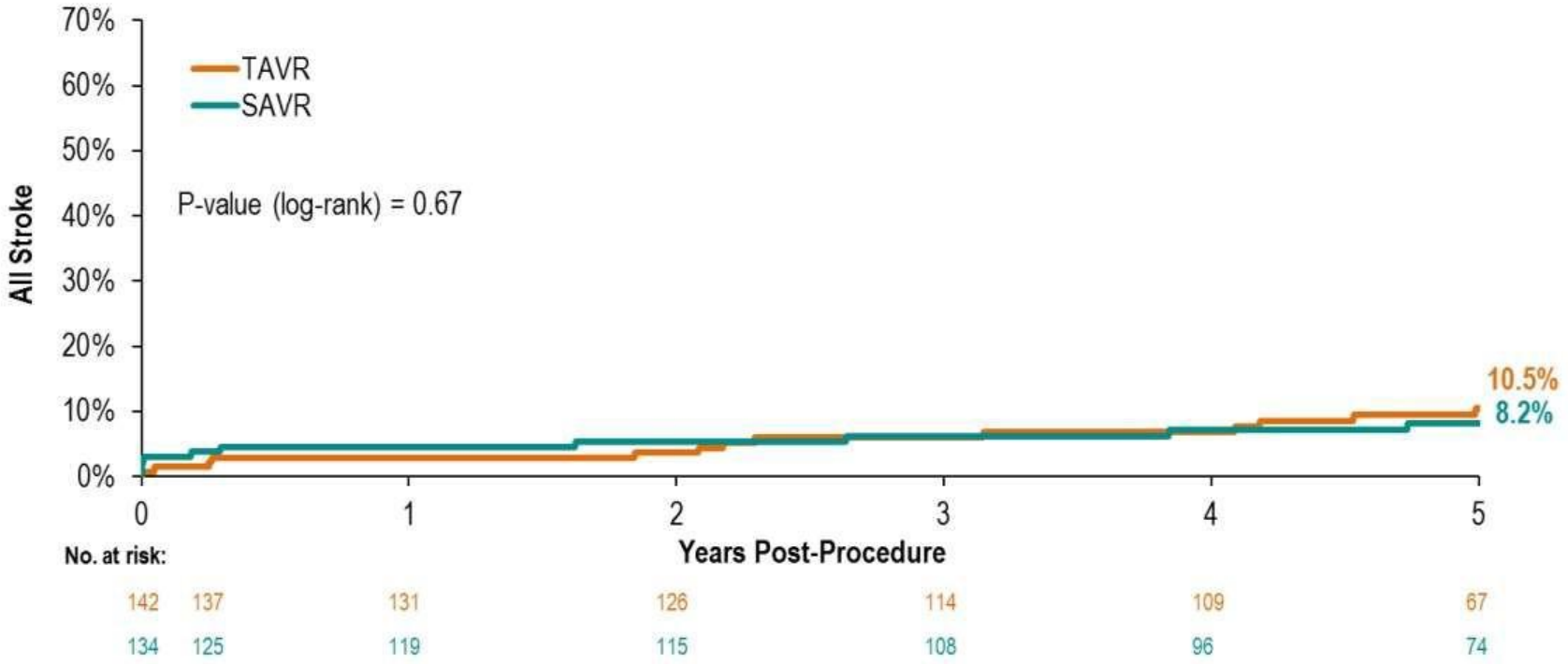
5-YEAR OUTCOMES FROM THE NOTION-I TRIAL: TAVR VS. SAVR IN LOWER RISK PATIENTS

Lars Sondergaard, MD, DMSc
Professor of Cardiology
Rigshospitalet
Copenhagen, Denmark

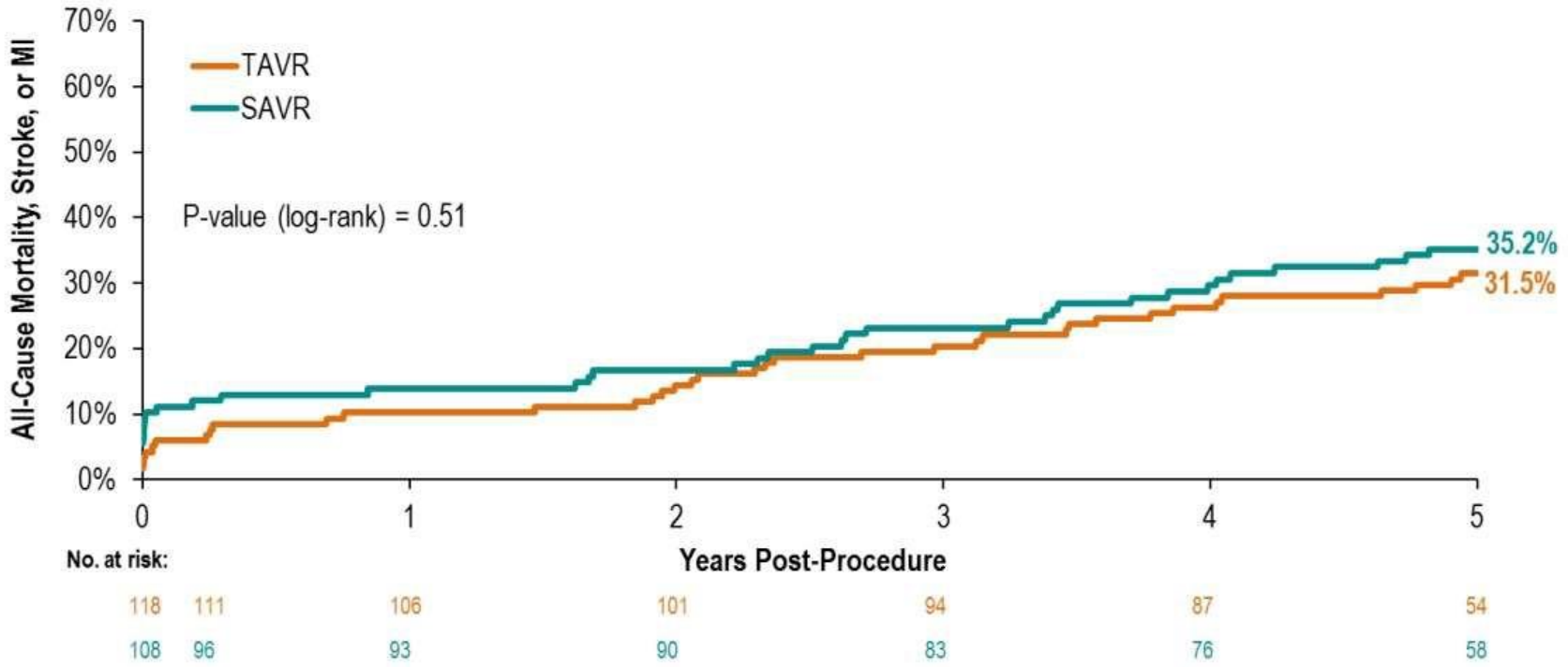
ALL-CAUSE MORTALITY



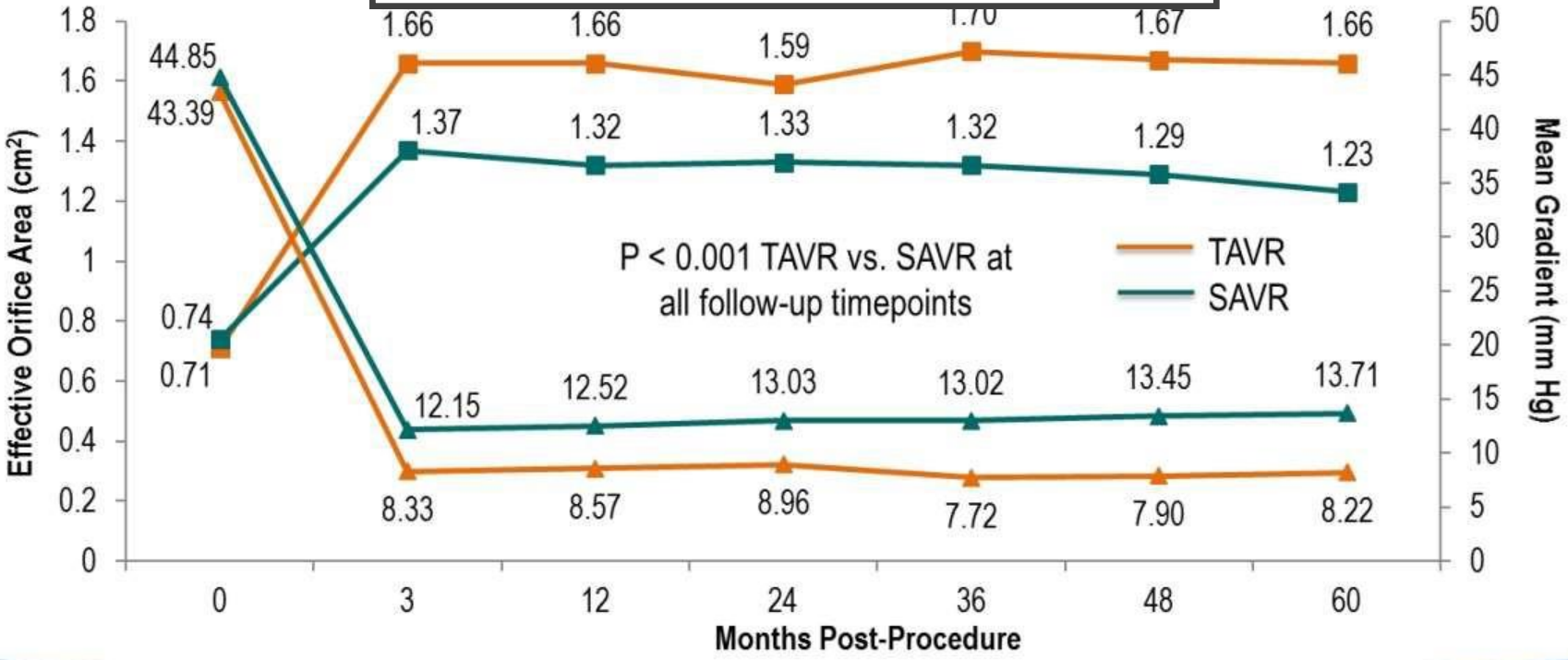
STROKE


70%
60%
50%
40%
30%
20%
10%
0%
All Stroke
TAVR
SAVR
P-value (log-rank) = 0.67
10.5%
8.2%
0
1
2
3
4
5
Years Post-Procedure
No. at risk:
142 137 131 126 114 109 67
134 125 119 115 108 96 74

ALL-CAUSE MORTALITY, STROKE, OR MI: STS<4%

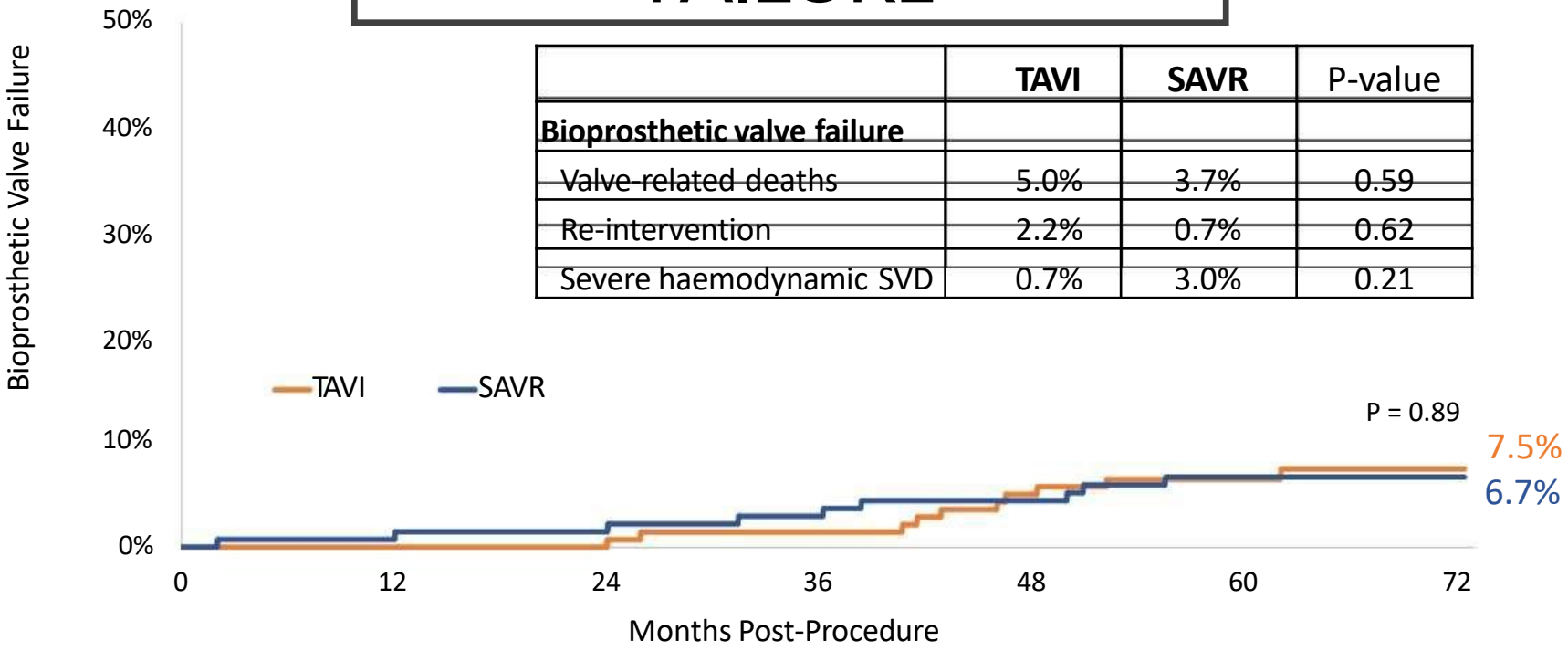


AORTIC VALVE PERFORMANCE



BIOPROSTHETIC VALVE FAILURE

	TAVI	SAVR	P-value
Bioprosthetic valve failure			
Valve-related deaths	5.0%	3.7%	0.59
Re-intervention	2.2%	0.7%	0.62
Severe haemodynamic SVD	0.7%	3.0%	0.21

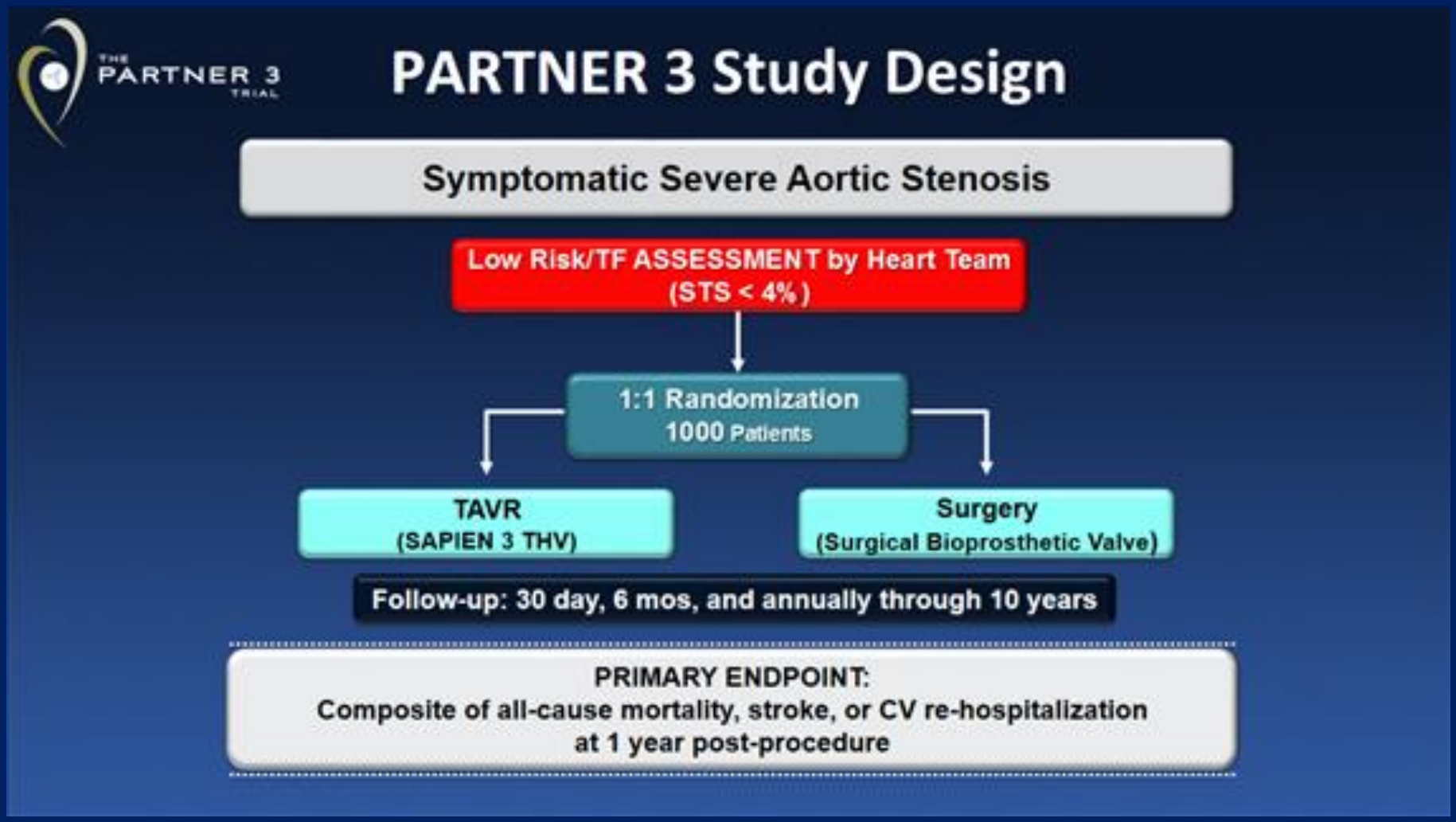


Background (2)

PARTNER 3

- RCT 1:1
- vs. Surgery
- N = 1000 pts

Low Risk


THE PARTNER 3 TRIAL
PARTNER 3 Study Design
Symptomatic Severe Aortic Stenosis
Low Risk/TF ASSESSMENT by Heart Team
(STS < 4%)
1:1 Randomization
1000 Patients
TAVR
(SAPIEN 3 THV)
Surgery
(Surgical Bioprosthetic Valve)
Follow-up: 30 day, 6 mos, and annually through 10 years
PRIMARY ENDPOINT:
Composite of all-cause mortality, stroke, or CV re-hospitalization
at 1 year post-procedure

Key Inclusion Criteria

Severe Calcific Aortic Stenosis

- AVA ≤ 1.0 cm^2 or AVA index ≤ 0.6 cm^2/m^2
- Jet velocity ≥ 4.0 m/s or mean gradient ≥ 40 mmHg, AND
  - NYHA Functional Class ≥ 2, OR
  - Abnormal exercise test with severe SOB, abnormal BP response, or arrhythmia, OR
  - Asymptomatic with LVEF < 50%

Low Surgical Risk

- Determined by multi-disciplinary heart team
- STS < 4%
- Adjudicated by case review board

THE PARTNER 3 TRIAL

Key Exclusion Criteria

Anatomic

- Aortic annulus diameter < 16 mm or > 28 mm (3D imaging)
- Bicuspid valve (CT imaging)
- Severe AR (> 3+) or MR (> 3+)
- Severe LV dysfunction (LVEF < 30%)
- Severe calcification of aortic valvar complex (esp. LVOT)
- Vascular anatomy not suitable for safe femoral access
- Complex CAD: ULM, Syntax score > 32, or not amenable for PCI
- Low coronary takeoff (high risk for obstruction)

Clinical

- Acute MI within 1 month
- Stroke or TIA within 90 days
- Renal insufficiency (eGFR < 30 ml/min) and/or renal replacement Rx
- Hemodynamic or respiratory instability
- Frailty (objective assessment; > 2/4+ metrics)

THE PARTNER 3 TRIAL

SAPIEN Valve Evolution

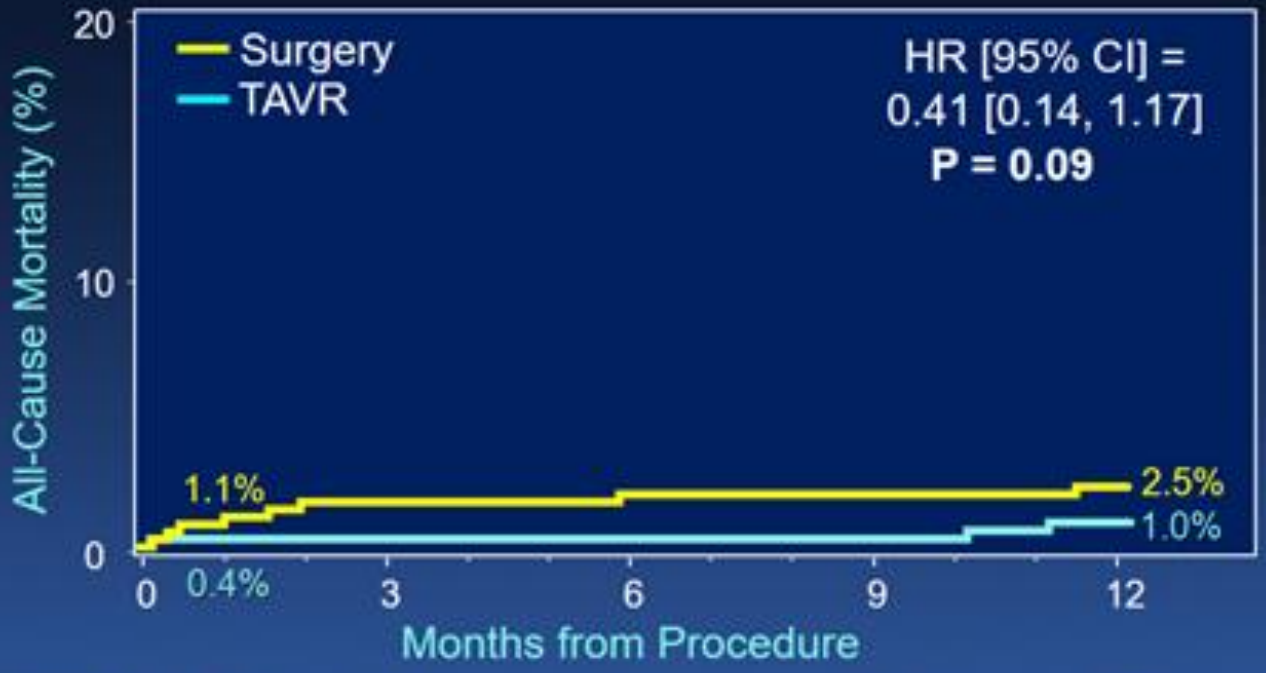
	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility			
Available Valve Sizes			
FDA Approval of Valve:	PARTNER 1 2011	PARTNER 2 2014	PARTNER 3 2015

THE PARTNER 3 TRIAL Procedural & Hospital Findings

% or mean ± SD

Variable	TAVR (N=496)	Surgery (N=454)	P-value
Conscious Sedation	65.1%	NA	NA
Procedure Time (min)	58.6 ± 36.5	208.3 ± 62.2	<0.001
Fluoroscopy Time (min)	13.9 ± 7.1	NA	NA
Aortic Cross-Clamp Time (min)	NA	74.3 ± 27.8	NA
Total CPB Time (min)	NA	97.7 ± 33.8	NA
Median ICU Stay (days)	2.0	3.0	<0.001
Median Total LOS (days)	3.0	7.0	<0.001
Discharge to Home/Self-care	96.0%	73.1%	<0.001
Concomitant Procedures	7.9%	26.4%	<0.001

All-Cause Mortality



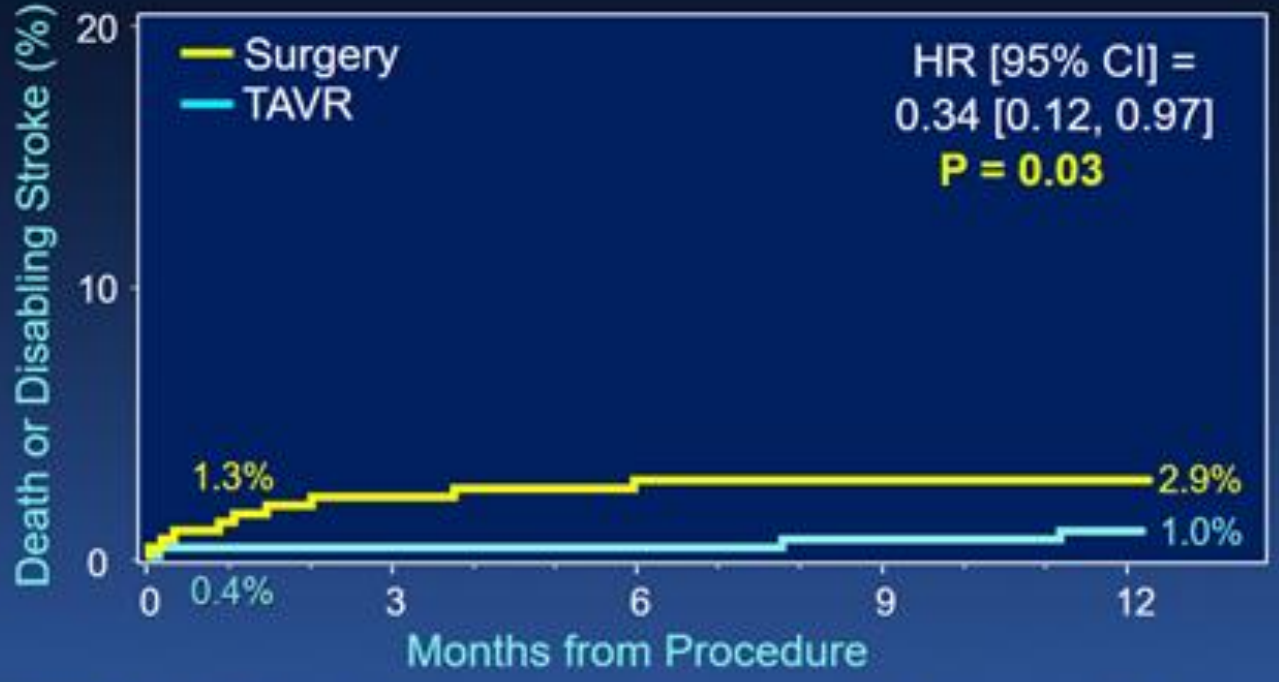
Number at Risk:						
Surgery	454	445	438	433	431	427
TAVR	496	494	494	493	492	488

THE PARTNER 3 TRIAL

All Stroke

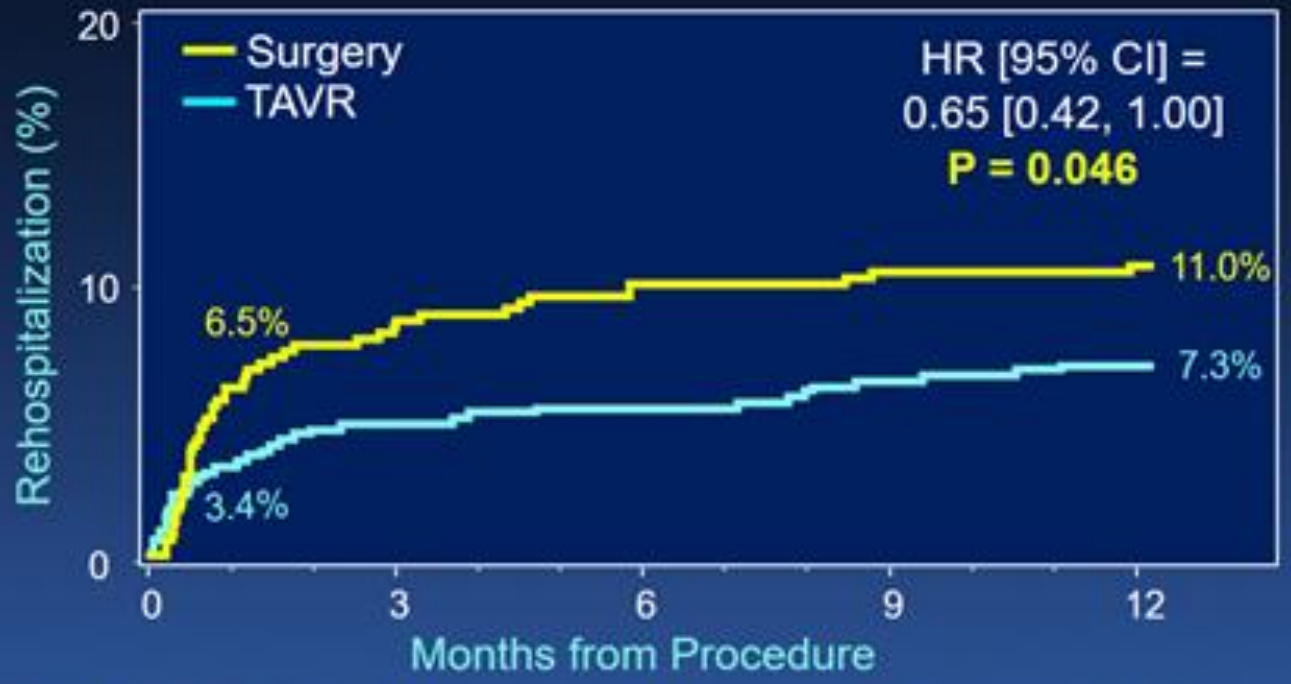
Number at Risk:						
Surgery	454	435	427	423	421	417
TAVR	496	491	491	489	487	484

Death or Disabling Stroke



Number at Risk						
Surgery	454	444	436	432	430	426
TAVR	496	494	494	493	491	488

Rehospitalization

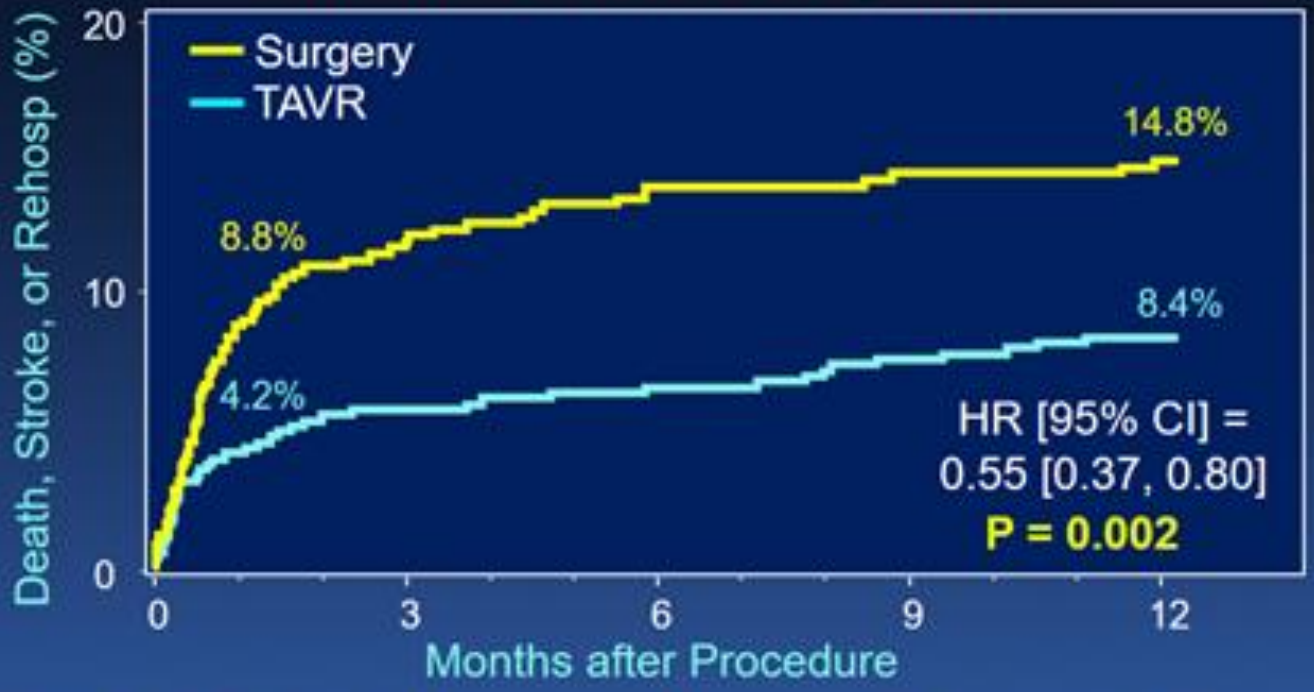


Number at risk:						
Surgery	454	416	399	389	385	382
TAVR	496	477	469	465	459	453

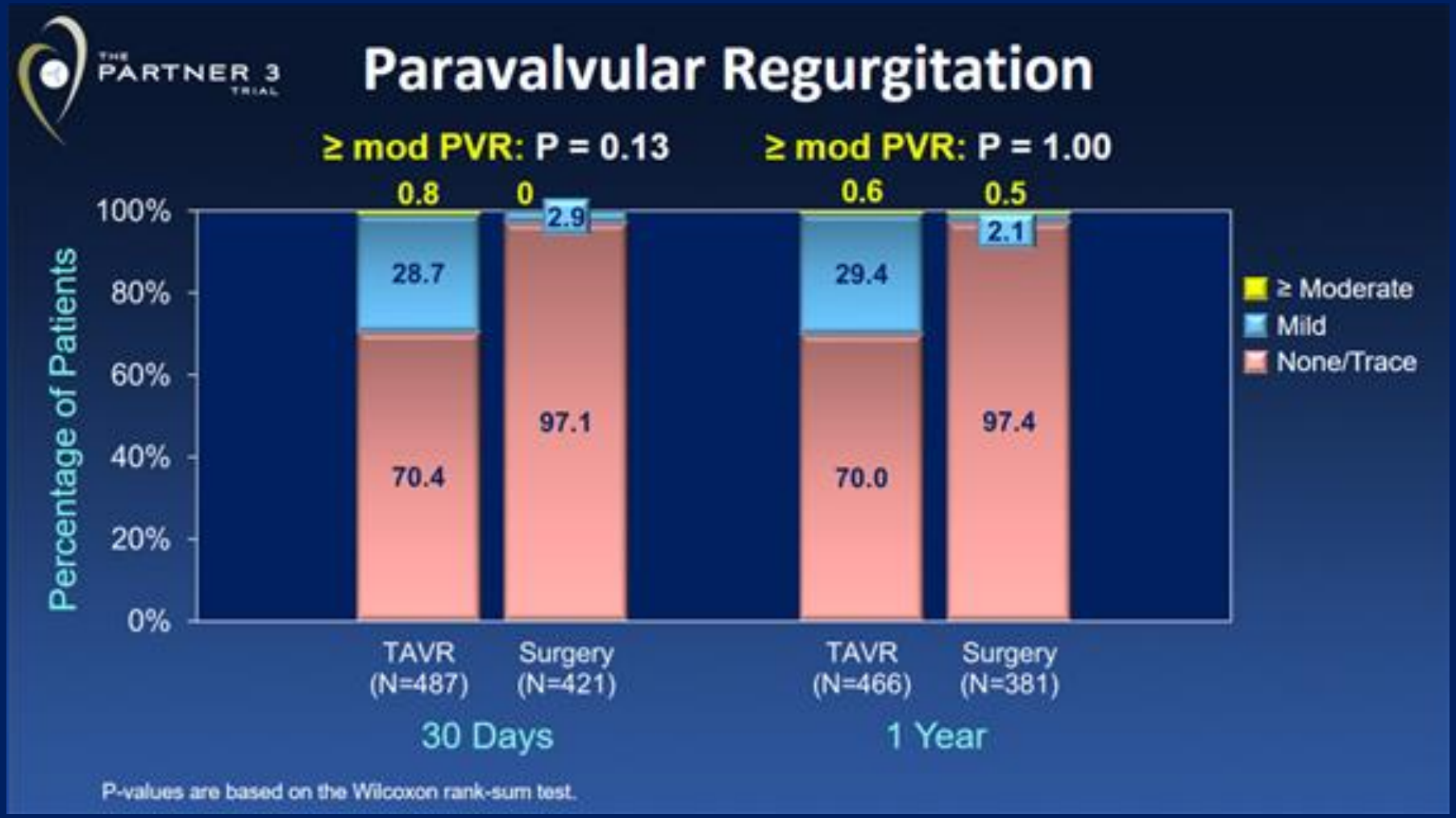
THE PARTNER 3 TRIAL

Primary Endpoint Sensitivity Analyses

Intention-to-Treat Population



Number at Risk:						
Surgery	497	420	395	382	378	374
TAVR	503	478	469	462	456	451


THE PARTNER 3 TRIAL
Paravalvular Regurgitation
≥ mod PVR: P = 0.13
≥ mod PVR: P = 1.00
0.8
0
2.9
0.6
0.5
2.1
28.7
29.4
97.1
97.4
70.4
70.0
100%
80%
60%
40%
20%
0%
Percentage of Patients
≥ Moderate
Mild
None/Trace
TAVR (N=487)
Surgery (N=421)
TAVR (N=466)
Surgery (N=381)
30 Days
1 Year
P-values are based on the Wilcoxon rank-sum test.

The PARTNER 3 Trial

Conclusions (1)

In a population of severe symptomatic aortic stenosis patients who were at low surgical risk, TAVR (using the SAPIEN 3 valve) compared to surgery:

- Significantly reduced the primary endpoint of death, stroke, or rehospitalization by 46% at 1-year.
  - Components of the primary endpoint favored TAVR, both at 30 days and 1 year
  - Multiple sensitivity analyses confirmed robustness of the primary endpoint findings

The PARTNER 3 Trial

Conclusions (2)

- Secondary endpoints adjusted for multiple comparisons indicated that TAVR reduced new-onset AF, index hospitalization days, and a measure of poor treatment outcome (death or low KCCQ score at 30 days).
- Other secondary endpoint analyses also showed reduced bleeding after TAVR and no differences in the need for new permanent pacemakers, major vascular complications, coronary obstruction, and mod-severe PVR.
- Some secondary endpoints favored surgery, including reduced new LBBB, reduced mild PVR, and lower aortic valve gradients.


THE PARTNER 3 TRIAL
The PARTNER 3 Trial
The NEW ENGLAND JOURNAL of MEDICINE
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients
The NEW ENGLAND JOURNAL of MEDICINE
OCTOBER 21, 2010
Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery
The NEW ENGLAND JOURNAL of MEDICINE
Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients
The NEW ENGLAND JOURNAL of MEDICINE
JUNE 9, 2011
Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients


S NAVY

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

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BACKGROUND

Among patients with aortic stenosis who are at intermediate or high risk for death with surgery, major outcomes are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. There is insufficient evidence regarding the comparison of the two procedures in patients who are at low risk.

METHODS

We randomly assigned patients with severe aortic stenosis and low surgical risk to undergo either TAVR with transfemoral placement of a balloon-expandable valve or surgery. The primary end point was a composite of death, stroke, or rehospitalization at 1 year. Both noninferiority testing (with a prespecified margin of 6 percentage points) and superiority testing were performed in the as-treated population.

RESULTS

At 71 centers, 1000 patients underwent randomization. The mean age of the patients was 73 years, and the mean Society of Thoracic Surgeons risk score was 1.9% (with scores ranging from 0 to 100% and higher scores indicating a greater risk of death within 30 days after the procedure). The Kaplan–Meier estimate of the rate of the primary composite end point at 1 year was significantly lower in the TAVR group than in the surgery group (8.5% vs. 15.1%; absolute difference, −6.6 percentage points; 95% confidence interval [CI], −10.8 to −2.5; P<0.001 for noninferiority; hazard ratio, 0.54; 95% CI, 0.37 to 0.79; P=0.001 for superiority). At 30 days, TAVR resulted in a lower rate of stroke than surgery (P=0.02) and in lower rates of death or stroke (P=0.01) and new-onset atrial fibrillation (P<0.001). TAVR also resulted in a shorter index hospitalization than surgery (P<0.001) and in a lower risk of a poor treatment outcome (death or a low Kansas City Cardiomyopathy Questionnaire score) at 30 days (P<0.001). There were no significant between-group differences in major vascular complications, new permanent pacemaker insertions, or moderate or severe paravalvular regurgitation.

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.)

We estimated that a sample of 864 patients would provide the trial with 90% power to show the non-inferiority of TAVR to surgery with regard to the primary end point at 1 year, assuming a Kaplan–Meier estimate of the rate of 14.6% in the TAVR group and 16.6% in the surgery group. A sample

The median time from randomization to the index procedure was 11 days. One TAVR procedure was converted to surgery, and one surgical procedure was aborted. Concomitant procedures were performed in 7.9% of the patients in the TAVR group and in 26.4% of the patients in the surgery group. Concomitant coronary revascularization was performed in 6.5% and 12.8%, respectively. In the TAVR group, conscious sedation was used in 65.1% of the patients. In the surgery

5.08). The percentage of patients with life-threatening or major bleeding was 3.6% in the TAVR group as compared with 24.5% in the surgery group (hazard ratio, 0.12; 95% CI, 0.07 to 0.21).

Subgroup	No. of Patients	TAVR	Surgery	Difference (95% CI)	P Value for Interaction
		no. of events/total no. (%)		*percentage points*	
Overall	950	42/496 (8.5)	68/454 (15.1)	−6.6 (−10.8 to −2.5)	
Age					0.21
≤74 yr	516	29/273 (10.6)	36/243 (14.9)	−4.3 (−10.1 to 1.5)	
>74 yr	434	13/223 (5.8)	32/211 (15.3)	−9.5 (−15.3 to −3.7)	
Sex					0.27
Female	292	13/161 (8.1)	24/131 (18.5)	−10.4 (−18.3 to −2.5)	
Male	658	29/335 (8.7)	44/323 (13.8)	−5.1 (−9.9 to −0.3)	
STS-PROM score					0.98
≤1.8	464	21/232 (9.1)	36/232 (15.7)	−6.7 (−12.6 to −0.7)	
>1.8	486	21/264 (8.0)	32/222 (14.5)	−6.5 (−12.2 to −0.8)	
Left ventricular ejection fraction					0.48
≤65	384	20/208 (9.6)	30/176 (17.2)	−7.6 (−14.5 to −0.7)	
>65	524	21/264 (8.0)	32/260 (12.4)	−4.4 (−9.6 to 0.7)	
NYHA class					0.54
I or II	687	23/341 (6.8)	50/346 (14.5)	−7.8 (−12.4 to −3.2)	
III or IV	263	19/155 (12.3)	18/108 (16.9)	−4.7 (−13.5 to 4.1)	
Atrial fibrillation					0.67
No	786	33/418 (7.9)	51/368 (14.0)	−6.1 (−10.5 to −1.7)	
Yes	163	9/78 (11.6)	17/85 (20.3)	−8.7 (−19.9 to 2.5)	
KCCQ overall summary score					0.27
≤70	407	23/219 (10.5)	37/188 (19.9)	−9.4 (−16.5 to −2.4)	
>70	536	18/275 (6.5)	29/261 (11.2)	−4.6 (−9.2 to 0.2)	

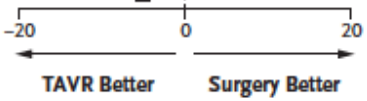


Figure 2. Subgroup Analyses of the Primary Composite End Point of Death from Any Cause, Stroke, or Rehospitalization.

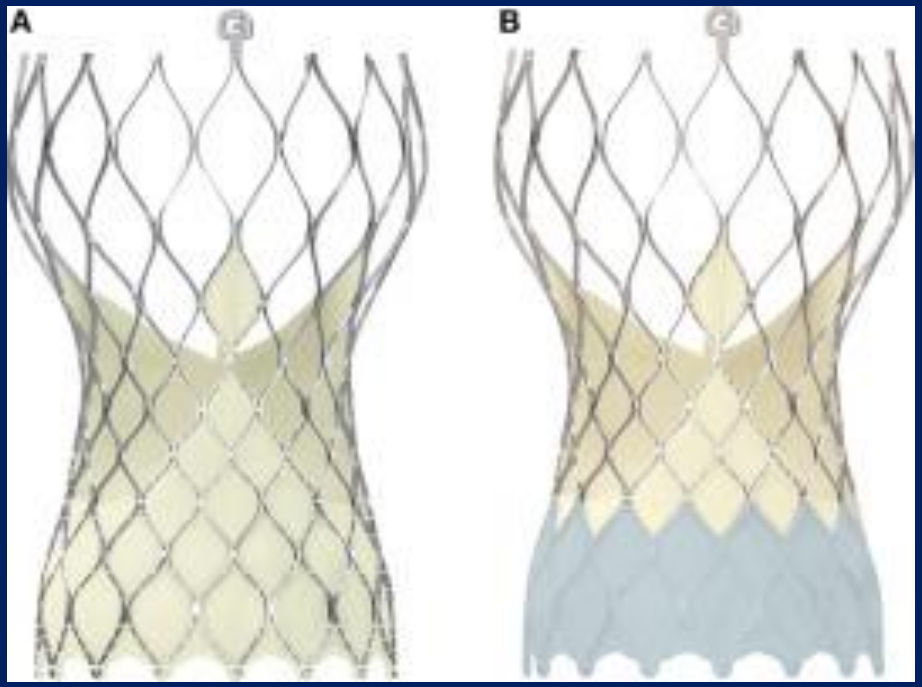
All percentages are Kaplan–Meier estimates. Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) scores range from 0 to 100%, with higher scores indicating a greater risk of death within 30 days after the procedure. Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores 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.

0.6% and 0.5% at 1 year). The percentage of patients with mild paravalvular regurgitation at 1 year was higher with TAVR than with surgery (29.4% vs. 2.1%). There were no episodes of valve thrombosis associated with clinical events. Six asymptomatic patients (five in the TAVR group and one in the surgery group) had findings suggestive of valve thrombosis, including increased valve gradients and evidence on imaging of restricted leaflet motion. Details regarding echo-

The most important limitation of this trial is that our current results reflect only 1-year outcomes and do not address the problem of long-term structural valve deterioration.[33,34] Definitive conclusions regarding the advantages and disadvantages of TAVR as compared with surgery (with either bioprosthetic or mechanical valves) depend on long-term follow-up. In this trial involving younger, low-risk patients, the protocol requires clinical and echocardiographic follow-up to continue for at least 10 years.

This trial has several other limitations. First, in this trial, as in previous TAVR trials, adjudication of end points was not blinded, which could have resulted in bias in outcome assessment. Second, the results apply only to the defined trial population, which excluded patients with poor transfemoral access, bicuspid aortic valves, or other anatomical or clinical factors that increased the risk of complications associated with either TAVR or surgery. Third, the findings cannot be extrapolated to TAVR performed with other systems or by less experienced operators.[35,36] Fourth, more patients in the surgery group than in the TAVR group withdrew from the trial (both early and late). Fifth, missing data regarding NYHA class, 6-minute walk-test distance, KCCQ score, and follow-up echocardiograms were not fully accounted for with multiple imputation. Sixth, this analysis did not examine the rate and relevance of asymptomatic valve thrombosis.[37,38] This issue is being examined in a randomized subtrial, in which 435 patients are undergoing serial computed tomographic angiography for the detection of abnormalities in valve-leaflet function, with investigators unaware of imaging findings.

CoreValve SURTAVI Trial



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

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BACKGROUND

Transcatheter aortic-valve replacement (TAVR) is an alternative to surgery in patients with severe aortic stenosis who are at increased risk for death from surgery; less is known about TAVR in low-risk patients.

METHODS

We performed a randomized noninferiority trial in which TAVR with a self-expanding supraannular bioprosthesis was compared with surgical aortic-valve replacement in patients who had severe aortic stenosis and were at low surgical risk. When 850 patients had reached 12-month follow-up, we analyzed data regarding the primary end point, a composite of death or disabling stroke at 24 months, using Bayesian methods.

RESULTS

Of the 1468 patients who underwent randomization, an attempted TAVR or surgical procedure was performed in 1403. The patients' mean age was 74 years. The 24-month estimated incidence of the primary end point was 5.3% in the TAVR group and 6.7% in the surgery group (difference, −1.4 percentage points; 95% Bayesian credible interval for difference, −4.9 to 2.1; posterior probability of noninferiority >0.999). At 30 days, patients who had undergone TAVR, as compared with surgery, had a lower incidence of disabling stroke (0.5% vs. 1.7%), bleeding complications (2.4% vs. 7.5%), acute kidney injury (0.9% vs. 2.8%), and atrial fibrillation (7.7% vs. 35.4%) and a higher incidence of moderate or severe aortic regurgitation (3.5% vs. 0.5%) and pacemaker implantation (17.4% vs. 6.1%). At 12 months, patients in the TAVR group had lower aortic-valve gradients than those in the surgery group (8.6 mm Hg vs. 11.2 mm Hg) and larger effective orifice areas (2.3 cm^2 vs. 2.0 cm^2).

CONCLUSIONS

In patients with severe aortic stenosis who were at low surgical risk, TAVR with a self-expanding supraannular bioprosthesis was noninferior to surgery with respect to the composite end point of death or disabling stroke at 24 months. (Funded by Medtronic; ClinicalTrials.gov number, NCT02701283.)


S NAVY

Use of TAVR in patients at low surgical risk requires compelling evidence of safety and effectiveness, given the low mortality and stroke incidence with aortic-valve surgery in relatively young, healthy patients.[9] Other outcomes, such as aortic-valve reintervention, coronary-artery obstruction, permanent pacemaker use, and longer-term valve durability, are metrics that also require scrutiny in this population. One small randomized study of TAVR with a self-expanding bioprosthesis as compared with surgery provides support for the safety of TAVR with a self-expanding bioprosthesis in low-risk patients up to 5 years after the procedure.[10,11]

the Declaration of Helsinki. Patients were enrolled at 86 centers in Australia, Canada, France, Japan, the Netherlands, New Zealand, and the United

that TAVR would be noninferior to surgery with respect to the primary end point with a noninferiority margin of 6%. The primary end point was

From March 28, 2016, to November 27, 2018, a total of 1468 patients underwent randomization; 734 were assigned to TAVR and 734 were assigned to surgery. After randomization, the assigned procedure was not attempted in 12 patients assigned to TAVR and 53 patients assigned to surgery; in 3 patients assigned to surgery, TAVR was attempted instead (Fig. S2 and Results section in the Supplementary Appendix). The as-treated cohort included 1403 patients: 725 in the TAVR group and 678 in the surgery group.

Demographic and baseline characteristics and cardiac risk factors are shown in Table 1. The mean age of the patients was 74 years, 34.9% were women, and all the patients were at low surgical risk. There were no significant differences between the two treatment groups. Among patients who were assigned to the surgery group, the baseline characteristics of those who actually underwent surgery were similar to the characteristics of those who did not undergo surgery (Table S5 in the Supplementary Appendix). A detailed description of procedural end points is provided in the Results section in the Supplementary Appendix.

At this prespecified interim analysis, 12-month follow-up was available for 432 patients in the TAVR group and 352 in the surgery group; 24-month follow-up was available for 72 patients in the TAVR group and 65 patients in the surgery group. The median follow-up time in each group was 12.2 months.

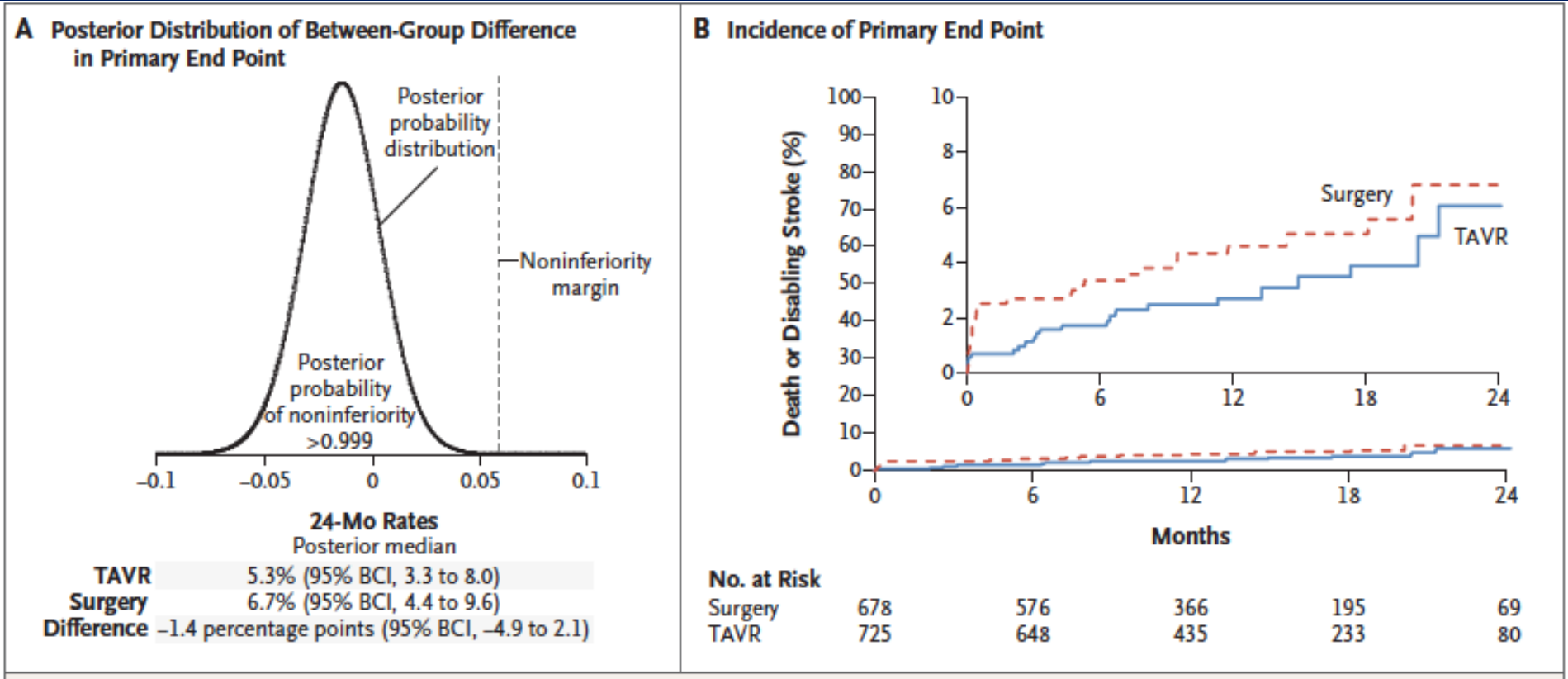


Figure 1. Posterior Distribution and Time-to-Event Curves for the Primary End Point.

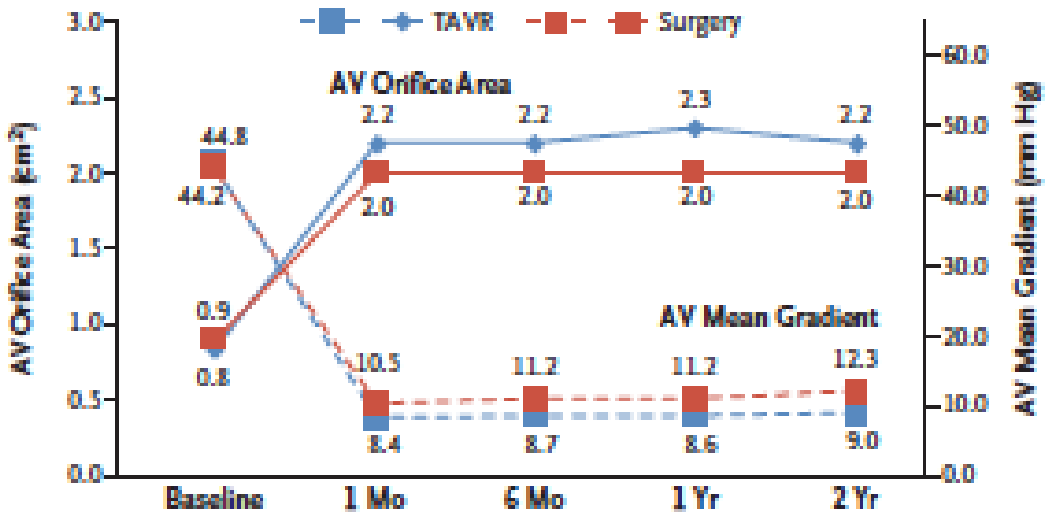
The posterior distribution for the difference between the treatment groups in the incidence of death from any cause or disabling stroke at 24 months (the primary end point), shown in Panel A, confirmed that the noninferiority criterion for the primary end point was met. BCI denotes Bayesian credible interval, and TAVR transcatheter aortic-valve replacement. Panel B shows Kaplan–Meier time-to-event curves for the primary end point. The inset shows the same data on an enlarged y axis.

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

End Point	30 Days			12 Months		
	TAVR	Surgery	Difference, TAVR–Surgery (95% BCI)	TAVR	Surgery	Difference, TAVR–Surgery (95% BCI)
	% of patients		*percentage points*	*% of patients*		*percentage points*
Death from any cause or disabling stroke	0.8	2.6	–1.8 (–3.2 to –0.5)	2.9	4.6	–1.8 (–4.0 to 0.4)
Death from any cause	0.5	1.3	–0.8 (–1.9 to 0.2)	2.4	3.0	–0.6 (–2.6 to 1.3)
Death from cardiovascular cause	0.5	1.3	–0.8 (–1.9 to 0.2)	1.7	2.6	–0.9 (–2.7 to 0.7)
All stroke	3.4	3.4	0.0 (–1.9 to 1.9)	4.1	4.3	–0.2 (–2.4 to 1.9)
Disabling	0.5	1.7	–1.2 (–2.4 to –0.2)	0.8	2.4	–1.6 (–3.1 to –0.3)
Nondisabling	3.0	1.7	1.2 (–0.3 to 2.9)	3.4	2.2	1.1 (–0.6 to 2.9)
Transient ischemic attack	0.6	0.8	–0.2 (–1.2 to 0.7)	1.7	1.8	–0.2 (–1.6 to 1.3)
30-Day composite safety end point†	5.3	10.7	–5.4 (–8.3 to –2.6)	NA	NA	NA
Life-threatening or disabling bleeding	2.4	7.5	–5.1 (–7.5 to –2.9)	3.2	8.9	–5.7 (–8.4 to –3.1)
Major vascular complication	3.8	3.2	0.6 (–1.4 to 2.5)	3.8	3.5	0.3 (–1.7 to 2.3)
Acute kidney injury stage 2 or 3	0.9	2.8	–1.8 (–3.4 to –0.5)	0.9	2.8	–1.8 (–3.4 to –0.5)
Atrial fibrillation	7.7	35.4	–27.7 (–31.8 to –23.6)	9.8	38.3	–28.5 (–32.8 to –24.1)
Permanent pacemaker implantation	17.4	6.1	11.3 (8.0 to 14.7)	19.4	6.7	12.6 (9.2 to 16.2)
Myocardial infarction	0.9	1.3	–0.4 (–1.5 to 0.7)	1.7	1.6	0.1 (–1.3 to 1.5)
Coronary-artery obstruction	0.9	0.4	0.5 (–0.3 to 1.4)	0.9	0.4	0.5 (–0.3 to 1.4)
Endocarditis	0.1	0.2	–0.1 (–0.7 to 0.3)	0.2	0.4	–0.2 (–0.9 to 0.5)
Valve thrombosis	0.1	0.1	0.0 (–0.4 to 0.4)	0.2	0.3	–0.1 (–0.9 to 0.5)
Aortic reintervention	0.4	0.4	0.0 (–0.8 to 0.7)	0.7	0.6	0.0 (–1.0 to 0.9)
Hospitalization for heart failure	1.2	2.5	–1.3 (–2.8 to 0.1)	3.2	6.5	–3.4 (–5.9 to –1.0)

than in the surgery group (Table 3). Moderate or severe total aortic regurgitation was present at 30 days in 3.5% of the patients in the TAVR group and in 0.5% in the surgery group. Severe patient–prosthesis mismatch occurred at 12 months in 1.8% of the patients in the TAVR group and in 8.2% in the surgery group (Table S11 in the Supplementary Appendix).

death or disabling stroke at 24 months. TAVR with a self-expanding supraannular bioprosthesis was associated with a lower incidence of disabling stroke, acute kidney injury, bleeding events, and atrial fibrillation than surgery but with a higher incidence of aortic regurgitation and permanent pacemaker use. Both TAVR and surgery provided functional improvement at 12 months, but the TAVR group had better recovery at 30 days, as indicated by the KCCQ score.



No. of Patients with Echocardiographic Data					
AV mean gradient					
TAVR	712	699	619	409	71
Surgery	673	634	542	339	62
AV orifice area					
TAVR	632	610	544	341	59
Surgery	590	541	467	293	53

Figure 2. Aortic-Valve Orifice Area and Mean Gradient to 24 Months.

Shown are the aortic-valve (AV) mean gradient (dashed lines) and the effective AV orifice area (solid lines) for the TAVR group and the surgery group at all time points after the procedure.

regurgitation were higher in the TAVR group. Longer-term follow-up will be necessary to understand the implications of these various valve characteristics on structural valve deterioration and long-term outcomes. We found a low incidence (<1%) of bioprosthetic-valve thrombosis, endocarditis, or need for aortic-valve reintervention with both self-expanding and surgical bioprostheses.

Our study has several limitations. The most important limitation is that this prespecified interim analysis occurred when 850 patients had reached 12 months of follow-up, and complete 24-month follow-up of the entire cohort has not been reached. Definitive conclusions regarding the advantages and disadvantages of TAVR as compared with surgery await long-term clinical and echocardiographic follow-up, which is planned to continue through 10 years for all patients. Second, although the amount of missing data in the trial was small, some patients did not have complete follow-up data on NYHA functional class, KCCQ scores, and echocardiography. Third, end-point adjudication could not be performed in a blinded manner for all end points, which may have resulted in bias in end-point assessment. Fourth, we excluded patients with bicuspid aortic valves and those who were candidates for mechanical valves. Finally, the latest-generation Evolut PRO bioprosthesis was used in only 22.3% of the patients who received TAVR.

In conclusion, in a randomized trial involving patients with severe aortic stenosis who were at low risk for death from surgery, TAVR with a self-expanding supraannular bioprosthesis was noninferior to surgical aortic-valve replacement with respect to death from any cause or disabling stroke at 24 months.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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2) ΟΡΙΣΜΟΣ ΕΛΑΧΙΣΤΑ ΕΠΕΜΒΑΤΙΚΗΣ AVR

STS database: Κάθε αντικατάσταση αορτικής που δεν εκτελείται με πλήρη στερνοτομή ή/και με τη χρήση της εξωσωματικής κυκλοφορίας (+TAVI)

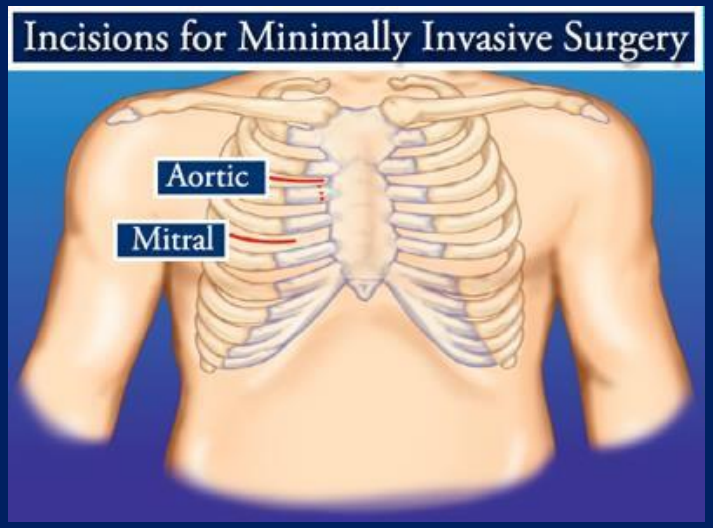
Schmitto JD, Mokashi SA, Cohn LH. Minimally-invasive valve surgery. **J Am Coll Cardiol 2010**;56:455-62.

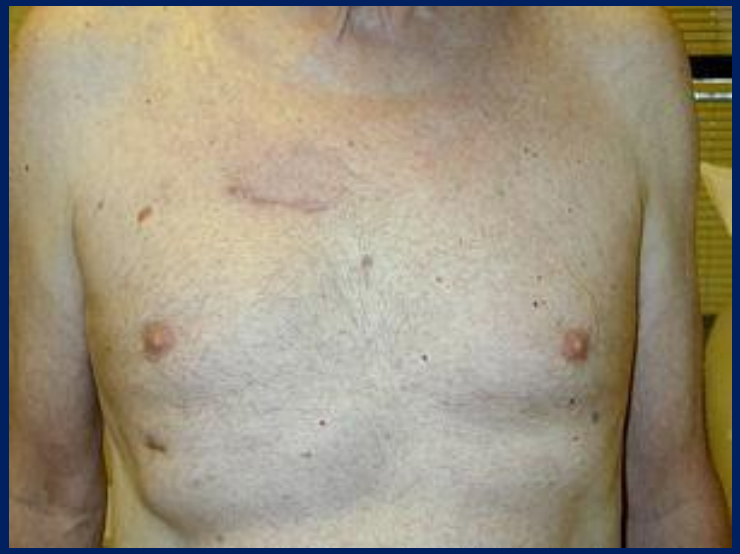
STS National Database Spring 2008, Executive Summary. Duke Clinical Research Institute, Durham, NC (**2008**).

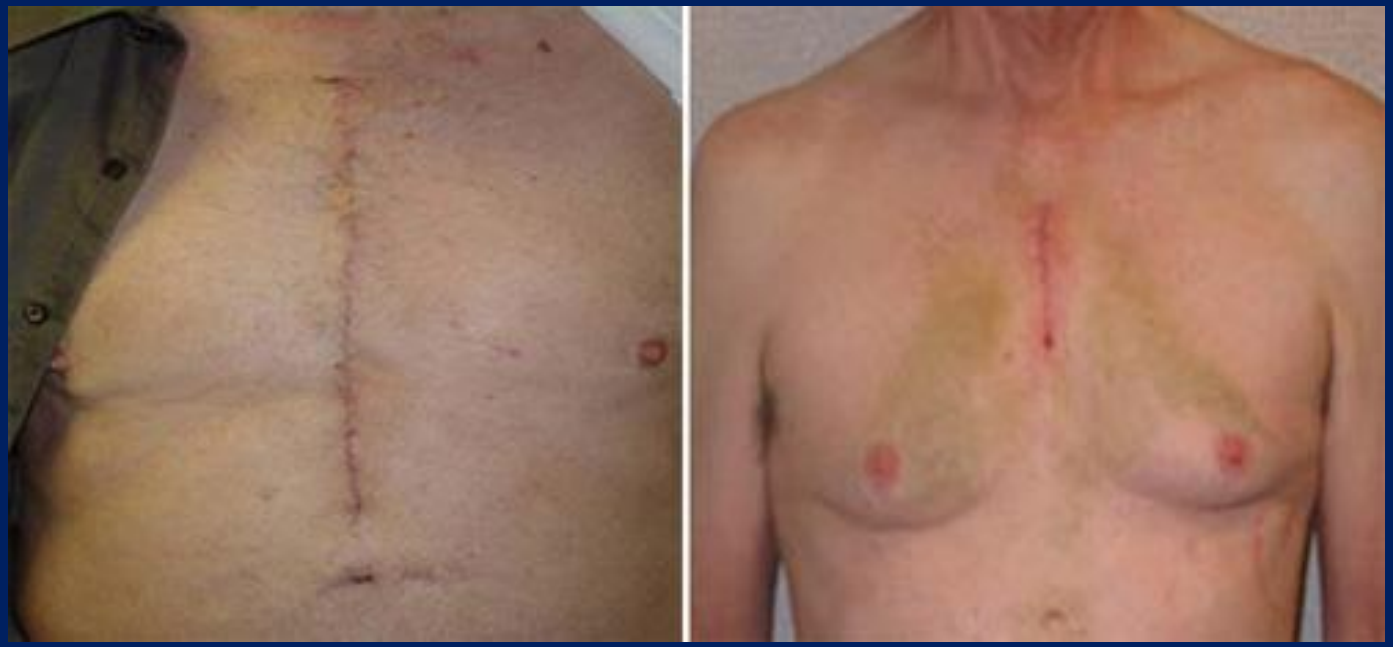
ΟΦΕΛΗ ΤΗΣ MISAVR VS AVR

- **Ταχύτερη ανάνηψη**
- **Μικρότερη ενδονοσοκομειακή νοσηλεία**
- **Αισθητικά βελτιωμένη τομή.**
- **Μείωση ποσοστού λοιμώξεων τραύματος.**
- **Βελτιώνει την περιεγχειρητική αναπνευστική λειτουργία λόγω σταθερότητας στέρνου.**
- **Ελάττωση μετεγχειρητικού πόνου.**
- **Ελάττωση απώλειας αίματος και μεταγγίσεων.**
- **Ευκολότερο REDO λόγω μερικής περικαρδιοτομής.**
- **Λιγότερη υποστήριξη για ανάνηψη ασθενών.**
- **Μικρότερο κόστος.**

MIAVR

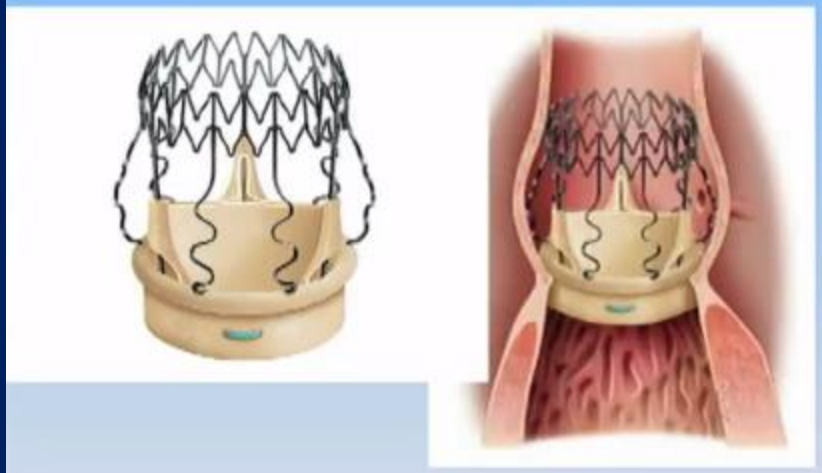




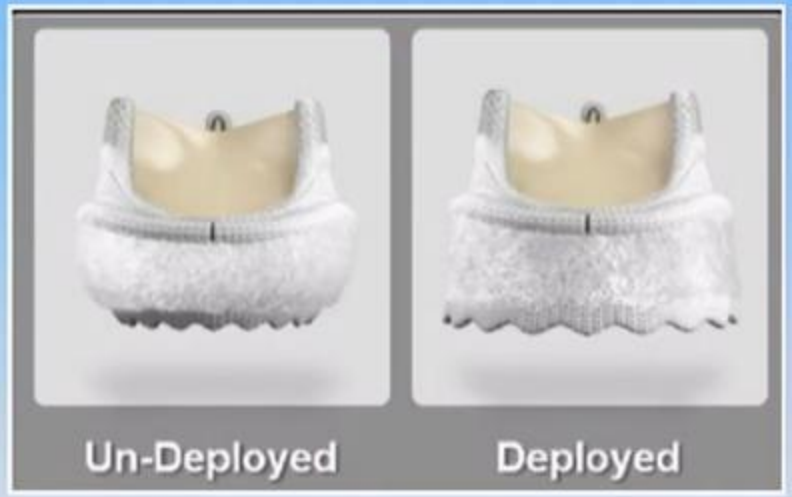


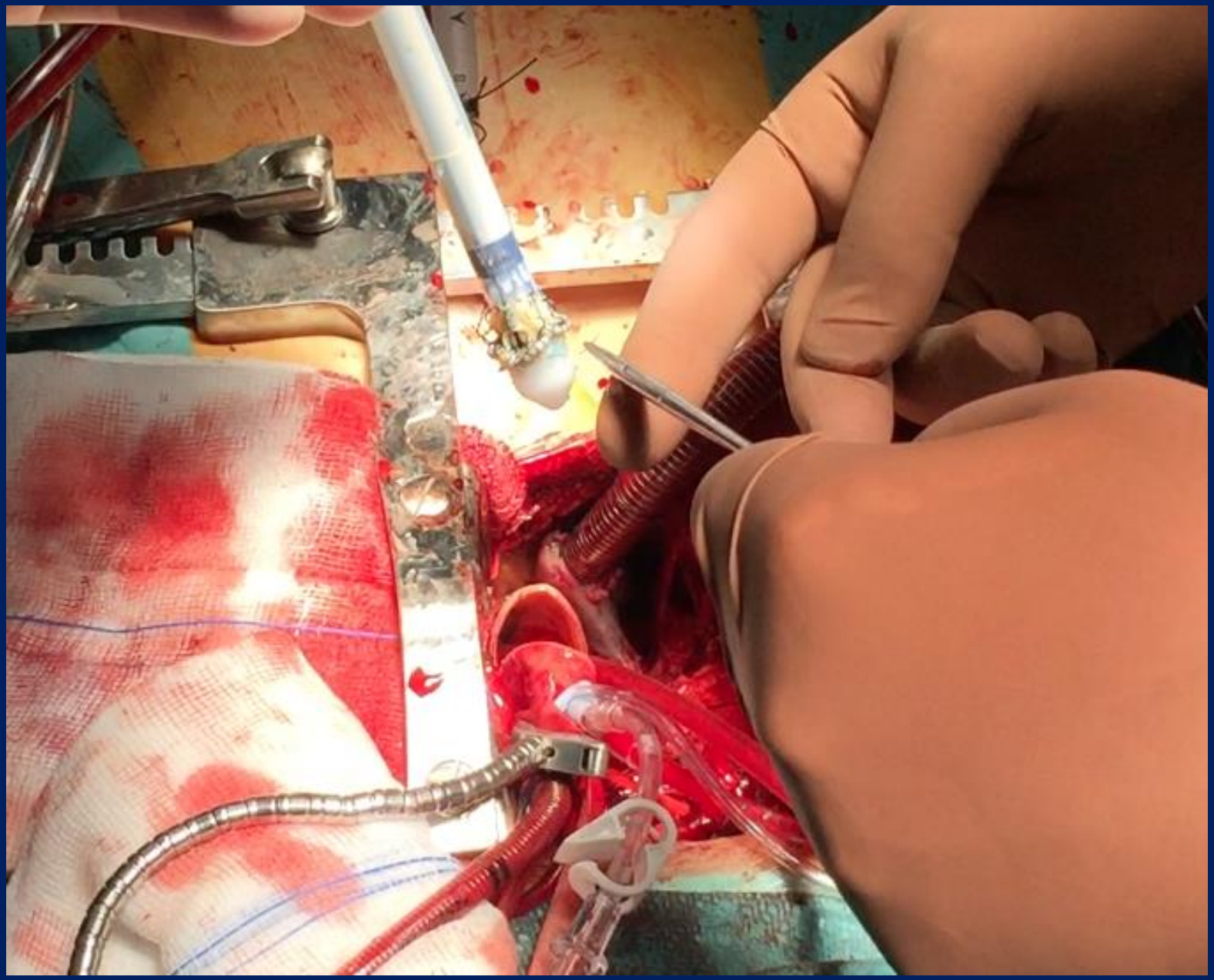
"Hybrid" bioprosthetic valves

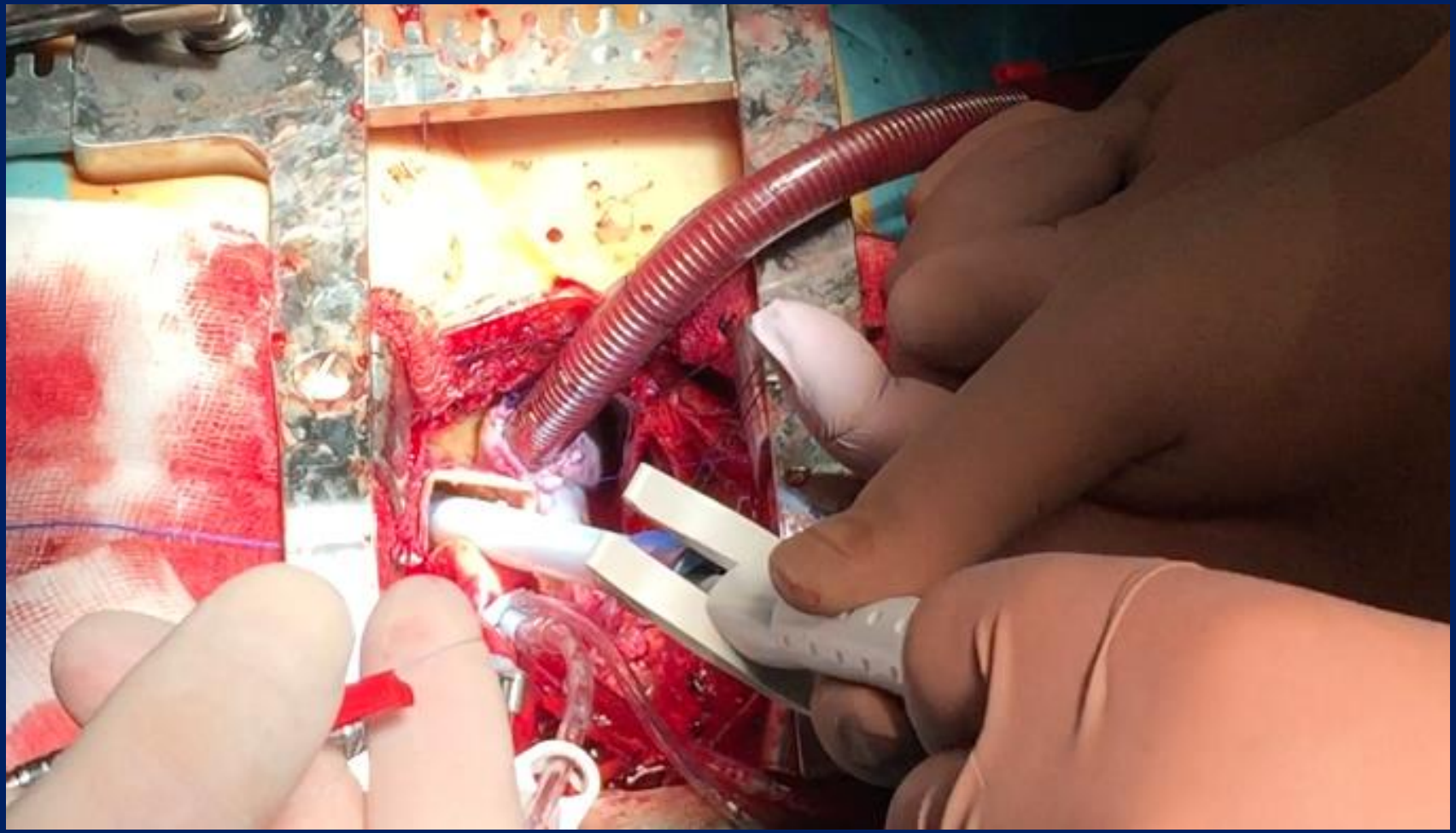
- **<u>Sutureless</u> AVR**
- *Perceval - S* *(Sorin, Italy)*

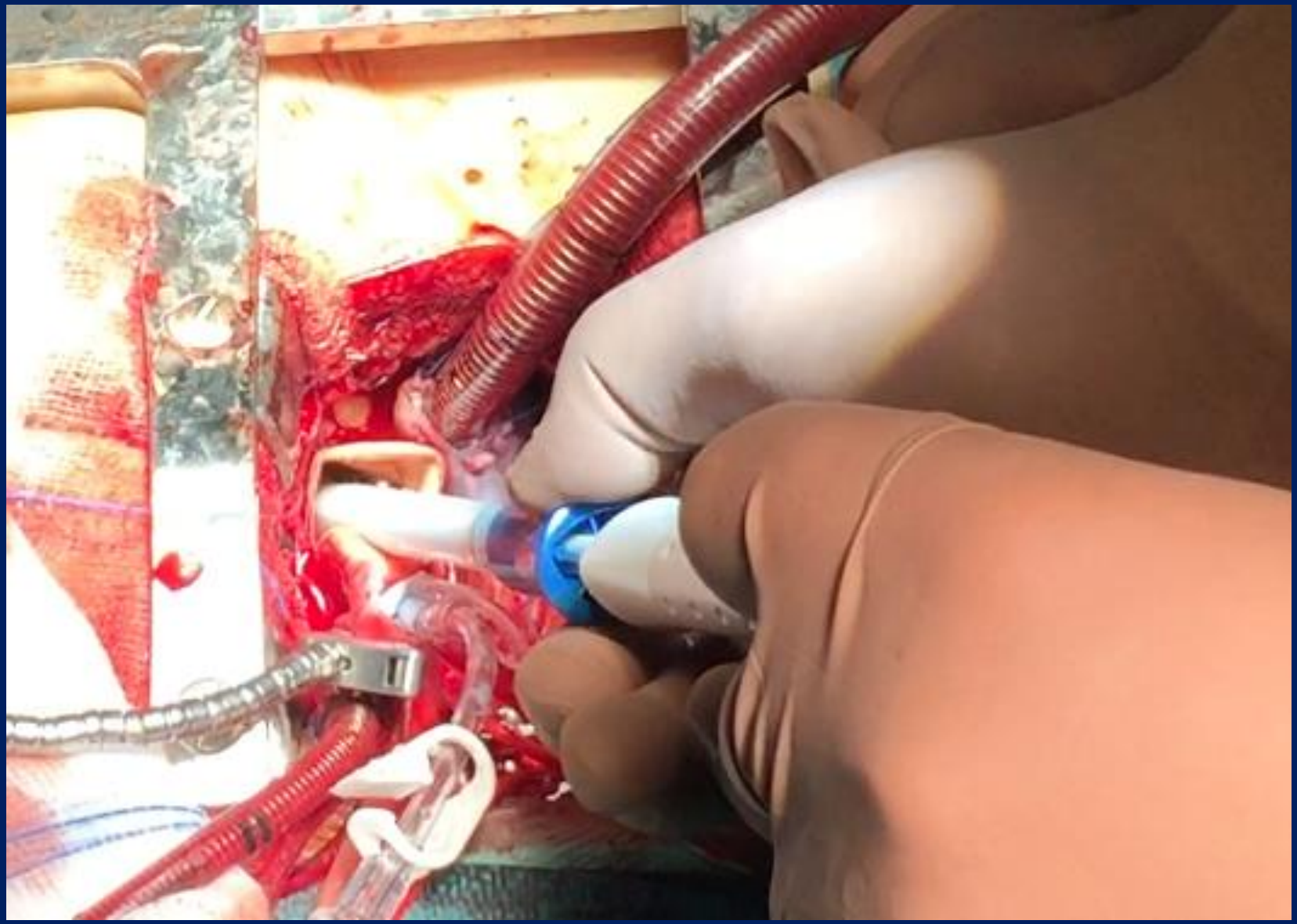


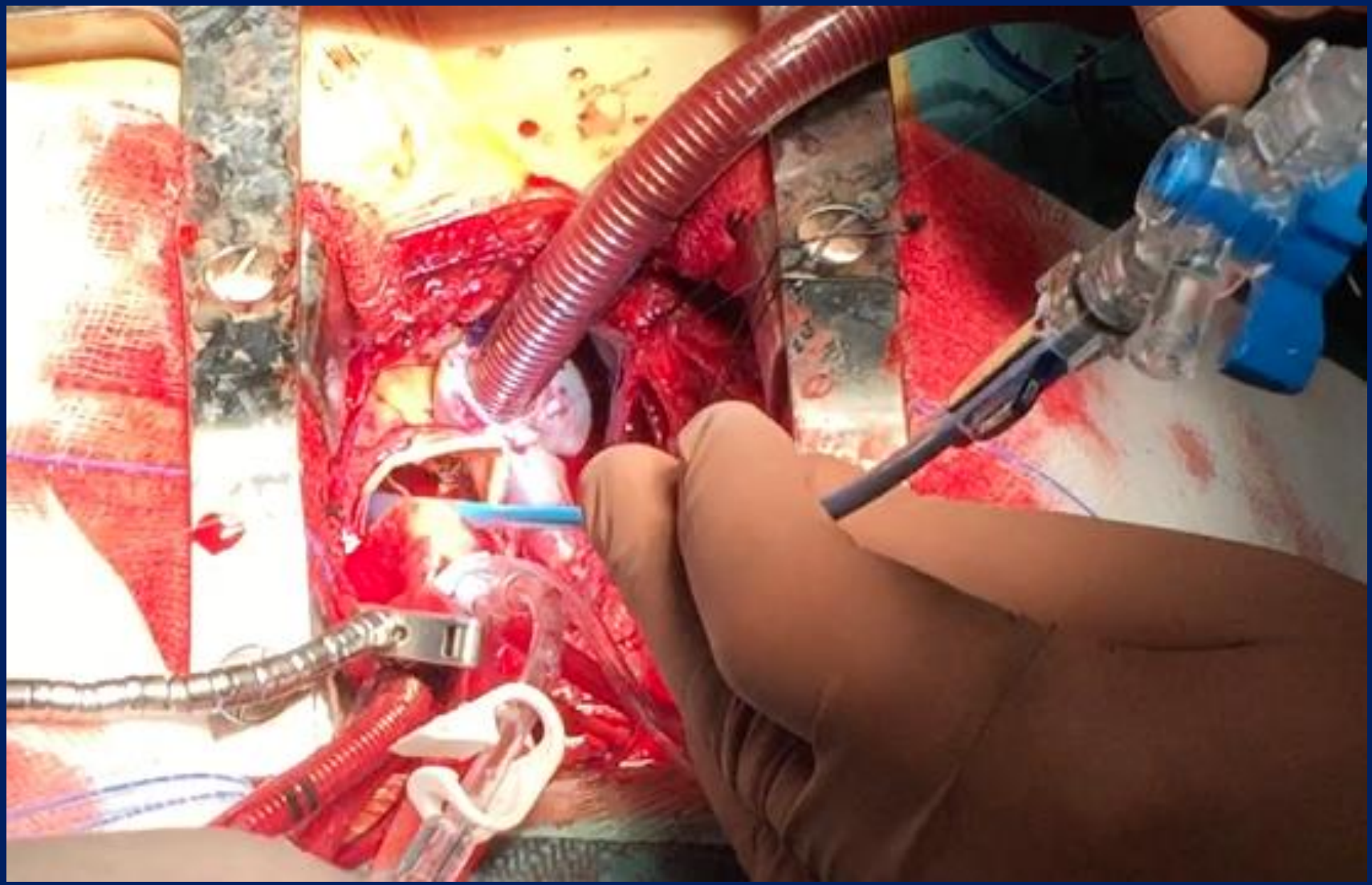
- **<u>Rapid deployment AVR</u>**
- *Edwards Intuity Elite*
  (Edwards, USA).







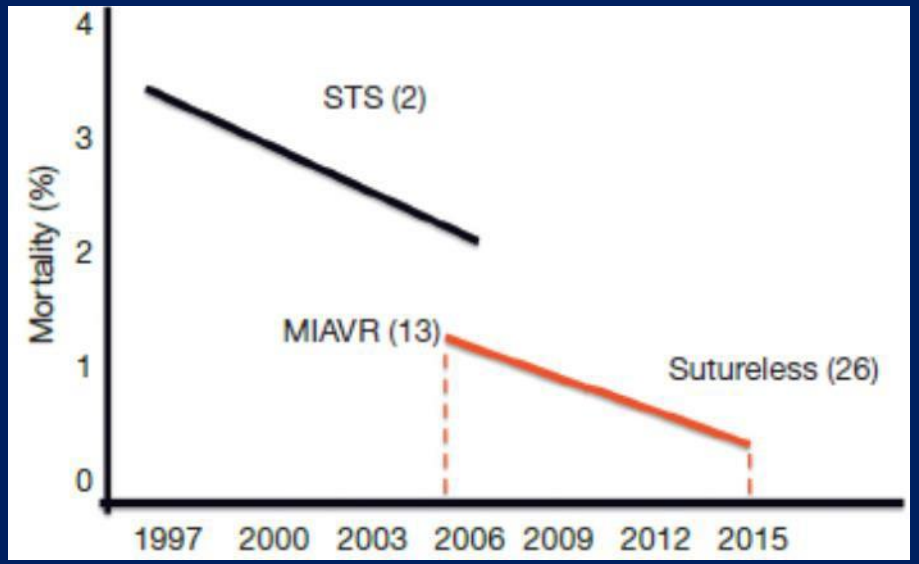




THE COMBINATION OF MIAVR USING SUTURELESS/FAST DEPLOYMENT VALVES HAS IMPROVED POSTOPERATIVE MORTALITY

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**.



European Journal of Cardio-Thoracic Surgery Advance Access published June 25, 2015

European Journal of Cardio-Thoracic Surgery (2015) 1–6
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

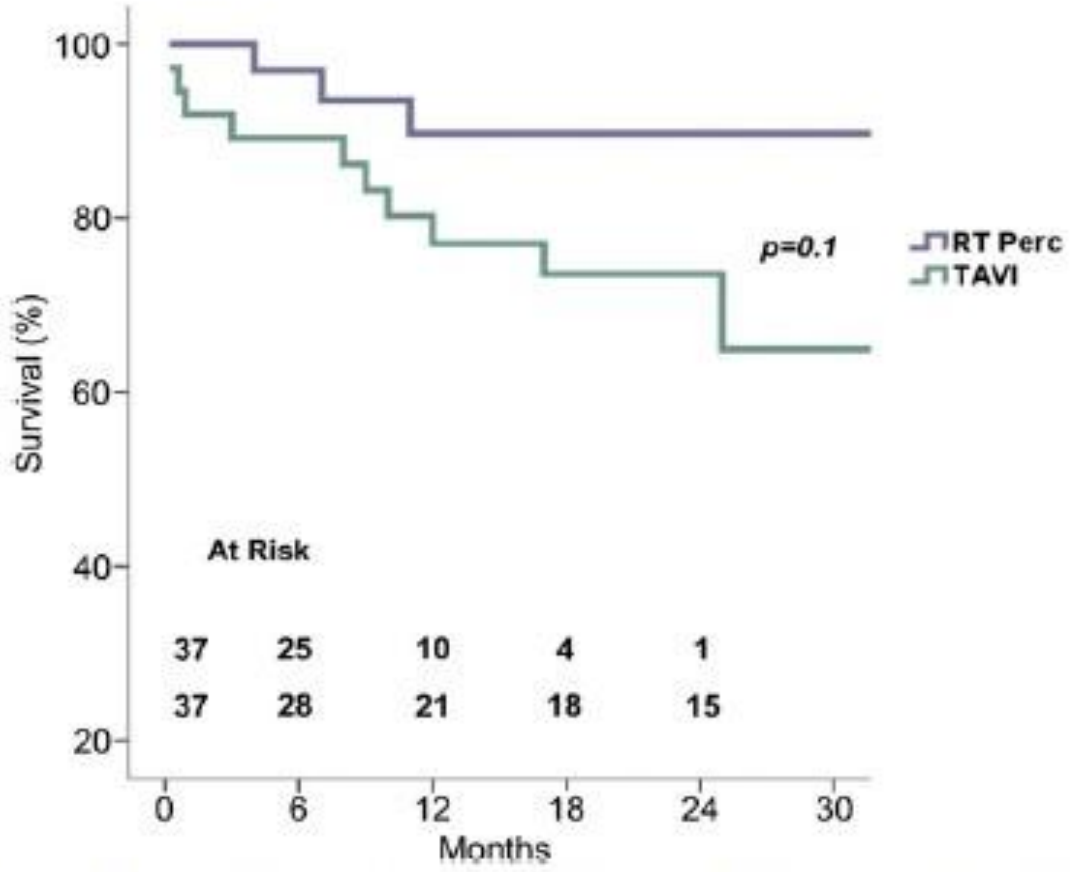


Figure 1: Survival between two matched groups. TAVI: transcatheter aortic valve implantation; RT: right anterior minithoracomy.

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%)

Journal of Cardiology
Volume 67, Issue 6, June 2016, Pages 504-512

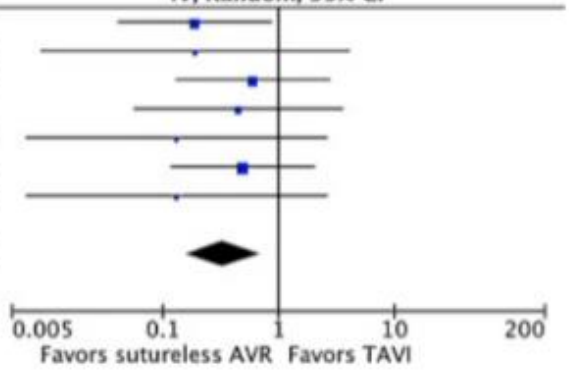
Original article

Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation: A meta-analysis of comparative studies

Hisato Takagi MD, PhD, Takuya Umemoto MD, PhD, for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Study or Subgroup	Sutureless AVR Events	Total	TAVI Events	Total	Weight	Odds Ratio IV, Random, 95% CI
Biancari 2015* [7]	2	144	10	144	22.4%	0.19 [0.04, 0.88]
D'Onofrio 2012 [8]	0	38	2	38	5.6%	0.19 [0.01, 4.08]
Doss 2012 [9]	3	27	5	29	22.4%	0.60 [0.13, 2.80]
Kamperidis 2015 [6]	1	48	10	221	12.3%	0.45 [0.06, 3.59]
Miceli 2015* [5]	0	37	3	37	5.9%	0.13 [0.01, 2.64]
Muneretto 2015 [10]	3	53	6	55	25.5%	0.49 [0.12, 2.07]
Santarpino 2014 [11]	0	37	3	37	5.9%	0.13 [0.01, 2.64]
Total (95% CI)		**384**		**561**	**100.0%**	**0.33 [0.16, 0.69]**
Total events	9		39			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.31$, df = 6 (P = 0.89); $I^2 = 0\%$
Test for overall effect: Z = 2.97 (P = 0.003)

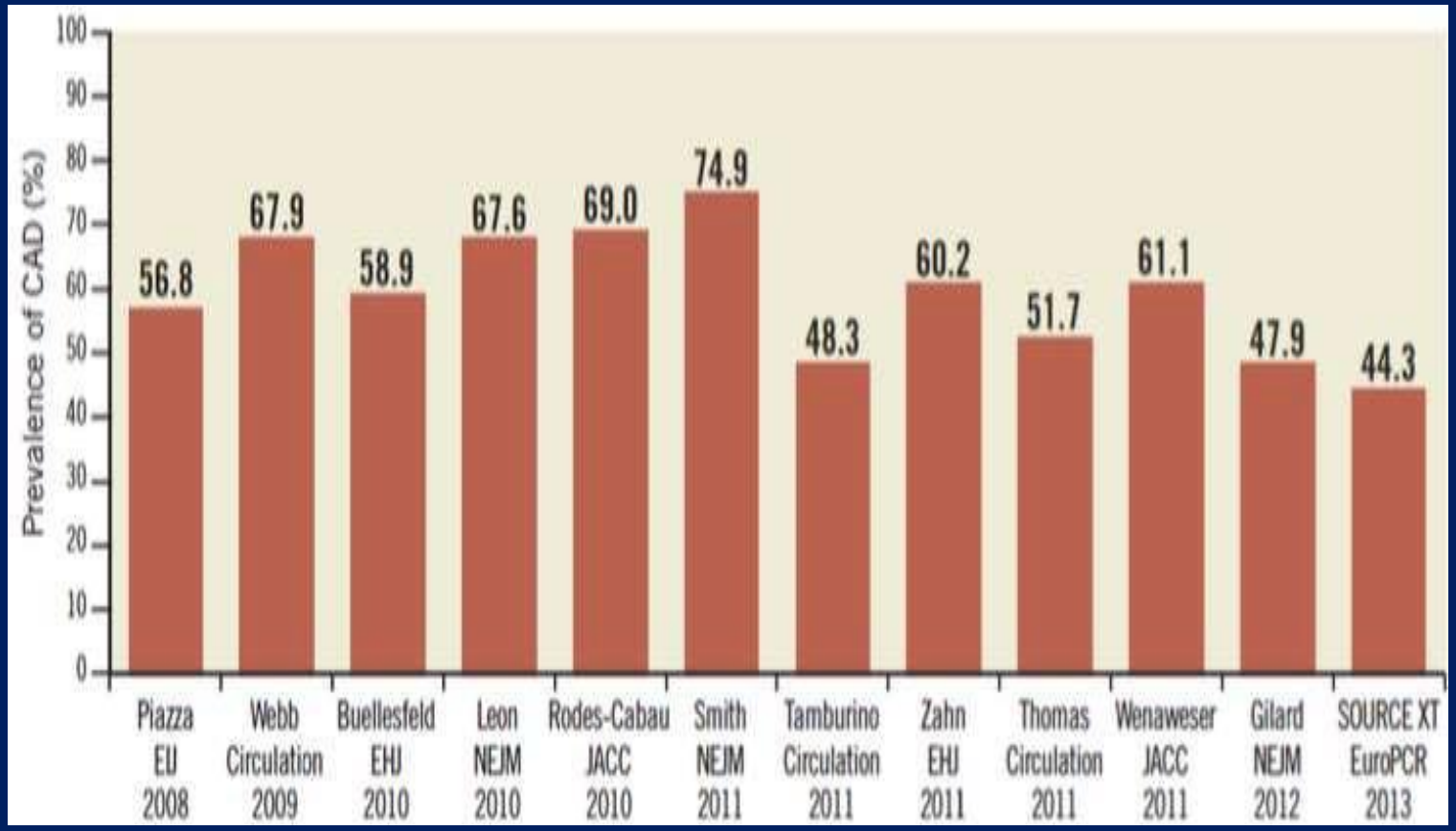


ΣΥΝΥΠΑΡΞΗ ΣΤΕΦΑΝΙΑΙΑΣ ΝΟΣΟΥ

CORONARY ARTERY DISEASE IN TAVR PATIENTS

Incidence

In pts. undergoing TAVR the prevalence of significant CAD is reported between 44% - 75%

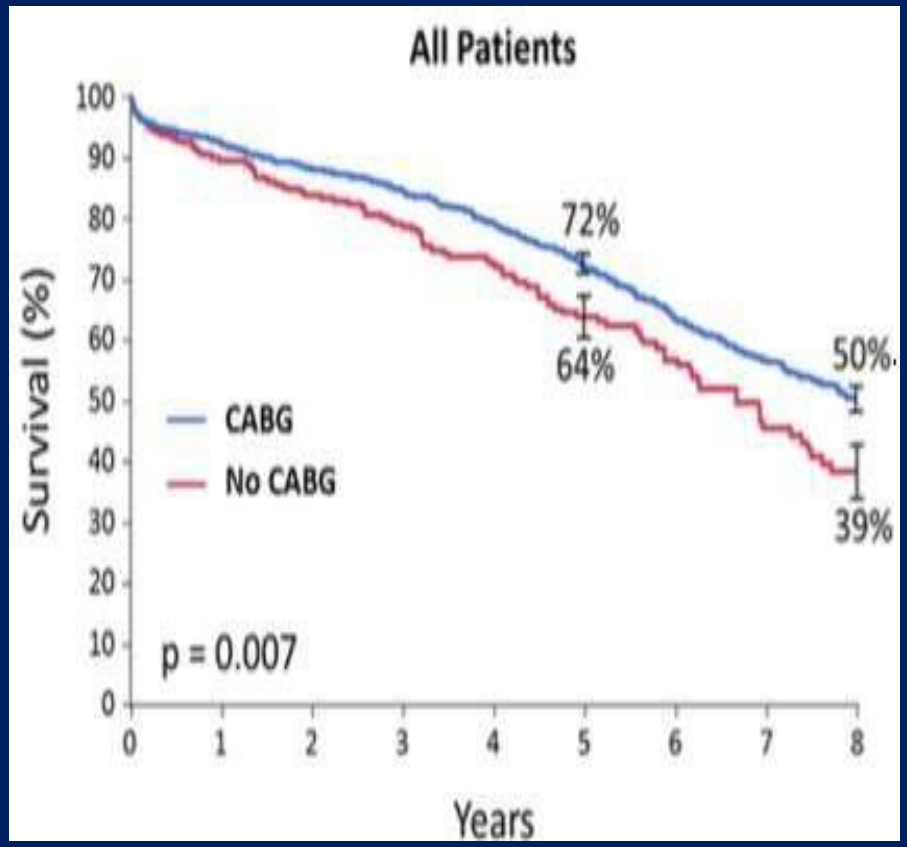


EuroInterv 2013; 9:S63

The prognostic impact of concomitant coronary artery bypass grafting during aortic valve surgery: Implications for revascularization in the transcatheter era

1308 consecutive pts. with significant CAD (>50% stenosis) undergoing AVR with or with out CABG between 2001 and 2010

Simultaneous CABG and SAVR reduces risk late mortality



J Thorac Cardiovasc Surg 2015;149:451-60

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THE PRESENT AND FUTURE

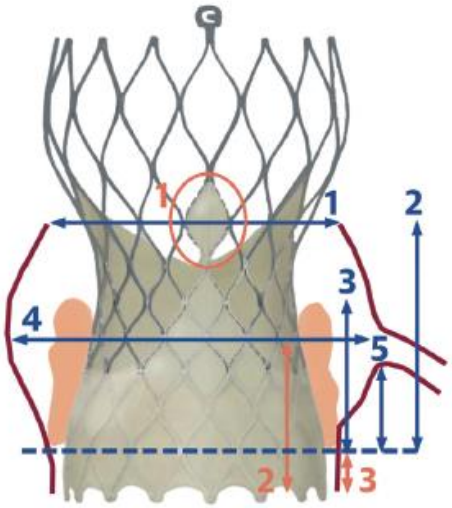
STATE-OF-THE-ART REVIEW

Coronary Angiography and Percutaneous Coronary Intervention After Transcatheter Aortic Valve Replacement

Matias B. Yudi, MBBS,[a] Samin K. Sharma, MD,[a] Gilbert H.L. Tang, MD, MSc, MBA,[b] Annapoorna Kini, MD[a]

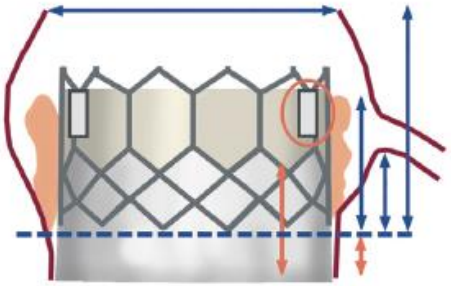
CENTRAL ILLUSTRATION Coronary Reaccess After TAVR

Factors Impacting Coronary Access



Anatomical

1. Sinotubular junction dimensions
2. Sinus height
3. Leaflet length and bulkiness
4. Sinus of Valsalva width
5. Coronary height

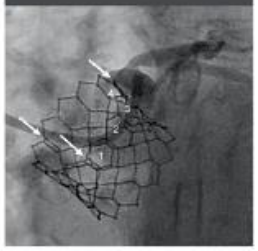


Device and Procedural

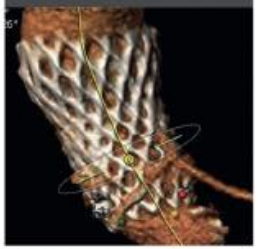
1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth

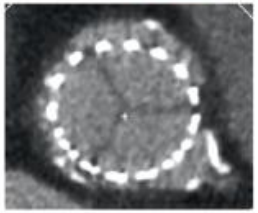
Imaging Evaluation

Fluoroscopy



MDCT





Yudi, M.B. et al. J Am Coll Cardiol. 2018;71(12):1360-78.

Summary of factors impacting coronary access and imaging evaluation after TAVR. MDCT = multidetector computed tomography; TAVR = transcatheter aortic valve replacement.

TABLE 1 Summary of the Largest Published Studies (N > 5 Patients) on Coronary Angiography and PCI After TAVR

First Author (Ref. #), Year Published	No. of Patients (Valve Used)	Study Summary on Feasibility of Coronary Angiography and PCI	Catheters Used
Chetcuti et al. (18), 2016	169 (CoreValve [Medtronic, Galway, Ireland])	190 coronary angiography or PCI; PCI attempted in 113 cases 75 cases in 72 patients with both catheterization reports and angiography reviewed Successful coronary angiography: • 97.9% (186 of 190) possible in overall group • 96.0% (72 of 75) possible from catheterization reports and angiography reviewed Successful PCI: • 91.2% (103 of 113) possible in overall group • 81.6% (31 of 38) possible among the 75 cases reviewed	LCA (N = 74): • Judkins 59.5% • FL4 4.1% • EBU 4.1% • Amplatz 1.4% • Other 6.8% • Unknown 24.3% RCA (N = 70): • Judkins 42.9% • Amplatz 5.7% • Williams 1.4% • FR4 1.4% • EBU 1.4% • Unknown 47.1%
Zivelonghi et al. (19), 2017	66 41 (Sapien 3 [Edwards Lifesciences, Irvine, California]) 25 (Evolut R [Medtronic])	Angiogram and FFR assessed pre- and post-TAVR Successful coronary angiography: • 98.0% (65 of 66) successful diagnostic angiogram performed (6 semiselective angiograms requiring wiring [2 cases with Sapien 3 and 4 cases with Evolut R) • 1 nondiagnostic angiogram with Evolut R (presumed due to high valve implantation) Successful PCI: • 100% (17 of 17 [5 Evolut R, 12 Sapien 3) with 5 cases requiring rotational atherectomy (3 Evolut R, 2 Sapien 3)	• Initial strategy was to use EBU and JR catheters Sapien 3: • standard catheters used Evolut R: • 6 of 25 cases needed a change of catheter (from EBU to JL) • Generally, a smaller catheter was used (JL3.5 instead of JL4 and EBU3.0 instead of EBU3.5) • For horizontal aorta: JL3.5 and 3DRC
Blumenstein et al. (20), 2015	35 19 (Sapien XT) 10 (CoreValve) 4 (Symetis Acurate [Boston Scientific, Marlborough Massachusetts]) 1 (Portico [Abbott, Lake Bluff, Illinois]) 1 (JenaValve [Irvine, California])	• 3.5% (35 of 1,000) patients required angiography and/or PCI post-TAVR • 33.0% (10 of 35) had angiography during index hospitalization • 76.0% (23 of 30) with delayed angiography had known CAD pre-TAVR. • 80.0% femoral access Successful coronary angiography: • Sapien XT: 100% (19 of 19) selective angiograms • Jena Valve: 100% (1 of 1) selective angiograms • CoreValve: 90.0% (9 of 10): 3 selective angiograms (1 used usual catheters, 2 required different catheter); 6 were nonselective angiograms; 1 nondiagnostic angiogram post-valve-in-valve procedure • Portico: 100% (1 of 1) nonselective due to interference between catheter and stent mesh. Needed microcatheter to stabilize system for PCI • Symetis Acurate: 100% (4 of 4): 2 selective angiograms; 2 nonselective angiograms due to prosthesis being too high Successful PCI: • 100% (10 of 10 [8 Sapien XT, 1 Portico, 1 Symetis Acurate]); no self-expanding valve patient required PCI	Sapien XT: • Standard catheters used CoreValve: • LCA: JL3.5 • RCA: AR1 Portico: • LCA: JL3.5 • RCA: AR 1 Symetis Acurate: • LCA: AL2 • RCA: AR1
Htun et al. (21), 2017	28 (CoreValve)	43 coronary angiographies in 28 patients: Successful coronary angiography: • 97.0% selective engagement of LCA • 90.0% selective engagement of RCA Successful PCI: • 29 of 29 (100%) lesions	LCA: • JL (86.0%), EBU, AL2, GuideLiner RCA: • JR4 (93.0%), 3DRC, IM
Allali et al. (22), 2016	17 (CoreValve)	24 PCI procedures to 29 lesions Indication: STEMI 8.3%; NSTEMI 20.8%. Median time: TAVR to PCI = 17.7 months (range: 1–72 months) Successful PCI: • Procedural success 95.8% (1 periprocedural death) • 9 of 15 cases required different guides to pre-TAVR PCI • 4 cases: suboptimal support • 1 case: rotational atherectomy	LCA: • JL (95.0%) • EBU (5.0%) RCA: • JR4.0/JR4.5 (67.0%) • AR2 (33.0%)
Boukantar et al. (23), 2017	16 (CoreValve)	Indications: Angina: 3 NSTEMI: 7 Silent ischemia: 3 Worsening left ventricular function: 3 Successful coronary angiography: • 9 of 16 successful angiograms (no patient had selective engagement of both coronary arteries; only 2 had selective RCA engagement) Successful PCI: • 6 of 7, one failed PCI due to poor backup support related to nonselective LM cannulation	LCA: • EBU3.5/3.75 for all RCA: • No RCA PCI performed

Continued on the next page

TABLE 1 Continued

First Author (Ref. #), Year Published	No. of Patients (Valve Used)	Study Summary on Feasibility of Coronary Angiography and PCI	Catheters Used
Chakravarty et al. (24), 2016	9 4 (CoreValve) 5 (Sapien)	Left main PCI post-TAVR Indication: 7 of 9: NSTEMI 2 of 9: stable angina Successful PCI: • 9 of 9 (100% cases)	No details

3DRC = 3-dimensional right coronary; AL = Amplatz left; AR = Amplatz right; CAD = coronary artery disease; EBU = extra backup; FFR = fractional flow reserve; FL = femoral left; FR = femoral right; IM = internal mammary; JL = Judkins left; LCA = left coronary artery; LM = left main; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; STEMI = ST-segment elevation myocardial infarction; TAVR = transcatheter aortic valve replacement.

CONCLUSIONS

Coronary angiography and PCI in patients after TAVR can be challenging. Intricate knowledge of the valve design and its relationship with the coronary ostia, sinus of Valsalva, and STJ anatomies can help predict the difficulty in coronary reaccess and identify a strategy to manage these patients. Proposed algorithms on cardiac catheterization and PCI may aid troubleshooting in the management of these complex clinical scenarios.

ΠΑΡΑΒΑΛΒΙΔΙΚΗ ΔΙΑΦΥΓΗ

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Valvular performance and aortic regurgitation following transcatheter aortic valve replacement using Edwards valve versus CoreValve for severe aortic stenosis: A Meta-analysis☆,☆☆

Samit Bhatheja [a], Hemang B. Panchal [a], Neil Barry [b], Debabrata Mukherjee [c], Barry F. Uretsky [d], Timir Paul [a,*]

[a] *Division of Cardiology, Department of Internal Medicine, East Tennessee State University, 329 N State of Franklin Rd, Johnson City, TN, 37604*
[b] *Department of Internal Medicine, East Tennessee State University, VA Building #1, Johnson City, TN*
[c] *Division of Cardiology, Department of Internal Medicine, Texas Tech University, 4800 Alberta, El Paso, TX, 79905*
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A B S T R A C T

Objectives: To compare incidence of aortic regurgitation (AR), paravalvular AR and valvular performance with Doppler hemodynamic parameters following transcatheter aortic valve replacement (TAVR) with Edwards valve (EV) versus CoreValve (CV). Currently, there are scarce data on post-TAVR echocardiographic outcomes comparing EV and CV.

Methods: PubMed and the Cochrane Center Register of Controlled Trials were searched through May 2015. Twenty studies ($n = 11,244$) comparing TAVR procedure that used EV ($n = 6445$) and CV ($n = 4799$) were included. End points were post-TAVR moderate to severe AR and paravalvular AR, effective orifice area (EOA), mean trans-aortic pressure gradient (MPG), peak trans-aortic pressure gradient (PPG) and left ventricular ejection fraction (LVEF). The mean difference (MD) or relative risk (RR) with 95% confidence interval (CI) was computed and $p < 0.05$ was considered as a level of significance.

Results: Moderate to severe AR and paravalvular AR were significantly lower in EV group (RR: 0.57, CI: 0.52–0.63, $p < 0.00001$ and RR: 0.40, CI: 0.25–0.63, $p < 0.0001$ respectively) compared to CV group. EOA and PPG were not significantly different between EV and CV groups. MPG was significantly lower among patients in CV group (MD: 1.08, CI: 0.05–2.10, $p = 0.04$). LVEF was significantly higher in patients in EV group (MD: 2.26, CI: 0.77–3.74, $p = 0.03$).

Conclusions: This study showed CV is associated with higher incidence of post-TAVR moderate to severe paravalvular AR. Echocardiographic valvular performance measures (MPG, LVEF) showed minimal but significant difference, which may not be clinically significant.

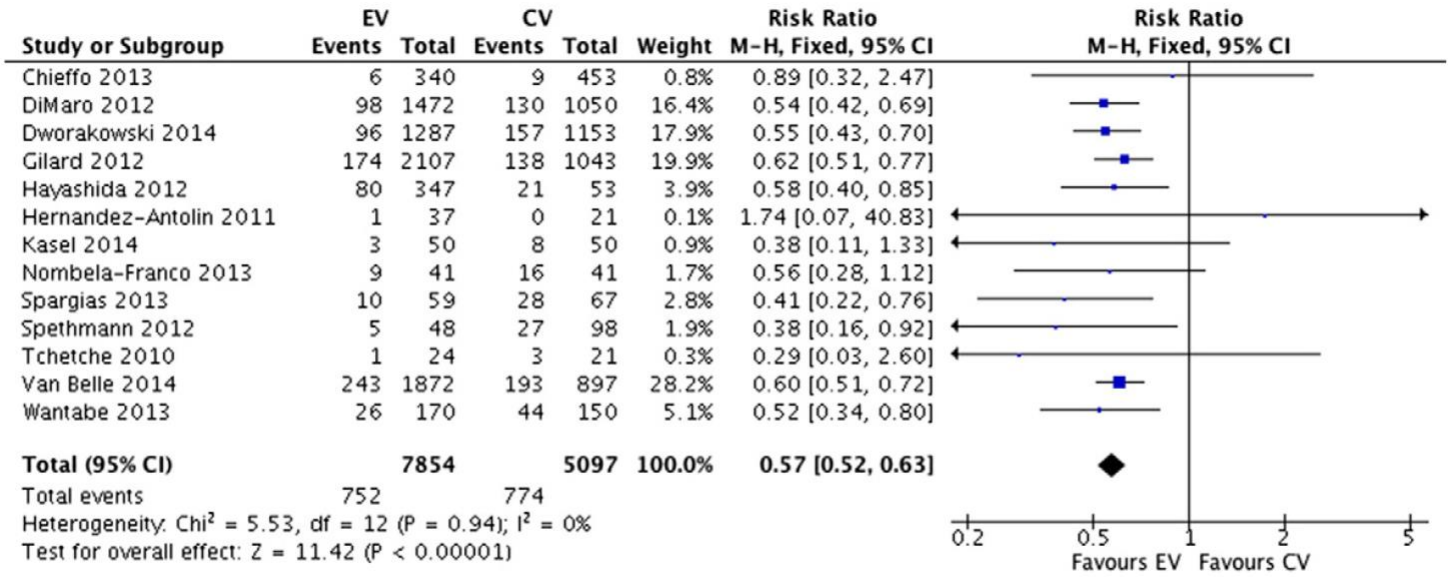


Fig. 2. Meta-analysis comparison of incidence of post-TAVR moderate to severe AR between EV and CV. AR = aortic regurgitation, CV = CoreValve, EV = Edwards Valve, TAVR = transcatheter aortic valve replacement.

(Post-TAVR paravalvular AR)

Study or Subgroup	EV Events	EV Total	CV Events	CV Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Abdel-Wahab 2014	3	118	35	276	35.1%	0.20 [0.06, 0.64]
Abdel-Wahab Choice 2014	2	121	7	120	11.8%	0.28 [0.06, 1.34]
Attias 2010	14	72	2	11	5.8%	1.07 [0.28, 4.08]
Nombela-Franco 2013	9	41	16	41	26.8%	0.56 [0.28, 1.12]
Tarsia 2014	5	56	12	53	20.6%	0.39 [0.15, 1.04]
Total (95% CI)		**408**		**501**	**100.0%**	**0.40 [0.25, 0.63]**
Total events	33		72			

Heterogeneity: Chi² = 4.59, df = 4 (P = 0.33); I² = 13%

Test for overall effect: Z = 3.93 (P < 0.0001)

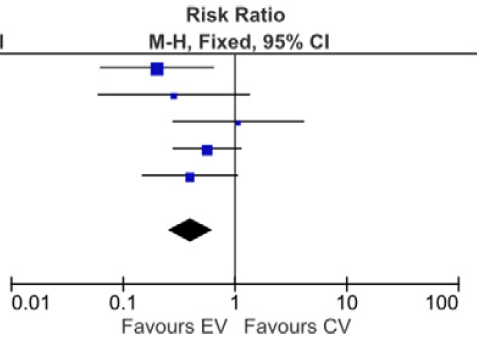


Fig. 3. Meta-analysis comparison of incidence of post-TAVR paravalvular AR between EV and CV. AR = aortic regurgitation, CV = CoreValve, EV = Edwards Valve, TAVR = transcatheter aortic valve replacement.

ΔΥΣΛΕΙΤΟΥΡΓΙΑ ΔΕΞΙΑΣ ΚΟΙΛΙΑΣ

Early effects of transcatheter aortic valve implantation and aortic valve replacement on myocardial function and aortic valve hemodynamics: Insights from cardiovascular magnetic resonance imaging

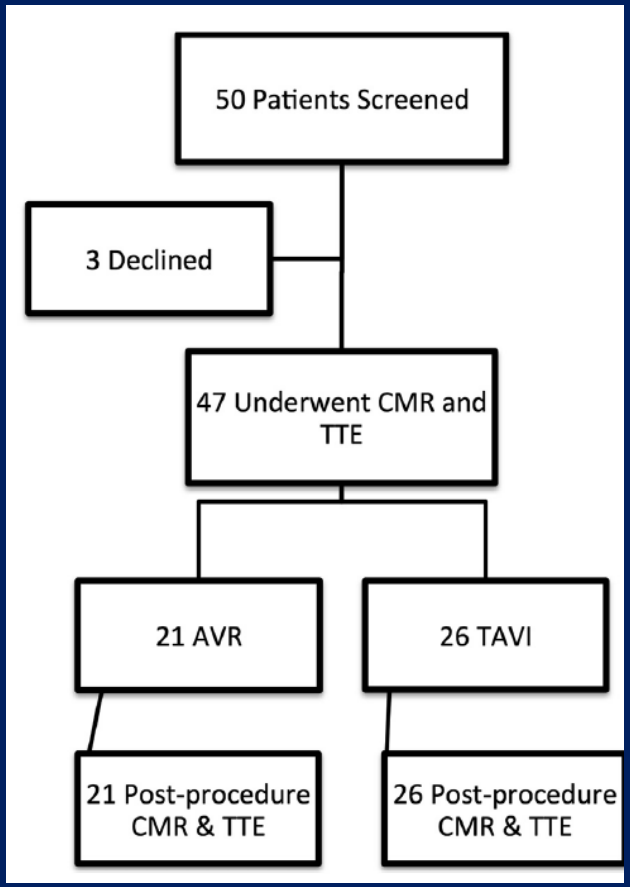
Gareth Crouch, MBBS,[a,b] Jayme Bennetts, MBBS,[a,b] Ajay Sinhal, MD,[c] Phillip J. Tully, PhD,[b] Darryl P. Leong, PhD,[a] Craig Bradbrook, MRS,[c] Amy L. Penhall, BSc,[c] Carmine G. De Pasquale, PhD,[a,c] Adhiraj Chakrabarty, MBBS,[c,d] Robert A. Baker, PhD,[a,b] and Joseph B. Selvanayagam, DPhil[a,c,d]

Objectives: There remains a paucity of mechanistic data on the effect of transcatheter aortic valve implantation (TAVI) on early left and right ventricular function and quantitative aortic valve regurgitation. We sought to assess and compare the early effects on myocardial function and aortic valve hemodynamics of TAVI and aortic valve replacement (AVR) using serial cardiovascular magnetic resonance (CMR) imaging and echocardiography.

Methods: A prospective comparison study of 47 patients with severe aortic stenosis undergoing either TAVI (n = 26) or high-risk AVR (n = 21). CMR (for left ventricle/right ventricle function, left ventricular mass, left atrial volume, and aortic regurgitation) was carried out before the procedure and early postprocedure (<14 days).

Results: Groups were similar with respect to Society of Thoracic Surgeons score (TAVI, 7.7 vs AVR, 5.9; $P = .11$). Preoperative left ventricular (TAVI, 69% ± 13% vs AVR, 73% ± 10%; $P = .10$) and right ventricular (TAVI, 61% ± 11% vs AVR, 59% ± 8%; $P = .5$) ejection fractions were similar. Postoperative left ventricular ejection fraction was preserved in both groups. In contrast, decline in right ventricular ejection fraction was more significant in the TAVI group (61%-54% vs 59%-58%; $P = .01$). Postprocedure aortic regurgitant fraction was significantly greater in the TAVI group (16% vs 4%; $P = .001$), as was left atrial size (110 vs 84 mL; $P = .02$). Further analysis revealed a significant relationship between the increased aortic regurgitant fraction and greater left atrial size ($P = .006$), and a trend toward association between the decline in right ventricle dysfunction and increased postprocedure aortic regurgitation ($P = .08$).

Conclusions: There was no significant difference in early left ventricular systolic function between techniques. Whereas right ventricle systolic function was preserved in the AVR group, it was significantly impaired early after TAVI, possibly reflecting a clinically important pathophysiologic consequence of paravalvular aortic regurgitation. (J Thorac Cardiovasc Surg 2015;149:462-70)



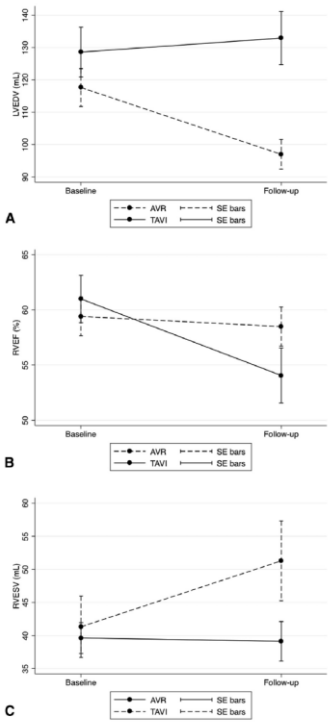


FIGURE 3. Differential effects of open aortic valve replacement (*AVR*) and transcatheter aortic valve implantation (*TAVI*) on indices of cardiac remodeling and function. A, left ventricular end-diastolic volume (*LVEDV*). B. Right ventricle ejection fraction (*RVEF*). C, Right ventricular end-systolic volume (*RVESV*). *SE*, Standard error.

Our results demonstrate for the first time that TAVI is associated with early RV dysfunction. This may reflect the higher incidence of AR with TAVI and explain the recent observation of increased long-term mortality in this setting.

ΔΙΑΡΚΕΙΑ ΖΩΗΣ

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

2016 euro PCR

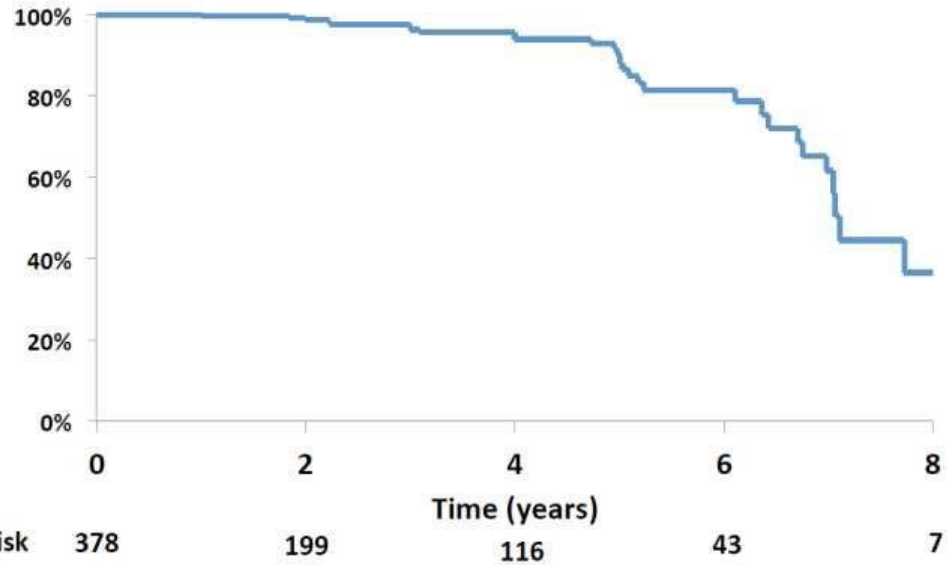
First look at long-term durability of transcatheter heart valves:
Assessment of valve function up to 10-years after implantation

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

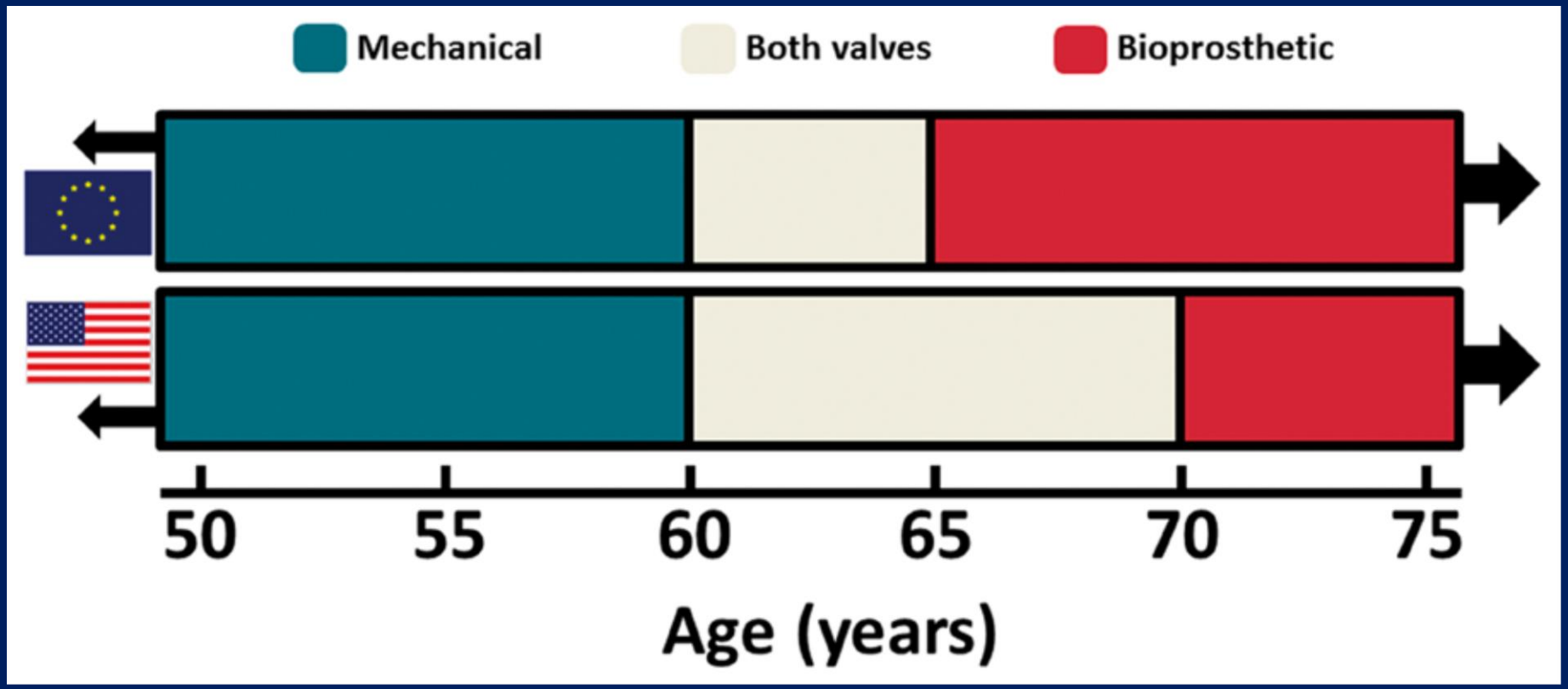
On behalf of coauthors: Helene Eltchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Matheus Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone,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

2016 euro PCR

Freedom from THV degeneration



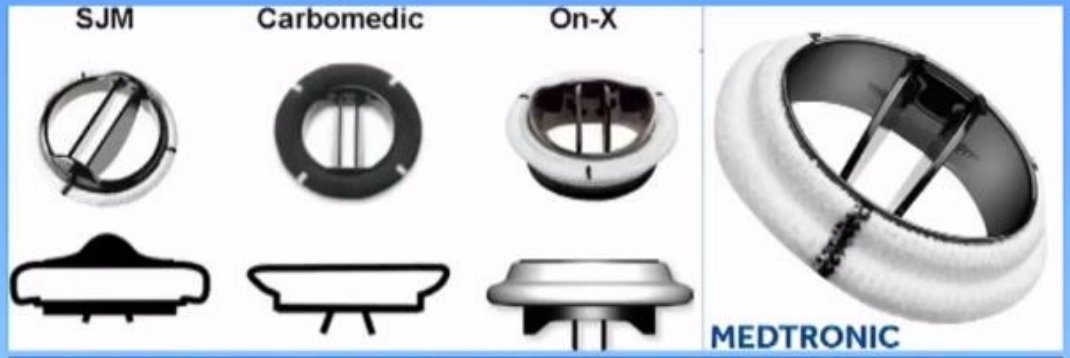
THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.
KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.



From: Mechanical versus bioprosthetic aortic valve replacement

Eur Heart J. 2017;38(28):2183-2191. doi:10.1093/eurheartj/ehx141

Mechanical aortic valves for the treatment of AVS: the first option up to 2000



Comparison of FDA Submission Data

EOA's for Mechanical Aortic Prosthetic Heart Valves*

Valve Size	On-X[1]	CMI[2]	ATS[3]	SJM Regent[4]
19	1.5	0.9	1.2	1.7
21	1.8	1.3	1.5	2.0
23	2.3	1.4	1.7	2.5
25	2.7	1.5	2.1	2.6
27	2.9	2.2	2.5	3.5
29	2.9	3.2	3.1	3.5
31		3.2	3.1	

1. On-X® Prosthetic Heart Valve. Summary of Safety and Effectiveness Data submitted to the United States Food and Drug Administration. PMA P000037. Approval date May 30, 2001 and October 11, 2002
2. CarboMedics® Prosthetic Heart Valve. Summary of Safety and Effectiveness Data submitted to the United States Food and Drug Administration. PMA P900060. Approval date April 13, 1993
3. ATS Open Pivot® Bileaflet Heart Valve. Summary of Safety and Effectiveness Data submitted to the United States Food and Drug Administration. PMA P990046. Approval date October13, 2000
4. SJM Regent® Valve. Clinical Study Summary (package insert)

Bioprosthetic aortic valves – differences

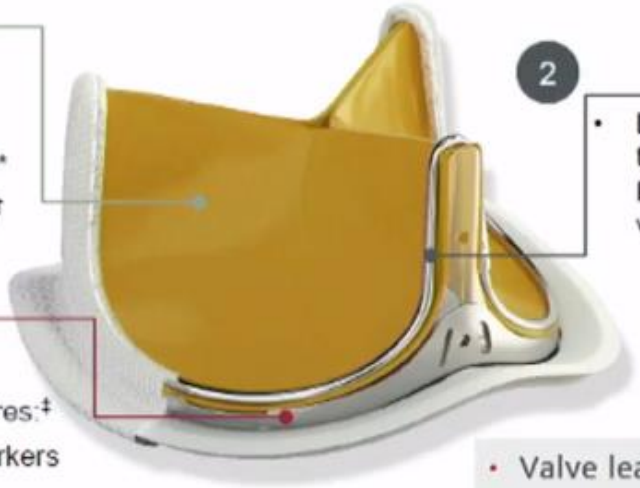
- Hemodynamic **performance**
- Long – term **durability**
- Facility for future **ViV** TAVI

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

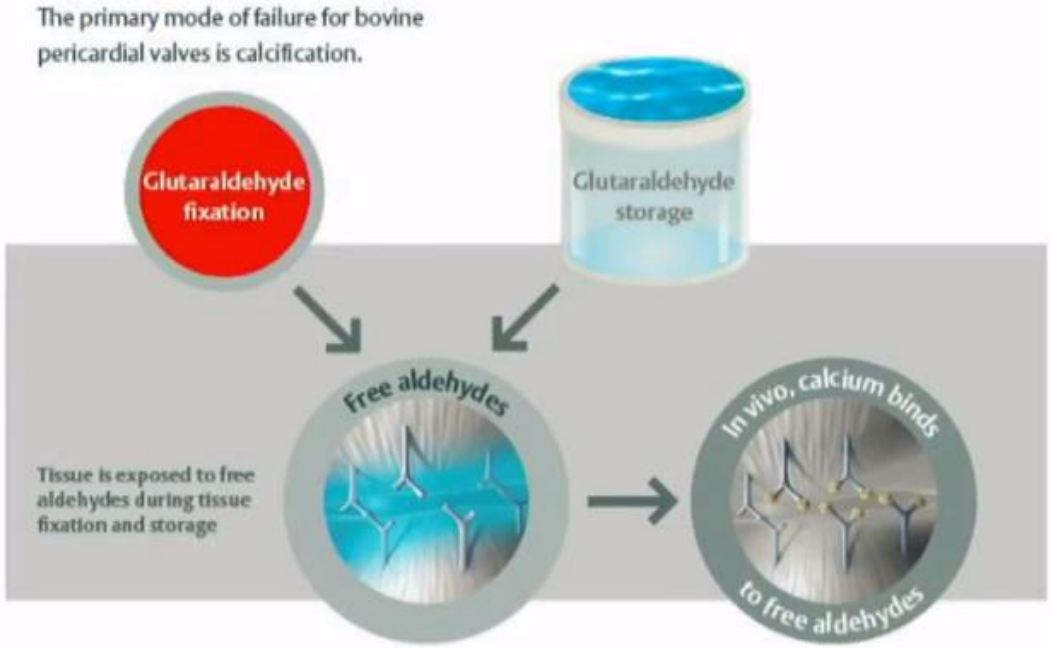
- Valve leaflets: Bovine pericardium
- Stent: Cobalt-chromium alloy, polyester
- Fabric covering stent: Polyester cloth
- Valve sewing ring: Silicone rubber

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.

Multiple factors influence tissue calcification, some of which are inherent to the current technology (e.g. free aldehydes)



Tissue exposure to free aldehydes during glutaraldehyde fixation and storage is a major cause of calcification.

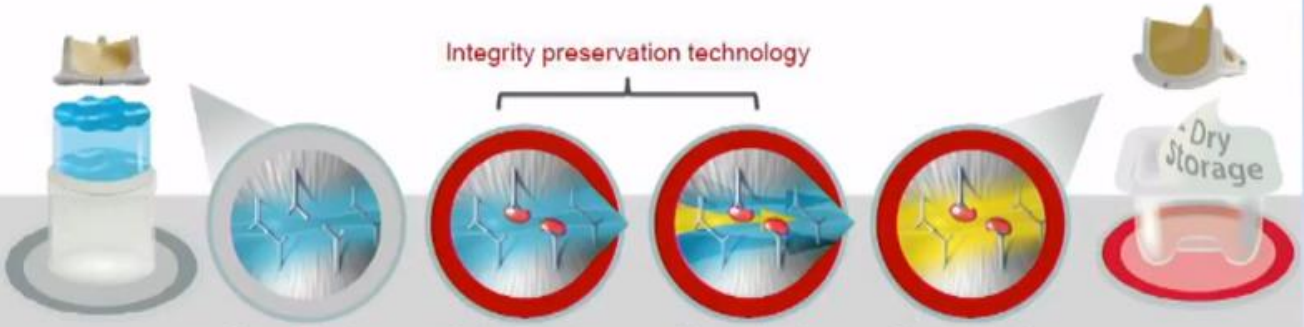
Schoen FJ, Levy RJ. Ann Thorac Surg. 2005;79:1072–80

Glycerolization

The valves undergo treatment with a glycerol and ethanol mix, which displaces most of the water present in the pericardial tissue and replaces it with glycerol. As a result of glycerolization, the valves can be packaged and **stored dry, without the need for any liquid-based storage solution such as glutaraldehyde**.

RESILIA tissue is bovine pericardial tissue transformed by the addition of a novel integrity preservation technology

- Integrity preservation technology incorporates two proprietary features with a new way to virtually eliminate free aldehydes while preserving and protecting the tissue



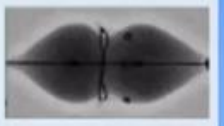
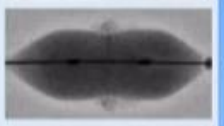
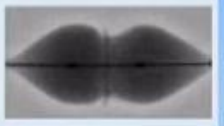
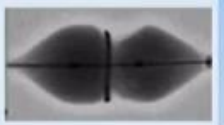
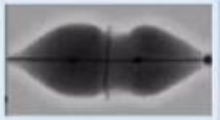
RESILIA tissue:
Rationale and pre-clinical data

Bart Meuris, MD, PhD
University Hospitals Leuven, Belgium

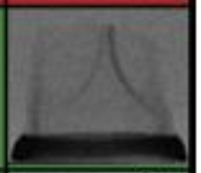
Bioprosthetic aortic valves – differences

- Facility for **future ViV TAVI**

- **Residual stenosis (PPM) ⟶ ring fracture**
- **Coronary artery obstruction ⟶ stent protection/Basilica**
- Valve thrombosis
- Unknown durability

Medtronic (Minneapolis, Minnesota)	Mosaic Tissue valve		Porcine	Inside		
	Hancock II Tissue valve		Porcine	Inside		
St. Jude Medical (St. Paul, Minnesota)	Epic (Biocor) valve		Porcine	Inside		
	Epic Supra (Biocor Supra) valve		Porcine	Inside		
	Trifecta		Bovine Pericardium	Outside		
Sorin (Milan, Italy)	Mitroflow		Bovine Pericardium	Outside		
	Soprano Armonia		Bovine Pericardium	Inside		
Vascutek (Inchinnan, United Kingdom)	Aspire		Porcine	Inside		

Transcatheter Valve-in-Valve and Valve-in-Ring for Treating Aortic and Mitral Surgical Prosthetic Dysfunction. Paradis et al. JACC (66), 2015

Manufacturer/ Brand	Valve Size	Bard TRU Balloon Fracture/Pressure	Bard Atlas Gold Balloon Fracture/Pressure	Appearance After Fracture
St. Jude Trifecta 	19 mm 21 mm	NO NO	NO NO	
St. Jude Biocor Epic 	21 mm	YES / 8 ATM	YES / 8 ATM	
Medtronic Mosaic 	19 mm 21 mm	YES / 10 ATM YES / 10 ATM	YES / 10 ATM YES / 10 ATM	
Medtronic Hancock II 	21 mm	NO	NO	
Sorin Mitroflow 	19 mm 21 mm	YES / 12 ATM YES / 12 ATM	YES / 12 ATM YES / 12 ATM	
Edwards MagnaEase 	19 mm 21 mm	YES / 18 ATM YES / 18 ATM	YES / 18 ATM YES / 18 ATM	
Edwards Magna 	19 mm 21 mm	YES / 24 ATM YES / 24 ATM	YES / 24 ATM YES / 24 ATM	

1. Balloons sized 1 mm larger than valve size.
2. Medtronic Mosaic and Sorin Mitroflow have no metal in ring therefore appearance after fracture unchanged.

Fig 3. Summary of bench testing of high pressure balloon inflation to fracture the valve frame of commercial US surgical tissue valves. (ATM = atmospheres; TRU = Tru Dilation.)

The maximum gain in diameter that can be achieved with ring fracture (BVF) is between **3 and 4 mm**:

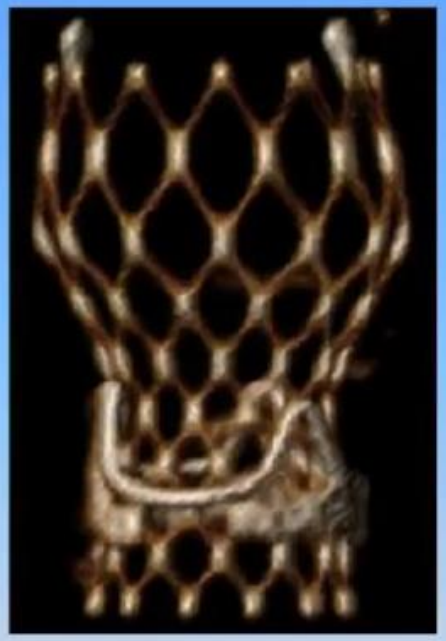
Stented AV No **21**

BVF ⇩

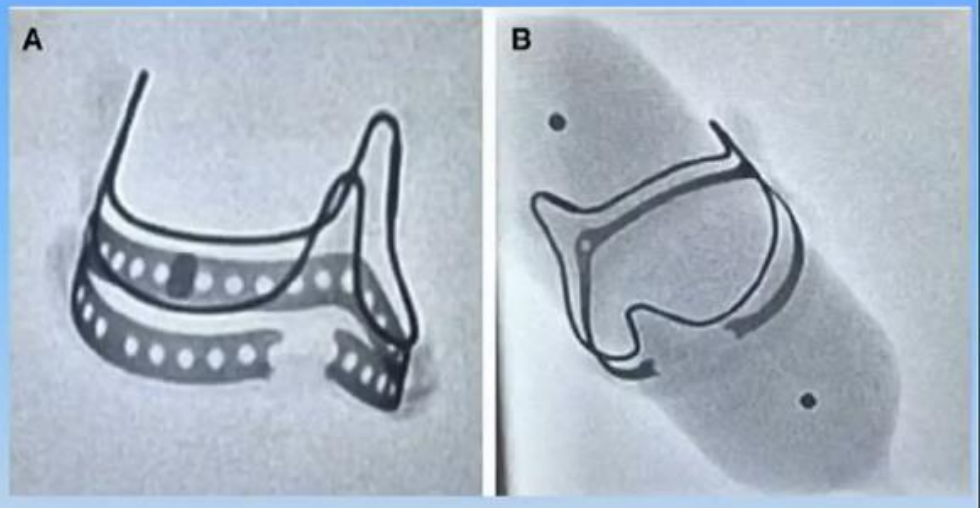
internal valve dimension **24-25** mm

Bioprosthetic Valve Fracture Improves the Hemodynamic Results of Valve-in-Valve Transcatheter Aortic Valve Replacement

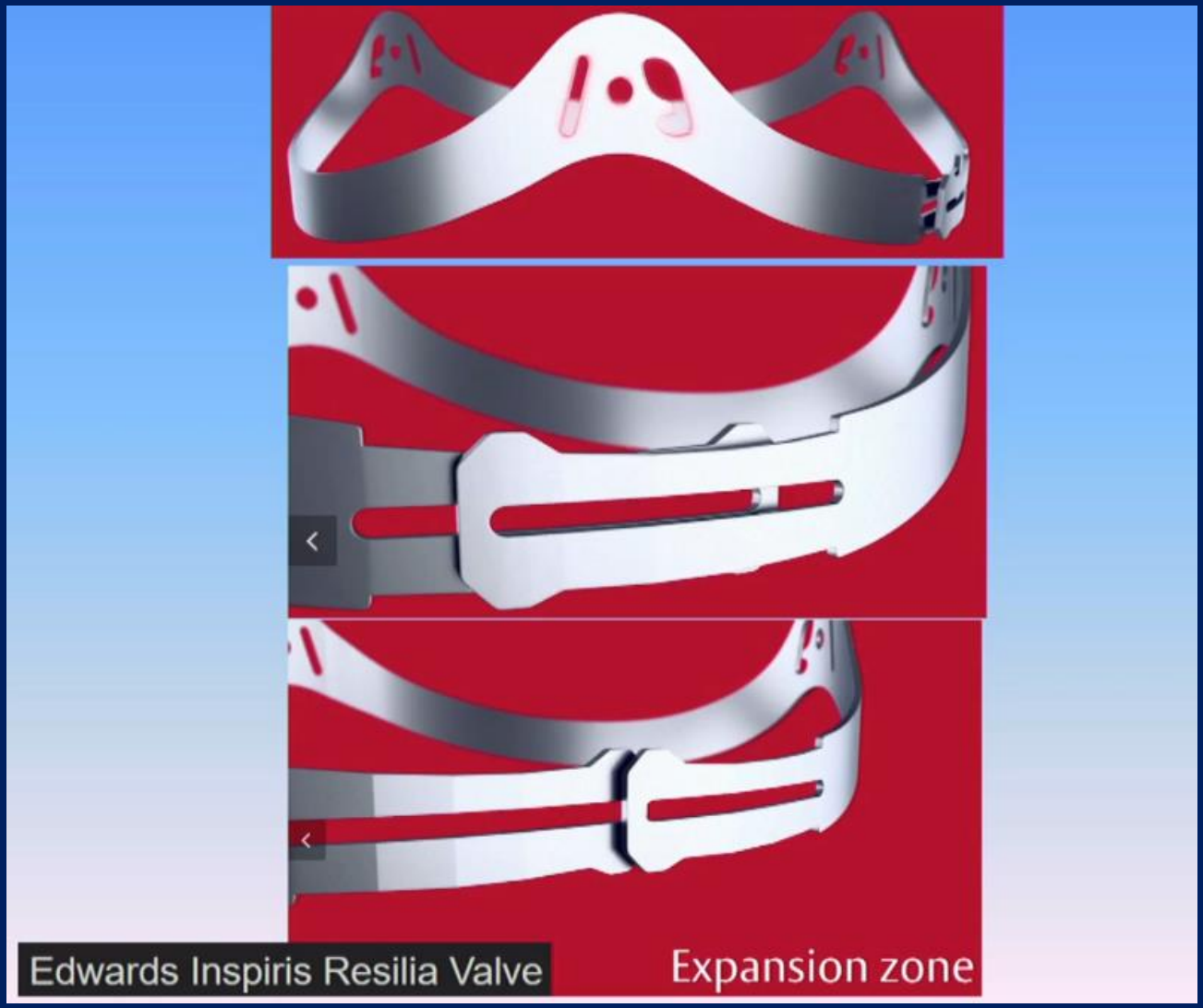
Circ Cardiovasc Interv. 2017;10:e005216



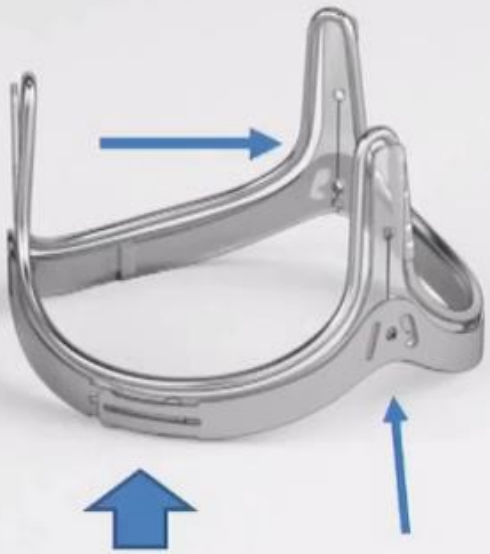
CT reconstruction VIV: 23-mm CoreValve Evolut R in a 19-mm Edwards Magna, followed by bioprosthetic valve fracture (BVF).

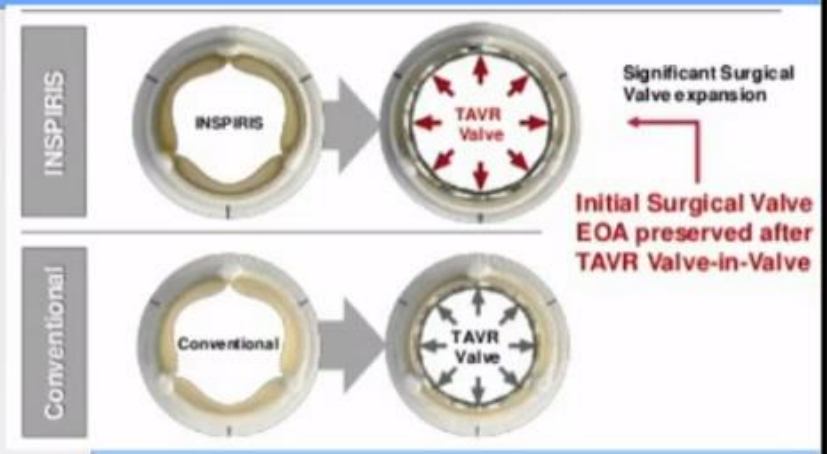


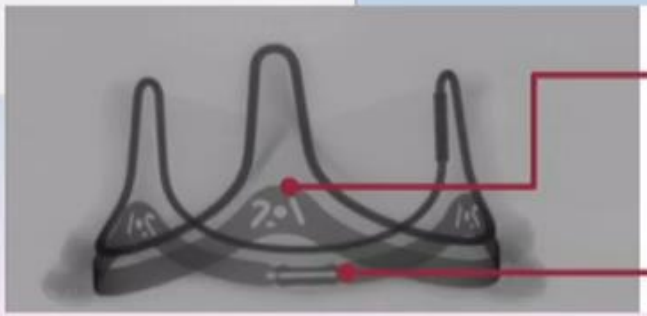
Fractured Magna (A) and Magna Ease (B) bioprosthetic valves


Edwards Inspiris Resilia Valve
Expansion zone

Edwards Inspiris Resilia Valve







European Journal of Cardio-Thoracic Surgery 0 (2019) 1–8
doi:10.1093/ejcts/ezy459

ORIGINAL ARTICLE

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Biological or mechanical prostheses for isolated aortic valve replacement in patients aged 50–65 years: the ANDALVALVE study†

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Key question

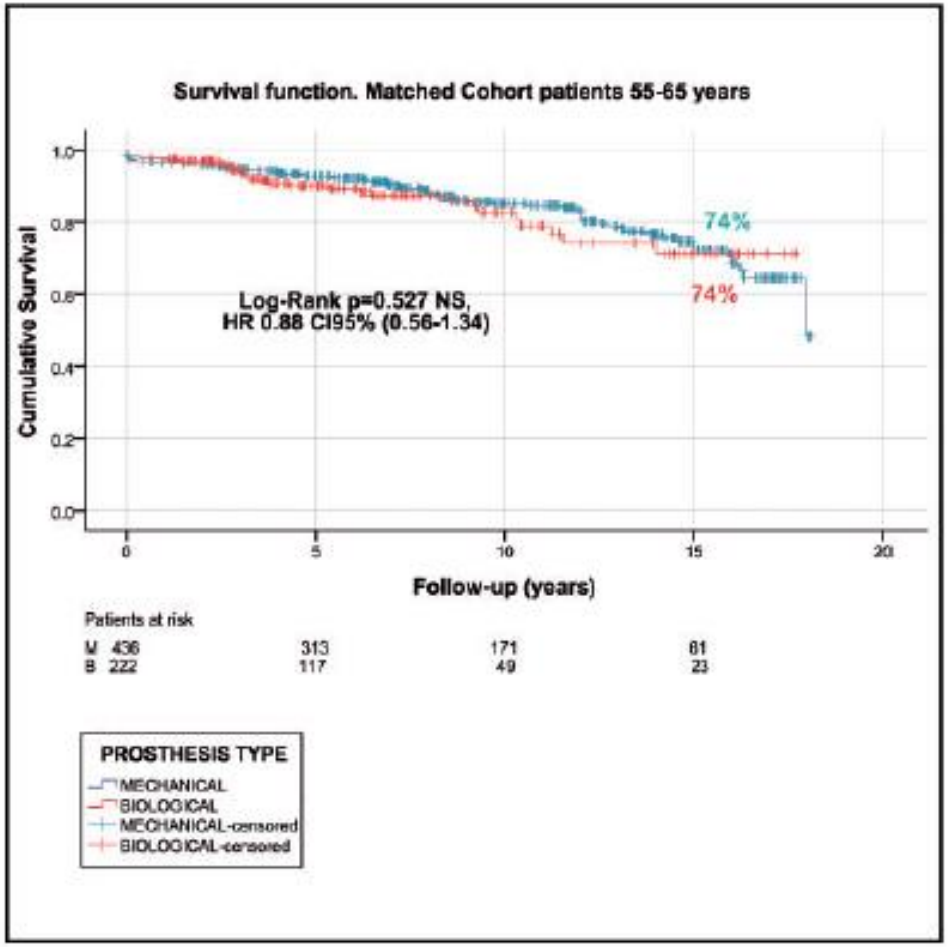
Which type of prosthesis performs better in patients between 50 and 65 years after aortic valve replacement: mechanical or biological?

Key finding(s)

Similar 15-year survival rates in patients older than 55 years. More bleeding with mechanical prostheses. More reoperations with biological prostheses.

Take-home message

Biological prostheses in patients older than 55 years are a reasonable choice.



ΣΥΜΠΕΡΑΣΜΑΤΑ

Well informed patient preference

TAVI

- Porcelain aorta
- High surgical risk
- Liver failure
- Re-do with patent grafts
- Severe COPD
- Serious chest deformities
- Intermediate-high risk

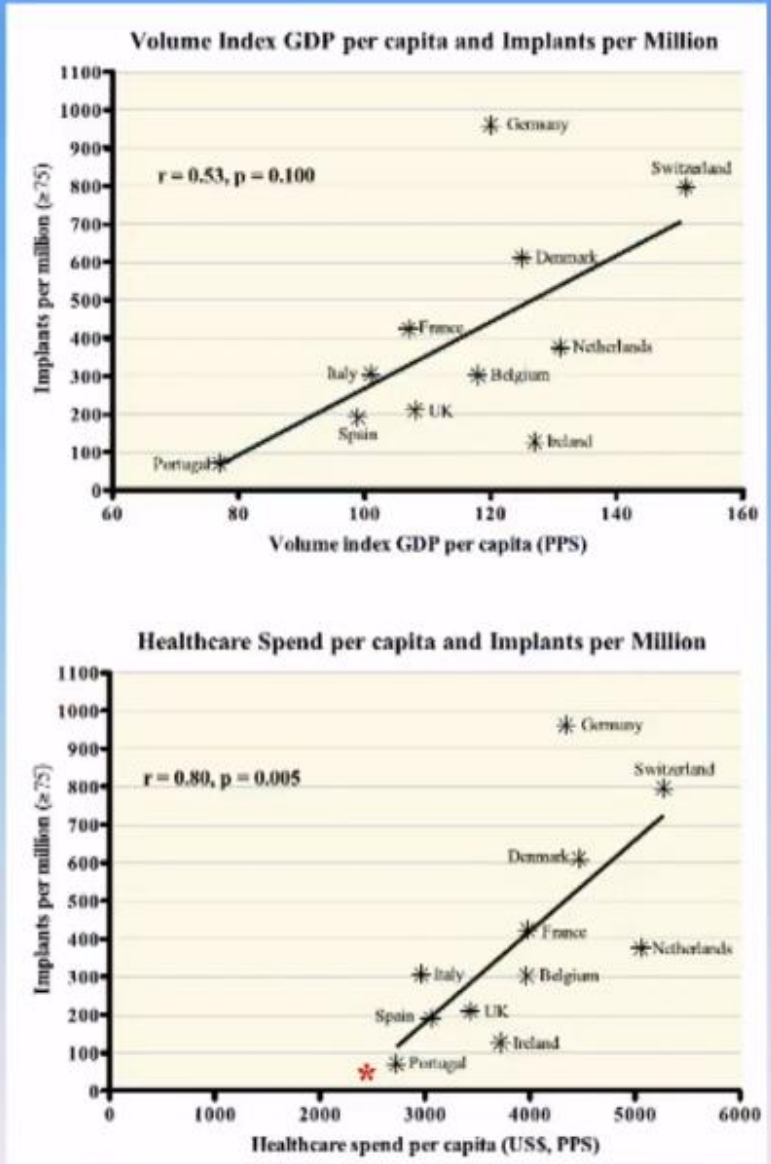
SAVR

- Younger patients
- Bicuspid valve
- AR
- Ao aneurysm
- Endocardtis
- Concomitant
- Rheumatic valve
- Intermediate - low risk

Heart Team

Factors Influencing TAVR Adoption in Europe

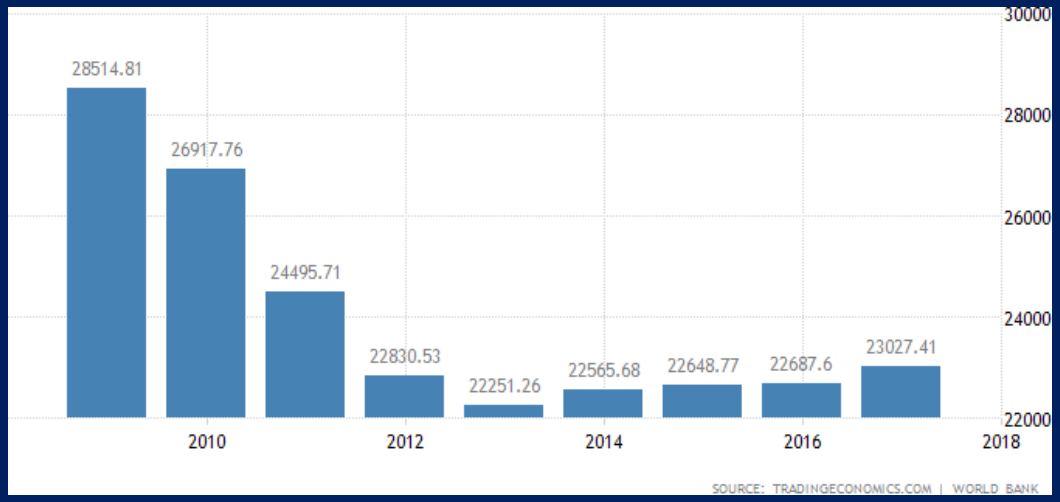
TAVR Adoption in Europe



* Greece ≈ 50 TAVIs / million

Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. JACC 2013

GREECE GDP


28514.81
26917.76
24495.71
22830.53
22251.26
22565.68
22648.77
22687.6
23027.41
30000
28000
26000
24000
22000
2010
2012
2014
2016
2018
SOURCE: TRADINGECONOMICS.COM | WORLD BANK

Περιεπεμβατική θνητοτητα νοσηρότητα

Η ‘μοντέρνα’ TAVI ίσως να μην έχει σημαντική διαφορά στην επιβίωση 30 ημερών σε μεσαίου κινδύνου ασθενείς (>80 ετών) σε σχέση με την SAVR με βάση τυχαιοποιημένες μελέτες

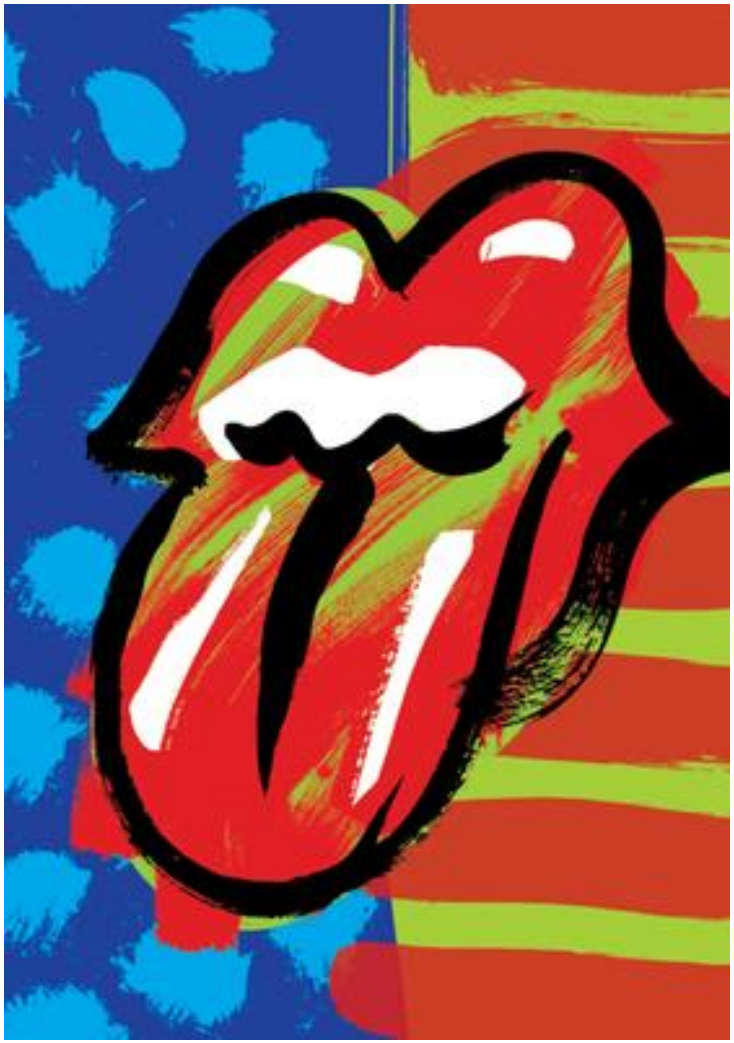
Η TAVI είναι κατώτερη της SAVR στη μεσοπρόθεσμη επιβίωση σε ασθενείς μεσαίου κινδύνου >80 ετών με βάση αναδρομικά τυχαιοποιημένες μελέτες από βάσεις δεδομένων του ‘αληθινού κόσμου’

Η transfemoral TAVI πλεονεκτεί έναντι της SAVR στην περιεπεμβατική χρήση παραγώγων αίματος, στον κίνδυνο επιδείνωσης της νεφρικής λειτουργίας και στην επίπτωση κολπικής μαρμαρυγής

Η TAVI υστερεί της SAVR στην ανάγκη εμφύτευσης βηματοδότη και στην υπολειπόμενη παραβαλβιδική διαφυγή.

“The only big things I’ve purchased are my dad’s heart valve and a Rolls Royce for my parents, for their anniversary.”

Lady GaGa



Mick Jagger Undergoes Successful Heart Valve Procedure

2:45 PM PDT 4/4/2019 by Dave Brooks, Billboard

Getty Images

Mick Jagger

Thank you for your attention