

Medium-low risk patients with AS: conventional, sutureless or TAVI?

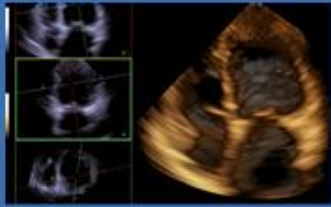
Francesco Musumeci MD, FETCS

**Director Department of Cardiac Surgery
and Regional Cardiac Transplantation**

Ospedale S. Camillo, *Rome, Italy*

www.eurovalvecongress.com





EuroValve

January 26-27, 2017

Faculty disclosure

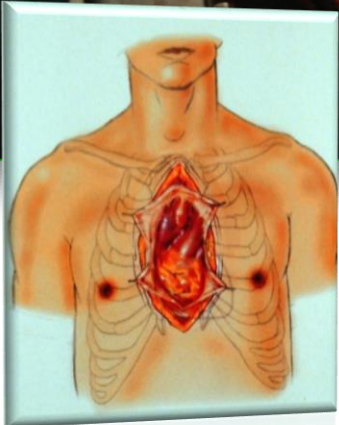
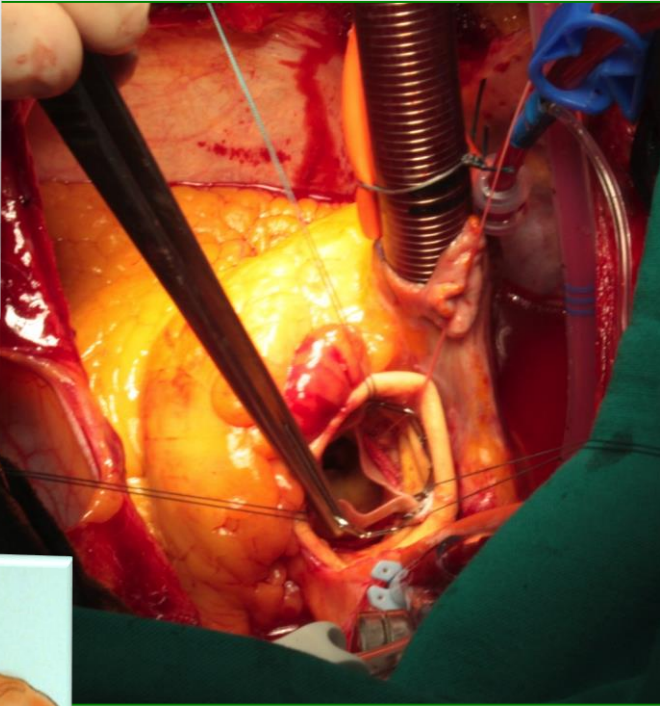
Francesco Musumeci

I have **no financial relationships** to disclose.

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AORTIC VALVE SURGERY

Which are
today early
and late
results of
conventional
surgery?

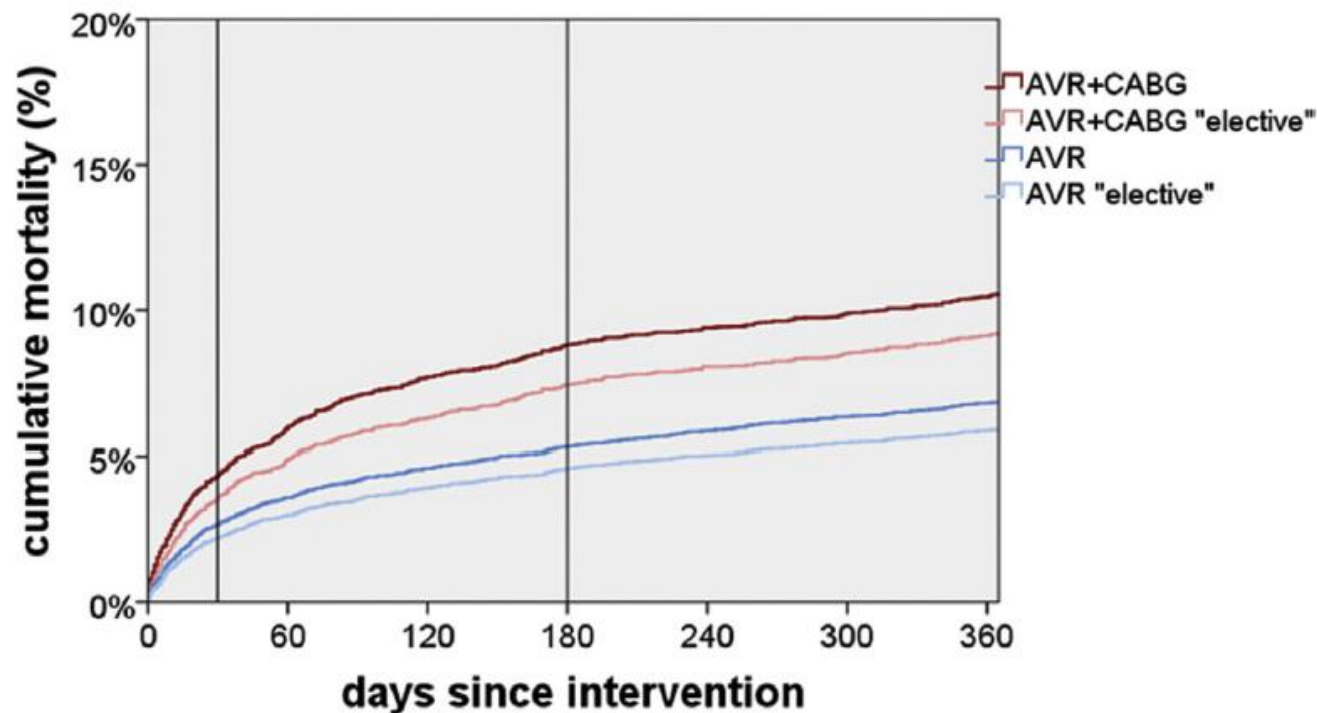


Current Results of Surgical Aortic Valve

Rep
Val

David
Helge
Hans
Rüdiger
Friedrich
Thomas
Konstantin
Christoph

Heart Center
Gefäßchirurgie
Germany
Munich, Germany
Saarland
Herzstiftung
Düsseldorf

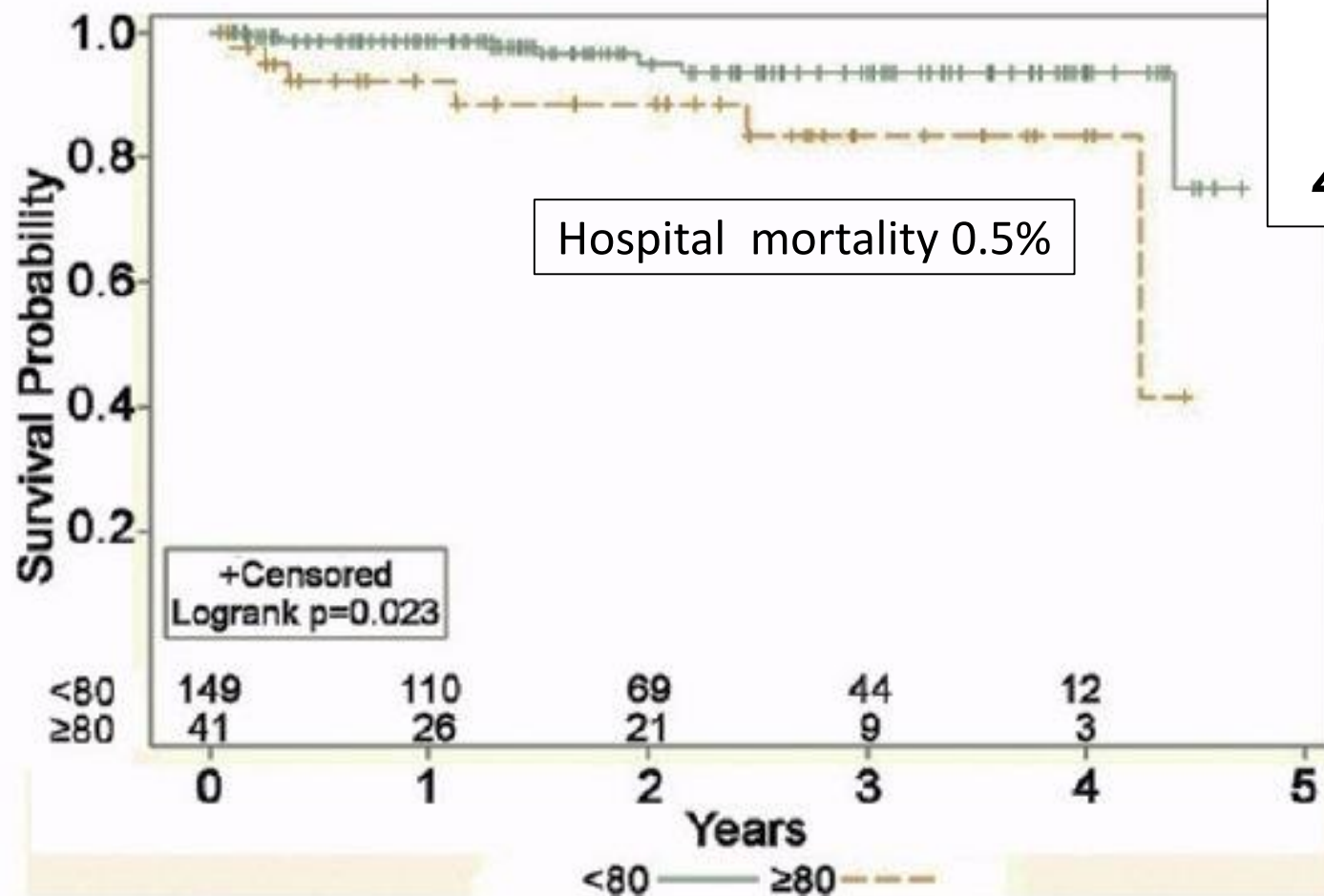


Death	sAVR (el.)	sAVR	sAVR+CABG (el.)	sAVR+CABG
In-hospital	1.9%	2.3%	3.5%	4.4%
180 Days	4.6%	5.3%	7.4%	8.8%
365 Days	5.9%	6.8%	9.2%	10.6%

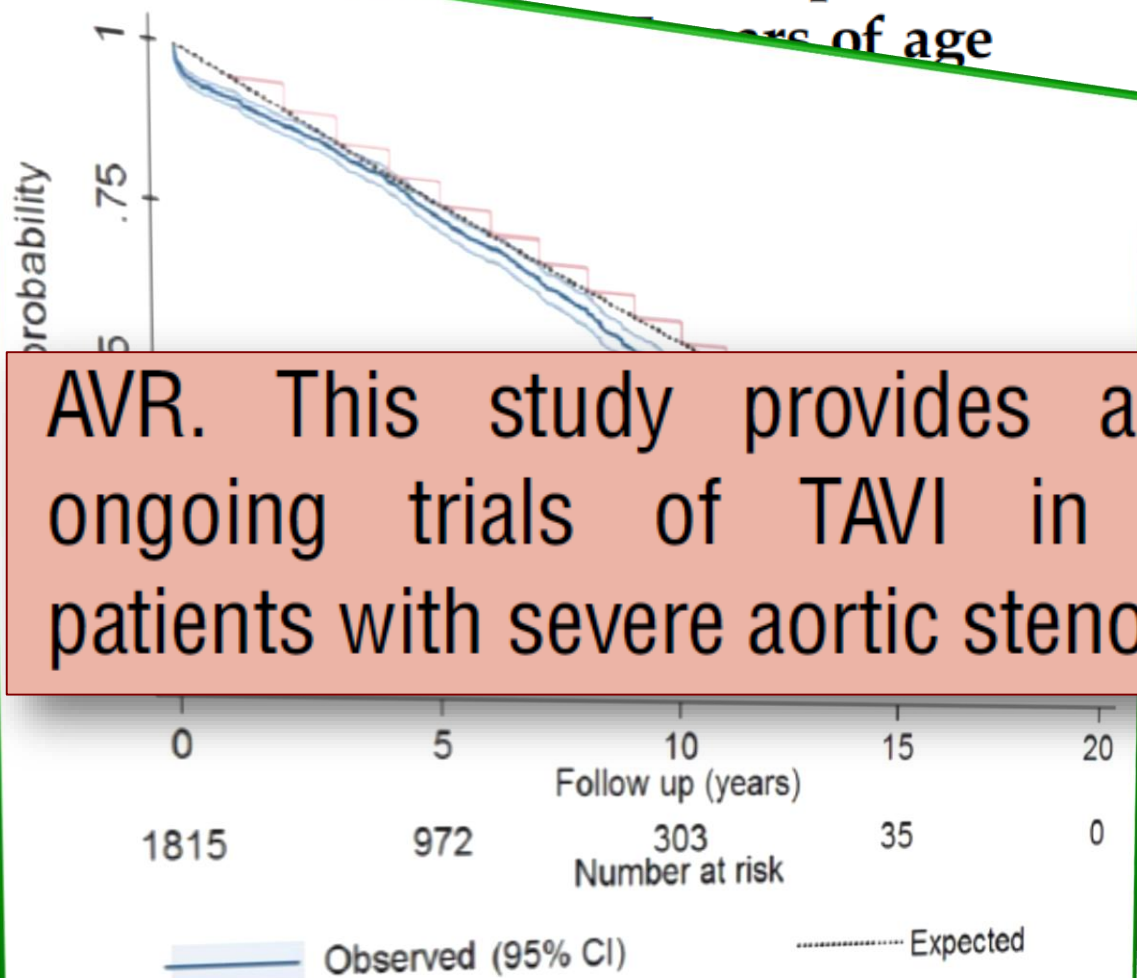
Contemporary Perioperative Results of Isolated Aortic Valve Replacement for Aortic Stenosis

S. Chris Malaisrie, MD, Patrick M. McCarthy, MD, Edwin C. M

190 patients
(mean age
 68 ± 13 yrs,
41pz > 80 yrs)



openheart Long-term survival after surgical aortic valve replacement among patients over 65 years of age



Fiorentino,¹ Gianni D Angelini,^{1,2}

KEY QUESTIONS

AVR. This study provides a benchmark for ongoing trials of TAVI in intermediate-risk patients with severe aortic stenosis.

patients over 65 years of age undergoing AVR and compares this to the expected survival of the general population. It demonstrates that long-term survival in this patient group is excellent.

How might this impact on clinical practice?

- Outcomes following AVR in elderly patients are excellent and, therefore, age should not be a factor when considering patients for surgical AVR. This study provides a benchmark for ongoing trials of TAVI in intermediate-risk patients with severe aortic stenosis.

cohort patients and the reference (operation year, age

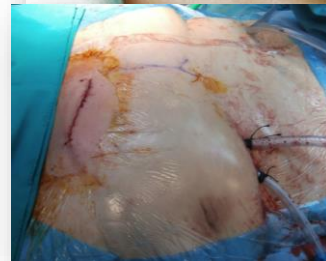
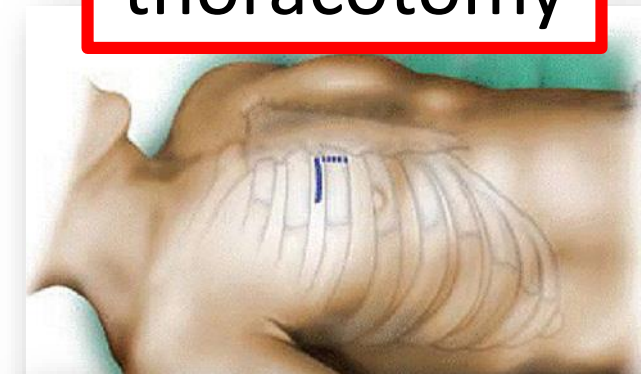
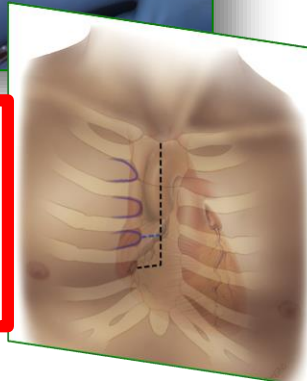
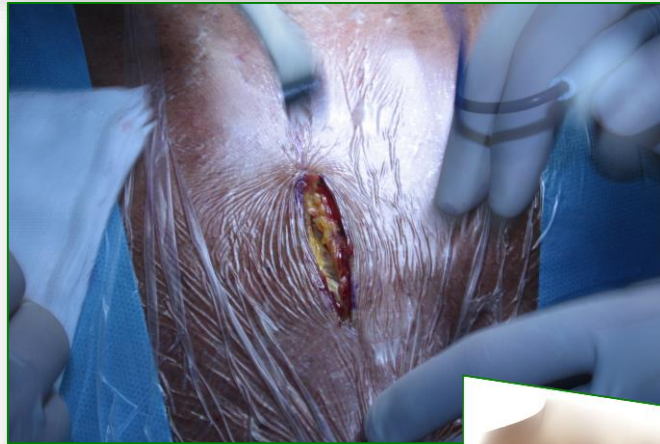
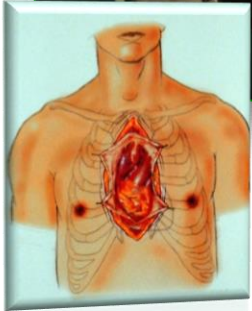
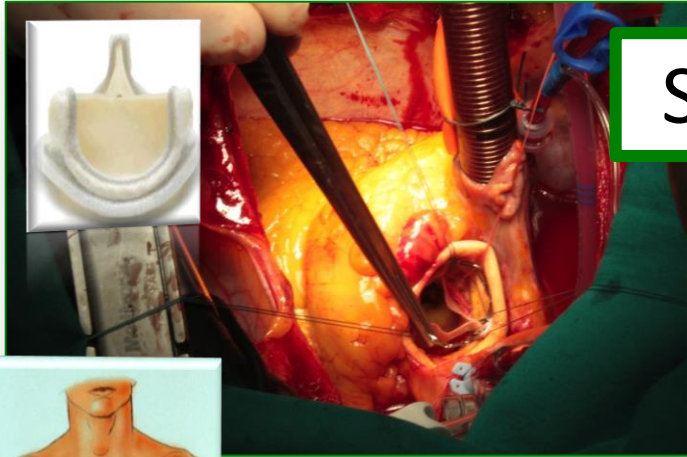
AORTIC VALVE SURGERY

Sternotomy

Surgical
options

Mini-
thoracotomy

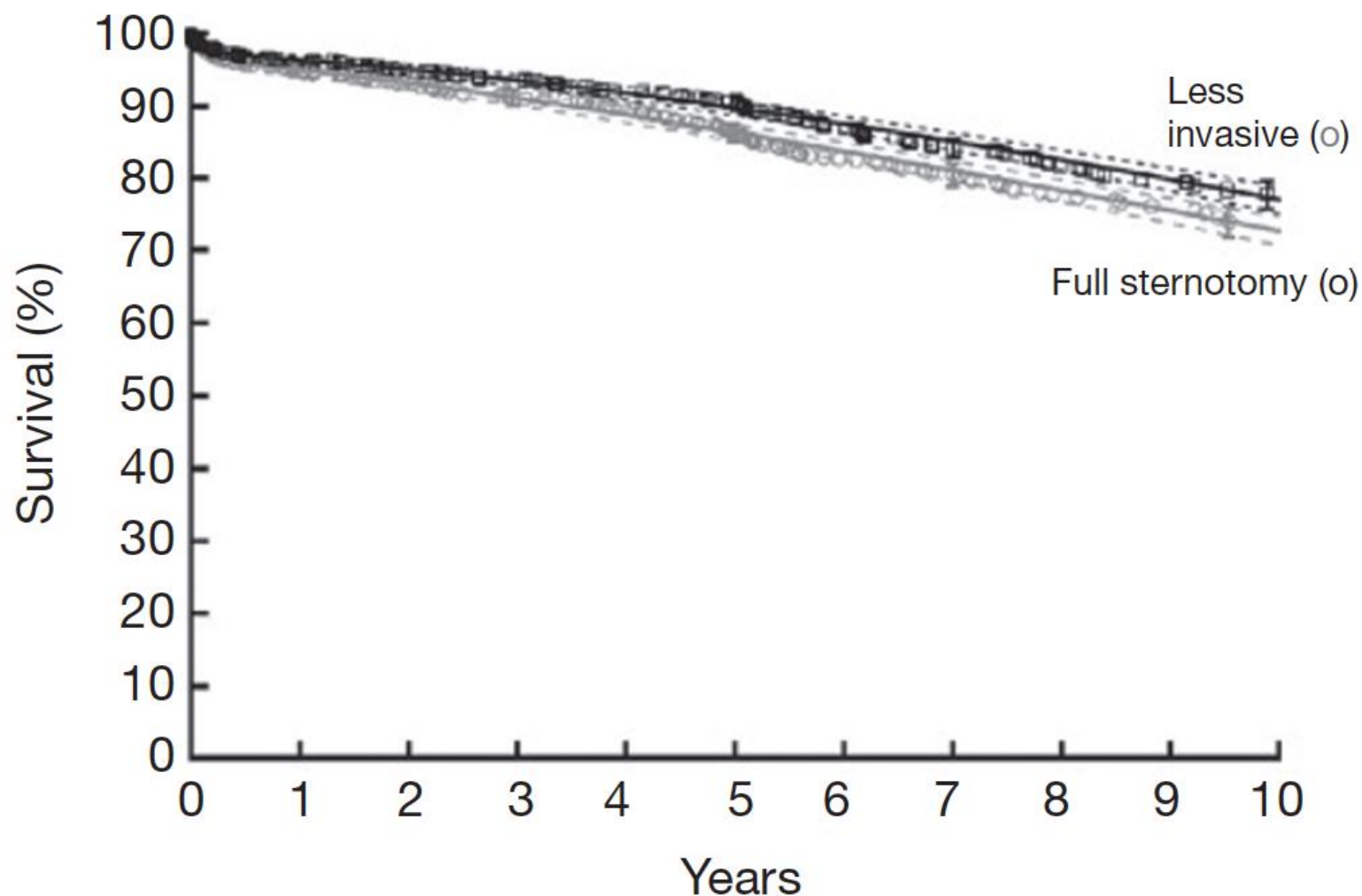
Mini-
sternotomy



Minimally invasive aortic valve surgery: Cleveland Clinic experience

Douglas R. Johnston, Eric E. Roselli

Heart
Corr
4419



Minimally Invasive and Conventional Aortic Valve Replacement: A Propensity Score Analysis

Daniyar Gilmanov, MD, Stefano Bevilacqua, MD, Michele Murzi, MD, Alfredo G. Cerillo, MD, Tommaso Gasbarri, MD, Enkel Kallushi, MD, Antonio Miceli, MD, and Mattia Glauber, MD

Department of Adult Cardiac Surgery, G. Pasquinucci Heart Hospital, Gabriele Monasterio Foundation, Massa, Italy

Background. The study aimed to compare the short-term results of aortic valve replacement through minimally invasive and sternotomy approaches.

Methods. This is a retrospective, observational, cohort study of prospectively collected data on 709 patients

8 vs 7 hours, $p = 0.022$). Overall in-hospital mortality was identical between the groups (1.64 vs 1.64%, $p = 1.0$). No difference in the incidence of major and minor post-operative complications and related morbidity was observed. Minimally invasive aortic valve replacement

To conclude, in our experience, minimally invasive isolated aortic valve surgery is a reproducible procedure as safe and effective as AVR through sternotomy, with similar morbidity and mortality, and reduces assisted ventilation duration, the need for blood product transfusion, and incidence of post-surgery AF.

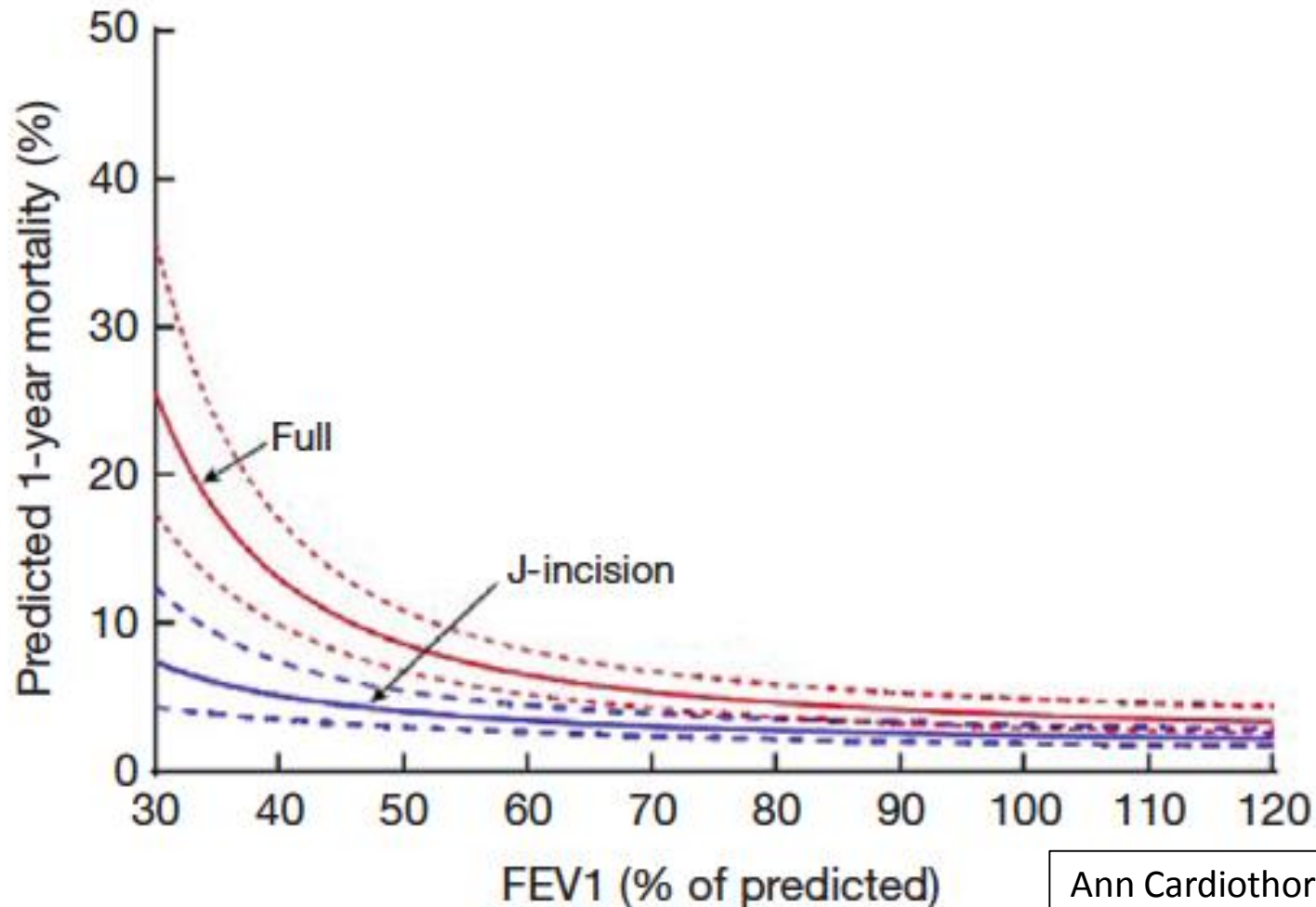
Minimally invasive aortic valve surgery: Cleveland Clinic experience

Don

Heart

Corres

44195



Ann Cardiothorac Surg 2015

Predicted 1-year risk-adjusted mortality according to preoperative FEV1% stratified by approach

Outcomes of Minimally Invasive Valve Surgery Versus Median Sternotomy in Patients Age 75 Years or Greater

Joseph Lamelas, MD, Alejandro Sarria, MD, Or Andres M. Pineda, MD, and Gervasio A. Lama

oValve

**Elderly
patients**

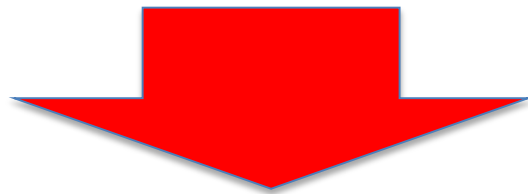
Table 3. Results

Outcomes	Median Sternotomy	Right Minithoracotomy	<i>p</i> Value
Postoperative complications (%)	38 (45)	25 (21)	<0.001
In-hospital death (%)	8 (9.5)	2 (1.7)	0.01
Stroke (%)	4 (4.8)	4 (3.4)	0.61
Reoperation for bleeding (%)	5 (6)	8 (6.7)	0.83
Prolonged ventilation (%)	32 (38)	23 (19)	0.003
Renal failure (%)	14 (16.7%)	1 (0.8%)	<0.001
Wound infection (%)	5 (6%)	1 (0.8%)	0.03
Intensive care unit length of stay hours (IQR)	119 (57–193)	52 (44–93)	<0.001
Total hospital length of stay days (IQR)	12 (9–20)	7 (6–10)	<0.001



Minimally Invasive

Advantages



Smother post-op recovery
particular in the elderly,
obese and in sick patients

Lawrence 00 07 0047



Do rapid deployment aortic valves improve outcomes compared with standard surgical aortic valve replacement?



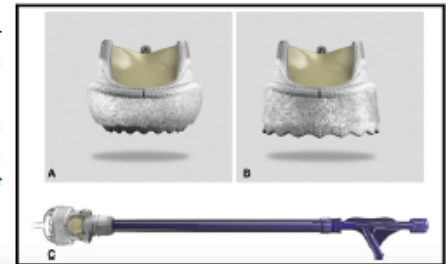
Early outcomes after isolated aortic valve replacement with rapid deployment aortic valve

Thorsten C. W. Wahlers, MD, PhD,^a Axel Haverich, MD,^b Michael A. Borger, MD, PhD,^c Malakh Shrestha, MBBS, PhD,^b Alfred A. Kocher, MD,^d Thomas Walther, MD, PhD,^c Matthias Roth, MD,^c Martin Misfeld, MD,^c Friedrich W. Mohr, MD, PhD,^c Joerg Kempfert, MD,^c Pascal M. Dohmen, MD, PhD,^f Christoph Schmitz, MD,^g Parwis Rahmanian, MD,^a Dominik Wiedemann, MD,^d Francis G. Duhay, MD,^h and Günther Laufer, MD^d

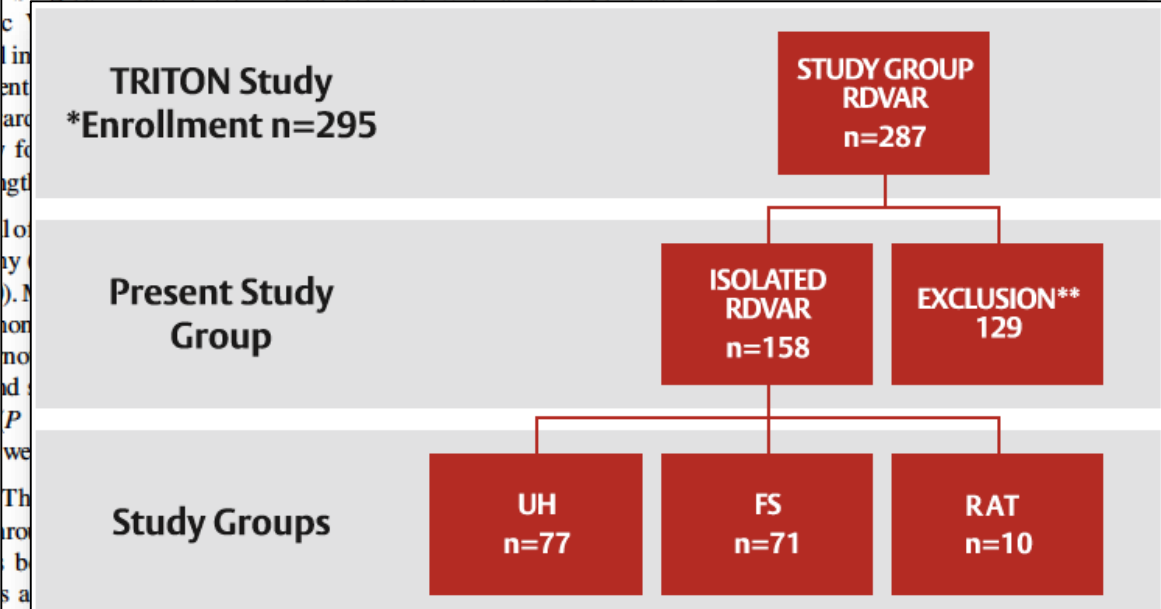
ABSTRACT

Minimally invasive aortic valve replacement is associated with favorable outcomes; however, several meta-analyses have reported significantly longer times compared with a full sternotomy. We examined the early safety outcomes after isolated rapid deployment aortic valve replacement using a minimally invasive surgical approach in patients enrolled in the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve trial.

Surgical Treatment of Aortic Stenosis With a Next Generation



TRITON Trial
Prospective, non
randomized, single
arm, multicenter
trial with the
EDWARD INTUITY
Valve



Further, low in-hospital mortality and new permanent pacemaker rates were observed regardless of surgical approach. (J Thorac Cardiovasc Surg 2016;151:1639-47)

INTUITY

Early outcomes after isolated aortic valve replacement with rapid deployment aortic valve

Longer operating time with RAT

TABLE 3. Procedural outcomes

Variable	FS n:	MUS n:	Right thoracotomy	Overall MIS	All approaches	P value			
	mean ± SD	mean ± SD	n: mean ± SD	(MUS + RAT) n:	n: mean ± SD	P value*	FS vs MIS†	FS vs RAT†	MIS vs RAT†
	(min, max) median	(min, max) median	(min, max) median	(min, max) median	(min, max) median				
CPB time (min)	71: 71.6 ± 41.8 (39.0, 366.0) 63.0	77: 69.6 ± 19.1 (40.0, 138.0) 68.0	10: 122.2 ± 22.1 (97.0, 161.0) 116.0	87: 75.7 ± 25.6 (40.0, 161.0) 70.0	158: 73.9 ± 33.8 (39.0, 366.0) 66.5	<.0001	.9277	<.0001	<.0001
Crossclamp time (min)	71: 43.5 ± 32.5 (13.0, 293.0) 37.0	77: 43.1 ± 13.1 (23.0, 107.0) 40.0	10: 88.3 ± 18.6 (64.0, 117.0) 82.5	87: 48.3 ± 20.0 (23.0, 117.0) 41.0	158: 46.1 ± 26.4 (13.0, 293.0) 40.0	<.0001	.9930	<.0001	<.0001
Skin-to-skin time (min)	70: 158.5 ± 53.0 (92.0, 455.0)	77: 116.0 ± 33.0 (64.0, 293.0) 82.5	10: 141.0 ± 33.0 (92.0, 293.0)	87: 157.5 ± 44.0 (92.0, 293.0)	158: 159.0 ± 40.0 (92.0, 293.0)	<.0001	.9930	<.0001	<.0001

CONCLUSIONS

These data suggest that isolated RDAVR through a UHS can lead to shorter crossclamp times than have been historically reported in the surgical literature (Table 5). This benefit may facilitate minimally invasive AVR by lessening the concern over prolonged crossclamp times, which have been reported in meta-analyses. Further, a low in-hospital mortality, early (<30 days) mortality, and new permanent pacemaker implant rates were observed regardless of surgical approach; however, longer-term follow-up is necessary to further evaluate the benefits of these surgical approaches.

TABLE 4. Discharge outcomes

Variable	
Hospital length of stay (d)	69
ICU length of stay (h)	69
Intermediate care length of stay (h)	69
In-hospital mortality	2.3

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n:

P
value

.08

.39

.01

.72



Perioperative outcomes with sutureless versus stented biological aortic valves in elderly persons

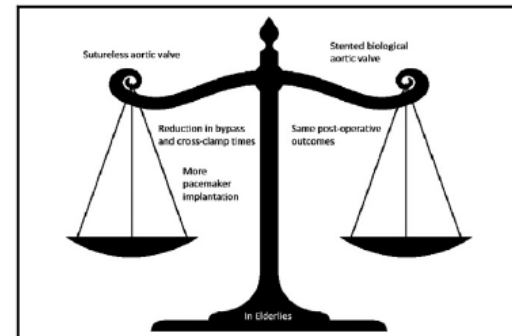
Jessica Forcillo, MD, MSc, Denis Bouchard, MD, PhD, Anthony Nguyen, MD, MSc, Louis Perrault, MD, PhD, Raymond Cartier, MD, Michel Pellerin, MD, MSc, Philippe Demers, MD, MSc, Louis Mathieu Stevens, MD, PhD, and Michel Carrier, MD, MBA

ABSTRACT

Objectives: Sutureless aortic valves are deemed suitable for patients considered at high risk for surgery. The objective of this study is to evaluate the perioperative results of implanting a sutureless valve in elderly persons, compared with a stented biological valve in the aortic position.

Methods: Between 2011 and 2015, 76 patients underwent aortic valve replacement with the Perceval prosthesis (Sorin Group, Saluggia, Italy). The group was compared with 319 consecutive patients who received aortic valve replacement with the stented valve in that same period.

Results: The mean age of patients was 83 ± 2 years in the Perceval group and 83 ± 3 years in the stented valve group ($P = .3$). Preoperative demographics were similar in both groups. Median cardiopulmonary bypass and crossclamp times were lower in the Perceval group than in the stented valve group ($P < .001$). Mortality was 5% in the Perceval group and 6% in the stented valve group.



Sutureless aortic valve versus stented biological aortic valve.

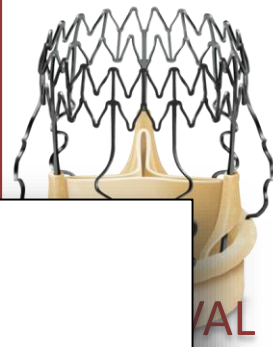
Central Message

Sutureless aortic valve prosthesis decreases cardiopulmonary bypass time in elderly per-

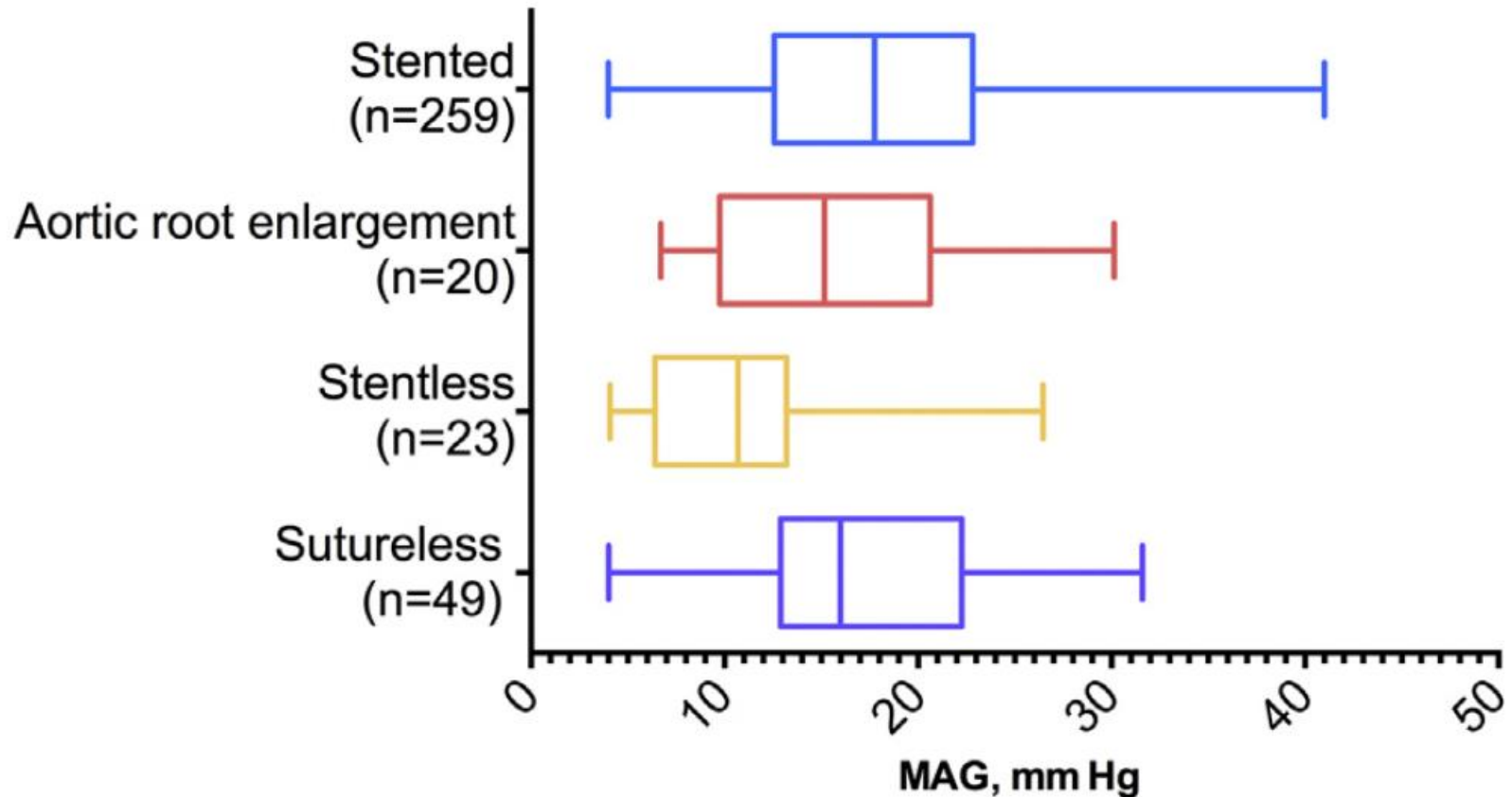
Conclusions: Aortic valve replacement with a sutureless prosthesis resulted in shorter aortic crossclamp and bypass times compared with a stented biological prosthesis. The reduced cardiopulmonary bypass and aortic crossclamp times obtained using the Perceval prosthesis did not translate into perioperative gains in our population of elderly patients. (J Thorac Cardiovasc Surg 2016;151:1629-36)

tion of a pacemaker for third-degree AV block with the use of sutureless valves.

Management of small aortic annulus in the era of sutureless valves: A comparative study among different biological options



AL



Conclusions: In our study, stentless AVR and Trifecta bioprostheses had the best hemodynamic outcomes. The Perceval sutureless prosthesis provides reasonable hemodynamic performance and is a safe alternative. (J Thorac Cardiovasc Surg

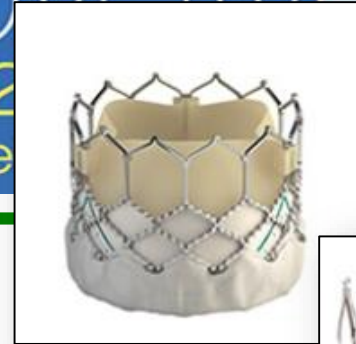
SUTURELESS AORTIC VALVE

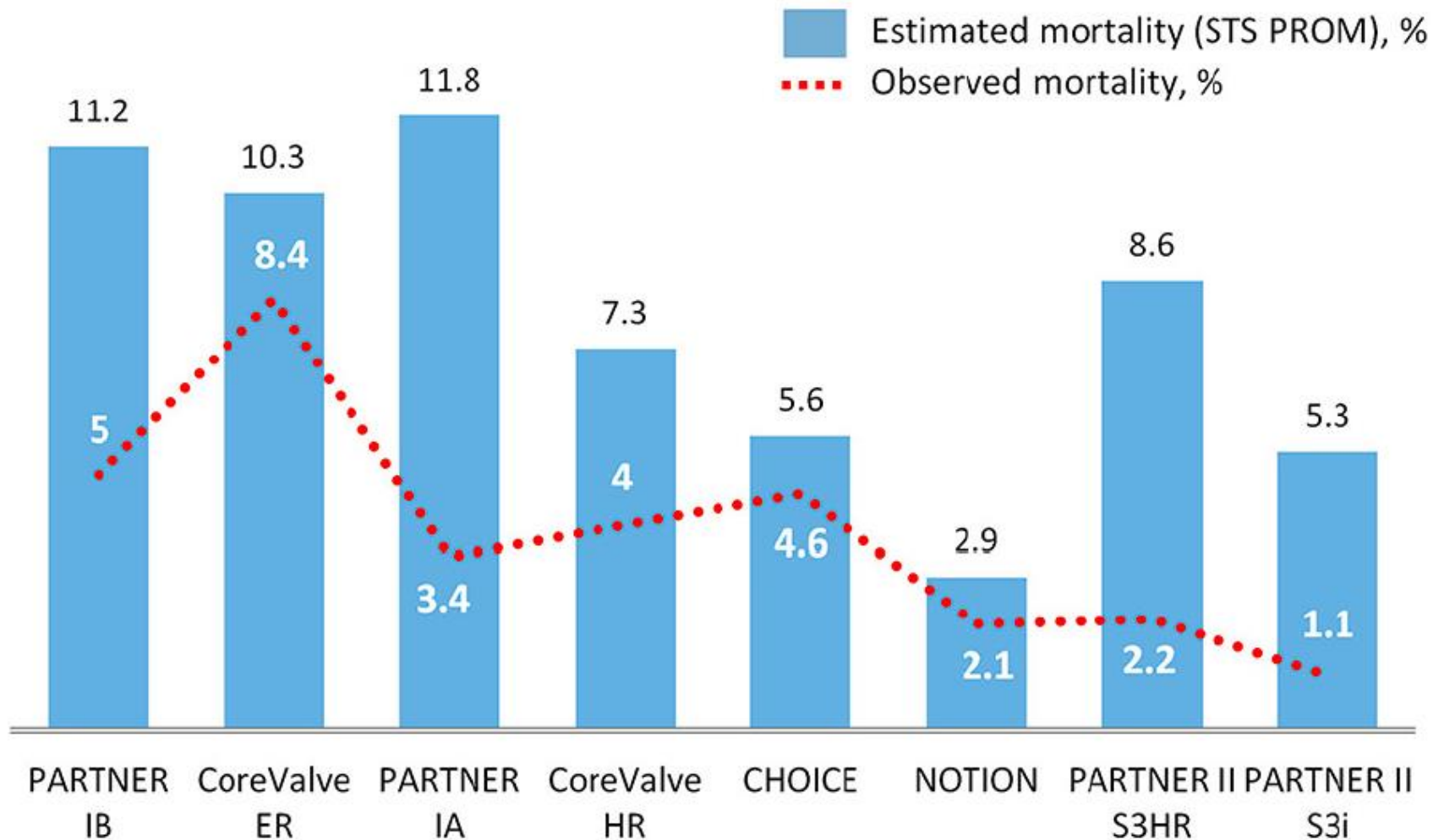
- Similar early results to stented valve
- May facilitate MICS procedures
- Reduce X-clamp and CPB time.
- Lower gradients than comparable stented alternatives.
- Good option for patients with small aortic root





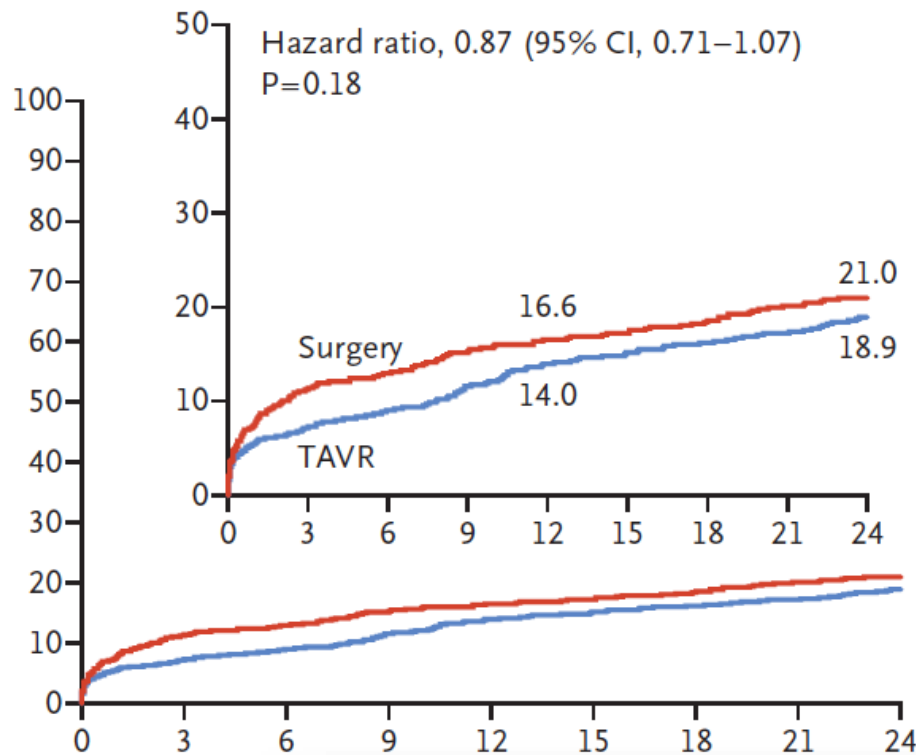
With current result
with Surgery, is there a
place for TAVI in Low
to Intermediate risk
patients with Severe
Aortic Valve Stenosis?





Estimated and observed all-cause 30-day mortality after TAVI in randomized trials and FDA approval studies.

Death from Any Cause
or Disabling Stroke (%)



No. at Risk

TAVR	994	917
Surgery	944	826

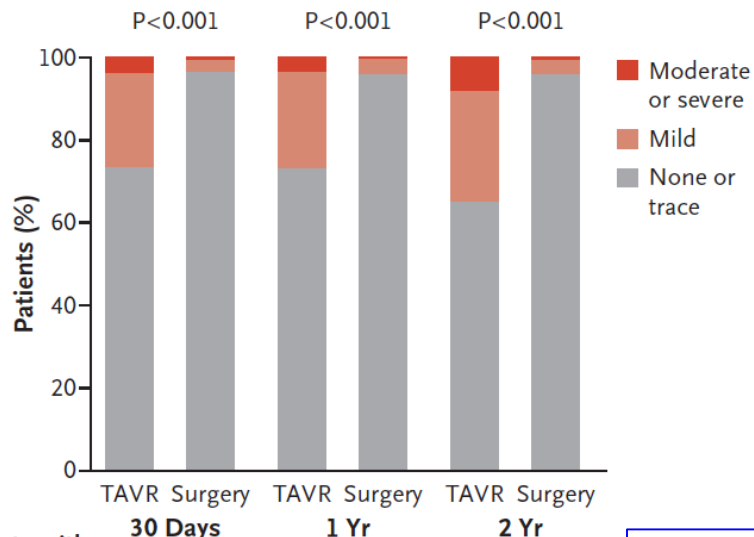
Alfredo T
Rebe

GLAND MEDICINE

**Only 2 years
follow-up**

In conclusion, we found that in intermediate-risk patients with severe symptomatic aortic stenosis, surgical and transcatheter valve replacement were similar with respect to the primary end point of death or disabling stroke for up to 2 years and resulted in a similar degree of lessening of cardiac symptoms.

Paravalvular Aortic Regurgitation



No. of Patients with Echocardiographic Findings

TAVR	872	728	600
Surgery	757	611	514

Lars G. Svensson, M.D., Ph.D., Susan D. Craig Miller, M.D., Howard C. Augustus D. Pichard, M.D., Sam

The SAPIEN XT valve used in this trial has now been replaced by the SAPIEN 3 valve

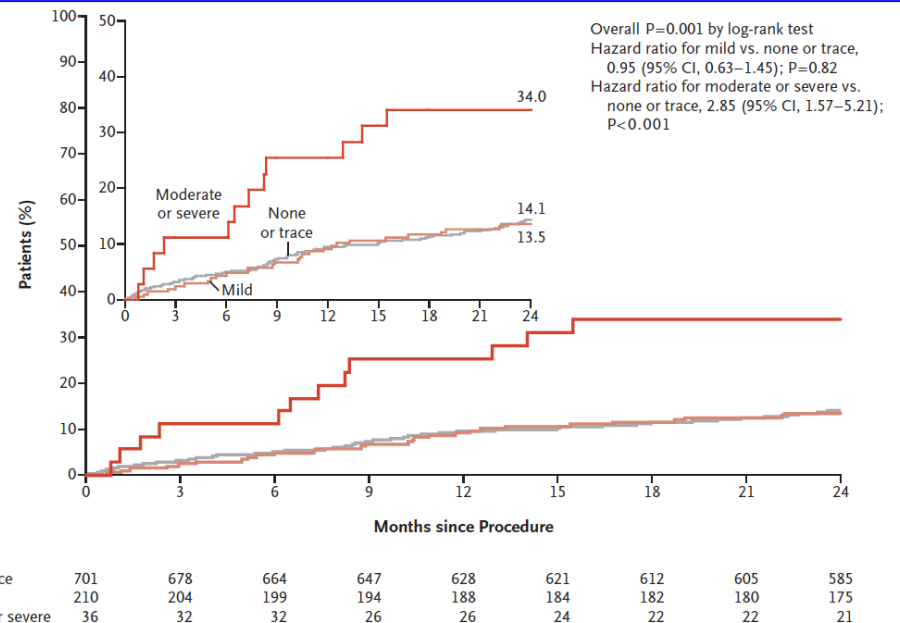
ENGLAND
of MEDICINE

APRIL 28, 2016

VOL. 374 NO. 17

Transcatheter Aortic-Valve Replacement

Death from any cause, according to severity of Paravalvular Aortic Regurgitation





Propensity of transcatheter conventional aortic stenosis

Javier Castrodeza^{1*}

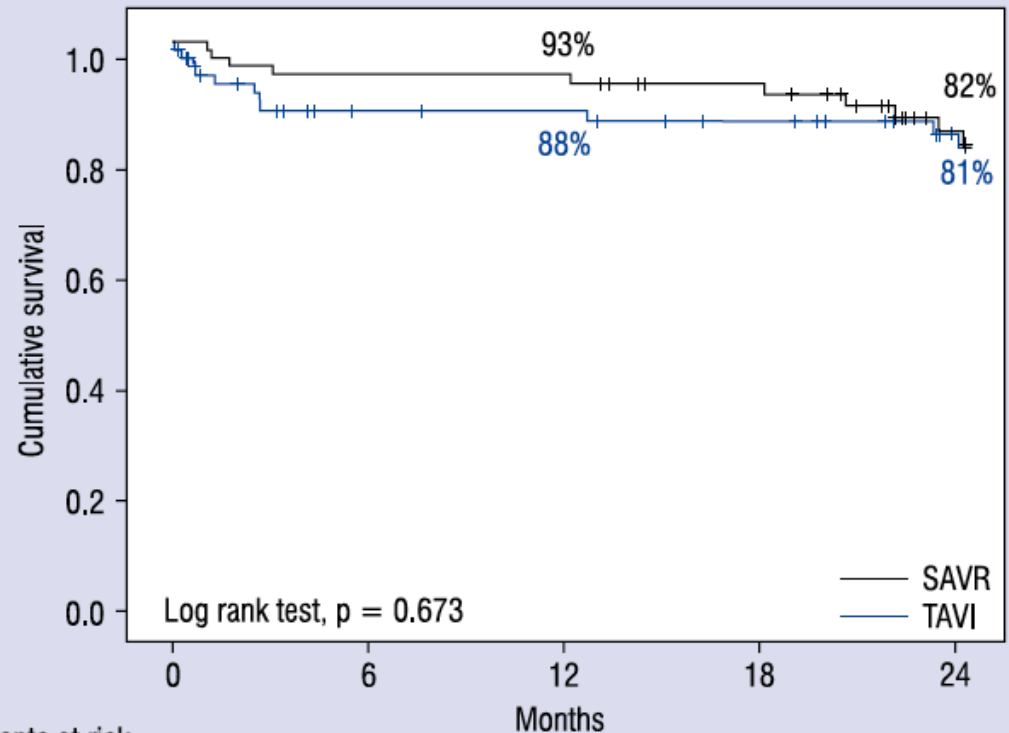
Javier Tobar¹, Irene

Paol Rojas¹, Lu

¹Cardiology Depart

²Cardiac Surgery Dep

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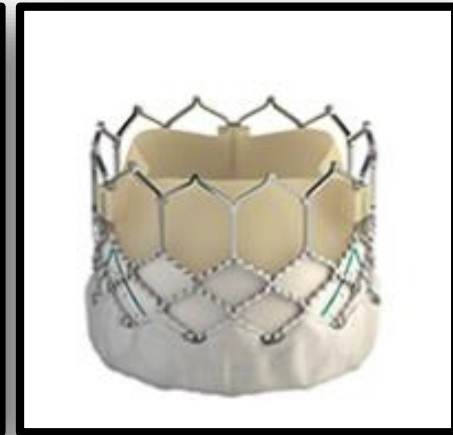


No. of patients at risk

SAVR	70	68	65	62	57
TAVI	70	66	61	61	56

Conclusions: TAVI is feasible and shows comparable results to surgery in terms of early, 1-year mortality, as well as cerebrovascular events in patients with severe aortic stenosis and intermediate-low operative risk. Better transvalvular gradients, yet higher rates of AR were found, however, newer devices presented comparable rate of AR. (Cardiol J 2016; 23, 5: 541–551)

VS



Do rapid deployment aortic valves improve outcomes compared with **Transcatheter Aortic Valve Implantation**?

Central Message

In a propensity-matched analysis, SU-AVR, compared with TAVI, had better device success and a lower incidence of PVL but similar 30-day and 1-year mortality.



Perspective

The search for the ideal valve substitute for “intermediate-risk” patients (the so-called “grey zone”) is ongoing. This propensity-matched analysis shows that SU-AVR and TAVI are both good solutions. TAVI provides better gradients and a shorter length of stay, but SU-AVR has less PVL. These results may provide help in choosing the best therapeutic option for each patient.

Objective Transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SU-AVR) are suitable alternatives for aortic stenosis. The aim of this study is to compare early outcomes of TAVI and SU-AVR.

Methods: Data were analyzed on patients who underwent SU-AVR. Two matched cohorts (TAVI and SU-AVR) were identified based on propensity scores; all analyses were repeated using a per-protocol analysis. Outcomes were defined according to the STS/AHA Research Consortium-2 criteria.

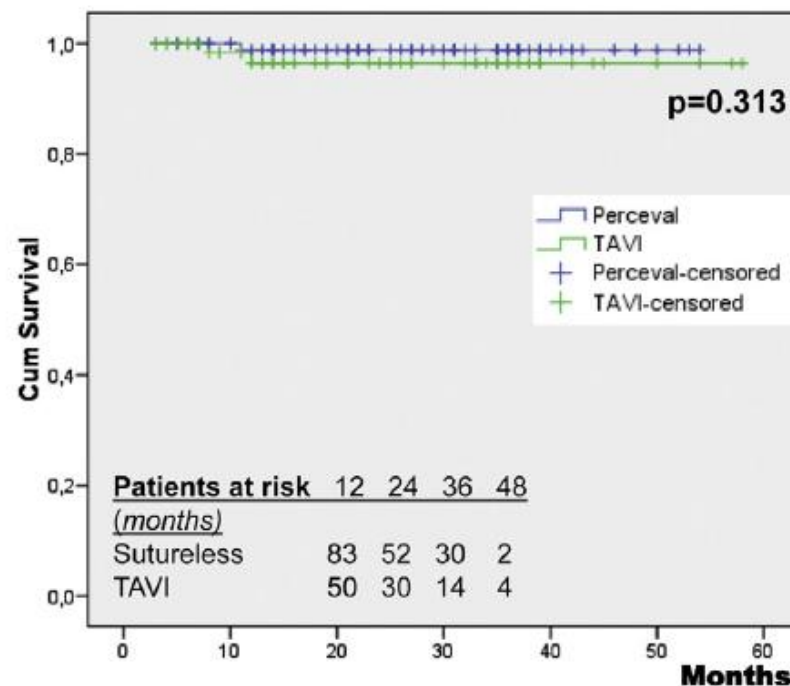
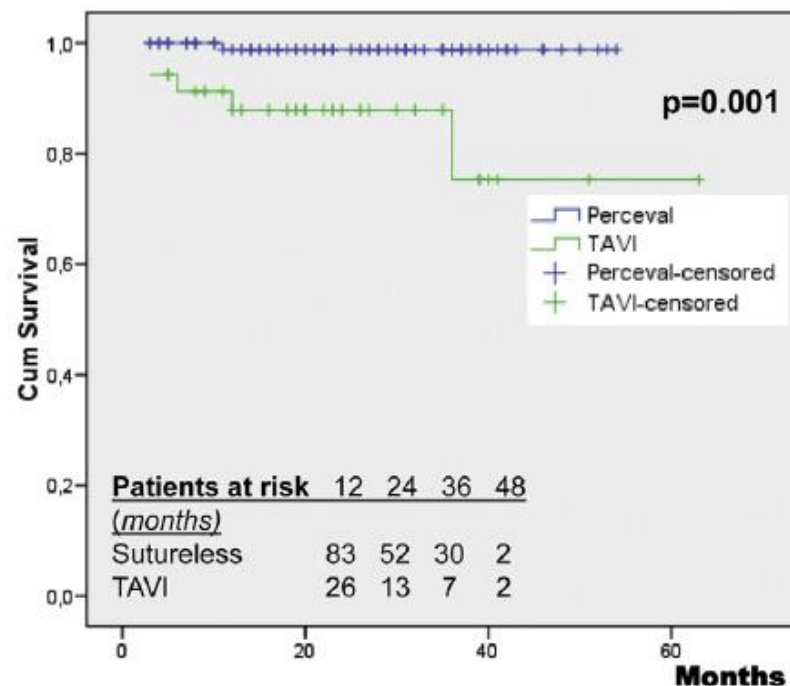
Results: A total of 2177 patients were included in the analysis: 1092 treated with TAVI; 292 (13.4%) treated with SU-AVR. The incidence of mortality in TAVI and SU-AVR patients was 7.1% and 2.1%, respectively, at 1 year. No significant difference in mortality in the 214 matched patient pairs (3.7% vs 4.6%, respectively, $P = .08$). Patients treated with TAVI showed a lower incidence of PVL (1.9% vs 98.6%; $P < .001$) and pacemaker implantation (1.9% vs 12.9%; $P < .001$) but a higher incidence of any paravalvular leakage (12.9% vs 4.6%; $P < .001$).

Conclusions: SU-AVR is associated with better outcomes in terms of PVL, compared with TAVI. Nevertheless, TAVI was more likely to receive a permanent pacemaker. Both procedures provide good results in patients who have severe symptomatic aortic stenosis. In the multiple therapeutic options available, patient selection is most appropriate for their clinical and anatomic characteristics. (Cardiovasc Surg 2016;152:99-109)

Clinical Outcome and Cost Analysis of Sutureless Versus Transcatheter Aortic Valve Implantation With Propensity Score Matching Analysis



Sutureless vs TAVI with para-valvular insufficiency Sutureless vs TAVI without para-valvular insufficiency



survival rate. The costs associated to the 2 procedures are similar when the cost of the

New TAVI prostheses, by minimizing the risk of paravalvular leak (e.g., Lotus or Sapien 3), may achieve comparable if not better results than those reported with surgical AVR

Transcatheter heart valve failure: a systematic review

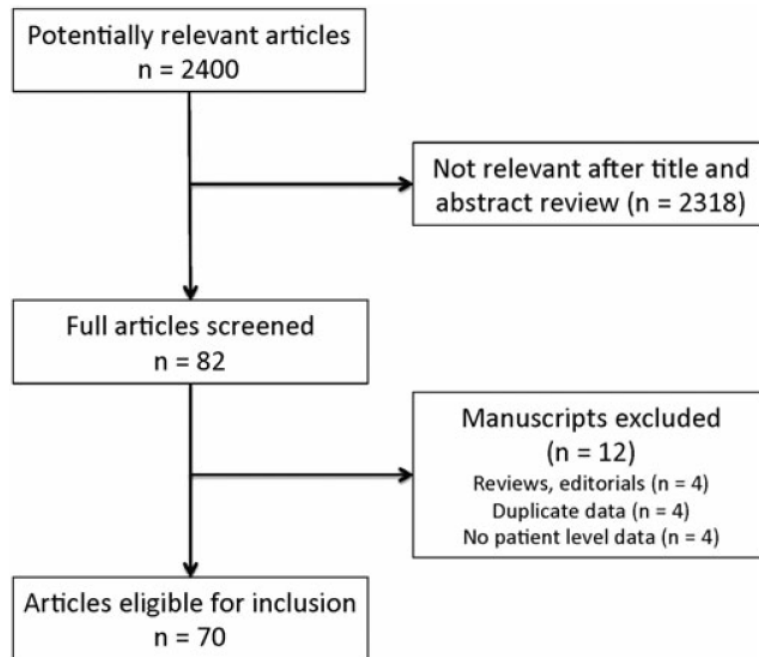


Figure 1 Electronic literature search. Summary of the literature search results.

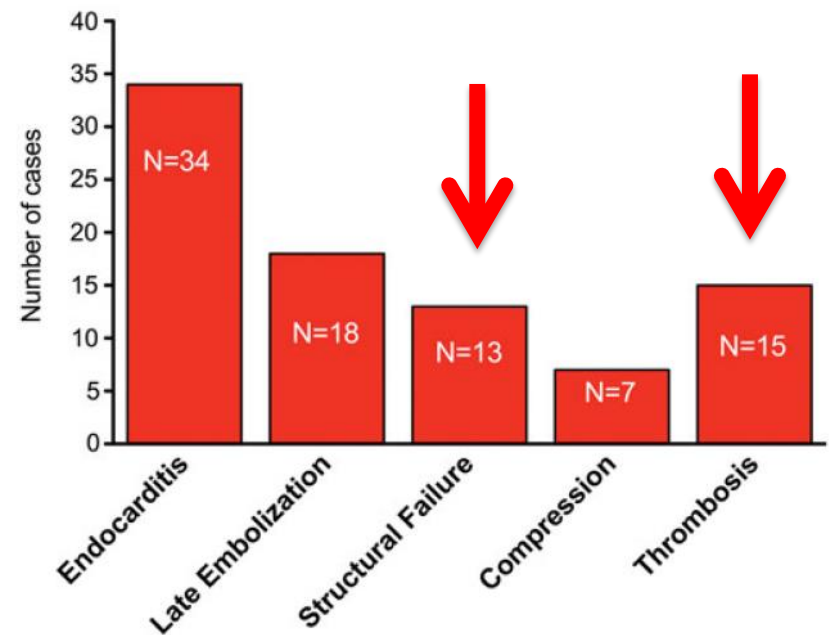


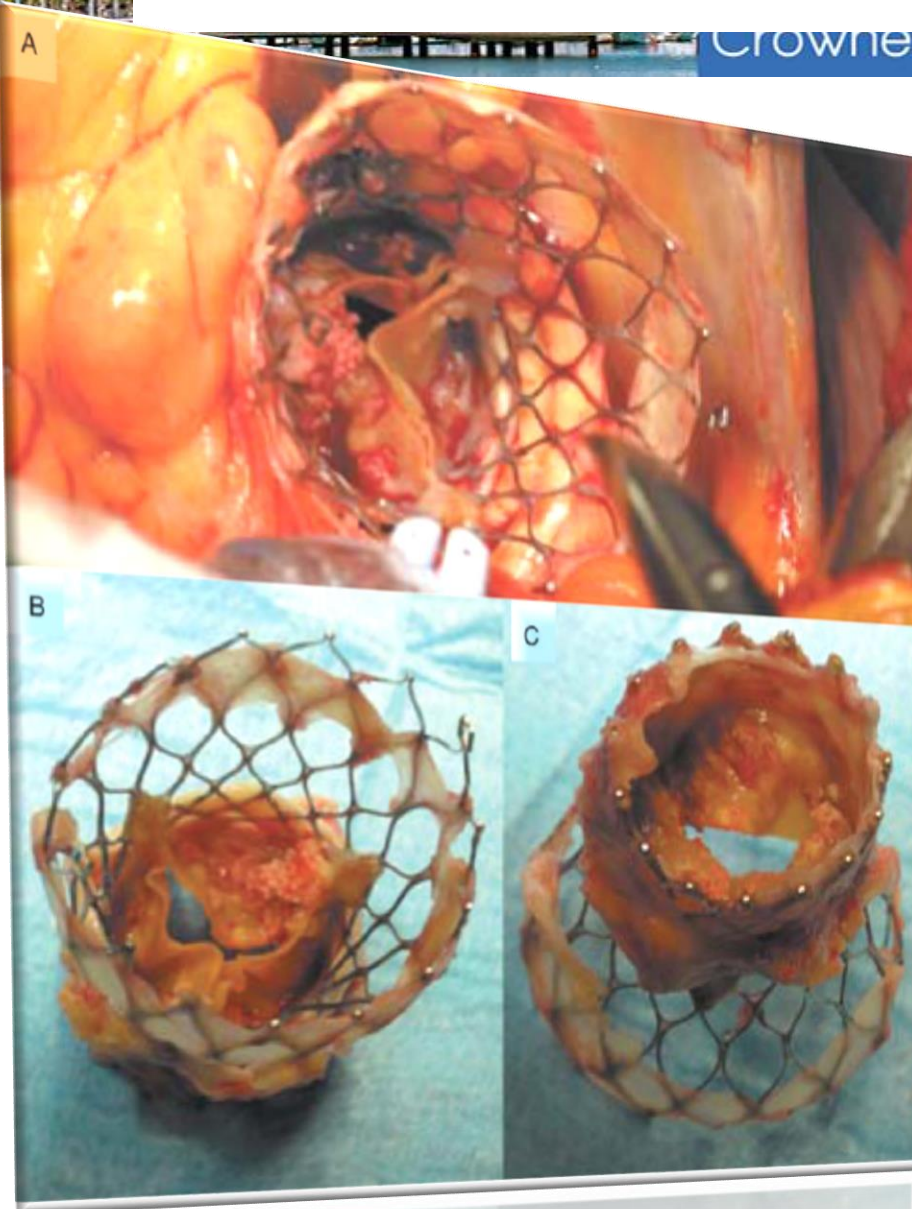
Figure 2 Transcatheter heart valve failure. Aetiology of transcatheter heart valve failure in this systematic review.

THV structural failure

Crowne Plaza Barcelona Fira Center, SPAIN

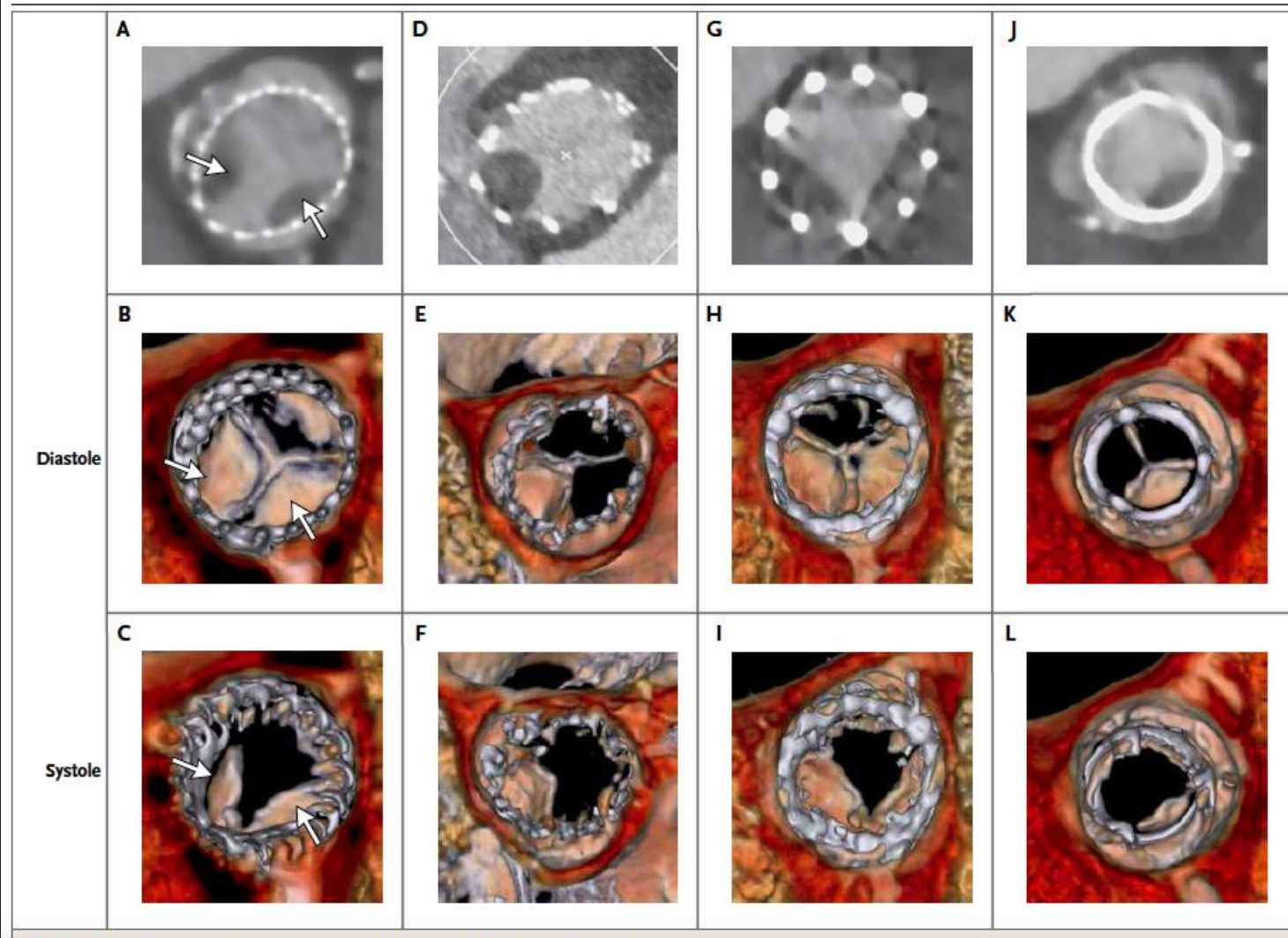
Causes

- Severe leaflet calcification
- Cusp rupture
- THV under expansion
- Tissue ingrowth causing restrictive leaflet function



Transcatheter heart valve failure: a systematic review

- The study highlights several modes of TAVI failure that **will be seen with greater frequency** as experience with the technique increases.
- It is likely that the current case report and small series literature on TAVI failure reflects a **significant under-reporting of events**.

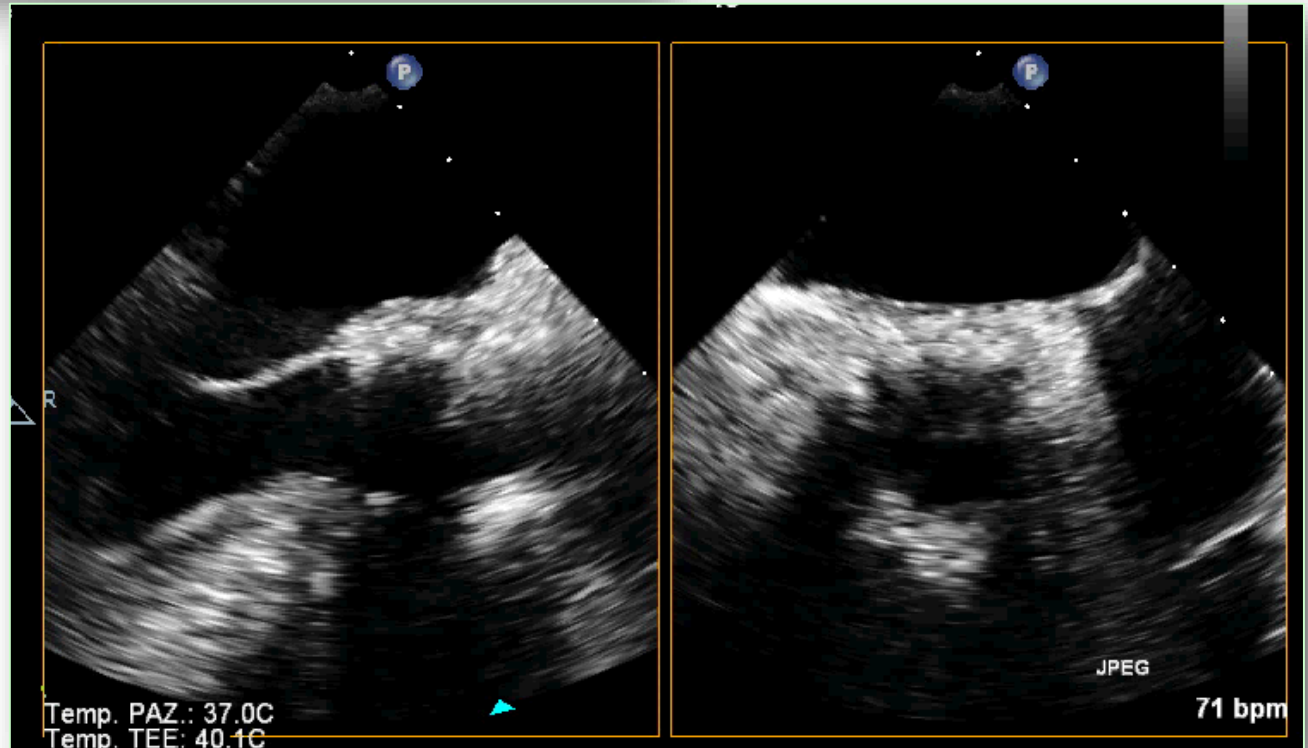


CONCLUSIONS

Reduced aortic-valve leaflet motion was shown in patients with bioprosthetic aortic valves. The condition resolved with therapeutic anticoagulation. The effect of this finding on clinical outcomes including stroke needs further investigation. (Funded

THV

thrombosis





THV thrombosis

ve
2017

Crowne Plaza Barcelona Nord Center, SPAIN



THV structural failure

EuroPCR 2016

Half of transcatheter heart valves show degeneration within 10 years of TAVI

On Kaplan-Meier analysis, the curve for **freedom from degeneration** drops from **94% at 4 years** to **82% at 6 years** and to approximately **50% at 8 years** among surviving patients



In conclusion



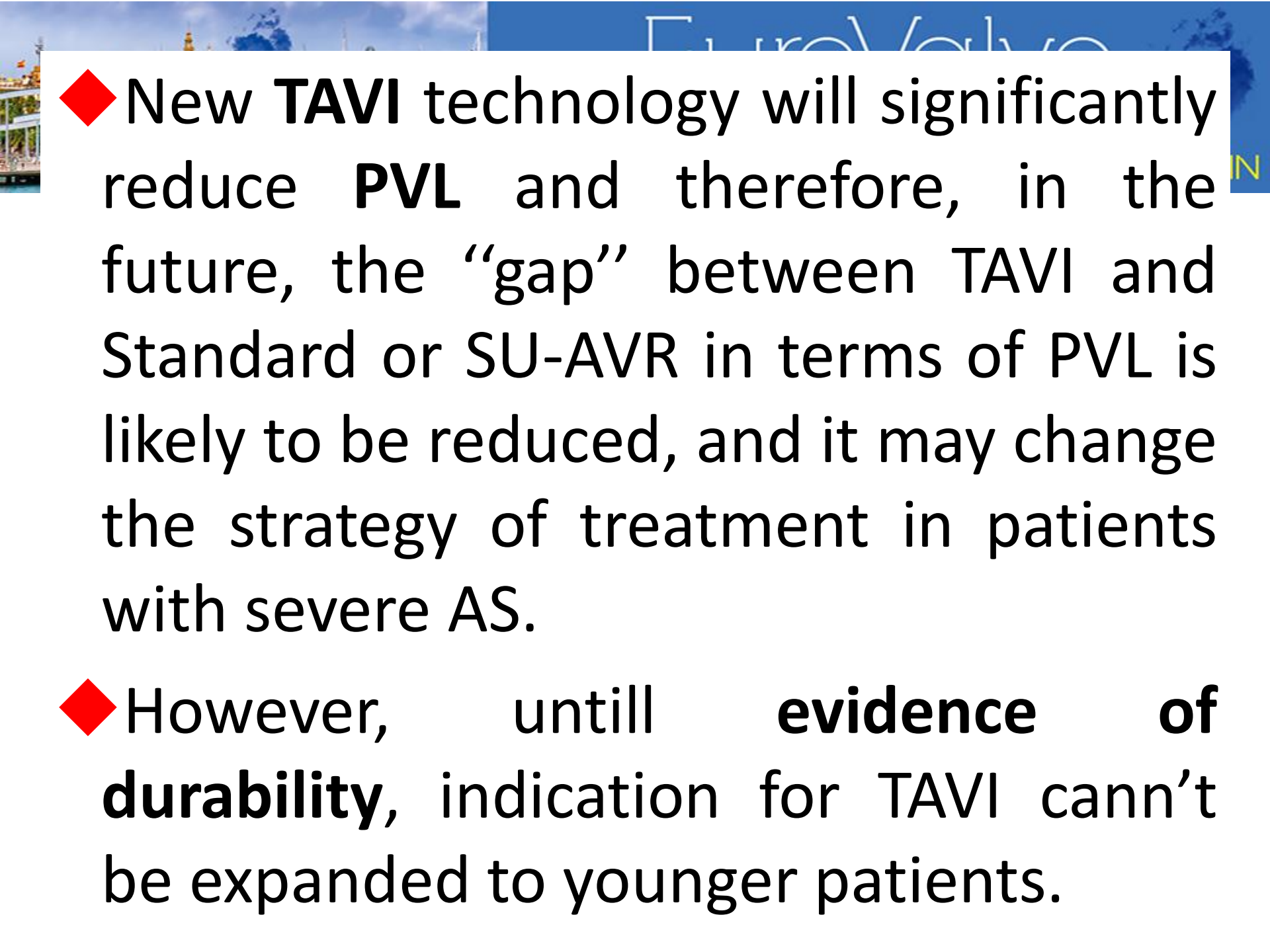
- ◆ Currently, conventional Aortic Valve replacement remains the ***standard*** for Medium-Low risk patients with AS.
- ◆ A **Minimally Invasive approach** may improve outcome in elderly, obese and sicker patients.



- ◆ Short-term excellent outcomes can be achieved with **sutureless valve**. It may be a good option for **small aortic root**. The shorter surgical time may play a crucial role in **very sick patients**.
- ◆ However, longer-term follow-up is necessary to further evaluate durability and benefits of these valves.



◆ **TAVI** has become a safe and effective therapy for patients with aortic stenosis, with early comparable results to surgery in patients with severe AS and intermediate to low operative risk.



◆ New **TAVI** technology will significantly reduce **PVL** and therefore, in the future, the “gap” between TAVI and Standard or SU-AVR in terms of PVL is likely to be reduced, and it may change the strategy of treatment in patients with severe AS.

◆ However, until **evidence of durability**, indication for TAVI can't be expanded to younger patients.

The background of the image is a photograph of the Colosseum in Rome at night. The ancient amphitheater is illuminated from within, with warm yellow lights glowing through its multiple tiers of arches. The structure is set against a dark, black night sky. In the foreground, the dark, silhouetted ground and some distant city lights are visible. Overlaid on this image is the text "Thank you for your attention!" in a large, white, italicized serif font. The text is slanted diagonally across the frame, starting from the upper left and ending in the lower right. The word "Thank" is on the top line, "for your" is on the second line, and "attention!" is on the third line. The exclamation mark is particularly large and prominent.

*Thank you
for your attention!*