Sutureless AVR

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Livanova Symposium, Homa hotel Tehran 2018

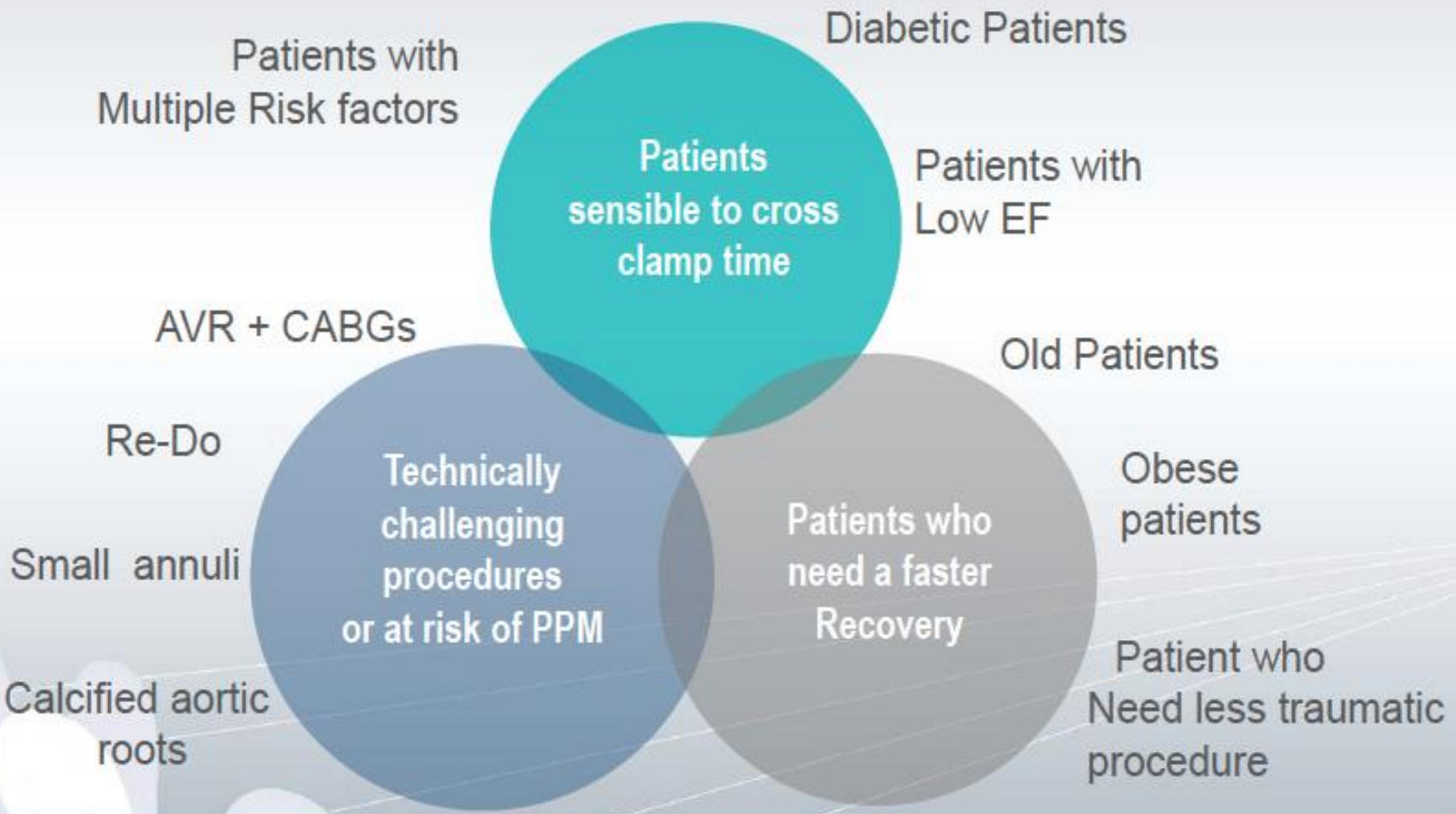
Overview

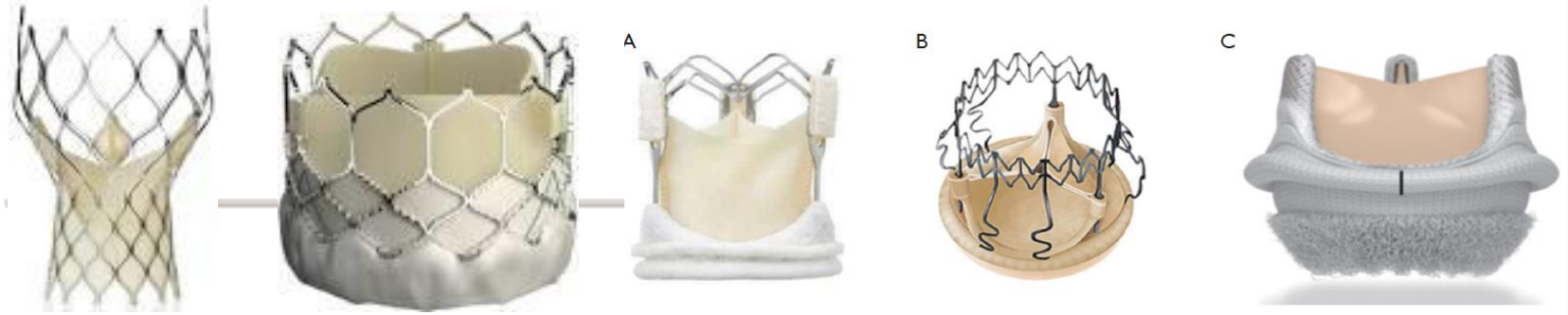
- AS: The most common cardiac valve disorder in western countries.
- Prevalence : 3% of >75 Yrs.
- Increasing number of high risk elderly patients with different comorbidities.
- (STS) database shows that the number of patients older than 80 years has increased from 12% to 24% during the past 20 years
- Less invasive approaches may decrease the morbidity and mortality

What Are the Main Indications and Contraindications?

Categories Benefiting the Most

Who can benefit the most?



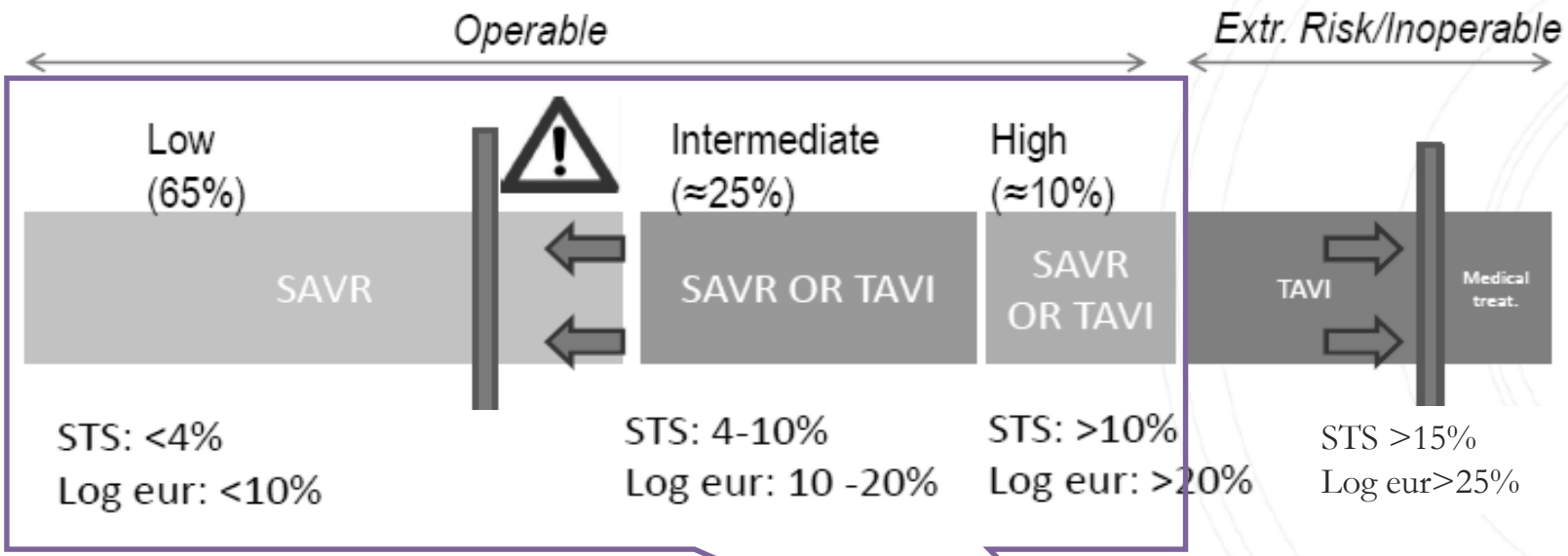


ıre 1 Commercially available sutureless aortic valves. (A) 3F Enable (Medtronic, Minneapolis, USA); (B) Perceval S (Sorin, Salug
'); (C) Intuity Elite (Edward Lifesciences, Irvine, USA).

TAVI Versus Sutureless AVR

Recent technologies and possible solutions

Sutureless as alternative to conventional valves for all operable pts



Sutereless AVR

TAVI

- Expensive
- Need for anesthesia
- Need for X-ray (radiation)
- Indirect vision
- Compressed valve tissue & Implantation
- Higher incidence of paraleakage
- Embolic showering
- Higher incidence of Coronary ostium occlusion
- Less pain

Sutureless AVR

- Less expensive
- Need for anesthesia
- Need for CPB & AOX
- Direct vision
- Valve resection and replacement
- Less Paravalvular leakage
- Less embolic events!
- Rarely coronary ostium occlusion
- Less PPM need!

WHY sutureless AVR

- Sutureless AVR decrease pump time and ischemic time
- Facilitate Mini-AVR
- Good hemodynamic outcomes
- Easy way to approach small or even calcified aortic roots
- Low incidence of paravalvular leakage

Comparison of Patient Outcome - Early Mortality

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

Department of Cardiovascular Surgery, Shizuoka Medical Center, Shizuoka, Japan

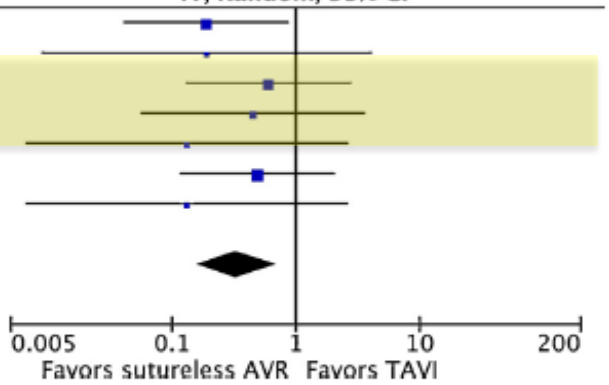
"Compared with TAVI, sutureless AVR may be associated with a reduction in early mortality and postoperative paravalvular AR".

H. Takagi, T. Umemoto / Journal of Cardiology xxx (2015) xxx–xxx

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)



ig. 1. Forest plot of odds ratios for early mortality among patients assigned to sutureless aortic valve replacement (AVR) versus transcatheter aortic valve implantation TAVI).

I, confidence interval; IV, inverse variance.

Online-published ahead of print.

Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation: A meta-analysis of comparative studies. *Tagaki et al. J Cardiol. 2015 Oct 14. pii: S0914-5087(15)00296-8*

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

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

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

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

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

The Journal of Thoracic and Cardiovascular Surgery • ■ 2013

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

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CONCLUSIONS

In conclusion, removal of the diseased native valve may enhance procedural quality by avoiding paravalvular leak. In combination with minimally invasive sutureless AVR, this may become the first-line treatment for high-risk patients considered in the gray zone between TAVI and conventional surgery. Further larger, prospective, randomized studies are warranted to confirm our results.

Months

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

Why sutureless Technique

- A recent retrospective analysis of 979 patients with aortic valve stenosis demonstrated that aortic cross-clamp time was a significant independent predictor of cardiovascular morbidity
- A reduction in aortic cross-clamp demonstrated better morbidity outcomes, particularly in patients with a reduced left ventricular ejection fraction (LVEF) ≤40% or in patients in diabetes mellitus.

Ranucci M, Frigiola A, Menicanti L, et al. Aortic cross-clamp time, new prostheses, and outcome in aortic valve replacement. J Heart Valve Dis 2012;21:732-9.

Paravalvular leakage ?

- Incidence of paravalvular leakage 2-4%, while was 12% in PARTNER trial

Paravalvular leak complications appeared to be a function of the SUTURELESS-AVR learning curve, with significant reduction over time

Ann Cardiothorac Surg 2015;4(2):123-130

- In a recent randomized trial comparing the Edwards Intuity sutureless valve with a conventional stented bioprosthesis , significantly lower mean transvalvular gradient (8.5 *vs.* 10.3 mmHg) and lower PPM (0% *vs.* 15%) was found for the sutureless cohort

Head SJ, Mokhles MM, Osnabrugge RL, et al. The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years. Eur Heart J 2012;33:1518-29.

Interactive CardioVascular and Thoracic Surgery 20 (2015) 90–95
doi:10.1093/icvts/ivu340 Advance Access publication 15 October 2014

ORIGINAL ARTICLE – ADULT CARDIAC

Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement

Claudio Muneretto[a], Gianluigi Bisleri[a,*], Annalisa Moggi[a], Lorenzo Di Bacco[a], Maurizio Tespili[c], Alberto Repossini[a] and Manfredo Rambaldini[a]

Abstract

OBJECTIVES: Although the use of transcatheter aortic valve replacement (TAVR) has recently become an attractive strategy in extremely high-risk patients undergoing aortic valve replacement (AVR), the most appropriate treatment option in patients with an intermediate- to

had undergone TAVR (G1 = 95.2 ± 3.3% vs G2 = 91.6 ± 3.8% vs G3 = 70.5 ± 7.6%; $P = 0.015$).

CONCLUSIONS: This preliminary study suggests that the use of TAVR in patients with an intermediate- to high-risk profile is associated with a higher rate of perioperative complications and decreased survival at the 24-month follow-up compared with the use of conventional surgery or sutureless valves.

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surgery or sutureless valves.

Keynote Lecture Series

Minimally invasive aortic valve surgery: state of the art and future directions

Mattia Glauber, Matteo Ferrarini, Antonio Miceli

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

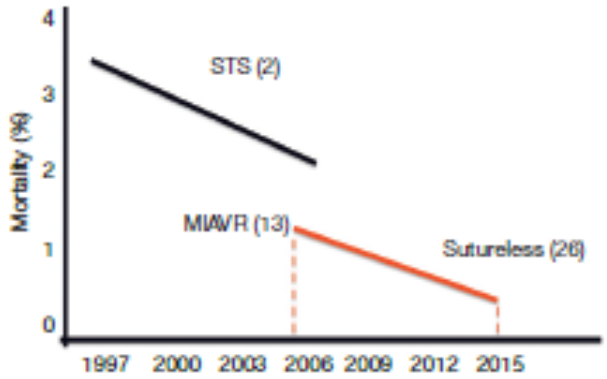

Figure 4 The combination of minimally invasive aortic valve replacement using sutureless/fast deployment valves has improved postoperative mortality. Black line: in-hospital mortality reduction from 3.4% in 1997 to 2.6% in 2006 for isolated AVR according to STS data (2). Red line: the introduction of sutureless valves associated with MIAVR has decreased the inhospital mortality from 1.6% in 2005 to 0.7% in 2013 (13,26). AVR, aortic valve replacement; MIAVR, minimally invasive aortic valve replacement; STS, Society of Thoracic Surgeon.

Minimally invasive aortic valve surgery: state of the art and future directions

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

approaches. Compared with conventional surgery, MIAVR has been shown to reduce postoperative mortality and morbidity, providing faster recovery, shorter hospital stay and better cosmetics results, requires less rehabilitations resources and consequently cost reduction. Despite these advantages, MIAVR is limited by the longer cross-clamp and cardiopulmonary bypass (CPB) times, which have raised some concerns in fragile and high risk patients. However, with the introduction of sutureless and fast deployment valves, operative times have dramatically reduced by 35-40%, standardizing this procedure. According to these results, the MIAVR approach using sutureless valves may be the "real alternative" to the transcatheter aortic valve implantation (TAVI) procedures in high risk patients "operable" patients. Prospective randomized trials are required to confirm this hypothesis.

Systematic Review

Sutureless aortic valve replacement: a systematic review and meta-analysis

Kevin Phan[1], Yi-Chin Tsai[2], Nithya Niranjan[1], Denis Bouchard[3], Thierry P. Carrel[4], Otto E. Dapunt[5], Harald C. Eichstaedt[6], Theodor Fischlein[7], Borut Gersak[8], Mattia Glauber[9], Axel Haverich[10], Martin Misfeld[11], Peter J. Oberwalder[5], Giuseppe Santarpino[7], Malakh Lal Shrestha[10], Marco Solinas[9], Marco Vola[12], Tristan D. Yan[1], Marco Di Eusanio[13]

Ann Cardiothorac Surg 2015;4(2):100-111

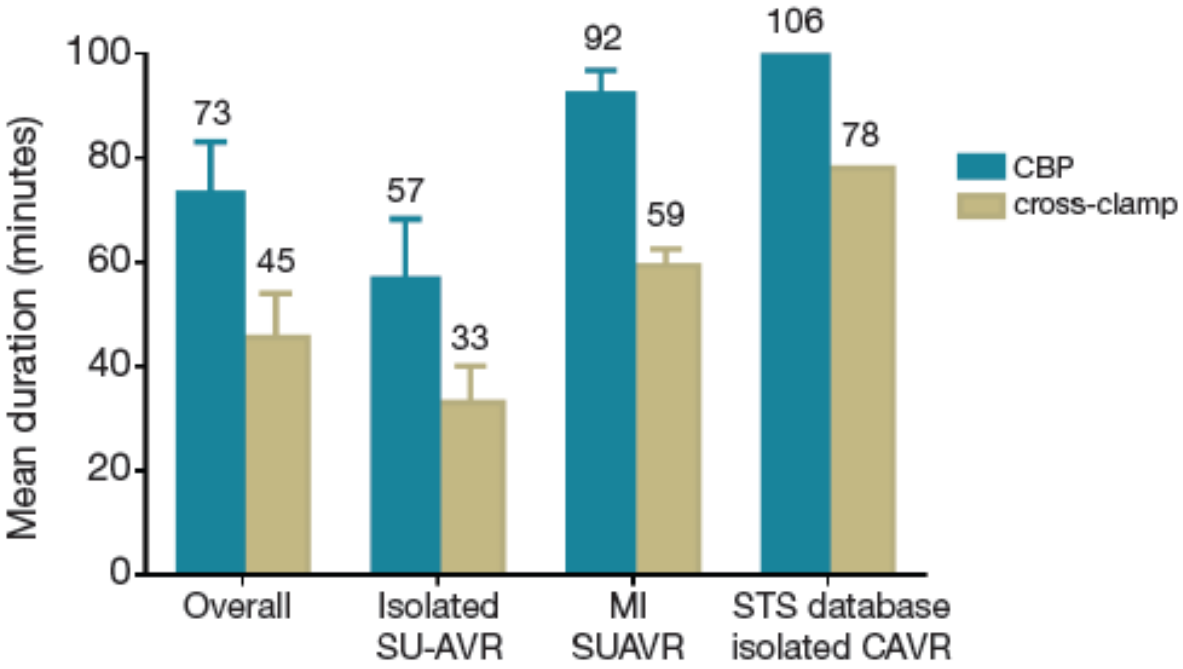

Table 6 Poole

Parameter	erogeneity P value
Early outcome	
30 day morta	0.341
Strokes	0.632
Valve degene	0.062
Paravalvular	0.007
Renal failure	0.856
Up to 1-year fo	
All-cause mo	0.007
Strokes	0.092
Valve degene	0.79
Paravalvular	<0.001
Permanent p	0.256
Renal failure	0.012
Endocarditis	0.012

CPB, cardiopu

Conclusions

In summary, sutureless valves provide the possibility of AVR with shortened CPB and cross-clamp times, thereby facilitating minimally invasive approaches as well as concomitant cardiac surgery for high-risk patients. Current short-term clinical evidence indicates similar mortality and complication rates compared to conventional AVR, with satisfactory hemodynamic performance. Long-term follow-up data, adequately powered sample sizes and future randomized studies and registry data are required to adequately assess the durability and long-term complications of SU-AVR.

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Do we need sutureless or self-anchoring aortic valve prostheses?

Malakh Shrestha

Cardiothoracic, Transplantation & Vascular Surgery, Hannover Medical School, Germany

More than 60 peer reviewed academic papers have been published to date about these valves (6-13). These studies have shown that self-anchoring valves not only 'work' but also compare well against conventional sutured valves

(I) The results of AVR with these valves in geriatric patients are promising, with mortality of approximately 3% for isolated AVR and under 5% in combined AVR and CABG (7,8). This compares favorably against results published with conventional sutured valve prostheses

(II) Isolated AVR with self-anchoring valves can be performed with X-clamp time under 20 minutes

(III) Absence of sutures makes minimally invasive AVR possible even in patients with small calcified aortic roots

Ann Cardiothorac Surg 2015;4(2):175-177

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Conclusions

Therefore, the question of whether we need 'self-anchoring valves' is not only redundant, but the time may have come for these type of valves to be considered as the 'valve of choice' for higher risk geriatric patients who may be 'high risk' for conventional valves but ineligible for TAVIs. Additionally, 'self-anchoring' valves will increase the armament of surgeons in treating 'technically difficult' group of patients needing AVR with small calcified aortic roots and those coming back after aortic root replacement with homograft. These valves should also help in broadening the application of minimally invasive AVR.

TABLE 1. Design Characteristics

	Edwards INTUITY	Sorin Perceval S	Medtronic 3F Enable
CE mark	2012	2011	2012
Available patient follow-up	3 y	5 y	5 y
Design platform	Bovine pericardium, trileaflet, balloon expandable, stainless steel cloth-covered frame	Bovine pericardium, trileaflet, self-expandable nitinol frame with additional proximal and distal rings for annulus fixation	Three equal sections of equine pericardial tissue forming tubular structure, self-expandable nitinol frame covered in polyester fabric, equally spaced commissural tabs reinforced with polyester material
Available sizes	19, 21, 23, 25, 27 mm	21, 23, 25 mm	19, 21, 23, 25, 27, 29 mm
Rinsing	2 times, 60 s each	Not required	3 times 120 s each
Sutures	3 actual sutures	None/only guiding sutures	0/1 actual suture
Collapsible	Crimped	Yes, with collapsing tool	Yes, manual folding

OPEN

Current Clinical Evidence on Rapid Deployment Aortic Valve Replacement

Sutureless Aortic Bioprostheses

Glenn R. Barnhart, MD and Malakh Lal Shrestha, MBBS, PhD†*

- Mortality : 1.4 - 3.2 %
- Stroke: 1.9 – 2.4%
- PPM need: 1.7 - 3%
- Post-op AVMG: 7.4-8.8 mmHg
- Mild paravalvular leakage: 1.4 -12.1 %
- Significant PVL: 0.3-0.6 %

- Re-exploration for bleeding:2.5 -4.6%
- AOX: 34-41 min
- CPB: 60-66 min.

Innovations • Volume 11, Number 1, January/February 2016

RHC experience

Six patient (F/M= 2/4)
Mean Age : 74

HTN: 100%
DM:50%
COPD:33%
FC II: 4 FC III: 2

Early post-op results

Early mortality	None
Follow up	Up to 8 month
Stroke	none
TPM	2 patients (33%)
PPM	None
Ventilation time	10+/-3 Hour
ICU stay	3+/-1 days

AOX	41+/-12 min.
CPB	60+/-16 min.
BSA	1.65+/-0.04
AVMG	8+/-3 mmHg
Post-op LVEF	46+/-4
Post-op bleeding	360+/-50 ml
Re-exploration	None

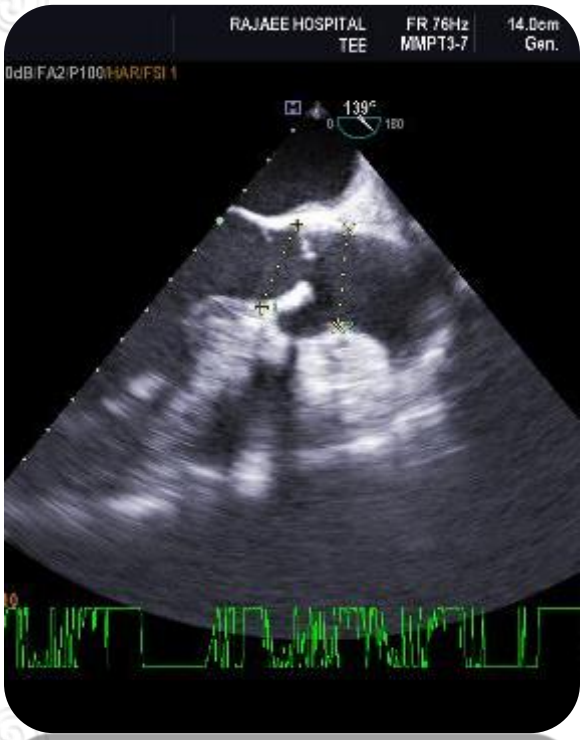
- **Concomitant procedure:**

  CABG 2 graft(Lima-LAD plus vein graft): 2 patients

Valves size:

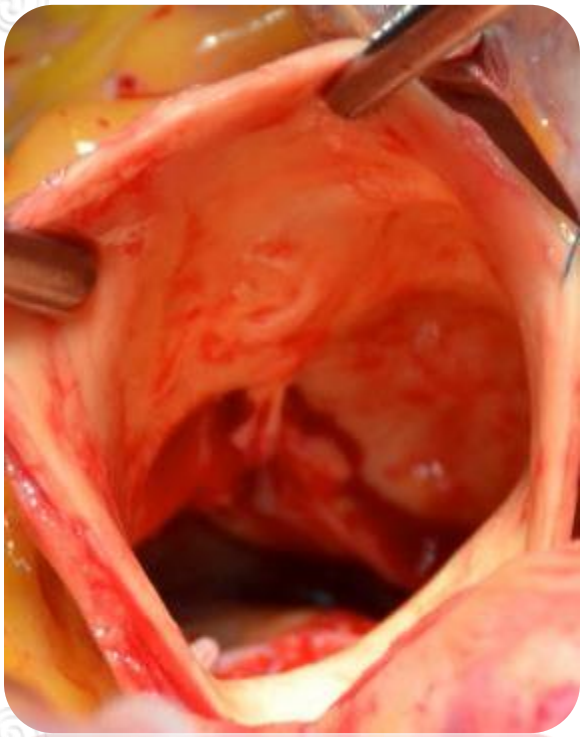
Small:	1 cases
Medium:	2 cases
Large:	1 cases
X-large	2 cases

	Intra-op		Early post-op		Follow up	
Transvalvular Leakage	No: Trivial Mild >mild	2 1 2 1	No: Trivial Mild >mild	3 2 1 0	No: Trivial Mild >mild	3 2 1 0
Paravalvular leakage	No: Trivial Mild >mild	3 1 1 1	No: Trivial Mild >mild	4 1 1 0	No: Trivial Mild >mild	4 1 1 0

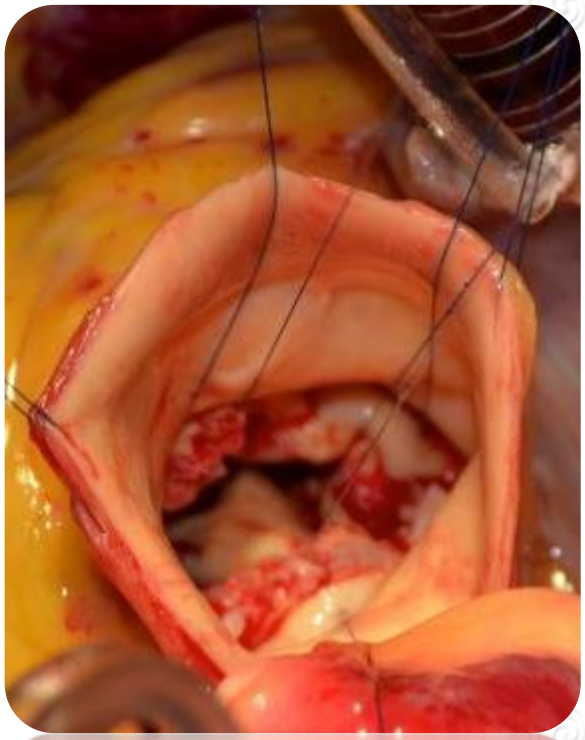


Pre op Echo Surgical view of AV

Case Presentation



Decalcification



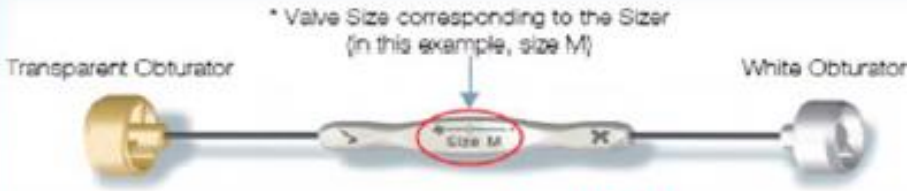
Guiding suture

Sizing the valve

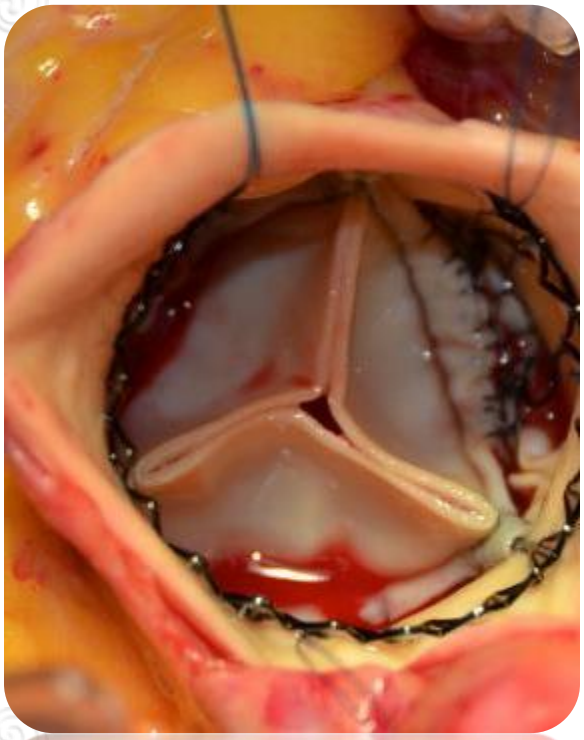
- the transparent obturator of the chosen sizer has to pass through the annulus

&

- the white obturator of the sizer must not pass through the annulus



If so, the valve size identified on the sizer handle must be chosen (*)



Valve deployment Balloon Dilation

Video brief presentation