Sutureless
Rapid deployment
Tissue valves

Alireza A. Ghavidel MD

Professor of Cardiac Surgery

Rajaie Cardiovascular Medical & Research center

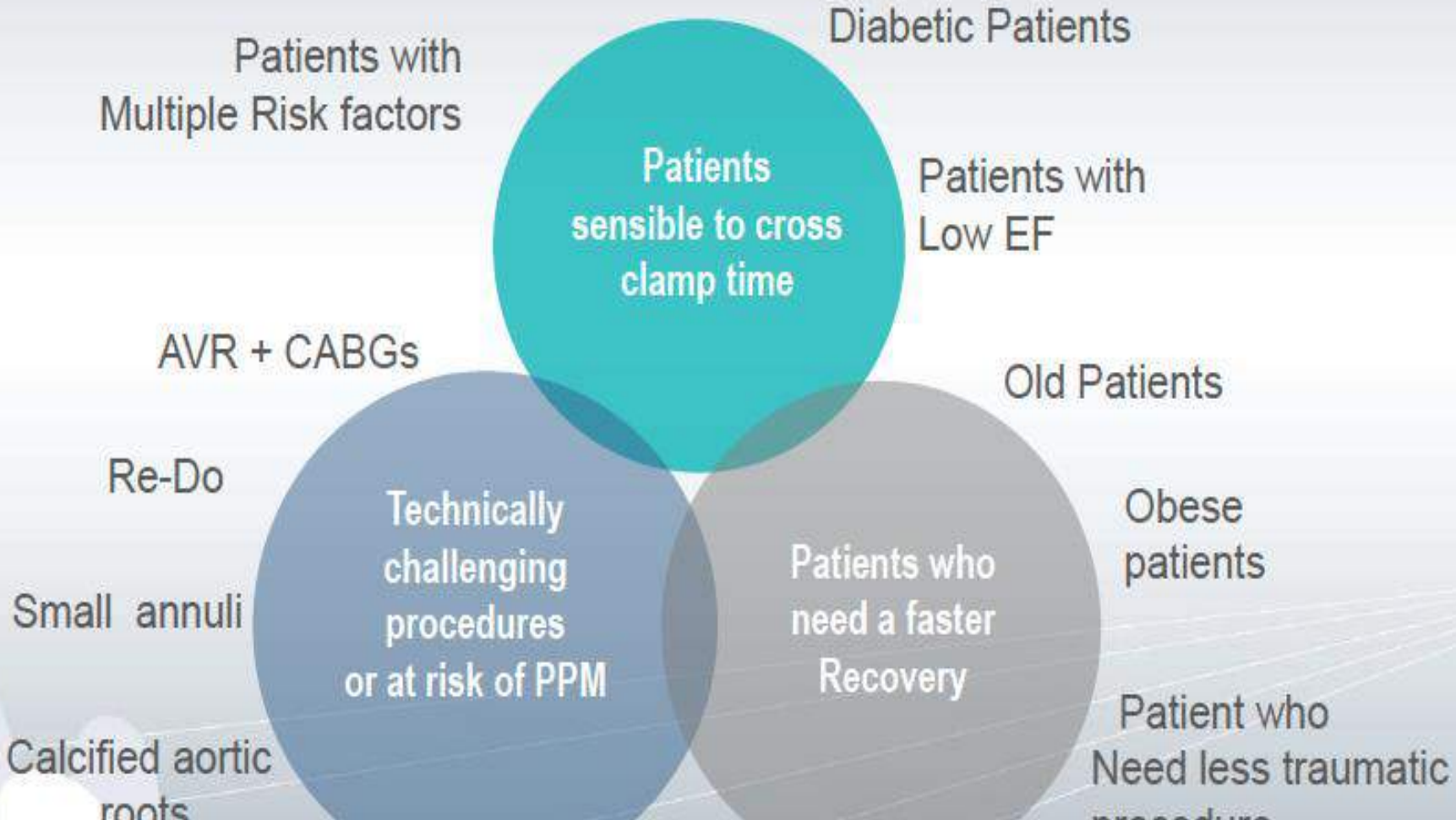
Overview

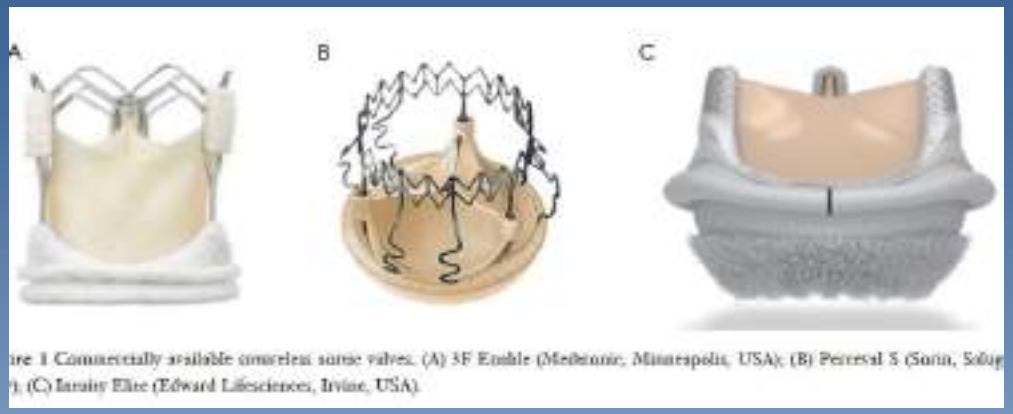
* AS: The most common cardiac valve disorder in western countries.
* Prevalence : 3% of >75 Yrs.
* Increasing number of high risk elderly patients with different comorbidities.
* (STS) database shows that the number of patients older than 80 years has increased from 12% to 24% during the past 20 years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

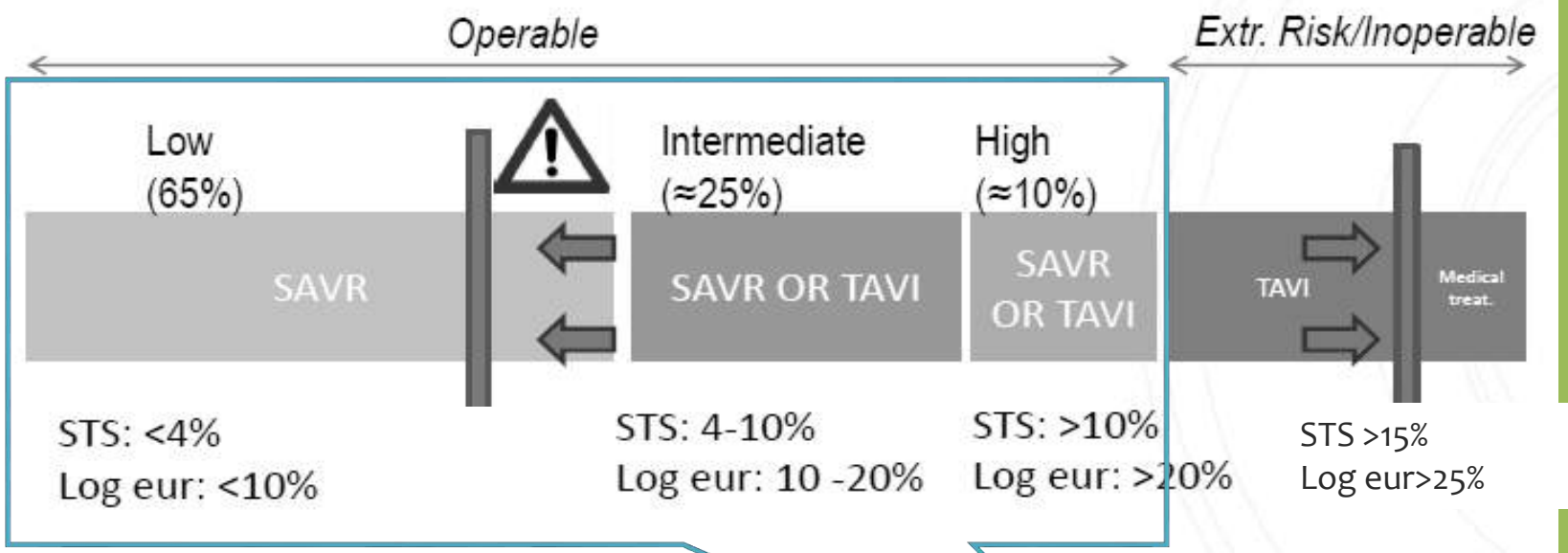




TAVI Versus Sutureless AVR

Recent technologies and possible solutions

Sutureless as alternative to conventional valves for all operable pts



SU AVR

TAVR

- 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
- Less ICU stay
- Rapid recovery
- Less infection?

SAVR

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

WHY SAVR ?

* 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

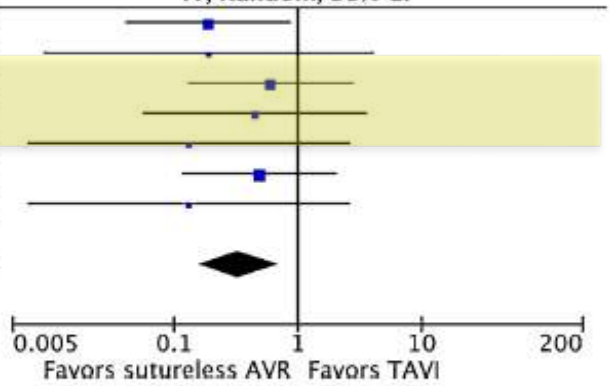
"Compared with TAVI, sutureless AVR may be associated with a reduction in early mortality and postoperative paravalvular AR".

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

	Sutureless AVR		TAVI			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	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

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]

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.

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.

Keynote Lecture Series

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

Mattia Glauber, Matteo Ferrarini, Antonio Miceli

Cardiac Surgery and Great Vessels Department, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Milan, Italy

Correspondence to: Antonio Miceli, MD, PhD. Cardiac Surgery and Great Vessels Department, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Via Favarelli 16, 20149 Milano, Italy. Email: antoniomiceli79@alice.it.

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

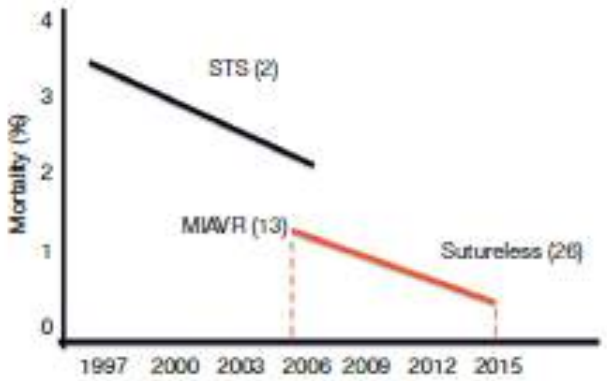


Figure 4 The combination of minimally invasive aortic valve replacement using sutureless/fast deployment valves has improved postoperative mortality. Black line: in-hospital mortality reduction from 3.4% in 1997 to 2.6% in 2006 for isolated AVR according to STS data (2). Red line: the introduction of 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

Mattia Glauber, Matteo Ferrarini, Antonio Miceli

Cardiac Surgery and Great Vessels Department, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Milan, Italy

Correspondence to: Antonio Miceli, MD, PhD. Cardiac Surgery and Great Vessels Department, Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Via Favarelli 16, 20149 Milano, Italy. Email: antoniomiceli79@alice.it.

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

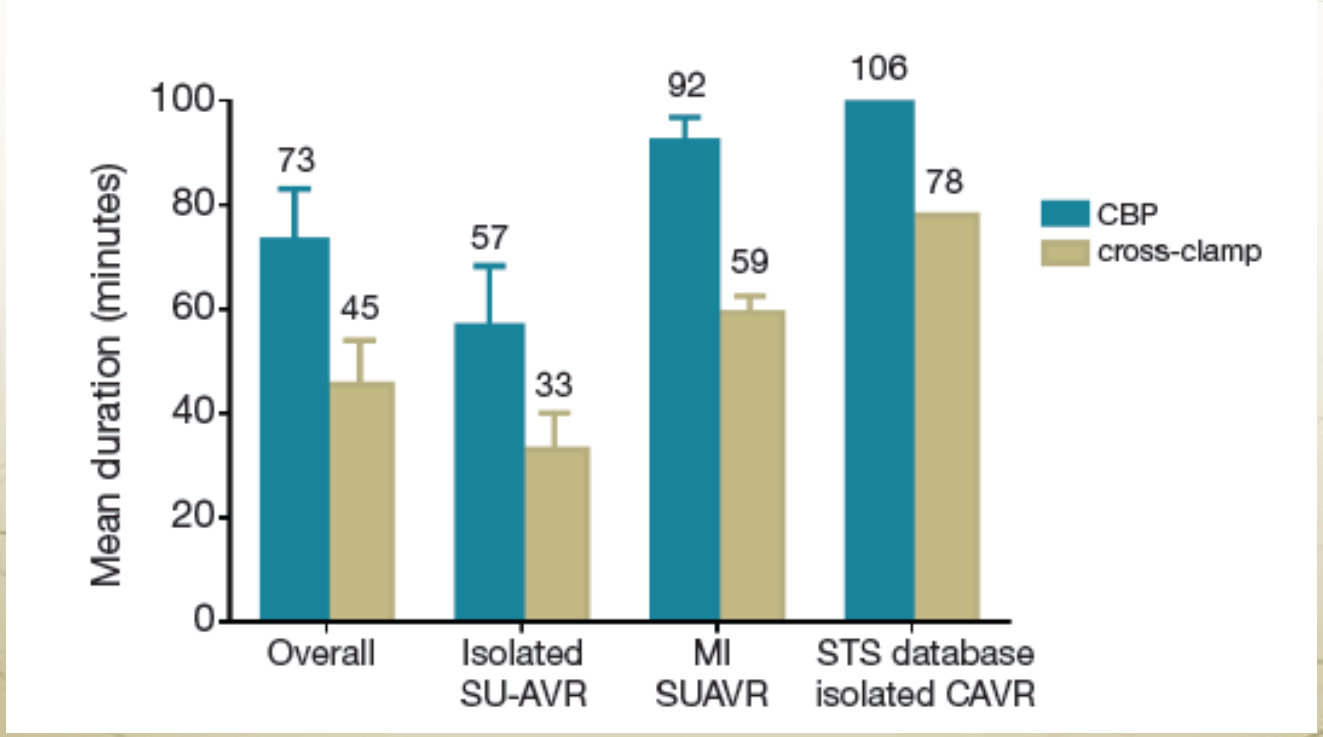


Table 6 Poole

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.

Annals of cardiothoracic surgery, Vol 4, No 2 March 2015

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

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

Malakh Shrestha

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

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

- Subjects with previous implantation of prostheses which won't be replaced by Perceval
- Multiple valve replacement or repair
- Aneurysmal dilation or dissection of the ascending aortic wall
- Congenital bicuspid aortic valve
- Known hypersensitivity to nickel alloys
- Anatomical characteristics indicating enlargement of aortic root (e.g. if the ratio of the sinotubular junction Ø and the annulus Ø is larger than 1.3)

Pro-op assessment of the patient's anatomical characteristics is important:

REF	SIZE	AORTIC ANNULUS DIAMETER [A] (mm)	AORTIC ROOT HEIGHT (mm)	SINOTUBULAR JUNCTION DIAMETER [≤1,3 A] (mm)
PVS21	S	19-21	< 21.0	≤ 24,7-27,3
PVS23	M	21-23	< 22.5	≤ 27,3-29,9
PVS25	L	23-25	< 24.0	≤ 29,9-32,5
PVS27	XL	25-27	< 25.0	≤ 32,5-35,1

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= 3/6)
Mean Age : 74

HTN: 100%
DM:50%
COPD:44%
FC II: 6 FC III: 3

Early post-op results

Early mortality	None
Follow up	Up to 15 month
Stroke	none
TPM	2 patients (23%)
PPM	None
Ventilation time	9+/-3 Hour
ICU stay	3+/-1 days

AOX	43+/-8 min.
CPB	63+/-20 min.
BSA	1.73+/-0.04
AVMG	36+/-8mmHg
Post-op LVEF	46+/-4
Post-op bleeding	480+/-150 ml
Re-exploration	None

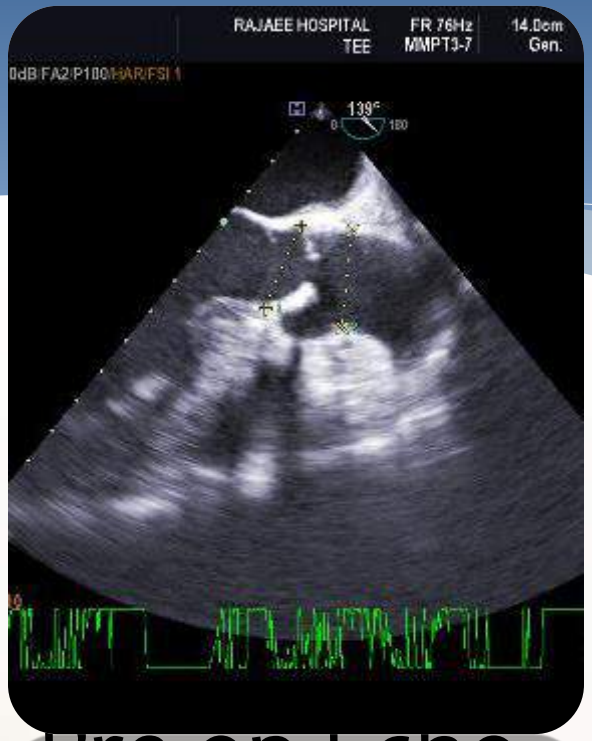
* **Concomitant procedure:**

  CABG 2 graft(Lima-LAD plus vein graft): 3patients

Valves size:

Small:	1 cases
Medium:	2 cases
Large:	3cases
X-large	3 cases

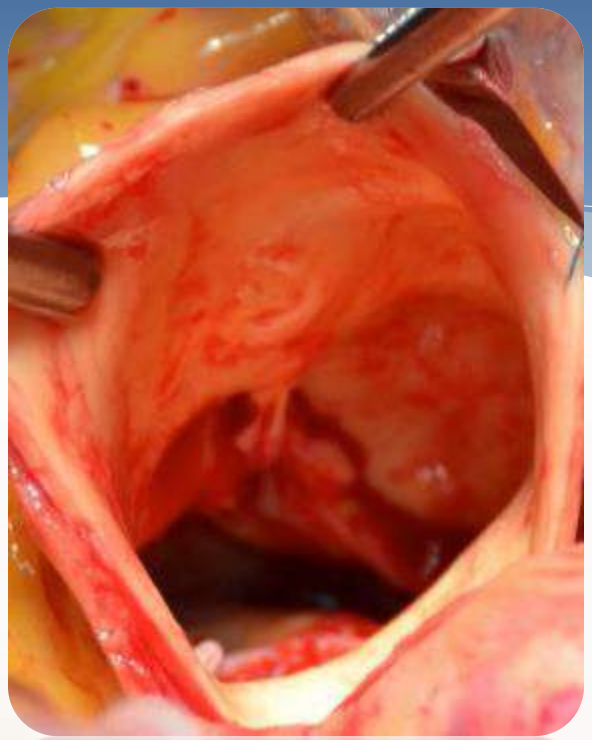
	Intra-op	Early post-op	Follow up
Transvalvular Leakage	No: 2 Trivial 1 Mild 4 >mild 2	No: 5 Trivial 2 Mild 2 >mild 0	No: 5 Trivial 2 Mild 2 >mild 0
Paravalvular leakage	No: 5 Trivial 2 Mild 1 >mild 1	No: 5 Trivial 2 Mild 2 >mild 0	No: 5 Trivial 3 Mild 1 >mild 0



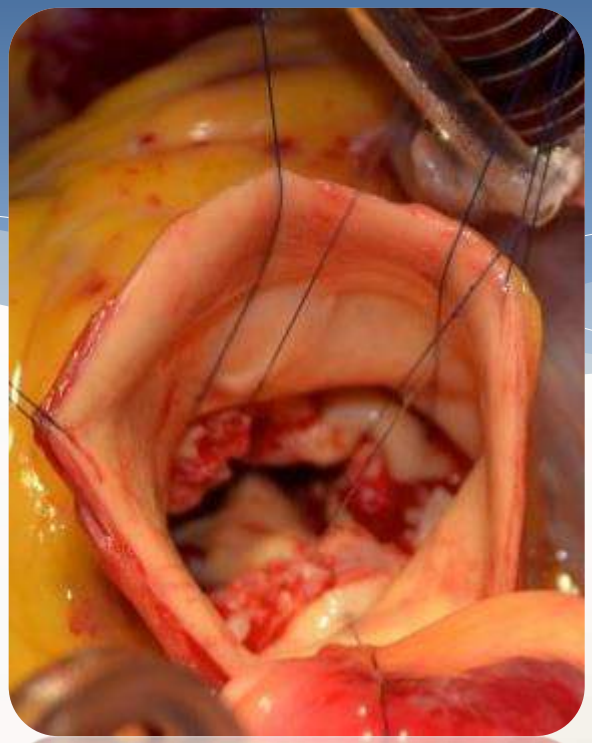
Pre op Echo

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

Quick description

Easy,Safe

Rapid

Good hemodynamic

Facilitate Mini approaches

Less expensive

Brakes and Bumps!!!

Video brief presentation

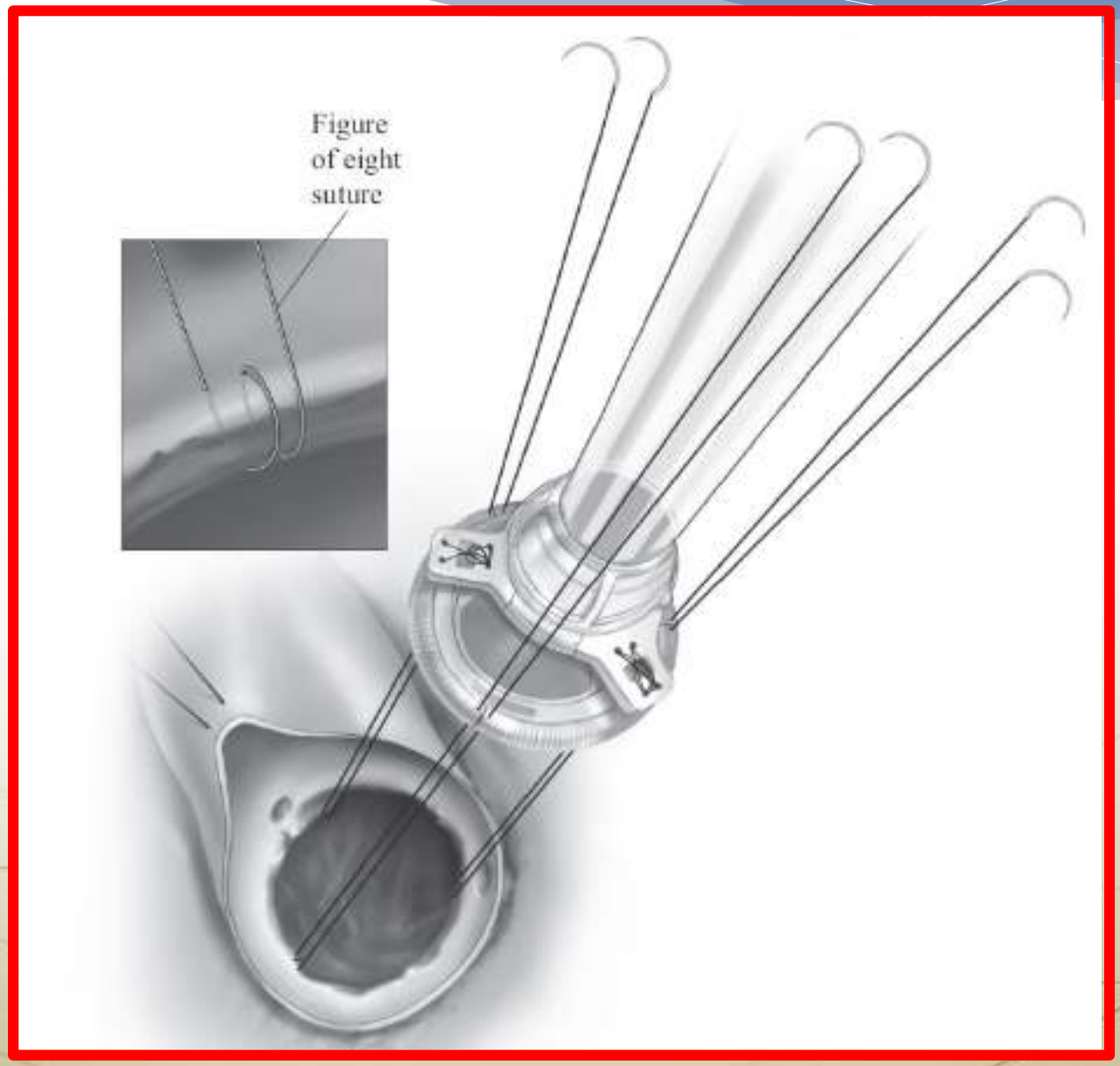
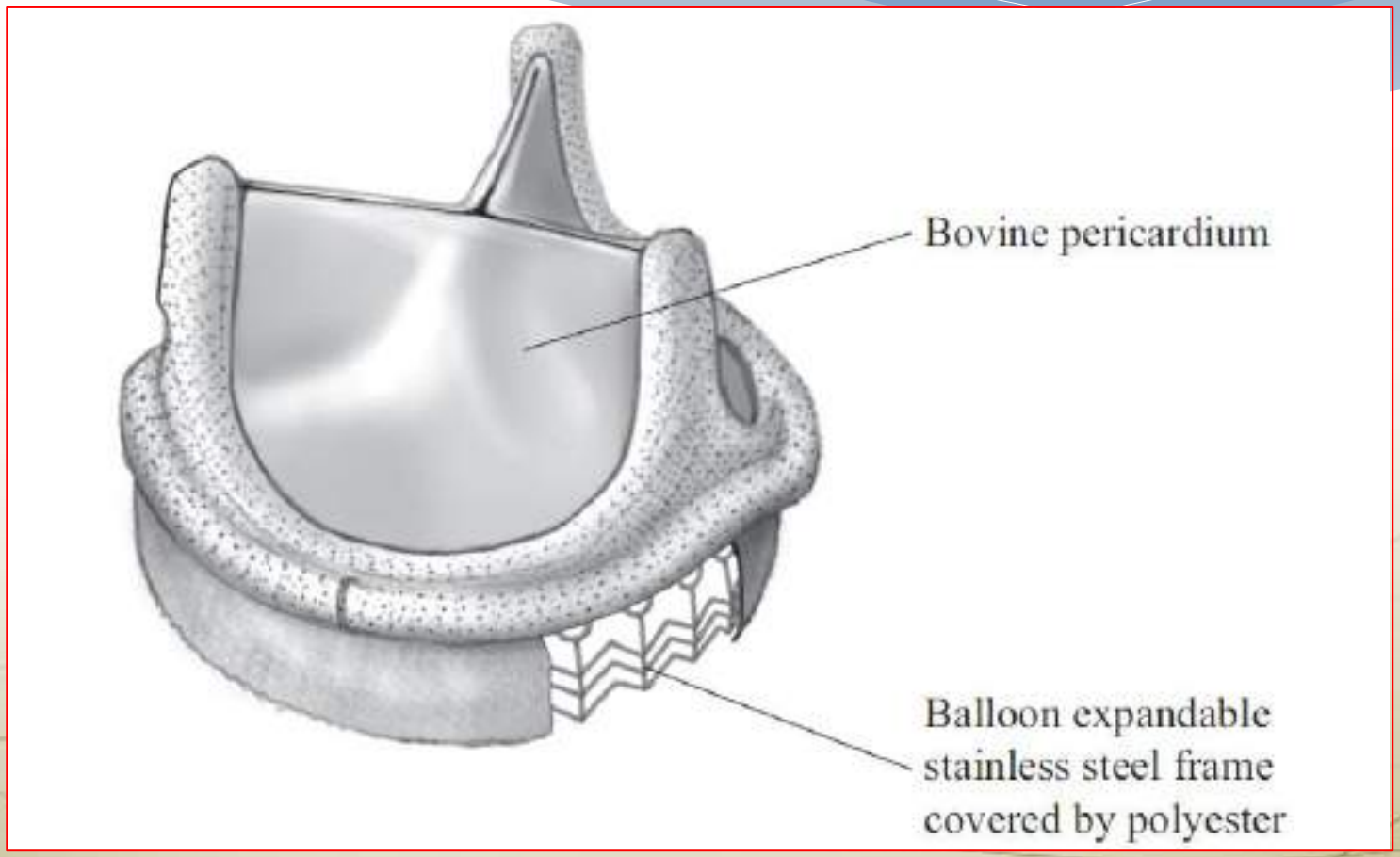


Figure
of eight
suture


Bovine pericardium
Balloon expandable
stainless steel frame
covered by polyester

Sutureless aortic valve replacement as an alternative treatment for patients belonging to the "gray zone" between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis

Augusto D'Onofrio, MD,[a] Antonio Messina, MD,[b] Roberto Lorusso, MD,[c] Ottavio R. Alfieri, MD,[d] Melissa Fusari, MD,[e] Paolo Rubino, MD,[f] Mauro Rinaldi, MD,[g] Roberto Di Bartolomeo, MD,[h] Mattia Glauber, MD,[i] Giovanni Troise, MD,[b] and Gino Gerosa, MD[a]

Methods: We reviewed 468 TA-TAVIs performed in 20 centers from April 2008 to May 2011, and 51 SU-AVRs performed in 3 centers from March to September 2011. Based on a propensity score analysis, 2 groups with 38 matched pairs were created. Variables used in the propensity analysis were age, sex, body surface area, New York Heart Association class, logistic EuroSCORE, peripheral vascular disease, chronic obstructive pulmonary disease, aortic valve area, mitral regurgitation, and left ventricular ejection fraction.

Results: Preoperative characteristics of the 2 groups were comparable. Hospital mortality was 5.3% and 0% in the TA-TAVI and SU-AVR groups, respectively ($P = .49$). We did not observe stroke or acute myocardial infarction in the 2 groups. Permanent pacemaker implantation was needed in 2 patients of each group (5.3%, $P = 1.0$). Dialysis was required in 2 patients (5.3%) in the SU-AVR group and in 1 patient (2.7%) in the TA-TAVI group ($P = 1.0$). Predischarge echocardiographic data showed that the incidence of paravalvular leak (at least mild) was greater in the TA-TAVI group (44.7% vs 15.8%, $P = .001$), but there were no differences in terms of mean transprosthetic gradient (10.3 ± 5 mm Hg vs 11 ± 3.7 mm Hg, $P = .59$).

Conclusions: This preliminary experience showed that, in patients at high risk for conventional surgery, SU-AVR is as safe and effective as TA-TAVI and that it is associated with a lower rate of postprocedural paravalvular leak. (J Thorac Cardiovasc Surg 2012;144:1010-8)

Interactive CardioVascular and Thoracic Surgery 17 (2013) 778–783
doi:10.1093/icvts/ivt291 Advance Access publication 12 July 2013

ORIGINAL ARTICLE – ADULT CARDIAC

Aortic valve replacement in geriatric patients with small aortic roots: are sutureless valves the future?†

Malakh Shrestha*, Ilona Maeding, Klaus Höffler, Nurbol Koigeldiyev, Georg Marsch, Thierry Siemeni, Felix Fleissner and Axel Haverich

Division of Cardiac-Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany

* Corresponding author. Division of Cardiac-Thoracic, Transplantation and Vascular Surgery, Hanover Medical School, Carl-Neuberg-Str. 1, 30625 Hannover, Germany. Tel: +49-511-5326238; fax: +49-511-5328156; e-mail: shrestha.malakh.lal@mh-hannover.de (M. Shrestha).

Abstract

OBJECTIVES: Aortic valve replacement (AVR) in geriatric patients (>75 years) with small aortic roots is a challenge. Patient–prosthesis mismatch and the long cross-clamp time necessary for stentless valves or root enlargement are matters of concern. We compared the results of AVR with sutureless valves (Sorin Perceval), against those with conventional biological valves.

METHODS: Between April 2007 and December 2012, 120 isolated AVRs were performed in patients with a small annulus (≤22 mm) at our centre. In 70 patients (68 females, age 77.4 ± 5.5 years), conventional valves (C group) and in 50 patients (47 females, age 79.8 ± 4.5 years), sutureless valves (P group) were implanted. The Logistic EuroSCORE of the C group was 16.7 ± 10.4 and that of the P group 20.4 ± 10.7, ($P = 0.054$). Minimal-access surgery [illegible] nts in the P group.

Shorter AOX, CPB time
Greater EOA,
No need for root enlargement
Simplify Mini-AVR

RESULTS: The cardiopulmonary by[illegible] 14.2 min vs 58.7 ± 20.9 and 30.1 ± 9 min in the P group, ($P < 0.0$[illegible] mortality was 4.3% ($n = 3$) in the C group and 0 in the P group[illegible] roup and 14% ($n = 7$) in the P group, (n.s.).

CONCLUSIONS: This study highlights the advantages of sutureless valves for geriatric patients with small aortic roots reflected by shorter cross-clamp and CPB times, even though most of these patients were operated on via a minimally invasive access. Moreover, due to the absence of a sewing ring, these valves are also almost stentless, with greater effective orifice area (EOA) for any given size. This may potentially result in better haemodynamics even without the root enlargement. This is of advantage, as several studies have shown that aortic root enlargement can significantly increase the risks of AVR. Moreover, as seen in this series, these valves may also enable a broader application of minimally invasive AVR.

Keywords: Small aortic root • Elderly patients • Aortic valve stenosis • Sutureless aortic valve

Received: 2016.05.02
Accepted: 2016.06.14
Published: 2016.10.03

Valve-in-Valve Replacement Using a Sutureless Aortic Valve

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEFG 1,2 Pascal M. Dohmen
BDE 3 Lukas Lehmkuhl
DEF 1 Michael A. Borger
DE 1 Martin Misfeld
DE 1 Friedrich W. Mohr

1 Department of Cardiac Surgery, Heart Centre Leipzig, University of Leipzig, Leipzig, Germany
2 Department of Cardiothoracic Surgery Faculty of Health Sciences University of The Free State, Bloemfontein, South Africa
3 Department of Radiology, Heart Centre Leipzig, University of Leipzig, Leipzig, Germany

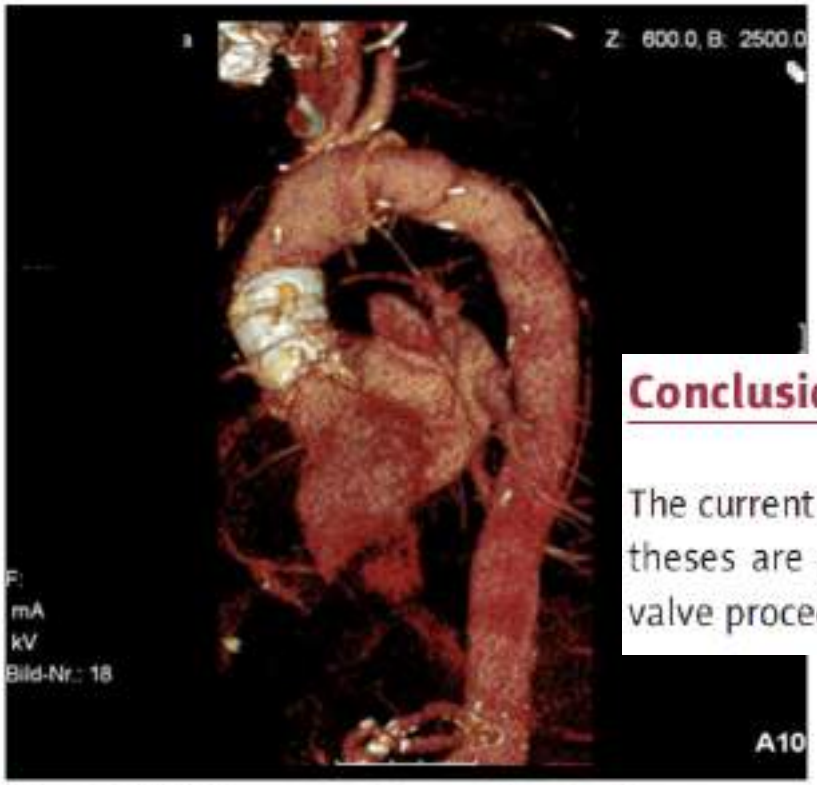


Figure 1. Multi-slice computed tomography of a 61-year-old female patient with a heavily calcified aortic

Conclusions

The current case report demonstrates that sutureless bioprostheses are a safe and efficient option for surgical valve-in-valve procedures, which can reduce morbidity and mortality.

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]

Background: Sutureless aortic valve replacement (SU-AVR) has emerged as an innovative alternative for treatment of aortic stenosis. By avoiding the placement of sutures, this approach aims to reduce cross-clamp and cardiopulmonary bypass (CPB) duration and thereby improve surgical outcomes and facilitate a minimally invasive approach suitable for higher risk patients. The present systematic review and meta-analysis aims to assess the safety and efficacy of SU-AVR approach in the current literature.

Methods: Electronic searches were performed using six databases from their inception to January 2014. Relevant studies utilizing sutureless valves for aortic valve implantation were identified. Data were extracted and analyzed according to predefined clinical endpoints.

Results: Twelve studies were identified for inclusion of qualitative and quantitative analyses, all of which were observational reports. The minimally invasive approach was used in 40.4% of included patients, while 22.8% underwent concomitant coronary bypass surgery. Pooled cross-clamp and CPB duration for isolated AVR was 56.7 and 46.5 minutes, respectively. Pooled 30-day and 1-year mortality rates were 2.1% and 4.9%, respectively, while the incidences of strokes (1.5%), valve degenerations (0.4%) and paravalvular leaks (PVL) (3.0%) were acceptable.

Conclusions: The evaluation of current observational evidence suggests that sutureless aortic valve implantation is a safe procedure associated with shorter cross-clamp and CPB duration, and comparable complication rates to the conventional approach in the short-term.

OPEN

Current Clinical Evidence on Rapid Deployment Aortic Valve Replacement

Sutureless Aortic Bioprostheses

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

sutures to ensure accurate and stable valve positioning. The 3F Enable and Perceval S valves both have novel nitinol self-expanding frames, whereas the INTUITY valve is composed of a standard Carpentier-Edwards PERIMOUNT (CEP) Magna Ease aortic bioprosthetic valve mounted on a balloon-expandable stent. In the latter case, the pericardial valve tissue is neither compressed nor traumatized. The manufacturing considerations for these valves are unique to each model and deserve comment. The INTUITY valve is made of bovine pericardium and undergoes the same tissue fixation and anticalcification treatment as the PERIMOUNT Magna Ease valve that currently is in widespread clinical use. Excellent long-term durability of PERIMOUNT valves have been reported in three recently published studies.[6,9,35] In contrast, long-term durability is uncertain for either equine (3F Enable) or bovine (Perceval S) pericardial tissue mounted on a nitinol frame. Because a central tenet when choosing the appropriate bioprosthetic valve for a patient is the freedom from valve explantation for structural valve deterioration, the long-term performance of equine and bovine pericardial valves mounted on a nitinol frame must be carefully scrutinized and proven to have equivalent or superior clinical outcomes compared with conventional stented surgical bovine pericardial valves. Obviously, this may require many years of long-term clinical follow-up; however, unlike the current target population for TAVR—prohibitive and extreme high-risk patients with few treatment options—most patients undergoing RDAVR are, in fact, suitable candidates for AVR using a standard commercially available bioprosthesis. Accordingly, long-term valve durability should not be compromised in these patients for the putative advantage of lessening the aortic XCT. This point cannot be overemphasized as better clinical outcomes are reported with percutaneous AVR and its use becomes expanded into lower risk and younger patient populations, where long-term

6;11:7–14)

and outstanding long-term results that were unheard of even a decade ago. The transition from conventional surgical AVR to rapid deployment AVR by our specialty must be performed in a deliberate and methodical fashion so that the benefits accrued during the last 55 years will not be squandered.

Journal of Geriatric Cardiology (2016) 13: 504–510

Symposium: Transcatheter aortic valve implantation

· Open Access ·

Guest Editor: Prof. Khalil Fattouch

Aortic valve replacement with sutureless and rapid deployment aortic valve prostheses

Paolo Berretta[1], Marco Di Eusanio[1,2]

Abstract

Aortic valve stenosis is the most common valve disease in the western world. Over the past few years the number of aortic valve replacement (AVR) interventions has increased with outcomes that have been improved despite increasing age of patients and increasing burden of comorbidities. However, despite such excellent results and its well-established position, conventional AVR has undergone great development over the previous two decades. Such progress, by way of less invasive incisions and use of new technologies, including transcatheter aortic valve implantation and sutureless valve prostheses, is intended to reduce the traumatic impact of the surgical procedure, thus fulfilling lower risk patients' expectations on the one hand, and extending the operability toward increasingly high-risk patients on the other. Sutureless and rapid deployment aortic valves are biological, pericardial prostheses that anchor within the aortic annulus with no more than three sutures. The sutureless prostheses, by avoiding the passage and the tying of the sutures, significantly reduce operative times and may improve outcomes. However, there is still a paucity of robust, evidence-based data on the role and performance of sutureless AVR. Therefore, strongest long-term data, randomized studies and registry data are required to adequately assess the durability and long-term outcomes of sutureless aortic valve replacement.

J Geriatr Cardiol 2016; 13: 504–510. doi:10.11909/j.issn.1671-5411.2016.06.006

Interactive CardioVascular and Thoracic Surgery 23 (2016) 861–868
doi:10.1093/icvts/ivw259 Advance Access publication 29 August 2016

ORIGINAL ARTICLE – ADULT CARDIAC

Cite this article as: Toledano B, Bisbal F, Camara ML, Labata C, Berastegui E, Gálvez-Montón C et al. Incidence and predictors of new-onset atrioventricular block requiring pacemaker implantation after sutureless aortic valve replacement. Interact CardioVasc Thorac Surg 2016;23:861–8.

ORIGINAL ARTICLE

Incidence and predictors of new-onset atrioventricular block requiring pacemaker implantation after sutureless aortic valve replacement

Beatriz Toledano[a], Felipe Bisbal[a,*], Maria Luisa Camara[b], Carlos Labata[a], Elisabet Berastegui[b], Carolina Gálvez-Montón[c], Roger Villuendas[a], Axel Sarrias[a], Teresa Oliveres[a], Damià Pereferrer[a], Xavier Ruyra[b,†] and Antoni Bayés-Genís[a,c,†]

[a] Department of Cardiology, Heart Institute–Hospital Germans Trias i Pujol, Badalona, Spain
[b] Department of Cardiac Surgery, Heart Institute–Hospital Germans Trias i Pujol, Badalona, Spain
[c] ICREC Research Program, Health Science Research Institute Germans Trias i Pujol, Badalona, Spain

Abstract

OBJECTIVES: In high-risk patients with severe aortic stenosis, aortic valve replacement (AVR) with a sutureless Perceval prosthesis (SU-AVR) can be performed instead of conventional AVR or transcatheter aortic valve implantation. Little data are available regarding postoperative conduction disorders after SU-AVR. We aimed to determine the incidence and predictors of new-onset complete atrioventricular block (NO-AVB) requiring permanent cardiac stimulation following SU-AVR.

METHODS: We studied consecutive patients who underwent SU-AVR between 2013 and 2015. Early patients underwent partial aortic decalcification and subannular valve implantation (standard technique), while later patients underwent complete/symmetrical decalcification and intra-annular valve deployment (modified technique). Predictive baseline and procedural variables and electrocardiographic parameters were identified using a logistic regression model.

RESULTS: We included 140 patients (mean age, 78 ± 6.5 years; mean Log EuroSCORE II, 8.9 ± 10%; 28.6% concomitant myocardial revascularization). The most common postoperative conduction disturbances were LBBB (25%), NO-AVB (12.1%) and first-degree atrioventricular block (AVB) (7.9%). The incidence of NO-AVB was 61% lower with the modified versus the standard technique ($P = 0.04$). NO-AVB predominantly appeared within 24 h post-surgery, occurring >24 h post-surgery in only 2 patients (both with baseline conduction defects). Independent predictors of NO-AVB included baseline left QRS axis deviation (LaQD; $P = 0.03$), first-degree AVB ($P < 0.01$) and standard surgical technique ($P = 0.02$).

CONCLUSIONS: NO-AVB is a frequent complication following SU-AVR, and its incidence strongly depends on the surgical technique. Baseline first-degree AVB and LaQD independently predict NO-AVB and should be considered when deciding the duration of postoperative electrocardiographic monitoring.