ORIGINAL ARTICLE

Braz J Cardiovasc Surg 2024;39(4):e20230155
https://doi.org/10.21470/1678-9741-2023-0155

Sutureless Aortic Valve Replacement *vs.* Transcatheter Aortic Valve Implantation in Patients with Small Aortic Annulus: Clinical and Hemodynamic Outcomes from a Multi-Institutional Study

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ABSTRACT

Objective: This study aimed to compare hemodynamic performances and clinical outcomes of patients with small aortic annulus (SAA) who underwent aortic valve replacement by means of sutureless aortic valve replacement (SUAVR) or transcatheter aortic valve implantation (TAVI).

Methods: From 2015 to 2020, 622 consecutive patients with SAA underwent either SUAVR or TAVI. Through a 1:1 propensity score matching analysis, two homogeneous groups of 146 patients were formed. Primary endpoint: all cause-death at 36 months. Secondary endpoints: incidence of moderate to severe patient-prosthesis mismatch (PPM) and incidence of major adverse cardiovascular and cerebrovascular events (MACCEs)

Results: All-cause death at three years was higher in the TAVI group (SUAVR 12.2% *vs.* TAVI 21.0%, *P*=0.058). Perioperatively, comparable hemodynamic performances were recorded in terms of indexed effective orifice area (SUAVR 1.12 ± 0.23 cm^2/m^2 *vs.* TAVI 1.17 ± 0.28 cm^2/m^2, *P*=0.265), mean transvalvular gradients (SUAVR 12.9 ± 5.3 mmHg *vs.* TAVI 12.2 ± 6.2 mmHg, *P*=0.332), and moderate-to-severe PPM (SUAVR 4.1% *vs.* TAVI 8.9%, *P*=0.096). TAVI group showed a higher cumulative incidence of MACCEs at 36 months (SUAVR 18.1% *vs.* TAVI 32.6%, *P*<0.001). Pacemaker implantation (PMI) and perivalvular leak ≥ 2 were significantly higher in TAVI group and identified as independent predictors of mortality (PMI: hazard ratio [HR] 3.05, 95% confidence interval [CI] 1.34-6.94, *P*=0.008; PPM: HR 2.72, 95% CI 1.25-5.94, *P*=0.012).

Conclusion: In patients with SAA, SUAVR and TAVI showed comparable hemodynamic performances. Moreover, all-cause death and incidence of MACCEs at follow-up were significantly higher in TAVI group.

Keywords: Transcatheter Aortic Valve Replacement. Aorta Valve. Hemodynamics. Prostheses and Implants. Propensity Scores.

Abbreviations, Acronyms & Symbols

AS	= Aortic stenosis	OCEAN-TAVI	Optimized transCathEter vAlvular interventioN-Transcatheter Aortic Valve Implantation
AV	= Atrioventricular		
AVR	= Aortic valve replacement	PAD	= Peripheral artery disease
BEV	= Balloon-expandable valves	PARTNER	= Placement of AoRTic TraNscathetER Valves
BMI	= Body mass index	PM	= Pacemaker
BSA	= Body surface area	PMI	= Pacemaker implantation
CAD	= Coronary artery disease	PPM	= Patient-prosthesis mismatch
CI	= Confidence interval	PVL	= Perivalvular leak
COPD	= Chronic obstructive pulmonary disease	SAA	= Small aortic annulus
CPB	= Cardiopulmonary bypass	SB	= Stentless bioprostheses
CVA	= Cerebrovascular accident	SD	= Standard deviation

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Article received on April 18th, 2023.
Article accepted on August 21st, 2023.

EOA	**= Effective orifice area**	**SEV**	**= Self-expandable valves**
EuroSCORE	**= European System for Cardiac Operative Risk Evaluation**	**STS**	**= Society of Thoracic Surgeons**
EF	**= Ejection fraction**	**SUAVR**	**= Sutureless aortic valve replacement**
Gmax	**= Maximum gradient**	**TA**	**= Transapical**
Gmean	**= Mean gradient**	**TAVI**	**= Transcatheter aortic valve implantation**
HR	**= Hazar ratio**	**TAVI-SMALL**	**= International Multicenter Registry to Evaluate the Performance of Self-Expandable Valves in Small Aortic Annuli**
HTN	**= Hypertension**		
ICU	**= Intensive care unit**		
IQR	**= Interquartile range**	**TF**	**= Transfemoral**
iEOA	**= Indexed effective orifice area**	**TIA**	**= Transitory ischemic attack**
MACCEs	**= Major adverse cardiovascular and cerebrovascular events**	**VARC**	**= Valve Academic Research Consortium**
MAV	**= Mechanical invasive ventilation**		

INTRODUCTION

Small aortic annulus (SAA) is an anatomic feature that represents an important concern in patients undergoing aortic valve replacement (AVR)[1]. Small sizes (≤ 23 mm) of stented aortic bioprostheses have an effective orifice area (EOA) smaller than the native aortic valve area, which may lead to patient-prosthesis mismatch (PPM)[1,2]. As a matter of fact, PPM occurs when the EOA of a normally functioning prosthetic valve is too small in relation to the patient's body surface[2].

The presence of moderate (< 0.85 cm^2/m^2 and > 0.65 cm^2) or severe (< 0.65 cm^2/m^2) PPM has been demonstrated to produce detrimental effects on patients' outcomes, jeopardizing left ventricular reverse remodeling, hypertrophy regression, and functional recovery[1,3].

Surgical aortic annulus enlargement was demonstrated to be a viable surgical strategy to reduce PPM rate, allowing surgeons to implant larger bioprostheses. However, aortic annulus enlargement increases surgical complexity and risks and is rarely performed[4]. Nevertheless, the use of stentless bioprostheses (SB) reduced the risk of PPM in patients with SAA since the absence of a rigid stent allows the use of larger prostheses. However, the major drawback of SB is the increased ischemic and cardiopulmonary bypass (CPB) times for implant, despite no differences in terms of intensive care unit (ICU) and hospital length of stay were demonstrated[5,6].

Several studies showed that transcatheter aortic valve implantation (TAVI) offered better hemodynamic results with a reduced incidence of PPM especially in patients with a SAA[7,8]. In this specific subset of population, self-expandable valves (SEV) showed better hemodynamic performances when compared to balloon-expandable valves (BEV)[9,10].

Sutureless aortic valves proved to have larger EOAs for any given size compared to stented bioprostheses and to provide good hemodynamic performances, comparable to stentless valves. In addition, sutureless valves can be implanted with significantly shorter aortic cross-clamping and CPB times, overcoming the drawback of SB[11]. Patients receiving sutureless valves had shorter invasive ventilation time and ICU and hospital stay as well as the need for red blood cell transfusions when compared to stented valves[11].

The aim of this study was to compare hemodynamic performances and outcomes of sutureless aortic valve replacement (SUAVR) *vs.* TAVI in elderly patients affected by aortic stenosis (AS) with a small aorta undergoing surgical AVR employing balloon-expandable or self-expandable bioprostheses.

METHODS

Study Design

This European multi-institutional retrospective study included patients with a SAA (echocardiographic diameter ≤ 21 mm) who underwent AVR by means of either surgical SUAVR or TAVI for isolated AS.

The study protocol was approved by the Institutional Review Board of each participating center (University of Brescia approved the present study with NP 1870). Data were collected from May 2015 to December 2020 from five European centers. A total of 320 and 302 patients with a SAA were recruited for the SUAVR and TAVI groups, respectively.

A propensity score matching analysis was performed to reduce selection bias. Following 1:1 propensity score matching, 146 patients from each treatment group were selected to obtain two homogeneous populations.

Patients in the surgical group were treated with Perceval® S valve (LivaNova PLC, London, United Kingdom) size S (19-21 mm) or M (21-23 mm), while patients in the TAVI group were treated with either SAPIEN XT®/SAPIEN 3® (Edwards Lifesciences, Irvine, California, United States of America) size 23, CoreValve™/Evolut™ R (Medronic, Minneapolis, Minnesota, United States of America) size 23 or 26, or Acurate TA™ (Symetys SA, Ecublens, Switzerland) size S.

Transthoracic echocardiography was performed at baseline, at discharge, and at the first and third years postoperatively in all patients. Moderate to severe PPM was defined as indexed EOA

(iEOA) (moderate PPM iEOA < 0.85 cm^2/m^2; severe PPM iEOA < 0.65 cm^2/m^2)[1]. Transesophageal echocardiography was performed to assess intraoperative implant success according to Valve Academic Research Consortium (VARC) III criteria[12]. Prosthetic aortic valve regurgitation was defined moderate to severe according to VARC III criteria (vena contracta > 4 mm, pressure half-time 200-500 ms, regurgitant volume > 30 ml/beat)[12].

As far as TAVI concerns, oversizing was analyzed by the physicians involved in the individual case and did not exceed 20%. For sutureless valves, oversizing was not performed, as recommended in the Company's manual.

Study Endpoints

The primary endpoints of the study were all-cause mortality and hemodynamic valve performances (mean/peak gradients, EOA, iEOA, moderate-severe PPM). Secondary endpoints included major adverse cardiovascular and cerebrovascular events (MACCEs) defined as follows: all-cause death, stroke/transitory ischemic attack (TIA), endocarditis, reoperation, pacemaker implantation (PMI), and perivalvular leak (PVL) ≥ 2.

Statistical Analysis

The normality of continuous distributions was assessed using the Kolmogorov-Smirnov test. Normally and skewed distributed variables were presented as mean with standard deviation and median with 25th and 75th percentiles (interquartile range boundaries), respectively. Student's *t*-test or Mann-Whitney U test were used for normally distributed or skewed distributed variables, respectively. Categorical variables were expressed as frequency and percentage and were compared using the Chi-square test.

Preoperative covariates were adjusted with 1:1 nearest-neighbour propensity score matching without replacement (caliper 0.06), obtaining two balanced groups (matched [Table 1] and unmatched [Table E1]). Balance check was performed analyzing the standard mean difference between the two groups. A visual inspection of the standard mean difference with the Love plot was also performed. The matched standardized differences of each covariate in the matched population were < 10% (Figure 1).

The Kaplan-Meier method was used to assess overall survival and freedom from MACCE. Group difference analysis was evaluated using the log-rank test. A univariate and multivariate Cox-regression analysis was performed to further assess late mortality. Follow-up information was completed by patient or physician contact.

Microsoft® Office Excel 365 software (Microsoft, Redmond, Washington) was used for data extraction and statistical analyses were conducted applying IBM Corp. Released 2017, IBM SPSS Statistics for MAC, version 25.0, Armonk, NY: IBM Corp. and R Project for Statistical Computing, version 3.6.2, using the "MatchIt" package.

RESULTS

Operative Results

In the SUAVR group, a minimally invasive strategy was adopted in 60.2% of patients (ministernotomy 52.7%, right anterior thoracotomy 7.5%); in the remaining patients, a median sternotomy was performed. Furthermore, Perceval® S size S was used in 84 (57.6%) patients while size M valve was implanted in 62 (43.4%) patients.

Among TAVI patients, SAPIEN 3® or SAPIEN XT® BEV N. 23 was used in 109 (109/146 [74.6%]) patients, 26 (17.8%) patients had Evolut™ R/CoreValve™ SEV (size 23: 18 patients; size 26: eight patients), and 11 (7.6%) patients had a size S Acurate TA™ self-expandable bioprosthesis. Moreover, in 71.9% of patients, TAVI procedure was carried out through transfemoral (TF) approach, while transapical (TA) approach was adopted in 26.0% of cases, and subclavian, transaortic, and transcarotid approaches in 2.0% of the remaining cases.

A second valve implantation was required for technical failure in three (2.0%) patients in the TAVI group (two patients undergoing Edwards SAPIEN® and one patient receiving an Evolut™ R valve).

Emergency conversion to open surgery was required during three (2.0%) procedures: left coronary ostium obstruction and for aortic annular rupture occurred in one (0.7%) and two (1.4%) patients, respectively. In the SUAVR group, one patient was converted to stented valve implantation due to intraoperative annular rupture, while one patient required a second cross-clamp for valve repositioning (Table E2).

Early Postoperative Results

Postoperative echocardiography at discharge showed comparable mean gradients between groups (matched: SUAVR 12.9 ± 5.33 mmHg; TAVI 12.16 ± 6.24 mmHg, *P*=0.523), as well as comparable postoperative iEOA (matched: SUAVR 1.12 ± 0.13 cm^2/m^2; TAVI 1.17 ± 0.31 cm^2/m^2, *P*=0.798) (Figure 2). No differences were reported in terms of postoperative moderate to severe PPM between SUAVR and TAVI (matched: SUAVR 4.1% *vs.* TAVI 8.9%, *P*=0.096). Moreover, no differences were reported between BEV and SEV TAVI in terms of PPM (matched: BEV 10.1% *vs.* SEV 5.2%, *P*=0.391).

Thirty-day all-cause mortality was higher in the TAVI group (matched: SUAVR 1.4% *vs.* TAVI 6.2%, *P*<0.032). Of note, as a subgroup analysis, TA group showed a higher mortality rate compared to TF approach (TA: 13.2% *vs.* TF: 3.7%, *P*=0.03), while no difference in terms of 30-day mortality rate is reported between BEV (5.5%) and SEV (8.8%) (*P*=0.569).

Cumulative incidence of MACCE at 30-days was superior in the TAVI group (matched: SUAVR 10.2% *vs.* TAVI 18.4%, *P*=0.045). On this regard, a higher incidence of atrioventricular (AV) blocks requiring PMI occurred in the TAVI group, both in the matched and unmatched population (matched: SUAVR 4.79% *vs.* TAVI 11.64%, *P*=0.033; unmatched: SUAVR 6.9% *vs.* TAVI 12.2, *P*=0.022), as well as a higher incidence of PVL ≥ 2 was reported in the TAVI group (matched: SUAVR 1.4% *vs.* TAVI 6.8%, *P*=0.017). Moreover, the TAVI group had a significantly higher rate of vascular complications requiring surgical or endovascular interventions (matched: SUAVR 0.68% *vs.* TAVI 9.59%, *P*<0.001).

There were no significant differences between the groups in terms of incidence of stroke/TIA (matched: SUAVR 0.7% *vs.* TAVI 2.6%, *P*=0.370) and acute renal failure (matched: SUAVR 3.5% *vs.* TAVI 7.5%, *P*=0.122).

A superior rate of postoperative transfusions was accounted in the SUAVR group (matched: SUAVR 24.6% *vs.* TAVI 2.7%, *P*<0.001). Conversely, higher incidences of infections requiring antibiotic therapy were reported in the TAVI group (unmatched: SUAVR 3.75% *vs.* TAVI 8.28%, *P*=0.017), however this was not significant

Table 1. Patients' preoperative characteristics.

	Unmatched			Matched		
	TAVI (n=302)	Perceval® (n=320)	*P*-value	TAVI (n=146)	Perceval® (n=146)	*P*-value
Age (years)	83.23 ± 5.58	79.63 ± 5.68	< 0.001	81.14 ± 6.01	81.19 ± 5.29	0.946
BMI (kg/m^2) (mean ± SD)	25.81 ± 4.96	25.15 ± 5.07	< 0.001	24.9 ± 5.27	24.9 ± 5.08	0.623
BSA (m^2) (mean ± SD)	1.63 ± 0.28	1.60 ± 0.16	< 0.001	1.58 ± 0.19	1.57 ± 0.18	0.619
Females	274 (90.7%)	291 (90.9%)	< 0.001	129 (88.4%)	130 (89.0%)	0.853
STS risk score (mean ± SD)	8.08 ± 5.21	4.93 ± 3.82	< 0.001	6.14 ± 3.93	6.04 ± 4.66	0.838
EuroSCORE II (mean ± SD)	7.91 ± 5.48	5.27 ± 4.56	< 0.001	5.47 ± 4.02	5.65 ± 4.86	0.729
Redo	46 (15.2%)	17 (5.3%)	< 0.001	15 (10.3%)	14 (9.6%)	0.845
Hypertension	298 (98.7%)	255 (79.7%)	0.002	119 (81.5%)	124 (84.9%)	0.287
Dyslipidemia	172 (57.0%)	155 (48.4%)	0.483	76 (52.1%)	69 (47.3%)	0.483
Diabetes	149 (49.3%)	87 (27.2%)	< 0.001	61 (41.8%)	54 (37.0%)	0.402
COPD	33 (10.9%)	47 (14.7%)	0.057	17 (11.6%)	22 (15.1%)	0.377
Clearance < 30	55 (18.2%)	19 (5.9%)	< 0.001	19 (13.0%)	20 (13.7%)	0.863
CAD	138 (45.7%)	70 (21.9%)	< 0.001	48 (32.9%)	48 (32.9%)	0.999
PAD	32 (10.6%)	37 (11.6%)	0.391	9 (6.2%)	18 (12.3%)	0.069
CVA (previous)	28 (9.3%)	15 (4.7%)	0.059	11 (7.5%)	9 (6.2%)	0.643
Ejection fraction (mean ± SD)	57.6 ± 10.8	60.2 ± 10.3	0.014	58.7 ± 10.6	58.5 ± 10.7	0.854
Preoperative echocardiography						
Gmax (mean ± SD)	80.8 ± 20.2	82.4 ± 25.5	0.813	82.2 ± 19.8	80.2 ± 22.5	0.407
Gmean (mean ± SD)	50.1 ± 13.8	50.3 ± 16.6	0.616	51.8 ± 13.3	50.8 ± 16.1	0.555
Effective orifice area (cm^2) (mean ± SD)	0.64 ± 0.2	0.65 ± 0.21	0.361	0.63 ± 0.20	0.64 ± 0.21	0.635
Mean aortic annulus (mm) (mean ± SD)	20.4 ± 0.5	20.3 ± 0.6	0.853	20.3 ± 0.7	20.2 ± 0.8	0.733

BMI=body mass index; BSA=body surface area; CAD=coronary artery disease; COPD=chronic obstructive pulmonary disease; CVA=cerebrovascular accident; EuroSCORE=European System for Cardiac Operative Risk Evaluation; Gmax=maximum gradient; Gmean=mean gradient; PAD=peripheral artery disease; SD=standard deviation; STS=Society of Thoracic Surgeons; TAVI=transcatheter aortic valve implantation

after propensity matching (matched: SUAVR 1.4% *vs.* TAVI 4.8%, *P*=0.172). Postoperative results are listed in Table 2 for the matched and in Table E3 for the unmatched groups.

Follow-up Results

Mean follow-up was 24.4 ± 11.1 months. All-cause death was significantly higher in the TAVI group at 36 months in the unmatched population (36 months: SUAVR 11.5%, 95% confidence interval [CI] 7.6-15.6%; TAVI 19.9%, 95% CI 13.1-26.2%, *P*=0.022) (Figure 3A), and close to be significant in the matched population (36 months: SUAVR 12.2%, 95% CI 6.1-17.9%; TAVI 21.0%, 95% CI 12.3-28.8%, *P*=0.058) (Figure 3B).

At 36 months, a significantly higher incidence of moderate to severe PPM and PVL occurred in the TAVI group when compared to SUAVR (PPM matched: SUAVR 8.2% *vs.* TAVI 15.7%, *P*=0.047; PVL matched: SUAVR 6.1% *vs.* TAVI 13.9%, *P*=0.031) (Table 2, Supplementary Figure 1).

The multivariable Cox regression analysis (time-dependent variable) showed PMI and PPM as independent predictors of death (PMI hazard ratio [HR] 3.05, 95% CI 1.34-6.94, *P*=0.008; PPM HR 2.72, 95% CI 1.25-5.94, *P*=0.012).

Patients undergoing TAVI showed a higher cumulative incidence of MACCEs at 36 months (unmatched: SUAVR 17.2%, 95% CI 10.4-21.2 *vs.* TAVI 29.4%, 95% CI 22.0-36.2, *P*<0.001; matched: SUAVR 18.1%, 95% CI 10.1-25.6 vs. TAVI 32.6%, 95% CI 26.0-48.1, *P*<0.001) (Figure 4A-B).

At multivariable Cox regression analysis, TAVI was identified as an independent predictor for MACCEs (HR 2.65, 95% CI 1.26-3.86, *P*=0.003).

DISCUSSION

To our knowledge, this is the first multi-institutional study comparing the hemodynamic performances of sutureless aortic valves *vs.* TAVI in patients with a SAA. Although not being randomized, this retrospective analysis was designed as propensity matched comparison to reduce confounding factors.

The major findings of this study were: 1) SUAVR and TAVI showed up to one year comparable hemodynamic performances in terms

Table E1. Preoperative patients' characteristics in unmatched groups.

	Unmatched		
	TAVI (n = 302)	Perceval® (n = 320)	*P*-value
Age (years)	83.23 ± 5.58	79.63 ± 5.68	< 0.001
BMI (kg/m^2) (mean ± SD)	25.81 ± 4.96	25.15 ± 5.07	< 0.001
BSA (m^2)(mean ± SD)	1.63 ± 0.28	1.60 ± 0.16	< 0.001
Female sex	274 (90.7%)	291 (90.9%)	< 0.001
STS risk score (mean ± SD)	8.08 ± 5.21	4.93 ± 3.82	< 0.001
EuroSCORE II (mean ± SD)	7.91 ± 5.48	5.27 ± 4.56	< 0.001
Redo	46 (15.2%)	17 (5.3%)	< 0.001
Hypertension	298 (98.7%)	255 (79.7%)	0.002
Dyslipedemia	172 (57.0%)	155 (48.4%)	0.483
Diabetes	149 (49.3%)	87 (27.2%)	< 0.001
COPD	33 (10.9%)	47 (14.7%)	0.057
Clearance < 30	55 (18.2%)	19 (5.9%)	< 0.001
CAD	138 (45.7%)	70 (21.9%)	< 0.001
PAD	32 (10.6%)	37 (11.6%)	0.391
CVA (previous)	28 (9.3%)	15 (4.7%)	0.059
Ejection fraction (mean ± SD)	57.6 ± 10.8	60.2 ± 10.3	0.014
Preoperative echocardiography			
Gmax (mean ± SD)	80.8 ± 20.2	82.4 ± 25.5	0.813
Gmean (mean ± SD)	50.1 ± 13.8	50.3 ± 16.6	0.616
Effective orifice area, cm^2 (mean ± SD)	0.64 ± 0.2	0.65 ± 0.21	0.361
Mean aortic annulus (mm) (mean ± SD)	20.4±0.5	20.3±0.6	0.853

BMI=body mass index; BSA=body surface area; CAD=coronary artery disease; COPD=chronic obstructive pulmonary disease; CVA=cerebrovascular accident; EuroSCORE=European System for Cardiac Operative Risk Evaluation; Gmax=maximum gradient; Gmean=mean gradient; PAD=peripheral artery disease; SD=standard deviation; STS=Society of Thoracic Surgeons; TAVI=transcatheter aortic valve implantation

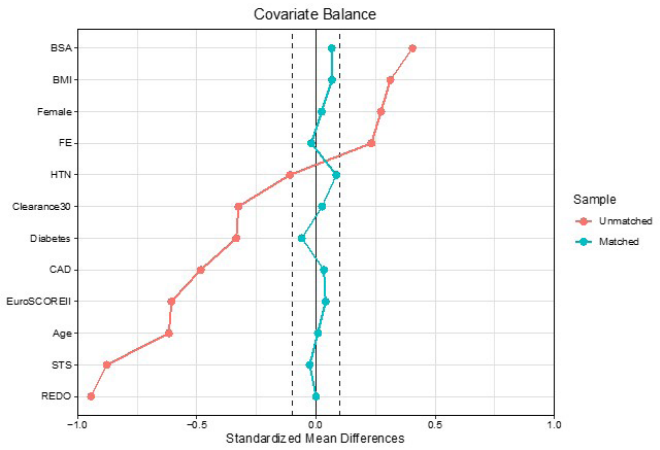


Fig. 1 - *Propensity score Love plot. BMI=body mass index; BSA=body surface area; CAD=coronary artery disease; EuroSCORE=European System for Cardiac Operative Risk Evaluation; EF=ejection fraction; HTN=hypertension; STS=Society of Thoracic Surgeons.*

of iEOA, transvalvular gradients, and incidence of moderate to severe PPM; 2) at three years, patients treated with TAVI showed a significant reduction of iEOA with a significant higher rate of moderate to severe PPM when compared to SUAVR; 3) at one and three years, TAVI group showed a higher all-cause mortality when compared to SUAVR, significantly in the unmatched population; 4) at one and three years, TAVI group showed a significantly higher rate of MACCEs in the matched and unmatched groups; 5) multivariable Cox regression analysis showed PPM and PMI as independent predictors of mortality (matched PPM: HR 2.72, 95% CI 1.25-5.94, *P*=0.012) (matched: PMI: HR 5.2, 95% CI 2.0-14.3, *P*=0.012). The current study analyzed the influence of treatment strategy in patients with AS and SAA for which the risk of suboptimal valve hemodynamics and PPM is relevant.

PPM is a well-known condition which may occur in patients with SAA both after surgical AVR and TAVI procedures. Small size of stented bioprostheses (≤ 21 mm) in surgical AVR likely leads to PPM in patients with body surface area (BSA) > 1.7[1,13]. The risk of PPM

Table E2. Intraoperative patients' characteristics.

	Unmatched			Matched		
	TAVI	**Perceval®**	***P*-value**	**TAVI**	**Perceval®**	***P*-value**
	(n = 302)	**(n = 320)**		**(n=146)**	**(n=146)**	
Non elective procedures	11 (3.64%)	4 (1.25%)	0.056	6 (4.1)	2 (1.4%)	0.151
MAV > 48 hours	10 (3.3%)	8 (2.5%)	0.709	5 (3.4%)	5 (3.4%)	1'000
ICU stay, hours (median, IQR)	21 (18-24)	22 (19-24)	0.144	20 (18-24)	21 (18-24)	0.283
Valve diameter (median, IQR)	23 (23-23)			23 (23-23)		
CPB time (min) (mean ± SD)		65.2 ± 28.7			61.2 ± 25.7	
Aortic cross-clamping time (min) (mean ± SD)		42.5 ± 19.7			39.9 ± 18.8	
Perceval® size						
Size S		198 (61.8%)			84 (57.6%)	
Size M		122 (28.2%)			62 (42.4%)	
Surgical approach						
Sternotomy		107 (33.4%)			58 (39.7%)	
Ministernotmy		194 (60.6%)			77 (52.7)	
Anterior minithoracotomy		19 (6.0%)			11 (7.5%)	
TAVI approach						
Transapical	90 (29.8%)			38 (26.0%)		
Transfemoral	198 (65.5%)			105 (71.9%)		
Other transvessel	14 (4.7%)			3 (2.1%)		

CPB=cardiopulmonary bypass; ICU=intensive care unit; IQR=interquartile range; MAV=mechanical invasive ventilation; SD=standard deviation; TAVI=transcatheter aortic valve implantation

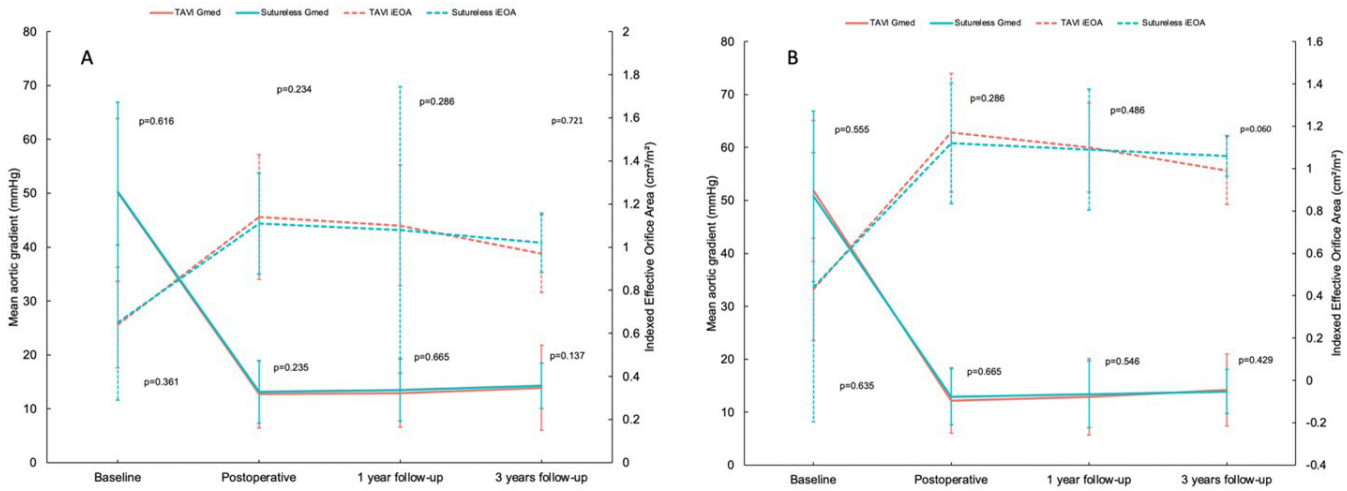


Fig. 2 - *A) Mean gradient (Gmean) and indexed effective orifice area (iEOA) at baseline, discharge, 1 year, and 3 years in unmatched population. B) Mean gradient and iEOA at baseline, discharge, 1 year, and 3 years in matched population. TAVI=transcatheter aortic valve implantation.*

Table 2. Postoperative outcomes.

	Unmatched			Matched		
	TAVI (n=302)	Perceval® (n=320)	*P*-value	TAVI (n=146)	Perceval® (n=146)	*P*-value
30-day all-cause mortality	26 (8.61%)	4 (1.3%)	< 0.001	9 (6.1)	2 (1.4%)	0.032
Permanent PM implantation	37 (12.2%)	22 (6.9%)	0.022	17 (11.6%)	7 (4.8%)	0.033
Red blood cell transfusion	11 (3.6%)	75 (23.4%)	< 0.001	4 (2.7%)	36 (24.6%)	< 0.001
Life-threatening bleeding	5 (1.66%)	12 (3.8%)	0.109	2 (1.4%)	4 (1.4%)	0.409
Acute renal failure (stage 2-3, VARC III)	16 (5.3%)	8 (2.5%)	0.071	11 (7.5%)	5 (3.5%)	0.122
Infections requiring antibiotic therapy	25 (8.3%)	13 (4.0%)	0.021	2 (1.4%)	7 (4.8%)	0.172
Vascular complications	24 (7.9%)	5 (1.6%)	< 0.001	14 (9.6%)	2 (1.4%)	< 0.001
Stroke/TIA	11 (3.6%)	7 (2.2%)	0.279	4 (2.7%)	1 (0.7%)	0.370
Myocardial infarction	5 (1.66%)	3 (0.9%)	0.426	3 (2.1%)	1 (0.7%)	0.313
Postoperative Echocardiography						
Gmax (mean ± SD)	21.8 ± 8.3	23.1 ± 8.1	0.628	22.5 ± 8.4	23.2 ± 9.2	0.523
Gmean (mean ± SD)	12.7 ± 6.3	13.1 ± 5.8	0.234	12.2 ± 6.2	12.9 ± 5.3	0.265
Effective orifice area (cm^2) (mean ± SD)	1.59 ± 0.27	1.51 ± 0.21	0.342	1.63 ± 0.26	1.55 ± 0.15	0.286
iEOA (cm^2/m^2) (mean ± SD)	1.14 ± 0.29	1.11 ± 0.13	0.235	1.17 ± 0.28	1.12 ± 0.23	0.337
PVL ≥ grade II	16 (5.3%)	7 (2.2%)	0.039	10 (6.8%)	2 (1.4%)	0.017
Moderate to severe PPM	23 (7.6%)	15 (4.6%)	0.127	13 (8.9%)	6 (4.1%)	0.096
1-year Echocardiography						
Gmax (mean ± SD)	21.8 ± 8.3	23.1 ± 8.1	0.628	23.5 ± 8.4	24.2 ± 9.2	0.523
Gmean (mean ± SD)	12.9 ± 6.3	13.5 ± 5.8	0.286	12.9 ± 6.2	13.4 ± 5.3	0.265
Effective orifice area (cm^2) (mean ± SD)	1.49 ± 0.24	1.45 ± 0.21	0.632	1.52 ± 0.22	1.50 ± 0.19	0.486
iEOA (cm^2/m^2) (mean ± SD)	1.10 ± 0.28	1.08 ± 0.13	0.665	1.11 ± 0.21	1.09 ± 0.23	0.537
PVL ≥ grade II	23 (7.6%)	14 (4.3%)	0.050	13 (8.2%)	5 (3.4%)	0.050
Moderate to severe PPM	28 (9.2%)	21 (6.5%)	0.127	15 (10.2%)	7 (4.7%)	0.078
3-year Echocardiography						
Gmax (mean ± SD)	25.5 ± 7.3	24.7 ± 8.2	0.423	26.5 ± 7.3	25.8 ± 8.2	0.632
Gmean (mean ± SD)	13.9 ± 7.9	14.3 ± 4.2	0.721	14.2 ± 6.8	13.9 ± 4.2	0.429
Effective orifice area (cm^2) (mean ± SD)	1.30 ± 0.26	1.39 ± 0.15	0.027	1.33 ± 0.26	1.41 ± 0.15	0.096
iEOA (cm^2/m^2) (mean ± SD)	0.97 ± 0.18	1.02 ± 0.21	0.137	0.99 ± 0.19	1.06 ± 0.15	0.057
PVL ≥ grade II	36 (11.9%)	24 (7.5%)	0.058	20 (13.9%)	9 (6.1%)	0.031
Moderate to severe PPM	41 (13.5%)	30 (9.3%)	0.098	23 (15.7%)	12 (8.2%)	0.047

Gmax=maximum gradient; Gmean=mean gradient; iEOA=indexed effective orifice area; PM=pacemaker; PPM=patient-prosthesis mismatch; PVL=perivalvular leak; SD=standard deviation; TAVI=transcatheter aortic valve implantation; TIA=transitory ischemic attack; VARC=Valve Academic Research Consortium

may be reduced by using annulus enlargement techniques, allowing the use of larger bioprostheses[14]. However, annulus enlargement is seldom performed[7], as reported by Pibarot et al., which found in the Placement of AoRTic TraNscathetER Valves (PARTNER) cohort A analysis, that patients undergoing surgical AVR had a significantly higher incidence of moderate and severe PPM when compared to TAVI. In addition, in patients with a SAA treated with stented bioprosthesis, severe PPM were found in more than one-third of cases (34%), clearly indicating a suboptimal surgical treatment[7].

However, the issue of PPM remains relevant even in patients undergoing transcatheter valve implantation, since Pibarot et al., in the PARTNER trial Cohort-A analysis, reported in the subset TAVI group with SAA an incidence of moderate and severe PPM of 27% and 20%, respectively[7].

Herrmann et al.[15], analyzing data on more than 60,000 patients undergoing TAVI from the STS/ACC TVT Registry™, reported an incidence of moderate and severe PPM of 25% and 12%, respectively. These authors showed that PPM was associated with a

Table E3. Postoperative outcomes in unmatched groups.

	Unmatched		
	TAVI	Perceval®	*P*-value
	(n = 302)	(n = 320)	
30-day all-cause mortality	26 (8.61%)	4 (1.3%)	< 0.001
Permanent PM implantation	37 (12.2%)	22 (6.9%)	0.022
Red blood cell transfusion	11 (3.6%)	75 (23.4%)	< 0.001
Life-treatening bleeding	5 (1.66%)	12 (3.8%)	0.109
Acute renal failure (stage 2-3, VARC III)	16 (5.3%)	8 (2.5%)	0.071
Infections requiring antibiotic therapy	25 (8.3%)	13 (4.0%)	0.021
Vascular complications	24 (7.9%)	5 (1.6%)	< 0.001
Stroke/TIA	11 (3.6%)	7 (2.2%)	0.279
Myocardial Infarction	5 (1.66%)	3 (0.9%)	0.426
Postoperative echocardiography			
Gmax (mean ± SD)	21.8 ± 8.3	23.1 ± 8.1	0.628
Gmean (mean ± SD)	12.7 ± 6.3	13.1 ± 5.8	0.234
Effective orifice area, cm^2 (mean ± SD)	1.59 ± 0.27	1.51 ± 0.21	0.342
EOA index, cm^2/m^2 (mean ± SD)	1.14 ± 0.29	1.11 ± 0.13	0.235
PVL ≥ grade II	16 (5.3%)	7 (2.2%)	0.039
Moderate to severe PPM	23 (7.6%)	15 (4.6%)	0.127
1-year echocardiography			
Gmax (mean ± SD)	21.8 ± 8.3	23.1 ± 8.1	0.628
Gmean (mean ± SD)	12.9 ± 6.3	13.5 ± 5.8	0.286
Effective orifice area, cm^2 (mean ± SD)	1.49 ± 0.24	1.45 ± 0.21	0.632
EOA index, cm^2/m^2 (mean ± SD)	1.10 ± 0.28	1.08 ± 0.13	0.665
PVL ≥ grade II	23 (7.6%)	14 (4.3%)	0.050
Moderate to severe PPM	28 (9.2%)	21 (6.5%)	0.127
3-year echocardiography			
Gmax (mean ± SD)	25.5 ± 7.3	24.7 ± 8.2	0.423
Gmean (mean ± SD)	13.9 ± 7.9	14.3 ± 4.2	0.721
Effective orifice area, cm^2 (mean ± SD)	1.30 ± 0.26	1.39 ± 0.15	0.027
EOA index, cm^2/m^2 (mean ± SD)	0.97 ± 0.18	1.02 ± 0.21	0.137
PVL ≥ grade II	36 (11.9%)	24 (7.5%)	0.058
Moderate to severe PPM	41 (13.5%)	30 (9.3%)	0.098

EOA=effective orifice area; Gmax=maximum gradient; Gmean=mean gradient; PM=pacemaker; PPM=patient-prosthesis mismatch; PVL=perivalvular leak; SD=standard deviation; TAVI=transcatheter aortic valve implantation; TIA=transitory ischemic attack; VARC=Valve Academic Research Consortium

significant higher mortality and rehospitalization for heart failure at one year postoperatively[15]. Data from TAVI Registries (International Multicenter Registry to Evaluate the Performance of Self-Expandable Valves in Small Aortic Annuli [TAVI-SMALL], Optimized transCathEter vAlvular interventioN-Transcatheter Aortic Valve Implantation [OCEAN-TAVI]), reporting outcomes in SAA patients, are consistent with the results of the abovementioned study[8,16].

Results of the present study confirm these findings and confirm the progressive decrease of the iEOA over time in the TAVI group, with a constant increase of moderate to severe PPM incidence[16]. Progressive reduction of the iEOA may be due to an early degeneration process of TAVI caused by leaflet stress, and/or to a progressive degeneration and calcification of the "left-in-place" native valve[17]. Moderate and severe structural valve deterioration at mid-term in TAVIs have been reported up to 10.8% and 12.9%, respectively[18].

Sutureless aortic valves were designed to overcome the major hemodynamic drawbacks of stented bioprostheses. The absence of an outer stent provides a greater EOA with a significant lower incidence of PPM when compared to stented valves[18-20]. On this

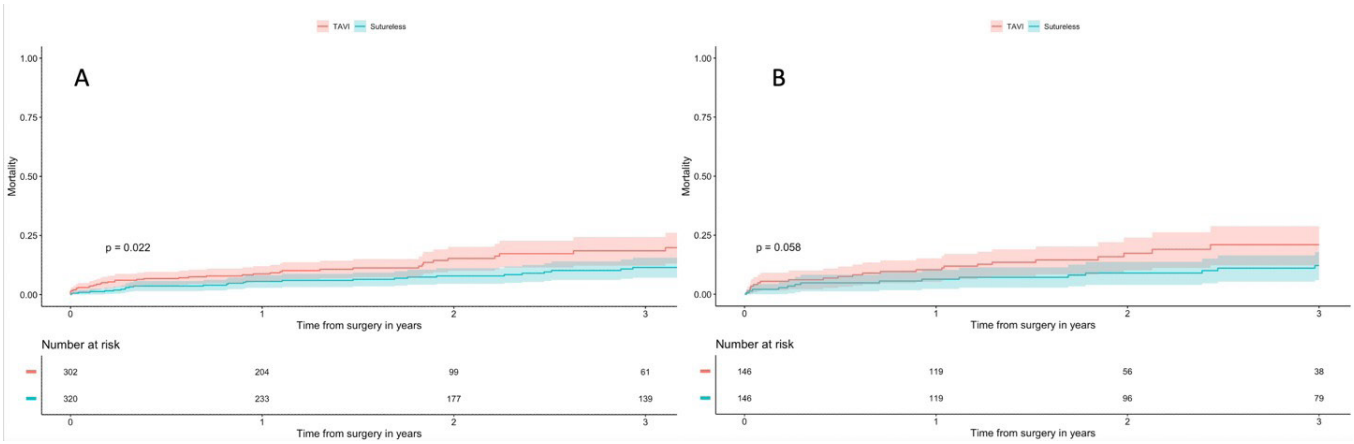


Fig. 3 - *A) All-cause death Kaplan-Meier curves (unmatched groups). B) All-cause death Kaplan-Meier curves (matched groups). TAVI=transcatheter aortic valve implantation.*

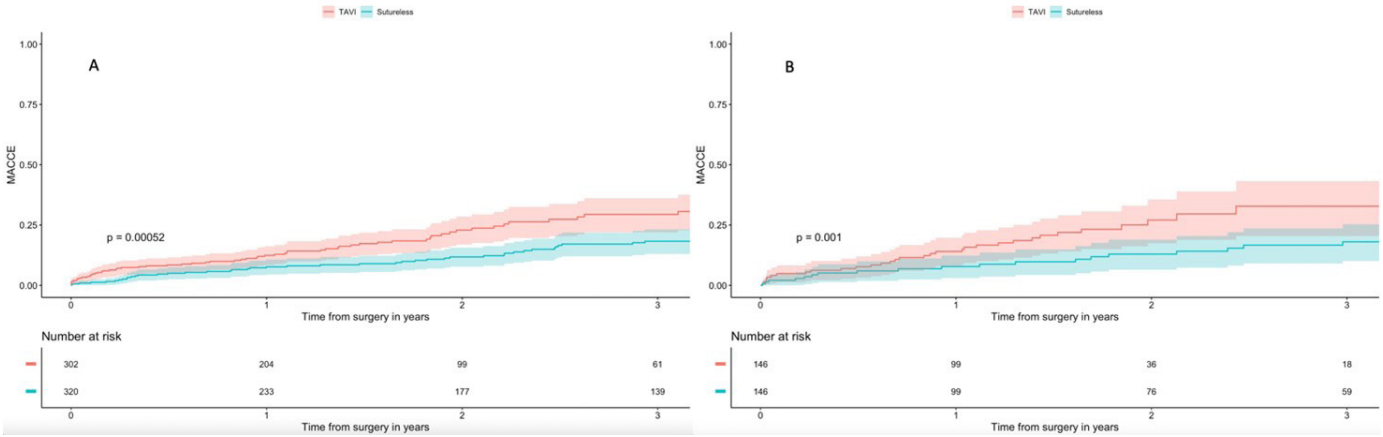
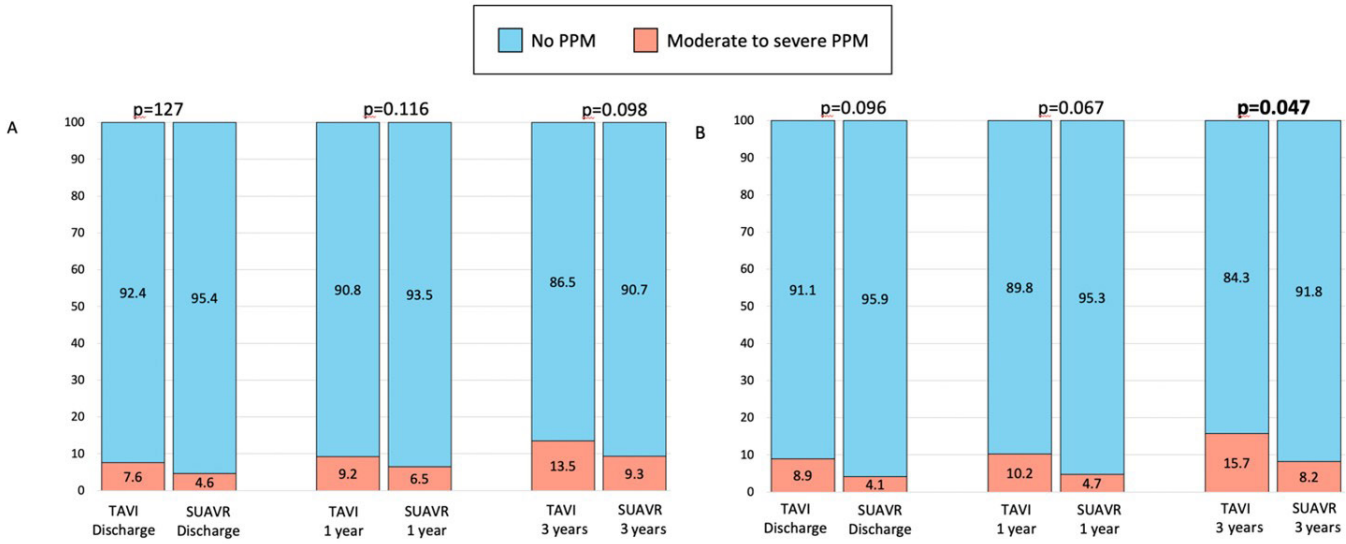


Fig. 4 - *A) Major adverse cardiovascular and cerebrovascular event (MACCE) incidence, Kaplan-Meier curves (unmatched groups). B) MACCE incidence, Kaplan-Meier curves (matched groups). TAVI=transcatheter aortic valve implantation.*



Supplementary Fig. 1 - *Comparison of patient-prosthesis mismatch (PPM) at discharge, 1 year, and 3 years between sutureless aortic valve replacement (SUAVR) and transcatheter aortic valve implantation (TAVI) in unmatched (A) and matched (B) populations.*

regard, Tasca et al. demonstrated in small valve sizes (sutureless small and medium) an *in-vitro* hemodynamic performance as those of native aortic valves. These data are consistent with the outcomes reported by Shalabi and Rubino[18,21] that showed in patients with SAA a postoperative mean iEOA of 1.12 cm^2/m^2 at rest[19], with an increment of 30% of iEOA during stress echocardiography[21]. However, some technical pitfalls, such as sutureless oversizing and an incomplete annular decalcification, may jeopardize SUAVR hemodynamics, increasing the risk of valve dysfunction and PPM as reported by Belluschi and Glauber[20,22].

One of the main findings of the current study is a stable and reliable hemodynamic performance of SUAVR without a significant iEOA reduction over time, avoiding the late development of PPM. Meuris et al. analyzing a large series of sutureless AVR demonstrated a survival freedom from structural valve degeneration of 97% at 10 years[23].

Of note, in this study, the presence of moderate to severe PPM increased 2.5-fold the risk of mortality at follow-up. Similarly, Pibarot et al. reported in 2006 a two-fold and an 11-fold incremented risk of mortality for patients with moderate and severe PPM, respectively[1].

An additional important finding of the present study is the incidence of moderate to severe PVL significantly higher in the TAVI cohort when compared to the SUAVR group (6.8% *vs.* 1.4%, respectively), which is consistent with previous studies[3,8,9] and TAVI registries (OCEAN-TAVI, PARTNER II)[9,24], showing that moderate to severe PVL increases over the years, particularly in BEV. This is associated with a significant decrease in survival at two years[24].

This study showed significantly higher rates of mortality in the TAVI group (6.1%) when compared to the SUAVR group (1.4%) at 30 days. The early mortality rate of the TAVI group could be explained by the higher percentage of patients undergoing TA procedures in this study (26.0%), higher than those in PARTNER II and Surgical Replacement and Transcatheter Aortic Valve Implantation (or SURTAVI) (17.2% and 0%, respectively). However, mortality of the TAVI group at one year and three years was significantly higher than SUAVR only in the unmatched group (Figure 3). These outcomes on TAVI patients are consistent with results reported in the OCEAN-TAVI registry and TAVI-SMALL at 12 and 36 months[9]. It should be remembered that these patients had a lower BSA than the average population (< 1.60 m^2 in the matched group), meaning, besides a smaller aortic annulus, smaller vascular accesses[25]. Consequently, transvessel approaches were either not always viable or carried an elevated risk of vascular complications, making the TA approach the most feasible option.

A relevant finding of the current study is the incidence of AV blocks and left bundle branch block requiring permanent PMI that was significantly higher in the TAVI group than in the SUAVR group (11.5% *vs.* 4.5%, respectively). Those results are consistent with data from the OCEAN-TAVI and TAVI-SMALL registries (13.3% and 15.6%, respectively), while data concerning SUAVR are comparable to those reported in literature[18]. The lower incidence of PMI in SUAVR, which basically has the same expandable self-anchoring stent of TAVI, may be explained by the removal in SUAVR of the native aortic valves and annular calcification, which may reduce the compression causing injury to the conduction tissue[22]. At multivariable Cox regression analysis of the overall study population, the PMI implantation was an important predictor of mortality with a three-fold increased risk of death at three years (HR: 3.05, 95% CI 1.34-6.94).

Limitations

The major limitation of the current study is the lack of randomization. This could be only partially corrected by propensity score matching, which reduced the heterogeneity between groups, but could not eliminate enrollment biases. However, enrollment biases may be also present in randomized comparisons when selection at the entry point of the studies takes only a small percentage of patients having the inclusion criteria.

CONCLUSION

In conclusion, this study showed that postoperative hemodynamic performances of TAVI *vs.* SUAVR are comparable up to one year postoperatively. However, TAVI patients showed a decline in hemodynamic performance and an increase in PPM at three years, suggesting early device degeneration.

TAVI patients are burdened over time by an increased incidence of moderate to severe PVL and by higher rates of permanent PMI.

PPM and PMI were associated with a significant reduction in survival both in SUAVR and TAVI groups.

In patients with AS and SAA, sutureless bioprostheses significantly improved hemodynamics and MACCEs at three years when compared to TAVI.

No financial support.
No conflict of interest.

Authors' Roles & Responsibilities

LDB	Substantial contributions to the conception of the work; drafting the work; final approval of the version to be published
MDA	Substantial contributions to the acquisition, analysis, and interpretation of data for the work; final approval of the version to be published
MDE	Substantial contributions to the acquisition of data for the work; revising the work; final approval of the version to be published
FR	Drafting the work and revising it; final approval of the version to be published
MS	Substantial contributions to the acquisition of data for the work; revising the work; final approval of the version to be published
MB	Substantial contributions to the acquisition, analysis, and interpretation of data for the work; drafting the work; final approval of the version to be published
TF	Substantial contributions to the acquisition of data for the work; revising the work; final approval of the version to be published
SB	Revising the work; final approval of the version to be published
TF	Substantial contributions to the acquisition of data for the work; revising the work; final approval of the version to be published
CM	Substantial contributions to the conception of data for the work; drafting the work and revising it; final approval of the version to be published

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