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ORIGINAL ARTICLE

Immediate outcome after sutureless versus transcatheter aortic valve replacement

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Abstract The aim of this study was to compare the immediate outcome of patients undergoing transcatheter (TAVI) versus surgical aortic valve replacement with the sutureless Perceval bioprosthesis (SU-AVR). This is a retrospective multicenter analysis of 773 patients who underwent either TAVI (394 patients, mean age, 80.8 ± 5.5 years, mean EuroSCORE II 5.6 ± 4.9 %) or SU-AVR (379 patients, 77.4 ± 5.4 years, mean EuroSCORE II 4.0 ± 3.9 %) with or without concomitant myocardial revascularization. Data on SU-AVRs were provided by six European institutions (Belgium, Finland, Germany, Italy and Sweden) and data on TAVIs were provided by a single institution (Catania, Italy). In-hospital mortality was 2.6 % after SU-AVR and 5.3 % after TAVI ($p = 0.057$). TAVI was associated with a significantly high rate of mild (44.0 vs. 2.1 %) and moderate–severe paravalvular regurgitation (14.1 vs. 0.3 %, $p < 0.0001$) as well as the need for permanent pacemaker implantation (17.3 vs. 9.8 %, $p = 0.003$) compared with SU-AVR. The analysis of patients within the 25th and 75th percentiles interval of EuroSCORE II, i.e., 2.1–5.8 %, confirmed the findings of the overall series. One-to-one propensity score-matched analysis resulted in 144 pairs with similar baseline characteristics and operative risk. Among these matched pairs, in-hospital mortality (6.9 vs. 1.4 %, $p = 0.035$) was significantly higher after TAVI. SU-AVR with the Perceval prosthesis in intermediate-risk patients is associated with excellent immediate survival and is a valid alternative to TAVI in these patients.

Keywords Aortic valve replacement · Sutureless · Transcatheter · Perceval · TAVI · AVR

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Introduction

Transcatheter aortic valve implantation (TAVI) has been shown to effectively expand the therapeutic possibilities in patients with aortic valve disease unfit for aortic valve replacement (AVR) [1]. However, its increased costs, the lack of removal of the calcified aortic valve and the resultant risk of paravalvular leakage, coronary occlusion and aortic rupture have been recognized as important limitations of TAVI [2–4]. Because of these reasons, a number of sutureless aortic valve bioprostheses [5] have been developed to facilitate AVR and reduce the duration of

aortic cross-clamping and its related adverse events [6, 7]. We have recently shown that the sutureless Perceval aortic valve bioprosthesis (Sorin Biomedica Cardio Srl, Sallugia, Italy) is associated with excellent results in patients with intermediate operative risk [8]. The aim of the present study is to compare the immediate outcomes after TAVI and surgical aortic valve replacement with this sutureless valve bioprosthesis (SU-AVR).

Materials and methods

This is a retrospective analysis of a consecutive series of patients who were operated on from June 2007 to April 2014 at six European institutions (Belgium, Finland, Germany, Italy and Sweden). Data on consecutive TAVIs were obtained from a single institution with a large experience in transcatheter procedures (Ferrarotto Hospital, University of Catania, Italy).

Permission to perform this study was granted by the ethical committee of each participating center. The inclusion criterion for this study was any SU-AVR with or without concomitant coronary artery bypass grafting (CABG) employing the Perceval S sutureless aortic valve prosthesis. Similarly, patients who underwent TAVI (any access) with or without concomitant myocardial revascularization were included in the present analysis. Patients undergoing any other concomitant cardiac procedure were excluded. Data on patients' characteristics and operative details were retrieved retrospectively from patients' records. Data on coronary artery disease and poor mobility were not available from all centers and were not considered in this analysis. The operative risk of these patients was estimated according to the EuroSCORE II [9]. Only patients with complete data on EuroSCORE II variables were included in the present analysis. Baseline and operative characteristics of these patients are summarized in Tables 1 and 3. Follow-up data were retrieved by reviewing hospital records and contacting the patient or her/his cardiologist/general practitioner or from national registries.

The main outcome end point of this study was in-hospital mortality. Secondary outcome end points were device success, paravalvular regurgitation, stroke, bleeding, de novo dialysis, permanent pacemaker implantation and reoperation for prosthetic valve-related complications. Device success was defined according to the VARC-2 criteria, i.e., a procedure not associated with any major adverse events such as periprocedural mortality, conversion to replacement with a conventional aortic valve prosthesis, mean transvalvular gradient <20 mmHg, failure to implant a single valve prosthesis or moderate–severe valvular regurgitation [10].

Statistical analysis was performed using an SPSS version 22.0 statistical software (IBM SPSS Inc., Chicago, Ill., USA). Fisher exact test, Chi-square test and Mann–Whitney test were used for univariate analysis. No attempt to replace missing values was made. Multivariate analysis was performed using logistic regression. The area under the receiver operating characteristic (ROC) curve was used to represent the regression probabilities. Since the study groups significantly differed in a number of baseline variables, a propensity score was calculated by logistic regression to estimate the probability of being assigned to the TAVI or SU-AVR treatment. This propensity score was calculated in a non-parsimonious way including all preoperative variables (age, gender, insulin-dependent diabetes, creatinine clearance, New York Heart Association class, Canadian Cardiovascular Society class IV, pulmonary disease, extracardiac arteriopathy, recent myocardial infarction, left ventricular ejection fraction, systolic pulmonary pressure, critical preoperative status, elective procedure, previous cardiac surgery and permanent pacemaker).

Since no data were available on the prevalence and pattern of coronary artery disease, any myocardial revascularization procedure associated with TAVI or SU-AVR was not considered for the calculation of the propensity score. This decision was based also on the current policy of TAVI-only approach in patients with coronary artery disease undergoing transcatheter procedure, as the value of concomitant coronary revascularization in these patients is controversial [11–13]. The obtained propensity score was used for adjusted analysis in the overall series and for one-to-one propensity score matching. The caliper width chosen was 0.2 times the standard deviation of the propensity score, i.e., 0.066. To identify a "gray area" of indication for either SU-AVR or TAVI, a comparative analysis of the results of these two treatment strategies was performed in patients within the 25th and 75th percentiles interval of EuroSCORE II. This was done because a number of patients undergoing SU-AVR are considered to be at too low risk for being treated with TAVI based on EuroSCORE II. Similarly, SU-AVR is most often contraindicated in patients with very high EuroSCORE II. A $p < 0.05$ was considered to be statistically significant.

Results

This study included 394 patients who underwent TAVI (mean age 80.8 ± 5.5 years, mean EuroSCORE II 5.6 ± 4.9 %) and 379 patients (77.4 ± 5.4 years, mean EuroSCORE II 4.0 ± 3.9 %) who underwent SU-AVR with or without concomitant myocardial revascularization at six European centers.

The study groups from the overall series markedly differed in a number of baseline characteristics and comorbidities (Table 1). The lack of data on coronary artery

Table 1 Baseline characteristics of patients who underwent transcatheter (TAVI) versus sutureless aortic valve replacement (SU-AVR)

Clinical variables	Overall series			25th–75th percentiles of ESII			PS-matched pairs		
	SU-AVR 379 patients	TAVI 394 patients	*p* value	SU-AVR 180 patients	TAVI 209 patients	*p* value	SU-AVR 144 patients	TAVI 144 patients	*p* value
Age (years)	77.4 ± 5.4	80.8 ± 5.5	<0.0001	78.9 ± 5.3	81.5 ± 4.9	<0.0001	79.4 ± 5.4	79.0 ± 6.0	0.745
Females	236 (62.3)	229 (58.1)	0.239	113 (62.8)	135 (64.6)	0.710	88 (61.1)	90 (62.5)	0.808
Insulin-dependent diabetes	37 (9.8)	11 (2.8)	<0.0001	16 (8.9)	5 (2.4)	0.005	6 (4.2)	5 (3.5)	0.759
Creatinine clearance			<0.0001			<0.0001			0.476
50–85 ml/min	150 (39.6)	158 (40.1)		75 (41.7)	91 (43.5)		67 (46.5)	73 (50.7)	
<50 ml/min	85 (22.4)	203 (51.5)		44 (24.4)	109 (52.2)		46 (31.9)	48 (33.3)	
New York Heart Association class			0.655			0.779			0.610
III	255 (67.3)	264 (67.0)		129 (71.7)	141 (67.5)		101 (70.1)	94 (65.3)	
IV	24 (6.3)	30 (7.6)		11 (6.1)	12 (5.7)		7 (4.9)	11 (7.6)	
CCS class IV	12 (3.2)	46 (11.7)	<0.0001	3 (1.7)	17 (8.1)	0.005	6 (4.2)	6 (4.2)	1.000
Pulmonary disease	63 (16.6)	136 (34.5)	<0.0001	35 (19.4)	67 (32.1)	0.005	38 (26.4)	35 (24.3)	0.684
Extracardiac arteriopathy	83 (21.9)	27 (6.9)	<0.0001	43 (23.9)	7 (3.3)	<0.0001	12 (8.3)	13 (9.0)	0.834
Recent myocardial infarction	6 (1.6)	68 (17.3)	<0.0001	3 (1.7)	24 (11.5)	<0.0001	5 (3.5)	3 (2.1)	0.723
Left ventricular ejection fraction			<0.0001			0.225			0.798
31–50 %	57 (15.0)	100 (25.4)		28 (15.6)	41 (19.6)		26 (18.1)	23 (16.0)	
21–30 %	3 (0.8)	23 (5.8)		1 (0.6)	5 (2.4)		3 (2.1)	2 (1.2)	
≤20 %	0	5 (1.3)		0 (0)	1 (0.5)		0 (0)	0 (0)	
Sys. pulmonary artery pressure			<0.0001			<0.0001			0.983
31–55 mmHg	140 (36.9)	256 (65.0)		73 (40.6)	148 (70.8)		75 (52.1)	74 (51.4)	
>55 mmHg	37 (9.8)	51 (12.9)		20 (11.1)	22 (10.5)		17 (11.8)	18 (12.5)	
Critical preoperative state	3 (0.8)	0	0.117	1 (0.6)	0 (0)	0.463	0 (0)	0 (0)	–
Elective procedure	363 (95.8)	394 (100)	<0.0001	176 (97.8)	209 (100)	0.030	144 (100)	144 (100)	–
Previous cardiac surgery	33 (8.7)	60 (15.2)	0.005	13 (7.2)	5 (2.4)	0.029	12 (8.3)	15 (10.4)	0.544
Aortic valve surgery	12 (3.2)	9 (2.3)	0.511	3 (1.7)	0 (0)	0.098	6 (4.2)	4 (2.8)	0.520
Permanent pacemaker	10 (2.6)	35 (8.9)	<0.0001	6 (3.3)	10 (4.8)	0.472	7 (4.9)	7 (4.9)	1.000
EuroSCORE II (%)	4.0 ± 3.9	5.6 ± 4.9	<0.0001	3.4 ± 1.0	3.7 ± 1.1	0.002	4.1 ± 3.2	3.6 ± 2.6	0.117

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses; definition criteria for preoperative variables are according to EuroSCORE II

ES EuroSCORE II, *PS* propensity score

disease prevented a more in-depth analysis of the baseline differences between the study groups. Coronary revascularization was performed in 25.6 % patients who underwent SU-AVR and in 2.0 % patients who underwent TAVI (Tables 2, 3). Operative data are summarized in Tables 2 and 3. SU-AVR through a mini-sternotomy or mini-thoracotomy was performed in 54.1 % patients. TAVI was performed through a transfemoral approach in 97.7 % patients.

Device success was similar after either treatment method. SU-AVR was associated with a higher rate of mean postoperative transvalvular gradient >20 mmHg compared with TAVI (16.1 vs. 2.3 %, $p < 0.0001$, missing data not replaced) and this was the main contributor of defining device failure among SU-AVR patients.

TAVI was associated with significantly higher rate of mild and moderate–severe paravalvular regurgitation (Table 1) as well as need of permanent pacemaker implantation compared with SU-AVR.

In-hospital mortality was 2.6 % after SAVR and 5.3 % after TAVI ($p = 0.057$).

Figure 1 shows that the distribution of patients according to EuroSCORE II reflected a strategy of SU-AVR in patients with rather low operative risk, whereas TAVI was most frequently employed in those with increased risk. To compare the efficacy and safety of these two treatment methods in the so-called "gray area", of intermediate operative risk, we performed a sub-analysis that included only patients within the 25th and 75th percentiles interval of EuroSCORE II, i.e., 2.07–5.78 %. The immediate

Table 2 Operative data on patients who underwent aortic valve replacement with the Perceval S sutureless aortic valve bioprosthesis

Operative data	No. (%)
Access	
Mini-sternotomy	190 (50.1)
Mini-thoracotomy	15 (3.9)
Concomitant coronary artery bypass surgery	97 (25.6)
No. of distal anastomoses	1.9 ± 1.0
Crystalloid cardioplegia	50 (13.2)
Hypothermic circulatory arrest	5 (1.3)
Perceval S bioprosthesis size	
Small (21 mm)	41 (10.8)
Medium (23 mm)	141 (37.2)
Large (25 mm)	162 (42.7)
Extra large (27 mm)	35 (9.2)
Overall series	
Aortic cross-clamping time (min)	48 ± 22
Aortic cross-clamping time <30 min	64 (17.1)
Cardiopulmonary bypass time (min)	77 ± 29
Cardiopulmonary bypass time <60 min	108 (28.5)
Isolated aortic valve replacement	
Aortic cross-clamping time (min)	42 ± 17
Aortic cross-clamping time <30 min	64 (22.5)
Cardiopulmonary bypass time (min)	71 ± 24
Cardiopulmonary bypass time <60 min	100 (35.5)

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses

Table 3 Operative data on patients who underwent transcatheter aortic valve implantation

Operative data	No. (%)
Access	
Transfemoral	385 (97.7)
Subclavian	3 (0.8)
Transaortic	2 (0.5)
Transapical	4 (1.0)
Concomitant percutaneous coronary intervention	8 (2.0)
Valve prosthesis size	
23 mm	59 (15.0)
25 mm	1 (0.3)
26 mm	183 (46.4)
27 mm	1 (0.3)
29 mm	125 (31.7)
30 mm	20 (5.1)
Type of prosthesis	
CoreValve	286 (72.6)
SAPIEN	99 (25.1)
Portico	2 (0.6)
Lotus	2 (0.6)

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses

outcome of this subgroup of patients was similar to the outcome observed in the overall series (Table 4). However, the difference in terms of permanent pacemaker implantation was not statistically significant in this subgroup of patients.

A propensity score was estimated by logistic regression and its area under the ROC curve was 0.886 (95 %CI 0.862–0.909). In the overall series, logistic regression adjusted for propensity score showed that TAVI tended to be associated with higher risk of in-hospital mortality compared with SU-AVR ($p = 0.069$, OR 2.554, 95 %CI 0.930–7.016).

One-to-one propensity score-matched analysis resulted in 144 pairs with similar baseline characteristics and operative risk. Among these matched pairs, 26.4 % of SU-AVR patients underwent concomitant coronary surgery and one TAVI patient (0.7 %) underwent concomitant percutaneous coronary intervention. Besides the increased incidence of paravalvular regurgitation among TAVI patients, only the risk of reoperation for major bleeding and for repair of vascular complications significantly differed between the study groups. However, in-hospital mortality was significantly higher after TAVI compared with SU-AVR (6.9 vs. 1.4 %, $p = 0.035$) (Table 4).

Discussion

The present study showed that SU-AVR was associated with favorable early results when compared with a patient population treated with TAVI. This confirms the results of two recent small studies [14, 15]. In particular, SU-AVR seems to be associated with a significantly lower risk of moderate to severe postoperative paravalvular regurgitation, with fairly similar rates of stroke and de novo dialysis. The risk of permanent pacemaker implantation was significantly higher after TAVI in the overall series, but the difference between the treatment methods did not reach statistical significance in the 25th–75th percentiles interval of EuroSCORE II subset as well as in the propensity-matched pairs. The differences between the risk for reoperation for vascular access complications and for major bleeding were typically associated with the treatment method and their incidences were rather low. Furthermore, this analysis showed that TAVI and SU-AVR can be associated with similar device success rates. Failure of the device was mainly due to significant paravalvular regurgitation after TAVI and to a mean transvalvular gradient >20 mmHg after SU-AVR.

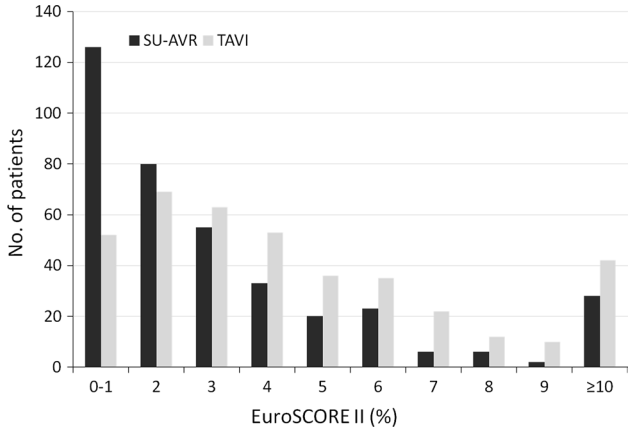

Fig. 1 Patients' distribution to transcatheter (TAVI) versus sutureless aortic valve replacement (SU-AVR) according to EuroSCORE II

The main finding of this study is the significant difference in the immediate survival after TAVI and SU-AVR. These results can be attributed to marked differences in the baseline characteristics of these two study groups and reflect a strategy toward transcatheter treatment in those patients with significantly increased operative risk. However, Fig. 1 demonstrates that a number of intermediate-risk patients as stratified by EuroSCORE II were treated by TAVI. This policy was likely due to the favorable results of TAVI compared with conventional aortic valve replacement and the increasing evidence of the durability of transcatheter deployed bioprostheses [1]. Indeed, the present TAVI series was associated with markedly better and immediate (94.7 vs. 92.2 %) survival rate compared with a pooled rate of 14 recent studies evaluating the results of TAVI [1]. This means that the results of the present TAVI population can be considered excellent and that it is likely to behave favorably compared with surgery with the use of conventional bioprostheses in high-risk patients. However, this comparative analysis suggests that SU-AVR could possibly lead to improved results of conventional aortic valve surgery by reducing aortic cross-clamping time and cardiopulmonary duration. The present data showed that SU-AVR may allow aortic valve replacement with or without coronary surgery with a myocardial ischemia time below 60 min. Santarpino et al. [16] showed that aortic cross-clamp and cardiopulmonary bypass times were 39 and 34 % shorter after SU-AVR compared with conventional aortic valve replacement (both $p < 0.0001$). Their data are not enough to quantify the potential clinical benefits related to shortening of the duration of myocardial ischemia and exposure to cardiopulmonary bypass [17], but we may assume that SU-AVR allows a shorter operative time which may be of critical importance to improve the outcome of patients with intermediate operative risk.

Procedure-related costs are important aspects to be considered in the evaluation of the present results. We did not perform a formal cost analysis of these two treatment methods, but an evident difference in the costs of these two valve prostheses is expected. At the first author's institution, the current cost of a Perceval prosthesis is about 5,000 euros,

Table 4 Immediate postoperative data on patients who underwent transcatheter (TAVI) and surgical aortic valve replacement with sutureless Perceval S bioprosthesis (SU-AVR)

Postoperative outcome	Overall series			25th–75th percentiles of ESII			PS-matched pairs		
	SU-AVR 379 patients	TAVI 394 patients	*P* value	SU-AVR 108 patients	TAVI 208 patients	*P* value	SU-AVR 144 patients	TAVI 144 patients	*P* value
Device success	305 (80.5)	309 (78.4)	0.481	146 (81.1)	168 (80.4)	0.856	115 (79.9)	112 (77.8)	0.665
Paravalvular regurgitation			<0.0001			<0.0001			<0.0001
None	370 (97.6)	163 (41.9)		174 (96.7)	93 (44.7)		140 (97.2)	66 (46.5)	
Mild	8 (2.1)	171 (44.0)		5 (2.8)	88 (42.3)		3 (2.1)	55 (38.7)	
Moderate–severe	1 (0.3)	55 (14.1)		1 (0.6)	27 (13.0)		1 (0.7)	21 (14.8)	
Conversion to conventional AVR	2 (0.5)	0 (0)	0.240	1 (0.6)	0 (0)	0.463	0 (0)	0 (0)	–
Stroke	9 (2.4)	5 (1.3)	0.251	2 (1.1)	2 (1.0)	1.000	0 (0)	3 (2.1)	0.122
De novo dialysis	11 (2.9)	3 (0.8)	0.031	5 (2.8)	1 (0.5)	0.100	3 (2.1)	0 (0)	0.247
Pacemaker implantation	37 (9.8)	68 (17.3)	0.003	20 (11.0)	35 (16.8)	0.112	16 (11.2)	22 (15.4)	0.296
Vascular access complication	0 (0)	45 (11.4)	<0.0001	0 (0)	28 (13.4)	<0.0001	0 (0)	15 (10.4)	<0.0001
Reoperation for major bleeding	14 (3.7)	0 (0)	<0.0001	9 (5.0)	0 (0)	0.001	6 (4.2)	0 (0)	0.013
In-hospital mortality	10 (2.6)	21 (5.3)	0.057	2 (1.1)	8 (3.8)	0.115	2 (1.4)	10 (6.9)	0.035

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses

ESII EuroSCORE II

whereas a Sapien 3 costs about 20,000 euros. Furthermore, TAVI requires incremental costs related to prosthesis implantation-related technology and to an increased number of personnel involved in this procedure. On the other hand, the shorter time to implant a sutureless valve prosthesis may lead to a reduction in the duration of the surgical procedure and, in turn, a reduction of operating room-related costs.

These results should be interpreted with caution because of differences in the baseline characteristics of these two study populations. Although we attempted to stratify the risk of these patients by EuroSCORE II and to adjust for such differences using a propensity score method, a number of important risk factors might have been left unrecognized in this registry and still could have guided the clinicians through the decision-making process. Patients of TAVI group were treated at a single institution, which may itself be a limitation of this comparative analysis. However, collection of data on TAVI performed in these participating centers was practically unfeasible in most of the participating centers. Furthermore, we did not have the chance to get data on TAVI from any multicenter series. At the time of study planning, we believed that a comparison with reported pooled results of TAVI [1] would have been insufficient and that individual patient data from a clinical series of TAVIs would have been necessary for a reliable comparative analysis. The present TAVI group confirms to be a valid control series, as its results are otherwise similar or even better than those of other series as shown in a previous meta-analysis [1]. Therefore, we believe that the present TAVI series is a valuable control series in terms of number of patients and its results.

In conclusion, the present study showed that SU-AVR may provide favorable early results when compared with a patient population treated with TAVI. The use of sutureless Perceval bioprosthesis is associated with a rather low incidence of significant paravalvular regurgitation and excellent immediate postoperative survival. SU-AVR is a valid alternative to TAVI in intermediate-risk patients.

Conflict of interest This study was not financially supported. Dr. Peter Svenarud and Dr. Carmelo Mignosa are proctors for Sorin Group Srl, Saluggia, Italy. Dr. Antonino S. Rubino received a research grant from Sorin Group Srl, Saluggia, Italy. Theodor Fischlein is a consultant for Sorin Group Srl, Saluggia, Italy. All other authors do not have any conflicts of interest to disclose related to this paper.

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