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Operative outcome of patients at low, intermediate, high and 'very high' surgical risk undergoing isolated aortic valve replacement with sutureless and rapid deployment prostheses: results of the SURD-IR registry

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Abstract

OBJECTIVES: The ideal strategy for the treatment of severe aortic valve stenosis in patients of varying risk categories has become a debated topic in the last years: should the transcatheter or surgical approach be adopted? The aim of this study was to evaluate the outcomes of low-, intermediate-, high- and very high-risk patients undergoing sutureless, rapid deployment aortic valve replacement.

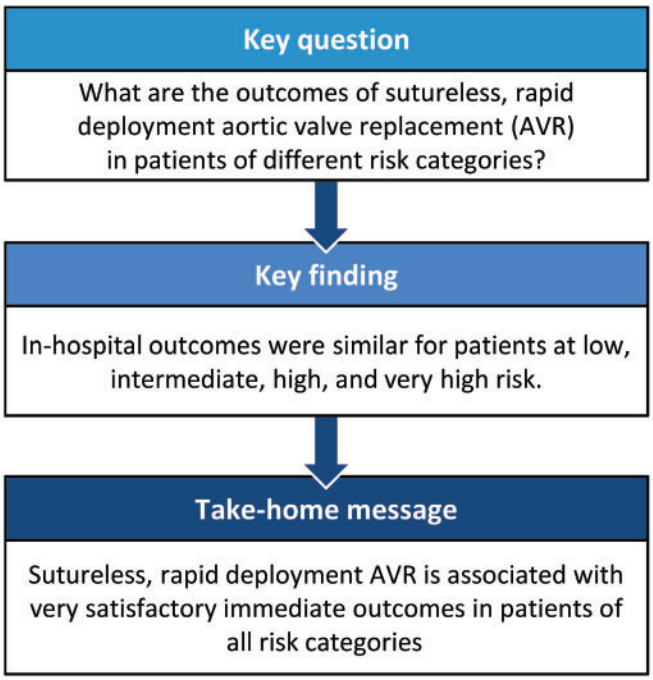
METHODS: From 2007 to 2017, data on a total of 3651 patients were collected from the Sutureless and Rapid Deployment Aortic Valve Replacement International Registry (SURD-IR). Of these, 2057 patients who underwent primary isolated aortic valve replacement were considered for this analysis and classified as being at low (EuroSCORE <5; $n = 500$), intermediate (EuroSCORE 5–10; $n = 901$), high (EuroSCORE 11–20; $n = 500$) and very high (EuroSCORE >20; $n = 156$) preoperative risk.

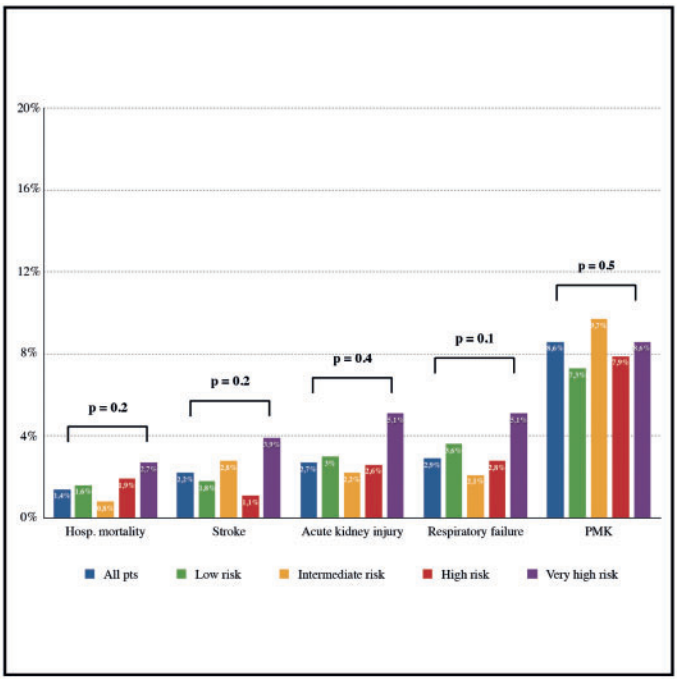
RESULTS: Overall, a less invasive approach was used in 74.1% of patients and represented the most frequent (>50%) approach in all risk categories. The Perceval prosthesis was used more frequently than other devices, especially in patients at high and very high risk. Hospital mortality was 1.6%, 0.8%, 1.9% and 2.7% in low-, intermediate-, high- and very high-risk patients, respectively, with no significant differences among subgroups. Similarly, postoperative complication rates were similar across the different risk categories.

†The first two authors contributed equally to the study.

CONCLUSIONS: Surgical aortic valve replacement using sutureless, rapid deployment biological valve prostheses is associated with excellent results and represents a safe and effective treatment option for patients with severe aortic valve stenosis. This seems to be particularly true in patients with a higher risk profile.

Keywords: Aortic valve replacement • Aortic valve stenosis • Sutureless aortic valve • Rapid deployment aortic valve





INTRODUCTION

In the last decade, the most appropriate treatment for patients with severe aortic valve stenosis has become one of the most debated issues in cardiac surgery. The main reason was the advent of transcatheter aortic valve implantation (TAVI) that has revolutionized both the treatment and prognosis of those patients [1] who were often considered at very high risk for conventional surgical aortic valve replacement (SAVR) [2]. In addition, less and minimally invasive cardiac surgery (MICS) techniques and the availability of prostheses that can be implanted very quickly has made surgery a real option for patients deemed inoperable [3].

A key aspect surrounding this debate is the optimal risk assessment by the 'Heart Team', which is one of the most important organizational points in the current guidelines [4].

In addition to TAVI, SAVR and MICS, sutureless, rapid deployment aortic valve replacement (SURD-AVR) has also proved successful in improving the outcome in high-risk patients and is now performed on a routine basis in many centres worldwide [5]. However, available data on sutureless, rapid deployment prostheses are limited, with most results deriving from clinical trials, and little is known about the 'real-world' experience [6].

The International Valvular Surgery Study Group (IVSSG) was established to provide more robust data on the use of sutureless, rapid deployment prostheses [7]. The IVSSG consists of a consortium of research centres that evaluate current management and outcomes of valvular surgery, with a special focus on SURD-AVR. It represents an important opportunity to shape clinical guidelines, optimize patient outcomes and set future directions for research.

This study aims to assess SURD outcomes in different risk categories, also in relation to other treatment options.

MATERIALS AND METHODS

The Sutureless and Rapid Deployment Aortic Valve Replacement International Registry (SURD-IR) was established in 2015 and enrolled patients at 18 large referral centres in Europe, Australia and Canada [7]. The registry includes all patients who received 1 of the 3 sutureless or rapid deployment prosthetic models currently, or until recently, available on the market (Perceval S, Livanova PLC, London, UK; Edwards Intuity/Intuity Elite, Edwards Lifesciences, Irvine, CA, USA; and Enable 3F, Medtronic, MN, USA).

Ethical approval was obtained at each participating centre. Participating SURD-IR centres enrolled between 40 and 735 patients and collected information on demographics, patient comorbidities, functional status, imaging studies, surgical data, postoperative course, clinical and haemodynamic outcomes.

More than 190 variables were collected for each patient and saved in a centralized database, as previously described [8]. Isolated variables reported by <25% of centres were excluded from the analysis.

Table 1: Patient demographics ($n = 2057$)

	Logistic EuroSCORE					
	0–5, % (*n*)	>5–10, % (*n*)	>10–20, % (*n*)	>20, % (*n*)	Total, % (*n*)	*P*-value
Male gender	59.4 (297/500)	33.3 (300/900)	28.36 (143/500)	26.9 (42/156)	38 (782/2056)	<0.001
Age (years), mean ± SD	69.5 ± 6.8	76.9 ± 5.1	80.1 ± 5	80.3 ± 5.2	76.2 ± 6.9	<0.001
Hypertension	80.9 (377/466)	81.3 (699/860)	82.3 (387/470)	82.2 (111/135)	81.5 (1574/1931)	0.90
Diabetes	29.9 (140/468)	26.3 (224/851)	29.4 (137/466)	35.3 (47/133)	28.6 (548/1918)	0.10
Obesity	29.4 (145/494)	27.3 (243/889)	25.6 (126/492)	17 (26/153)	26.6 (540/2028)	0.020
Dyslipidaemia	60.1 (265/441)	57.4 (424/739)	57.7 (225/390)	61 (64/105)	58.4 (978/1675)	0.80
Smoking	23.8 (92/386)	19.7 (114/580)	18 (55/306)	28.4 (21/74)	21 (282/1346)	0.050
AF	5.5 (20/364)	11.7 (74/635)	13 (48/368)	22.9 (25/109)	11.3 (167/1476)	<0.001
PMK	1.9 (9/469)	2.4 (20/842)	5.1 (23/454)	6.6 (10/151)	3.2 (62/1916)	0.002
NYHA class						<0.001
I	6.3 (29/457)	5.3 (44/831)	5.4 (25/466)	2.9 (4/140)	5.4 (102/1894)	
II	49.9 (228/457)	43.1 (358/831)	38.84 179/466)	24.3 (34/140)	42.2 (799/1894)	
III	42.9 (196/457)	48.6 (404/831)	51.7 (241/466)	57.1 (80/140)	48.6 (921/1894)	
IV	0.9 (4/457)	3 (25/831)	4.5 (21/466)	15.7 (22/140)	3.8 (72/1894)	
Valve disease						0.030
Stenosis	65.2 (302/463)	67.6 (581/860)	60.2 (291/483)	57.7 (90/156)	64.4 (1264/1962)	
Insufficiency	1.7 (8/463)	0.5 (4/860)	0.6 (3/483)	0.6 (1/156)	0.8 (16/1962)	
Mixed	33 (153/463)	31.9 (274/860)	39.1 (189/483)	47.7 (65/156)	34.7 (681/1962)	
Other		0.1 (1/860)			0.1 (1/1962)	
Aortic valve gradient, mean ± SD	53.6 ± 17.2	50.8 ± 16.6	49.5 ± 16.2	51.3 ± 18.5	51.3 ± 16.9	0.020
BAV	10 (29/290)	4.7 (26/556)	4.4 (12/270)	2.1 (2/96)	5.7 (69/1212)	0.003
LVEF ≤50%	7.3 (36/490)	12.9 (113/874)	28.1 (134/477)	45.9 (67/146)	17.6 (350/1987)	<0.001
Pulmonary HTN	9.7 (33/341)	12.2 (74/609)	33.2 (108/325)	56.7 (59/104)	19.9 (274/1379)	<0.001
Active endocarditis		0.1 (1/788)	0.2 (1/444)		0.1 (2/1810)	0.80
CAD	19 (56/295)	23.5 (94/400)	40.2 (76/189)	46.7 (21/45)	26.6 (247/929)	<0.001
Cerebrovascular disease	5.1 (20/390)	7.9 (53/670)	17.3 (58/336)	23.3 (24/103)	10.3 (155/1499)	<0.001
Renal insufficiency	32.3 (142/439)	44.6 (321/720)	41.4 (155/374)	47.2 (50/106)	40.8 (668/1639)	<0.001
Dialysis	0.5 (2/394)	0.7 (4/595)	1.5 (5/324)	1 (1/103)	0.8 (12/1416)	0.50
Chronic lung disease	7.7 (34/444)	15.9 (124/779)	18.4 (80/434)	25.7 (35/136)	15.2 (273/1793)	<0.001

AF: atrial fibrillation; BAV: bicuspid aortic valve; CAD: coronary artery disease; HTN: hypertension; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PMK: pacemaker; SD: standard deviation.

In this analysis, patients were classified as low (log EuroSCORE 0–5), intermediate (log EuroSCORE >5–10), high (log EuroSCORE >10–20) and 'very high' risk (log EuroSCORE >20). Preoperative, intraoperative and postoperative outcome variables were compared among the 4 groups. The categorization of patients according to the logistic EuroSCORE was chosen because at the time of the start of the analysis this score system was the most widely used in the participating centres.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation, and categorical variables as percentages. Where continuous variables did not follow a normal distribution (tested using the Kolmogorov–Smirnov test for normality and Q–Q plots), the median and the interquartile range were reported. Percentages were calculated using a number of patients with available data as the denominator. Categorical variables were compared using the χ^2 test. Normally distributed continuous data were compared using the unpaired *t*-test or one-way analysis of variance, as appropriate. The level of significance α was set at 5%. Adjustments for multiple testing were not performed. The statistical analysis was conducted using the SPSS 22.0 statistical software package (SPSS, Chicago, IL, USA).

RESULTS

Patient characteristics

Out of the 3651 patients enrolled in the SURD-IR from 2007 to 2018, 2371 (64.9%) patients underwent primary isolated SURD-AVR and were considered for this analysis. Of these, 219 (9.2%) patients were excluded because of missing EuroSCORE data and 95 (4%) patients were excluded because they received the 'off-market' Enable valve. The final study cohort ($n = 2057$) was divided into 4 groups according to patients' risk level: (i) low risk ($n = 500$, 24.3%), (ii) intermediate risk ($n = 901$, 43.8%), (iii) high risk ($n = 500$, 24.3%) and (iv) very high risk ($n = 156$, 7.6%).

Preoperative risk factors are reported in Table 1. As expected, risk factors were more common in the high- and very high-risk groups, both of which had a higher average age (>80 years) compared with the low- and intermediate-risk groups (69.5 years and 76.9 years, respectively) ($P < 0.001$).

The choice to perform an aortic valve replacement or TAVI was made on the basis of specific criteria at each centre. However, all participating centres used as main criterion the 'Heart Team' decision with assessment of patient frailty rather than the patient age.

The high- and very high-risk groups more frequently suffered from coronary artery disease ($P < 0.001$) and left ventricular

Table 2: Operative data

	Logistic EuroSCORE					
	0–5, % (*n*)	>5–10, % (*n*)	>10–20, % (*n*)	>20, % (*n*)	Total, % (*n*)	*P*-value
Full sternotomy	19 (87/458)	22.8 (167/731)	31.6 (132/418)	48.1 (64/133)	25.9 (450/1740)	<0.001
MICS	81 (371/458)	77.2 (564/731)	68.4 (286/418)	51.9 (69/133)	74.1 (1290/1740)	<0.001
Ministernotomy	44.3 (203/458)	42.5 (311/731)	37.1 (155/418)	30.8 (41/133)	40.8 (710/1740)	0.010
Minithoracotomy	36.9 (169/458)	34.6 (253/731)	31.3 (131/437)	21.1 (28/133)	33.4 (581/1740)	0.005
Valve type						<0.001
Perceval	59.8 (299/500)	79.4 (715/901)	84.2 (421/500)	80.8 (126/156)	75.9 (1561/2057)	
Intuity/Intuity Elite	40.2 (201/500)	20.6 (186/901)	15.8 (79/500)	19.2 (30/156)	24.1 (496/2057)	
CPB time, mean ± SD	78.3 ± 32.7	75.7 ± 32.8	77.4 ± 28.2	81.8 ± 32.6	77.2 ± 31.7	0.10
Clamp time, mean ± SD	50.7 ± 21.8	48 ± 22.5	49.4 ± 22.5	53.5 ± 26	49.4 ± 22.2	0.020
Valve malpositioning	1.1 (3/268)	1 (5/519)	0.4 (1/277)		0.8 (9/1150)	0.60

CPB: cardiopulmonary bypass; MICS: minimally invasive cardiac surgery; SD: standard deviation.

Table 3: In-hospital outcomes

	Logistic EuroSCORE					
	0–5, % (*n*)	>5–10, % (*n*)	>10–20, % (*n*)	>20, % (*n*)	Total, % (*n*)	*P*-value
Hospital mortality	1.6 (8/487)	0.8 (7/854)	1.9 (9/475)	2.7 (4/147)	1.4 (28/1963)	0.20
Stroke	1.8 (8/434)	2.8 (20/704)	1.1 (4/362)	3.9 (4/102)	2.2 (36/1602)	0.20
Low cardiac output	1.4 (5/369)	0.6 (4/660)	1.2 (4/332)		0.9 (13/1455)	0.40
Bleeding (requiring chest reopening)	3.4 (15/445)	3.2 (22/678)	5.1 (16/313)	7.1 (7/98)	3.9 (60/1534)	0.20
AKI (grade >1)	3 (13/437)	2.2 (15/677)	2.6 (9/342)	5.1 (5/98)	2.7 (42/1554)	0.40
Dialysis	1.9 (7/362)	0.9 (5/574)	2.2 (6/275)	2.6 (2/78)	1.6 (20/1289)	0.30
AF	19.6 (83/424)	28 (217/774)	28.1 (114/406)	31.1 (33/106)	26.1 (447/1710)	0.005
PMK	7.3 (29/395)	9.7 (67/688)	7.9 (28/354)	8.4 (9/107)	8.6 (133/1544)	0.50
Respiratory failure	3.6 (18/500)	2.1 (19/901)	2.8 (14/500)	5.1 (8/156)	2.9 (59/2057)	0.10
Sepsis	0.9 (3/331)	1.7 (10/599)	3.9 (12/309)	4.1 (3/73)	2.1 (28/1312)	0.030
ICU stay, median (IQR)	2 (1–2.8)	1 (1–3)	1 (1–3)	1 (1–3)	1 (1–3)	0.50
Hospital stay, median (IQR)	9 (7–13)	9 (7–14)	9 (7–13)	9 (7–12)	9 (7–13)	0.20

AKI: acute kidney injury; AF: atrial fibrillation; ICU: intensive care unit; IQR: interquartile range; PMK: pacemaker.

dysfunction ($P < 0.001$). As expected, serious comorbidities such as renal insufficiency ($P < 0.001$), chronic lung disease ($P < 0.001$) and cerebrovascular disease ($P < 0.001$) were more frequent in higher-risk patients (Table 1).

Operative data

Overall, a less invasive approach was used in 74.1% of patients and represented the most frequent (>50%) approach in all risk categories. The use of full sternotomy increased in higher-risk patients, whereas a less invasive (ministernotomy or minithoracotomy) access was preferred in lower-risk patients (Table 2).

The Perceval sutureless device was implanted in 1561 (75.9%) patients and the Intuity rapid deployment model in 496 (24.1%) patients.

The Perceval prosthesis was more frequently implanted in high (84.2%) and very high-risk (80.8%) patients compared with the Intuity valve (high risk 15.8%; very high risk 19.2%) ($P < 0.001$) (Table 2). Although mean cardiopulmonary bypass time was similar among groups, surgery in the very high-risk patients was associated with significantly longer ischaemic times ($P = 0.020$) (Table 2). Valve malpositioning occurred in 9 patients (0.8%), but no difference was found among groups.

In-hospital outcomes

Overall in-hospital mortality was 1.4% ($n = 28$). In-hospital mortality was 1.6%, 0.8%, 1.9% and 2.7% in the low-, intermediate-, high- and very high-risk groups, respectively, with a trend to higher mortality in higher-risk patients ($P = 0.2$). Postoperative stroke occurred in 36 (2.2%) patients with a rate of 1.8%, 2.8%, 1.1% and 3.9% in the low-, intermediate-, high- and very high-risk groups, respectively ($P = 0.20$). The incidence of acute kidney injury (2.7%, $n = 42$) and respiratory failure (2.9%, $n = 59$) was similar among groups ($P = 0.40$ and $P = 0.10$, respectively). Low-risk patients had a lower rate of postoperative atrial fibrillation compared to patients of higher-risk groups (19.6% vs 28%, 28.1% and 31.1%; $P = 0.005$) (Table 3). A total of 133 (8.6%) patients suffered from conduction disorders requiring permanent pacemaker implantation; no association was observed between pacemaker implantation and the patients' risk profile ($P = 0.30$) neither a difference between the 2 valve models (Perceval 9.3% vs Intuity 7.1%, $P = 0.1$). As previously reported [8], the rate of pacemaker implantation considerably decreased over the observational period from 17.2% to 5.4% ($P = 0.002$).

No difference was found in post-procedural significant (moderate to severe) aortic regurgitation, which was 0.7% in low-risk

Table 4: Postoperative echocardiographic data

	Logistic EuroSCORE					
	0–5, % (*n*)	>5–10, % (*n*)	>10–20, % (*n*)	>20, % (*n*)	Total, % (*n*)	*P*-value
AR ≥ mild	7.1 (21/296)	8.4 (46/546)	11.2 (29/260)	17.6 (16/91)	9.4 (112/1193)	0.010
AR grade						
Mild	5.8 (17/296)	6.9 (38/546)	9.3 (24/260)	16.5 (15/91)	7.9 (94/1193)	0.010
Moderate	0.7 (2/296)	1.5 (8/546)	0.8 (2/260)	1.1 (1/91)	1.1 (13/1193)	0.70
Severe			0.8 (2/260)		0.2 (2/1193)	0.70
AV gradient, mean ± SD	13.4 ± 5.4	13.6 ± 5.6	13.7 ± 5.8	13 ± 5.9	13.5 ± 5.6	0.70
Peak AV gradient, mean ± SD	24.7 ± 9.4	25.9 ± 9.6	26.1 ± 11.1	25.2 ± 10.9	25.6 ± 10	0.40
LVEF, mean ± SD	60.6 ± 7.3	59.8 ± 8.9	56.2 ± 11	50.6 ± 14.1	58.4 ± 9.9	<0.001

AR: aortic regurgitation; AV: aortic valve; LVEF: left ventricular ejection fraction; SD: standard deviation.

patients, 1.5% in intermediate-risk patients, 1.6% in high-risk patients and 1.1% in very high-risk patients ($P = 0.70$). Nevertheless, very high-risk patients more likely exhibited mild aortic regurgitation compared with lower-risk groups ($P = 0.010$) (Table 4).

DISCUSSION

Sutureless, rapid deployment aortic tissue valve prostheses that were implanted in patients included in the SURD-IR registry are a safe and effective alternative to conventional SAVR and are associated with improved clinical outcomes [8]. Our results demonstrate that these devices are effective, versatile and ensure excellent results in patients of different risk levels.

Our study has an obvious and expected end point: different outcomes may be observed in the 4 groups of patients at low, intermediate, high and very high risk. However, this artifice allows us to make several statements. Although preoperative risk factors significantly differed across the 4 groups, no significant differences were reported in terms of immediate outcome. On this basis, we may speculate that sutureless and rapid deployment prostheses, by facilitating a less invasive approach and accelerating implantation, provide immediate good results mainly due to smaller surgical stress to the patients; this may be especially true for those in the higher risk category. Obviously, longer-term outcomes may differ across the 4 groups with widely different prognoses.

The results of this study may have important practical implications. Although published trials report an increasing number of patients who are referred for a TAVI procedure, our study shows that SURD-AVR is associated with a favourable outcome even in high- and very high-risk patients who are usually considered as candidates for TAVI.

Moreover, the use of sutureless and rapid deployment prostheses allowed the adoption of a less invasive approach in up to two-thirds of the study patients and in 50% of the high-risk patients, with good immediate results in all risk group categories. The high prevalence of MICS procedures in our registry may have had an important impact on the results, particularly for patients at higher risk.

A comparison between conventional prostheses and SURD has not been made by any published trial so far. However, there are ongoing studies addressing this issue (PERSIST-AVR, NCT02673697). Trials have shown that SURD-AVR is associated with clinical advantages mainly resulting from a significant reduction in ischaemic time compared to conventional SAVR. In small single-centre studies, SURD-AVR was found to be associated with shorter hospital stay, less need for transfusions and reduced hospital costs [5, 9]. In a multicentre study, Dalén *et al.* [10] compared patients operated on with SURD + MICS versus patients operated on through full sternotomy who received conventional prostheses. These authors reported a higher incidence of transfusions in the 'non' SURD-AVR patients and a higher rate of pacemaker implantation in the SURD patients. However, it was not possible to know if the advantage provided by SURD on transfusions was related to SURD *per se* or to the less invasive approach. These considerations reinforce the significance of our registry, which included a high number of patients treated with and without MICS, though a control group is missing.

In comparison to TAVI studies, our results show at least comparable immediate outcomes. In low-risk patients, the mortality rate was lower than that recorded in the NOTION trial [11] (1.5% vs 2.1%). Additionally, in the NOTION trial, the rate of life-threatening bleeding complications in the surgery group was unexpectedly high (20.9%), with 10.4% patients developing cardiogenic shock.

In the PARTNER 2 trial [12], which compared SAVR with TAVI in intermediate-risk patients, in-hospital mortality of TAVI patients was exactly the same as that recorded in our surgical group (0.9%).

For patients at high risk, the PARTNER trial cohort A seems to be the most suitable comparison [13], where in-hospital mortality following TAVI was almost twice as high as that of our SURD-AVR group (3.4% vs 1.8%).

The most interesting piece of data concerns to patients deemed at very high risk, a patient population comparable to that included in the PARTNER trial cohort B [1]. In this trial, in-hospital mortality was 2-fold higher than that observed in our study (2.6% vs 5%).

These comparisons, though flawed by several limitations, may fuel the debate on the best treatment for patients with severe aortic valve stenosis. This patient population may be more and more frequently selected to undergo the transcatheter procedure in the future, but the results of the SURD-IR registry and those of 'real-life' studies on the outcome of TAVI [14] will continue to question this trend. Additionally, regarding the extension of the indications of TAVI prostheses to younger and low-risk patients, long-term data on these prosthetic models are only speculative at present and not supported by data in implanted patients with adequate clinical and echocardiographic follow-up.

Moreover, risk assessment should not be restricted to risk estimation by risk scores traditionally used for SAVR procedures, which often fail to provide a comprehensive evaluation of patient characteristics [15]. In our study, based 'only' on risk scores, patients were categorized as being at low-, intermediate-, high- or prohibitive risk for SAVR. Notwithstanding this, it is not uncommon that patients classified as very high risk (i.e. log EuroSCORE >20) are scheduled for SAVR because of specific anatomical factors, and that some classified as intermediate or low risk may be referred for TAVI [12].

CONCLUSION

In conclusion, the SURD-IR may contribute to the search for the most appropriate treatment for patients with severe aortic valve stenosis and may help to refine the decision-making process. To date, SAVR using a sutureless and rapid deployment device allows surgeons to obtain very satisfactory immediate outcomes in patients of all risk categories. However, randomized controlled studies comparing conventional SAVR, SURD-AVR and TAVI with sufficient long-term follow-up combined with additional information (e.g. cost-effectiveness data) are required before any definitive conclusion can be drawn. However, the 'real-life' nature of the SURD-IR registry, which involved centres worldwide, makes the data obtained safe and highly interesting, while keeping debate on these new devices and procedures open.

Conflict of interest: Thierry A. Folliguet is in charge of 'PERSIST-AVR' Trial as investigator. Carmelo Mignosa and Emmanuel Villa are proctors for LivaNova. Alberto Albertini receives consulting and lecture fees from LivaNova.

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