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Minimally invasive aortic valve replacement with sutureless and rapid deployment valves: a report from an international registry (Sutureless and Rapid Deployment International Registry)†

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Abstract

OBJECTIVES: The impact of sutureless and rapid deployment (SURD) valves on the clinical outcomes of patients undergoing minimally invasive aortic valve replacement (MI-AVR) has still to be defined. The aim of this study was to assess clinical characteristics and in-hospital results of patients receiving SURD-AVR through less invasive approaches in the large population of the Sutureless and Rapid Deployment International Registry (SURD-IR).

METHODS: Of the 1935 patients who received primary isolated SURD-AVR between 2009 and 2018, a total of 1418 (73.3%) underwent MI interventions and were included in this analysis. SURD-AVR was performed using upper ministernotomy in 56.4% ($n = 800$) of cases and anterior right thoracotomy in 43.6% ($n = 618$). Perceval S was implanted in 1011 (71.3%) patients and Edwards Intuity or Intuity Elite in 407 (28.7%) patients.

RESULTS: Overall in-hospital mortality and stroke rates were 1.7% and 2%, respectively. A definitive pacemaker implantation was reported in 9% of cases and significantly decreased over the observational period, from 20.6% to 5.6% ($P = 0.002$). The Perceval valve was associated with shorter operative times and was more frequently implanted in patients receiving anterior right thoracotomy incision. The Intuity valve was preferred in younger patients and revealed superior postoperative haemodynamic results.

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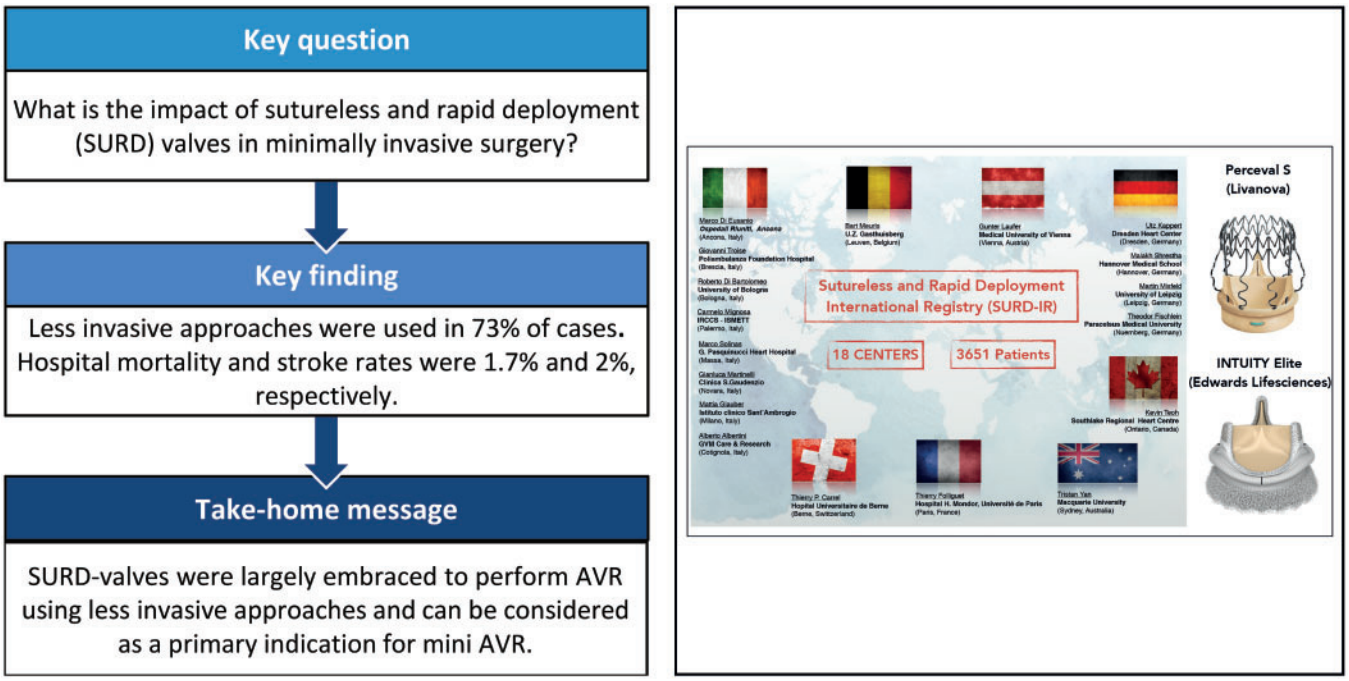
CONCLUSIONS: SURD-AVR was largely performed through less invasive approaches and can be considered as a primary indication in MI surgery. In the SURD-IR cohort, MI SURD-AVR using both Perceval and Intuity valves appeared a safe and reproducible procedure associated with promising early results.

Keywords: Minimally invasive aortic valve replacement • Sutureless valve • Rapid deployment valve • Aortic valve replacement • Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry



INTRODUCTION

Minimally invasive aortic valve replacement (MI-AVR) was popularized in the 1990s and has gradually been recognized as a less traumatic approach when compared with median sternotomy.

Currently, the upper ministernotomy (MS) and the anterior right thoracotomy (ART) are the most common approaches for MI-AVR. Although both approaches have been associated with multiple clinical benefits compared with standard sternotomy, the acceptance of MI-AVR has been low in the surgical community [1, 2]. This is likely due to the perceived increased surgical complexity of MI-AVR approaches that may lead to prolonged operative times when compared with conventional AVR.

Sutureless and rapid deployment valves have been developed to facilitate the implantation and shorten the operative times—regardless of the chosen surgical approach—while maintaining the advantages of surgical excision of the degenerated aortic valve. However, the broad impact of these prostheses on the clinical outcomes when used with a MI approach is still unclear. In this setting, the Sutureless and Rapid Deployment International Registry (SURD-IR), being the largest worldwide registry enrolling patients undergoing sutureless and rapid deployment aortic valve replacement (SURD-AVR), gives the opportunity to perform large cohort analyses of patients treated with this new technology [3]. The aim of this study was to assess clinical characteristics and in-hospital results of patients who underwent isolated SURD-AVR through MI approaches in the SURD-IR population.

METHODS

Study population, data collection and analysis

The SURD-IR is a multicentric retrospective and prospective registry founded by a consortium of 18 large research centres—the International Valvular Surgery Study Group (IVSSG)— with the aim to evaluate the current management of valve diseases and the outcomes of valvular surgery [4]. The rationale and methods of SURD-IR have been previously published [3, 4]. In brief, the study population includes patients undergoing sutureless and rapid deployment aortic valve replacement (SURD-AVR) intervention, using any available sutureless and rapid deployment valve prosthesis, through conventional sternotomy or a less invasive approach. Valve prosthesis types included Perceval S (LivaNova PLC, London, UK), Edwards Intuity/Intuity Elite (Edwards Lifesciences, Irvine, CA, USA) and Enable 3F (Medtronic, Minneapolis, MN, USA). 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. Following electronic data submission, each data set was evaluated to ensure that all patients were over 18 years old. All variables between data sets were assessed, with identical variables stored into a centralized database. Isolated variables reported by <25% of centres were excluded from analysis. The definitions of the main variables are described in the Supplementary Material. Individually missing data and centre-specific non-reported data

Table 1: Patient demographics (n = 1418)

	Total, *n/N*	Percentage	Perceval, *n/N*	Percentage	Intuity, *n/N*	Percentage	*P*-value
Male	521/1418	36.7	330/1011	32.6	191/407	46.9	<0.001
Age (n = 1417), mean ± SD	75.9 ± 7		76.7 ± 6.5		73.8 ± 7.8		<0.001
NYHA class (n = 1284)							0.02
I	70	5.5	47	5.3	23	5.8	
II	619	48.2	450	50.7	169	42.6	
III	558	43.5	361	40.7	197	49.6	
IV	37	2.9	29	3.3	8	2	
Hypertension	1000/1260	79.4	697/866	80.5	303/394	76.9	0.2
Obesity	376/1393	27	267/994	26.9	109/399	27.3	0.9
BMI (n = 1385), mean ± SD	27.4 ± 5		27.5 ± 5		27.4 ± 5.2		0.7
Diabetes	377/1337	28.2	270/946	28.5	107/391	27.4	0.7
Dyslipidaemia	618/1151	53.7	430/784	54.8	188/367	51.2	0.3
AF	131/1202	10.9	98/912	10.7	33/290	11.4	0.7
PM	34/1299	2.6	29/974	3	5/325	1.5	0.2
BAV	40/743	5.4	23/444	5.2	17/299	5.7	0.9
Aortic valve disease							<0.001
Aortic valve stenosis	826/1341	61.6	553/971	57	273/370	73.8	
Aortic valve regurgitation	19/1341	1.4	7/971	0.7	12/370	3.2	
Mixed aortic valve disease	495/1341	36.9	410/971	42.2	85/370	23	
Other	1/1341	0.1	1/971	0.1			
Peak AVG (n = 748) (mmHg), mean ± SD	82.1 ± 25.2		79.8 ± 25.3		84.8 ± 24.6		0.001
Mean AVG (n = 812) (mmHg), mean ± SD	51.3 ± 17.1		49 ± 17		54.6 ± 16.8		<0.001
LVEF%, mean ± SD	58.7 ± 9.5		58.6 ± 9.6		58.9 ± 8.8		0.5
LVEF >50	1167/1385	84.3	832/994	83.7	335/391	85.7	0.4
LVEF 30–50	204/1385	14.7	150/994	15.1	54/391	13.8	0.4
LVEF <30	14/1385	1	12/994	1.2	2/391	0.5	0.4
Dialysis	8/1219	0.7	7/911	0.8	1/308	0.3	0.7
Chronic lung disease	193/1220	15.8	146/888	16.4	47/332	14.2	0.4
Logistic EuroSCORE (n = 1290) (%)	8.6 ± 6.2		9.4 ± 6.5		6.8 ± 4.9		<0.001

AF: atrial fibrillation; AVG: aortic valve gradient; BAV: bicuspid aortic valve; BMI: body mass index; LVEF: left ventricle ejection fraction; NYHA: New York Heart Association; PM: pacemaker; SD: standard deviation.

were coded separately. Clinically important absent data were queried with the submitting centre. Data were assessed for clinical face validity and internal validity. Ethics approval was obtained at each of the participating centres [3].

At the time of our study, we examined 3651 patients enrolled in the registry between April 2007 and February 2018. Patients who underwent combined surgical procedures, reoperative AVR or implantation of the off-market Enable 3F valve, as well as patients with incomplete data on surgical approach were excluded from the analysis. The choice to perform standard sternotomy or MI-AVR, as well as the addition of a computed tomography scan to the preoperative work-up, was made on the basis of specific criteria at each centre.

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 interquartile range (IQR) were reported. Percentages were calculated with the available data as the denominator. Normally distributed continuous data were compared with unpaired *t*-test or one-way analysis of variance as appropriate. Categorical variables were compared by χ^2 test. The Cochran–Armitage test was used to evaluate linear trends across time groups. Univariable analyses were performed to determine relationships between measured variables and in-hospital mortality. Valve type and variables that achieved *P*-values <0.05 in the univariable analyses were introduced in multivariable analysis to estimate the independent effects of risk factors for hospital mortality.

RESULTS

Patient population

Of the 1935 patients who received primary isolated SURD-AVR, a total of 1418 (73.3%) underwent an MI intervention and were included in this analysis. The mean age of the study population was 75.9 ± 7 years (range 41–92) with female predominance (63.3%, n = 897) and an average logistic EuroSCORE of 8.6 ± 6.2. The main indications for SURD-AVR were degenerative aortic stenosis in 826 (61.6%) patients, aortic regurgitation (AR) in 19 (1.4%) patients and mixed aortic valve disease in 495 (36.9%) patients. A bicuspid aortic valve was present in 5.4% of cases. The baseline characteristics of the study cohort are listed in Table 1.

Perceval S was implanted in 1011 (71.3%) patients and Edwards Intuity or Intuity Elite in 407 (28.7%) patients. Compared with the Perceval valve, the Intuity valve was more likely to be used in younger patients (mean age 73.8 vs 76.7 years; $P < 0.001$) with a higher prevalence of male gender (46.9% vs 32.6%; $P < 0.001$) and low incidence of pulmonary hypertension (18.6% vs 26.8%, $P = 0.04$). As a result of a higher risk profile, patients who received a Perceval valve had a higher logistic EuroSCORE compared to the Intuity group (9.4% vs 6.8%; $P < 0.001$) (Table 1).

CONVENTIONAL VALVE OPERATIONS

Table 2: Operative data

	Total, % (*n*/*N*)	Perceval, *n*/*N* (%)	Intuity, *n*/*N* (%)	*P*-value	MS, *n*/*N* (%)	ART, *n*/*N* (%)	*P*-value
Ministernotomy	56.4 (800/1418)	46.6 (471/1011)	80.8 (329/407)	<0.001			
ART	43.6 (618/1418)	53.4 (540/1011)	19.2 (78/407)	<0.001			
Conversion to full sternotomy	1 (12/1238)	1.1 (10/899)	0.6 (2/339)	0.5	0.9 (6/639)	1 (6/599)	0.9
Perceval S	71.3 (1011/1418)				58.9 (471/800)	87.4 (540/618)	<0.001
Intuity/Intuity Elite	28.7 (407/1418)				41.1 (329/800)	12.6 (78/618)	<0.001
Valve malpositioning	1.4 9/638	1.6 (7/438)	1 (2/200)	0.7	1.2 (6/490)	2 (3/148)	0.9
CPB time (*n* = 1369) (min), mean ± SD	83.6 ± 30.4	81.2 ± 28.9	89.4 ± 30.1	<0.001	77.9 ± 26.6	90.8 ± 32.2	<0.001
Clamp time (min) (*n* = 1375), mean ± SD	53.4 ± 21.3	51.2 ± 20.4	59 ± 22.6	<0.001	49.2 ± 18	58.8 ± 23.8	<0.001

ART: anterior right thoracotomy; CPB: cardiopulmonary bypass; MS: ministernotomy; SD: standard deviation.

Table 3: In-hospital outcomes

	Total, *n*/*N*	Percentage	Perceval, *n*/*N*	Percentage	Intuity, *n*/*N*	Percentage	*P*-value
Hospital mortality	23/1340	1.7	17/936	1.8	6/404	1.5	0.8
Stroke	23/1131	2	17/787	2.2	6/344	1.7	0.8
Low cardiac output	11/1059	1	10/772	1.3	1/287	0.3	0.3
Respiratory insufficiency	45/1418	3.2	36/1011	3.6	9/407	2.2	0.2
New onset atrial fibrillation	333/1141	29.2	254/802	31.7	79/339	23.3	0.004
New AV block requiring PM	87/968	9	56/562	10	31/406	7.6	0.3
Aortic regurgitation (*n* = 1146)	50/703	7.1	36/450	8	14/253	5.5	0.2
Mild	43/703	6.1	31/450	6.9	12/253	4.7	0.5
Moderate	7/703	1	5/450	1.1	2/253	0.8	0.5
Severe							
Bleeding requiring revision	45/1084	4.2	29/685	4.2	16/399	4	0.9
AKI >stage 1	39/1108	3.5	28/701	4	11/407	2.7	0.3
Dialysis	11/811	1.4	8/406	2	3/405	0.7	0.2
Sepsis	24/918	2.6	23/686	3.4	1/232	0.4	0.02
Wound complications	36/842	4.3	26/660	3.9	10/182	5.5	0.4
ICU stay (*n* = 983) (days), median (IQR)	1 (1–2)		1 (1–2)		2 (1–2.5)		<0.001
Hospital stay (*n* = 1084) (days), mean ± SD	10.8 ± 7.6		9.4 ± 6.5		6.8 ± 4.9		<0.001

AKI: acute kidney injury; AV: atrioventricular; ICU: intensive care unit; IQR: interquartile range. PM: pacemaker; SD: standard deviation.

Operative outcomes

SURD-AVR was performed using upper MS in 56.4% (*n* = 800) of the cases and ART in 43.6% (*n* = 618). Overall mean cardiopulmonary bypass (CPB) time and cross-clamp (XC) time were 83.6 ± 30.4 and 53.4 ± 21.3 min, respectively. Compared with MS, ART interventions were associated with significantly longer operative durations (CPB time 90.8 vs 77.9 min; clamp time 58.8 vs 49.2 min; $P < 0.001$). A conversion to full sternotomy was required in 12 patients (1%) with no difference between the initial surgical approaches (MS 0.9%, ART 1%, $P = 0.9$) (Table 2).

The Perceval valve was associated with a considerably higher rate of ART compared with the Intuity valve (53.4% vs 19.2%, $P < 0.001$). Despite that, the procedural times were shorter in patients who received Perceval valve than in those receiving the Intuity valve (CPB time 81.2 vs 89.4 min; clamp time 51.2 vs 59 min; $P < 0.001$). Devices implantation success rate was 98.1% with no difference between both surgical approaches ($P = 0.9$) and the type of implanted valves ($P = 0.8$) (Table 2).

In-hospital outcomes and haemodynamics

Overall in-hospital mortality was 1.7%, being 1.8% in patients following Perceval valve implantation and 1.5% in those who received Intuity valve ($P = 0.8$). The rate of main postoperative complications was similar between valve groups (Table 3); stroke occurred in 2% of patients (*n* = 23), acute kidney injury (>stage 1) in 3.5% (*n* = 39), respiratory insufficiency in 3.2% (*n* = 45) and bleeding requiring revision in 4.2% (*n* = 45). Compared with the Intuity group, the Perceval group was associated with a higher incidence of postoperative atrial fibrillation (31.7% vs 23.3%, $P = 0.004$) and sepsis (3.4% vs 0.4%, $P = 0.02$). A definitive pacemaker (PM) implantation was reported in 9% of cases (Perceval 10%, Intuity 7.6%; $P = 0.3$) and significantly decreased over the observational period, from 20.6% (2009–2010) to 5.6% (2017–2018) ($P = 0.002$) (Fig. 1). No difference was found comparing PM implantation rates between valve sizes (Perceval: small = 7.1%, medium = 10.3%, large = 9.4% and extra large = 13.4%, $P = 0.7$) (Intuity: 19 = 1.1%, 21 = 14.9%, 23 = 6.3%, 25 = 9%, 27 = 6.1%, $P = 0.5$). Average peak and mean pressure gradients were 24.8 ± 8.9 and 14.3 ± 5.9 mmHg, respectively, in the Perceval group and 21.3 ± 8.6 and 11.5 ± 4.9 mmHg in the Intuity group ($P < 0.001$). When compared with each corresponding Perceval size, the Intuity valve confirmed to be associated with significant lower prosthesis gradients (Table 4). Postoperatively, no patient experienced severe AR, 7 (1%) patients had moderate AR (Perceval *n* = 5, 1.1%; Intuity *n* = 2, 0.8%; $P = 0.5$) and 43 (6.1%) patients had mild AR (Perceval *n* = 31, 6.9%; Intuity *n* = 12, 4.7%; $P = 0.4$).

On multivariable analysis, the malposition of the valve emerged as the only independent predictor of hospital mortality [odds ratio (OR) 16.2, 95% confidence interval 2.55–10.8; $P = 0.03$] (Table 5). The occurrence of valve malpositioning resulted in substantially longer CPB and XC times (126 vs 71 min and 79 vs 44 min, respectively; $P < 0.001$), greater low cardiac output state (22.2% vs 1%, $P = 0.02$) and higher rate of respiratory failure (20% vs 3.2%, $P = 0.02$) and postoperative dialysis (22.2% vs 1%, $P = 0.006$).

DISCUSSION

In recent years, the treatment of aortic valve pathology is increasingly focused towards developing and popularizing less invasive procedures. MI-AVR and (mostly) transcatheter aortic valve implantation (TAVI) caseloads have steadily increased, leading to a paradigm shift in the treatment of aortic valve disease [5]. When compared with conventional AVR, MI-AVR has been described to be associated with superior clinical outcomes in terms of reduction of postoperative complication rates and transfusion requirements, decreasing length of postoperative stay, and patient satisfaction [2, 6–8]. Nevertheless, despite these promising findings, the use of MI-AVR surgery remains disappointingly low and most of AVR interventions are still performed via full sternotomy [9]. The poor penetration of MI-AVR within the surgical community is likely due to the increased technical difficulty of this type of interventions that may lead to prolonged operative duration. In this setting, sutureless and rapid deployment valves that facilitate and shorten the implantation process are likely to simplify and promote MI-AVR [10–13]. Our findings strongly confirm this observation; in SURD-IR study cohort, almost 75% of cases were performed through MI approaches (1418 of 1935). This high adoption rate of MI-AVR interventions (73.3%) was 3 times as frequent as the 23% observed rate in the German Aortic Valve Registry (GARY) [1]. Furthermore, our current study did not reveal significant prolonged operative duration, despite the MI approaches. The mean CPB and XC times were 83.6 and 53.4 min, respectively. These values compare favourably with those reported in other conventional AVR registries, such as the GARY (CPB time 84 min, XC time 60 min) and the Society of Thoracic Surgeons (STS) database (CPB time 104.9 min, XC time 77 min) [1, 14]. Thus, by reducing the operative durations and enabling an easier prosthesis implantation via limited access, the sutureless and rapid deployment valves have demonstrated to overcome the main limitations of MI-AVR interventions, and can be considered as a primary indication in MI surgery.

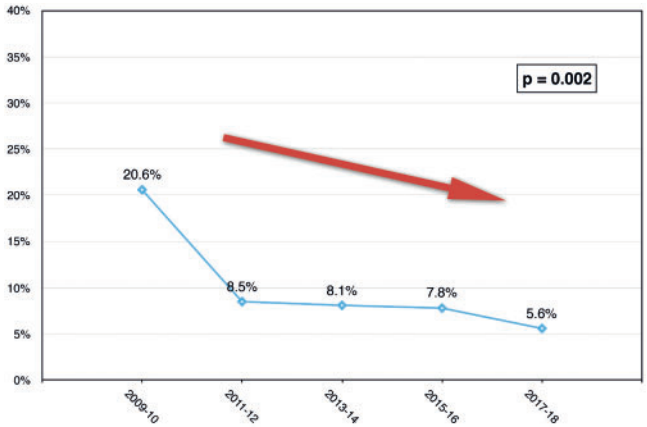


Figure 1: Pacemaker implantation rate over the observational period.

MI SURD-AVR yielded very good outcomes. Overall in-hospital mortality and stroke rate were 1.7% and 2%, respectively, and were similar to those observed in recent 'real-world' analyses after isolated AVR [1, 14].

Clinical trials revealed that SURD-AVR was associated with an increased risk of conduction disorders [13, 15]. In the population of the Registry, the overall rate of PM implantation was 9%. However, as previously reported [3], SURD-AVR experienced a significant decrease of postoperative PM implantation rate over the observational period. In this setting, SURD-AVR has improved by optimizing the surgical technique without technical modifications of the devices. In particular, avoiding low valve positioning and oversizing has contributed to considerably reducing the occurrence of postoperative conduction abnormalities [16, 17]. In the present series, the rate of PM implantation declined from 20.6% (in 2009–2010) to 5.6% (in 2017–2018) ($P = 0.002$). The latter compares satisfactorily with the rate reported for sutured AVR and was much lower than those rates reported after TAVI [1, 14, 18, 19].

While SURD-AVR was associated with a low rate of postoperative AR (moderate AR 1%, mild AR 6.1%), this value was still higher than those reported in conventional AVR procedures. In

Table 4: Valve prostheses: postoperative haemodynamics

	Perceval	Intuity	*P*-value	BSA (Perceval) (kg/m^2)	BSA (Intuity) (kg/m^2)	*P*-value
Peak pressure gradient (mmHg)	24.8 ± 8.9	21.3 ± 8.7	<0.001	1.83 ± 0.2	1.86 ± 0.2	0.08
Perceval S–Intuity 19/21 ($n = 297$)	28.8 ± 8.6	24.5 ± 9.1	0.02	1.72 ± 0.2	1.76 ± 0.2	0.05
Perceval M–Intuity 21/23 ($n = 583$)	26.5 ± 9.5	21.5 ± 7.4	<0.001	1.79 ± 0.2	1.81 ± 0.2	0.11
Perceval L–Intuity 23/25 ($n = 582$)	23.1 ± 7.5	19.8 ± 7.9	0.003	1.89 ± 0.2	1.92 ± 0.2	0.09
Perceval XL–Intuity 25/27 ($n = 230$)	22.6 ± 9.7	17.8 ± 7.6	0.007	1.96 ± 0.2	1.99 ± 0.2	0.19
Mean pressure gradient (mmHg)	14.3 ± 5.9	11.5 ± 4.9	<0.001	1.83 ± 0.2	1.86 ± 0.2	0.08
Perceval S–Intuity 19/21 ($n = 297$)	16.1 ± 5.6	13.6 ± 5.1	0.007	1.72 ± 0.2	1.76 ± 0.2	0.05
Perceval M–Intuity 21/23 ($n = 583$)	15.7 ± 6.7	11.8 ± 4.4	<0.001	1.79 ± 0.2	1.81 ± 0.2	0.11
Perceval L–Intuity 23/25 ($n = 582$)	13.2 ± 4.9	10.3 ± 4.3	<0.001	1.89 ± 0.2	1.92 ± 0.2	0.09
Perceval XL–Intuity 25/27 ($n = 230$)	12.1 ± 5.7	8.9 ± 3.9	<0.001	1.96 ± 0.2	1.99 ± 0.2	0.19

Values are expressed as mean ± SD.

BSA: body mass index; L: large; M: medium; S: small; SD: standard deviation; XL: extra large.

Table 5: Multivariable analysis for hospital mortality

Variables	Multivariable		
	P-value	OR	95% CI
Age	0.4	1.1	0.97–1.04
NYHA class	0.2	1.8	0.78–4.39
Surgical approach (MS versus ART)	0.9	1	0.02–1.01
Valve malpositioning	0.03	16.2	2.55–10.8
Valve type (Perceval versus Intuity)	0.8	1.2	0.37–3.84

ART: anterior right thoracotomy; CI: confidence interval; MS: ministernotomy; NYHA: New York Heart Association; OR: odds ratio.

SURD-IR, the degree of AR did not affect early results, but the impact on the long term remains to be evaluated.

Currently, MS incision is the most widely used approach for MI-AVR. The lower prevalence of ART may be attributed to the fact that ART is a more challenging and long procedure requiring more technical skills. Nevertheless, in the population of the registry, the rate of ART (43.6%) was considerably higher than those reported in previous series [2, 20, 21]. Although the clinical relevance of this observation is arguable, because current evidence shows similar results between patients undergoing ART and MS [8], this strongly supports the assumption that sutureless and rapid deployment valves facilitate and help to promote MI-AVR, regardless of the type of surgical approach. The patients undergoing ART were more likely to receive the Perceval valve than the Intuity valve (87.4% vs 12.6%, $P < 0.001$). These findings may be due to the preference of the centres for access and valve choice, and favoured by the shortened operative times observed in Perceval patients. Perceval valve was associated with a significant time benefit in terms of reduced CPB and XC times, both in ART (CPB time 86.4 vs 120.3 min; XC time 55.2 vs 83.4 min) and in MS (CPB time 74.9 vs 82.1 min; XC time 46.4 vs 53.1 min) approach ($P < 0.001$). This was not followed by any differences in clinical outcomes with regard to mortality and major postoperative complications, when compared with the Intuity group (Table 3).

The Intuity valve was more likely to be implanted in younger patients compared to the Perceval. Almost 13% of Intuity patients were younger than 65 years, compared with 4.6% in the Perceval group ($P < 0.001$). This observation needs to be interpreted with caution; both Perceval and Intuity were associated with excellent mid-term outcomes [15, 22–25]; however, given their recent development, there is no robust evidence yet on the role and performance of these valves in the long term. However, we may speculate that SURD-IR surgeons had a better feeling in the long term with the Intuity valve because the durability of this prosthesis based on the standard Carpentier-Edwards Perimount Magna Ease may be comparable to the conventional valve.

SURD-AVR has been associated with better haemodynamic performances when compared with conventional AVR [13, 26–29]. In the present series, overall mean and peak pressure gradients were 14.3 and 24.7 mmHg, respectively, in the Perceval group, and 11.5 and 21.3 mmHg in the Intuity group ($P < 0.001$). Considering the predominantly small-to-medium-sized annular diameter of the study population, these values can be considered satisfactory. Subgroup analysis of the implanted prosthesis sizes confirmed that valve pressure gradients were significantly lower for the Intuity group compared with the Perceval group (Table 4). As reported by others [30], a possible explanation of this observation may be the balloon-deployable frame of the Intuity, which is expanded in the inflow part of the left ventricular outflow tract. It may limit active constriction of the left ventricular outflow tract during systole, leading to more laminar blood flow through the prosthesis.

Recent clinical trials reported a technical success rate for SURD-AVR ranging from 92% to 95% [24, 28]. In this study cohort, despite the MI incisions, the overall rate of successful device implantation was 98.1%, with no differences between surgical approaches (MS 98.2%, ART 98%) and valve types (Perceval 97.9%, Intuity 98.5%). However, valve malpositioning emerged as a strong risk factor for operative mortality (OR 16.2).

Limitations

This study has the limitations of any observational registry involving no adjudication of patient inclusion and data collection and the lack of comparative arms. A propensity score-matched analysis was not used to minimize selection bias. Because of the retrospective nature of the registry, there is no core laboratory to review images, and the investigators are responsible for data reporting from their own institutions. A majority of institutions participating may be somewhat biased because surgeons participated in first-in-man and in CE market studies. However, the SURD-IR is the largest and the only independent SURD-AVR registry, including all available sutureless and rapid-deployment valves. Thus, it reflects a 'real-world' picture and gives a valuable opportunity to assess this new technology.

CONCLUSIONS

Sutureless and rapid deployment valve technologies were largely embraced by SURD-IR surgeons to perform AVR through a less invasive approach. In the SURD-IR population, MI SURD-AVR using both Perceval and Intuity valves appeared a safe and reproducible procedure associated with promising early results. When compared with the Intuity, the Perceval valve was associated with shorter operative times and was more frequently implanted in patients receiving ART approach. The Intuity prosthesis was preferred in younger patients and was associated with superior postoperative haemodynamic results. Long-term outcomes have still to be analysed in the future.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

Conflict of interest: Martin Andreas is a proctor for Edwards Lifesciences and Advisory Board Member for Medtronic, Inc. 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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