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Sutureless versus rapid deployment aortic valve replacement: results from a multicentric registry

Running Head: Sutureless vs. Rapid Deployment AVR

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ABSTRACT

Background. To compare clinical and hemodynamic in-hospital outcomes of patients undergoing sutureless versus rapid deployment aortic valve replacement (SURD-AVR) in the large population of the Sutureless and Rapid Deployment International Registry (SURD-IR).

Methods. We examined 4695 patients who underwent isolated or combined SURD-AVR. The “sutureless” Perceval valve was used in 3133 patients and the “rapid deployment” Intuity in 1562. Potential confounding factors were addressed by the use of propensity score matching. After matching, 2 well-balanced cohorts of 823 pairs (isolated SURD-AVR) and 467 pairs (combined SURD-AVR) were created.

Results. Patients who received Perceval and Intuity valves showed similar in-hospital mortality and rate of major postoperative complications. Perceval was associated shorter cross clamp and cardiopulmonary bypass time. In the isolated SURD-AVR group, patients receiving Perceval were more likely to undergo anterior right thoracotomy incision. Postoperative transvalvular gradients were significantly lower for the Intuity valve compared to those of the Perceval valve, either in isolated and combined SURD-AVR. The Intuity valve was associated with a lower rate of postoperative mild aortic regurgitation.

Conclusions. Our results confirm the safety and efficacy of SURD-AVR regardless of the valve type. The Perceval valve was associated with reduced operative times and increased anterior right thoracotomy incision. The Intuity valve showed superior hemodynamic outcomes and a lower incidence of postoperative mild aortic regurgitation.

Keywords: sutureless valve; rapid deployment valve; aortic valve replacement; Sutureless and Rapid Deployment International Registry (SURD-IR)

INTRODUCTION

Over the last decade, sutureless and rapid deployment (SURD) valves have emerged as a valid treatment option in patients who require surgical aortic valve replacement (AVR)¹. Because of the simplified and faster deployment, SURD valves demonstrated reduction of the procedural times, facilitation of minimally invasive approaches and a simplified valve implantation in challenging anatomical settings²⁻⁵. Moreover, SURD prostheses revealed superior hemodynamic results when compared with conventional aortic bioprostheses^{3,4}. Currently, two types of SURD valves are available on the market: the “sutureless” Perceval valve (Livanova PLC, London, UK) and the “rapid deployment” Intuity Elite (Edwards Lifesciences, Irvine, CA, USA). The current literature comparing clinical and hemodynamic outcomes of these two valve technologies is limited^{6,7}. The aim of this study was to compare procedural and in-hospital outcomes of patients undergoing SURD-AVR using the Perceval and the Intuity valves in the large population of the Sutureless and Rapid Deployment International Registry (SURD-IR)⁸.

PATIENTS AND METHODS

Study design and patient population

The SURD-IR is an international multicentric registry that includes patients undergoing SURD-AVR using any available sutureless and rapid deployment prosthesis. Details of the registry have been published previously⁹ and the definitions of the relevant variables are reported in the supplementary material. At the time of the present study, 4695 patients undergoing isolated SURD-AVR (n=3196) or combined SURD-AVR (n=1499) were enrolled (2007-2019). Combined SURD-AVR included patients who received SURD-AVR with any type of associated procedures. Data were stratified by the type of valve prosthesis (Perceval vs. Intuity) and presented using statistical methods controlling for potential confounding factors [propensity score (PS) analysis]. The SURD-IR study protocol was approved by the Ethics Committees of all participating centers and patients gave informed consent.

Statistical analysis

Continuous variables were expressed as mean±standard deviation or median and interquartile range, and categorical variables as percentages. Comparison between groups was made using Wilcoxon-Mann-Whitney test for continuous variables and χ^2 test or Fisher exact test for categorical variables, as appropriate. To account for potential confounding effects and treatment allocation bias in our analyses, PS matching was performed to generate 2 study cohorts (isolated SURD-AVR and combined SURD-AVR) of matched Perceval-treated and Intuity- treated patients. Details on PS-matching were reported in the supplementary material.

The association between hospital length of stay and the observed baseline and periprocedural parameters was evaluated using a bivariate regression model. All factors that achieved $p < 0.1$ on bivariate analysis (supplementary table 1) were included in the multiple regression model to identify the independent predictors of hospital stay. The goodness-of-fit measure for the linear regression model was evaluated using the adjusted R-squared coefficient. The SPSS 27.0 statistical software package (SPSS, Chicago, IL) was used for statistical calculations.

RESULTS

Baseline characteristics

Isolated SURD-AVR

In the isolated SURD-AVR group, 2290 (71.7%) patients received the Perceval valve and 906 (28.3%) the Intuity valve. Baseline characteristics are presented in table 1. In the unmatched cohort, patients treated with Perceval were older with a higher prevalence of female gender and were associated with a higher logistic EuroSCORE compared to the Intuity patients. After PS-matching 823 pairs were selected. The 2 matched groups were well balanced in terms of patients' characteristics and risk assessment.

Combined SURD-AVR

In the combined SURD-AVR cohort the Perceval valve was used in 843 (56.2%) patients and the Intuity valve in 656 (43.8%) patients. In the unmatched cohort, patients who received Perceval were older with a higher prevalence of female gender, pulmonary hypertension, peripheral vascular disease, prior cardiac surgery and

urgent/emergent status. Patients treated with the Intuity valve presented with higher rates of advanced NYHA class symptoms and cerebrovascular disease and were more likely to undergo atrial fibrillation surgery and thoracic aortic surgery. These differences were controlled after PS matching, where 467 matched pairs were included (table 2).

Procedural and in-hospital outcomes

To account for the potential confounding effects of preoperative and intraoperative risk factors, procedural and in-hospital outcomes were compared among propensity-matched cohorts.

Isolated SURD-AVR

The operative data are reported in table 3. Patients receiving Perceval were more likely to undergo anterior right thoracotomy (ART) incision and were associated with shorter procedural times compared with Intuity patients. In-hospital mortality and major postoperative complications rates were similar between groups (table 4). Patients receiving Perceval had a shorter length of stay. After adjusting for the other factors influencing the length of stay (supplementary table 1), the Perceval valve [adjusted regression coefficient (β) -0.133, CI -0.012 - -0.234, $p < 0.001$] and the enrolling center (β 0.101, CI 0.021 – 0.313, $p = 0.011$) emerged as independent predictors for hospital stay, on multiple regression analysis (adjusted R-squared 0.09).

Postoperative transvalvular pressure gradients were significantly lower for the Intuity valve. This result was confirmed after comparing each corresponding Perceval and Intuity valve size (figure 1). While the incidence of moderate to severe aortic regurgitation (AR) was similar between groups, the Intuity valve was associated with a lower rate of mild AR.

Combined SURD-AVR

Procedural and in hospital outcomes are shown in tables 3 and 4. Operative times were shorter in patients treated with Perceval compared with those treated with Intuity. In-hospital outcomes were comparable between groups. The Perceval group showed a shorter length of stay. Perceval valve (β -0.087, $p = 0.041$) and the occurrence of postoperative AV block requiring pacemaker (β 0.103, $p = 0.001$) were identified as independent predictors of hospital stay (adjusted R-squared 0.08).

Postoperative echo data confirmed that the Intuity valve was associated with lower transvalvular gradients (figure 2) and a reduced rate of mild AR.

COMMENT

The present PS-matched analysis on 4695 patients represents the largest study comparing Perceval and Intuity valve prostheses. We found that:

- 1) Perceval and Intuity valves provided comparable clinical results in terms of early mortality and incidence of major postoperative complications,
- 2) the Perceval valve required shorter operative times and was more likely to be used in patients who received ART when compared with the Intuity valve,
- 3) the Intuity prosthesis was associated with lower transvalvular gradients and a reduced incidence of postoperative mild AR.

Demographics and risk profile

In SURD-IR valve prosthesis selection is left at the discretion of the surgeon choice according to the institutional practice. Analysis of patients' demographics showed significant differences between Perceval and Intuity groups. In the unmatched cohort, the Perceval valve was more likely to be used in older and high-risk patients compared with the Intuity valve. Accordingly, younger patients were more frequently treated with the Intuity valve. Almost 11% of the Intuity patients were younger than 65 years, compared with 4.6% in the Perceval group ($p<0.001$). This observation was likely related to the fact that the Perceval valve was initially approved for use only in older patients. Moreover, we may speculate that SURD-IR surgeons believed in a better long-term durability of the Intuity prosthesis. This was likely based on the assumption that it would be of similar durability to the standard Perimount Magna Ease valve (Edwards Lifesciences, Irvine, USA). In this regard, however, several multicentric observational studies demonstrated excellent mid-term results for both the Perceval and the Intuity prostheses¹⁰. Conversely, data on long term valve performance and durability are still limited to few single center series^{11,12}. In a recent study of 700 consecutive patients receiving the Intuity valve, the Vienna group reported a 7-year freedom from structural valve degeneration of 95.3% with stable valve hemodynamics over the years¹¹. Similarly, the Leuven group examined the late outcomes in 468

consecutive patients treated with the Perceval valve¹². Analysis of valve performance showed stability over time with a 10-year freedom from structural valve degeneration of 97%. Thus, whereas these results are promising and similar to those reported for the conventional bioprostheses, the available data are still underpowered to warrant an extensive use of Intuity and/or Perceval valve in a younger population. In this respect, however, it has to be marked that both SURD valves showed to be a valid target for transcatheter valve-in-valve procedures in patients presenting with structural valve degeneration¹³.

Procedural and clinical outcomes

The treatment of aortic valve disease is increasingly focused on developing and popularizing minimally invasive procedures (MICS). Because of the simplified and shortened valve implantation process, SURD prostheses demonstrated to be a viable tool to facilitate and promote MICS¹⁴. In the present series over 75% of the isolated SURD-AVRs were performed through less invasive approaches. While, valve comparison showed a higher rate of MICS in the Intuity group compared with the Perceval group, the Perceval valve was more frequently implanted in patients receiving ART compared with the Intuity valve. As previously observed¹⁵, the variability of the surgical approaches between the SURD-IR participating centers may partially account for this difference. However, this finding was also likely related to the different valve technologies. Indeed, the collapsed design of the stentless Perceval valve allows for a better visualization of the aortic annulus and facilitates valve positioning compared with the stented Intuity valve. Thus, the use of Perceval valve may have promoted the extensive adoption of ART approach in this subgroup of patients.

Despite the increased rate of ART, Perceval valve demonstrated a significant time benefit in terms of CPB and cross clamp times when compared with the Intuity valve. Patients receiving Perceval had around 15-16 minutes less of cross clamp time and 21-22 minutes shorter CPB time, regardless of the type of intervention. Also these findings may be related to the collapsed design of Perceval valve that maximizes visualization and simplifies valve implantation. However, the reduced operative times were not followed by any differences in clinical outcomes with regard to mortality and major postoperative complications.

The observed difference in the length of hospital stay between patients treated with Perceval and Intuity is an important area of comment. Indeed, reducing the hospital stay and shortening patient recovery should be considered key elements to evaluate the results of contemporary valve interventions, mainly in patients

undergoing minimally invasive procedures. In our series, the use of Perceval was associated with a significant reduction in hospital length of stay when compared with Intuity, and this result was confirmed after controlling for the other observed predictors of hospital stay. However, it has to be disclosed that our multivariable model contained an inherently high amount of variability that remains unexplainable based on the measured covariates (adjusted R-squared: isolated SURD-AVR 0.09, combined SURD-AVR 0.08). Thus, further specifically designed studies are needed to obtain more robust evidence in this setting.

Conduction disorders requiring PM implantation have emerged as a noteworthy complication associated to SURD-AVR. In our series the rate of PM was 9.1% and 7.9% for Perceval and Intuity, respectively, in the isolated SURD-AVR cohort ($p=0.84$), and 11.1% and 10.3% in the combined SURD-AVR cohort ($p=0.52$). These findings indicate that the occurrence of conduction abnormalities was not related to the different type of valves and both the self-expanding nitinol Perceval stent and the Intuity balloon expandable skirt may similarly increase the risk of compression and injury of the atrioventricular conduction system. Recent studies suggested that by optimizing the valve implantation technique and identifying the proper predictors for postoperative conduction disorders the incidence of PM implantation can substantially decrease^{16–18}. Indeed, although the PM rate remains higher than those reported in conventional AVR interventions, in the SURD-IR the overall incidence of PM decreased from 12.8% to 5.9% over the years, with no difference between two valve types¹⁴.

Hemodynamics

SURD-AVR has been proved as hemodynamically advantageous compared with conventional AVR due to the absence of a suture ring with larger effective orifice area, resulting in lower transvalvular gradients in clinical and in vitro studies^{3,4,19,20}. In our analysis, valve comparison revealed substantially lower overall mean and peak transvalvular gradients in patients receiving Intuity than in those receiving Perceval. Moreover, size by size comparison validated these findings for each prosthesis size. These results may support the in vitro observation that the specific inflow frame design of the Intuity valve is effective in widening the left ventricular outflow tract and allowing for a more laminar blood flow through the valve and consequently reducing the transvalvular pressure gradients. As previously suggested, this distinctive design feature of the Intuity valve may reduce the risk of prosthesis-patient mismatch, particularly in those patients with a small aortic annulus²¹.

Although SURD-AVR was associated with low rates of postoperative AR, the incidence still remains higher than those reported in conventional AVR⁸. However, the increased surgical experience with the valve implantation technique have demonstrated to reduce markedly the occurrence of postoperative AR in the recent years, with values that compare favorably with those observed following conventional AVR¹⁴. In our series, low and similar rates of moderate to severe AR were observed in the Intuity and Perceval groups. Conversely the incidence of mild AR were higher in patients receiving Perceval compared with those treated with Intuity. As observed in patients undergoing transcatheter aortic valve replacement, it may be assumed that the balloon expandable technology of the Intuity valve allows for a better and complete sealing compared with the self-expandable Perceval valve. Although, the lower rate of AR may be associated with improved long term results favoring the use of Intuity in younger patients, the real impact of mild AR following SURD-AVR needs to be further investigated through longer follow-up observations. In this regard, experience with conventional AVR suggested that the occurrence of mild AR has no significant impact on the late patients outcomes²². Conversely, recent evidence on transcatheter valve replacement showed that even mild AR may have detrimental effect on the mid-term results²³.

Study limitations

This study has the limitations of any observational registry involving no adjudication of patient inclusion and data collection. There is no core laboratory to review images, and the investigators are responsible for data reporting from their own institutions. Most of the participating centers use only one type of SURD valve, therefore the variability in patients' selection, surgical techniques and postoperative management between the SURD-IR centers may have partially accounted for the observed differences. Despite PS-matching the influence of unknown confounders cannot be excluded. Data collection was restricted to variables defined at the launch of this registry and not according to pre-defined selection criteria as in randomized trials.

CONCLUSIONS

The present analysis is the largest multicentric study comparing the Perceval and the Intuity valves. Our results confirm that SURD-AVR is a safe and efficacious alternative to conventional AVR regardless of the valve prosthesis type. Perceval valve implantation demonstrated to require shorter operative times and to promote

ART approach. The Intuity prosthesis was preferred in younger patients and was associated with superior hemodynamic results and a lower incidence of mild postoperative AR.

Conflict of interest.

M. Andreas is proctor/consultant: Edwards, Abbott, Medtronic. The other Authors have nothing to disclose.

REFERENCES

1. Santarpino G, Berretta P, Fischlein T et al. Operative outcome of patients at low, intermediate, high and ‘very high’ surgical risk undergoing isolated aortic valve replacement with sutureless and rapid deployment prostheses. *European Journal of Cardio-Thoracic Surgery*.2019;56:38-43.
2. Berretta P, Andreas M, Carrel TP et al. Minimally invasive aortic valve replacement with sutureless and rapid deployment valves: a report from an international registry. *Eur J Cardiothorac Surg*.2019;56:793-799.

3. Borger MA, Dohmen PM, Knosalla C et al. Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial. *Eur J Cardiothorac Surg*.2016;50:713-720.
4. Meco M, Montisci A, Miceli A et al.Sutureless Perceval Aortic Valve Versus Conventional Stented Bioprostheses: Meta-Analysis of Postoperative and Midterm Results in Isolated Aortic Valve Replacement. *J Am Heart Assoc*.2018;7:e006091.
5. Villa E, Messina A, Cirillo M et al. Perceval sutureless valve in freestyle root: new surgical valve-in-valve therapy. *Ann Thorac Surg*.2013;96:e155-7
6. D'Onofrio A, Salizzoni S, Filippini C et al. Surgical aortic valve replacement with new-generation bioprostheses: Sutureless versus rapid-deployment.*J Thorac Cardiovasc Surg*.2019;159:432-442
7. Flynn CD, Williams ML, Chakos A et al. Sutureless valve and rapid deployment valves: a systematic review and meta-analysis of comparative studies. *Annals of Cardiothoracic Surgery*.2020;9:364-374.
8. Di Eusanio M, Berretta P. The sutureless and rapid-deployment aortic valve replacement international registry: lessons learned from more than 4,500 patients. *Ann Cardiothorac Surg*.2020;9:289-297.
9. Di Eusanio M, Phan K, Berretta P et al. Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR): early results from 3343 patients. *Eur J Cardiothorac Surg*.2018;54:768-773.
10. Williams ML, Flynn CD, Mamo AA et al. Long-term outcomes of sutureless and rapid-deployment aortic valve replacement: a systematic review and meta-analysis. *Ann Cardiothorac Surg*.2020;9:265-279.
11. Coti I, Haberl T, Scherzer S et al. Outcome of rapid deployment aortic valves: long-term experience after 700 implants. *Ann Cardiothorac Surg*. 2020;9:314-321.
12. Szeceł D, Eurlings R, Rega F, et al. Perceval sutureless aortic valve implantation: mid-term outcomes. *Ann Thorac Surg*. 2020;doi:10.1016/j.athoracsur.2020.06.064
13. Landes U, Dvir D, Schoels W, et al. Transcatheter aortic valve-in-valve implantation in degenerative rapid deployment bioprostheses. *EuroIntervention*. 2019;15:37-43.
14. Berretta P, Arzt S, Fiore A et al. Current trends of sutureless and rapid deployment valves: an 11-year experience from the Sutureless and Rapid Deployment International Registry.*European Journal of Cardio-Thoracic Surgery*.2020;58:1054-1062.

15. Andreas M, Berretta P, Solinas M, et al. Minimally invasive access type related to outcomes of sutureless and rapid deployment valves. *Eur J Cardiothorac Surg.*2020; 58:1063-1071
16. Vogt F, Moscarelli M, Nicoletti A, et al. Sutureless Aortic Valve and Pacemaker Rate: From Surgical Tricks to Clinical Outcomes. *Ann Thorac Surg.*2019;108:99-105.
17. Berretta P, Montecchiani L, Vagnarelli F, et al. Conduction disorders after aortic valve replacement: what is the real impact of sutureless and rapid deployment valves.*Annals of Cardiothoracic Surgery.*2020;9:386-395.
18. Coti I, Schukro C, Drevinja F, et al. Conduction disturbances following surgical aortic valve replacement with a rapid-deployment bioprosthesis. *J Thorac Cardiovasc Surg.* 2020; doi:10.1016/j.jtcvs.2020.01.083
19. Tasca G, Vismara R, Mangini A, et al. Comparison of the Performance of a Sutureless Bioprosthesis With Two Pericardial Stented Valves on Small Annuli: An In Vitro Study. *Ann Thorac Surg.*2017;103:139-144.
20. Ai L, Chen H, Lin V, Bapat VN. Rapid Deployment Aortic Valves Deliver Superior Hemodynamic Performance In Vitro.*Innovations.*2017;12:338-345.
21. Theron A, Gariboldi V, Grisoli D, et al. Jaussaud N, Morera P, Lagier D, Leroux S, Amanatiou C, Guidon C, Riberi A, Collart F. Rapid Deployment of Aortic Bioprosthesis in Elderly Patients With Small Aortic Annulus. *The Annals of Thoracic Surgery.*2016;101:1434-1441.
22. L S Rallidis IEM, I Ikonmidis, P Nihoyannopoulos.Natural history of early aortic paraprosthetic regurgitation: a five-year follow-up. *Am Heart J.*1999;138:351-357.
23. Ando T, Briasoulis A, Telila T et al. Does mild paravalvular regurgitation post transcatheter aortic valve implantation affect survival?A meta-analysis. *Catheter Cardiovasc Interv.*2018;91:135-147.

Table 1. Isolated SURD-AVR: patients' characteristics

Characteristics	Overall Cohort			Propensity-Matched Cohort		
	Perceval (n=2290)	Intuity (n=906)	Standardized difference ^a	Perceval (n=823)	Intuity (n=823)	Standardized difference
Female	64.3	51.9	25.9	57.5	54.7	5.7
Age, mean±SD	76.8±6.6	73.8±8.2	44.3	75.4±7.3	74.8±7.3	8.5
NYHA III-IV	49	59.5	-20.1	53.9	57.1	-6.4
Hypertension	82.4	79.6	7.4	80.9	81	0.1
Obesity	26.3	28.3	-4.6	27.6	28.2	-4.3
BMI, mean±SD	27.3±4.8	27.7±4.9	-7.2	27.6±4.7	27.9±4.9	-1.8
BSA, mean±SD	1.79±0.19	1.86±0.2	-24.3	1.81±0.17	1.84±0.19	-7.4
Diabetes	28.9	26	6.3	28.4	27	3.2
Smoking	23.8	17.4	14.8	19.6	18.1	3.5
Atrial fibrillation	12.4	15	-7.5	14	14.1	-0.4
Pacemaker	3.7	4	-1.5	4	2.3	1.7
Surgical indications			47.2			9.7
Ao.stenosis	62.7	84.6		79.7	81.3	
Ao. regurgitation	0.8	1.6		0.6	1.6	
Mixed disease	36.5	13.8		19.7	17.1	
Pulmonary Hypertension	25.9	13.1	13.7	17.3	14.2	1.2
Cerebrovascular disease	10.6	12.9	-7.6	11.4	12.3	-2.8
Peripheral vascular disease	14.5	6.4	22.9	9.6	6.8	7.7
Renal insufficiency	63.3	67	-11.5	63.8	66.4	-6.5
Chronic lung disease	14.3	15.7	-4.2	16	15.3	1.8
LVEF%, mean±SD	58.5±9.9	58.8±9.7	16.5	58.7±9.7	58.9±9.6	4.4
Reintervention	6.6	4	10.4	5	4.3	3.2
Urgent/emergent status	4.9	3.1	8.2	4	3.3	3.2
Logistic Euroscore (%), median (IQR)	8.1 (5.5-12.3)	5.9 (3.5-9.9)	30.9	7.2 (4.9-11.1)	6.6 (3.7-10.8)	9.4

Values are percentages unless otherwise indicated.

BMI: body mass index. BSA: body surface area. IQR: interquartile range. LVEF: left ventricular ejection fraction. SD: standard deviation.

Table 2. Combined SURD-AVR: patients' characteristics

Characteristics	Overall Cohort			Propensity-Matched Cohort		
	Perceval (n=843)	Intuity (n=656)	Standardized difference ^a	Perceval (n=467)	Intuity (n=467)	Standardized difference
Female	55.5	40.7	30.1	47.1	46	2.4
Age, mean±SD	77.4±6.8	74.1±7.1	46.6	75.8±7.2	75.4±6.2	4.7
NYHA III-IV	57.1	68.6	-26	64	67	-4.2
Hypertension	84	83.1	2.1	83.3	83.9	-2.1
Obesity	26.5	27.9	-3.2	27.8	27.4	0.6
BMI, mean±SD	27.1±4.4	27.6±4.8	-9.8	27.5±4.4	27.4±4.8	1
BSA, mean±SD	1.79±0.2	1.88±0.2	-25.1	1.82±0.18	1.85±0.19	-6.8
Diabetes	31.4	30	3.1	31.3	31.7	-0.8
Smoking	27.4	17.4	26.7	21	19.9	2.7
Atrial fibrillation	21.2	23.9	-6.4	21.8	22.9	-2.4
Pacemaker	5.4	5.5	-0.1	5.2	5.1	0.4
Surgical indications			6.8			0.7
Ao. stenosis	68.7	71.2		69.6	70.3	
Ao. regurgitation	2.7	3.8		2.9	3.2	
Mixed valve disease	28.6	25		27.5	26.5	
Pulmonary Hypertension	41.8	27.4	31.9	32.8	31.9	1.9
Cerebrovascular disease	13.9	21.3	-18.3	18	18.6	-1.4
Peripheral vascular disease	18.9	14.2	13.2	16.7	16.1	2.1
Renal insufficiency	74.4	75.9	-3.2	73.6	74.4	-2.7
Chronic lung disease	17.7	16.2	4.2	17.6	17.1	1.4
LVEF%, mean±SD	56.6±12.2	55.3±11.9	10.9	56.2±12.8	55.8±12.1	3.9
Reintervention	8.7	6.1	10.7	7.9	6.6	5.4
Urgent/emergent status	12.2	5.5	30.2	6.9	6.6	0.8
Concomitant procedures						
CABG	72.1	70	4.7	72.6	73	-1.1
Septal myectomy	8.1	6.4	6.8	6.6	6.9	-1.4
Mitral surgery	14.9	15.4	-1.2	16.3	15.2	3.1
Tricuspid surgery	5.7	8.2	-9.2	6.9	7.1	-0.5
Atrial fibrillation surgery	6.2	11	-15.4	8.1	9	-2.6

Thoracic aorta surgery	2.6	11	-26.7	3.9	5.1	-4.4
Other	4.7	1.2	12.1	2.4	1.7	5.5
Logistic Euroscore (%), median (IQR)	9.2 (6.2-14.9)	8.2 (4.8-14.5)	5.8	8.8 (5.8-14.8)	8.4 (5-14.5)	1.6

Values are percentages unless otherwise indicated.

BMI: body mass index. BSA: body surface area. IQR: interquartile range. LVEF: left ventricular ejection fraction. SD: standard deviation.

Table 3. Operative data

Characteristics	Isolated SURD-AVR			Combined SURD-AVR		
	Perceval (n=823)	Intuity (n=823)	P-value	Perceval (n=467)	Intuity (n=467)	P-value
Full-sternotomy	25.4	19.9	0.031	93.1	94.7	0.61
Minimally invasive accesses	74.6	80.1	0.031	6.9	5.3	0.61
<i>Mini-sternotomy</i>	43.4	58.7	<0.001	4.9	4.7	0.91
<i>ART</i>	31.2	21.4	<0.001	2	0.6	0.12
Valve malpositioning	1.6	2.1	0.23	2.1	1.5	0.63
CPB time (min.), median (IQR)	63 (47-84)	85 (67-107)	<0.001	93 (70-126)	114 (90-145)	<0.001
<i>Full-sternotomy</i>	57 (41-82)	80 (61-100)	<0.001	93 (70-128)	116 (90-147)	<0.001
<i>Mini-sternotomy</i>	61 (50-78)	78 (62-97)	<0.001	85 (78-104)	100 (89-108)	<0.001
<i>ART</i>	68 (50-87)	111 (100-125)	<0.001	126 (98-162)	101 (87-131)	<0.001
Clamp time,(min.), median (IQR)	39.5 (29-53)	54 (43-72)	<0.001	63 (47-89)	79 (61-102)	<0.001
<i>Full-sternotomy</i>	37 (27-50)	51 (40-64)	<0.001	63 (47-86)	79 (61-102)	<0.001
<i>Mini-sternotomy</i>	38 (30-50)	50 (41-63)	<0.001	54 (45-78)	60 (50-80)	<0.001
<i>ART</i>	45 (32-58)	77 (67-89)	<0.001	100 (54-117)	78 (61-106)	<0.001

Values are percentages unless otherwise indicated

ART: anterior right thoracotomy. CPB: cardiopulmonary bypass.

Table 4. In-hospital and hemodynamics outcomes

Characteristics	Isolated SURD-AVR			Combined SURD-AVR		
	Perceval (n=823)	Intuity (n=823)	P-value	Perceval (n=467)	Intuity (n=467)	P-value
In-hospital mortality	1.6	1	0.51	4.5	3.4	0.24
Stroke	2.4	2.8	0.54	4.5	2.8	0.22
Low cardiac output	2.2	1.2	0.25	7	5.4	0.24
Ventilatory support>72h	3.4	3.2	0.72	5.8	6.9	0.42
Atrial fibrillation	28.7	29.4	0.83	30.6	25.1	0.051
Pacemaker	9.1	7.9	0.84	11.1	10.3	0.52
Bleeding	4	3.2	0.22	5.8	6	0.93
Acute Kidney Injury (>stage 1)	3.9	3	0.091	7.9	7.7	0.62
ICU stay (days), median (IQR)	2 (1-4)	2 (1-3)	0.13	2 (1-4)	2.3 (1-5)	0.22
Hospital stay (days), mean±SD	10.3±6.1	13.1±8.3	<0.001	11.3±7.1	14.1±8.3	0.008
Peak gradient (mmHg), mean±SD	26.5±10.2	21.5±9.7	<0.001	25.9±11.7	19.6±8.1	<0.001
Mean gradient (mmHg), mean±SD	14.5±5.9	11.6±5.5	<0.001	14.1±5.6	10.5±4.4	<0.001
Aortic regurgitation	10.9	6.1	<0.001	62 (13.2)	21 (4.5)	<0.001
Mild	9.6	4.5		53 (11.3)	15 (3.2)	
Moderate	1.2	1.2		8 (1.7)	3 (0.6)	
Severe	0.1	0.4		1 (0.2)	3 (0.6)	
LVEF%, mean±SD	57.3±8.6	55.5±7.6	<0.001	54.7±10.6	53.4±7.9	0.031

Values are percentages unless otherwise indicated

ICU: intensive care unit. LVEF: left ventricular ejection fraction. SD: standard deviation

FIGURE LEGENDS

Figure 1. Isolated SURD-AVR: size by size comparison between Perceval and Intuity pressure gradients.

Figure 2. Combined SURD-AVR: size by size comparison between Perceval and Intuity pressure gradients.