Surgical aortic valve replacement with new-generation bioprostheses: Sutureless versus rapid-deployment

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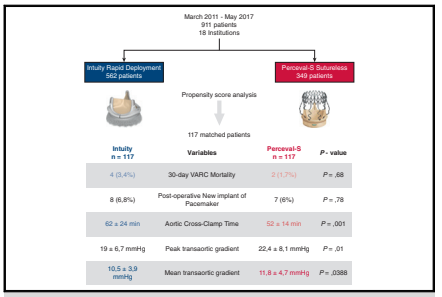
ABSTRACT

Objectives: The aim of this retrospective multicenter study was to compare early clinical and hemodynamic outcomes of Perceval-S sutureless (Livanova, London, United Kingdom) and Intuity rapid-deployment (Edwards Lifesciences, Irvine, Calif) bioprostheses.

Methods: Data from patients who underwent isolated or combined aortic valve replacement with Perceval-S and with Intuity bioprostheses at 18 cardiac surgical institutions were analyzed. Propensity matching was performed to identify similar patient cohorts.

Results: We included 911 patients from March 2011 until May 2017. Perceval-S and Intuity valves were implanted in 349 (38.3%) and in 562 (61.7%) patients, respectively. Propensity score identified 117 matched pairs. In the matched cohort, device success was 99.1% and 100% in Perceval-S and Intuity group, respectively ($P = 1.000$). Thirty-day Valve Academic Research Consortium mortality occurred in 2 (1.7%) and 4 (3.4%) patients in the Perceval-S and in Intuity group, respectively ($P = .6834$). The rate of postoperative new permanent pacemaker implantation was 6% (7 patients) and 6.8% (8 patients) in the Perceval-S and in Intuity group, respectively ($P = .7896$). Perceval-S valve implantation requires significantly shorter aortic crossclamp and cardiopulmonary bypass times than Intuity valve implantation (aortic crossclamp time for isolated, 52 ± 14 minutes vs 62 ± 24 minutes; $P < .0001$). Peak transaortic gradients were 22.4 ± 8.1 mm Hg and 19.6 ± 6.7 mm Hg ($P = .0144$), whereas mean gradients were 11.8 ± 4.7 mm Hg and 10.5 ± 3.9 mm Hg ($P = .0388$) in the Perceval-S and Intuity groups, respectively.

Conclusions: Sutureless Perceval-S and rapid-deployment Intuity bioprostheses provide good and similar early clinical and hemodynamic outcomes. Perceval-S valve implantation requires shorter crossclamp and cardiopulmonary bypass times, whereas Intuity valve implantation provides lower transaortic peak and mean gradients. (J Thorac Cardiovasc Surg 2020;159:432-42)



Study devices, study population, analysis, and main findings of the study.

Central Message

Sutureless Perceval-S (Livanova, London, United Kingdom) and rapid-deployment Intuity (Edwards Lifesciences, Irvine, Calif) bioprostheses represent a good option for patients with aortic valve stenosis. They provide good and similar early clinical and hemodynamic outcomes.

Perspective

Sutureless Perceval-S (Livanova, London, United Kingdom)and rapid-deployment Intuity (Edwards Lifesciences, Irvine, Calif) bioprostheses have enriched the portfolio of aortic valve substitutes. They facilitate minimally invasive procedures and enable to perform aortic valve replacement with reduced surgical times. Therefore, they now represent a good surgical option, especially for patients undergoing combined procedures and/or minimally invasive aortic valve replacement.

See Commentaries on pages 443 and 445.

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Abbreviations and Acronyms

AVR = aortic valve replacement
EuroSCORE = European system for cardiac operative risk evaluation
INTU-ITA = Italian Registry of the Intuity Valve
STS = Society of Thoracic Surgeon
VARC-2 = Valve Academic Research Consortium-2

Scanning this QR code will take you to the article title page to access supplementary information.

Sutureless and rapid-deployment bioprostheses have been recently introduced into clinical practice and have expanded the already rich portfolio of aortic valve substitutes for patients undergoing aortic valve replacement (AVR) for severe aortic valve stenosis. They are implanted in the aortic position after leaflet removal and annular decalcification in the same manner as conventional bioprostheses but they do not require placement of circumferential annular sutures because they have self-anchoring systems similar to those of transcatheter aortic valve bioprostheses. There are 2 main advantages of these devices: reduction of surgical times and simplification of minimally invasive procedures.[1-4] There are only 2 commercially available devices with these characteristics: the sutureless Perceval-S (Livanova, London, United Kingdom) and the rapid-deployment Intuity (Edwards Lifesciences, Irvine, Calif). Because there are few published comparisons of these 2 devices,[5] the aim of this retrospective multicenter study was to compare early clinical and hemodynamic parameter outcomes of patients undergoing AVR with the Perceval-S and with the Intuity bioprostheses. In particular, primary outcomes were early mortality and pacemaker implantation rate; secondary outcomes were surgical times and hemodynamic data.

PATIENTS AND METHODS

Patient-informed consent for treatment, data collection, and analysis for scientific purposes was always collected. Because this was a retrospective study on commercially available devices, protocol submission to the ethics committee has been waived; however, ethics permission was granted by the regional ethics committee in centers where it was deemed necessary. The Italian Registry of the Intuity Valve (INTU-ITA) was approved by the appropriate ethics committee.

In this study, we included 911 patients who underwent isolated or combined Perceval-S or Intuity valve implantation for severe aortic valve stenosis at 18 centers from March 2011 until May 2017. In particular, the Perceval-S and the Intuity valves were implanted in 349 (38.3%) and in 562 (61.7%) patients, respectively. The choice to implant a Perceval-S or an Intuity device instead of a conventional bioprosthesis was based on the policy of every center and ultimately it was left at the discretion of each implanting surgeon because there are no specific recommendations about the use of a sutureless/rapid deployment or a standard aortic prosthesis.

Sutureless AVR With Perceval-S

Data from 349 patients who underwent isolated AVR for aortic valve stenosis with the Perceval-S bioprosthesis at 3 European centers between March 2011 and February 2016 were included in this analysis. All procedures were performed under general anesthesia through full sternotomy, ministernotomy (inverted T or J shape) or right anterior thoracotomy according to the preference of implanting surgeons and to the policy of each single center. The Perceval-S bioprosthesis is built on a self-expandable nitinol stent that has the dual role of supporting the valve and fixing it in place with 3 bovine pericardial leaflets. The implanting technique has been already described.[6] Differently from the rapid-deployment Intuity valve, during Perceval-S implantation the 3 guiding sutures are removed from the annulus, allowing defining this device a truly sutureless bioprosthesis.

Rapid-Deployment AVR With Intuity Valve

Data from the INTU-ITA were used in this study. The INTU-ITA is a real-world, all-comers independent multicenter registry that includes all patients who underwent isolated or combined AVR with the Intuity valve (and its evolution Intuity Elite [Edwards Lifesciences]) at participating centers. For this analysis, we included 562 patients from 16 Italian cardiac surgery institutions in a time period that goes from April 2012 through May 2017. Because the Intuity valve is not approved for patients with aortic insufficiency, all patients included in the registry underwent AVR for severe aortic valve stenosis. Data were collected at each study site and then anonymously sent to the University of Padua (coordinating center) for storage and analysis. All procedures were performed under general anesthesia through full sternotomy, ministernotomy (inverted T or J shape) or right anterior thoracotomy according to the preference of implanting surgeons and to the policy of each single center. The Intuity aortic valve system is built on the Carpentier-Edwards Perimount (Edwards Lifesciences) platform (3 bovine pericardial leaflets) with a subanular balloon-expandable skirt, similar to a transcatheter valve stent that serves both for anchoring and sealing. The implanting technique has already been described.[7] During Intuity implantation the 3 guiding annular sutures are tied and not removed, so this prosthesis is not truly a sutureless valve but it is rather described as a rapid-deployment device.

Preoperative variables were defined according to European system for cardiac operative risk evaluation (EuroSCORE) definitions[8] and postoperative outcomes were defined according to the updated Valve Academic Research Consortium (VARC-2) definitions.[9] We decided to use VARC-2 definitions to allow easy comparison between these data and those of transcatheter aortic valve replacement that will likely represent a potential competitor for these procedures in the near future. Patients underwent clinical and echocardiographic assessment at the study site before the operation and at hospital discharge.

Because the Perceval-S bioprosthesis comes in 4 sizes (small, medium, large, and extra-large) and the Intuity valve has 5 sizes (19 mm, 21 mm, 23 mm, 25 mm, and 27 mm), we compared postoperative gradients making both possible couplings:

- Nineteen millimeters versus size small, 21 mm versus size medium, 23 mm versus size large, and 25 mm versus size extra-large; as well as
- Twenty-one millimeters versus size small, 23 mm versus size medium, 25 mm versus size large, and 27 mm versus size extra-large.

Statistical Analysis

Data are shown as frequencies and percentage or as mean ± standard deviation for categorical and continuous variables, respectively. 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 reduce possible differences between patients with Perceval-S or Intuity valve and obtain unbiased estimation of the treatment effect, we performed a propensity score analysis; that is, the probability of receiving the Intuity valve conditionally on a priori selected variables. A multivariable logistic regression model was performed with the presence of the Intuity valve as the dependent variable. Variables included in the propensity score model were age, gender, body surface area, arterial hypertension, New York Heart Association functional class, chronic obstructive pulmonary disease, glomerular filtration rate, hemoglobin value, preoperative heart rhythm, preoperative mean aortic gradient, preoperative aortic regurgitation, preoperative mitral regurgitation, preoperative left ventricular ejection fraction, isolated or combined procedure, EuroSCORE-2 and Society of Thoracic Surgeons (STS) score. The *C* statistic was reported as goodness of fit of the propensity score model. To make more comparable 2 different matched cohorts analyses, a greedy algorithm was used. The greedy algorithm proceeds sequentially to the lowest digit match on propensity score. Goodness of matched pairs is defined as those with the least absolute difference in matched propensity score. All statistical tests were 2-sided. The statistical analysis was performed using the SAS version 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

Study Population

Baseline and preoperative echocardiographic characteristics of the overall population are shown in Table 1. It clearly appears that before matching the 2 cohorts have many preoperative differences that ultimately lead to a higher risk profile in the Perceval-S group. In fact, patients undergoing AVR with the Perceval-S have higher EuroSCORE II (4.36% ± 4.47% vs 3.25% ± 3.19%; $P < .0001$) and higher STS score (4.18% ± 3.10% vs 2.54% ± 1.94%; $P < .0001$). After propensity score analysis, 117 matched pairs were selected (*C* statistic, 0.900). The 2 matched cohorts appear well balanced in terms of baseline variables and, as a consequence, preoperative risk assessment is similar. Furthermore, preoperative echocardiographic variables are similar between matched groups. The balance between matched groups is shown in Table 2 with standardized differences for the baseline and the preoperative echocardiographic variables used for the propensity matching.

Surgical Procedure

Table 3 shows intraoperative variables of the matched groups. Intraoperative variables of the unmatched groups are shown in Table E1. Valve size distribution is as follows: Perceval-S small, medium, large, and extra-large were implanted in 15 (12.8%), 40 (34.2%), 42 (35.9%), and in 20 (17.1%) patients, respectively, whereas Intuity 19 mm, 21 mm, 23 mm, 25 mm, and 27 mm were implanted in 19 (16.3%), 44 (37.6%), 37 (31.6%), 11 (9.4%), and 6 (5.1%) patients, respectively. Perceval-S implantation requires significantly shorter aortic crossclamp and cardiopulmonary bypass times (aortic crossclamp time for isolated AVR in the matched groups: 52 ± 14 minutes vs 62 ± 24 minutes; $P < .0001$). We did not observe significant differences in terms of intraoperative death, intraoperative moderate/severe aortic regurgitation requiring prosthesis replacement, or reimplantation between the matched groups. As a consequence, device success, according to VARC-2 definitions, in the matched groups was 99.1% (116 patients) and 100% (117 patients) ($P = 1.000$).

Postoperative Outcomes

Postoperative clinical and echocardiographic outcomes in the matched population are shown in Table 4. Postoperative clinical and echocardiographic outcomes in the unmatched population are shown in Table E2. The incidence of acute myocardial infarction, stroke (disabling and not disabling), and acute kidney injury was similar between the groups, The rate of permanent pacemaker implantation was not significantly different: 6% (7 patients) and 6.8% (8 patients) in the Perceval-S and in the Intuity groups, respectively ($P = .7896$). Thirty-day mortality according to VARC-2 definitions was 2.2% (20 patients) in the overall population and it was similar between groups (Perceval-S 1.7%, Intuity 3.4%; $P = .6834$). We observed significantly lower peak and mean aortic gradients in the Intuity cohort (peak, 22.45 ± 8.11 mm Hg vs 19.56 ± 6.67 mm Hg; $P = .0188$ and mean, 11.84 ± 4.70 mm Hg vs 10.47 ± 3.87 mm Hg; $P = .0388$). Figure 1 shows the comparison of peak and mean gradients at discharge of the study devices by size and with both possible couplings (see the Methods). Although statistical significance was reached only for some size comparisons, there was a trend toward lower gradients of the Intuity valves in all size comparisons.

DISCUSSION

The portfolio of aortic valve substitutes includes many alternatives: conventional aortic valve prostheses (biological and mechanical), stentless valves (pericardial and porcine root), transcatheter devices, sutureless devices, and rapid-deployment bioprostheses. Sutureless and rapid-deployment valves, despite the similar concept based on a self-anchoring mechanism into the aortic annulus with no need for annular sutures, have several differences in terms of design and structure. In this study, we compared early clinical and hemodynamic outcomes of the only 2 commercially available sutureless (Perceval-S) and rapid-deployment (Intuity) devices using propensity score analysis, to better understand their behavior and to provide surgeons with more data to make the best choice when selecting the most appropriate device for patients with aortic valve stenosis. The main findings of our study are that the Perceval-S and Intuity bioprostheses provide similar outcomes in terms of major early clinical end points, including pacemaker implantation rate; the Perceval-S valve requires shorter surgical times; and the Intuity valve provides lower postoperative aortic gradients.

TABLE 1. Baseline and preoperative echocardiographic characteristics of the overall population

Characteristic	Total (n = 911)	Perceval-S* (n = 349)	Intuity† (n = 562)	*P* value
Age (y)	76.54 ± 7.4	79.31 ± 6.42	74.82 ± 7.68	<.0001
Male gender	405 (44.5)	115 (33.0)	290 (51.6)	<.0001
Body surface area (m^2)	1.77 ± 0.19	1.75 ± 0.19	1.78 ± 0.18	.0054
Body mass index	26.90 ± 4.50	27.48 ± 4.86	26.54 ± 4.24	.0033
Arterial hypertension	746 (81.9)	306 (87.7)	440 (78.3)	.0003
Diabetes mellitus	230 (25.2)	100 (28.7)	130 (23.1)	.0622
Insulin therapy	52 (5.7)	22 (6.3)	30 (5.3)	.3455
NYHA functional class				<.0001
I	56 (6.1)	10 (2.9)	46 (8.2)	
II	376 (41.3)	120 (34.4)	256 (45.6)	
III	433 (47.5)	201 (57.6)	232 (41.3)	
IV	46 (5.0)	18 (5.2)	28 (5.0)	
Peripheral arterial disease	167 (18.3)	59 (16.9)	108 (19.2)	.3807
COPD	134 (14.7)	37 (10.6)	97 (17.3)	.0058
Neurologic dysfunction	24 (2.6)	10 (2.9)	14 (2.5)	.7317
Creatinine (mg/dL)	1.03 ± 0.70	1.01 ± 0.53	1.04 ± 0.77	.9836
Creatinine ≥2 mg/dL	27 (3.0)	13 (3.7)	14 (2.5)	.2857
GFR (mL/min/1.73 m^2)	65.17 ± 26.44	60.29 ± 24.90	67.32 ± 26.83	.0001
Dialysis	6 (0.7)	3 (0.9)	3 (0.5)	.6802
Hemoglobin (g/dL)	12.70 ± 1.67	12.27 ± 1.52	12.96 ± 1.71	<.0001
Cardiac rhythm				.0002
Sinus rhythm	705 (77.4)	284 (81.4)	421 (74.9)	
Permanent AF	137 (15.0)	37 (10.6)	100 (17.8)	
Paroxysmal AF	23 (2.5)	3 (0.9)	20 (3.6)	
Pacemaker	46 (5.0)	25 (7.2)	21 (3.7)	
Previous AMI				.4054
<90 d	37 (4.1)	16 (4.6)	21 (3.7)	
≥90 d	38 (4.2)	11 (3.2)	27 (4.8)	
Coronary artery disease	363 (39.8)	142 (40.7)	221 (39.3)	.6575
Previous cardiac surgery	66 (7.2)	27 (7.7)	39 (6.9)	.6519
EuroSCORE II	3.67 ± 3.77	4.36 ± 4.47	3.25 ± 3.19	<.0001
STS score	3.15 ± 2.56	4.18 ± 3.10	2.54 ± 1.94	<.0001
Peak aortic gradient (mm Hg)	79.41 ± 23.38	77.92 ± 23.51	80.35 ± 23.27	.0936
Mean aortic gradient (mm Hg)	48.50 ± 15.25	47.46 ± 15.36	49.14 ± 15.16	.0466
Aortic regurgitation				.0055
Mild	379 (41.6)	170 (48.7)	209 (37.2)	
Moderate	166 (18.2)	52 (14.9)	114 (20.3)	
Severe	44 (4.8)	17 (4.9)	27 (4.8)	
Mitral regurgitation				<.0001
Mild	436 (47.9)	196 (56.2)	240 (42.7)	
Moderate	122 (13.4)	54 (15.5)	68 (12.1)	
Severe	23 (2.5)	10 (2.9)	13 (2.3)	
LVEF (%)	58.36 ± 9.74	57.42 ± 9.73	58.95 ± 9.70	.0122

Values are presented as mean ± standard deviation or absolute number (%). *NYHA*, New York Heart Association; *COPD*, chronic obstructive pulmonary disease; *GFR*, glomerular filtration rate; *AF*, atrial fibrillation; *AMI*, acute myocardial infarction; *EuroSCORE*, European system for cardiac operative risk evaluation II; *STS*, Society of Thoracic Surgeons; *LVEF*, left ventricular ejection fraction. *Livanova, London, United Kingdom. †Edwards Lifesciences, Irvine, Calif.

TABLE 2. Baseline and preoperative echocardiographic characteristics: Standardized differences before and after matching

Characteristic	All			Matched		
	Perceval-S* (n = 349)	Intuity† (n = 562)	*d*	Perceval-S* (n = 117)	Intuity† (n = 117)	*d*
Age (y)	79.31 ± 6.42	74.82 ± 7.68	–0.63	78.33 ± 6.70	77.97 ± 5.37	–0.06
Male gender	115 (33.0)	290 (51.6)	–0.38	45 (38.5)	46 (39.3)	–0.02
Arterial hypertension	306 (87.7)	440 (78.3)	–0.25	102 (87.2)	100 (85.5)	–0.05
NYHA functional class			0.38			0.07
I	10 (2.9)	46 (8.2)		6 (5.1)	7 (6.0)	
II	120 (34.4)	256 (45.6)		55 (47.0)	56 (47.9)	
III	201 (57.6)	232 (41.3)		53 (45.3)	52 (44.4)	
IV	18 (5.2)	28 (5.0)		3 (2.6)	2 (1.7)	
COPD	37 (10.6)	97 (17.3)	0.19	15 (12.8)	15 (12.8)	0.00
GFR (mL/min/1.73 m^2)	60.29 ± 24.90	67.32 ± 26.83	0.27	60.53 ± 23.79	63.07 ± 25.40	0.10
Hemoglobin (g/dL)	12.27 ± 1.52	12.96 ± 1.71	0.42	12.39 ± 1.42	12.54 ± 1.72	0.10
Cardiac rhythm			0.31			0.16
Sinus rhythm	284 (81.4)	421 (74.9)		91 (77.8)	96 (82.1)	
Permanent AF	37 (10.6)	100 (17.8)		15 (12.8)	14 (12.0)	
Paroxysmal AF	3 (0.9)	20 (3.6)		3 (2.6)	1 (0.9)	
Pacemaker	25 (7.2)	21 (3.7)		8 (6.8)	6 (5.1)	
EuroSCORE II	4.36 ± 4.47	3.25 ± 3.19	–0.29	3.98 ± 3.06	3.95 ± 2.98	–0.01
STS score	4.18 ± 3.10	2.54 ± 1.94	–0.63	3.55 ± 2.16	3.47 ± 2.42	–0.04
Mean aortic gradient (mm Hg)	47.46 ± 15.36	49.14 ± 15.16	0.11	46.10 ± 16.04	44.79 ± 15.52	–0.08
Aortic regurgitation			0.24			0.15
Mild	170 (48.7)	209 (37.2)		79 (67.5)	76 (65.0)	
Moderate	52 (14.9)	114 (20.3)		24 (20.5)	29 (24.8)	
Severe	17 (4.9)	27 (4.8)		6 (5.1)	7 (6.0)	
Mitral regurgitation			0.37			0.08
Mild	196 (56.2)	240 (42.7)		81 (69.2)	77 (65.8)	
Moderate	54 (15.5)	68 (12.1)		21 (17.9)	23 (19.7)	
Severe	10 (2.9)	13 (2.3)		3 (2.6)	4 (3.4)	
LVEF (%)	57.42 ± 9.73	58.95 ± 9.70	0.16	58.09 ± 10.37	58.74 ± 9.52	0.06
Surgical procedure			0.37			0.03
Combined	175 (50.14)	187 (33.27)		57 (48.72)	63 (53.85)	
Isolated	174 (49.86)	375 (66.73)		60 (51.28)	54 (46.15)	

Values are presented as mean ± standard deviation or absolute number (%). *d*, Standardized difference; *NYHA*, New York Heart Association; *COPD*, chronic obstructive pulmonary disease; *GFR*, glomerular filtration rate; *AF*, atrial fibrillation; *EuroSCORE*, European system for cardiac operative risk evaluation II; *STS*, Society of Thoracic Surgeons; *LVEF*, left ventricular ejection fraction. *Livanova, London, United Kingdom. †Edwards Lifesciences, Irvine, Calif.

Postoperative Pacemaker Implantation

The anchoring system of the Perceval-S and Intuity valves is similar to transcatheter devices and therefore postoperative permanent pacemaker implantation rate is a concern related to the use of these devices.[10-12] In fact, the Perceval-S self-expanding nitinol stent and the Intuity balloon-expandable skirt generate compression on the left ventricular outflow tract, potentially damaging the conduction tissue. The incidence of pacemaker implantation in our study is 4.6% in the Perceval-S group and 6.2% in the Intuity group, with no statistical significance. These values are slightly higher than those commonly reported for conventional bioprostheses.[13] Meco and colleagues[14] in a meta-analysis report a significantly higher incidence of pacemaker implantation in patients undergoing Perceval-S valve implantation (7.9%) compared with those receiving conventional bioprostheses (3.1%). Furthermore, in the same meta-analysis, the authors report shorter aortic crossclamp time (40 minutes vs 66 minutes) and better hemodynamic parameter performance (mean aortic gradient, 10 mm Hg vs 13 mm Hg) in the Perceval-S group.

Surgical Times

The shortening of aortic crossclamp and cardiopulmonary bypass times, which have been shown to be strong independent predictors of postoperative morbidity and

TABLE 3. Intraoperative variables in the matched population

Variable	Matched population Perceval-S* (n = 117)	Intuity† (n = 117)	*P* value
Surgical approach			.2426
Full sternotomy	85 (72.6)	93 (79.5)	
Ministernotomy	32 (27.4)	23 (19.7)	
Minithoracotomy	0 (0)	1 (0.9)	
Cardiopulmonary bypass time (min)	90 ± 32	112 ± 48	<.0001
Isolated AVR	75 ± 18	89 ± 37	.0061
Combined procedures	105 ± 36	132 ± 49	.0012
Full sternotomy, isolated	71 ± 15	75 ± 56	.3277
Ministernotomy, isolated	82 ± 22	106 ± 40	.0035
Minithoracotomy, isolated	–	175‡	–
Aortic crossclamp time (min)	60 ± 21	83 ± 37	
Isolated AVR	52 ± 14	62 ± 24	<.0001
Combined procedures	69 ± 23	101 ± 36	.0074
Full sternotomy, isolated	47 ± 11	52 ± 16	<.0001
Ministernotomy, isolated	59 ± 16	74 ± 23	.1311
Minithoracotomy, isolated	–	–	.0172
Other surgical procedure			.0272
CABG	43 (36.8)	48 (41.0)	
Ascending aortic replacement	1 (0.9)	7 (6.0)	
Mitral procedure	2 (1.7)	5 (4.3)	
Other	11 (9.4)	3 (2.6)	
Intraoperative death	0 (0)	0 (0)	1.0000
Moderate-severe PVL	1 (0.9)	0 (0)	1.0000
Conversion to full sternotomy§	0 (0)	1 (0.9)	1.0000
VARC-2 device success	116 (99.1)	117 (100)	1.0000

Values are presented as mean ± standard deviation or absolute number (%). *AVR*, Aortic valve replacement; *CABG*, coronary artery bypass grafting; *PVL*, paravalvular leak; *VARC-2*, Valve Academic Research Consortium-2. *Livanova, London, United Kingdom. †Edwards Lifesciences, Irvine, Calif. ‡Only 1 case. §Cases started as minimally invasive procedures.

TABLE 4. Postoperative clinical and echocardiographic outcomes in the matched population

Variable	Matched population Perceval-S* (n = 117)	Intuity† (n = 117)	*P* value
VARC-2 AMI	0 (0)	0 (0)	1.0000
VARC-2 stroke			1.0000
Not disabling	0 (0)	0 (0)	
Disabling	3 (2.6)	3 (2.6)	
VARC-2 AKI			.5315
Grade 1	24 (20.5)	23 (19.7)	
Grade 2	1 (0.9)	4 (3.4)	
Grade 3	6 (5.1)	8 (6.8)	
CVVH	5 (4.3)	3 (2.6)	.7218
Pacemaker implantation	7 (6.0)	8 (6.8)	.7896
New-onset atrial fibrillation	46 (39.3)	45 (38.5)	.8933
VARC-2 all-cause mortality	2 (1.7)	4 (3.4)	.6834
Peak aortic gradient (mm Hg)	22.45 ± 8.11	19.56 ± 6.67	.0144
Mean aortic gradient (mm Hg)	11.84 ± 4.70	10.47 ± 3.87	.0388
Aortic regurgitation			.4962
Mild	11 (9.4)	16 (13.7)	
Moderate	1 (0.9)	2 (1.7)	
Severe	1 (0.9)	0 (0)	

Values are presented as mean ± standard deviation or absolute number (%). *VARC-2*, Valve Academic Research Consortium-2; *AMI*, acute myocardial infarction; *AKI*, acute kidney injury; *CVVH*, continuous veno-venous hemofiltration. *Livanova, London, United Kingdom. †Edwards Lifesciences, Irvine, Calif.

mortality,[15,16] are among the main theoretical advantages of Perceval-S and Intuity devices. In our analysis, the Perceval-S valve required shorter crossclamp time and cardiopulmonary bypass time than the Intuity valve. In isolated procedures, crossclamp time was 10 minutes shorter in the Perceval-S group (in the matched population). There are 2 possible explanation for this: faster implantation of the Perceval-S valve due to its collapsed design that maximizes visualization and facilitates positioning, and the greater case volume of the Perceval-S sites. In our study there were only 3 centers implanting the Perceval-S valve with an average of around 110 cases each, whereas there were 16 centers implanting the Intuity valve with an average volume of around 35 cases each. Aortic crossclamp time (Perceval-S: 52 minutes and Intuity: 62 minutes) and cardiopulmonary bypass time (Perceval-S: 75 minutes and Intuity: 89 minutes) found in our analysis are longer than those reported in other studies with the same devices,[6,17,18] probably reflecting the real-world nature of our data, as opposed to specifically designed protocols where the study device implantation is strictly monitored and there are just a few surgeons performing the operations. Nevertheless, this is consistent with a recently published report from the real-world German Aortic Valve Registry, where surgical times for Perceval-S and Intuity implantation were very similar to those found in our study.[19] However, these times are still shorter than those reported in the STS database (which contains real-world data as well)[20] for conventional surgical AVR (crossclamp time: 78 minutes and cardiopulmonary bypass time: 106 minutes), confirming the time-sparing property of these valves when compared with AVR with conventional bioprostheses. Although there are no specific studies on this subject, it is likely that the time-sparing property of these devices applies to surgeons who need 40 to 50 minutes to implant a standard aortic bioprosthesis, allowing for an even shorter crossclamp time. This advantage over conventional valves becomes important, especially in combined operations[21] where the time spent with the aortic valve may be significantly reduced and this is clearly

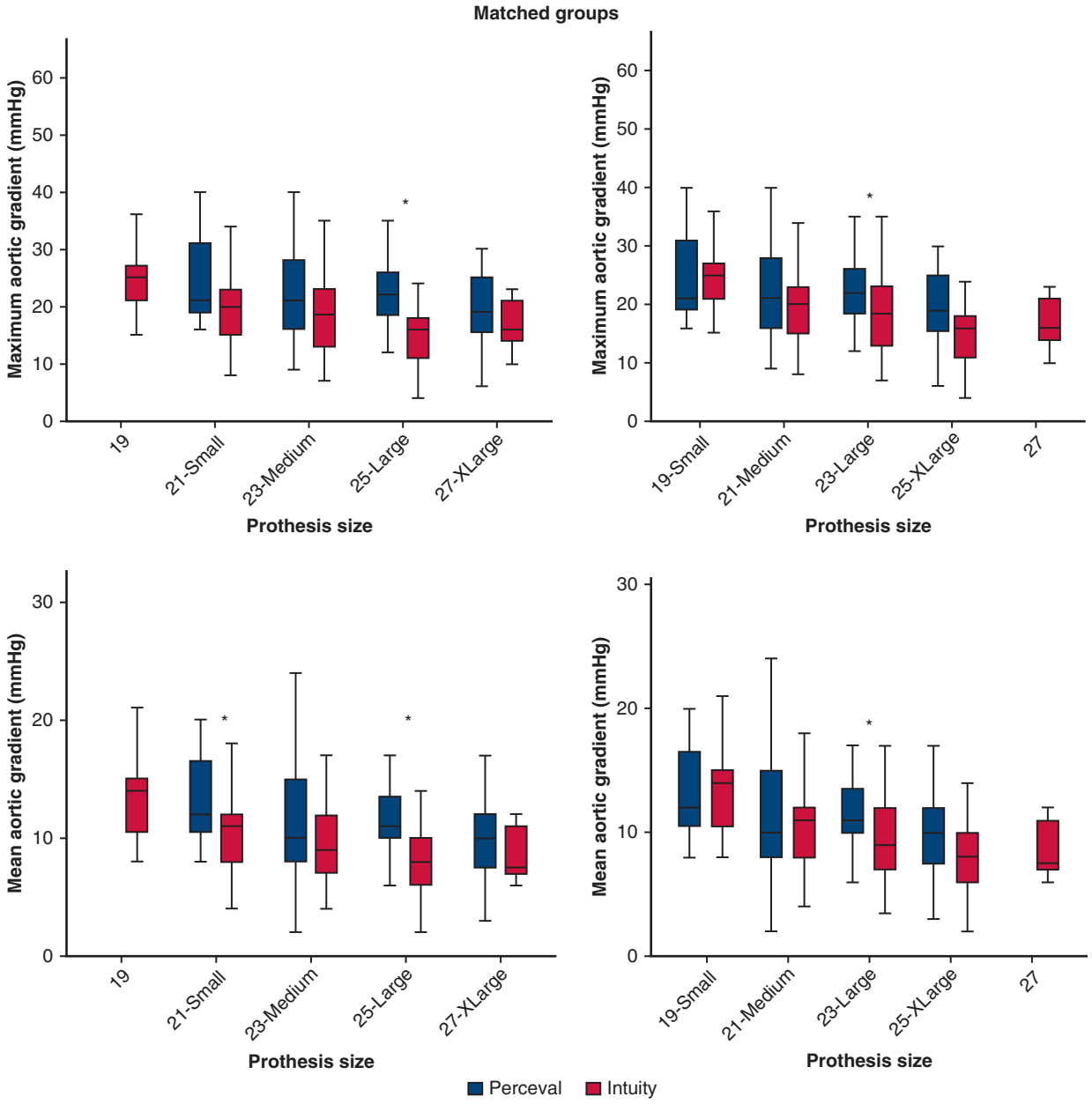

FIGURE 1. Box plot showing comparison of peak and mean transaortic gradients between the Perceval-S (Livanova, London, United Kingdom) and the Intuity (Edwards Lifesciences, Irvine, Calif) valves in the matched groups. All possible size couplings were performed: 19 mm versus small, 21 mm versus medium, 23 mm versus large, 25 mm versus extra-large; and 21 mm versus small, 23 mm versus medium, 25 mm versus large, and 27 mm versus extra-large. *$P < .005$.

confirmed by our population in which nearly 40% of patients underwent associated procedures.

Hemodynamic Parameter Data

Our data show significantly lower overall peak and mean gradients in the Intuity group and, as shown in Figure 1, this is confirmed in the size-by-size comparison. However, although this hemodynamic advantage of the Intuity valve is statistically significant, absolute numbers show a difference of just a few millimeters mercury between the 2 devices (peak gradient: 22 mm Hg vs 19 mm Hg, mean gradient: 11 mm Hg vs 10 mm Hg). Therefore, the real clinical influence of this difference will need further investigation through longer follow-up observations. Nevertheless, a recently published report with data from the INTU-ITA alone shows that peak and mean gradients remain stable up to 4 years after implantation.[22]

VIDEO 1. Description of the study with background, methods, and results followed by comment about the main findings. Video available at: https://www.jtcvs.org/article/S0022-5223(19)30977-8/fulltext.

Despite their similar clinical and hemodynamic behavior that makes both valves suitable for a majority of procedures, there are a few situations that might lead the choice toward 1 specific device. In particular, during minimally invasive AVR through right anterior thoracotomy the Perceval-S valve can be a better option because it is collapsed on its holder and visualization of the aortic annulus during positioning and deployment is maximized; on the other hand, Perceval-S implantation requires a higher transverse aortotomy that reduces space for proximal anastomoses and making ascending aorta replacement a little more demanding compared with Intuity valve implantation, which requires an aortotomy identical to that used for conventional AVR.

Limitations

The limitations of this study are mainly related to its retrospective and multicenter nature. There is heterogeneity in the number of cases performed in each center and also in dates of operation. There was only 1 center that implanted both Intuity and Perceval-S devices, all other centers implanted only 1 of the 2 study devices. There was no adverse event adjudication committee nor echocardiography core lab; therefore, adverse events were self-adjudicated by each center. However, for all serious adverse events reported in the database, centers were asked for confirmation. The hemodynamic parameter comparison of valve sizes between the devices may be debatable because the most appropriate analysis should be done using annular size (measured intraoperatively or with preoperative echocardiogram or with preoperative computed tomography scan), which was not available in this study.

CONCLUSIONS

According to our data, the sutureless Perceval-S and the rapid-deployment Intuity bioprostheses provide good and similar early clinical and hemodynamic outcomes. Perceval-S implantation requires shorter crossclamp and cardiopulmonary bypass times, whereas the Intuity valve provides lower transaortic peak and mean gradients (Video 1).

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://aats.blob.core.windows.net/media/18Apr30/20ABC%202.Adult%20Cardiac%20SS/S62_2.mp4.

Conflict of Interest Statement

Dr D'Onofrio has been a physician proctor for Edwards Lifesciences and for Symetis during the past 5 years but is not an active proctor. Drs Troise and Mignosa have financial relationships with Livanova. All other authors have nothing to disclose with regard to commercial support.

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Key Words: aortic valve, replacement, sutureless aortic bioprosthesis, rapid deployment aortic bioprosthesis

Discussion

Dr Vinod H. Thourani (*Washington, DC*). I would like to thank the Association for the privilege of discussing this very interesting and timely presentation as both the Intuity (Edwards Lifesciences, Irvine, Calif) and the Perceval (Livanova, London, United Kingdom) valves, which are now available in the United States. I really want to thank Dr D'Onofrio and his colleagues for this presentation. I would also like to thank you for sending me the manuscript in advance.

Overall, they saw a 30-day mortality of 1.7% in the Perceval valve and 3.4% in the Intuity valve; the pacemaker was roughly 6% in both groups. I really want to dive into some questions for you about your study.

I am very surprised, quite honestly, that you had an isolated crossclamp time of 52 minutes in the Perceval group and 62 minutes in the Intuity group, and this is for isolated aortic valve replacements, where commonly in busy aortic surgeons it is in the 40s and 50s for a stented valve. So does that mean that with this valve for those surgeons who think that they are going to have a crossclamp time in the 60s and 70s you get them down to 50 and 60 minutes? That will make it hard to convince a surgeon who has an average crossclamp time of 45 to 50 minutes to use these valves.

Dr Augusto D'Onofrio *(Padova, Italy)*. Thank you for the question, Dr Thourani. There are many possible explanations for this. One possible explanation is that Italian surgeons are not as good as US surgeons…

Dr Thourani. No, I don't think so.

Dr D'Onofrio. And I don't think so either. There is variability among different surgeons. I think that the time difference between the conventional bioprosthesis and the sutureless bioprosthesis is the same. In other words, if it takes 30 minutes for you to implant a stented conventional bioprosthesis, maybe it's going to take 20 minutes to implant a sutureless valve. So it doesn't matter how fast you are, there is always a savings of time because conventional valves take longer than sutureless valves. Furthermore, data from the Society of Thoracic Surgeons Registry show that the average crossclamp time for isolated aortic valve replacement is around 78 minutes and not 30 or 35 minutes. So if you look at these data from the real world you will be convinced that these valves could significantly help in reducing surgical times.

Dr Thourani. I think that's also important, because in the Perceval valve you had 3 sites versus the Intuity valve there were 16 sites. So I wonder if you looked at the site variability, whether that made a difference within the study results at all regarding the crossclamp times.

Dr D'Onofrio. You mean the size of the valve?

Dr Thourani. No. I am saying that the Perceval valve was done in only 3 sites and the Intuity was done in 16 sites. So clearly there is some variability. Among 16 sites there is going to be huge variability versus in 3 sites where there will be somewhat of a conformity.

Dr D'Onofrio. We looked at this because it was surprising for us. Actually, we found variability of surgical times between centers in the Intuity group, whereas we couldn't find a big time variability between the 3 centers in the Perceval group. The case volume is higher in the 3 Perceval centers with an average of around 100 cases for each group, whereas there is a wide range of patient numbers in the centers of the Intuity group. So this potentially had an influence.

But if we look at those centers that have the biggest experience with the Intuity valve, we still observe a longer crossclamp time with the Intuity valve compared with the Perceval

valve. And if you look at results coming from the German Aortic Valve Registry, we still observe this trend. The Intuity valve seems to need slightly longer cardiopulmonary bypass and crossclamp times compared with the Perceval valve.

Dr Thourani. That's great. A criticism for transcatheter aortic valve replacement has been that 20% to 25% of patients have some level of paravalvular leak at 1 year. Now, your echos are all based at discharge, not at 1 year, and here you show about a 10% to 14% rate of aortic regurgitation. First of all, is this paravalvular leak or is it central, and is that bothersome to you that you will have this rate and will it get worse over time? The first part of that question is, is that paravalvular leak or is that central?

Dr D'Onofrio. Well, this is mainly paravalvular leak even if it's a little bit difficult to understand, because we don't have an echo core lab, like in the most important transcatheter aortic valve replacement trials, and sometimes the echo reports that we have don't clearly specify if it's a paravalvular leak or if it's a central leak, so I cannot be 100% sure about that. But in our center we have looked at these patients over time and the trend is, like in transcatheter aortic valve replacement, to observe a reduced incidence of paravalvular leak over time. In our center, at 1 year we have around 7% to 8% of patients with mild paravalvular leak.

Dr Thourani. That's very important, because as we get into low-risk patients I think that we need to have <5% even mild paravalvular leak rate; that's what we can control.

Dr D'Onofrio. I agree, especially If we want to compete with transcatheter aortic valve replacement.

Dr Thourani. If you want to compete with something, and for us to have a 10% to 15% paravalvular leak rate I don't think is where our bar should be. Our bar should be much lower than that.

Dr D'Onofrio. Just another word about that.

Dr Thourani. Yes, of course.

Dr D'Onofrio. We have to consider that this series includes roll-in patients. There is a learning curve for this prosthesis especially in terms of sizing. In fact sizing is crucial in sutureless valve implantation. It's not like a conventional bioprosthesis where you can choose between 2 sizes and it doesn't make a big difference. With sutureless devices it's really crucial to size the valve properly to reduce leak after surgery.

Dr Thourani. Absolutely.

Dr D'Onofrio. For this reason the learning curve has a big influence.

Dr Thourani. And you really have true sizing instead of oversizing, which is what we do with the regular stented valves.

In the figures that you showed for your echocardiography, there was quite a variation in the gradients. I saw some that had standard deviations very high, into the 25- to 30-mm range, and this is at discharge, and we are talking mean gradients. So I'm not sure we really help those patients if they go home with a mean gradient of 20 to 25 mm. Can you explain why there is such variability? And those are not even in the smallest Perceval and Intuity valves, they were in the medium Perceval and Intuity valves, and that to me needs a little bit of explanation of why they are even above 15 or 20 mm.

Dr D'Onofrio. The discharge echo can be influenced by many variables. Among these is, for example, anemia and the hyperkinetic state that might increase gradients, and this is true also for conventional valves; sometimes gradients at discharge are higher than what we expect. But then we control these patients—after 3 or 6 months—often gradients go back to the normal range. So I don't think that this is going to be a real problem.

Our experience and my personal feeling is that these valves provide lower gradients if compared with conventional valves, especially in the Intuity valve that has a balloon-expandable skirt that dilates the left ventricular outflow tract. I believe that this is among the reasons for potential reduction of gradients with these valves.

Dr Thourani. I agree with you 100% and that's a reason to put this valve in, especially in small, obese women. So these need to be followed longer term to really provide participants who are going to put this in with good data that this actually is a beneficial thing.

I would like to ask you just in your personal practice what percentage are now a rapid-deployment or Perceval type of valve, what percentage are stented valves and what percentage are transcatheter aortic valve replacements?

Dr D'Onofrio. That's a good question. I would say that 50% receive a conventional valve, mainly bioprosthesis. We are a center with a high volume of bioprostheses. Then the other 50%, probably it's like 30% transcatheter aortic valve replacements and 20% sutureless and rapid-deployment valves.

I think that probably it doesn't make a lot of sense to implant a sutureless bioprosthesis in the setting of a full sternotomy and isolated aortic valve replacement. I think that these devices are more indicated in minimally invasive procedures and in combined operations, especially if we want to compete with transcatheter aortic valve replacement. Unfortunately we gave transcatheter aortic valve replacement to cardiologists and this of course is not good for us, so now we have to compete with transcatheter aortic valve replacements. So we have to offer our patients the latest technology combined with the least invasive possible, and these devices can be a good option.

Dr Thourani. Augusto, congratulations, eloquent paper, and the same with the preparation.

Dr D'Onofrio. Thank you.

Dr Joseph DeRose (*Bronx, NY*). That was an excellent presentation. I think there is 1 part about these rapid-deployment valves that we are not focusing on. Vinod alluded to it before, but time is so variable based on what kind of surgeon is doing the operation. However, I have found that this kind of facilitating technology is a really, really good tool for helping young surgeons and fellows learn how to do an aortic valve replacement, which is becoming harder and harder to teach because there is less and less open aortic valve surgery, and this becomes even more important when you are trying to teach people to do minimally invasive aortic valve surgery.

So my question is, in your series of all of these sites, how many sites included training programs where patients were enrolled? In other words, were patients enrolled in hospitals with fellowship training programs and were fellows involved in the operations?

Dr D'Onofrio. Thank you for your question. You are absolutely right. I would say that in this series around 50% of the centers are academic institutions, and so they routinely train surgeons for aortic valve replacement. You are right, but we still have to remember that these prostheses are not for everybody, and there are some particular anatomic conditions that do not allow a safe implantation of a sutureless bioprosthesis. So I strongly encourage everybody to keep on teaching conventional surgery to our residents together with new technologies.

TABLE E1. Intraoperative variables in the unmatched population

Variable	Total (n = 911)	Unmatched population Perceval-S* (n = 349)	Unmatched population Intuity† (n = 562)
Surgical approach			
Full sternotomy	624 (68.5)	257 (73.6)	367 (65.3)
Ministernotomy	265 (29.1)	91 (26.1)	174 (31.0)
Minithoracotomy	22 (2.4)	1 (0.3)	21 (3.7)
Cardiopulmonary bypass time (min)	94 ± 42	76 ± 35	105 ± 43
Isolated AVR	83 ± 37	61 ± 27	94 ± 36
Combined procedures	110 ± 45	91 ± 36	128 ± 45
Full sternotomy, isolated	76 ± 34	57 ± 27	87 ± 33
Ministernotomy, isolated	88 ± 36	66 ± 27	98 ± 36
Minithoracotomy, isolated	131 ± 46	79‡	133 ± 45
Aortic crossclamp time (min)	66 ± 31	52 ± 23	75 ± 32
Isolated AVR	59 ± 27	42 ± 18	67 ± 27
Combined procedures	78 ± 33	63 ± 23	93 ± 35
Full sternotomy, isolated	53 ± 25	38 ± 15	62 ± 25
Ministernotomy, isolated	62 ± 26	46 ± 19	68 ± 25
Minithoracotomy, isolated	88 ± 32	31‡	98 ± 39
Other surgical procedure			
CABG	267 (29.3)	136 (39.0)	131 (23.3)
Ascending aortic replacement	17 (1.9)	3 (0.9)	14 (2.5)
Mitral procedure	25 (2.7)	11 (3.2)	14 (2.5)
Other	53 (5.8)	25 (7.2)	28 (5.0)
Intraoperative death	0 (0)	0 (0)	0 (0)
Moderate-severe PVL	20 (2.2)	3 (0.9)	14 (2.5)
Conversion to full sternotomy§	5 (1.7)	0 (0)	5 (2.6)
VARC-2 device success	891 (97.8)	346 (99.1)	548 (97.5)

Values are presented as mean ± standard deviation or absolute number (%). *AVR*, Aortic valve replacement; *CABG*, coronary artery bypass grafting; *PVL*, paravalvular leak; *VARC-2*, Valve Academic Research Consortium-2. *Livanova, London, United Kingdom. †Edwards Lifesciences, Irvine, Calif. ‡Only 1 case. §Cases started as minimally invasive procedures.

TABLE E2. Postoperative clinical and echocardiographic outcomes in the unmatched population

Variable	Total (n = 911)	Whole population Perceval-S* (n = 349)	Whole population Intuity† (n = 562)
VARC-2 AMI	8 (0.9)	1 (0.3)	7 (1.2)
VARC-2 stroke			
Not disabling	24 (2.6)	5 (1.4)	19 (3.4)
Disabling	8 (0.9)	3 (0.9)	5 (0.9)
VARC-2 AKI			
Grade 1	170 (18.7)	53 (15.2)	117 (20.8)
Grade 2	23 (2.5)	5 (1.4)	18 (3.2)
Grade 3	44 (4.8)	10 (2.9)	34 (6.0)
CVVH	25 (2.7)	8 (2.3)	17 (3.0)
Pacemaker implantation	51 (5.6)	16 (4.6)	35 (6.2)
New-onset atrial fibrillation	267 (29.3)	103 (29.5)	164 (29.2)
VARC-2 all-cause mortality	20 (2.2)	5 (1.4)	15 (2.7)
Peak aortic gradient (mm Hg)	21.08 ± 8.41	24.05 ± 9.14	19.44 ± 7.49
Mean aortic gradient (mm Hg)	11.42 ± 4.71	12.67 ± 5.21	10.74 ± 4.27
Aortic regurgitation			
Mild	92 (10.1)	24 (6.9)	68 (12.1)
Moderate	9 (1.0)	1 (0.3)	8 (1.4)
Severe	1 (0.1)	1 (0.3)	0 (0)

Values are presented as mean ± standard deviation or absolute number (%). *VARC-2*, Valve Academic Research Consortium-2; *AMI*, acute myocardial infarction; *AKI*, acute kidney injury; *CVVH*, continuous veno-venous hemofiltration. *Livanova, London, United Kingdom. †Edwards Lifesciences, Irvine, Calif.