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Avoiding oversizing in sutureless valves leads to lower transvalvular gradients and less permanent pacemaker implants postoperatively

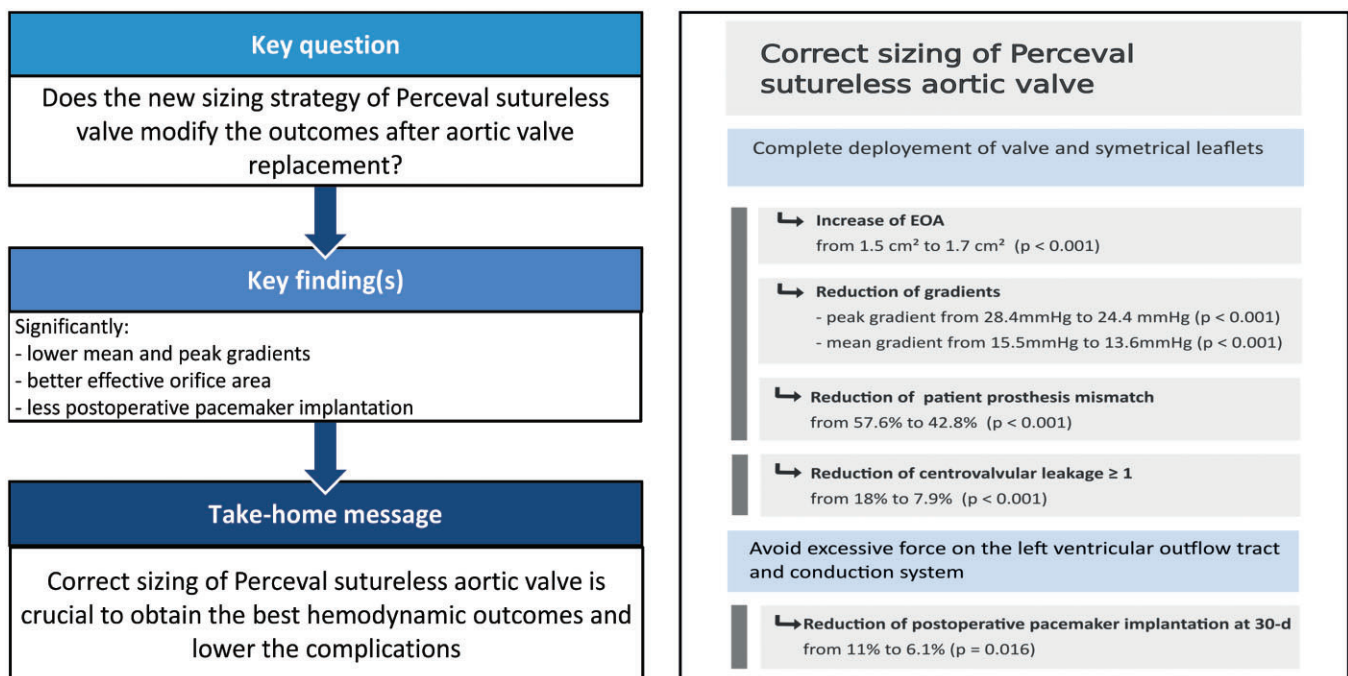
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Abstract

OBJECTIVES: The aim of this study was to evaluate the impact of changing the sizing strategy in aortic valve replacement using the Perceval sutureless prosthesis on haemodynamic outcomes and postoperative pacemaker implantation.

METHODS: Retrospective analysis of patients implanted with the Perceval valve between 2007 and 2019 was performed by comparing patients implanted before the modification of sizing strategy (OLD group) and after (NEW group). The outcome parameters evaluated were the implanted prosthesis size, haemodynamical profile and postoperative pacemaker implantation.

RESULTS: The entire patient cohort (784 patients) consisted of 52% female patients, with a mean age of 78.53 [standard deviation (SD): 5.8] years and a mean EuroSCORE II of 6.3 (range 0.7–76). In 55.5% of cases, surgery was combined. The NEW cohort had more male

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patients (54.6% vs 43.4%) ($P = 0.002$). Mean implanted valve size, corrected for body surface area, was significantly lower in the NEW cohort (13.1, SD: 1.4 vs 13.5, SD: 1.4 mm/m², $P < 0.001$). The 30-day mortality was 3.4%. Peak and mean transvalvular gradients at discharge were significantly lower in the NEW versus OLD groups: 24.4 mmHg (SD: 9.2) versus 28.4 mmHg (SD: 10.3) ($P < 0.001$) and 13.6 mmHg (SD: 5.3) versus 15.5 mmHg (SD: 6.0) ($P < 0.001$). The mean effective opening area and the indexed effective opening area, respectively, increased from 1.5 cm² (SD: 0.5) and 0.85 cm²/m² (SD: 0.27) in the OLD group to 1.7 cm² (SD: 0.5) and 0.93 cm²/m² (SD: 0.30) in the NEW group ($P < 0.001$). No difference was found in paravalvular leakage $\geq 1/4$. Centrovalvular leakage $\geq 1/4$ significantly decreased from 18% to 7.9% ($P < 0.001$). With the new sizing, the new postoperative pacemaker implantation rate decreased significantly from 11% to 6.1% ($P = 0.016$).

CONCLUSIONS: Correct sizing of sutureless aortic valves is crucial to obtain the best possible haemodynamics and avoid complications.

Keywords: Surgical aortic valve replacement • Sutureless • Pacemaker • Aortic transvalvular gradient

ABBREVIATIONS

AVR	Aortic valve replacement
BSA	Body surface area
EOA	Effective orifice area
EOAi	Indexed effective orifice area
LBBB	Left bundle branch block
PPI	Postoperative pacemaker implantation
PPM	Patient-prosthesis mismatch
SD	Standard deviation
TAVR	Transcatheter aortic valve replacement

INTRODUCTION

A decade ago, aortic sutureless valves like Perceval (Corcym, Milan, Italy) were introduced into clinical practice. They enabled surgeons to perform aortic valve replacement (AVR) faster, they facilitated minimally invasive surgery and even challenged the results obtained with transcatheter aortic valve replacement (TAVR) [1, 2].

Well-documented advantages include the ease of use and the reduced bypass and cross-clamp times while safety has been demonstrated [2]. Despite the increasing place of TAVR in aortic valve stenosis, these advantages can be specifically beneficial in older patients, in minimal access surgery or during combined procedures.

Some authors however have reported on high postoperative pacemaker rates, elevated gradients and occasional incidents of stent infolding of these prostheses [3–5].

Oversizing has been described as a potential mechanism to explain those reports [3, 6]. It has also been illustrated by computed tomography imaging *ex vivo* as well as *in vivo* [6].

Vogt *et al.* have already suggested several technique adaptations to reduce the postoperative pacemaker implantation (PPI) rate in aortic sutureless valve [7]. In addition, preoperative predictors for PPI, like right bundle branch block, have been studied but are not yet completely identified [8, 9].

In October 2017, based on a root-cause analysis pointing towards oversizing as the main reason for complications, the manufacturer issued new recommendations towards proper sizing of the sutureless valve during surgery [6].

We hypothesized that this change in sizing strategy could impact positively postoperative pacemaker implantation rate as well as improve the haemodynamics of the prosthesis. To verify our hypothesis, we retrospectively compared patients implanted before and after the implementation of the new sizing strategy.

MATERIALS AND METHODS

Ethics statement

Permission to perform this analysis was granted by the ethics committee UZ/KU Leuven on 7 December 2020, with approval number s64845. Informed consent was not required given the retrospective nature of this study.

Patients

This work is a retrospective analysis of all patients implanted with a Perceval sutureless aortic valve in our institution (University Hospitals Leuven) since the first-in-man implantation in 2007 until 31 December 2019. In October 2017, following new instructions for use by the manufacturer, a new sizing strategy (cf. *infra*) for the prosthesis was used. The study population was divided into 2 groups depending on the sizing strategy, which was used: the cohort of patients before October 2017 ($N = 438$, OLD) and the cohort of patients after that ($N = 346$, NEW). Patients who were intended to receive a Perceval prosthesis but were implanted with another prosthesis were excluded from further analysis. During the initial period of 2007–2010, 3 subsets of patients (51 patients) were already included in prospective clinical trials with their own inclusion policy [10, 11]. None of those studies implied a change in the implantation technique.

Technique

The initial technique has been previously described [12]. The access was either a full sternotomy or minimally invasive (J-shaped sternotomy or left anterior thoracotomy) according to the procedure and the surgeon's preference.

There are 4 different sizes of Perceval S prosthesis: small, medium, large and extra-large. There is 1 sizer for each of these sizes. Each sizer carries 2 obturators: 1 white and 1 transparent.

Initially, after resection of the leaflets and decalcification, the size was chosen as the transparent obturator could pass through the annulus and the white one not. If the white side fitted into the annulus, a larger size was chosen (OLD). The new instruction for use advises that the white obturator also has to pass through the annulus with a light friction (NEW). So in case the white side fitted into the annulus, the size corresponding to that sizer was chosen, a clearly different strategy as in the OLD regime. There were no other operative technique changes especially concerning decalcification or guiding sutures.

Primary outcomes were the haemodynamic performances at discharge and the need for permanent pacemaker implantation

at 30 days postoperatively. Discharge echocardiograms were available in 768 patients. Mean and peak gradients were collected as well as paravalvular and central leakage. Implanted valve size was corrected for patients' body surface area (BSA). The effective orifice area (EOA) was also indexed for BSA [indexed EOA (EOAi)], based on the measured EOA at discharge. Patient-prosthesis mismatch (PPM) was calculated on basis of EOA at discharge indexed by BSA and defined as $<0.85 \text{ cm}^2/\text{m}^2$. EOA was available only for a subgroup of the 660 patients. Missing data were excluded from the analysis. The follow-up was closed on 31 May 2021.

Statistics

Continuous data are presented as means with standard deviations (SDs). Categorical data are expressed as proportions. Variables were tested for normality. A Student's *t*-test or Wilcoxon–Mann–Whitney test was used to compare continuous variables, and chi-square and Fisher exact tests were used to analyse categorical data. A *P*-value of <0.05 was considered statistically significant. Multivariable analysis was performed to adjust the effect of the new implantation technique on outcomes using binary logistic regression. Statistica (version 13.4, StatSoft Inc. Hamburg, Germany) was used for statistical analysis.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author, Bart Meuris.

RESULTS

Population

During the study period, 787 patients were intended to receive a Perceval prosthesis. Implantation was successful in 99.1% of the patients. A failure of implantation in 3 patients resulted in the implantation of another aortic valve prosthesis. Of the 784 patients implanted with the Perceval prosthesis, 438 patients were implanted before the change in sizing strategy (OLD group) and 346 patients were implanted after (NEW group). The main characteristics of the 2 groups of patients are listed in Table 1. There were significantly more men in the NEW group (54.6%) than in the OLD group (43.4%) ($P=0.002$). That difference results in a significantly higher BSA (1.82 ± 0.19 in the OLD group vs 1.87 ± 0.20 in the NEW group, $P=0.004$). Significantly more patients had a left bundle branch block (LBBB) in the NEW group (12.4% vs 7.8%, 0.029). The rate of recent myocardial infarction was lower in the NEW group (5.2% vs 10%, 0.013). There was no significant difference in the rate of isolated AVR (45.8% in the OLD group vs 43.1% in the NEW group, $P=0.443$) and combined procedures (54.2% in the OLD group vs 56.9% in the NEW group, $P=0.443$). Especially, no difference was found regarding associated atrial fibrillation ablation and myomectomy procedures.

The main operative and early postoperative outcomes are described in Table 2. No difference was found when comparing cardiopulmonary time, cross-clamp time, 30-day mortality or listed complications. The 30-day follow-up was complete for 100% of the patients. The 30-day mortality was 3.2% for the entire group and did not differ between the 2 cohorts.

Table 1: Main characteristics of patients and procedures

	OLD (n = 438)	NEW (n = 346)	P-Value
Female, n (%)	248 (56.6)	157 (45.4)	0.002
Age (years)	78.79 (SD: 5.11)	78.20 (SD: 6.57)	0.595
EuroSCORE II	6.40% (SD: 6.6)	6.19% (SD: 6.96)	0.674
BMI (kg/m ²)	27.37 (SD: 4.83)	27.83 (SD: 4.52)	0.171
BSA (m ²)	1.82 (SD: 0.19)	1.87 (SD: 0.20)	0.004
Obese (BMI > 30), n (%)	112 (25.6)	98 (28.3)	0.387
Previous cardiac surgery, n (%)	20 (4.6)	13 (3.8)	0.575
Endocarditis, n (%)	5 (1.1)	7 (2.0)	0.318
IDDM, n (%)	13 (3.0)	17 (4.9)	0.159
Recent myocardial infarct, n (%)	44 (10)	18 (5.2)	0.013
Pacemaker, n (%)	17 (3.9)	22 (6.4)	0.113
Preoperative ECG disturbance, n (%)			
Atrial fibrillation or flutter	60 (13.7)	36 (10.4)	0.162
RBBB	31 (7.1)	28 (8.1)	0.593
LBBB	34 (7.8)	43 (12.4)	0.029
AV block	50 (11.4)	48 (13.9)	0.302
Procedure, n (%)			
Isolated AVR	200 (45.7)	149 (43.1)	0.467
Combined procedure	238 (54.3)	197 (56.9)	0.467
Including CABG	172 (39.3)	127 (36.7)	0.463
Including multiple valves	76 (17.4)	67 (19.4)	0.469
Including AF ablation	25 (5.7)	28 (8.1)	0.187
Myomectomy, n (%)	4 (0.9)	2 (0.6)	0.593
Median sternotomy, n (%)	311 (71)	230 (66.5)	0.173
Minimally invasive approach, n (%)	127 (29)	116 (33.5)	0.173

AF: Atrial fibrillation; AV: atrioventricular; AVR: aortic valve replacement; BMI: body mass index; BSA: body surface area; CABG: coronary artery bypass grafting; ECG: electrocardiogram; IDDM: insulin-dependent diabetes mellitus; LBBB: left bundle branch block; RBBB: right bundle branch block; SD: standard deviation.

Table 2: Early operative outcomes

	OLD (n = 438)	NEW (n = 346)	P-Value
Conversion to sternotomy, n (%)	0	1 (0.3)	0.260
CPB time (min)	94.94 (SD:42.43)	90.84 (SD: 47.04)	0.213
Cross-clamp time (min)	61.73 (SD: 31.66)	60.63 (SD: 35.50)	0.650
30-Day mortality, n (%)	17 (3.9)	10 (2.9)	0.450
In-hospital mortality, n (%)	16 (3.7)	10 (2.9)	0.554
Bleeding requiring reintervention, n (%)	13 (3.0)	7 (2)	0.405
Tamponnade, n (%)	2 (0.5)	6 (1.7)	0.148
Stroke, n (%)	8 (1.8)	6 (1.7)	0.923
Postoperative dialysis, n (%)	6 (1.4)	2 (0.6)	0.477

CPB: cardiopulmonary bypass; SD: standard deviation.

Table 3: Distribution of implanted size of Perceval s^o

	OLD (n = 438)	NEW (n = 346)	P-Value
Small (21 mm), %, n (%)	26 (5.9)	37 (10.7)	0.015
Medium (23 mm), %, n (%)	154 (35.2)	113 (32.7)	0.463
Large (25 mm), %, n (%)	161 (36.8)	130 (37.6)	0.815
Extra-large (27 mm), %, n (%)	97 (22.1)	66 (19.2)	0.293
Mean implanted valve size corrected for BSA (mm/m ²)	13.5 (SD: 1.4)	13.1 (SD: 1.4)	<0.001

BSA: body surface area; SD: standard deviation.

Regarding the implanted size of the aortic valve prosthesis, there were significantly more size small prostheses used in the NEW group when compared with the OLD group (Table 3). The implanted prosthesis size indexed for the BSA was also significantly lower in the NEW group [13.1 mm/m² (SD: 1.4)] when compared with the OLD group [13.5 mm/m² (SD: 1.4)] ($P < 0.001$).

In 784 patients, a total of 768 discharge ultrasounds were performed resulting in 660 EOA measurements. Based on these records, peak and mean transvalvular gradients at discharge were significantly lower in the NEW group versus the OLD group: 24.4 ± 9.2 vs 28.4 ± 10.3 mmHg ($P < 0.001$) and 13.6 ± 5.3 vs 15.4 ± 6.0 mmHg ($P < 0.001$). The mean EOA increased from 1.5 ± 0.5 cm² in the OLD group to 1.7 ± 0.5 cm² in the NEW group ($P < 0.001$). Also, the EOAI increased from 0.85 ± 0.27 to 0.93 ± 0.29 cm² ($P < 0.001$). The prevalence of PPM at discharge significantly decreased from 57.5% to 42.6% ($P < 0.001$) (Table 4 and Fig. 1). Paravalvular leakage $\geq 1/4$ was seen in 1.7% of the patients, without any difference between the 2 cohorts. Centrovalvular leakage $\geq 1/4$ was significantly lower in the NEW group decreasing from 17.5% to 7.9% ($P < 0.001$) (Table 4). No valve migration or embolization was observed.

The number of postoperative definitive pacemaker implantation decreased after the modification of the strategy from 11% to 6.1% ($P < 0.001$). This diminution was significant when the whole group was considered as well as after the exclusion of patients who had already an implanted pacemaker at baseline. The timing between aortic valve surgery and pacemaker implantation was not significantly different (Table 4). We performed a multivariable analysis of pacemaker implantation. There was no significant difference in PPI in patients with prior myocardial infarction or preoperative LBBB. The sizing shift stays significant even after correction for gender, age and EuroSCORE.

DISCUSSION

The adjustments in the sizing strategy were done because oversizing can result in higher gradients due to incomplete leaflet opening and turbulent fluttering of the cusps [3]. Also, oversizing can cause higher pacemaker rates due to excessive force on the left ventricular outflow tract and the nearby conduction system [13].

In our results, the average implanted size indexed for BSA significantly decreased in the different cohorts. This confirms that the new implemented size strategy led to the implantation of smaller prostheses.

Importantly, no valve migration or embolization was observed during the studied period, which could have been theoretically caused by undersizing.

The haemodynamical profile and pacemaker implantation rate both changed over the study period. Based on the 768 ultrasounds performed, each haemodynamic parameter compared between OLD and NEW groups significantly improved. More specifically, the observed average mean and peak gradients were lower in the NEW group. This concurs with the previously described negative correlation between the indexed implanted valve size and the postoperative transvalvular gradients observed by Geršak *et al.* [13]. Furthermore, EOAI was significantly higher in the NEW cohort rising from 0.85 to 0.93 cm²/m². The PPM rate decreased to 42.8%. This equals the 43.8% rate described in a meta-analysis of SAVR including only series using the EOAI as a definition for PPM [14] but also equals the results from the TAVR group from the PARTNER 2 SAPIEN 3 Intermediate Risk registry where a 47% rate of PPM was found when using the same definition as ours [15].

Table 4: Hemodynamical outcomes and postoperative pacemaker implantation

	OLD (n = 438)	NEW (n = 346)	P-Value
Peak gradient (mmHg)	28.4 (SD: 10.3)	24.4 (SD: 9.2)	<0.001
Mean gradient (mmHg)	15.5 (SD: 6.0)	13.6 (SD: 5.3)	<0.001
Effective orifice area (cm ²)	1.5 (± 0.5)	1.7 (± 0.5)	<0.001
Indexed effective orifice area (cm ² /m ²)	0.85 (± 0.27)	0.93 (± 0.30)	<0.001
Patient–prosthesis mismatch, n (%)	212 (57.6)	125 (42.8)	<0.001
PVL ≥1, n (%)	7 (1.6)	5 (1.5)	0.855
CVL ≥1, n (%)	77 (18)	27 (7.9)	<0.001
PPI, n (%)	48 (11)	21 (6.1)	0.016
Time to PPI (days)	11.63 (SD: 4.69)	11.79 (SD: 6.3)	0.907

Time to PPI: time between surgery and PPI in days.

CVL: centrovalvular leakage; PPI: postoperative pacemaker implantation (during the first 30 postoperative days); PVL: paravalvular leakage; SD: standard deviation.

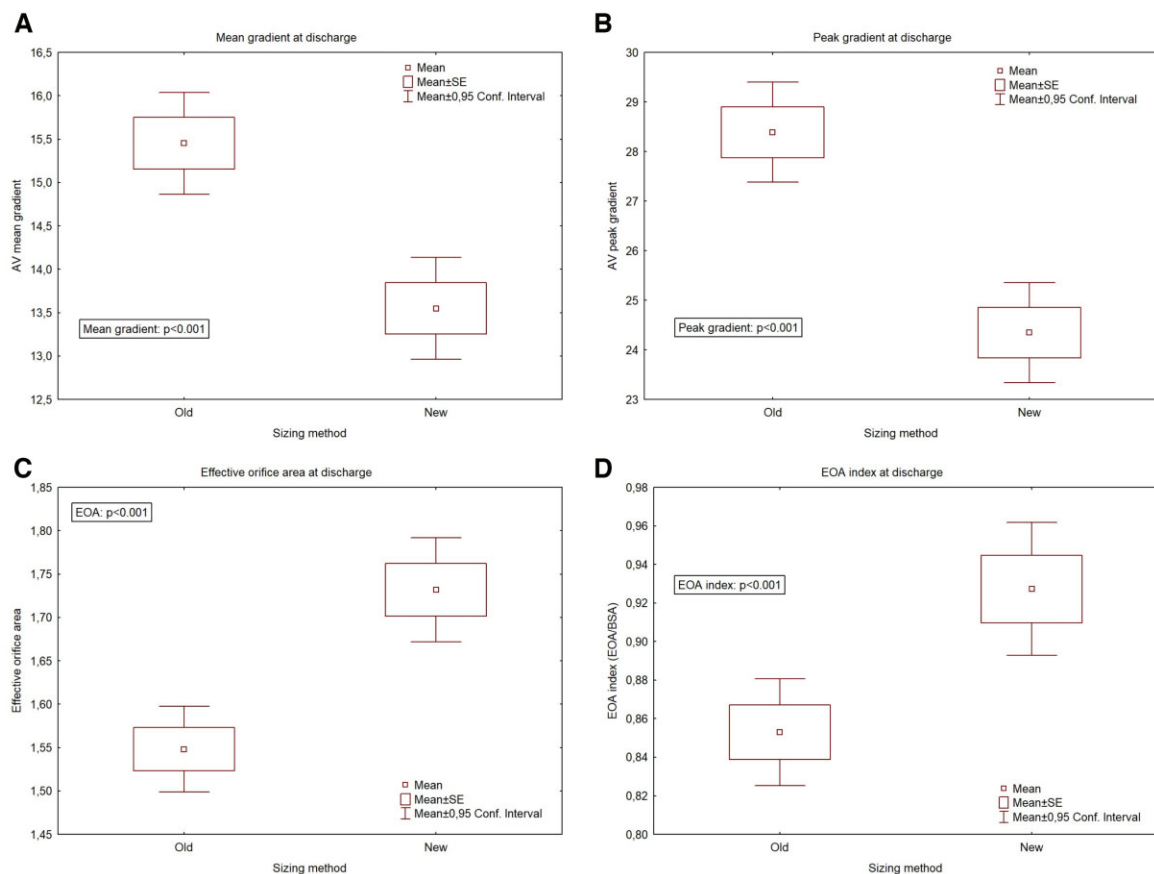


Figure 1: (A) Mean transvalvular gradient. (B) Peak transvalvular gradient. (C) Effective orifice area. (D) Indexed effective orifice area.

Interestingly, the number of patients with central valvular leakage of 1/4 or more significantly decreased. This is in accordance with the hypothesis that oversizing interferes with the geometry of the valve as expressed by Cerillo and Themudo [3, 6].

The 6.1% rate of PPI in the NEW group is significantly lower than what was observed before the change in sizing strategy. It is closer than what is expected in SAVR in this case mix of patients. The timing before pacemaker implantation was not

different between the 2 groups ruling out a different implantation strategy. There were significantly more patients in the OLD group who had a history of recent myocardial infarct but less who had a preoperative LBBB. Even if those characteristics are not specifically recognized as predictors for PPI after SAVR using a sutureless valve [9], they are in classical SAVR using sewed valves [16]. The decrease in PPI is in accordance with what Moscarelli *et al.* [17] observed in their meta-analysis

showing a reduction of PPI after 2016 and the publication of Geršak *et al.* [13] who finds that oversizing was a significant risk factor for PPI independently of the patient's age in a multivariable logistic regression model.

Reduction in postoperative pacemaker implantation, as well as PPM and postprocedural regurgitation, is recognized to improve the clinical course of the patients [17, 18, 19].

Limitations

Although these results show a benefit from the new sizing strategy implemented, the first limitation of our study is its retrospective non-matched design. Even if few patient characteristics were found to be statistically different, the main evolution, which was seen between the 2 cohorts, is the sex ratio evolving from a majority of females to a majority of males associated with a rise of the BSA. To minimize that bias, we confirmed our results using values indexed for BSA when possible.

Second, as our experience using sutureless valves significantly grew over the last decade, we cannot exclude that the improved results are partly due to a learning curve effect as described before in the SURD-ID registry. Nevertheless, the significant decrease that Di Eusano *et al.* [20] have shown occurs earlier in the experience with a higher rate during the learning curve than what we have seen. As the implantation of Perceval goes on, a propensity-matched analysis could overcome some of those limitations in the future.

Preoperative annulus measurements were not available for all patients and, therefore, we could not report the evolution of the relation between the implanted prosthesis size and the native aortic annulus.

CONCLUSIONS

Sutureless valves are changing the scope and potential of surgical AVR, by providing fast and elegant operations to a high variety of patients, both in isolated (minimally invasive) AVR and in combined surgery. Our data suggest that the new sizing technique, which avoids oversizing, results in better haemodynamics at discharge and lowers the rate of permanent pacemaker implantation while not increasing the risk of having more paravalvular leaks.

In conclusion, correct sizing of sutureless aortic valves is crucial to obtain the best possible haemodynamics and avoid complications.

Conflict of interest: Marie Lamberigts is a PhD student funded by a Corcym grant. Bart Meuris is consultant to Corcym.

Author contributions

Delphine Szeceł: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Validation; Visualization; Writing—original draft; Writing—review & editing. **Marie Lamberigts:** Data curation; Investigation. **Filip Rega:** Conceptualization; Data curation; Investigation; Supervision. **Peter Verbrugghe:** Conceptualization; Investigation; Supervision. **Christophe Dubois:** Conceptualization; Investigation; Supervision. **Bart Meuris:** Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Supervision; Validation; Visualization; Writing—original draft; Writing—review & editing.

Reviewer information

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