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Pacemaker after Sutureless and Rapid-Deployment Prostheses: A Progress Report from the SURD-IR

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Abstract

Objectives The aim of this study was to investigate the need for postoperative permanent pacemaker implantation (PPI) following sutureless and rapid-deployment aortic valve replacement (SuRD-AVR) in the context of a progress report from a large multicenter international registry (SURD-IR).

Methods We retrospectively analyzed 4,166 patients who underwent SuRD-AVR between 2008 and 2019. The primary outcome was the need for PPI before discharge. The study population was analyzed separately according to the implanted prostheses (Su cohort and RD cohort). Each cohort was divided into two groups based on the operation date: an early group ("EG" = 2008–2016) and a late group ("LG" = 2017–2019).

Results The rate of PPI decreased significantly in the Su cohort over time (EG = 10.8% vs LG = 6.3%, $p < 0.001$). In the Su cohort, a decrease in age, risk profile, and incidence

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of bicuspid aortic valve, increased use of anterior right thoracotomy, reduction of cardiopulmonary bypass time and of associated procedures, and more frequent use of smaller prostheses were observed over time. In the RD cohort, the rate of PPI was stable over time (EG = 8.8% vs LG = 9.3%, $p = 0.8$). In this cohort, a younger age, lower risk profile, and higher incidence of concomitant septal myectomy were observed over time.

Conclusion Our analysis showed a significant decrease in the PPI rate in patients who underwent Su-AVR over time. Patient selection as well as surgical improvements and a more accurate sizing could be correlated with this phenomenon. The RD cohort revealed no significant differences either in patient's characteristics or in PPI rate between the two time periods.

Introduction

Degenerative aortic valve stenosis is the most frequent valvular heart disease in western countries, and valve replacement is the gold standard for symptomatic severe cases.[1] In addition to the two established procedures (i.e., surgical aortic valve replacement [SAVR] and transcatheter aortic valve implantation [TAVI]), the last decade showed the rising of a third way, which is based on the concept of the surgical replacement, but taking some advantages of the TAVI prosthesis's design, such as the faster and simpler anchoring mechanism. This category includes the interventions performed with the sutureless (Perceval; LivaNova, Italy) and the rapid-deployment (Intuity; Edwards Lifesciences, California, United States) prostheses. Sutureless and rapid-deployment (SuRD)-AVR has been applied to high- and intermediate-risk populations with good clinical results.[2] However, concerns were raised because of the incidence of postprocedural permanent pacemaker implantation (PPI), which was higher than in conventional SAVR[3] and pretty similar to that observed following TAVI.[4] Possible factors associated with this complication have been assessed only in single-center studies with small sample populations. Moreover, recent analyses reported a reduction of this complication over time, suggesting the possible role of a time bias or learning curve effect.[2,5,6] For these reasons, we aimed to investigate the need for PPI following SuRD-AVR in a large cohort using a progress report approach.

Methods

We performed a retrospective cohort study of patients enrolled in the "Sutureless and Rapid Deployment International Registry" (SURD-IR), a multicentric international registry that includes patients undergoing SuRD-AVR, irrespective of the surgical access, in 19 large research centers. The rationale and methods of SURD-IR have been previously published.[7] Inclusion criteria were age older than 18 years and severe valve disease of the native aortic valve according to international guidelines referred for isolated or combined cardiac surgery. Exclusion criteria were prior pacemaker implantation, use of the off-market sutureless Enable 3F (Medtronic Inc., Minnesota, United States), lack of in-hospital data, and prior intervention on the aortic valve. For the present study, 4,166 patients who underwent SuRD-AVR between January 2008 and April 2019 were suitable for the analysis. Surgical techniques, the choice to perform a full-sternotomy or minimally invasive AVR, and the postoperative management were performed according to the specific standards at each center. Ethics approval was obtained at each of the participating centers.

Although they have been designed according to the same principle of reducing surgical times, the sutureless and rapid-deployment prostheses are deeply different in design, technology, and implantation techniques. Moreover, they have been introduced in different years (2008 for Perceval and 2010 for Intuity), and several centers included in the registry used only one type of prosthesis. Thus, to minimize inclusion and treatment bias, we decided to divide the study population according to the implanted prosthesis (Su cohort and RD- cohort) and to perform the statistical analysis separately.

According to a previous analysis of our register, a constant trend in reduction of the PPI rate starting from 2016 (from 8.1 to 5.9% on the whole registry's population) was reported.[2] This prior evidence was used as reference to divide the study population into two groups: the first including all patients who underwent surgery until December 2016 (early group, "EG") and the second with all patients between January 2017 and April 2019 (late group, "LG"). The time point division was agreed by all authors. The following data have been retrieved from the central database and compared between groups: patient baseline characteristics and comorbidities, functional status, surgical data, postoperative course, and clinical and hemodynamic outcomes.

The end point for the specific purpose of this analysis was the need for PPI during the hospital stay following the index procedure.

Statistical Analysis

Categorical variables are reported as absolute values and percentages. Percentages were calculated with the available data as the denominator. Continuous variables are expressed

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as mean ± standard deviation or median and interquartile range when continuous variables did not follow a normal distribution (tested using the Kolmogorov–Smirnov test for normality and Q–Q plots). Categorical variables were compared using a two-sided χ^2 analysis or Fisher's exact test, where appropriate.

Differences among patient groups for continuous variables were determined using unpaired *t*-test or one-way analysis of variance, as appropriate. A p-value < 0.05 was considered statistically significant. SPSS (version 25.0, IBM Corp.; New York, United States) was used for all analyses.

Results

Su Cohort: Patients Characteristics

During the study period, 2,604 patients underwent Su-AVR as isolated (1,790) or combined procedure (814). Of those, 1,934 belong to the EG and 670 to the LG. Patients' baseline characteristics are listed in ►**Table 1**. Patients in LG were significantly younger, has a slightly higher incidence of male, and had a lower incidence of obesity and chronic atrial fibrillation. Accordingly, both logistic EuroSCORE and EuroSCORE II were significantly lower. Interestingly, the

Table 1 Patients' demographics

	Sutureless cohort				Rapid-deployment cohort			
	Total ($n = 2,604$)	EG 2008–2016 ($n = 1,934$)	LG 2017–2019 ($n = 670$)	*p*-Value	Total ($n = 1,562$)	EG 2010–2016 ($n = 935$)	LG 2017–2019 ($n = 627$)	*p*-Value
Female	1,604 (61.6)	1,217 (62.9)	387 57.8	**0.02**	737 (47.2)	431 (46.1)	306 (48.9)	0.3
Age (y)	77 (±6.6)	77.6 (±6.3)	75.8 (±6.2)	<**0.001**	73.9 (±7.8)	74.3 (±7.7)	73.4 (±7.8)	**0.02**
NYHA class								
I	189 (7.5)	115 (6.2)	74 (11.3)	0.06	67 (4.3)	48 (5.2)	19 (3.1)	**0.01**
II	927 (37)	618 (33.3)	309 (47.4)		496 (32.2)	324 (35.2)	172 (27.7)	
III	1,270 (50.6)	1,005 (54.1)	265 (40.6)		903 (58.6)	506 (54.9)	397 (64)	
IV	122 (4.9)	118 (6.4)	4 (0.6)		75 (4.9)	43 (4.7)	32 (5.2)	
Hypertension	1,918 (86.2)	1,330 (85.3)	588 (88.4)	0.06	1,213 (80.8)	689 (78.4)	524 (84.2)	**0.005**
Obesity	700 (27.4)	545 (28.7)	155 (23.5)	**0.01**	431 (27.9)	259 (28)	172 (27.8)	1
Diabetes	740 (30.5)	535 (30.4)	205 (30.8)	0.8	415 (27.8)	253 (28.8)	162 (26.2)	0.3
AF	343 (18.4)	253 (20.1)	90 (14.7)	**0.004**	249 (18.7)	136 (18.5)	113 (19)	0.9
BAV	92 (4.1)	79 (5)	13 (2)	**0.001**	112 (8.4)	62 (7.4)	50 (10.3)	0.09
Aortic valve disease								
Stenosis	1,806 (72)	1,348 (73.1)	458 (69.1)	<**0.001**	1,181 (78.9)	708 (79.4)	473 (78.3)	0.5
Regurgitation	45 (1.8)	19 (1)	26 (3.9)		38 (2.5)	25 (2.8)	13 (2.2)	
Mixed disease	655 (26.1)	476 (25.8)	179 (27)		277 (18.5)	159 (17.8)	118 (19.5)	
Other	1 (0.04)	1 (0.1)	–		–	–	–	
Cerebrovascular disease	239 (11.2)	201 (11.7)	38 (9.3)	0.2	256 (16.5)	143 (15.4)	113 (18.2)	0.2
Renal insufficiency	1,236 (55.2)	887 (56)	349 (53.4)	0.3	810 (52.9)	448 (49.3)	362 (58.1)	**0.03**
Dialysis	23 (1.3)	15 (1.3)	8 (1.3)	1	13 (0.9)	7 (0.9)	6 (1)	1
Chronic lung disease	325 (14.4)	278 (15.1)	47 (11.5)	0.7	225 (15.7)	153 (18.9)	72 (11.6)	<**0.001**
Re-intervention	172 (6.6)	131 (6.8)	41 (6.1)	0.6	76 (4.9)	51 (5.5)	25 (4)	0.2
LVEF (%)	58.7 (±10.8)	58.9 (±10.9)	58.2 (±9.5)	0.2	57.4 (±10.8)	56.2 (±10.5)	59 (±11.1)	0.05
Peak AVG (mm Hg)	77 (±24.6)	76.7 (±25.3)	77.7 (±22.7)	0.4	81.2 (±27)	82.5 (±28.3)	79.1 (±24.8)	0.04
Mean AVG (mm Hg)	47.2 (±16.1)	47.2 (±16.7)	47.1 (±14.3)	0.8	50.1 (±17.6)	51.5 (±18.3)	49.6 (±16.4)	0.05
Logistic EuroSCORE (%)	8.1 [5.6–12]	8.6 [6.2–13.1]	6.9 [4.7–10.9]	<**0.001**	6.7 [4–11.7]	7 [4.3–11.7]	6.1 [3.3–11.6]	**0.02**
EuroSCORE II (%)	2.7 [1.6–5.2]	3.2 [1.8–6.4]	2.2 [1.3–3.7]	<**0.001**	2.3 [1.4–4.2]	2.4 [1.4–4.6]	2.1 [1.3–3.8]	**0.02**

Abbreviations: AF, atrial fibrillation; AVG, aortic valve gradient; BAV, bicuspid aortic valve; EG, early group; LG, late group; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.
Note: Values are presented as mean (±standard deviation), *n* (%), or median [interquartile range].

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pathological characteristics were also significantly different, with a lower incidence of bicuspid aortic valve (BAV) but more frequent relevant baseline aortic valve insufficiency.

Su Cohort: Operative Data

Operative data are shown in ►**Table 2**. Over time, a reduction in both full- and mini-sternotomy in favor of a more frequent use of anterior mini-thoracotomy was observed. Moreover, the incidence of combined procedures, mostly due to reduction of concomitant myocardial revascularization and septal myectomy, and consequently the cardiopulmonary bypass time, dropped significantly. A redistribution of sizing, with a significant increasing use of size "S," is worthy of attention.

Su Cohort: PPI and Other Outcomes

A marked reduction of PPI was observed between the groups (EG = 209/1,934 [10.8%] vs LG = 42/670 [6.3%], $p < 0.001$) (►**Table 3** and ►**Fig. 1**). The same reduction was also present in the subgroup of isolated procedures (EG = 129/1,282 [10.1%] vs LG = 33/508 [6.5%], $p = 0.02$). ►**Fig. 2** shows the analysis of PPI incidence according to implanted prosthesis's size. Beside the above-mentioned trend to undersizing, a significant reduction of PPI was found in those patients who received a prosthesis "L" (from 12.5 to 7.4%) and "XL" (from 12.6 to 4.4%).

RD Cohort: Patients Characteristics

The RD cohort consists of 1,562 patients operated between 2010 and April 2019 (EG = 935; LG = 627). Patients' baseline characteristics are shown in ►**Table 1**. Even in this cohort, a significant reduction of logistic EuroSCORE and EuroSCORE II has been observed over time, mainly due to a younger age in LG.

RD Cohort: Operative Data

Intraoperative variables are shown in ►**Table 2**. No significance differences were found in intraoperative variables, but the incidence of septal myectomy was twice higher in LG (3.8 vs 1.9%, $p = 0.03$). The use of different prosthesis sizes was not significantly different between EG and LG.

Table 2 Operative data

	Sutureless cohort				Rapid-deployment cohort			
	Total ($n = 2,604$)	EG 2008–2016 ($n = 1,934$)	LG 2017–2019 ($n = 670$)	*p*-Value	Total ($n = 1,562$)	EG 2010–2016 ($n = 935$)	LG 2017–2019 ($n = 627$)	*p*-Value
Full sternotomy	1,252 (48.2)	1,034 (53.5)	218 (32.6)	<**0.001**	777 (49.7)	472 (50.5)	305 (48.6)	0.5
Mini-sternotomy	943 (36.3)	747 (38.7)	196 (29.3)	<**0.001**	572 (36.6)	349 (37.3)	223 (35.6)	0.5
ART	404 (15.5)	149 (7.7)	255 (38.1)	<**0.001**	204 (13.1)	113 (12.1)	91 (14.5)	0.2
Valve label size[a]								
(−)/19 mm	–	–	–	<**0.001**	157 (10.1)	97 (10.4)	60 (9.6)	0.2
S/21 mm	396 (15.5)	259 (13.7)	137 (20.5)		412 (26.5)	251 (26.9)	161 (25.8)	
M/23 mm	949 (37.2)	723 (38.3)	226 (33.8)		496 (31.9)	312 (33.5)	184 (29.5)	
L/25 mm	880 (34.5)	665 (35.3)	215 (32.2)		355 (22.8)	198 (21.2)	157 (25.2)	
XL/27 mm	329 (12.9)	239 (12.7)	90 (13.5)		136 (8.8)	74 (7.9)	62 (9.9)	
Associated procedures	814 (31.3)	652 (33.7)	162 (24.2)	<**0.001**	656 (42)	377 (40.3)	279 (44.5)	0.1
CABG	622 (24)	503 (26.1)	119 (17.8)	<**0.001**	459 (29.4)	263 (28.1)	196 (31.3)	0.2
Mitral surgery	105 (4.2)	68 (3.7)	37 (5.5)	0.06	101 (6.5)	54 (5.8)	47 (7.5)	0.2
Tricuspid surgery	29 (1.2)	22 (1.2)	7 (1)	0.8	54 (3.5)	29 (3.1)	25 (4)	0.4
AF surgery	52 (2.1)	39 (2.2)	13 (1.9)	0.8	72 (4.6)	41 (4.4)	31 (4.9)	0.6
Thoracic aorta surgery	23 (0.9)	19 (1)	4 (0.6)	0.4	72 (4.6)	42 (4.5)	30 (4.8)	0.8
Septal myectomy	66 (2.7)	62 (3.4)	4 (0.6)	<**0.001**	42 (2.7)	18 (1.9)	24 (3.8)	**0.03**
CPB time (min)	67 [51–89]	77 [53–90]	61 [47–84]	<**0.001**	97 [74–123]	99 [75–124]	96 [73–123]	0.8
X-clamp time (min)	43 [32–60]	44 [32–60]	43 [32–62]	0.6	65 [49–85]	65 [48–84]	65 [50–87]	0.3
Valve malpositioning	22 (1.1)	13 (0.9)	9 (1.6)	0.3	24 (1.7)	16 (2.1)	8 (1.3)	0.3

Abbreviations: AF, atrial fibrillation; ART, anterior right thoracotomy; CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass; EG, early group; LG, late group.

Note: Values are presented as *n* (%) or median [interquartile range].

[a]Valve label sizes are different between sutureless and rapid-deployment cohorts and cannot be directly compared. The sutureless prosthesis is available in the following sizes: "S," which should cover a range of annulus between 19 and 21 mm; "M," between 21 and 23 mm; "L," between 23 and 25 m; and "XL" between 25 and 27 mm. The rapid-deployment is available in five sizes (ranging from 19 to 27 mm).

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Table 3 In-hospital outcomes

	Sutureless cohort				Rapid-deployment cohort			
	Total ($n = 2,604$)	EG 2008–2016 ($n = 1,934$)	LG 2017–2019 ($n = 670$)	*p*-Value	Total ($n = 1,562$) n %	EG 2010–2016 ($n = 935$)	LG 2017–2019 ($n = 627$)	*p*-Value
Hospital mortality	57 (2.3)	49 (2.5)	8 (1.4)	0.2	29 (1.9)	17 (1.8)	12 (1.9)	1
Stroke	70 (3.1)	50 (3.2)	20 (3.1)	1	40 (2.8)	28 (3.4)	12 (1.9)	0.1
Ventilatory support > 72 h	113 (4.8)	89 (4.6)	24 (5.8)	0.3	70 (4.5)	40 (4.3)	30 (4.8)	0.7
New-onset AF	631 (29)	530 (29.8)	101 (25.2)	0.07	374 (26.5)	227 (28.9)	147 (23.4)	**0.02**
PPI	251 (9.6)	209 (10.8)	42 (6.3)	<**0.001**	140 (9)	82 (8.8)	58 (9.3)	0.8
Bleeding requiring revision	74 (4.4)	51 (4.2)	23 (5.1)	0.4	68 (4.4)	45 (4.9)	23 (3.7)	0.4
AKI > stage 1	101 (5.9)	81 (5.9)	20 (5.8)	0.9	71 (4.7)	40 (4.3)	31 (5.4)	0.4
Temporary dialysis	54 (3.1)	40 (3)	14 (3.5)	0.6	37 (2.4)	18 (2)	19 (3)	0.2
ICU stay (d)	2 [1–3]	2 [1–3]	2 [1–3]	0.7	2 [1–3]	2 [1–3]	2 [1–3]	0.9
Hospital stay (days)	9 [7–13]	9 [7–14]	8 [7–12]	**0.02**	11 [8–17]	11 [8–17]	11 [8–18]	0.7
Aortic regurgitation	276 (11.9)	235 (14.2)	41 (6.3)	<**0.001**	88 (6)	58 (6.7)	30 (5.1)	0.5
Mild	241 (10.4)	211 (12.7)	30 (4.6)		61 (4.2)	40 (4.6)	21 (3.6)	
Moderate	32 (1.4)	21 (1.3)	11 (1.7)		18 (1.2)	13 (1.5)	5 (0.8)	
Severe	3 (0.1)	3 (0.2)	–		9 (0.6)	5 (0.6)	4 (0.7)	
Peak AVG (mm Hg)	26.3 (±10.1)	26.5 (±10.4)	25.7 (±9.3)	0.08	20.3 (±8.8)	20.6 (±8.9)	19.9 (±8.6)	0.3
Mean AVG (mm Hg)	14.2 (±5.6)	14.2 (±5.8)	14.2 (±5.2)	0.8	11.1 (±5)	11.1 (±5)	11.1 (±5)	1

Abbreviations: AF, atrial fibrillation; AKI, aortic kidney injury; AVG, aortic valve gradient; EG, early group; ICU, intensive care unit; LG, late group; PPI, permanent pacemaker implantation.
Note: Values are presented as mean (± standard deviation) or *n* (%), or median [interquartile range].

RD Cohort: PPI and Other Outcomes

The incidence of PPI was higher in LG, but not statistically significant (EG = 8.8% vs LG = 9.3%, $p > 0.05$; ►**Fig. 1**). In the subgroup of isolated AVR, no differences were observed (EG = 7.5% vs LG = 7.5%, $p > 0.05$). As shown in ►**Fig. 3**, no significant differences were observed in the analysis according to prosthesis's size. The only difference in clinical outcomes was a reduction in the incidence of new onset of atrial fibrillation (►**Table 3**).

Discussion

Concerns about a higher rate of PPI following SuRD-AVR limited the routine use of these prostheses in the low-risk population so far. Indeed, the incidence of PPI after SAVR with a standard prosthesis is reported to be between 2.6 and 3.9%.[8,9] Previous analyses, from our group as well as individual experiences, contributed to the hypothesis that the learning curve is one of the reasons for this outcome.[2,5,6] A learning curve effect is usually difficult to investigate as a variable. Indeed, it influences not only the implantation technique and the surgical performance, but also the patient's selection. Moreover, as the learning curve could be different between centers, researchers usually perform single center's analysis or enroll centers with similar characteristics to avoid this bias, making the collection of a large sample population difficult. The scope of our progress report was to address this problem without waiving a large sample size. We aimed to use this approach to shed light on the issue, to report a fair "state of the art" of the problem, and possibly to shorten the learning effect for the surgeons who are not yet confident with SuRD-AVR.

The main findings of our report are (1) the incidence of PPI following Su-AVR has significantly decreased over time and (2) PPI after RD-AVR has remained stable over time.

The reduction of PPI after Su-AVR has been already reported not only from our international register, but also from other single-center studies.[5,9] In the present report, several clinical variables, such as age, gender, obesity, history of atrial fibrillation, and risk profile, were found significantly different between the two temporal groups and possibly may have influenced the observed outcome. Interestingly, also anatomical and functional characteristics of the aortic valve, namely, the presence of a congenital BAV and the prevalence of pure aortic valve stenosis, were significantly different between the groups. The association of BAV with increased risk of PPI following aortic valve interventions has been already investigated in prior studies

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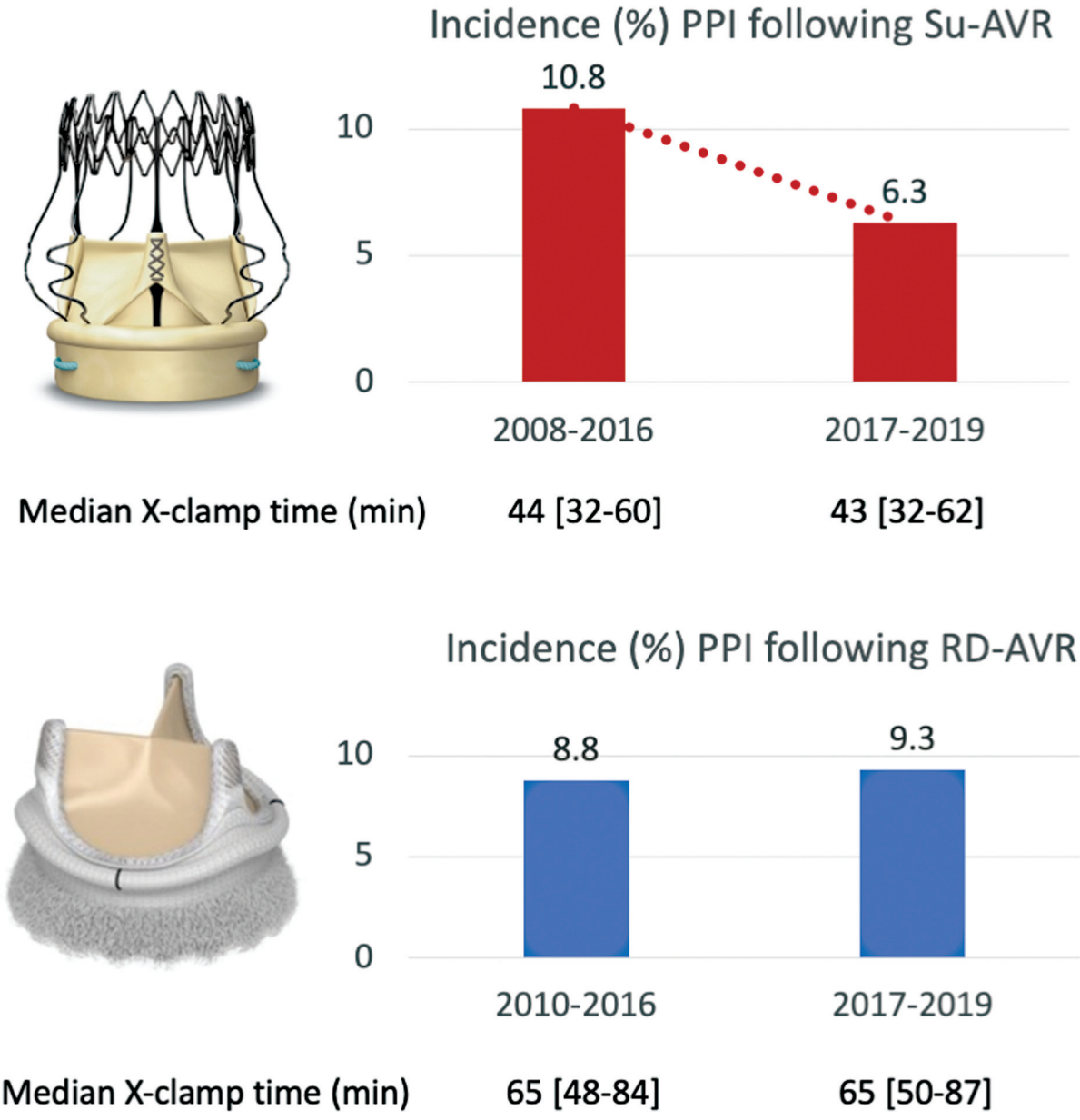

Fig. 1 Bar chart showing the incidence of PPI in the sutureless and rapid-deployment groups in the early and late period of time. A significant reduction of PPI following sutureless AVR has been observed in last years, together with changes in patients' characteristics. The same phenomenon has not been registered for rapid-deployment AVR, but any substantial difference in strategy has been recorded.

with conflicting results. Haunschild and colleagues reported no differences in PPI between patients with BAV and tricuspid valves in a matched population, but they found a higher rate of third-degree atrioventricular block in BAV patients.[10] Biswas and colleagues recently found a higher His-to-ventricular interval conduction in BAV patients, with an increased requirement for pacemaker therapy over a 10-year follow-up in comparison to a matched population with tricuspid aortic valve.[11] As previously reported, the overall incidence of PPI in BAV patients was 7.9% in our registry.[12] The lower incidence of aortic valve stenosis could also have contributed to the improvement of the outcome. Indeed, the main predominant etiology of aortic stenosis is the calcific degeneration, which may extend from the aortic ring to the bundle, provoking right bundle and left anterior hemiblock as well.[13]

In addition to the baseline variables, even changes in intraoperative strategies could be responsible for the reduction in PPI in Su cohort. We found a clear shift over time toward a more frequent use of anterior right thoracotomy and a reduction of combined procedures, mainly concomitant revascularization and septal myectomy. In other words, patients underwent a significantly simpler procedure, in a shorter time (as observed from the shorter cardiopulmonary bypass time). Less need for myocardial revascularization could be correlated to less conduction disturbances, as the conduction system is sensitive to ischemic conditions.[14]

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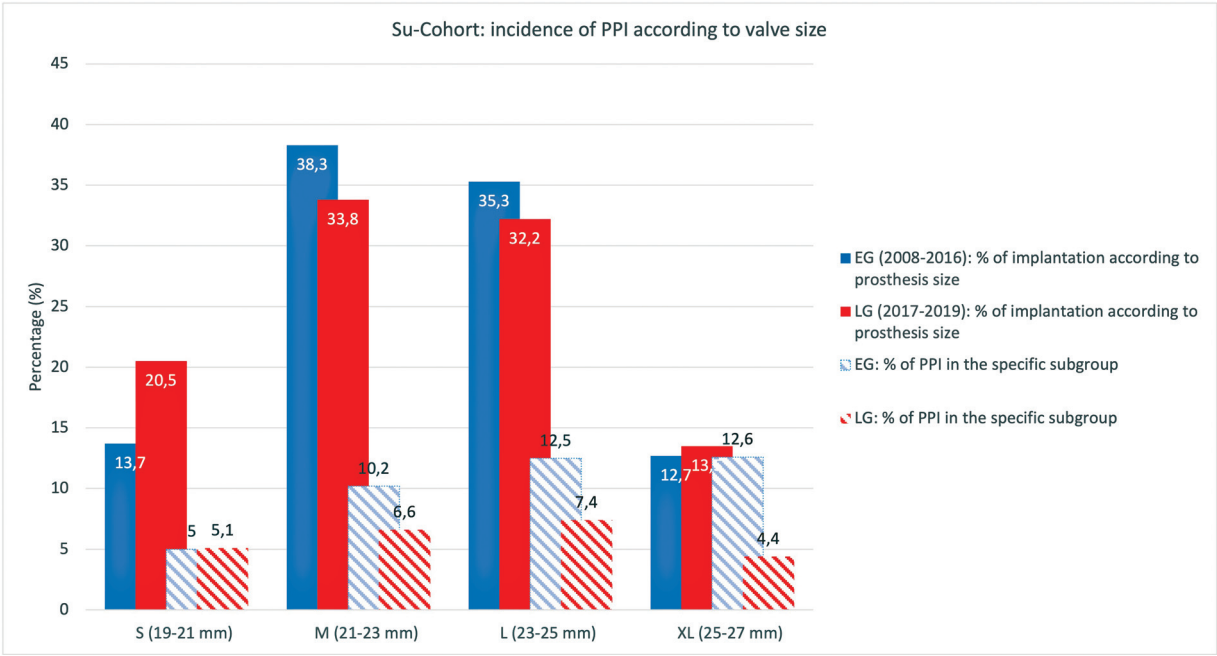

Fig. 2 Bar chart showing the use and distribution of PPI according to prosthesis's size in sutureless cohort.

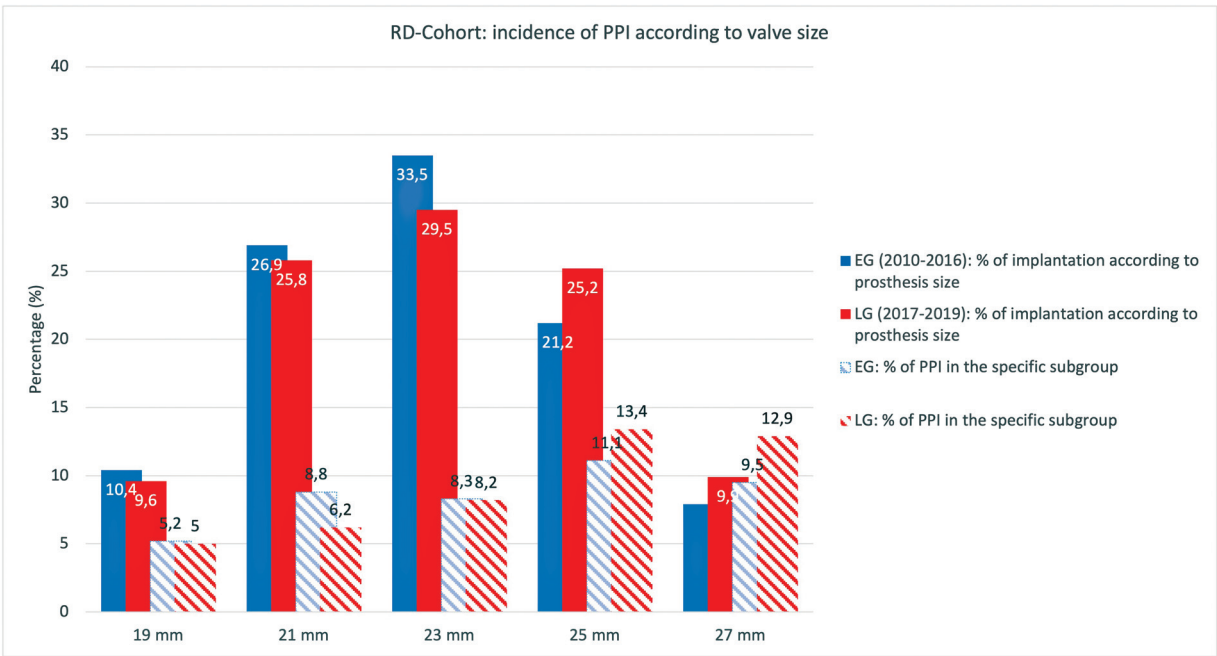

Fig. 3 Bar chart showing the use and distribution of the PPI according to prosthesis's size in rapid-deployment cohort.

However, the most interesting finding of our study is the significant reduction of PPI in two specific sizes of the Su prosthesis (the "L," covering annuli between 23 and 25 mm, and the "XL," between 25 and 27 mm). Remarkably, the use of these prostheses was not significant different in the LG, suggesting that the surgeons moved to a different sizing strategy in the most recent period. Indeed, the period of time of our LG coincides with the publications of several studies focused on the risks (e.g., stent recoil, higher gradients) correlated to the oversizing in Su-AVR.[15,16] The avoidance of oversizing could be correlated to a reduction of conduction injury, in accordance with the study of Geršak and colleagues.[17]

A possible alternative explanation of the reduction of PPI in patients receiving the "XL" prosthesis could be related to the introduction on the market in mid-2018 of an updated model called "Perceval Plus." Both Su and RD prostheses, despite the considerable structural differences, are based on the intra-annular position with an anchoring system based on radial forces. This can result in a damage of the left bundle branch fibers of His bundle, located close to the membranous septum, just beneath the commissures of the right and

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noncoronary cusps. This may explain the higher incidence of PPI with these new prostheses in comparison to conventional bioprostheses (which typically are placed in a supra-annular position). The use of the "Perceval Plus XL" characterized by a thinner annular ring and a different distribution of radial forces could have contributed to a reduction of PPI, at least in the XL group.

The RD cohort showed a stable rate of PPI. A recent multivariate analysis of Coti and colleagues performed on 700 patients showed that a baseline right bundle branch block, concomitant procedures in general and in particular concomitant myocardial revascularization are correlated with the atrioventricular block after RD-AVR.[18] Our findings—with the limitation of the missing electrocardiographic (ECG) data—are in line with those results, as the only significant differences over time were the younger age of patients in LG and a higher rate of septal myectomy. The latter finding must receive particular attention, as atrioventricular blocks belong to the typically consequences of subvalvular myectomy and this could explain the observed trend of higher rate over time (in the overall population, while the isolated AVR showed no changes).

Although the scope of the present analysis was not a direct comparison of the two prosthesis, it is worthy to highlight the differences in the Su and RD groups, not only in the outcomes (no reduction in PPI rate over time and consequently longer hospital stay: 11 vs 8 days), but also in the baseline and procedural variables (e.g., higher incidence of associated procedures in the RD group, 42 vs 31%). The choice of the prosthesis in the present study was at the discretion of the surgeon. As the two prostheses are structurally different, they could be more suitable in different scenario, thus influencing the prosthesis choice by the surgeon. For example, due to the smaller profile, some surgeon could prefer the RD prosthesis in cases requiring revascularization with multiple proximal anastomosis.

Summing up these observations, as well as the findings from the Su cohort, we may conclude that patient selection plays a crucial role in the strategy aiming to reduce the risk of PPI. Our findings do not exclude the possibility to obtain a similar reduction also in the RD cohort in the future, as we recently hypothesized.[19] Specific risk factors for pacemaker implantation (mainly right bundle branch block), which could be avoided by patient selection, may improve the pacemaker rate in the RD group in the future. However, the rapid-deployment and the sutureless prostheses are structurally different: the Su prosthesis does not protrude in the left ventricular outflow tract at all, unlike the RD prosthesis. If this aspect is relevant for the risk of developing atrioventricular blocks, especially when severe subvalvular calcifications are present,[4] it should be cleared in future studies.

Our data are drawn from a population in the seventh decade of life with a life expectancy of around 10 years. If the improvements of PPI rate, as observed in our study, will be confirmed in further studies with long-term follow-ups, the use of SuRD prostheses could be expanded to a younger and low-risk population, for which PPI could be undesirable due to the increased risks of all-cause mortality and heart failure hospitalization in a very long-term follow-up.[20]

Limitation of the Study

Limitations of the present study included its retrospective nature. Moreover, potentially important variables for the need for PPI, such as pathological preoperative ECGs, or preexisting conduction abnormalities, were not available in the dataset. The differences between Su and RD cohorts did not allow a direct comparison between these two groups. Our analysis is focused on the in-hospital outcome and does not investigate the mid- or long-term outcome.

Conclusion

The present analysis showed a significant decrease in in-hospital PPI requirement rate in patients who underwent Su-AVR over time. Patient selection as well as surgical modifications and a more accurate sizing are probably the main reasons for this phenomenon. The RD cohort revealed no differences in PPI between the two time periods so far, but there were also less differences in patient selection.

Authors' Contribution

All those who fulfil the criteria for authorship have been included as authors. The high number of coauthors is due to the number of involved centers, which allowed the analysis of such a big study population.

Conflict of Interest

C.M. and E.V. are proctors for Perceval/LivaNova. A.A. receives consulting and lecture fees from LivaNova. M.A. is proctor/speaker/consultant (Edwards, Abbott, Medtronic) and received institutional grants (Edwards, Abbott, Medtronic, LSI). T.F. is consultant for LivaNova. Other authors declared no conflicts of interest.

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