Perioperative outcomes with sutureless versus stented biological aortic valves in elderly persons

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ABSTRACT

Objectives: Sutureless aortic valves are deemed suitable for patients considered at high risk for surgery. The objective of this study is to evaluate the perioperative results of implanting a sutureless valve in elderly persons, compared with a stented biological valve in the aortic position.

Methods: Between 2011 and 2015, 76 patients underwent aortic valve replacement with the Perceval prosthesis (Sorin Group, Saluggia, Italy). The group was compared with 319 consecutive patients who received aortic valve replacement with the stented valve in that same period.

Results: The mean age of patients was 83 ± 2 years in the Perceval group and 83 ± 3 years in the stented valve group ($P = .3$). Preoperative demographics were similar in both groups. Median cardiopulmonary bypass and crossclamp times were lower in the Perceval group than in the stented valve group ($P < .001$). Mortality was 5% in the Perceval group and 6% in the stented valve group ($P = .8$). There were more pacemaker implantations in the Perceval group than in the stented valve group (17% vs 8%; $P = .02$). A subgroup analysis of patients who underwent aortic valve replacement and concomitant procedures showed the same results as the entire cohort.

Conclusions: Aortic valve replacement with a sutureless prosthesis resulted in shorter aortic crossclamp and bypass times compared with a stented biological prosthesis. The reduced cardiopulmonary bypass and aortic crossclamp times obtained using the Perceval prosthesis did not translate into perioperative gains in our population of elderly patients. (*J Thorac Cardiovasc Surg* 2016;151:1629-36)

Sutureless aortic valve versus stented biological aortic valve.

Central Message

Sutureless aortic valve prosthesis decreases cardiopulmonary bypass time in elderly persons undergoing AVR with or without CABG surgery.

Perspective

This article evaluates perioperative outcomes of implanting these valves versus a stented biological valve in elderly persons. Despite a decrease in bypass and crossclamp times, we did not find a difference between groups in terms of mortality and morbidities, but we raised a flag regarding postoperative implantation of a pacemaker for third-degree AV block with the use of sutureless valves.

See Editorial Commentary page 1637.

Aging of the population is an established fact. Doctors are regularly confronted by the clinical challenges of treating older patients with advanced cardiovascular diseases and multiple comorbidities. With escalating health-care costs, it has become imperative to examine the outcomes of patients undergoing surgical interventions in older age groups. In 8 different studies including

1295 patients undergoing coronary artery bypass grafting (CABG) and valve replacement procedures, it has been shown that cardiac surgery, in carefully selected octogenarians and nonagenarians, is justified and can be performed with acceptable results. However, increased mortality and morbidities, as well as increase length of stay, are associated with this age group.¹⁻³ In this aging population, we find patients with multiple comorbidities and calcified ascending aorta and root. The actual challenge of our surgical specialty is to find strategies

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Abbreviations and Acronyms

AV	= atrioventricular
AVR	= aortic valve replacement
CABG	= coronary artery bypass grafting
euroSCORE	= European System for Cardiac Operative Risk Evaluation
ICU	= intensive care unit
IQR	= interquartile range
STS	= Society of Thoracic Surgeons
SV	= stented valve
TAVI	= transcatheter aortic valve implantation

to minimize the burden of an open cardiac surgery. Strategies aimed at reducing bypass and crossclamp times may reduce systemic inflammatory reaction and lead to decreased postoperative morbidities. Minimally invasive techniques also have been claimed to produce similar benefits.

Sutureless aortic valves have been introduced in practice in Europe since 2007 and in North America since 2009. This new technology is deemed suitable for patients who are considered at high risk for surgery. The Perceval S (Sorin Group, Saluggia, Italy) prosthesis is made of a trileaflet bovine pericardial valve mounted on an expandable metal frame of nitinol (equiatomic alloy of nickel and titanium). The Perceval S prosthesis has the special feature that it does not have to be surgically sutured into the implant site because this function is performed by the armature, which, along with supporting the valve edges, adapts itself to the aortic root to which it is anchored.

In high-risk patients aged more than 70 years, Santarpino and colleagues⁴ showed that implantation of the sutureless aortic valve Perceval reduced not only the operative time but also the number of transfusions received, intubation time, and length of stay in the intensive care unit (ICU).⁴ That same group published their 1-year results showing good hemodynamic profile and mean New York Heart Association functional class of 1.⁵ Other groups have duplicated their results.^{6,7}

The sutureless prosthesis could be an interesting option in elderly persons with small aortic roots. A study by Shrestha and colleagues⁸ showed that the implantation of the Perceval valve compared with a standard stented aortic valve prosthesis in patients aged more than 75 years resulted in no annulus enlargement in the Perceval group versus 2 cases of annulus enlargement in the stented valve (SV) group. All patients enrolled in this study had an annular size less than 22 mm. Some 24% of patients had a small Perceval valve, and 76% of patients had a medium Perceval valve. Perioperative and 5-year results showed no

difference in mortality between groups.⁸ As in the case of SVs, the Perceval valve offers greater effective orifice area for any given size.⁹

Sutureless valves have been used during minimally invasive surgery because of their short implantation time and ease of use.⁹ The safety of the valve has been demonstrated in various studies, especially in European centers, because of their longer experience with the sutureless prosthesis.⁷

The objective of the present study is to evaluate the perioperative results of implanting a sutureless valve, the Perceval S, compared with a biological aortic SV in elderly patients.

MATERIALS AND METHODS

Between 2011 and 2015, 76 patients aged 80 years or more underwent aortic valve replacement (AVR) with the Perceval prosthesis and 319 patients received a biological SV. We included all consecutive patients aged more than 79 years who had an isolated AVR procedure or an AVR and CABG. Other concomitant procedures, including aortic annulus enlargement, dilatation of the ascending aorta, and redo surgery, were excluded. The study was approved by the Ethics Committees of the Montreal Heart Institute, the Hôpital Sacré-Coeur de Montréal, and the Centre Hospitalier de l'Université de Montréal. All surgeons who participated in this study are part of the Université de Montréal Cardiac Surgery Division. Those surgeons operated at the 3 different sites mentioned previously.

Valves were implanted in patients according to standard surgical techniques. The valves used in the standard conventional AVR group were the Carpentier-Edwards Perimount (Edwards Lifesciences, Irvine, Calif), Carpentier-Edwards Magna Ease (Edwards Lifesciences), Medtronic Mosaic (Medtronic Inc, Minneapolis, Minn), Sorin Mitroflow (Sorin Group), St Jude Biocor porcine (St Jude Medical, St Paul, Minn), and St Jude Epic standard and Supra (St Jude Medical). The surgical approaches included full and mini-sternotomy and mini-thoracotomy for both types of valves.

The surgical technique used to implant the Perceval valve has been well described in the literature.⁷ In brief, the native valve is excised, the annulus is decalcified, and 3 sutures of Prolene are placed at the nadir of each sinus. The prosthesis of the proper size is deployed in the aortic annulus. A balloon is inflated inside the prosthesis at 4 atm during 30 seconds. The aortotomy is closed in a standard fashion. The stented biological prostheses were implanted according to the standard surgical technique.

When the Perceval S is used for a combined procedure (eg, AVR + CABG), the ascending aorta is cannulated close to the aortic arch to leave room for proper placement of the proximal saphenous vein graft anastomoses on the ascending aorta. The aortotomy also is performed higher to allow the stented cage of the Perceval valve to abut properly on the aortic wall. After deployment of the sutureless valve, the heart is gently mobilized to avoid prosthesis dislodgement and embolization.

Outcomes of interest were recorded according to the Society of Thoracic Surgeons (STS) Guidelines for Reporting Mortality and Morbidity after Cardiac Valve Interventions Guidelines.¹⁰ The primary outcome of interest was perioperative (within 30 days) mortality. Secondary outcomes of interest were perioperative course and complications, such as reexploration for bleeding, myocardial infarction, ICU length of stay, intubation time, hospitalization time, number of red blood cell transfusions, renal failure requiring dialysis or continuous venovenous hemofiltration, complete or partial atrioventricular (AV) bloc

requiring pacemaker implantation, atrial fibrillation, multiple organ failure, septicemia, and thromboembolic events (stroke, transient ischemic attack, and noncerebral embolic events). These outcomes were analyzed in the entire cohort of patients. A similar analysis was performed in the AVR and CABG subgroup to see if there was an advantage of using the Perceval valve in patients with a concomitant procedure. As an additional effort to control for systematic differences between patients receiving a Perceval valve and patients receiving an SV, a propensity score was constructed.

Statistical Analysis

Data were expressed as mean ± standard deviation or median (interquartile range [IQR]) for continuous variables, as appropriate, and categorical variables were expressed as a number (percentage). Brackets were used to present IQR as a measure of dispersion for median for variables with non-normal distributions. Differences between continuous variables were analyzed using Student *t* tests, and categorical variables were analyzed with chi-square tests.

Each patient who received a Perceval valve was propensity score matched to 1 patient receiving a standard AVR, using a 1:2 matching macro based on greedy algorithms. Variables included in the multivariable logistic regression model estimating the propensity score included female gender,

estimated glomerular filtration rate (using the Chronic Kidney Disease Epidemiology Collaboration formulae), presence of pulmonary hypertension, and aortic prosthesis implant size (categorized in 4 groups).¹¹ Patient characteristics before and after matching were compared using standardized differences. For 30-day mortality and hospital morbidity, logit-link generalized estimating equations were used accounting for matching. Likewise, identity-link normal-distribution generalized estimating equations were used for log-transformed cardiopulmonary bypass time, crossclamp time, chest tube drainage, number of transfusions, and length of stay. All statistical analyses were performed using SAS release 9.3 (SAS Institute Inc, Cary, NC).

RESULTS

Entire Perceval Group Compared With Standard Prosthesis Group

The mean age of patients was 83 ± 2 years in the Perceval group and 83 ± 3 years in the SV group (*P* = .3) (Table 1). Preoperative European System for Cardiac Operative Risk Evaluation (euroSCORE) II was 4.4% (IQR, 3.0%-8.7%) in the Perceval group and 4.5% (IQR, 2.9%-7.8%) in the

TABLE 1. Preoperative parameters for the entire cohort of patients

Parameters	Sutureless valve (N = 76)	Stented biological AVR (N = 319)	<i>P</i> value
Age, y	83 ± 2	83 ± 3	.315
Sex (female)	37 (49%)	149 (47%)	.756
BMI/BSA, kg/m ² , m ²	28 ± 4/2 ± 0	27 ± 5/2 ± 0	.094/.451
euroSCORE 2 (%)	4.4 (3.0-8.7)	4.5 (2.9-7.8)	.710
STS predicted mortality (%)	5.7 (4.3-8.6)	5.6 (4.2-7.8)	.588
Emergency/urgent surgery (%)	17 (22)	88 (28)	.328
Preoperative LVEF (%)	58 ± 9	58 ± 10	.702
Preoperative mean gradient (mm Hg)	47 ± 16	51 ± 19	.210
Procedures			.037
Isolated aortic replacement	43 (57%)	151 (47%)	
Aortic replacement and CABG	32 (42%)	168 (53%)	
Surgical indication			
Severe aortic stenosis	69 (91%)	279 (87%)	.421
Severe aortic regurgitation	7 (9%)	40 (13%)	.230
NYHA			.260
I	18 (24%)	48 (15%)	
II	25 (33%)	126 (39%)	
III	30 (39%)	125 (39%)	
IV	3 (4%)	20 (6%)	
Surgical approaches			
Minimally invasive approaches	14 (18%)	24 (8%)	.034
Sternotomy	62 (82%)	295 (92%)	
Aortic prosthesis			<.001
Carpentier-Edwards Perimount (Edwards Lifesciences, Irvine, Calif)	0 (0%)	30 (9%)	
Carpentier-Edwards Magna Ease (Edwards Lifesciences, Irvine, Calif)	0 (0%)	145 (46%)	
Medtronic Mosaic (Medtronic Inc, Minneapolis, Minn)	0 (0%)	8 (3%)	
Pericardial Mitroflow (Sorin Group, Saluggia, Italy)	0 (0%)	108 (34%)	
St Jude Biocor (St Jude Medical, St Paul, Minn)	0 (0%)	9 (3%)	
St Jude Epic Standard (St Jude Medical)	0 (0%)	2 (1%)	
St Jude Epic Supra (St Jude Medical)	0 (0%)	13 (4%)	
Others	76 (100%)	3 (1%)	

AVR, Aortic valve replacement; BMI, body mass index; BSA, body surface area; euroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons; LVEF, left ventricular ejection fraction; CABG, coronary artery bypass grafting; NYHA, New York Heart Association.

TABLE 2. Prosthetic aortic valve dimensions

	Sutureless valve		Stented biological AVR
Size	(N = 76)	Size (mm)	(N = 319)
Small	14 (18%)	19	35 (11%)
Medium	23 (30%)	21	93 (29%)
Large	31 (40%)	23	104 (33%)
Extra large	8 (11%)	25	65 (20%)
		27	21 (7%)
		29	1 (0%)

AVR, Aortic valve replacement.

SV group ($P = .7$). The STS score for predicted mortality was 5.7% (IQR, 4.3%-8.6%) in the Perceval group and 5.6% (IQR, 4.2%-7.8%) in the SV group ($P = .6$). Mean preoperative left ventricular ejection fraction was normal in both groups: $58\% \pm 9\%$ and $58\% \pm 10\%$, respectively ($P = .7$). Mean preoperative aortic gradients also were similar: 47 ± 16 mm Hg and 51 ± 19 mm Hg, respectively ($P = .18$) (Table 1). Prosthetic aortic valve dimensions are shown in Table 2.

Mean cardiopulmonary bypass times and crossclamp times were lower in the Perceval group than in the SV group: 64 ± 21 minutes versus 93 ± 37 minutes and 50 ± 22 minutes versus 74 ± 29 minutes, respectively ($P < .001$) (Table 3).

There were 4 perioperative deaths (5%) in the Perceval group and 19 deaths (6%) in the SV group ($P = .8$). Pacemaker implantation was more prevalent in the Perceval group (17% vs 8%; $P = .02$). There was no significant difference between the 2 groups in the incidence of any reoperation and tamponade ($P = .9$), myocardial infarction ($P = 1.0$), acute kidney injury ($P = .2$), renal failure requiring dialysis ($P = .2$), any cerebrovascular accident ($P = .9$), atrial fibrillation ($P = .3$), and septicemia ($P = .1$). ICU length of stay ($P = .5$), ICU reintubation ($P = .7$), readmission to ICU or from home ($P = .4$), number of red blood cell transfusions ($P = .8$), and hospitalization time ($P = .5$) also were similar between the 2 groups. There were no paravalvular leaks or patient-prosthesis mismatch in the 2 groups (Table 3).

Seven patients (10%) had complete AV block, and 6 patients had a low-grade AV block and new left bundle branch block after Perceval deployment. Four patients had preoperative atrial fibrillation, 3 patients had a first-degree AV block, 1 patient had a right bundle branch block, and 1 patient had a first-degree AV block and left bundle branch block.

Table 4 shows the preoperative and postoperative mean echocardiography gradients and aortic valve areas. There were no significant differences between groups (Table 4). The postprocedure mean gradient for small Perceval prosthesis was 16 ± 7 mm Hg with a mean aortic area of

TABLE 3. Perioperative outcomes of the entire cohort of patients

	Sutureless valve	Stented biological AVR	P value
Outcomes	(N = 76)	(N = 319)	
CPB (min)	60 (49-80)	85 (66-113)	<.001
Crossclamp (min)	46 (37-58)	68 (53-92)	<.001
ICU LOS (d)	2 (1-6)	2 (1-4)	.460
ICU reintubation	5 (7%)	17 (5%)	.664
ICU readmission	3 (4%)	21 (7%)	.381
Hospitalization time (d)	10 (7-15)	9 (7-14)	.538
Prolonged LOS >14 d	20 (26%)	77 (24%)	.702
Short LOS <6 d	18 (24%)	75 (24%)	.985
RBC transfusions	54 (71%)	229 (72%)	.805
Readmission postdischarge home	5 (7%)	30 (9%)	.368
Early complications <30 d			
Mortality <30 d (causes)	4 (5%)	19 (6%)	.817
Low cardiac output	2 (50%)	6 (32%)	.343
Stroke with permanent deficit	0 (0%)	1 (5%)	.272
Infection sepsis	2 (50%)	7 (37%)	.144
Multiple organ failure	0 (0%)	5 (26%)	.396
Acute kidney injury	32 (42%)	109 (34%)	.194
Atrial fibrillation	33 (43%)	158 (50%)	.338
Pacemaker implantation	13 (17%)	26 (8%)	.019
Renal failure requiring temporary dialysis	10 (13%)	27 (8%)	.207
CVVH			
Tamponade, reoperation for bleeding	6 (8%)	27 (8%)	.872
Any cerebrovascular accident	3 (4%)	14 (4%)	.865
Myocardial infarction	0 (0%)	0 (0%)	1.000
Paravalvular leak	0 (0%)	0 (0%)	1.000

Stroke is with or without sequelae/thromboembolic events: deep vein thrombosis and pulmonary embolism; reexploration for bleeding is hemorrhage and tamponade. AVR, Aortic valve replacement; CPB, cardiopulmonary bypass; ICU, intensive care unit; LOS, length of stay; RBC, red blood cell; CVVH, continuous venovenous hemofiltration.

1.5 ± 0.4 cm². Fourteen patients (14/76, 18%) underwent implantation of a small-sized Perceval prosthesis, and 25 patients (25/319, 8%) had a 19-mm or 21-mm SV prosthesis.

TABLE 4. Pre and post mean gradient (mm Hg) and aortic area (cm²)

	Sutureless valve	Stented biological AVR	P value
	(N = 76)	(N = 319)	
Preoperative mean gradient (mm Hg)	44.5 ± 16.6	46.3 ± 13.3	.5
Preoperative aortic area (cm ²)	0.8 ± 0.3	0.7 ± 0.2	.6
Postoperative mean gradient (mm Hg)	15.5 ± 7.3	14.6 ± 4.7	.5
Postoperative aortic area (cm ²)	1.5 ± 0.5	1.5 ± 0.4	.8

AVR, Aortic valve replacement.

TABLE 5. Perioperative outcomes in subgroup analysis patients with aortic valve replacement and coronary artery bypass grafting

Outcomes	Sutureless valve (N = 32)	Stented biological AVR (N = 168)	P value
CPB (min)	67 (61-81)	106 (88-127)	<.001
Crossclamp (min)	53 (50-67)	88 (69-102)	<.001
Time spent in surgery	148 (133-172)	198 (165-235)	<.001
ICU LOS (d)	2 (1-5)	3 (1-4)	.345
Hospitalization time (d)	11 (7-14)	8 (6-15)	.571
RBC transfusions	25 (78%)	128 (77%)	.936
Early complications <30 d			
Mortality <30 d (causes)	1 (3%)	8 (5%)	.602
Stroke with permanent deficit	0 (0%)	2 (1%)	.376
Acute kidney injury	11 (34%)	58 (35%)	.506
Atrial fibrillation	13 (41%)	77 (46%)	.376
Pacemaker implantation	4 (13%)	13 (8%)	.061
Paravalvular leak	0 (0%)	0 (0%)	1.000

AVR, Aortic valve replacement; CPB, cardiopulmonary bypass; ICU, intensive care unit; LOS, length of stay; RBC, red blood cell.

Subgroup Analyses

Isolated aortic valve replacement. A total of 43 patients underwent isolated AVR with the Perceval prosthesis (Table 1). Thirty-day mortality was similar in the 2 groups (3/43 [7%] in the Perceval group and 10/151 [7%] in the

SV group). Minimally invasive approaches (mini-sternotomy or thoracotomy) were used in 14 patients (14/43, 33%) with the Perceval valve compared with 24 patients (24/151, 16%) with the SV ($P = .103$). The 30-day mortality of patients who received the minimally invasive access procedure was 5% versus 7% for standard sternotomy ($P = .94$). The time in surgery was shorter: 110 minutes (IQR, 98-147) versus 142 minutes (IQR, 117-161) ($P < .001$). Bypass and crossclamp times also were lower in the minimally invasive approach group: 53 minutes (IQR, 44-66) $P < .001$ and 41 minutes (IQR, 35-48) $P < .001$, respectively, compared with 71 minutes (IQR, 57-85) $P < .001$ and 56 minutes (IQR, 43-66) $P < .001$, respectively, in the standard sternotomy group. There were no differences in all other perioperative outcomes.

Combined aortic valve replacement and coronary artery bypass grafting. euroSCORE II and STS scores, and demographics were similar in the 2 groups (Table 5). Mortality at 30 days was 3% (1/32 patients) in the Perceval group with CABG and 5% (8/168, 5%) in the SV group with CABG ($P = .6$). There was no difference in any morbidities (low cardiac output syndrome, reexploration for tamponade, acute kidney injury with or without dialysis, sepsis, pulmonary complication, multiorgan failure) ($P = .4$). ICU and hospital length of stay, and number of transfusions received were similar. The rate of pacemaker

TABLE 6. Propensity score matching (1:2): Demographics

Demographics	Sutureless valve (65)	Stented biological AVR (130)	Standardized difference
Age (y)	83 ± 3	83 ± 3	−15.7
Sex (male)	52	61	−19.5
BMI	28 ± 4	27 ± 5	19.8
Hypertension (%)	86	83	8.5
Diabetes	36	37	−2.8
Preoperative eGRF	51 (38-65)	56 (41-71)	−14.5
Peripheral vascular disease	3 (4.1)	2 (2.7)	7.5
Any prior neurologic event	7 (9.6)	10 (13.7)	−12.8
Chronic obstructive pulmonary disease	13 (20.0)	21 (16.2)	10.0
Ever smoker	3 (4.6)	7 (5.4)	−3.7
Prior cardiac surgery	4 (6.2)	4 (3.1)	14.7
Preoperative NYHA class III or IV	30 (46.2)	63 (48.5)	−4.6
LVEF <40%	3 (4.6)	8 (6.2)	−6.8
Aortic valve mean gradient	44 ± 17	45 ± 21	−8.8
Aortic valve area	0.74 ± 0.21	0.77 ± 0.21	−13.3
No. of diseased vessels, none	36 (55.4)	59 (45.4)	26.9
Logistic euroSCORE II	4.4% (2.8%-8.4%)	5.3% (3.1%-9.0%)	−10.6
STS 30-d mortality	5.6% (4.1%-8.4%)	5.8% (4.4%-7.9%)	−2.1
Diuretics	29 (44.6)	67 (51.9)	−14.7
Surgical approach			32.3
Aortic valve prosthesis size			2.1
Cardiopulmonary bypass time, min	59 (48-79)	85 (64-107)	−92.0
Crossclamp time, min	43 (37-53)	64 (51-89)	−97.1

Matched = standardized interval between −20 and 20. AVR, Aortic valve replacement; BMI, body mass index; eGRF, estimated glomerular filtration rate; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; euroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons.

use was 13% in the Perceval group and 8% in the SV group. Cardiopulmonary bypass and aortic crossclamp times were lower in the Perceval group (67 minutes [IQR, 61-81] and 53 minutes [IQR, 50-67] compared with the SV group 106 minutes [IQR, 88-127] and 88 minutes [IQR, 69-102]) ($P < .001$). The time spent in surgery was decreased in the Perceval group compared with standard AVR group (148 minutes [IQR, 133-172] and 198 minutes [IQR, 165-235]) ($P < .001$) (Table 5).

Propensity-matched group: Perceval versus standard prostheses. Sixty-five patients in the Perceval group were matched to 130 patients in the stented prosthesis group (Table 6). Bypass and crossclamp times were lower in the Perceval group: 59 minutes (IQR, 48-79) and 43 minutes (IQR, 37-53), respectively, versus 85 minutes (IQR, 64-107) and 64 minutes (IQR, 51-89) in the SV group, respectively (Table 6). There were no differences in perioperative outcomes. Pacemaker rates were similar in the 2 groups, and 30-day mortality was similar (Table 7).

DISCUSSION

The present study suggests that the sutureless prosthesis could be a reasonable alternative to standard AVR with a stented biological aortic valve to decrease the cardiopulmonary bypass and crossclamp times in patients aged 80 years or more. However, it did not translate into a reduction of postoperative adverse outcomes. With similar surgical risk (euroSCORE II and STS

FIGURE 1. We compared sutureless and stented biologic aortic valves in elderly patients.

score), we did not find significant differences in mortality and major morbidities between the 2 groups except for a higher rate of pacemaker implantation in the Perceval group. We studied a subgroup of patients who underwent AVR with concomitant CABG procedures and found a lower 30-day mortality in those who received the Perceval prosthesis, but this difference was not statistically significant (Figure 1).

Few studies have reported the rate of pacemaker implantation after sutureless AVR, but Santarpino and colleagues⁴ showed a rate of 6% in their study. Our rate of pacemaker implantation is lower than what is reported with the transapical valve, such as the CoreValve (Medtronic Inc) (33%),¹² but similar to rates with the Edwards Lifesciences SAPIEN valve (15%-20%).¹³

Nine of 13 patients in our study had a significant history of preoperative arrhythmia. The valve is made of a nitinol frame and descends down the left ventricular outflow tract. It could result in an increase in pressure on the membranous septum as the prosthesis expands and cause AV block, especially in patients with a history of bundle branch block. Sorin Group (Milan, Italy) recommends inflating the balloon at 4 atm for all valve sizes. It is different than what is seen with the transcatheter AVR prosthesis with a smaller volume inflation with a smaller prosthesis. This also might contribute to the high number of AV blocks. Supra-annular placement should be an alternative, but we need to be sure that there is enough calcium to anchor the valve. A less-aggressive decalcification of the annulus could be a way to avoid AV block, but may expose the patient to a greater risk of paravalvular leak. Several groups have reported reoperation for paravalvular leak (3%) as early as 13 days.^{7,14} One case report also showed patient-prosthesis mismatch in a patient who had a sutureless valve implanted.¹⁵ We did not encounter these types of

TABLE 7. Perioperative outcomes for patients matched 1:2

Perioperative outcomes	Sutureless valve (65)	Stented biological AVR (130)	P value
30-d Mortality	4 (6.2)	10 (7.7)	.70
Prolonged ventilation (>24 h)	4 (6.2)	5 (4.1)	.56
ICU LOS (first stay), d	2.0 (1.0-6)	2.0 (1.0-4)	.65
Reintubation	5 (7.8)	6 (4.7)	.39
Readmission to ICU	3 (4.6)	8 (6.2)	.65
Any transfusion	46 (70.8)	93 (71.5)	.92
Any cardiac reoperation	7 (10.8)	10 (7.7)	.49
Hospital LOS (d)	10 (6-15)	8 (7-13)	.33
Prolonged LOS (>14 d)	18 (27.7)	26 (20.0)	.26
Renal failure	9 (13.8)	11 (8.5)	.28
Acute kidney injury (delta creatinine >100 μ mol/L or >50%)	30 (46.2)	46 (35.4)	.14
Any cerebrovascular accident	2 (3.1)	7 (5.4)	.44
Postoperative myocardial infarction	0 (0)	1 (0.8)	.32
Atrial fibrillation	27 (41.5)	63 (48.5)	.36
New pacemaker implantation	10 (15.4)	13 (10.0)	.33
Multiple organ failure	0 (0)	2 (1.5)	.15
Any 30-d morbidity	55 (84.6)	99 (76.2)	.17
Destination at discharge			.51

AVR, Aortic valve replacement; ICU, intensive care unit; LOS, length of stay.

complications in our cohort of patients who had a Perceval valve or in patients with a standard AVR, but our follow-up remains short.

A study by Folliguet and colleagues⁷ in 2012 reported the midterm results of a prospective, multicenter clinical study. They evaluated the safety and efficacy of the Perceval S valve in 208 patients undergoing AVR with or without concomitant procedures. The mean follow-up time was 10 ± 20 months. The mean preoperative and postoperative gradients were 48.6 ± 18.6 mm Hg and 10.4 ± 4.3 mm Hg, respectively, and preoperative and postoperative mean effective orifice areas were 0.7 ± 0.2 cm² and 1.4 ± 0.4 cm². During follow-up, 9 patients (4%) required reoperation for paravalvular regurgitation: 7 early and 2 late reoperations.⁷ This shows good long-term hemodynamic results and a small percentage of reoperation for paravalvular leak.

In 2014, Santarpino and colleagues¹⁶ published a propensity-matched study comparing the clinical and echocardiographic outcomes between patients undergoing transcatheter aortic valve implantation (TAVI) and sutureless AVR. Their results showed that in-hospital mortality was similar between the groups ($P = .24$), as well as pacemaker implantation ($P = .18$) and neurologic events. However, predischARGE echocardiographic data showed a higher paravalvular leak rate in the TAVI group: 13.5% versus 0% ($P = .027$). At a mean follow-up of 18.9 ± 10.1 months, overall cumulative survival was 91.9% and significantly differed between groups: sutureless 97.3% versus TAVI 86.5% ($P = .015$).¹⁶ A group from the Mayo Clinic recently published their experience with surgical or transfemoral AVR using the SAPIEN transcatheter heart valve in nonagenarians. Operative mortality was similar, but there was an increased risk of vascular injury in the group treated with TAVI. In this case, the Perceval valve could be an alternative to a less-extensive surgery, although we were not able to prove in this article that shorter bypass and crossclamp times resulted in less postoperative adverse outcomes.¹⁷ Gilmanov and colleagues¹⁸ also showed decreased bypass and crossclamp times. However, this did not translate into decreased hospital mortality or incidence of postoperative complications except for a shorter duration of mechanical ventilation in the Perceval group.^{18,19} Further studies need to be performed to construct a proper algorithm for patients in the “gray zone” among the conventional surgical AVR, sutureless AVR, and TAVI approaches.

In our study, 19% of patients had a sutureless valve implanted by mini-sternotomy or thoracotomy versus 8% in the SV group. Surgeons found that sutureless valves are easier to implant and more suitable for a minimally invasive approach compared with the standard stented prosthesis. Borger and colleagues¹⁹ recently published a randomized multicenter trial comparing the outcomes of a sutureless aortic valve implanted by a minimally invasive approach

with a standard AVR by full sternotomy. They concluded that the minimally invasive approach with the sutureless valve resulted in significantly reduced ischemic time and better hemodynamic function in small annuli with no adverse clinical outcomes.¹⁹

Other complications related to AVR, such as perioperative thromboembolic events, myocardial infarction, reexploration for bleeding, and renal failure requiring dialysis, were comparable to those published in the literature.^{5,7} Recent results by 2 European centers including 281 patients who underwent AVR with the Perceval S valve showed that the overall survival at a median follow-up of 8 months was 90% with in-hospital mortality of 0.7% and fewer postoperative complications.²⁰ This sutureless valve is a proven technology with short-term follow-up and could now be included in our armamentarium for the treatment of aortic valve disease. However, longer follow-up and larger trials are needed to discriminate which specific population will benefit the most from this valve.

Bypass time and crossclamp times were shorter in the Perceval group, and this could lead to fewer transfusions and shorter ICU, intubation, and hospitalization times, as suggested by several studies.^{1,3,4} In the current experience, we did not find significant differences in these clinical parameters, although performing an AVR with the Perceval prosthesis resulted in a shorter procedural time with no increased risk of complications. Moreover, there are certainly nonmeasured variables that could be different in the 2 groups, such as the Folstein test, the 5-m walk test, and some other frailty parameters that could not be assessed because of the retrospective aspect of this study.

The appropriate surgical indications for the use of sutureless prostheses are in progress. Minimally invasive approaches and heavily calcified and small aortic roots in elderly but operable patients remain significant technical challenges that could be addressed with these newer prostheses as opposed to standard sutured prostheses. Although sutureless prostheses are not an alternative to transcatheter AVR, it will become an interesting option for high-risk and elderly patients who require concomitant CABG procedures with immediate postimplantation results in term of absence of paravalvular leak.

Study Limitations

This study is retrospective and may have a selection bias because the choice of the prosthesis was left to the patients and surgeons.

CONCLUSIONS

AVR with the sutureless Perceval prosthesis resulted in shorter aortic crossclamp and bypass times compared with the stented biological valve. The reduced cardiopulmonary bypass and aortic crossclamp times obtained using the

Perceval prosthesis did not translate into perioperative gains in our elderly patient population.

Conflict of Interest Statement

Philippe Demers reports lecture fees from Sorin. All other authors have nothing to disclose with regard to commercial support.

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