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Research Article

Single-Center, Multisurgeon Experience with a Sutureless Rapid Deployment Aortic Valve Prosthesis: A Clinical Analysis in the United States

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Background. The Perceval S is a sutureless, bovine pericardial aortic prosthesis on a nitinol stent, which has limited data on outcomes, as well as cost, from the United States. *Methods*. We performed a retrospective review of Perceval S implantation at a single center between 2015 and 2018. After exclusion criteria, we compared 234 patients who underwent sutureless aortic valve (SLV) implantation with 370 patients who underwent standard sutured aortic valves (SAVR). Hospital cost data were reviewed, and risk adjustment, done by propensity score and inverse probability weighting, was used to compare outcomes. *Results*. Compared to those undergoing SAVR, the SLV group was older and had a higher proportion of multicomponent operations, higher preoperative white blood cell count, higher rate of previous percutaneous coronary interventions, more comorbid conditions (diabetes, renal insufficiency, and dialysis), and more three-vessel coronary disease. For isolated AVR, partial upper hemisternotomy was more frequent in SLV. The mean cardiopulmonary bypass and cross-clamp times for isolated SLV were significantly lower than SAVR. After adjustment, the cohort was balanced. Operative differences for SLV were lower cross-clamp and pump time, larger valve size, more minimally invasive approaches, and shorter operating room times. There were no differences in other postoperative complications (postoperative atrial fibrillation, stroke, renal failure, prolonged ventilation, and in-hospital mortality; $p > 0.05$ for all). Mean and median hospital costs were higher in the SLV group, largely due to the cost of the implant. *Conclusion*. Sutureless tissue aortic valves can be used safely with lower cardiopulmonary bypass and clamp times than sutured prostheses and facilitate use of minimally invasive approaches. This valve may be advantageous in older, higher risk patients requiring more complex operations.

1. Introduction

Interest and use of rapid deployment, sutureless aortic valve prosthesis technology has grown quickly in recent years. The Perceval S is a self-anchoring bovine pericardial aortic prosthesis mounted on a nitinol stent. This valve has been approved for use in Europe since January 2011, and it received FDA approval in January 2016 for use in the United States. The valve can be used in aortic annular diameters from 19 mm to 27 mm and is available in sizes small (19–21 mm), medium (21–23 mm), large (23–25 mm), and extralarge (25–27 mm).

European studies suggest use of the valve is safe, shortens time in the operating room, and results in acceptable short-term outcomes [1–3] A German study of 83 high risk patients (mean EuroSCORE 10 ± 8%) showed 1.2% significant

paravalvular leak rate, in-hospital mortality of 2.4%, 6% PPM rate, and 12-month survival of 98% [4]. A more recent study from Spain in 2017 examined 448 patients undergoing Perceval implantation with EuroSCORE 11 ± 8 and showed 0.9% paravalvular leak rate, 9% PPM rate, and 12-month survival 98% [5]. The Perceval valve was offered as an option for higher risk patients who may benefit from a shortened cross-clamp time. Over time it was found to be valuable in other settings such as facilitating minimally invasive approaches [6, 7], small annulus [8, 9], active endocarditis [10], reoperative operations [11], as a platform for future valve in valve transcatheter valve implantations [12, 13], and for use in calcified homografts and other hostile aortic root situations [14, 15].

There has been considerable international clinical data and some European cost data presented. However, there is little in the way of cost analysis from the United States. In this study, we sought to review our single-center experience with three surgeons using the Perceval valve. We examined our clinical data, as well as the available cost data, to better understand how this technology can fit into the toolbox of the United States' cardiac surgeons.

2. Materials and Methods

2.1. Data Source. This is a single-center analysis using data from the Northern New England Cardiovascular Disease Study Group (NNECDSG) cardiac surgery registry. Data in the NNECDSG registry are validated against billing data from each hospital every 2 years to ensure complete capture of cases and accurate vital status at discharge. The institutional review boards at all seven hospitals have designated the NNECDSG as a quality improvement registry. The cost data used are from the medical center's administrative database. Costs were linked to the registry using patient identifiers.

2.2. Patient Groups, Inclusion and Exclusion Criteria, and Operative Details. We identified 604 aortic valve surgery patients who had either a sutureless aortic valve (SLV) device or a sutured aortic valve (SAVR). These procedures were performed at a single institution between August 2015 and December 2018 by three surgeons who implanted both valve types.

Patients under 30 years, those receiving mechanical valves or homografts, those with endocarditis, those with an aortic dissection, mitral valve replacement, or emergency presentation (i.e., presenting to medical care and requiring surgical intervention within hours on an emergent basis), or those having interventions on more than one valve were excluded. Hospital cost data (including the implant cost) were also reviewed.

2.3. Study End Points. The primary end point of this study was all-cause mortality. Secondary endpoints were other postoperative outcomes such as atrial fibrillation, prolonged ventilation, stroke, renal failure, pleural effusion, need for a permanent pacemaker, and cost.

2.4. Statistical Analysis. Baseline patient and disease characteristics between groups were summarized using percentages for categorical variables and means or medians for continuous variables. Statistical tests included chi-squared test, Student's *t*-test, and Wilcoxon rank-sum test for continuous variables. An inverse probability weight propensity approach was used to reduce confounding between patients undergoing an AVR with a traditional prosthetic device (SAVR) compared to those with a sutureless device (SLV). The propensity score was developed using a nonparsimonious multivariable logistic regression model. The model included previously identified comorbid conditions and other relevant clinical characteristics based on experience and published literature and includes surgical procedure, age, sex, body surface area, preoperative white blood cell count, prior percutaneous coronary intervention, prior CABG or valve surgery, vascular disease, diabetes, chronic obstructive pulmonary disease, congestive heart failure, preoperative dialysis or creatinine >1.3 mg/dL or more, prior stroke, ejection fraction, three-vessel coronary disease, recent myocardial infarction (within 7 days), and acuity at time of operation [16].

All p values were two-sided, and $p < 0.05$ was considered statistically different. Absolute standardized differences of means (SMD) are reported for the comparison between the two groups. Difference values of SMD <0.1 are generally considered to indicate that groups are comparable with regards to a particular variable; in other words, SMD values greater than 0.1 can be assumed to represent a statistically significant difference between the weighted populations. All data were analyzed with Stata statistical software, version 17 (Stata Corp, College Station, TX).

3. Results

Table 1 demonstrates the clinical characteristics in the population before and after inverse probability weighting. Between August 2015 and December 2018, the baseline population had 234 patients underwent SLV and 370 underwent SAVR at our institution. The differences in crude populations were as follows: SLV patients were older (68.0 vs. 71.6, $p < 0.01$), more likely to have diabetes (31.9% vs. 40.6%, $p = 0.03$), and were more likely to have had prior PCI (10.3% vs. 20.1%, $p < 0.01$). Sutureless patients also had a higher rate of a history of dialysis or a baseline creatinine >1.3 mg/dL ($p < 0.004$), and higher white blood cell counts ($p = 0.05$). SLV patients were more likely to also have three-vessel disease ($p < 0.001$) and to undergo concomitant coronary artery bypass graft procedure ($p < 0.01$). After IPW, there were no statistical differences between the two groups.

Operative characteristics of the SAVR vs. the SLV groups with IPW weighting are shown in Table 2. After IPW, the SLV patients had larger mean valve size (SMD = 0.65) and had more patients undergoing minimally invasive approaches rather than full sternotomy (SMD = 0.45), shorter mean cross-clamp (SMD = 0.49), on-pump (SMD = 0.43), and total operating room times (SMD = 0.21).

Table 1: Preoperative characteristics of baseline and IPW-weighted populations in patients undergoing SLV vs. SAVR.

	Crude			Weighted characteristics after IPW		
	SAVR $N = 370$	SLV $N = 234$	p value*	SAVR	SLV	SMD
	N (%) or mean (SD)			Weighted % or mean (SE)		
Primary procedure						
Isolated valve	205 (55.4%)	95 (40.6%)	<0.01	49.2	48.9	0.012
CABG + valve	165 (44.6%)	139 (59.4%)		50.80	51.10	
Patient characteristics						
Age at surgery, years						
Mean (SD)	68.0 (9.7)	71.6 (8.3)	<0.01	69.5 (0.52)	70.2 (0.64)	0.08
<60	74 (20.0)	26 (11.1)	<0.01	16.4	15.8	0.015
60–69	132 (35.7)	68 (29.1)		32.7	32.7	0.002
70–79	132 (35.7)	102 (43.6)		38.7	39.3	0.012
>80	32 (8.7)	38 (16.2)		12.2	12.2	0.001
Female (%)	101 (27.3%)	73 (31.2%)	0.30	29.00	29.30	0.01
Body surface area, m^2						
Mean (SD)	2.0 (0.3)	2.0 (0.2)	0.31	2 (0.02)	2 (0.01)	0.018
<1.70	27 (7.3%)	24 (10.3%)	0.40	8.5	8.3	0.007
1.70–1.99	134 (36.2%)	86 (36.8%)		37	36.8	0.006
≥2.00	209 (56.5%)	124 (53.0%)		54.5	55	0.009
Disease characteristics						
Preoperative WBC count >12,000 mm^3	5 (1.4%)	9 (3.8%)	0.05	2	2.3	0.018
Prior CABG surgery	3 (0.8%)	3 (1.3%)	0.57	0.51	0.56	0.009
Prior valve surgery	13 (3.5%)	14 (6.0%)	0.15	4	4.4	0.006
Prior PCI	38 (10.3%)	47 (20.1%)	<0.01	14.8	15	0.006
Prior CVA	16 (4.3)	18 (7.7)	0.08	4.3	4.1	0.008
Preoperative atrial fibrillation	67 (18.1%)	49 (20.9%)	0.39	18.8	19	0.007
Comorbid disease						
Vascular disease	202 (54.6%)	114 (48.7%)	0.16	51.6	50.3	0.027
Diabetes	118 (31.9%)	95 (40.6%)	0.03	34.2	35.1	0.017
COPD	73 (19.7%)	50 (21.4%)	0.63	20.5	20	0.011
Smoker	45 (12.2%)	22 (9.4%)	0.29	11.6	9.6	0.067
Congestive heart failure	138 (37.3%)	88 (37.6%)	0.94	36.5	36.1	0.007
History of dialysis or creatinine >1.3 mg/dL	33 (8.9%)	39 (16.7%)	<0.001	13.1	12	0.008
Prior myocardial infarction ≤7 days	13 (3.5%)	15 (6.4%)	0.09	5.3	5.6	0.007
Three-vessel coronary disease	72 (18.3)	87 (32.8)	<0.01	14.7	15.2	
Ejection fraction (%)						
Mean (SD)	57.4 (10.1)	57.3 (9.3)	0.96	57.7 (0.51)	57.3 (0.69)	0.037
<40	28 (7.6%)	14 (6.0%)	0.43	6.9	6.8	0.002
40–49	20 (5.4%)	20 (8.5%)		5.3	6.9	0.064
50–59	126 (34.1%)	81 (34.6%)		34.1	34.9	0.017
≥60	196 (53.0%)	119 (50.9%)		53.8	51.4	0.048
Priority at surgery			0.11			
Urgent	86 (23.2%)	68 (29.1%)		25.4	25.4	0.001
Elective	284 (76.8%)	166 (70.9%)		74.6	74.6	0.001

SAVR: surgical aortic valve replacement; SD: standard deviation; SMD: standardized mean difference of the mean; CABG: coronary artery bypass graft surgery; WBC: white blood cell; PCI: percutaneous coronary intervention; COPD: chronic obstructive pulmonary disease; CVA: cerebrovascular accident and stroke. *p values obtained from chi-squared tests and two sample t-tests.

Table 3 examines patient outcomes by valve type after IPW adjustment. SAVR had a significantly higher mean total hours of ventilation (SMD = 0.21), CTICU length of stay (SMD = 0.21), and a higher rate of prolonged ventilation (SMD = 0.16). SLV had a higher rate of permanent pacemaker or ICD placement (SMD = 0.11). Other examined postoperative variables that showed no difference included blood transfusions, atrial fibrillation, stroke, in-hospital mortality, return to the OR for bleeding, renal failure, pleural effusion, and mean length of stay.

Table 4 represents our cost analysis after performing IPW. Hospital costs were higher for the SLV group, with a mean total cost of $78,945 (vs. $75,152 in SAVR and SMD = 0.118) and median total costs of $79,025 (vs. $75,512 in SAVR and SMD = 0.108). SLV had a higher cost than SAVR in the categories of room costs ($8,695 vs. %7,793 and SMD = 1.117) and respiratory costs ($3,374 vs. $2,835 and SMD = 0.141). Notably, the most significant cost difference was within the medical supplies total and subcategories; SLV had higher cost of valve implant ($16,568 vs. $11,163 and SMD = 1.078) as well as pacemaker costs ($7,040 vs. $6,889),

Table 2: Intraoperative characteristics of IPW-weighted populations in patients undergoing SLV vs. SAVR.

	SAVR Weighted % or mean (SE)	SLV	SMD
Operative characteristics			
Aortic valve size			
Mean (SE)	23.8 (0.14)	25.3 (0.12)	0.65
19–21 mm, small	25.2	3.9	0.65
22–23 mm, medium	29.1	21.8	0.17
24–25 mm, large	22.6	31.7	0.20
26–27 mm, extralarge	18.0	42.6	0.56
>27 mm	5.1	0.0	0.31
Operative approach			
Full sternotomy	91.7	75.6	0.45
Minimally invasive approaches	8.4	24.3	0.45
Cardioplegia use			
None	0.0	0.0	0.05
Blood	24.4	21.4	0.07
Crystalloid	0.3	1.2	0.12
Both	75.2	77.4	0.05
Cardioplegia delivery method			
None	0.2	0.0	0.05
Antegrade	18.3	28.9	0.25
Retrograde	3.4	1.8	0.10
Both	78.1	69.4	0.20
Mean cross-clamp time (minutes)	90.8 (2.14)	71.6 (2.64)	0.49
Mean pump time (minutes)	125.6 (2.9)	98.9 (3.3)	0.43
Mean OR time (hours)	5.1 (0.08)	4.4 (0.15)	0.21
Intraoperative blood transfusion	21.8	21.0	0.01

SAVR: surgical aortic valve replacement; SD: standard deviation; SMD: standardized mean difference of the mean; CABG: coronary artery bypass graft surgery. [a]Minimally invasive approaches include partial sternotomy, right or left parasternal incision, right thoracotomy, limited (mini) thoracotomy, and other thoracotomy procedures. $^*p$ values for dichotomous and categorical variables are corrected, weighted, Pearson chi-squared statistics that account for weighted data (design-based F statistic). $^*p$ values for continuous variables obtained from adjusted Wald tests.

Table 3: Postoperative characteristics of IPW-weighted populations in patients undergoing SLV vs. SAVR.

	SAVR Weighted % or mean (SD)	SLV	SMD
Postoperative characteristics			
Mean total ventilation (hours)	26.4 (5.8)	14.8 (2.5)	0.21
Mean CTICU length of stay (hours)	59.3 (6.5)	47.7 (3.9)	0.21
Postoperative blood transfusion	39.7	35.1	0.03
Atrial fibrillation	35.2	37.6	0.05
Permanent stroke	2.1	2.7	0.04
In-hospital mortality	0.9	0.5	0.105
Return to the OR for bleeding	11.4	8.7	0.13
Renal failure or insufficiency	0.5	0.0	0.09
Prolonged ventilation	11.5	7.0	0.16
Permanent pacemaker or ICD	6.8	10.0	0.11
Pleural effusion	16.9	16.4	0.01
Mean length of stay (days)	7.5 (0.34)	6.7 (0.31)	0.03

SAVR: surgical aortic valve replacement; SLV: sutureless valve; SD: standard deviation; SMD: standardized mean difference of the mean; CABG: coronary artery bypass graft surgery; CTICU: cardiothoracic intensive care unit.

Table 4: Cost analysis of IPW-weighted populations in patients undergoing SLV vs. SAVR.

	SAVR	SLV	SMD
Total hospital costs (in USD)			
Mean (SD)	75,152	78,945	0.118
Median (IQR)	75,512	79,025	0.108
Itemized costs (in USD)			
Room costs, total	7,793	8,695	0.117
Pharmacy	6,889	7,074	0.031
Medical supplies, total	29,632	32,873	0.443
Pacemaker	6,889	7,040	0.275
Implant	11,163	16,568	1.078
ICU costs	12,461	12,256	0.021
Lab costs	2,457	2,312	0.072
Radiology	961	1,012	0.063
Operating room, total	9,088	8,466	0.147
RBC transfusion costs	294	205	0.187
Respiratory	2,835	3,374	0.141
Cardiology	2,034	1,993	0.039
Other services	112	107	0.022
Other costs	164	242	0.152

SAVR: surgical aortic valve replacement; SLV-: sutureless valve; IQR: interquartile range; SD: standard deviation; SMD: standardized mean difference; USD: United States dollar; CABG: coronary artery bypass graft surgery.

leading to a total medical supplies cost of $32,873 in SLV vs. $29,632 in SAVR (SMD = 0.443). SAVR had a higher cost than SLV in just two categories: total operating room cost ($9,088 vs. $8,466 and SMD = 0.147) and RBC transfusion costs ($294 vs. $205 and SMD = 0.187).

4. Discussion

This study presents an examination of a single-center adoption of a sutureless valve, the Perceval, in a United States' center. Like other studies, we showed shorter cardiopulmonary bypass and aortic cross-clamp times with good outcomes. Hospital costs were found to be higher for patients that received SLV when compared to SAVR. Inverse probability weighting allowed us to effectively compare outcomes in this situation where patients undergoing one intervention (SLV) were more likely to have more comorbidities and be more frail than those receiving the other intervention (SAVR). Table 1 demonstrates that in crude analysis, SLV patients were indeed more likely to have comorbid conditions (i.e., prior PCI, prior CVA, three-vessel disease, a history of dialysis, or baseline creatinine >1.3 mg/dL). In the IPW analysis, there were no statistically significant differences in baseline characteristics between the SLV and SAVR, indicating the new populations were effectively weighted.

The Europeans have a longer and more extensive experience with SLV that has been quite favorable. In reviewing that the literature in the early reports in isolated AVR using SLV were encouraging, showing safety and good hemodynamic results [4, 17]. In the Cavalier trial, Perceval valves were placed in 628 patients in several European centers from 2010 to 2013 with a mean cross-clamp time of 32 minutes and postoperative mean gradient of about 10 mmHg [18]. Thirty-day overall and valve-related mortality rates were 3.7% and 0.5%, respectively. The valve explant rate was 0.6%, and stroke rate was 2.1%. Five year data were presented by Shrestha et al. in 2016 and showed similar short-term outcomes in 731 patients undergoing AVR from 2007 to 2012 [19]. There was a 1% incidence of late major paravalvular leak. Early mortality was about 2%, at 1 year was 8%, and at 5 years was 25%. The average mean gradient at 5 years was 7.8 mmHg.

The postoperative mean gradients reported in studies of sutureless valves are interesting and may suggest an implanting learning curve. When an oversized SLV is placed, the mean gradient may be elevated due to decreased leaflet excursion. In a large German registry review of over 20,000 patients undergoing isolated SAVR, three alternative valves (sutureless or rapid deployment models) were compared. The Perceval valve was less likely to be a smaller-sized valve (≤21 mm) (Perceval 10% of patients, balloon expandable INTUITY valve (Edwards Lifesciences, Irvine, California) 25%, and self-expanding, nitinol-based 3F Enable valve (Medtronic, Dublin, Ireland) 27%; $p < 0.001$). The median postoperative mean aortic valve gradient was the highest in the Perceval (14 mmHg, INTUITY 9 mmHg and Enable 10 mmHg; $p < 0.001$), and permanent pacemaker was the highest with Perceval (11%, INTUITY 7% and Enable 7%; $p < 0.02$) [20]. We also found that SLV patients, on average, had higher proportions receiving larger valves, and overall had a higher mean valve size (Table 2). However, it is noted that SAVR had all cases of a valve implanted that was >27 mm, as 27 mm is the largest valve (extralarge) size available for the Perceval SLV valve. It is common for surgeons to place the largest valve possible, but right-sizing of this valve allows for optimal hemodynamics and avoidance of permanent pacemaker. Subsequent studies have shown the PPM rate can be reduced by changes in the implantation technique [21]. In our experience, this PPM rate decrease came along with a change in the implantation technique that was introduced in 2018. We began to decrease the depth at which the guiding sutures were placed so that they were less into the nadir of the sinuses, especially in the right coronary cusp, to prevent the valve from sitting deeper in the left ventricular outflow tract, thus less likely to impinge on the conduction system. It was also felt to be important to fully debride the region to avoid calcium damage to the conduction system [22].

In terms of comparisons to stented surgical valves, a 2014 study compared Perceval to Carpentier–Edwards Perimount aortic prostheses showing lower CPB and cross-clamp times with SLV [23]. The postoperative peak gradients were lower with SLV, but the average mean gradients were not different in similarly sized valves (approximately 23 mm for both groups). There was no difference in PPM rates in this small study. A 2015 study from France compared hemodynamic performance of small Perceval prostheses in elderly patients with larger size Perceval valves and found no difference in postoperative mean gradient (10.3 mmHg for small valves and 11.3 mmHg for medium and large valves; $p = 0.20$), indexed effective orifice area (0.84 cm^2/m^2 for small and 0.86; $p = 0.76$), or presence of patient prosthesis mismatch (absent in 45% vs. 43%, moderate in 45% vs. 39% and severe in 10% vs. 20%; $p = 0.6$) [24]. At a median follow-up of 1.5 years, the echo measurements and survival also did not differ.

This discussion would not be complete without also addressing another option for aortic valve replacement: transcatheter aortic valve replacement (TAVR). Trials in low-risk patients with severe aortic stenosis have shown that transcatheter aortic valve replacement (TAVR) is at least comparable in short-term outcomes when compared to surgical aortic valve replacement [25, 26]. It was found that TAVR resulted in less stroke, bleeding, atrial fibrillation, and shorter length of stay with similar valve performance at one year. However, there has not been a randomized control trial directly comparing sutureless valves and TAVR to date. Several retrospective studies comparing SLV to older TAVR technology showed TAVR at a disadvantage due to higher rates of vascular complications, paravalvular leak, permanent pacemaker, and renal failure. Since then, these complications have been largely mitigated with advancements in TAVR technology. Interestingly, two studies with midterm patient-matched outcome data showed no difference in survival at one year, but a survival advantage for Perceval at two years; 97.3% vs. 86.5%, $p = 0.015$ and 94.9% vs. 79.5%, $p = 0.02$ [27, 28]. There is interest in understanding how TAVR will compare with SLV in mid- and long-term outcomes.

In our study, SLV patients were more likely to have undergone a minimally invasive procedure rather than a full sternotomy (24.3% minimally invasive in SLV vs. just 8.4% in the SAVR group, SMD = 0.45). Several studies have previously demonstrated that sutureless valve technology facilitates minimally invasive approaches. Prior to the introduction of SLV at our center, upper hemisternotomy was performed for SAVR in patients who were deemed appropriate per surgeon discretion. SLV facilitated further use of minimally invasive techniques, including right anterior thoracotomy. The Sutureless and Rapid Deployment International Registry published results of 1935 patients undergoing SAVR with sutureless and rapid deployment valves and showed 73% were implanted in a minimally invasive fashion [29]. In contrast, overall use of mini approaches to SAVR has been reported to be 15% in the United States, 12% in the United Kingdom, and 25% in Germany [30]. It is clear that for SAVR to compete, surgeons should work to improve outcomes and utilize minimally invasive approaches for patients who are not currently candidates for transcatheter technology.

There have been concerns raised about possible complications associated with sutureless valve technology, particularly regarding reports of increased paravalvular leak

in the early experience [31]. The cause of paravalvular leak is often due to incorrect sizing of the valve. There is certainly a learning curve associated with new valve technology and ensuring proper sizing is important. It has been the practice of our group to not accept more than trace paravalvular leak on the intraoperative postimplant echocardiogram. Migration is extremely rare, but has been reported—two clinical situations have been described. The first is in double, aortic, and mitral valve replacement where the two prostheses interact and the sutureless valve becomes unstable [32]. There appears to be potentially predictive factors including a short aorticomitral curtain (<6 mm) and the angle of the aorta and mitral annuli. The second is infective endocarditis after sutureless valve placement [10]. If there is a large annular abscess, the valve may become unstable and at risk of migration. Our experience with a single case has suggested that early surgery in these cases may be beneficial.

Durability of SLV implantation is being studied as well. It has been shown in the European literature that the 5-year durability data are reasonable. In a 2016 multicenter paper, Shrestha et al. showed a late (more than 30 days after implant) explant rate of 1.5%, major paravalvular leak rate of 1%, endocarditis 1.6%, and AV block in 1.4% [19]. In a series of 486 consecutive patients at Leuven University Hospital, Dr. Meuris et al. found that there were no explants for structural valve degeneration [22]. In our current series, no valves have been explanted for structural valve degeneration. However, it does appear that sutureless valves will offer a good platform for the future valve in valve TAVR as it is essentially a stentless valve [12]. For a small Perceval valve, a 23 mm Edwards S3 TAVR valve can be considered.

There are economic considerations when using new technology, and to date, there has been few data shown on cost in the United States for this procedure. Sutureless valves often cost more than standard aortic prostheses. A study from Germany showed the use of sutureless valves resulted in lower cost based on savings in diagnostics and hospital length of stay [33]. At our institution, during the study period, the overall mean cost for SLV valve implantation was $3,793 more than SAVR (Table 4). This was indeed a statistically significant difference, though it is worth noting that this mean cost difference represents just a 5% increase from the SAVR cost. We found that in matched cohorts, the largest difference in cost was within the medical supplies' category, both with a higher cost of the SLV implant itself, as well as higher costs for pacemakers within the SLV group (Table 4). The patients in the SLV group were older, sicker, and more likely to have undergone more complex operations, logically leading to higher overall costs. Unfortunately, our cost data were complete only for overall medical supplies cost, which always included valve cost, but did not have enough data points which separated valve cost specifically from the larger category of medical supplies' cost. However, despite this, the overall OR time, cross-clamp, and CPB times were all higher in the SAVR group. Given the results of cost difference analysis after IPW, we hypothesize these differences are due to the SLV implant being more expensive, as well as an overall higher rate of need for multicomponent operations, permanent pacemaker, or ICD, leading to further higher costs in the medical supplies' category, as well as the other costs' category, which included professional fees.

5. Limitations

There are limitations to this study inherent to this type of investigation. It is a retrospective review based on prospectively collected data. We examined data from three surgeons performing both types of aortic valve implantation concurrently, but there may be remaining bias despite inverse probability weighting. Early in the experience with SLV, there was a conscious decision to place the valve in older and sicker patients. As the outcomes were shown to be good and experience improved, the SLV was used in a wider patient population. There was also an ongoing learning curve and changes to the implantation technique, as evidenced by decreasing need for PPM. Finally, cost data were not as granular as necessary for a full analysis on cost breakdowns, allowing only for our limited analysis.

6. Conclusion

We present an analysis on the clinical adoption of the implantation of sutureless prostheses in the United States and have demonstrated acceptable short-term outcomes as compared to standard aortic valve replacement. These sutureless valves also facilitate the use of minimally invasive approaches and result in lower cardiopulmonary bypass and cross-clamp times, which may be beneficial for more frail patient populations or those undergoing multicomponent operations. SLV demonstrated a marginal, though still statistically significant, increase in cost. We feel this valve offers another tool for surgeons in an era of TAVR growth [34].

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

M.P. Robich is the speaker of Bureau/Honoraria LivaNova. R. Quinn is the consultant/Advisory Board, CryoLife, LivaNova.

References

[1] W. Flameng, M.-C. Herregods, H. Hermans et al., "Effect of sutureless implantation of the perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes," *The Journal of Thoracic and Cardiovascular Surgery*, vol. 142, no. 6, pp. 1453–1457, 2011.

[2] M. Shrestha, T. Folliguet, B. Meuris et al., "Sutureless perceval S aortic valve replacement: a multicenter, prospective pilot trial," *Journal of Heart Valve Disease*, vol. 18, no. 6, pp. 698–702, 2009.

[3] M. Shrestha, N. Khaladj, C. Bara, K. Hoeffler, C. Hagl, and A. Haverich, "A staged approach towards interventional aortic valve implantation with a sutureless valve: initial

human implants," *Thoracic & Cardiovascular Surgery*, vol. 56, no. 07, pp. 398–400, 2008.

[4] G. Santarpino, S. Pfeiffer, J. Schmidt, G. Concistrè, and T. Fischlein, "Sutureless aortic valve replacement: first-year single-center experience," *The Annals of Thoracic Surgery*, vol. 94, no. 2, pp. 504–509, 2012.

[5] E. Berastegui García, M. L. Camara Rosell, F. Estevez Cid et al., "Perceval less invasive aortic replacement register: multicentric Spanish experience with the perceval S bioprosthesis in moderate–high-risk aortic surgery," *Interactive Cardiovascular and Thoracic Surgery*, vol. 26, no. 4, pp. 596–601, 2018.

[6] T. Fischlein, S. Pfeiffer, J. Sirch, F. Vogt, G. Santarpino, and F. Pollari, "Sutureless valve implantation via mini J-sternotomy: a single center experience with 2 Years mean follow-up," *Thoracic & Cardiovascular Surgery*, vol. 63, no. 6, pp. 467–471, 2015.

[7] G. Santarpino, F. Pollari, S. Pfeiffer, and T. Fischlein, "Sorin perceval S aortic valve implantation through a mini-sternotomy approach," *Annals of Cardiothoracic Surgery*, vol. 4, no. 2, pp. 191-192, 2015.

[8] I. Belluschi, S. Moriggia, A. Giacomini et al., "Can perceval sutureless valve reduce the rate of patient-prosthesis mismatch?" *European Journal of Cardio-Thoracic Surgery*, vol. 51, no. 6, pp. 1093–1099, 2017.

[9] P. Dedeilias, N. G. Baikoussis, E. Prappa, D. Asvestas, M. Argiriou, and C. Charitos, "Aortic valve replacement in elderly with small aortic root and low body surface area; the perceval S valve and its impact in effective orifice area," *Journal of Cardiothoracic Surgery*, vol. 11, no. 1, p. 54, 2016.

[10] E. Roselló-Díez, G. Cuerpo, F. Estévez et al., "Use of the perceval sutureless valve in active prosthetic aortic valve endocarditis," *The Annals of Thoracic Surgery*, vol. 105, no. 4, pp. 1168–1174, 2018.

[11] G. Santarpino, S. Pfeiffer, G. Concistrè, and T. Fischlein, "REDO aortic valve replacement: the sutureless approach," *Journal of Heart Valve Disease*, vol. 22, no. 5, pp. 615–620, 2013.

[12] U. Landes, A. Sagie, and R. Kornowski, "Transcatheter aortic valve implantation in degenerative sutureless perceval aortic bioprosthesis," *Catheterization and Cardiovascular Interventions*, vol. 91, no. 5, pp. 1000–1004, 2018.

[13] N. Mangner, D. Holzhey, M. Misfeld, and A. Linke, "Treatment of a degenerated sutureless sorin Perceval® valve using an Edwards SAPIEN 3," *Interactive Cardiovascular and Thoracic Surgery*, vol. 26, no. 2, pp. 364–366, 2018.

[14] G. A. Chiariello, E. Villa, A. Messina et al., "Perceval valve-in-valve implant for full root xenograft failure," *Journal of Cardiac Surgery*, vol. 32, no. 9, pp. 567–570, 2017.

[15] A. Lio, A. Miceli, M. Ferrarini, and M. Glauber, "Perceval S valve solution for degenerated freestyle root in the presence of chronic aortic dissection," *The Annals of Thoracic Surgery*, vol. 101, no. 6, pp. 2365–2367, 2016.

[16] E. R. Nowicki, N. J. O. Birkmeyer, R. W. Weintraub et al., "Multivariable prediction of in-hospital mortality associated with aortic and mitral valve surgery in Northern New England," *The Annals of Thoracic Surgery*, vol. 77, no. 6, pp. 1966–1977, 2004.

[17] T. A. Folliguet, F. Laborde, K. Zannis, G. Ghorayeb, A. Haverich, and M. Shrestha, "Sutureless perceval aortic valve replacement: results of two European centers," *The Annals of Thoracic Surgery*, vol. 93, no. 5, pp. 1483–1488, 2012.

[18] F. Laborde, T. Fischlein, K. Hakim-Meibodi et al., "Clinical and haemodynamic outcomes in 658 patients receiving the perceval sutureless aortic valve: early results from a prospective European multicentre study (the cavalier trial)," *European Journal of Cardio-Thoracic Surgery*, vol. 49, no. 3, pp. 978–986, 2016.

[19] M. Shrestha, T. Fischlein, B. Meuris et al., "European multicentre experience with the sutureless perceval valve: clinical and haemodynamic outcomes up to 5 Years in over 700 patients," *European Journal of Cardio-Thoracic Surgery*, vol. 49, no. 1, pp. 234–241, 2016.

[20] S. Ensminger, B. Fujita, T. Bauer et al., "Rapid deployment versus conventional bioprosthetic valve replacement for aortic stenosis," *Journal of the American College of Cardiology*, vol. 71, no. 13, pp. 1417–1428, 2018.

[21] F. Vogt, A. M. Dell'Aquila, and G. Santarpino, "How to prevent pacemaker implantation after sutureless aortic valve replacement: tips and tricks," *The Annals of Thoracic Surgery*, vol. 104, no. 2, pp. 720-721, 2017.

[22] D. Szecel, R. Eurlings, F. Rega, P. Verbrugghe, and B. Meuris, "Perceval sutureless aortic valve implantation: midterm outcomes," *The Annals of Thoracic Surgery*, vol. 111, no. 4, pp. 1331–1337, 2021.

[23] K. C. König, T. Wahlers, M. Scherner, and J. Wippermann, "Sutureless perceval aortic valve in comparison with the stented carpentier-edwards Perimount aortic valve," *Journal of Heart Valve Disease*, vol. 23, no. 2, pp. 253–258, 2014.

[24] E. Villa, A. Messina, F. Laborde et al., "Challenge for perceval: aortic valve replacement with small sutureless valves--a multicenter study," *The Annals of Thoracic Surgery*, vol. 99, no. 4, pp. 1248–1254, 2015.

[25] M. J. Mack, M. B. Leon, V. H. Thourani et al., "Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients," *New England Journal of Medicine*, vol. 380, no. 18, pp. 1695–1705, 2019.

[26] J. J. Popma, G. M. Deeb, S. J. Yakubov et al., "Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients," *New England Journal of Medicine*, vol. 380, no. 18, pp. 1706–1715, 2019.

[27] A. D'Onofrio, S. Salizzoni, A. S. Rubino et al., "The rise of new technologies for aortic valve stenosis: a comparison of sutureless and transcatheter aortic valve implantation," *The Journal of Thoracic and Cardiovascular Surgery*, vol. 152, no. 1, pp. 99–109, 2016.

[28] A. Miceli, D. Gilmanov, M. Murzi et al., "Minimally invasive aortic valve replacement with a sutureless valve through a right anterior mini-thoracotomy versus transcatheter aortic valve implantation in high-risk patients," *European Journal of Cardio-Thoracic Surgery*, vol. 49, no. 3, pp. 960–965, 2016.

[29] P. Berretta, M. Andreas, T. P. Carrel et al., "Minimally invasive aortic valve replacement with sutureless and rapid deployment valves: a report from an international registry (sutureless and rapid deployment international registry)," *European Journal of Cardio-Thoracic Surgery*, vol. 56, no. 4, pp. 793–799, 2019.

[30] C. P. Young, S. Sinha, and H. A. Vohra, "Outcomes of minimally invasive aortic valve replacement surgery," *European Journal of Cardio-Thoracic Surgery*, vol. 53, no. 2, pp. ii19–ii23, 2018.

[31] F. Fleissner, U. Molitoris, M. Shrestha, and A. Martens, "Stent distortion after sutureless aortic valve implantation: a new complication seen with a novel surgical technique," *Interactive Cardiovascular and Thoracic Surgery*, vol. 20, no. 3, pp. 436–438, 2015.

[32] M. Rossi, L. Cristodoro, D. Roger, V. Pennisi, G. Pisano, and P. Fratto, "Double valve failure due to perceval sutureless

aortic valve migration," *Journal of Heart Valve Disease*, vol. 27, no. 1, pp. 124–126, 2018.

[33] F. Pollari, G. Santarpino, A. M. Dell'Aquila et al., "Better short-term outcome by using sutureless valves: a propensity-matched score analysis," *The Annals of Thoracic Surgery*, vol. 98, no. 2, pp. 611–617, 2014.

[34] K. Ohlrich, M. Robich, C. Raymer et al., *Single Center, Multi-Surgeon Experience with a Sutureless Rapid Deployment Aortic Valve Prosthesis: A Clinical and Economic Analysis in the United States*, Authorea, New York City, NY, USA, 2022.