Single center, multi-surgeon experience with a sutureless rapid deployment aortic valve prosthesis: A clinical and economic analysis in the United States

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Abstract

Background The Perceval S is a sutureless, rapid deployment, bovine pericardial aortic prosthesis on a nitinol stent, which has limited data on outcomes and 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 262 patients who underwent sutureless aortic valve (SLV) implantation with 394 patients who underwent standard sutured aortic valves (SAVR). Hospital cost data was reviewed, and risk adjustment, done by propensity score and inverse probability weighting, was used to compare outcomes. Results The SLV group was older, had more females, and had a higher proportion of multicomponent operations. For isolated AVR, partial upper hemisternotomy was more frequent in SLV. The median cardiopulmonary bypass and cross clamp times for isolated SLV were significantly lower than SAVR. SLV had a risk-adjusted 11.3% permanent pacemaker (PPM) rate vs 6.1% in SAVR (p=0.016). There were no differences in other postoperative complications (postoperative atrial fibrillation, stroke, renal failure, prolonged ventilation; P>.05 for all). Mortality at any time did not differ between groups. Median hospital costs were higher in the SLV group, likely due to permanent pacemaker rate leading to longer length of stay. 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 with cost neutrality. This valve may be advantageous in older, higher risk patients requiring complex operations.

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Background

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Methods

We performed a retrospective review of Perceval S implantation at a single center between 2015 and 2018. After exclusion criteria, we compared 262 patients who underwent sutureless aortic valve (SLV) implantation with 394 patients who underwent standard sutured aortic valves (SAVR). Hospital cost data was reviewed, and risk adjustment, done by propensity score and inverse probability weighting, was used to compare outcomes.

Results

The SLV group was older, had more females, and had a higher proportion of multicomponent operations. For isolated AVR, partial upper hemisternotomy was more frequent in SLV. The median cardiopulmonary bypass and cross clamp times for isolated SLV were significantly lower than SAVR.

SLV had a risk-adjusted 11.3% permanent pacemaker (PPM) rate vs 6.1% in SAVR (p=0.016). There were no differences in other postoperative complications (postoperative atrial fibrillation, stroke, renal failure, prolonged ventilation; P>.05 for all). Mortality at any time did not differ between groups. Median hospital costs were higher in the SLV group, likely due to permanent pacemaker rate leading to longer length of stay.

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 with cost neutrality. This valve may be advantageous in older, higher risk patients requiring complex operations.

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 extra-large (25-27 mm). Early European studies suggested use of the valve was safe, shortened times in the operating room and resulted in acceptable short term outcomes.¹⁻³

In a study from Germany of 83 high risk patients (mean EuroSCORE $10\pm8\%$) showed 1.2% significant paravalvular leak rate, in-hospital mortality of 2.4%, 6% PPM rate, and 12 month survival of 98%.⁵ A more modern study from Spain in 2017 examined 448 patients undergoing Perceval implantation with EuroS-CORE 11±8, and showed 0.9% paravalvular leak rate, 9% PPM rate, and 12 month survival 98%.⁶ 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 approaches7,8, small annulus9,¹⁰, active endocarditis¹¹, re-operative operations¹², as a platform for future valve in valve transcatheter valve implantations^{13,14}, and use in calcified homografts and other hostile aortic root situations^{15,16}.

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 where the financial impact of adopting new technology is becoming more important. In this study we sought to review our single center experience with three surgeons using the Perceval valve. We examined our clinical and cost data to better understand how this technology can fit into the toolbox of cardiac surgeons in the United States in an era of increasing TAVR volume.

Materials and Methods

Data Source Patients for this study were drawn 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 but one of the seven hospitals have designated the NNECDSG a quality improvement registry, and, for this reason, patient consent is waived. The last hospital obtains patient consent. For information about patient survival beyond hospital discharge, the NNECDSG data were linked to the National Death Index (through 2001) and the Social Security Administration Master Death File with complete data through the end of 2010. In 2012, the NNECDSG became a certified user of the Social Security Administration data and, as such, receives monthly updates of death data as well as death data from the departments of vital statistics of Maine, New Hampshire, and Vermont.

Patient Groups and Operative Details

We compared 262 patients who underwent sutureless aortic valve (SLV) implantation with 394 patients who underwent standard sutured aortic valves (SAVR). These operations occurred between August 2015 and December 2018 and were performed by three surgeons who use both valve types at a single institution. Patients with mechanical valves or homografts and those with endocarditis, aortic dissection or emergency presentation were excluded. Hospital cost data (including the valve cost) were reviewed.

Study End Points

The primary end point of this study was all-cause mortality among patients undergoing aortic valve replacement. In addition, we examined whether mortality outcomes differed based on type of operation and type of valve used for the operation. Other outcomes studied included operative times, postoperative morbidity (reoperation for bleeding, perioperative stroke, acute kidney injury, mediastinitis or sternal dehiscence, pneumonia, and prolonged ventilation), and length of hospitalization.

Statistical Analysis

Baseline characteristics between groups were compared by using the c2 test for categorical variables and the Wilcoxon rank-sum test for continuous variables. To account for differences between groups, a nonparsimonious, multivariable propensity model was used. The model included surgical procedure, age, sex, body surface area, preoperative white blood cell count, prior percutaneous coronary intervention, vascular disease, diabetes, chronic obstructive pulmonary disease, congestive heart failure, preoperative dialysis or creatinine of 2 mg/dL or more, New York Heart Association class 4, prior stroke, ejection fraction, left main stenosis 50% or greater, three-vessel coronary disease, recent myocardial infarction (within 7 days), acuity at time of operation, and hospital where operation was performed. Standardized differences (std dif) of means are reported for the comparison between the two groups in the unadjusted and inverse probability weighting adjusted data. Hazard ratios (HRs) and 95% confidence limits were generated by using Cox proportional hazard regression models. All data were analyzed with Stata statistical software, version 14.1 (Stata Corp, College Station, TX).

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 265 patients undergo SLV and 394 underwent SAVR at our institution, the IPW weighted population had 258 patients undergo SLV and 394 undergo SAVR. In the baseline population, SLV patients had a greater mean age and were more likely to have had prior PCI (p<0.001), diabetes (p=0.01), a history of dialysis or creatinine >1.3 mg/dL (p=0.006), prior MI (p=0.008), or three-vessel disease (p<0.001). They were also more likely to have undergone a concomitant CABG with their SLV procedure (p<0.001). With these characteristics weighted after IPW, there were only significant differences found between SLV and SAVR regarding three characteristics; SLV patients were more likely to have prior PCI (p=0.01), prior CVA (p=0.05), and a history of three vessel disease (p=0.02).

Operative characteristics of the SLV and SAVR groups with IPW weighting are shown in Table 2. In the baseline population, SLV patients larger mean valve size (p<0.001), had more patients undergo minimally invasive approaches versus full sternotomy (p<0.001), shorter cross-clamp (p<0.001), on-pump (p<0.001), and total OR times (p=0.025).

There were few significant postoperative characteristic differences between the two groups, which are reflected in Table 3. The baseline population differed significantly only with SLV patients having a higher rate of rhythm disturbance requiring a permanent device permanent pacemaker or ICD (p=0.016), and longer median length of stay (p<0.001). The weighted population differed significantly in only one aspect; the SAVR group had a longer mean total ventilation time when compared to SLV (p=0.04). There was no difference in permanent pacemaker rate (10.7% in SLV vs 6.3% in SAVR, p=0.06). The pacemaker rate in the SLV group decreased over the study period from 14% to 4.2%. There was also no difference in length of stay.

Table 4 represents our cost analysis. In the crude analysis, hospital costs were higher for the SLV group, with a mean total cost of \$71,600 (vs \$61,100 in SAVR, p=0.018) and median total costs of \$57,390 (vs \$46,700 in SAVR, p<0.001). For isolated valve procedure, the mean cost was \$43,650 for SLV and \$38,914 in SAVR (p=0.003). For CABG with valve procedure, the SLV group had a mean cost of \$61,487, while the SAVR group had a mean cost of \$53,777 (p=0.07). The cost subcategories in which SLV had higher costs were room costs (p<0.001), pharmacy (p<0.001), total medical supplies (p<0.001) (including sterile supply and implant costs), ICU costs (p=0.002), radiology (p<0.001), respiratory (p<0.001), professional fees (p=0.005), and other costs (p=0.022). After IPW, there were no differences in median cost (\$68,023 in SLV and \$62,676 in SAVR; p=0.20).

Discussion

This study presents the first examination of cost data on sutureless, rapid deployment values in the United States. Like many studies we showed shorter cardiopulmonary bypass and aortic cross clamp times with good outcomes. Also shown was an initially high permanent pacemaker rate that declined over time. Hospital costs between SLV and standard sutured values were not different.

Overall, outcomes with SLV have been good. The Europeans have a longer and more extensive experience. In reviewing that literature the early reports in isolated AVR were encouraging, showing safety and good hemodynamic results.^{4,5} In the Cavalier Trial,¹⁷ 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 post-operative mean gradient of about 10 mmHg. 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 2012.¹⁸ There was a 1% incidence of late major paravalvular leak. Early mortality was about 2%, 1 year 8% and 5 year was 25%. The average mean gradient at 5 years was 7.8 mmHg.

The post-operative mean gradients reported in studies of rapid deployment valves are interesting and may suggest a 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 rapid deployment valves 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<.001). The median postoperative mean aortic valve gradient was highest in the Perceval (14 mmHg, INTUITY 9 mmHg and Enable 10 mmHg; P<.001), and permanent pacemaker was highest with Perceval (11%, INTUITY 7% and Enable 7%; P<.02). 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 implantation technique.¹⁹

Comparisons have been made to stented surgical valves and transcatheter aortic valve replacements (TAVR). A 2014 study compared Perceval to Carpentier-Edwards Perimount aortic prostheses showing lower CPB and cross-clamp times with SLV.²⁰ The post-operative 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 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 post-operative mean gradient (10.3 mmHg for small valves and 11.3 mmHg for medium and large valves; P=.20), indexed effective orifice area ($0.84 \text{ cm}^2/\text{m}^2$ for small and 0.86; P=.76) or presence of patient prosthesis mismatch (absent in 45% v. 43%, moderate in 45% v. 39% and severe in 10% v. 20%; P=0.6). At a median follow up of 1.5 years the echo measurements and survival did not differ. This suggests that a stentless valve in the small aortic root can provide good hemodynamics.²¹

Recently published industry sponsored clinical 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.^{22,23}In both trials TAVR resulted in less stroke, bleeding, atrial fibrillation and shorter length of stay with similar valve performance at one year. The type of surgical valve used in these trials was left to the surgeon, and it is not clear if certain prostheses have any advantage. There have been no randomized control trials comparing sutureless valves to date. Several retrospective studies comparing older TAVR technology showed some advantages to SAVR with sutureless valves (lower rates of vascular complications, paravalvular leak, permanent pacemaker, and renal failure) which have been largely mitigated with advancements in TAVR technology. Interestingly, two studies with mid-term 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 = .015 and 94.9% vs. 79.5%, P = $.02.^{24,25}$ There is great interest in understanding how TAVR will compare with SAVR in mid- and long-term outcomes. Similar to our findings, a number of studies have demonstrated that sutureless valve technology facilitates minimally invasive approaches. 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.²⁶ In contrast, overall use of mini approaches to SAVR have been reported to be 15% in the United States, 12% in the United Kingdom and 25% in Germany.²⁷ 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. There have been reports of paravalvular leak, especially in the early experience.²⁸ 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 post implant echocardiogram. Thrombocytopenia has also been described. In one study the average platelet count at discharge after Perceval implantation was 102,000 +- 28,000 which was significantly lower than Edwards Intuity rapid deployment valve.²⁹ Another study compared Perceval (n=72 patients) to Perimount Magna Ease (n=101 patients) and showed a greater maximum drop in platelet count at a mean of post-operative day 2.3 (58% in Perceval vs. 44% in Magna Ease; P=.0001), less likely recovery to pre-operative levels by discharge (26% in Perceval and 44% in Magna Ease; P=.018), and more red blood cell (P=.007) and platelet (P=.009) transfusion with Perceval. We did not appreciate a significant difference in bleeding rates or transfusion, and often treated the thrombocytopenia expectantly if there were no bleeding complications. Migration is extremely rare, but has been reported.³⁰ 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. There appears to be potentially predictive factors including a short aorticomitral curtain (< 6 mm) and the angle of the aorta and mitral annuli. These factors are currently being studied. The second is infective endocarditis after sutureless valve placement. 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 the valve is being studied as well. It has been shown in the European literature that the 5-year durability data is reasonable. In a 2016 multicenter paper, Shrestha et al.¹⁸ 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%. At the 2019 American Association for Thoracic Surgery annual meeting Dr. Meuris presented 11-year data on 486 consecutive patients at Leuven University Hospital. In their series there were no explants for structural valve degeneration. The manuscript and additional long-term data are pending. 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 future valve in valve TAVR as it is essentially a stentless valve.³¹ For a small Perceval valve a 23 mm Edwards S3 TAVR valve can be considered.

There are economic considerations when using new technology, and date there have been no data on cost in the United States for this procedure. Sutureless and rapid deployment valves often cost more than standard aortic prostheses. At our institution, during the study period, the Perceval valve cost approximately \$5,670 more than sutured valves. A study from Germany showed use of sutureless valves resulted in lower cost based on savings in diagnostics and hospital length of stay.³² In our current study we found that a higher pacemaker rate incurred extra cost. There have been excellent descriptions of techniques to reduce pacemaker rate³³, and our group has been able to continue decreasing the need to post-operative permanent pacemakers.

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 on ongoing learning curve and changes to the implantation technique, as evidenced by decreasing need for PPM.

Conclusion

We present the first analysis on cost of the implantation of sutureless valves compared with standard aortic valve prostheses in the United States and have demonstrated acceptable short-term outcomes. These rapid deployment valves also facilitate the use of minimally invasive approaches and result in lower cardiopulmonary bypass and cross-clamp times, which may be beneficial in older patients and higher-risk multicomponent operations. We have also demonstrated cost neutrality, and the decreasing incidence of heart block over

time likely due to changes in implantation technique. We feel this valve offers another tool for surgeons in an era of TAVR growth.

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vs SAVR							
	Baseline	Baseline	Baseline	Baseline	Weighted characte		
	Perceval	SAVR	p-value*	SMD	Perceval		
	N = 265	N = 394			N = 258		
	N (%) or Mean	(SD)			Weighted $\%$ or		
Primary procedure		. ,	< 0.001	0.307	-		
Isolated valve	107 (40.4)	219(55.6)			45.63		
CABG + valve	158 (59.6)	175(44.4)			54.37		
Age at surgery, years							
			0.001	0.400			

Table 1 – Preoperative characteristics of baseline and IPW-weighted populations in patients undergoing SLV

	Perceval $N = 265$	$\begin{array}{l} \mathbf{SAVR} \\ \mathbf{N} = 394 \end{array}$	p-value*	SMD	Perceval $N = 258$
	N (%) or Mean (SD)		0.001	0.007	Weighted % or
Primary procedure	107(40.4)	910 (FF c)	< 0.001	0.307	45 69
Isolated valve	107 (40.4) 159 (50 c)	219(55.6)			45.03
CABG + valve	158(59.6)	175(44.4)			54.37
Age at surgery, years	71.6.(9.2)	(0, 0, (0, 7))	<0.001	0.409	70.00 (0.50)
Mean (SD)	(1.0 (8.3))	68.0(9.7)	< 0.001	0.408	$70.82 \ (0.56)$
< 50	2(0.8)	13(3.3)	<0.001	-0.181	0.0
50 - 59	26(9.8)	05(10.5)		-0.198	11.98
60 - 69	79(29.8)	143(36.3)		-0.138	33.13
70 - 79	116(43.8)	140(35.5)		0.169	41.68
80	42 (15.8)	33 (8.4)		0.23	12.61
Female (%)	86(32.5)	112(28.4)	0.27	0.087	30.72
Body Surface Area (BSA), m ²					
Mean (SD)	2.0(0.2)	2.0(0.3)	0.33	-0.079	2.02(0.01)
< 1.70	29 (10.9)	31 (7.9)	0.38	0.105	9.51
1.70-1.99	98 (37.0)	145(36.8)		0.004	39.41
2.00	138(52.1)	218 (55.3)		-0.065	51.08
Disease characteristics		<i>.</i>			
Preoperative WBC count $> 12,000 \text{ mm}^3$	9(3.4)	5(1.3)	0.063	0.141	2.18
Prior CABG surgery	4(1.5)	4(1.0)	0.57	0.044	1.12
Prior valve surgery	17(6.4)	18(4.6)	0.3	0.081	5.68
Prior PCI	52(19.6)	40(10.2)	< 0.001	0.268	18.77
Comorbid disease					
Preoperative atrial fibrillation	61 (23.0)	79(20.1)	0.36	0.072	21.5
Vascular disease	$127 \ (47.9)$	215 (54.6)	0.094	-0.133	49.11
Diabetes	122 (31.0)	107 (40.4)	0.013	0.197	36.31
COPD	57(21.5)	82~(20.8)	0.83	0.017	20.73
Smoking	27 (10.2)	48(12.2)	0.43	-0.063	10.47
Congestive Heart Failure	111 (41.9)	154 (39.1)	0.47	0.057	38.92
History of dialysis or creatinine >1.3	43 (16.2)	36(9.1)	0.006	0.21	2.85
Prior CVA	22 (8.3)	20(5.1)	0.096	0.129	8.84
Prior Myocardial Infarction			0.008		
No	190(71.7)	323 (82.0)		-0.167	73.83
7 days	17(6.4)	17(4.3)		0.093	5.62
> 7 days	58 (21.9)	54(13.7)		0.135	20.55
Left main stenosis $[?]$ 50%	42 (15.8)	47(11.9)	0.15	0.113	14.5
Three-vessel disease	87 (32.8)	72 (18.3)	< 0.001	0.338	30.41
Ejection fraction (%)		× ,			
Mean (SD)	56.4(10.2)	57.4(10.1)	0.23	-0.096	56.87(0.67)
< 40	21 (7.9)	29 (7.4)	0.34	0.021	7.21
40-49	24(9.1)	24(6.1)		0.112	7.93
50-59	96 (36.2)	133(33.8)		0.052	36.38
60	124 (46.8)	208(52.8)		-0.12	48.48
	()	()			

	Baseline	Baseline	Baseline	Baseline	Weighted characte
Priority at surgery			0.074	-0.141	
Urgent	82 (30.9)	97(24.6)			27.02
Elective	183 (69.1)	297(75.4)			72.98

Table 2- Intraoperative characteristics of baseline and IPW-weighted populations in patients undergoing SLV vs $\rm SAVR$

Operative charactertistics Aortic Valve Size Mean (SD) 19 - 21mm, small 22-23mm, medium 24-25mm, large 26-27mm, extra-large > 27mmOperative approach Full sternotomy Minimally invasive approaches^a Cardioplegia used None BloodCrystalloid Both Cardioplegia delivery method None Antegrade RetrogradeBoth Median cross-clamp time (minutes) Median pump time (minutes) Median OR Time (hours) Intraoperative blood transfusion Abbreviation: savr - surgical aortic valve replacement; sd - standard deviation; smd - standardized mean difference; cabg: c ^aminimally invasive approaches include partial sternotomy, right or left parasternal incision, right thoracol p-values obtained from chi-squared tests, wilcoxon rank-sum tests, or two sample t-tests as appropriate p-values for dichotomous and categorical variables are corrected, weighted, pearson chi-squared statistics that account for w

p-values for continuous variables obtained from adjusted wald tests

Table 3- Postoperative characteristics of baseline and IPW-weighted populations in patients undergoing SLV vs $\rm SAVR$

Mean total ventilation (hours) Mean CTICU length of stay (hours) Median CTICU length of stay (hours) Postoperative blood transfusion Atrial fibrillation Permanent stroke In-hospital Mortality Renal failure or insufficiency (new STS defn) Prolonged ventilation Permanent pacemaker or ICD Pleural effusion Median Length of stay (days)

Abbreviation: savr - surgical aortic valve replacement; sd - standard deviation; smd - standardized mean difference; cabg: c *aminimally invasive approaches include partial sternotomy, right or left parasternal incision, right thoracol* p-values obtained from chi-squared tests, wilcoxon rank-sum tests, or two sample t-tests as appropriate p-values for disheterment and externational variables are corrected, weighted partial sternotomy chi squared tests that account for weighted partial sternotomy.

p-values for dichotomous and categorical variables are corrected, weighted, pearson chi-squared statistics that account for w p-values for continuous variables obtained from adjusted wald tests

Table 4- Cost analysis of baseline (crude) populations in patients undergoing SLV vs SAVR

Total hospital costs (in \$10,000s) Mean (SD) Median (IQR) By Procedure: Isolated valve CABG + valveItemized costs (in \$s) Room costs, total Semi-private (two beds) Recovery room Pharmacy Medical supplies, total General Sterile supply Pacemaker Other implant ICU costs Lab costs Radiology Operating room, total General Minor surgery Anesthesia RBC transfusion costs, mean (SD)

Respiratory Emergency Room, mean (SD) Cardiology EKG/EEG Other services, mean (SD) Professional fees Other costs, mean (SD)

Abbreviations: SAVR - Surgical Aortic Valve Replacement; IQR - interquartile range; SD - standard deviate Overall missing cost data: 47 semi-private room, 447 recovery room, 8 general medical supplies, 128 sterile medical supplies p-values obtained from chi-squared tests, Wilcoxon rank-sum tests, or two sample t-tests as appropriate Overall missing cost data: 47 semi-private room, 447 recovery room, 8 general medical supplies, 128 sterile medical supplies p-values obtained from chi-squared tests, Wilcoxon rank-sum tests, or two sample t-tests as appropriate Overall missing cost data: 47 semi-private room, 447 recovery room, 8 general medical supplies, 128 sterile medical supplies p-values obtained from chi-squared tests, Wilcoxon rank-sum tests, or two sample t-tests as appropriate Overall missing cost data: 47 semi-private room, 447 recovery room, 8 general medical supplies, 128 sterile medical supplies p-values obtained from chi-squared tests, Wilcoxon rank-sum tests, or two sample t-tests as appropriate Overall missing cost data: 47 semi-private room, 447 recovery room, 8 general medical supplies, 128 sterile medical supplies p-values obtained from chi-squared tests, Wilcoxon rank-sum tests, or two sample t-tests as appropriate Overall missing cost data: 47 semi-private room, 447 recovery room, 8 general medical supplies, 128 sterile medical supplies p-values obtained from chi-squared tests, Wilcoxon rank-sum tests, or two sample t-tests as appropriate