

Article

Outcomes of Pledged versus Nonpledged Suture Technique for Isolated Aortic Valve Replacement

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Abstract

Objective: To compare outcomes of pledged versus nonpledged suture techniques for aortic valve replacement (AVR). **Methods:** This was a retrospective study utilizing an institutional database of AVRs performed at our center between 2010 and 2020. All patients who underwent isolated surgical AVR were included, while those who underwent concomitant procedures were excluded. Patients were dichotomized into those who underwent pledged vs. nonpledged AVR, and 1:1 propensity score matching (PSM) was employed. Clinical and echocardiographic outcomes were compared. Kaplan-Meier survival estimation and Cox regression were performed. Cumulative incidence functions were generated for all-cause readmissions and for heart-failure readmissions. Freedom from major adverse cardiac and cerebrovascular events (MACCE) were also analyzed and compared using Kaplan-Meier methods. **Results:** A total of 2240 patients were identified. PSM yielded 892 matched pairs. Mean gradient was significantly higher in the pledged group ($p < 0.001$), but patients in this group had a smaller median valve size implanted. There were no significant differences in paravalvular leak rates. Kaplan-Meier survival estimates, cumulative incidence of readmissions, and freedom from MACCE were not significantly different between groups. **Conclusion:** Long-term survival, readmission rates, and freedom from MACCE are comparable after pledged and nonpledged AVR. There were no differences in paravalvular leak rates between the two techniques.

Keywords

pledged; aortic valve; AVR

Introduction

Aortic valve replacement (AVR) prevails as the mainstay of therapy for severe aortic stenosis. As indications for transcatheter aortic valve replacement (TAVR) expand and this less invasive strategy becomes more popular, it becomes increasingly critical to consider the lifetime management of the aortic valve when counselling patients through a decision between TAVR and surgical aortic valve replacement (SAVR). This consideration for SAVR is particularly relevant for young patients with small annuli. Thus, investigating and optimizing SAVR outcomes is as important as ever. While several studies have looked at the effect of valve prosthesis type on SAVR outcomes [1–4], fewer studies have focused on the surgical technique of valve implantation. Implantation of conventional surgical valves may be performed through 3 different suture techniques: continuous suture, simple interrupted (nonpledged) sutures, or interrupted, pledged horizontal mattress sutures. Theoretical tradeoffs between techniques include speed, size of prosthesis that may be implanted, risk of paravalvular leak, and durability, especially in the setting of a fragile or heavily calcified annulus. While a number of studies have investigated continuous suture technique, comparing it with more conventional techniques, fewer studies have specifically looked at the effects of pledget use during AVR [5–9]. Optimal technique for valve implantation is still debated among surgeons, and use of pledged or nonpledged sutures is one of the technical aspects that still lacks consensus due to conflicting findings in the literature [10,11]. In order to better understand the impact of pledged or nonpledged technique on postoperative outcomes including paravalvular leak rates, readmission rates, and freedom from major adverse cardiac and cerebrovascular events (MACCE), we present a large, propensity-matched study of our institutional experience with pledged versus nonpledged AVR.

Patients and Methods

Patient Population and Study Design

This was a retrospective, observational study utilizing an institutional database of surgical aortic valve replacements performed at our center between 2010 and 2020. Inclusion criteria involved all patients who had an isolated surgical aortic valve replacement, including elective, urgent, and emergent AVR. In order to minimize confounding, to specifically study the impact of surgical technique on outcomes of AVR and to minimize differences in operative characteristics, we excluded patients who underwent concomitant operations such as coronary artery bypass grafting or mitral valve surgery. Definitions and terminology were consistent with the Society of Thoracic Surgeons (STS) database. This study was approved by the Institutional Review Board of the University of Pittsburgh on 4/17/2019 (STUDY18120143), with written consent being waived.

The study aimed to compare clinical and echocardiographic outcomes between patients who underwent pledgeted versus nonpledgeted AVR. Long-term survival, all-cause readmissions, and heart failure readmissions were compared between the two groups. Follow-up data was obtained from the clinical warehouse that contains all long-term survival data for patients undergoing cardiac and aortic surgery at the University of Pittsburgh Medical Center.

Statistical Methods and Analysis

Primary stratification was between the pledgeted AVR group and the nonpledgeted AVR group. Due to differences in baseline characteristics, propensity score matching (PSM) was performed using 1:1 greedy nearest neighbor matching without replacement and with a caliper of 0.2 of the standard deviation of the Logit propensity score. Logistic regression was used to calculate the propensity score based on the following baseline characteristics: age, sex, body mass index, diabetes, hypertension, chronic obstructive pulmonary disease, peripheral vascular disease, cerebrovascular disease, heart failure, arrhythmia, status, redo cardiac surgery, ejection fraction, creatinine, and prosthetic valve type. After matching, analysis accounted for the matched pairs. McNemar's test was used to assess the statistical significance of the risk difference for categorical variables, and the student's *t*-test or Wilcoxon signed rank test was used for continuous variables. Standardized mean differences were calculated and reported. Continuous variables were presented as mean \pm standard deviation for normally distributed data or median and interquartile range (IQR) for non-normally distributed data. Categorical data were reported by frequency and percentage.

Unadjusted survival estimates were generated using Kaplan-Meier methods and compared using cluster log-

rank statistics. A Cox proportional hazards regression model was used for the multivariable analysis of mortality. The assumption of proportional hazards was validated using Schoenfeld residuals, and model fit statistics were compared in a stepwise fashion until the smallest Akaike information criterion (AIC) was achieved. Cumulative incidence functions were generated for all-cause readmissions and for heart-failure readmissions, where death was treated as a competing risk. Kaplan Meier methods were also used to analyze freedom from major adverse cardiac and cerebrovascular events (MACCE), including revascularization, myocardial infarction, stroke, or death. All statistical analyses were performed using SAS/STAT Version 15.2 (SAS Institute Inc., Cary, NC, USA). All tests were 2-sided with an alpha level of 0.05 designated to indicate statistical significance.

Operative Techniques

Following median sternotomy, aortic and right atrial cannulation were performed. A retrograde cardioplegia catheter was placed. Cardiopulmonary bypass was instituted, and a left ventricular vent was placed through the right superior pulmonary vein. A root vent was also placed. The aorta was cross clamped, and cardioplegia was administered. A transverse aortotomy was performed. Commissural traction sutures were placed. The valve leaflets were excised and the annulus was debrided. The annulus was sized, and an appropriately sized prosthesis was selected.

For pledgeted AVR, an interrupted non-everting mattress suture technique was used in all cases. For nonpledgeted AVR, either an interrupted technique with multiple non-everting sutures or a continuous suture technique was used, as described in prior studies [12]. The pledgeted suture technique was performed using multiple pledgeted 2-0 Ti-Cron™ (Covidien, Dublin, Ireland) sutures placed in a non-everting fashion. In the nonpledgeted group, either an interrupted technique or a continuous suture technique was performed. The interrupted technique was performed using multiple non-pledgeted non-everting 2-0 Ti-Cron sutures, while the running technique was performed using two or three 2-0 polypropylene sutures placed at each commissure. Each end of the suture was then passed through the sewing ring of the prosthetic valve until the nadir of the sinus where the suture from the adjacent sinus was met. The valve was seated, the sutures were tightened and the valve was secured by tying down the knots. After ensuring no coronary obstruction, the aortotomy was closed in two layers. The patient was then weaned from bypass.

Results

A total of 2240 patients were identified, 1096 of whom underwent pledgeted AVR and 1144 of whom underwent nonpledgeted AVR (**Supplementary Table 1**). PSM yielded 892 matched pairs. Results of PSM are displayed

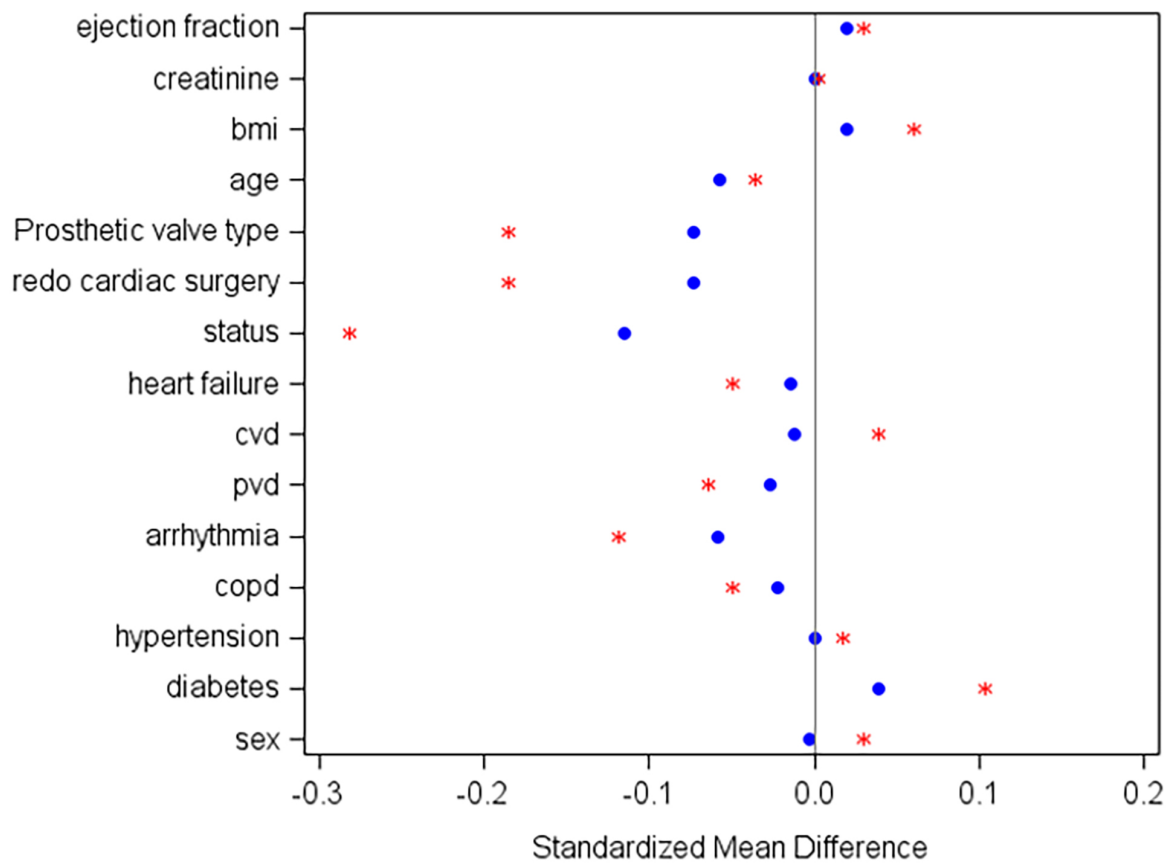


Fig. 1. LOVE plot displaying results of PSM. * unmatched, ● matched. bmi, body mass index; cvd, cerebrovascular disease; pvd, peripheral vascular disease; copd, chronic obstructive pulmonary disease; PSM, propensity score matching.

Table 1. Baseline characteristics after PSM.

Variable	Nonpledgeted (n = 892)	Pledgeted (n = 892)	SMD before matching	SMD after matching
Age	70.00 [62.00–77.0]	68.00 [60.00–77.0]	0.04	0.06
Sex (female)	335 (37.56%)	334 (37.44%)	0.03	0.00
Diabetes	275 (30.83%)	291 (32.62%)	0.10	0.04
Hypertension	736 (82.51%)	736 (82.51%)	0.02	0.00
Chronic obstructive pulmonary disease	203 (22.76%)	195 (21.86%)	0.05	0.02
Peripheral vascular disease	119 (13.34%)	111 (12.44%)	0.12	0.03
Cerebrovascular disease	165 (18.50%)	161 (18.05%)	0.06	0.01
Heart failure	284 (31.84%)	278 (31.17%)	0.04	0.01
Arrhythmia	151 (16.93%)	132 (14.80%)	0.12	0.06
Status			0.28	0.12
Elective	698 (78.25%)	654 (73.32%)		
Urgent	176 (19.73%)	225 (25.22%)		
Emergent	18 (2.02%)	13 (1.46%)		
Redo cardiac surgery	207 (23.21%)	180 (20.18%)	0.19	0.07
Body mass index	28.90 [25.46–34.0]	29.40 [25.90–33.7]	0.06	0.02
Ejection fraction	58.00 [55.00–63.0]	58.00 [53.00–63.0]	0.02	0.03
Creatinine	1.00 [0.80–1.20]	0.98 [0.80–1.10]	0.01	0.00
Prosthetic valve type			0.19	0.07
Bioprosthetic	630 (70.63%)	642 (71.97%)		
Mechanical	156 (17.49%)	159 (17.83%)		
Unknown	106 (11.88%)	91 (10.20%)		

PSM, propensity score matching; SMD, standardized mean difference.

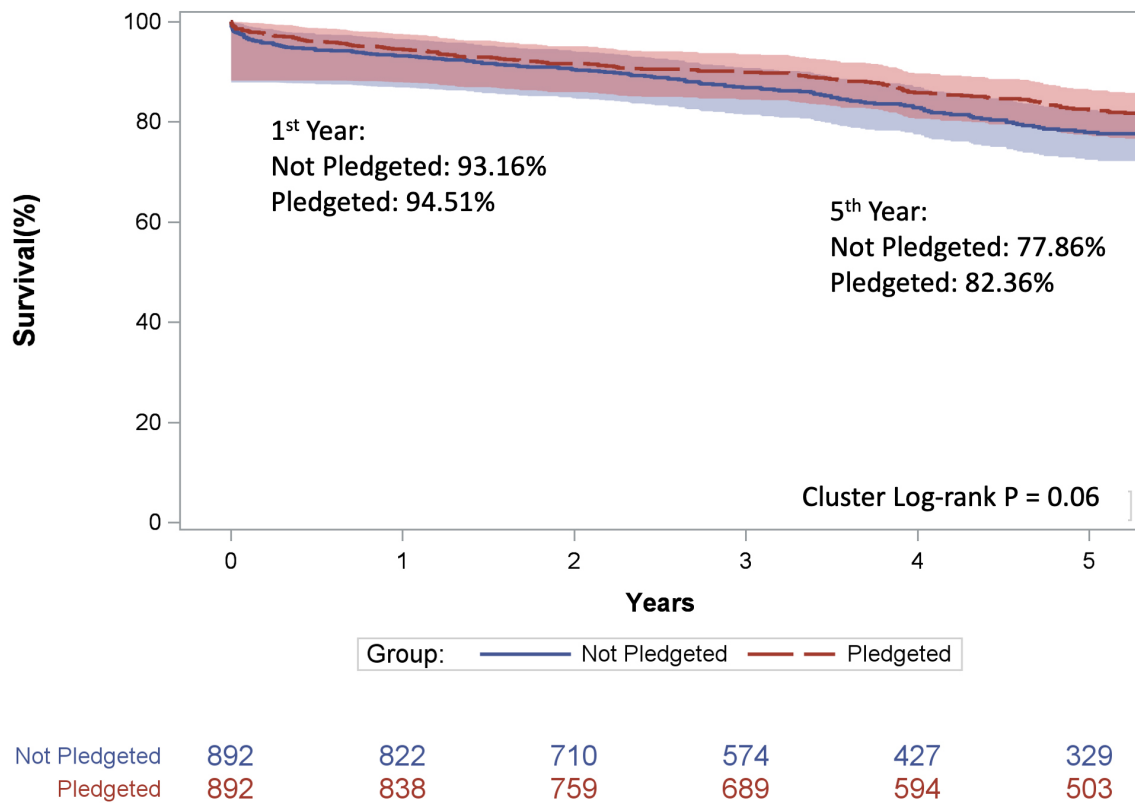


Fig. 2. Kaplan-Meier survival estimates for matched cohorts of pledgeted and nonpledgeted aortic valve replacement (AVR).

in a LOVE plot (Fig. 1). Out of the 15 baseline variables that were matched on, standardized mean difference (SMD) was ≤ 0.1 for 14 of the variables and was < 0.15 for the remaining variable, indicating well-balanced groups (Table 1). Additionally, AIC for the model was 2922.13 and C-statistic was 0.677.

Median STS predicted risk of mortality score in the nonpledgeted group was 1.91 [1.17–3.30] and in the pledgeted group was 1.64 [1.01–2.90], ($p < 0.001$). Intraoperative variables are displayed in Table 2. Median valve size implanted in the nonpledgeted group was 25.0 [23.0–27.0] compared to 23.0 [21.0–25.0] in the pledgeted group ($p < 0.001$). In the nonpledgeted group, cardiopulmonary bypass time was 89.0 [65.0–120.0] minutes and cross clamp time was 67.0 [46.0–92.0] minutes, compared to 98.0 [83.0–118.0] and 76.0 [64.0–92.0] minutes, respectively, in the pledgeted group ($p < 0.001$).

Postoperative outcomes in the unmatched cohort are reported in **Supplementary Table 2**, while outcomes in the matched cohort are summarized in Table 3. After matching, operative mortality was higher in the nonpledgeted group (3.25% vs. 1.79%, $p = 0.050$). Patients in the nonpledgeted group were also significantly more likely to undergo reoperation for any cause in the postoperative period (7.85% vs. 5.27%, $p = 0.028$). There were no statistically significant differences in rates of blood product use, stroke, acute renal failure, atrial fibrillation, or prolonged mechanical ventilation. Mean gradient was significantly higher in the pledgeted

group ($p < 0.001$), but patients in this group had a smaller median valve size implanted. There were no significant differences in paravalvular leak (PVL) rates.

Follow-up in the matched cohort was 5.46 [3.21–7.30] years in the pledgeted group and 3.80 [2.34–6.49] years in the nonpledgeted group ($p < 0.001$). Kaplan Meier survival estimates comparing the matched groups demonstrated a trend towards increased survival in the pledgeted AVR group at 5 years (82.36% vs. 77.86%), though this did not reach statistical significance (Fig. 2, $p = 0.06$ cluster log-rank). Similarly, on multivariable Cox regression, pledgeted AVR was associated with a decreased hazard of death as compared to nonpledgeted AVR, though this was not statistically significant (Table 4, hazard ratio (HR): 0.85, 95% confidence interval (CI): 0.71–1.03, $p = 0.09$).

Competing-risk cumulative incidence estimates of all-cause readmissions were comparable in the matched groups (Fig. 3, $p = 0.08$), as were cumulative incidence estimates of heart-failure readmissions (Fig. 4, $p = 0.43$). Kaplan-Meier curves showing freedom from MACCE at 1 and 5 years were also comparable between groups in the matched sample (Fig. 5, $p = 0.60$, cluster log-rank).

In order to assess for any potential time bias in this study, we conducted a sub-analysis on outcomes of pledgeted and nonpledgeted AVR by year. **Supplementary Tables 3,4** display outcomes of this subanalysis. **Supplementary Table 3** displays number and percentage of nonpledgeted and pledgeted AVRs per year. Pledget use increased

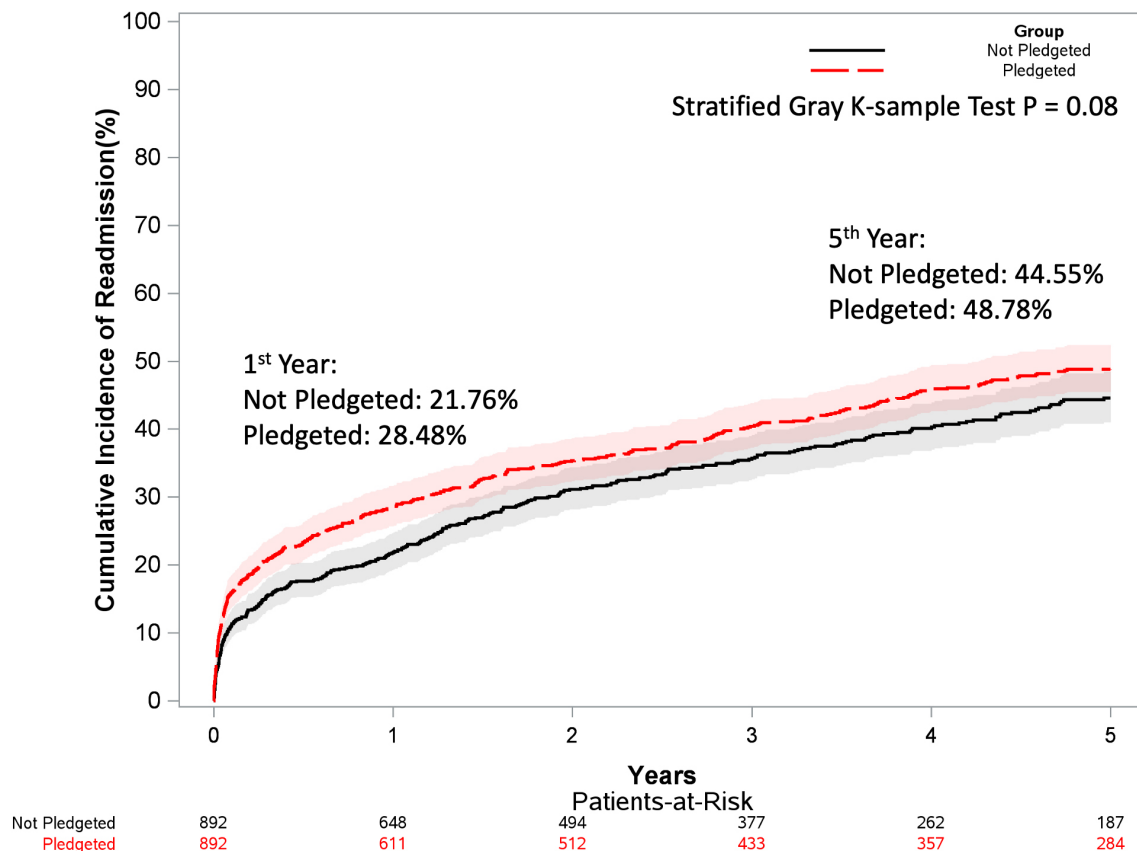


Fig. 3. Cumulative incidence function for all-cause readmissions among matched cohorts of pledged and nonpledged AVR.

Table 2. Intraoperative variables in the propensity-matched groups.

Variable	Nonpledged (n = 892)	Pledged (n = 892)	p-value
Prosthetic valve type			0.53
Bioprosthetic	630 (70.63%)	642 (71.97%)	
Mechanical	156 (17.49%)	159 (17.83%)	
Unknown	106 (11.88%)	91 (10.20%)	
Median valve size	25.0 [23.0–27.0]	23.0 [21.0–25.0]	<0.001
Cardiopulmonary bypass time	89.0 [65.0–120.0]	98.0 [83.0–118.0]	<0.001
Cross clamp time	67.0 [46.0–92.0]	76.0 [64.0–92.0]	<0.001

per year until 2016. After 2016, the nonpledged technique became increasingly utilized while use of the pledged technique decreased. On comparison of mortality, readmissions, and heart failure readmissions, we found no temporal relationships between the surgical methods in each year.

Discussion

This was a large, single-center propensity matched study comparing outcomes of AVR using a pledged versus nonpledged suture technique. Operative mortality in this entire cohort of isolated AVRs was 2.3% (52/2240) [13]. Kaplan-Meier estimates and Cox regression demonstrated a trend towards increased survival and a decreased hazard of death, respectively, for pledged AVR, though these findings did not reach statistical significance. Cumulative in-

cidence of readmissions and freedom from MACCE were comparable between the matched groups. There were also no significant differences in PVL rates, and the overall rate of moderate-severe PVL in the entire matched cohort was less than 1%.

The appeal for a nonpledged technique stems from reduced operative times and less foreign material in the outflow tract, potentially reducing transvalvular gradients; however, a primary concern with this strategy is the potential for an increased risk of PVL. While our study found no differences in PVL in the matched cohorts, patients in the nonpledged group had higher operative mortality and all-cause reoperation rates in the short-term. One potential explanation for the differences in these immediate post-operative outcomes is variation between surgeons. Since individual surgeons typically tend to perform AVRs using

Table 3. Postoperative clinical and echocardiographic outcomes after PSM.

Variable	Nonpledgeted (n = 892)	Pledgeted (n = 892)	p-value
Operative mortality (STS definition)	29 (3.25%)	16 (1.79%)	0.050
Reoperation (for any cause)	70 (7.85%)	47 (5.27%)	0.028
Blood product transfusion	251 (28.14%)	264 (29.60%)	0.497
Stroke	17 (1.91%)	12 (1.35%)	0.349
Prolonged ventilation (>24 hrs)	75 (8.41%)	54 (6.05%)	0.055
New-onset renal failure	29 (3.25%)	18 (2.02%)	0.104
Atrial fibrillation	338 (37.89%)	335 (37.56%)	0.883
Length of stay (days)	6.00 [5.00–10.00]	7.00 [5.00–10.00]	0.033
Mean aortic valve gradient	8.00 [6.00–11.00]	11.00 [8.00–15.10]	<0.001
Aortic Regurgitation			0.010
Trace	190 (21.30%)	133 (14.91%)	
Mild	64 (7.17%)	73 (8.18%)	
Moderate	11 (1.23%)	21 (2.35%)	
Severe	4 (0.45%)	4 (0.45%)	
Paravalvular leak			0.199
Trace	16 (1.79%)	25 (2.80%)	
Mild	8 (0.90%)	15 (1.68%)	
Moderate	2 (0.22%)	4 (0.45%)	
Severe	1 (0.11%)	3 (0.34%)	
Ejection fraction	55.00 [55.00–60.00]	55.00 [52.50–60.00]	0.134

STS, Society of Thoracic Surgeons.

Table 4. Cox multivariable regression for mortality.

Variable	Hazard Ratio	95% Confidence Interval	p-value
Pledgeted (ref: nonpledgeted)	0.85	0.71, 1.03	0.09
Female sex (ref: male)	1.13	0.93, 1.37	0.22
Diabetes	1.23	1.02, 1.49	0.03
Chronic obstructive pulmonary disease	1.38	1.13, 1.69	<0.001
Arrhythmia	1.14	0.89, 1.47	0.30
Peripheral vascular disease	1.34	1.07, 1.69	0.01
Cerebrovascular disease	1.62	1.31, 1.99	<0.001
Heart failure	1.44	1.18, 1.76	<0.001
Status (ref: elective)			<0.001
Urgent	1.80	1.48, 2.20	
Emergent	2.56	1.43, 4.58	
Age	1.02	1.01, 1.03	<0.001
Creatinine	1.17	1.10, 1.24	<0.001
Cross clamp time	0.99	0.99, 1.00	0.001
Cardiopulmonary bypass time	1.01	1.01, 1.01	<0.001

AIC = 6585.8.

the same technique (i.e., pledgeted or nonpledgeted) every time, we cannot control for the effect of operator variability and experience in this matched study. A previous unmatched single-center study of smaller sample size comparing pledgeted and nonpledgeted AVR also found no differences in PVL rates between the two techniques. Operative mortality in that series was 3.1% for pledgeted AVR vs. 2.5% for nonpledgeted ($p = 0.66$), and the group thus concluded that nonpledgeted AVR is safe and equivalent to pledgeted AVR [10].

Another important question is whether the risk of prosthesis-patient mismatch differs using these two suture techniques for AVR. A recent experimental study found that the use of pledgets during AVR had a negative impact on hemodynamic performance by causing flow disturbances, which resulted in increased mean gradients and decreased effective orifice areas [14]. Indeed, lower rates of moderate-severe prosthesis-patient mismatch have been demonstrated in patients with small annuli who underwent nonpledgeted, as compared to pledgeted, AVR [11]. Moreover, when compared to a simple interrupted suture tech-

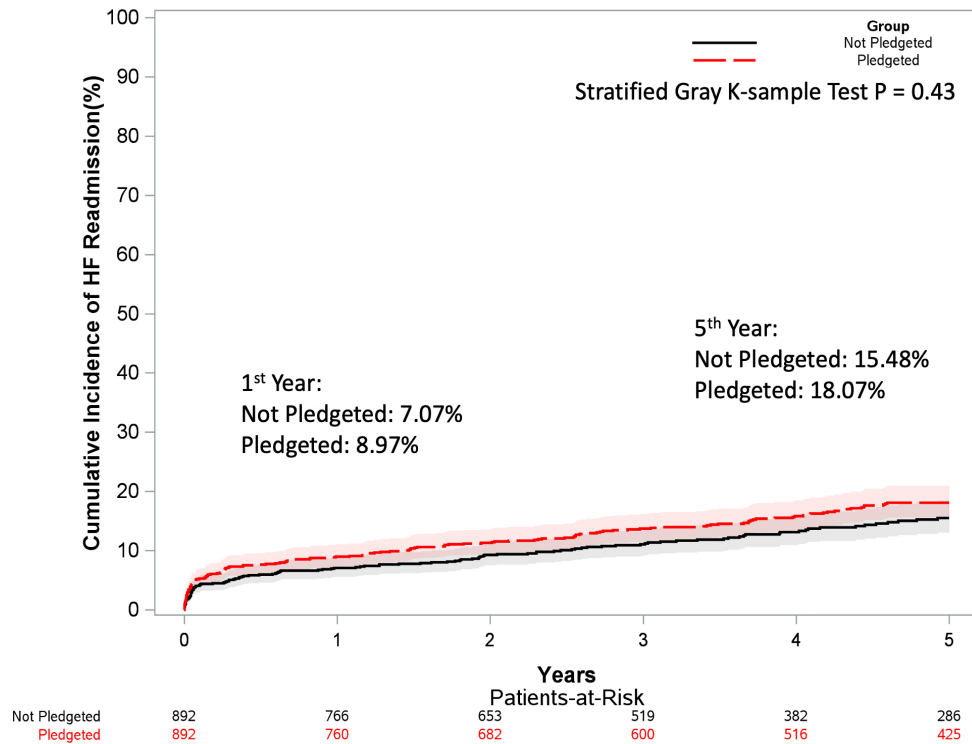


Fig. 4. Cumulative incidence function for heart-failure readmissions among matched cohorts of pledged and nonpledged AVR.

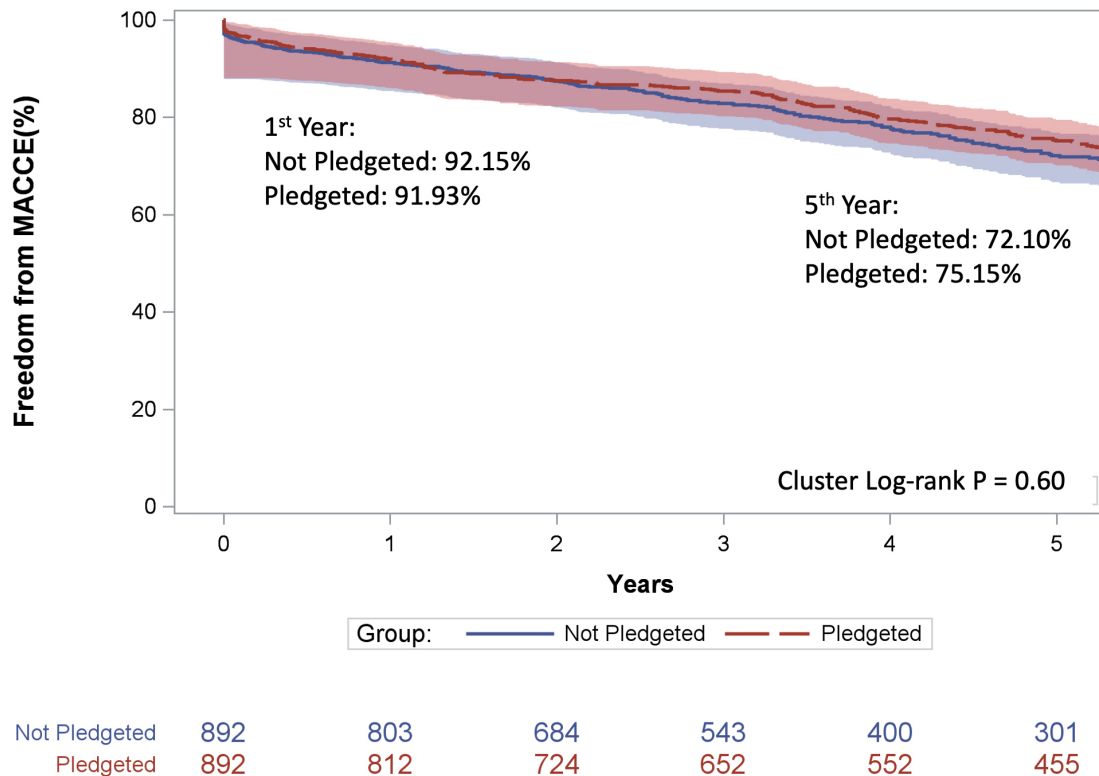


Fig. 5. Freedom from major adverse cardiac and cerebrovascular events (MACCE) at 1 and 5 years in matched cohorts of pledged and nonpledged AVR.

nique, the traditional technique of pledgeted non-everting mattress suture has been shown to yield smaller effective orifice areas and higher mean gradients [15]. In our study, too, the pledgeted group had significantly higher mean gradients; however, these patients had smaller valves implanted, which may or may not be inherently related to the suture technique that was used. We were unable to match on valve size, as it would have resulted in the exclusion of a large proportion of patients from analysis and thus would have introduced considerable selection bias. Without this or preoperative annulus size/left ventricular outflow tract diameter, a robust comparison of prosthesis-patient mismatch in the matched cohorts was not possible.

While reoperation rates were compared in the short-term in this study, durability of each technique remains in question. With longer follow-up, rates of reoperative valve replacement should be compared. Follow-up of at least 10 to 15 years would be required to enable assessment of valve durability and compare durability and valve reintervention between pledgeted and nonpledgeted techniques. Importantly, annular friability and degree of calcification may be relevant to choice of suture technique and may impact resultant durability, and these variables were not directly accounted for in this study.

Limitations

This study is limited by its retrospective design and inherent risk for selection bias. This study was propensity matched, but matching was incomplete (i.e., not every patient was reflected in analyses), which may also contribute to selection bias. However, the majority of the population was still captured in matched pairs (79.6% of the entire cohort). The study is additionally limited by lack of long-term echocardiographic follow-up to assess and compare valve durability following the two surgical techniques. Moreover, we were unable to match on valve size and do not have measurements for preoperative left ventricular outflow tract, ascending aortic, or aortic sinus diameters available, thereby precluding a robust comparison of prosthesis-patient mismatch risk between the two groups. Finally, the inability to account for operator variability and experience may be a source of bias. Future prospective studies on this topic may be beneficial to overcome these limitations.

Conclusion

Five-year survival, readmission rates, and freedom from MACCE are comparable between pledgeted and nonpledgeted AVR. Paravalvular leak rates are low and are similar with either technique. Future studies should match on preoperative annulus size and should include long-term data on aortic valve reinterventions. Future studies should also include long-term data on valve durability.

Abbreviations

AVR, aortic valve replacement; BSA, body surface area; MACCE, major adverse cardiac and cerebrovascular events; PSM, propensity score matching; PVL, paravalvular leak; SAVR, surgical aortic valve replacement; SMD, standardized mean difference; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.

Availability of Data and Materials

All data points generated or analyzed during this study are included in this published article.

Author Contributions

SY contributed to the design of this work, interpretation of the data, and drafting of the manuscript. VB contributed to the design of this work and interpretation of the data. JAB and ND contributed to acquisition and analysis of the data. YW analyzed the data. DSG, DK, JB, PY, DC, and IS revised the work critically for important intellectual content and interpreted the data and contributed to the conception of the work. All authors read and approved the final manuscript. All authors contributed to editorial changes in the manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board of the University of Pittsburgh on 4/17/2019 (STUDY18120143), with written consent being waived.

Acknowledgment

Not applicable.

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Conflict of Interest

IS and DS receive institutional research support from Atricure, Abbott, Boston Scientific, and Medtronic. No personal fees. None of these are related to this manuscript.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.59958/hsf.6793>.

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