Original Article

Echocardiographic characteristics of paravalvular leak following surgical aortic valve replacement: a retrospective cohort study

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Background: Paravalvular leak (PVL) is a recognized complication following surgical aortic valve replacement (SAVR), with a reported incidence ranging from 1% to 10%. Although some patients with mild PVL remain asymptomatic, others may develop clinically significant complications such as heart failure or hemolysis, underscoring the importance of early detection and timely intervention. While previous research has largely emphasized the risk factors and prognostic implications of PVL, limited literature focuses on the detailed echocardiographic characteristics of both the native aortic valve prior to SAVR and the PVL itself following surgery. Therefore, the objective of this study was to investigate the echocardiographic features of PVL after SAVR—specifically its origin, severity, and correlation with the calcified location of the preprocedural aortic valve.

Methods: This retrospective cohort study, conducted at a single academic institution, investigated all SAVR procedures performed from June 2010 to October 2022. PVL was identified using intraoperative transesophageal echocardiography (TEE) and transthoracic echocardiography (TTE) within 1 year postoperatively. The echocardiographic characteristics of PVL after SAVR, including its origin and severity, as well as its correlation to the calcified location of the preprocedural aortic valve, were investigated along with the incidence.

Results: Of the total 948 SAVR cases, PVL was identified in 77 (8.1%) intra- and/or postoperatively. Ten of the 77 cases were excluded from the analysis due to missing stored echocardiographic images, resulting in 67 PVL cases being investigated. The origin of PVL was identified in 62 cases on a short-axis (SAX) view of the aortic valve, with the most common site being the mid-portion of right coronary cusp (RCC) of the native aortic valve position in 22 cases (35.5%), followed by the non-coronary cusp (NCC) and the left coronary cusp (LCC), each in 12 cases (19.4%). Calcification of the preprocedural native aortic valve, ranging from mild to severe, was observed in 38 cases (56.7%). Among these 38 cases with a calcified native valve, the location of PVL was identified in 36 cases, showing a significant correlation between the location of calcification and the position of PVL ($r=0.74$, $P<0.001$). Of the 67 PVL cases detected intraoperatively and/or postoperatively, severity was mild in 58 cases (86.6%) and moderate in 9 cases (13.4%), with no severe cases.

Conclusions: PVL following SAVR was observed in 8.1% of cases either intraoperatively or within the first year postoperatively. The majority of PVL cases were mild in severity. The most common site of PVL was the mid-portion of the RCC at the native aortic valve position. A significant correlation was found between the location of calcification in the preoperative native valve and the site of PVL.

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Keywords: Paravalvular leak (PVL); aortic valve replacement; echocardiography; cardiac surgery

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Introduction

Paravalvular leak (PVL) is a known complication associated with surgical aortic valve replacement (SAVR). The incidence of PVL has been reported to range between 1% and 10% (1,2). The clinical presentation of PVL varies widely among patients. Those with insignificant PVL remain asymptomatic and can be managed with careful monitoring and follow-up (3). In contrast, patients with significant PVL often experience critical symptoms, including heart failure and hemolysis (4,5). These severe manifestations of PVL require urgent medical attention and intervention, underscoring the importance of early detection, effective management strategies, and a thorough understanding of PVL characteristics.

Several reports have been published on PVL following SAVR; however, many focus on prognosis and risk factors (6,7). Reports specifically addressing the inherent nature of PVL itself are limited. Therefore, the primary objective of this study is to elucidate the echocardiographic characteristics of PVL following SAVR while investigating the potential correlation with preprocedural aortic valve characteristics. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-2024-1989/rc).

Highlight box

Key findings

- This study identified paravalvular leak (PVL) in 8.1% of surgical aortic valve replacement (SAVR) cases, with the majority of cases being mild in severity.
- PVL was most frequently observed at the mid-portion of the right coronary cusp (RCC). Additionally, significant correlations were identified between PVL locations and calcification sites in the preprocedural aortic valve.

What is known and what is new?

- PVL is a known complication following SAVR. Previous research has primarily focused on its incidence, risk factors, and prognosis; however, few studies have investigated the echocardiographic characteristics of PVL or its relation to the preprocedural aortic valve.
- This study provides new insights into the specific locations and severity of PVL and its association with aortic valve calcification, offering a detailed echocardiographic perspective on PVL following SAVR.

What is the implication, and what should change now?

- The findings suggest that thorough preoperative assessment of calcification sites on the aortic valve may help guide adjustments in surgical approaches to minimize the risk of PVL. Additionally, because PVL severity can evolve postoperatively, clear shared decision-making with patients and close postoperative follow-up are essential.
- Larger multicenter studies are recommended to validate these findings and refine effective clinical strategies for PVL detection and management following SAVR.

Methods

This single-center retrospective cohort study was conducted at a tertiary care university hospital and approved by the Ethics Committee (University of Iowa Institutional Review Board; 202304620) and individual consent for this retrospective analysis was waived. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). All patients who underwent elective or emergency SAVR surgery from June 1, 2010, to October 31, 2022 were included. Among these, patients diagnosed with PVL following SAVR were enrolled for analysis to investigate echocardiographic characteristics. All echocardiographic images were stored in the IntelliSpace Cardiovascular system (Philips Healthcare, Andover, MA, USA). Patients without stored echocardiographic images were excluded from the analysis.

Pathophysiological information regarding the native or prosthetic aortic valve prior to SAVR was analyzed using intraoperative transesophageal echocardiography (TEE) images. Information regarding PVL following SAVR was analyzed using either intraoperative TEE or postoperative transthoracic echocardiography (TTE) images obtained within 1 year after SAVR surgery. All intraoperative TEE images were recorded by a fellowship-trained attending cardiac anesthesiologist assigned to the cardiac surgical case, and all postoperative TTE images were obtained by the cardiology department. When multiple TTEs were

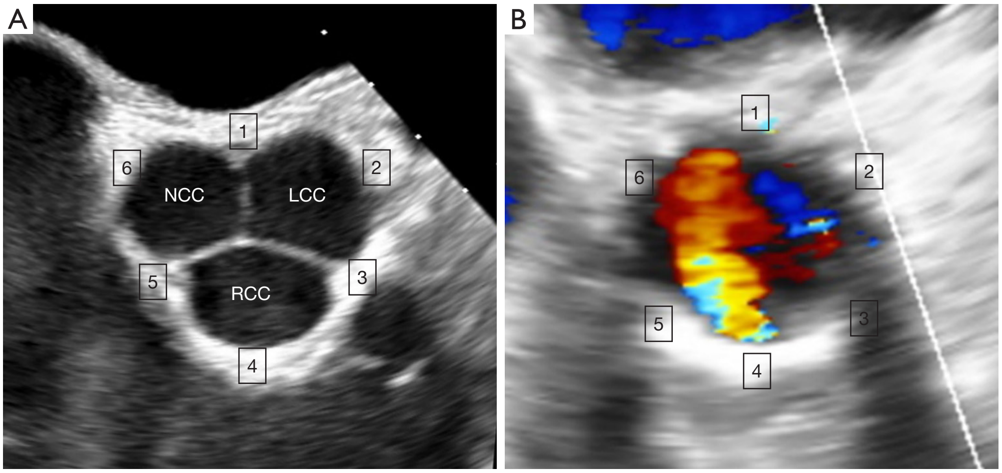

Figure 1 Adapted clock positions around the aortic valve in a short-axis view by transesophageal echocardiography. (A) The normal anatomy of the aortic valve using adapted clock positions, with position 1 corresponding to the traditional 12 o'clock location and position 4 to the 6 o'clock location. (B) A moderate paravalvular leak by color Doppler originating from the mid portion of the RCC at position 4. LCC, left coronary cusp; NCC, non-coronary cusp; RCC, right coronary cusp.

available within the 1-year postoperative period, the one farthest from the day of surgery was used for analysis. Intra- and postoperative echocardiographic images were separately reviewed and verified by two attending cardiac anesthesiologists specialized in perioperative echocardiography. If discrepancies arose, a third attending cardiac anesthesiologist specializing in perioperative echocardiography was consulted for final interpretation.

PVL was identified as a high-velocity regurgitant jet originating from the space between the prosthetic valve sewing ring and the aortic valve annulus (6). PVL severity was defined based on the ratio of PVL jet width to left ventricular outflow tract width: <25% as mild, 25–64% as moderate, and ≥65% as severe (8,9). The location of PVL was determined using a short-axis (SAX) view, with native trileaflet aortic valve positions used as a reference for numbering, regardless of whether the actual valves were trileaflet. Position 1 was designated at the commissure between the non-coronary cusp (NCC) and left coronary cusp (LCC), followed clockwise in the TEE by the mid-portion of the LCC as position 2, the commissure between the LCC and right coronary cusp (RCC) as position 3, the mid-portion of the RCC as position 4, the commissure between the RCC and NCC as position 5, and finally, the mid-portion of the NCC as position 6 (*Figure 1*). The location of calcification was determined using a SAX view. If calcification was observed in more than two locations or was extensive, the area with the most severe calcification was identified as the location. The degree of the calcification was classified as follows: 0, no calcification; 1, mildly calcified (small, isolated spots); 2, moderately calcified (multiple larger spots); and 3, heavily calcified (extensive thickening and calcification of all cusps) (10). In cases where the locations of both PVL and calcification were identified in a SAX view, the correlation between the site of most severe calcification and PVL location was investigated.

Statistical analysis

Continuous variables were presented as medians (interquartile range), and categorical variables as numbers (percentages). Patient characteristics, reviewed from the electronic medical record system (Epic Systems, Verona, WI, USA), were compared between patients with PVL (PVL group) and those without PVL (non-PVL group) using the Mann-Whitney *U* test or Fisher's exact test. Correlations between PVL and calcification locations were assessed using Pearson's method. A P value of <0.05 was considered statistically significant. Statistical analyses were performed using EZR (EZR; Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).

Results

During the study period, there were 948 cases involving

SAVR, of which 77 cases (8.1%) were identified with PVL intraoperatively and/or within 1 year postoperatively. Among these 77 cases, 10 cases without stored echocardiographic images were excluded from further investigation, resulting in 67 cases of PVL being analyzed (*Figure 2*).

Table 1 shows the patient characteristics of the PVL and non-PVL groups. Height, gender, and chronic kidney disease were not significantly different between the groups. Compared to the non-PVL group, the PVL group had a younger age {59 [43–71] *vs.* 65 [56–73] years, P<0.001}, lower weight {83 [71–95] *vs.* 90 [77–105] kg, P<0.001}, lower body mass index (BMI) [27.8 (24.4–31.9) *vs.* 30.1 (26.4–34.6) kg/m^2, P<0.001], lower body surface area (BSA) [1.95 (1.79–2.12) *vs.* 2.04 (1.87–2.21) m^2, P=0.007], a lower prevalence of diabetes mellitus [9 (13.4%) *vs.* 242 (27.8%), P=0.01], a higher preoperative ejection fraction (EF) [60% (55–65%) *vs.* 55% (50–60%), P=0.01], and a higher rate of previous cardiac surgery [15 (22.4%) *vs.* 112 (12.9%), P=0.04].

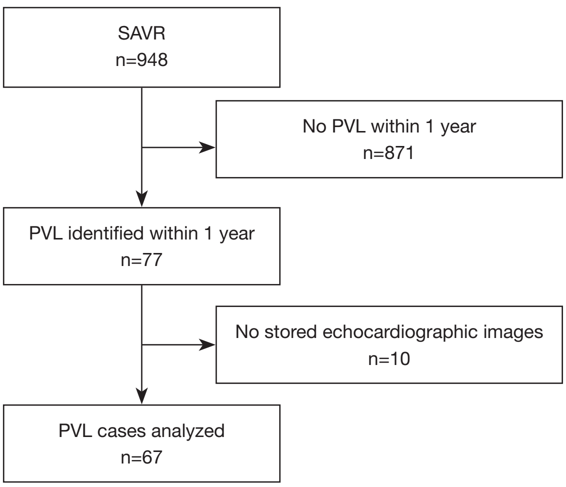

Figure 2 Flowchart of the study. PVL, paravalvular leak; SAVR, surgical aortic valve replacement.

Table 2 shows the characteristics of aortic valves, indications for SAVR, intraoperative variables, type of surgery, and size of the implanted prosthetic valve. Significant differences were observed between the PVL and non-PVL groups in terms of aortic valve type and indication for surgery (P=0.046 and P=0.02, respectively). Compared to the non-PVL group, the PVL group had a higher prevalence of bicuspid and prosthetic aortic valves prior to SAVR, as well as a higher prevalence of infective endocarditis. The PVL group also had longer cardiopulmonary bypass and aortic cross-clamp times than the non-PVL group {177 [136–242] *vs.* 143 [115–187] minutes, P<0.001; 143 [98–195] *vs.* 111 [89–149] minutes, P<0.001, respectively}. The type of surgery and the size of the implanted prosthetic valve were not significantly different between the groups.

Among the 67 PVL cases analyzed, intraoperative TEE images were available for review in 61 cases. Postoperative TTE images were available for review in 59 cases, with both intra- and postoperative echocardiographic images available

Table 1 Patient characteristics

Demographic data	PVL group (n=67)	Non-PVL group (n=871)	P value
Age (years)	59 [43–71]	65 [56–73]	<0.001
Height (cm)	172 [163–180]	173 [165–180]	0.29
Weight (kg)	83 [71–95]	90 [77–105]	<0.001
Body mass index (kg/m^2)	27.8 [24.4–31.9]	30.1 [26.4–34.6]	<0.001
Body surface area (m^2)	1.95 [1.79–2.12]	2.04 [1.87–2.21]	0.007
Female sex	20 (29.9)	250 (28.7)	0.89
Chronic kidney disease	12 (17.9)	168 (19.3)	0.87
Diabetes mellitus	9 (13.4)	242 (27.8)	0.01
Preoperative ejection function (%)	60 [55–65]	55 [50–60]*	0.01
Previous cardiac surgery	15 (22.4)	112 (12.9)	0.04

Data are expressed as n (%) or median [interquartile range]. *, two cases in the non-PVL group had no data on ejection fraction; therefore 869 patients were analyzed. PVL, paravalvular leak.

Table 2 Characteristics of aortic valves, indications for SAVR, intraoperative variables, type of surgery, and size of the implanted prosthetic valve

Variables	PVL group (n=67)	Non-PVL group (n=871)	P value
Types of native aortic valve			0.046
Trileaflet aortic valve	29 (43.3)	563 (64.6)	
Bicuspid valve	28 (41.8)	260 (29.9)	
Prosthetic aortic valve	10 (14.9)	48 (5.5)	
Indications for SAVR*			0.02
Aortic valve stenosis	32 (47.8)	512 (58.8)	
Aortic valve regurgitation	10 (14.9)	148 (17.0)	
Aortic valve stenosis and regurgitation	11 (16.4)	124 (14.2)	
Infective endocarditis	14 (20.9)	76 (8.7)	
Intraoperative variables			
Cardiopulmonary bypass time (minute)	177 [136–242]	143 [115–187]	<0.001
Aortic cross-clamp time (minute)	143 [98–195]	111 [89–149]	<0.001
Type of surgery			0.10
Isolated SAVR	39 (58.2)	409 (47.0)	
Size of the implanted prosthetic valve			0.37
17 mm	0 (0.0)	1 (<0.1)	
19 mm	3 (4.5)	67 (7.7)	
21 mm	18 (26.9)	189 (21.7)	
22 mm	0 (0.0)	1 (<0.1)	
23 mm	22 (32.8)	301 (34.6)	
25 mm	15 (22.4)	217 (24.9)	
26 mm	1 (1.5)	0 (0.0)	
27 mm	5 (7.5)	69 (7.9)	
29 mm	3 (4.5)	25 (2.9)	
31 mm	0 (0.0)	1 (<0.1)	

Data are expressed as n (%) or median [IQR]. *, eleven cases in the non-PVL group had no data on indication for surgery; therefore 860 patients were analyzed. PVL, paravalvular leak; SAVR, surgical aortic valve replacement; IQR, interquartile range.

in 53 cases. In 22 of these 53 cases, PVL was detected only on intraoperative TEE images, and in 9 cases, PVL was first noted postoperatively on TTE, with no evidence of its presence intraoperatively. PVL was diagnosed both intraoperatively and postoperatively in 22 of these 53 cases. The mean time from SAVR to postoperative TTE was 93 days (range, 35–273 days).

Table 3 shows the echocardiographic characteristics of aortic valves prior to SAVR. Calcification was observed in 38 cases, with mild calcification in 10 cases (14.9%), moderate in 13 cases (19.4%), and severe in 15 cases (22.4%). The most common sites of calcification were the commissure of the NCC and RCC (position 5) and the mid-portion of the NCC (position 6), each observed in 9 cases (23.7%).

Table 4 presents the intra- and postoperative characteristics of PVL identified by echocardiography. The location of PVL was identifiable in a SAX view in 62 cases (92.5%). In 5 cases where PVL was observed in the long-axis view, it was not visible in the SAX view. The most common location was the mid-portion of RCC (position 4)

Table 3 Echocardiographic characteristics of aortic valves prior to surgical aortic valve replacement

Echocardiographic characteristics	Values
Degree of calcification (n=67)	
None	29 (43.3)
Mild	10 (14.9)
Moderate	13 (19.4)
Severe	15 (22.4)
Location of calcification (n=38)	
Position 1	4 (10.5)
Position 2	7 (18.4)
Position 3	4 (10.5)
Position 4	5 (13.2)
Position 5	9 (23.7)
Position 6	9 (23.7)

Data are presented as n (%). Position numbers are represented as adapted clock positions around the native aortic valve anatomy, as shown in *Figures 1,3*.

Table 4 Paravalvular leak characteristics by echocardiography

Echocardiographic characteristics	Values
Location of paravalvular leak (n=62)	
Position 1	7 (11.3)
Position 2	12 (19.4)
Position 3	2 (3.2)
Position 4	22 (35.5)
Position 5	7 (11.3)
Position 6	12 (19.4)
Degree of paravalvular leak (n=67)	
Mild	58 (86.6)
Intraoperatively	47 (70.1)
Postoperatively	11 (16.4)
Moderate	9 (13.4)
Intraoperatively	5 (7.5)
Postoperatively	4 (6.0)

Data are presented as n (%). Position numbers are represented as adapted clock positions around the native aortic valve anatomy, as shown in *Figures 1,3*.

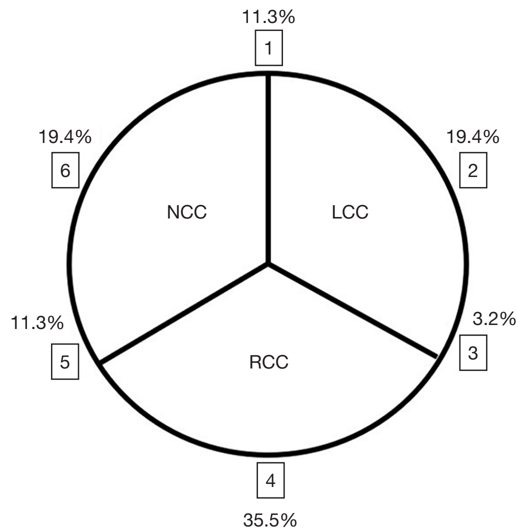

Figure 3 Distribution (%) of aortic paravalvular leak. Paravalvular leak observed in the short-axis view by echocardiography, presented in adapted clock positions around the native aortic valve anatomy. LCC, left coronary cusp; NCC, non-coronary cusp; RCC, right coronary cusp.

in 22 cases (35.5%), followed by the mid-portion of the LCC (position 2) and NCC (position 6), each observed in 12 cases (19.4%) (*Table 4* and *Figure 3*).

Of the 67 PVL cases detected intraoperatively and/or postoperatively, severity was mild in 58 cases (86.6%) and moderate in 9 cases (13.4%), with no severe cases. Among the 47 cases with mild intraoperative PVL, 11 underwent immediate intervention during the same surgery. In four of these cases, mild PVL persisted postoperatively. Of the five cases with moderate intraoperative PVL, three underwent immediate intervention; in one case, PVL was reduced to mild postoperatively, and in the other two cases, PVL was undetectable post-intervention. Moderate PVL was identified postoperatively in two cases where no PVL was detected intraoperatively by TEE. In one instance, mild PVL observed intraoperatively without intervention progressed to moderate postoperatively.

Among the 38 cases with a calcified native valve on intraoperative TEE, PVL was identified in 36 cases, showing a significant correlation between calcification location and PVL position (r=0.74, P<0.001) (*Figure 4*).

No patients underwent reoperation to repair PVL during the follow-up period. Five patients died within 1 year after

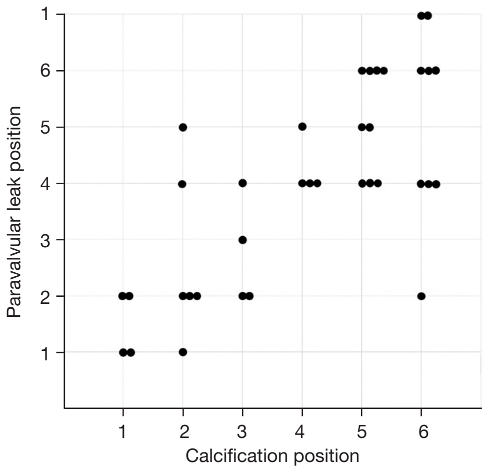

Figure 4 Correlation between calcification position and paravalvular leak position as observed by echocardiography. Each point represents one case, with calcification position observed prior to SAVR and paravalvular leak position observed following SAVR. The number positions form a circular sequence, where the position following 6 returns to 1, as shown in *Figures 1,3*. The repeated 1 on the y-axis is intentionally included to enhance intuitive understanding of the correlation between the paravalvular leak position and calcification, aiding data interpretation. The correlation coefficient is significant (r=0.74, P<0.001). SAVR, surgical aortic valve replacement.

surgery. Two patients experienced complicated recoveries and died before discharge, with no postoperative PVL. One patient with mild postoperative PVL died 6 months post-surgery due to sudden cardiac arrest of unknown cause. Another patient with mild postoperative PVL died 2 months post-surgery from infection. Lastly, one patient with moderate postoperative PVL died 11 months post-surgery due to acute heart failure, though the relationship with PVL was unclear.

Discussion

This study focused on the echocardiographic characteristics of PVL following SAVR, with PVL observed in 8.1% of cases. The most frequent PVL location was the mid-portion of the RCC, followed by the mid-portions of the NCC and LCC. A significant correlation was observed between the location of preoperative valve calcification and the location of PVL. The majority of PVL cases were classified as mild. Immediate interventions were often successful in reducing or eliminating PVL when detected intraoperatively. Although infrequent, some cases of PVL were first observed postoperatively without evidence of intraoperative PVL.

The incidence of PVL following SAVR in this study was similar to that reported in other studies (1,2,11). Degenerative valve diseases and prolonged cardiopulmonary bypass time have previously been identified as risk factors for PVL (6,7), and the patients in the PVL group in our study resembled those described in prior reports. The higher prevalence of bicuspid aortic valves and infective endocarditis observed in the PVL group could indicate an association with degenerative valve conditions and annular weakness (12-15). Additionally, the cases in the PVL group were likely more complex, as evidenced by the higher rate of redo cardiac surgeries and longer cardiopulmonary bypass and aortic cross-clamp times. Interestingly, the PVL group also had a significantly higher proportion of younger patients, as well as lower BMI, lower BSA, lower rates of diabetes mellitus, and higher preoperative EF. The reasons for these findings remain unclear and warrant further investigations.

It has been reported that PVL following valve replacement surgery tends to occur more frequently at specific locations (4,16). In our study, PVL was most commonly observed in the mid-portion of the RCC, possibly due to the surgical challenges associated with accessing this area during the procedure (17-19). Conversely, in cases with a calcified aortic valve, the location of PVL varied, tending to occur at the most heavily calcified sites. Severe calcification often requires complex techniques, which can impact surgical outcomes (20,21). This complexity, especially when intervention occurs near the aortic valve annulus, may explain the correlation observed in our study between the location of calcification and the occurrence of PVL.

In this study, immediate intervention for intraoperative PVL was performed during the same surgery in 11 cases of mild PVL and in three cases of moderate PVL. Similarly, previous studies have shown that PVL repair surgeries were conducted not only for severe PVL but also for mild PVL (4). This approach likely reflects a balance between the risks involved and the patient's overall condition on a case-by-case basis. Notably, mild PVL does not significantly affect mid-term prognosis (7,22), whereas patients with severe PVL can present with cardiac failure and hemolysis, impairing functional capacity and long-term survival (4,5,23,24). In the majority of cases in our study, PVL severity was mild and did not require any intervention during the available follow-up period. However, there were two cases where moderate PVL was first noted postoperatively and one case where intraoperative mild PVL worsened to a moderate level postoperatively, indicating that PVL severity can change over time. Therefore, reliance on a single-point echocardiographic examination at a single point is insufficient, and careful monitoring and follow-up are necessary, even if intraoperative PVL is mild or absent.

In recent years, machine learning technologies have shown promise in enhancing diagnostic accuracy and predicting clinical outcomes across various fields, including cardiology and cardiac surgery. In the context of PVL detection and management, machine learning could play a transformative role by automating and enhancing echocardiographic image analysis, potentially identifying subtle features that might elude human interpretation. Advanced image recognition algorithms, particularly those using deep learning, could be trained to detect PVL patterns, assess PVL severity, and predict PVL progression over time based on preoperative and intraoperative imaging characteristics (25,26). In the future, these technologies may provide clinicians with predictive insights into which patients are at higher risk for PVL following SAVR, enabling targeted preoperative planning and intraoperative adjustments (27). Insights from our study could inform the data used to train such models.

Our study uniquely characterizes the features of PVL using echocardiography at two critical time points: during the surgical procedure and within a one-year follow-up postoperatively. Unlike previous studies, which have primarily focused on prognosis and risk factors associated with PVL (6,7), our research offers a novel perspective by providing detailed echocardiographic characteristics of PVL, including its location, severity, correlation with calcified regions, and changes over time. Our findings enrich the existing body of knowledge and have the potential to guide more effective clinical strategies for managing patients with PVL, assisting clinicians in decisions regarding modifications to surgical techniques, refinements, and the necessity and timing of interventions. Future prospective studies are needed to refine effective methods for PVL detection and management following SAVR.

This study has several limitations that warrant consideration. First, it is a retrospective cohort study and therefore subject to inherent methodological constraints. However, because PVL is relatively rare, conducting a prospective study would be challenging. Second, the retrospective design limited the availability and quality of echocardiographic images, which may have affected data accuracy. To mitigate this, all echocardiographic findings were independently reviewed by two expert echocardiographers to enhance reliability. Third, postoperative TTE follow-up was limited to 1 year, precluding the assessment of long-term changes in PVL following SAVR. Fourth, this study included patients with both trileaflet and bicuspid aortic valves, as well as various etiologies of aortic valve disease, which may have introduced heterogeneity. However, because PVL is relatively rare, restricting the study population solely to one specific aortic valve pathology would have reduced the sample size and limited our ability to investigate key echocardiographic characteristics. Nevertheless, by including all patients with PVL, we aimed to better reflect real-world clinical scenarios and capture a broader range of surgical and anatomical challenges that can lead to PVL. We acknowledge that dedicated prospective or multi-institutional studies focusing on more homogeneous patient subsets—such as isolated trileaflet degenerative aortic stenosis—could yield more nuanced findings regarding PVL incidence, location, and severity. Finally, this study was conducted at a single center with a limited sample size, and the findings may not fully reflect variations across different institutions. Therefore, larger, multicenter studies are recommended to enable a more comprehensive analysis and improve the generalizability of the results.

Conclusions

PVL following SAVR occurred in 8.1% of cases, most frequently in the mid-portion of the RCC, followed by the mid-portions of the NCC and LCC. Additionally, a significant correlation was observed between calcification location and PVL. The majority of PVL cases were mild; however, severity could change over the one-year follow-up period, even in cases where PVL was initially undetected intraoperatively.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-2024-1989/rc

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the University of Iowa Institutional Review Board (No. #202304620) and individual consent for this retrospective analysis was waived.

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