



# Percutaneous Closure of Aortic and Mitral Paravalvular Leaks—Diagnostic and Therapeutic Considerations

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## Abstract

*Purpose of review* Paravalvular leak (PVL) represents a suboptimal procedural outcome resulting in an eccentric regurgitant jet following surgical or transcatheter aortic or mitral valve replacements. In this review, the role of integrated imaging modalities, including transthoracic echocardiography, transesophageal echocardiography, cardiac computed tomography, and cardiac magnetic resonance imaging, for the diagnosis and evaluation of aortic and mitral PVL is comprehensively discussed. Interventional procedures for aortic or mitral PVL using various percutaneous closure devices are reviewed. Clinical outcomes of percutaneous closure of PVL in aortic and mitral valves are summarized.

*Recent findings* PVL occurs in 6% to 15% of aortic valve and 7% to 17% of mitral valve procedures. Percutaneous device closure of PVL has shown an improved survival benefit. Successful reduction in PVL is associated with improved clinical outcomes.

*Summary* Multimodal imaging and inter-disciplinary discussion are essential for a high success rate of percutaneous closure of PVL. Further research on the pathophysiology of PVL and factors affecting complications are needed. A PVL closure device with various available shapes might be helpful for increasing procedural success rates.

## Introduction

Regurgitation through a paravalvular prosthetic defect is usually referred to as paravalvular leak (PVL); it is a common and under-recognized condition affecting 7% to 17% of mitral valve replacements and 6% to 15% of aortic valve replacements [1, 2]. Moderate to severe PVL after surgical or transcatheter aortic valve replacement (TAVR) is associated with increased mortality [3]. Tricuspid PVL and pulmonary PVL also occur but have been less frequently addressed.

PVL seems to occur most often in association with tissue friability, such as in infective endocarditis, corticosteroid use, and prior surgical valve replacement, and/or in the setting of severe annular calcification. PVL in TAVR is mainly due to malapposition of the stent due to severe aortic annular calcification, shape mismatch between annulus and prosthesis, or under-expansion of the transcatheter heart valve.

PVL can present with heart failure symptoms including dyspnea and fatigue, especially when regurgitation is moderate to severe. In the setting of poor left atrial and left ventricular compliance, even a small volume of regurgitation can markedly increase left atrial pressure and induce clinical symptoms. Pulmonary hypertension

can also occur with severe PVL. Hemolytic anemia may be severe and is common in small defects with high-velocity jets or defects with irregular shape when shear forces are increased [4].

The diagnosis of PVL is often challenging clinically because the murmur resulting from a PVL is often difficult to detect and acoustic shadowing from the prosthesis(es) may mask regurgitant jets on transthoracic echocardiography (TTE). Concomitant trans-valvular regurgitation may also mask PVL. Therefore, alternative imaging techniques are required to accurately diagnose PVL. Transesophageal echocardiography (TEE) and cardiac computed tomography angiography (CCTA) are essential tools to fully evaluate and characterize patients with suspected PVL.

When PVL is clinically significant, percutaneous PVL closure may be indicated to improve quality of life and to avoid repeat cardiac surgery [5]. Successful PVL closure is associated with improved survival [6].

In this review, we describe the contemporary diagnostic assessment and planning, interventional techniques, and device selection in percutaneous management of aortic and mitral PVL.

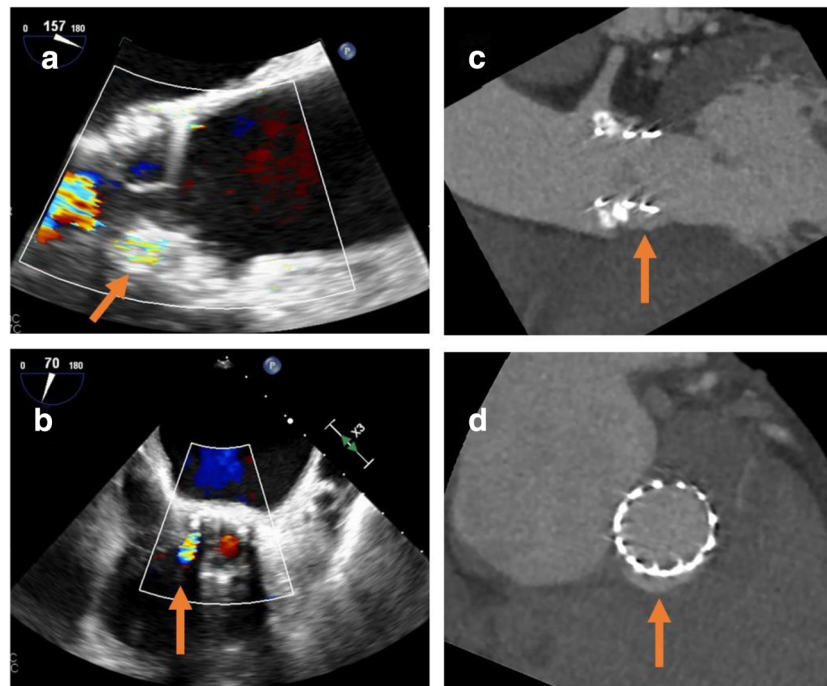
## Diagnosis and evaluation

### Assessment of aortic PVL

Two-dimensional (2D) TTE with color Doppler is commonly used for initial evaluation of patients with suspected aortic PVL. In surgical prosthesis, a turbulent eccentric jet is usually seen from the space between the prosthetic valve sewing ring and degenerated annulus. The prosthesis in TAVR is not sewed on the annulus and a PVL jet may occur at any point along the space between the aorta and the outer wall of the prosthesis which has a different shape among various types of prosthesis. The origin of aortic regurgitation can be best discriminated in parasternal long- and short-axis views but apical 3- and 4-chamber views may also be helpful. However, the capacity of TTE to diagnose PVL can be limited due to shadowing from the sewing ring or annular calcification. Posterior leaks may require careful apical views due to the acoustic shadowing from the prosthetic valves. A detailed

TEE, with its higher resolution and frame rates and better quantification of vena contracta, is often necessary to make a definitive assessment of severity and location, especially for posterior leaks (Fig. 1a, b).

Color flow Doppler can provide several useful parameters for determining PVL severity [7••]. Although the length and area of the regurgitant jet are useful qualitative measures, they correlate poorly with severity in PVL. Jet number, location, direction, and eccentricity can be identified by meticulous scanning of the whole valve. In eccentric jets, short-axis imaging below the valve may overestimate PVL severity. Deep transgastric views during TEE are useful for assessing jet severity. Vena contracta width (VCW) > 0.6 cm is specific for severe PVL and, however, is less certain in the presence of multiple smaller jets. Summing of the vena contracta area (VCA) may allow the addition of multiple jets. A circumferential extent of > 30° for the PVL is indicative of severe PVL. Large flow convergence in the aorta is indicative of severe PVL. Spectral Doppler assessment is less vulnerable to the position of the prosthesis, shadowing effects, and presence of artifacts as compared to color flow imaging. A holodiastolic flow reversal in the descending aorta on pulsed wave Doppler is consistent with at least moderate PVL. A pressure half-time < 200 ms on continuous wave Doppler suggests the presence of severe regurgitation, whereas a pressure half-time > 500 ms suggests mild regurgitation. Quantitative measures such as regurgitant volume (RVol), regurgitation fraction (RF), and effective regurgitant orifice area (EROA) are also useful in assessing severity of PVL. Aortic RVol can be derived as total left ventricular outflow track (LVOT) stroke volume minus systemic stroke volume measured in right ventricular outflow



**Fig. 1.** Mild-moderate (2+) paravalvular aortic regurgitation post-TAVR. Transesophageal echocardiography (a, b) shows diastolic flow (arrow) between the neo-right and noncoronary leaflets. Corresponding ECG-gated cardiac CTA shows the paravalvular leak (arrow) in the left ventricular outflow tract (c) and double-oblique short-axis (d) views.

track (RVOT). RF is the percentage of RVol over LVOT stroke volume. RVol > 60 ml, RF  $\geq$  50%, and EROA  $\geq$  0.30 cm<sup>2</sup> are considered severe aortic PVL. The spectral Doppler measures are influenced by a number of factors and should be considered alongside other quantitative parameters, such as vena contracta and flow convergence. The location of the aortic PVL is described using a clock-face notation in the “surgeons view.”

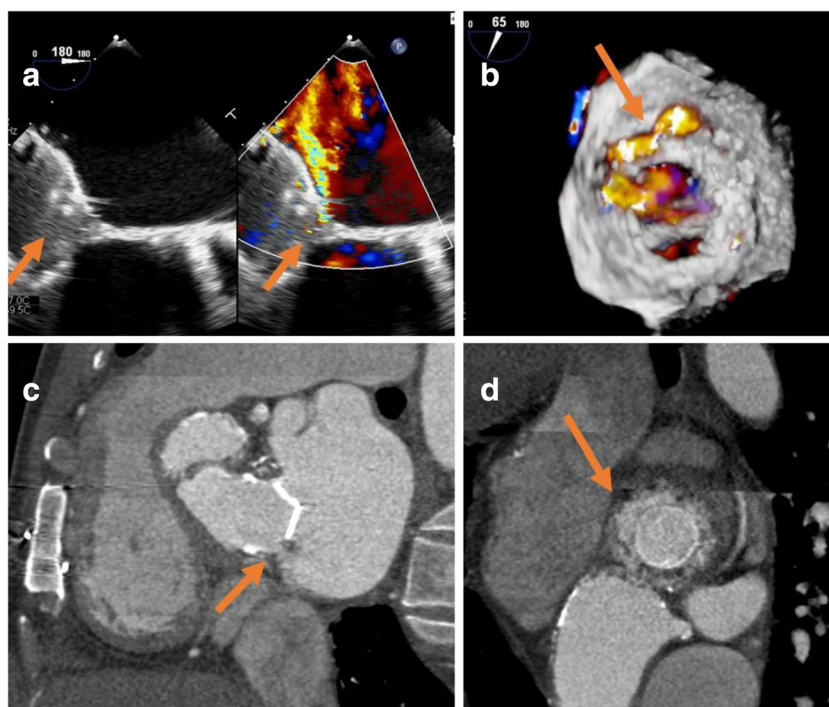
ECG-gated CCTA with its excellent spatial resolution can be complementary to echocardiography by characterizing the length, width, and area of the leak (Fig. 1c, d) [8]. CCTA can provide further help in preprocedural planning by providing optimal intraprocedural fluoroscopic plane angles, thus facilitating crossing of the defect. CCTA is especially useful for aortic PVL closure, where the defects can be difficult to localize with echocardiography [9]. However, CT can be limited when the blooming or beam hardening artifact occur due to the prosthetic valve or annular calcifications; exposure of contrast media and radiation also need to be considered for CT imaging.

Cardiac magnetic resonance (CMR) has many advantages for assessing PVL through the measurement of total RVol irrespective of the number of jets or their morphologies [10, 11]. Quantitative measurements are allowed even without gadolinium contrast if patients have a severe renal dysfunction. LV volume and fraction can be assessed using cine CMR sequences. Aortic RVol can be visualized in the cine CMR 3-chamber view using the steady-state free precession (SSFP) technique. Phase-contrast imaging using in-plane phase encoding can be useful for measuring RVol or RF when there is a susceptibility artifact from the device, which is a major limitation of CMR. CMR can be recommended when more than mild aortic PVL is suspected but the results from echocardiography are equivocal. Recommended CMR cutoffs for RF are similar to the values in echocardiography: mild < 30%, moderate 30–50%, and severe > 50% [12•].

## Assessment of mitral PVL

Mitral PVL may not be reliably detected using TTE due to acoustic shadowing, but PVL could be suspected from indirect signs, such as hyperdynamic left ventricular function in the setting of low cardiac output, evidence of increased flow through the mitral valve, increased gradient across the valve, or an unexplained rise in pulmonary artery pressure. TEE is particularly useful for evaluating mitral paravalvular defects and is ideal for guiding their closure. Mitral PVL are characterized by a color jet that originates in the left ventricle and passes into the left atrium, outside the valve sewing ring (Fig. 2a). Since a PVL defect can occur at any location around the ring, the prosthetic valve should be imaged in multiple planes and the entire sewing ring/prosthesis should be fully examined. 3D TEE has a superior accuracy in the evaluation of the leak, compared with 2D TEE, particularly for multiple and complex lesions (Fig. 2b). The defect location is best described using a clock-face notation using the “surgeons view.”

PVL can be expressed as a percentage of the circumference of the sewing ring in surgical implants or outer surface of the transcatheter prosthetic devices, with the use of 2D and 3D color flow Doppler imaging. Care must be taken to ensure that the image plane traverses the PVL defect at the level of the sewing ring. Otherwise, slight angulation away from this plane can result in an oblique view through the leak or include the jet expansion beyond the PVL defect, both of which result in an overestimation of the extent of the leak.



**Fig. 2.** Severe paravalvular mitral regurgitation post-mechanical MVR. Transesophageal echocardiography 2D (a) and 3D (b) shows systolic flow (arrow) adjacent to the outer sewing ring. Corresponding ECG-gated cardiac CTA shows the paravalvular leak (arrow) in oblique (c) and double-oblique short-axis (d) views.

It is important to identify the three components of PVL jets: flow convergence, vena contracta, and the jet area in the LA [7••]. When the PVL consists of more than one jet, consists of an eccentric shape, or is vulnerable to shadowing, assessment with color Doppler can be challenging. Morphological findings such as abnormal positioning of the device, flailed leaflet, and large flow convergence (i.e.,  $\geq 1$  cm) by proximal isovelocity surface area (PISA) radius are considered severe PVL. VCA by 3D planimetry has been shown to be useful to guide the selection of the type and size of the device. The principle is to define the PVL tract, allowing direct visualization of the anatomical regurgitant orifice. Accurate sizing requires the use of 3D color flow Doppler imaging. When the 3D color dataset is acquired, software allows PVL analysis in three orthogonal planes. A cross-sectional view defining the VCA is obtained and can be measured to accurately define the morphology and size of the defect.  $VCA \geq 0.4$  or  $\geq 2$  moderate jets are considered severe PVL. EROA by the PISA method  $\geq 0.4$ , RVol  $\geq 60$  ml, and RF  $\geq 50\%$  are classified as severe PVL. An integrative approach is needed in assessing mitral PVL. Available algorithms or suggestions are based on expert opinion, available data, and consensus guidelines pertaining to native valve regurgitation.

CCTA (Fig. 2c, d) may be complementary to echocardiography and have been shown to have better diagnostic performance for mitral PVL compared with TTE with higher sensitivity and negative predictive value, and also has a comparable diagnostic performance to TEE [13•]. CT and TEE had similar agreement for the localization of PVL. CT may add value to TEE when its images

are not satisfactory for evaluation because of acoustic shadows. The major limitation of CCTA is the inability to determine hemodynamic flow that is available with Doppler flow studies.

CMR imaging has the advantage in evaluation and quantification of PVL volume and fraction. However, its usage is based on the use of CMR in native regurgitation or surgical prosthesis only [14••]. CMR is recommended when Doppler assessment is unsatisfactory or inconsistent with the clinical findings. Phase-contrast imaging with through-plane phase-encoding may provide better assessment of PVL [15, 16]. RVol or RF can also be derived by calculating the difference between planimetry-based stroke volume from cine images and phase-contrast imaging-derived stroke volume. Partition values used with echocardiography are suggested as thresholds with CMR to grade mitral PVL severity [17]. CMR is also useful in determining the physiologic consequences of mitral PVL on reverse remodeling of LV and LA, with more accurate measurements of volumes and ejection fraction. CMR is limited when the patient has an implanted device, significant artifact around the device, or an underlying arrhythmia.

## Treatment

Repeat surgery to repair PVL is associated with significant mortality and morbidity [18, 19]. Percutaneous PVL closure is commonly performed to reduce the regurgitation and avoid cardiac surgery. American College of Cardiology/American Heart Association guidelines recommend percutaneous repair of paravalvular prosthetic valve regurgitation as a class IIa indication for patients with intractable hemolysis or a New York Heart Association class III or IV heart failure, who are at high risk of surgery, and with anatomically suitable defects in centers with expertise in this procedure. It is important for the cardiologist to have a comprehensive understanding of PVL anatomy and severity by integrating imaging from CT, TEE, and TTE and discussion with an interventional cardiologist, echocardiographer, and radiologist if PVL closure is to be entertained. In addition, the interventionalist should have precise knowledge about the size and location of the leak(s) and have a working experience with the available closure devices.

### Percutaneous closure of aortic PVL

Aortic PVL closure is most commonly performed in a retrograde approach. It is usually done under conscious sedation, unless prolonged TEE imaging is anticipated. Amplatzer Vascular Plug II (AVP II; Abbott Vascular) and PDA Occluder are commonly used in the USA and the AVP III (Abbott Vascular) may soon be available. The AVP IV device has been used for post-TAVR PVL. However, there are no specific devices currently approved by the Food and Drug Administration (FDA) for percutaneous closure of PVL. The rectangular/square-shaped paravalvular leak device from Occlutech (PLD; Occlutech) has been successful in many case series and registries [21••, 22••], and has CE mark approval but is not available in the USA.

Post-TAVR PVL due to device malposition may not be effectively treated with percutaneous closure and may require a valve-in-valve procedure [23]. PVL due to undersized or under-expanded prosthesis may be treated with balloon post-dilatation [24].

## Percutaneous closure of mitral PVL

Mitral PVL closure is generally done under general anesthesia with TEE guidance. An antegrade approach with transseptal puncture is the most common technique for mitral PVL closure but a transapical approach may also be used. A standard transseptal puncture is usually made posteriorly to avoid the aorta and superiorly for lateral defects or inferiorly for medial defects. The defects are crossed with 2D and 3D TEE guidance using steerable sheaths.

Amplatzer Duct Occluders, AVP II, and VSD devices have been used depending on defect size and valve type. AVP II was the most common device of choice for mitral PVL closure (60–90%) in countries where it is available. Mechanical prosthetic valves need extra caution during device deployment because entrapment of mechanical valve leaflets by a retention disk may occur.

## Outcomes of percutaneous PVL closure

Surgical management has long been the mainstay of treatment for PVL. However, reoperation is associated with a higher risk of adverse outcomes than the index procedure, including substantial morbidity and mortality [25, 26]. The 30-day mortality for surgical PVL closure was 10.7% despite an operative success of 98%. Long-term survival at 12 years was only 39.0% [19].

Successful closure is defined as mild or less residual regurgitant flow after the procedure. The technical success rates reported from individual centers of percutaneous aortic and/or mitral PVL closure vary from 60 to 90% (Table 1) [21••, 22••]. The severity of residual regurgitation after PVL closure predicts the amount of symptomatic relief and need for repeat procedures or surgery after PVL closure [21••, 27]. Sorajja et al. reported that the 3-year estimate of survival (i.e., no death or need for surgery) for those with no, mild, or moderate/severe PVL was 63.3%, 58.3%, and 30.3%, respectively. Although studies for percutaneous PVL closure are not randomized studies, successful PVL closure is associated with improved survival, functional class, and hemolytic anemia compared with unsuccessful closure [28]. Surgical and transcatheter techniques have been compared for their mortality and morbidity in several studies, but no randomized studies are available [29•]. Long-term survival, in nonrandomized reports, has been shown to be similar after surgical and percutaneous PVL closure.

Post-TAVR PVL closure showed similar results for symptom relief and success rate as compared to PVL closure in surgical prostheses [24, 30]. Although evidence for percutaneous management of post-TAVR PVL is limited, percutaneous closure is an important option in a group that is often at high risk of operative closure.

Even with initial success of the PVL closure, complications can occur, such as malfunction of valve leaflets due to the impingement from the closure device and device embolization [4]. A recent study demonstrated that the 30-day complication rate was 8.7% including sudden death, stroke, emergency surgery, and bleeding [27]. Coronary artery obstruction may occur with aortic PVL closure. Postoperative bleeding is common in patients with a transapical approach.

**Table 1. Studies of percutaneous closure for paravalvular leak after aortic or mitral valve replacement**

Study (Year)	Country	Period	Type of study	Number of patients
Garcia-Borbolla Fernandez et al. (2009)	Spain	~ 2009	Retrospective	8
Sorajja et al. (2011)	USA	2004–2011	Retrospective	126
Ruiz et al. (2011)	USA	2006–2010	Retrospective	43
Sorajja et al. (2014)	USA	2004–2013	Retrospective	200
Calvert et al. (2016)	UK and Ireland	2004–2015	Retrospective	259
Alkhouli et al. (2016)	USA	2006–2015	Retrospective	80
Garcia et al. (2017)	Spain	2002–2014	Retrospective (HOLE registry)	469
Alkhouli et al. (2017)	USA	1995–2015	Retrospective	195 percutaneous, 186 surgical
Wells et al. (2017)	USA	2007–2016	Retrospective	56 percutaneous, 58 surgical
Millan et al. (2017)	Canada	1994–2014	Retrospective	80 percutaneous, 151 surgical
Waterbury et al. (2017)	USA		Retrospective	18

Study (Year)	Valve type	Closure device	Technical success	Other results	Ref
Garcia-Borbolla Fernandez et al. (2009)	Mitral	100% ADO	62.5%		[31]
Sorajja et al. (2011)	78.5% mitral, 21.4% aortic	61.1% AVP II, 15.8% ADO 7.9% VSO	76%	64.3% 3-year survival. Degree of residual regurgitation is associated with survival free of death or surgery.	[27]
Ruiz et al. (2011)	74% mitral, 21% aortic, 5% both	68.9% ADO, 18.7% VSO, 8.3% AVP II, 4.1% ASO	86%	Freedom from cardiac-related death at 42 months was 91.9%.	[32]
Sorajja et al. (2014)	74% mitral, 26% aortic	77% AVP II, 10% ADO, 7% ASO, 6% VSO	89%	The 30-day MACE was 7%.	[33]
Calvert et al. (2016)	44% mitral, 53% aortic	62.5% AVP III, 3.9% PLD	91.0%	Mitral PVL was associated with higher MACE than aortic PVL. Residual leak was independently associated with death.	[21••]
Alkhouli et al. (2016)	Aortic	71% AVPII	62%	Successful PVL reduction resulted in quick and durable symptomatic relief and reduced the need for redo cardiac surgery.	[20•]
Garcia et al. (2017)	70.2% mitral, 29.8% aortic	87% AVP III	86.6%	30-day MACE was 5.6%	[22••]
Alkhouli et al. (2017)	All mitral	70.8% AVP II 6.7% ADO	70.1%	Success rate was higher in the surgical group. In-hospital MACE was more common after surgery.	[34•]



**Table 1.** (Continued)

Study (year)	Valve type	Closure device	Technical success	Other results	Ref
Wells et al. (2017)	57.1% mitral, 37.5% aortic, 5.4% pulmonary	5.1% ASO AVP II, AVP III	77%	Similar hospital, 30-day and 1-year outcomes between percutaneous and surgical groups	[35•]
Millan et al. (2017)	81.3% mitral, 18.8% aortic	N/A	68.8%	Reduced all-cause death with surgical treatment	[29•]
Waterbury et al. (2017)	All TAVR	56% AVP IV, 44% AVP II	78%	30-day all-cause mortality was 11%	[24]

AVP, Amplatzer Vascular Plug; ADO, Amplatzer ductal occluder; VSO, ventricular septal occluder; ASO, Amplatzer septal occluder; PLD, paravalvular leak device; TAVR, transcatheter aortic valve replacement; HHF, hospitalization for heart failure; MACE, major adverse cardiac events

## Conclusion

Percutaneous device closure has shown significant benefits for the management of aortic and mitral PVL. Comprehensive pre-procedural planning with multimodal imaging and cross-disciplinary discussion are needed to obtain a high success rate. Successful reduction in PVL is associated with improved long-term clinical outcomes. Further studies examining the pathophysiology of PVL and factors affecting hemolysis are needed. A PVL closure device with various available shapes might be helpful for increasing the procedure success rate.

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## Data availability

Not applicable

## Compliance with Ethical Standards

### Conflict of Interest

Sun-Joo Jang declares that he has no conflict of interest. Quynh A. Truong declares that she has no conflict of interest. Geoffrey Bergman declares that he has no conflict of interest. S. Chiu Wong declares that he has no conflict of interest. Bobak Mosadegh declares that he has no conflict of interest.

### Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

### Code availability

Not applicable

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