

Paravalvular Leak Closure: The Apical Approach

Imaging and procedural considerations for PVL closure via surgical and percutaneous transapical approaches.

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Paravalvular leak (PVL) is a rare but important complication that is seen with prosthetic valves implanted by either a surgical or transcatheter approach. The incidence of PVL in surgical patients has been noted to range from 2% to 10% in the aortic position and 7% to 17% in the mitral position.^{1,2} For transcatheter aortic valve replacement, the incidence of moderate PVL has been estimated to be 13.5% and 19.9% for the Sapien (Edwards Lifesciences, Irvine, CA) and CoreValve (Medtronic, Inc., Minneapolis, MN) devices, respectively.³

The majority of these leaks are trace to mild and are asymptomatic; however, moderate to severe PVL can occur, leading to significant hemodynamic and clinical consequences. Patients with symptomatic leaks can present with symptoms ranging from a decrease in functional class to severely decompensated congestive heart failure and/or hemolysis. In addition to its effect on patients' quality of life, persistent PVL has been shown to cause an increase in mortality.⁴

For symptomatic patients, PVL management has typically been either medical (heart failure therapy, erythropoietin injections, and blood transfusions) or surgical (repair of the leak or replacement of a prosthesis). During the last decade, there has been considerable development in the transcatheter management of PVLs, beginning with the first case series in 1992.⁵ Transcatheter closure involves obstructing the flow through the PVL by delivering coils or occluders at the site of leak, preventing or reducing the amount of regurgitation. To deliver these devices, multiple

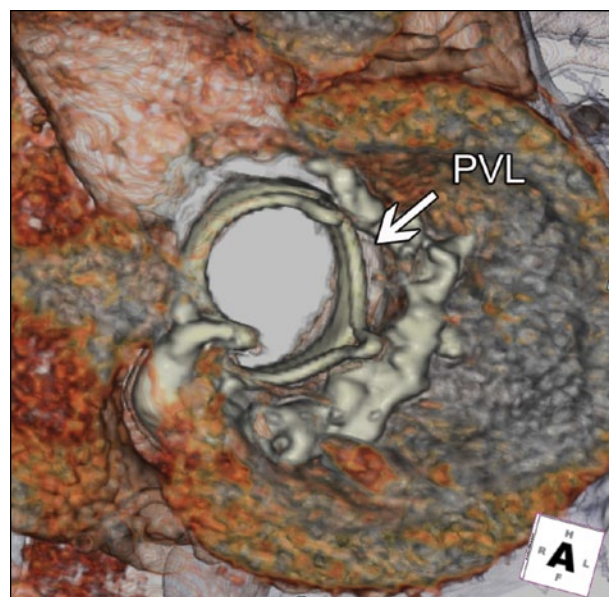


Figure 1. Electrocardiogram-gated three-dimensional CTA reconstruction showing a mitral PVL surrounded by extensive mitral annular calcification (white crescentic structure) seen from the LV side of the prosthesis.

approaches have been performed, including retrograde transaortic, antegrade transseptal, and more recently, transapical (TA).

The TA approach involves creating access into the left ventricular (LV) cavity by puncturing the LV wall near

the apex. Two methods of the TA approach are currently utilized, open surgical and completely percutaneous. This article reviews the utility and technique of transcatheter PVL closure using surgical and percutaneous TA approaches, with a focus on multimodality imaging, potential complications, and procedural outcomes associated with this procedure.

ROLE OF THE TA APPROACH

TA access was developed more than half a century ago as a route to access the LV cavity for hemodynamic measurement.^{6,7} With time, and as less invasive techniques were developed to measure hemodynamics, the use of the TA approach diminished. Recently, concurrent with advances in multimodality imaging, the TA approach is being reevaluated as a suitable access for many advanced transcatheter procedures. The reason for this revived interest is the ability of the TA approach to provide direct access into the LV cavity toward the aortic and mitral valves with greater operator control.

The TA approach has ultimately been shown to decrease fluoroscopic and procedural times for PVL closure, which is important for complex, prolonged interventions.⁸ The use of the TA approach has now been described in LV pseudoaneurysms, ventricular septal defects, transcatheter aortic valve replacement, mitral valve-in-valve implantation, and importantly, PVL closure.^{8,9}

UTILITY IN PVL CLOSURE

In our experience, the primary utility of TA access has been in the closure of PVLs. Factors that may favor the TA approach over other routes are the direction and tortuosity of the tract, the amount of calcification (mitral annular calcification in cases of mitral prostheses) (Figure 1), the presence of double mechanical valves, and peripheral atherosclerotic disease, which makes access via the transaortic or transeptal routes complicated.

For mitral PVLs, the TA approach provides a short and direct route to access the mitral valve. It is especially important for posteroseptal mitral PVLs, which are difficult to cross using transeptal and transaortic routes due to the steep angulations of delivery associated with these approaches. For aortic PVLs, retrograde transaortic access is usually preferred. However, when unable to cross via this approach, TA access can be used.

CONTRAINDICATIONS TO THE TA APPROACH

The TA route should be pursued with considerable caution in patients with a hypocoagulable state, or any other bleeding diathesis, due to the inherent risk of bleeding and vessel rupture associated with the procedure. Because

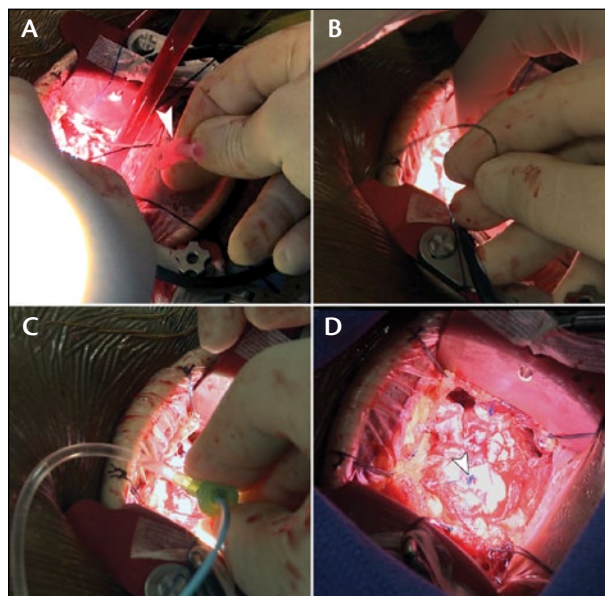


Figure 2. The steps of surgical TA access. Puncture of the LV wall with the needle (arrowhead) under direct surgical exposure after a minithoracotomy is performed (A). Introduction of the guidewire through the needle into the LV cavity (B). Introduction of the sheath over the guidewire (C). Closure of the TA puncture site using pledgeted sutures (arrowhead; D).

these procedures are usually performed in patients who have undergone previous surgical cardiac interventions, there is limited availability of data on TA puncture in the uninterrupted pericardium. Undisturbed native pericardium is considered to be a relative contraindication for TA access due to concerns for tamponade and pericardial effusion after the puncture. TA access should also be avoided in patients with near-systemic or systemic pulmonary artery hypertension.

TECHNICAL APPROACH

Preprocedural Planning and Guidance

A preprocedural evaluation on a patient-to-patient basis is an important aspect of planning for TA PVL closure and avoiding complications. Such evaluation requires the use of multimodality imaging with transthoracic echocardiography, transesophageal echocardiography (TEE), and CT angiography (CTA). For TA access, it is necessary to determine the site of entry from the skin to the epicardial LV apex that is away from overlying lung parenchyma and the coronary arteries, and in direct line with the PVL. Evaluating for areas of myocardial thinning, scarring, or focal wall abnormalities is equally important. Furthermore, excluding the presence of LV apical thrombus is essential.

CTA helps to measure the distance from the skin surface to the LV apex and to determine the optimal

intercostal space with the appropriate angle for entry. For evaluation of the PVL, multimodality imaging can size the PVL and determine the degree of paravalvular regurgitation. It is important to verify the distance between the PVL and the valve struts and leaflets to avoid impingement of the closure device to the adjacent structures. In our experience, fusion imaging has a considerable role in safe percutaneous TA PVL closure. Fusion imaging involves overlaying previous CTA or live echocardiographic images onto live fluoroscopy.

Open Surgical TA

Open surgical TA involves a hybrid approach, with the patient under general anesthesia and the presence of both interventional and surgical teams in the hybrid operating room. An anterolateral minithoracotomy is performed, and the LV apex visualized. Pledgeted purse-string sutures are then placed at the apex, and an access needle is introduced to puncture the apex (Figure 2A). Once in the LV cavity, a guidewire (depending upon the operator's preference) is introduced via the needle, and the needle is exchanged for a sheath (Figure 2B and 2C). An appropriate activated clotting time (> 250 seconds) using unfractionated heparin is subsequently achieved.

The access site can be closed surgically at the completion of intervention (Figure 2D). Direct visualization by surgical exposure during creation of TA access helps to visualize the blood vessels near the apex and the lung tissue, which in turn aids in avoiding any incidental puncture of vessels or the lung while gaining access. Although this technique helps to minimize bleeding complications, it is still a fairly traumatic procedure when considered in the context of the surgically high-risk populations in which these transcatheter procedures are primarily performed.

Direct Completely Percutaneous TA

Completely percutaneous TA access can be performed in the interventional catheterization laboratory with the patient maintained under general anesthesia and the surgical team on standby. The patient is positioned on the table with arms up or down, depending on whether the arms obstruct the skin entry point for puncture. The LV apex is punctured percutaneously using a 21-gauge micropuncture needle (7 cm) under CTA-fluoroscopy fusion imaging guidance (Figure 3A and 3B).^{8,10-12}

Role of Fusion Imaging in Percutaneous TA PVL Closure

CTA-fluoroscopy fusion imaging (HeartNavigator, Philips Healthcare, Andover, MA) can help to improve procedural success by facilitating access and improving the accuracy of percutaneous puncture.^{8,11} Segmentation of important cardiac and noncardiac structures of interest is

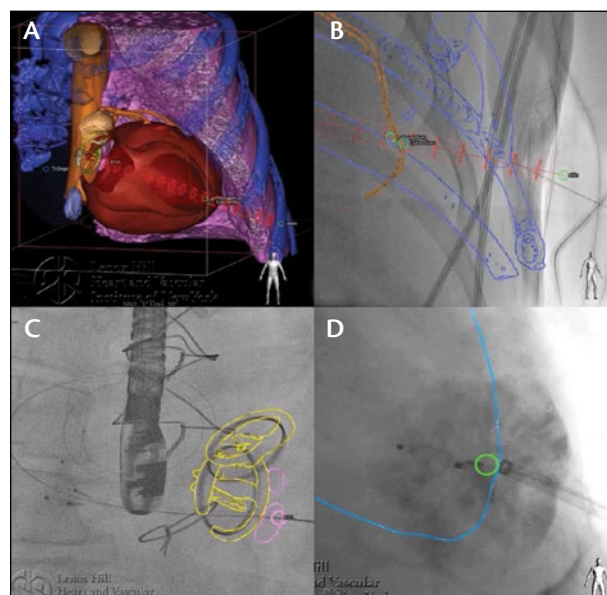


Figure 3. The steps of percutaneous TA access. Preprocedural planning using HeartNavigator software with segmentation of important cardiac and noncardiac structures (LV myocardium in red, prosthetic valve in yellow, lungs segmented in pink). Landmarks are placed for TA access (guidance cylinder in red, skin entry in blue, and PVL in pink) (A). CTA overlaid image onto fluoroscopy shows the micropuncture needle oriented for percutaneous puncture (guidance cylinder in red and ribs in blue) (B). Closure devices introduced via the sheath into the left atrium, across the PVL, for closure (prosthetic valve in yellow and safety wire across the leak) (C). Closure of the TA access using CTA-fluoroscopy fusion guidance (outline of LV epicardial surface and landmark of LV entry) (D).

performed and includes the left atrium, aorta, prosthetic valve(s), LV, lung parenchyma, and ribs. Landmarks for skin entry, LV epicardial entry, and the PVL are placed such that they are in direct line with one another. Next, coregistration is performed using internal radiopaque markers in the chest, such as prosthetic heart valves. The outline of segmented structures and landmarks is subsequently overlaid onto live fluoroscopy and used for guidance of TA puncture and PVL crossing.

TEE overlaid onto live fluoroscopy (ie, TEE-fluoroscopy fusion imaging [EchoNavigator, Philips Healthcare]) helps to further guide the procedure. It partially compensates for some limitations of CTA-fluoroscopy fusion by providing more dynamic procedural guidance. TEE-fluoroscopy fusion utilizes real-time live data of both modalities, reducing the limitation of cardiac motion, patient positioning, and physiologic variation between timing of preprocedural studies. On rare occasions, left ventriculography can also

be used during the procedure to help delineate the apex, as well as coronary angiography to assess the left anterior descending and/or diagonal arteries, for safer puncture.¹²

During puncture, contrast is injected through the needle to monitor the entry into the LV cavity. Larger needles (eg, 16-cm Chiba, St. Jude Medical, Inc., St. Paul, MN) may be required when the LV myocardium is > 5 cm from the skin surface. After the puncture is performed, a 0.018-inch guidewire is advanced, and the needle is exchanged for a 6-F radial sheath (Flexor radial introducer sheath, Cook Medical, Bloomington, IN) (Figure 3C). The patient is maintained at an appropriate activated clotting time (> 250 seconds) with unfractionated heparin after the puncture.

For closure of TA access under real-time fluoroscopic guidance, an Amplatzer device (off-label use previously reported by our group: 6-/4-mm Amplatzer duct occluder or 8-mm Amplatzer vascular plug II, St. Jude Medical, Inc.) is introduced through the sheath, and the distal disk is opened in the LV cavity. The device is then slowly withdrawn toward the puncture site, and contrast is injected to visualize the LV endocardial wall. The device is pulled back until resistance is felt, and the flat disk conforms to the endocardial surface (Figure 3D). The remainder of the device is unsheathed, with the body located within the myocardium. Once positioning of the device is confirmed, it is released. Surgiflo (Ethicon, Inc., Somerville, NJ) is used to fill the tract.

If properly performed, percutaneous TA access provides a less traumatic access in comparison to surgical TA access. Ultimately, the choice of approach to gain access into the LV cavity is governed by multiple factors, including operator preference/experience, patient characteristics, availability of imaging for preprocedure planning and procedural guidance, as well as previous attempts at LV access.

Proper closure of TA access is vital regardless of the preferred method, surgical or percutaneous, as it is the primary source of complications seen. Closure, as previously described, can be performed either surgically during the minithoracotomy by direct securing of the purse-string sutures or percutaneously by placing an off-label closure device.¹³ Sheaths smaller than 5 F may not require a closure device because the access point is usually occluded by the motion of the LV myocardium. More recently, purpose-specific occluders for the TA site are being evaluated to minimize complications even further.¹⁴

PVL CLOSURE

Multimodality imaging guidance by using TEE and CTA, as well as fusion imaging, holds a vital role in both planning and intraprocedure guidance of closure of PVLs (Figure 4A and 4B). Closure is similar for both surgical

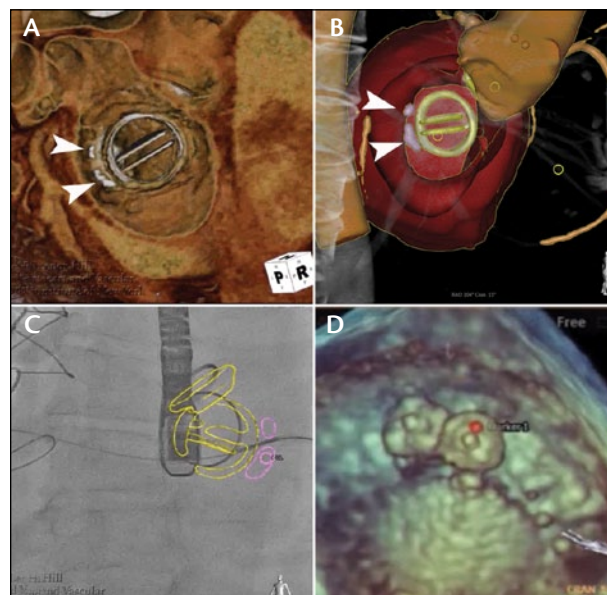


Figure 4. PVL closure under multimodality imaging guidance. Electrocardiogram-gated three-dimensional CTA reconstruction showing mitral PVL (arrowheads; A). The PVL (arrowheads) is visualized and segmented in the same patient prior to the procedure using HeartNavigator (B). CTA overlaid imaged onto fluoroscopy shows the crossing of the mitral PVL with guidewire (C). Intraprocedural three-dimensional TEE shows the implanted devices in the PVL (D).

and percutaneous TA approaches. After TA is established, a 5-F steerable catheter directs a hydrophilic guidewire toward the PVL (Figure 4C). After the leak is crossed with the wire and the position confirmed, the catheter is advanced across the defect into the left atrial for mitral PVL or LV for aortic PVL. The hydrophilic wire is removed, and an extra-support, exchange-length wire is placed. The catheter/sheath are exchanged for an appropriately sized sheath, depending on the device(s) to be positioned. Difficulty advancing the catheter and/or sheath may require the creation of an exteriorized arteriovenous (AV-TA and transeptal for mitral) or arterioarterial (AA-TA and trans-aortic for aortic) rail.

After the sheath is across the PVL, the closure device(s), along with a safety wire, are passed through the sheath. Devices currently being utilized for PVL closure have been designed for closure of other cardiac defects and are used in an off-label fashion. They include the Amplatzer family of occluders/plugs: the septal occluder, muscular ventricular septal defect occluder, duct occluder, and more recently, the vascular plug II (most commonly used in the United States) and vascular plug III (CE Mark approved).

Finally, the device(s) are slowly pulled back into the PVL until resistance is felt. For large PVLs, placement of

multiple devices deployed either sequentially or simultaneously may more densely fill the defect and ensure proper sealing. TEE helps to evaluate for any residual flow through the leak (Figure 4D). If an appropriate reduction in regurgitation is seen without prosthetic valve interference and the closure devices are stable, they can be released and the safety wire removed.

COMPLICATIONS

The major complications that have been reported for PVL closure include death (1.4%–2%); the need for emergent cardiac surgery (0.7%–2%); prosthetic valve interference by wire, sheath, or device (3.5%–5%); device embolization (0.7%–4%); and non-TA vascular complications (0.7%–2%), with an overall major adverse event rate of approximately 9% at 30 days. Additional complications such as progressive hemolysis, stroke, and rhythm aberrations have also been described.

Case series have been reported for safe TA access, with good technical success seen with surgical TA PVL closure^{10,15,16} and percutaneous TA PVL closure.^{8,17} In our previously published experience with 32 percutaneous TA access procedures (PVL closure, $n = 26$), we had complications in two cases (7.1%). The complications encountered included pericardial effusion ($n = 1$) and death due to electromechanical dissociation in a patient with suprasystemic pulmonary hypertension ($n = 1$). Similar complications, along with hemothorax, have also been noted in other studies in the literature.^{10,15,18}

OUTCOMES

A number of case series have been described in the literature that evaluate the safety and efficacy of transcatheter closure of PVLs. Technical success is usually described as correct deployment of a stable device in the leak with a lack of any significant residual regurgitation or valve interference and malfunction. The largest published case series dealing with transcatheter PVL closure (number of procedures, 141 and 57) report technical success in the range of 77% to 86%.^{17,19} But, due to the novelty of the technique, the literature is limited, and more experience will certainly help us to understand the finer technical aspects of this procedure.

SUMMARY

TA access for PVL closure can be pursued as a safe and effective route, especially for the anatomically hard-to-approach calcified tracts and posteroseptal mitral PVLs. It has been shown to decrease fluoroscopy times, as well as procedure times, in a selected subset of patients. Although there are a number of complications that can potentially be associated with this route,

there have been considerable advancements in imaging, specifically fusion imaging, to guide the procedure and minimize these complications. Further exploration into the safety and efficacy of TA can help us to better understand and delineate the utility of TA for PVL closure. ■

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