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REVIEW ARTICLE

# Transapical Access for Percutaneous Mitral Paravalvular Leak Repair

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**ABSTRACT**

Paravalvular leak (PVL) is a rare complication of mitral valve surgery that may result in serious clinical sequelae—including heart failure or hemolytic anemia. Treatment of these defects may be achieved with either percutaneous or open surgical repair, but recently, percutaneous approaches have become more popular due to their lower procedural risk. Percutaneous repair of mitral PVL can be performed from various access sites, including the femoral artery, femoral vein (via transeptal), or via transapical left ventricular access. The transapical approach provides simple, direct access to the entire mitral annulus—including areas that may not be reached from either transseptal or retrograde approaches. In addition, the short, in-line course from the apex to the mitral annulus simplifies delivery of large-caliber interventional equipment and limits procedural/fluoroscopy time. These advantages are counterbalanced by risk of complications, including left anterior descending coronary artery puncture and bleeding following sheath removal. This article reviews the literature addressing percutaneous PVL repair and the use of transapical access in the catheterization laboratory. We then describe our approach to percutaneous transapical mitral PVL repair.

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**KEYWORDS** Cardiac and cardiothoracic surgery; clinical cardiology; interventional cardiology

## Introduction

Paravalvular leak (PVL) is a rare but serious complication of heart valve surgery. Most PVLs are asymptomatic, however, 1–5% of patients develop serious clinical consequences such as heart failure, endocarditis, or hemolysis.[1,2] PVLs occur as a consequence of an incomplete seal between the ring of the implanted valve and the surrounding cardiac tissue. Known risk factors for PVL include annular calcification, small prosthetic size, inadequate suturing technique, and infection.[3] PVLs that are diagnosed within a year of surgery are most often secondary to technical complications of the mitral surgery; in contrast, PVLs identified later are most frequently a consequence of infectious endocarditis or annular calcification.[4] When repair is necessary, surgical or percutaneous approaches may be performed to occlude these defects.[1,5–11]

The incidence of PVL following valve replacement surgery is 5–17%.[12–14] PVL is more common in the mitral than the aortic position, and most significant complications occur in the mitral position.[12,13,15] The majority of PVLs are isolated defects (or holes), but multiple defects are identified in 27% of patients.[16] It is unclear whether PVLs occur more frequently in bioprosthetic or mechanical prosthetic valves.[12]

## Discussion

### Clinical implications of severe paravalvular leak

Patients with symptomatic PVLs present with congestive heart failure in over 90% of cases. Most report NYHA Class >III symptoms, with the timing of presentation being variable.[17–19] PVL size correlates directly with onset of symptoms; with larger defects resulting in early worse heart failure symptoms. Smaller PVLs may create high velocity jets, more often resulting in hemolysis. Hemolytic anemia is present in 30–75% of the cases referred for intervention.[17,18] The number of PVL defects does not appear to correlate with symptoms, but increasing numbers of defects increase the risk of associated hemolysis.[16] PVLs may increase or decrease in size if not repaired.[15,20] Spontaneous closure is rare, but has been reported.[21] Importantly, the presence of PVL results in turbulent blood flow, augmenting the risk for the development of infective endocarditis in the presence of bacteremia. If regurgitant flow is significant and not corrected, the natural history of PVL may mimic that of native valve regurgitation. Routine diagnostic testing suggestive of PVL includes clinical exam findings consistent with aortic or mitral regurgitation and laboratory findings consistent with heart failure and/or hemolysis.

### Paravalvular leak anatomy and diagnosis

The majority of PVLs are crescentic, oval, or round in shape. Their track can be parallel, perpendicular, or serpiginous in relation to the direction of prosthetic blood flow. The most common location for mitral PVLs are along the posterior wall (5–6 o'clock from the surgeon's perspective) and along the aortic-mitral curtain (10–11 o'clock).[17,22] The prevalence of PVL in the posterior mitral annulus has been attributed to the following: (1) the posterior annulus provides a limited surgical field of view for suturing; (2) the proximity of the circumflex

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artery may lead to more superficial suturing; and (3) calcification and fibrosis are more prevalent in the posterior annulus.[23] Aortic PVLs are more commonly located along non-coronary or right coronary cusps.[24]

Angiography has historically been used to assess the location, size, and hemodynamic severity of PVLs. However, it is difficult to determine the 3D anatomic and spatial characteristics of the defect using angiography, alone. Invasive assessment with test balloons to assess PVL size, distensibility, and hemodynamic implications of closure is no longer recommended due to the risk of balloon entrapment.

The definitive diagnosis of PVL usually requires echocardiography to confirm that the regurgitant flow is paravalvular, rather than intravalvular. Both transesophageal (TEE) and transthoracic (TTE) echocardiography are helpful in assessing prosthetic valve function and providing information on the spatial characteristics of PVL. Color doppler allows for identification of the location, direction, and severity of regurgitant blood flow. However, because the spatial resolution of 2-dimensional TEE and TTE is limited, the addition of 3D TEE provides critical additional information regarding the size and shape of the PVL (Figure 1).[23,25] This information is especially helpful during percutaneous closure procedures.[26] Real-time 3D TEE allows operators to visualize the length of the catheter or guidewire, identify the size, shape, and number of PVLs, and ensure that any deployed closure device does not impair movement of the valve leaflets (Figure 2).

PVLs may also be evaluated with EKG-gated computed tomographic angiography (CTA). These images can be retrospectively reconstructed to form 4D-reconstructions that allow for detailed visualization of the PVL. These images have been used to assist planning for percutaneous PVL closure procedures.[17] Like echocardiography, CTA is limited by artifact from high-density structures like the prosthetic valve and extensive calcification.

Cardiac magnetic resonance imaging (CMR) may also be used to image PVLs, particularly in pre-operative settings. CMR provides quantification of regurgitant flow and is

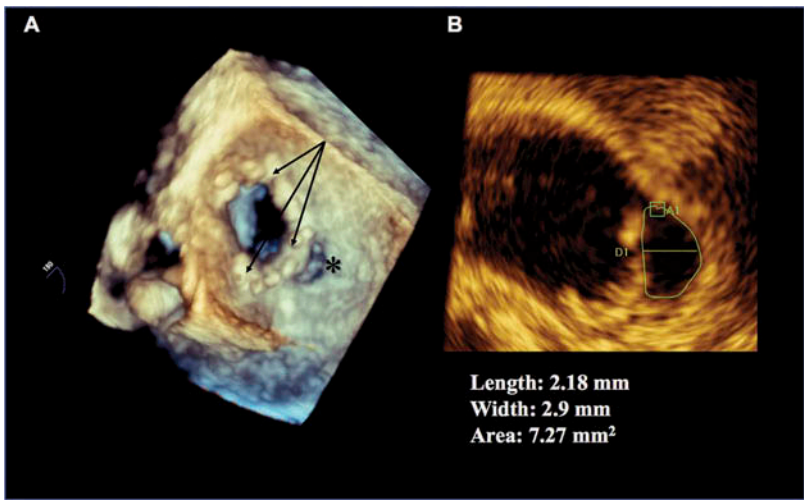


**Figure 1.** 3D and 2D-transesophageal echocardiographic assessment of a posterior mitral paravalvular leak. 3-dimensional echocardiography allows for a comprehensive understanding of the defect (*) and the location of surrounding structures (e.g., prosthetic annulus – arrows) (A). Measurement of the defect is done with 2D TEE imaging (B).

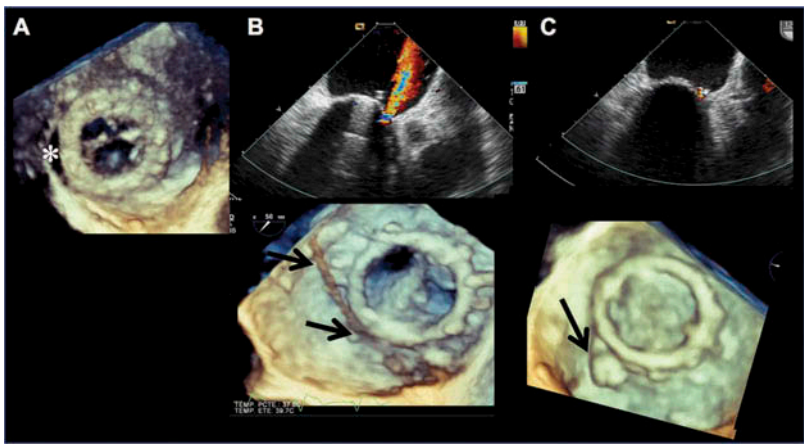


**Figure 2.** Real-time 3D echocardiographic guidance of percutaneous paravalvular leak repair procedure. 3D transesophageal guidance for percutaneous paravalvular leak repair allows for real-time assessment of the defect, wire, and equipment location. First, the defect is located (A). Next, the defect is crossed with a guidewire. Real-time 3D TEE is particularly helpful when confirming the guidewire (arrows, B) is passed through the paravalvular defect (B). After percutaneous closure is complete, location of the occluder device (black arrow, C) and absence of regurgitant flow is confirmed (C).

therefore especially useful for severity assessment when multiple leaks are present.[27] There are data supporting CMR quantitation of PVL following transcatheter aortic valve replacement, but less evidence for surgical valves or valves in the mitral position.[28–30] In addition, not all mechanical valves are compatible with CMR.

Recent, research-oriented 5-class (trace to severe) grading schemes for echocardiographic assessment of the severity of PVLs have been proposed for both the aortic and mitral positions.[31] These criteria are intended for research purposes and not intended to replace current guidelines, which use 3-class grading schemes. The recommended methods used to assess the severity of para-mitral valve regurgitation are similar to those used to evaluate native mitral regurgitation, including color flow regurgitant jet area, jet density, and systolic pulmonary venous flow reversal.[32] The proportion of the circumference of the sewing ring occupied by the regurgitant jet provides an approximate guide to severity, with >20% indicating severe regurgitation and <10% indicating mild regurgitation.[32] The proximal isovelocity surface area (PISA) measurement has not been validated in paravalvular regurgitation, but large PISA shell measurements of paravalvular regurgitant jets have been reported to be consistent with severe regurgitation.[33] Para-aortic regurgitation is also assessed with accepted criteria that are used to assess native aortic insufficiency, including pressure half-time, jet width, jet density, and diastolic flow reversal in the descending aorta.[32]

## Medical and surgical management of PVL

Medical therapy in symptomatic PVL is directed at symptom reduction by treating heart failure or anemia. Despite these interventions, the majority of patients with severe PVL require definitive, structural correction via either open surgery or transcatheter-based interventions.

Surgical correction improves overall survival and symptoms in patients with severe PVL, when compared to medical therapy, alone.[14] Surgery may include repair of the PVL or redo replacement of the prosthetic valve. Many approaches to surgical correction of mitral PVL have been described, but most involve either direct suturing, patching, or incorporation of autologous tissue from neighboring structures.[34–38] The choice of repair versus replacement depends largely on the specific etiology of PVL, location, and size of the leak. Operative mortality for surgical replacement of a dysfunctional mechanical or bioprosthetic valve is 5–14%.[39,40] Hospital mortality has been described as 13% for initial reoperation, with subsequent operations associated with significantly higher mortality.[41]

## Percutaneous paravalvular leak repair

Since first described in 1992, percutaneous transcatheter closure of PVL has become an attractive alternative to surgical correction.[5] A variety of techniques have been described.[1,5–11] Most techniques include passing a guidewire through the leak with real-time echocardiography and fluoroscopy guidance to ensure that the wire is indeed crossing the PVL. The size and shape of the defect determines the size of the delivery catheter used. The occlusion device is then deployed in the leak. Before and after release of the occlusion device, the operator must confirm free motion of the prosthetic leaflets, stable anchoring of the occlusion device, and reduction of regurgitant jet size.[42] Evidence comparing transcatheter intervention to surgical repair of PVL are limited, but a recent retrospective cohort demonstrated comparable 1-year mortality, re-intervention, and hospital readmission rates.[43]

At this time, the majority of percutaneous PVL repairs are performed with cylindrical or oval Amplatzer devices (St. Jude Medical, St. Paul, MN, USA), although vascular coils have also been used.[1,18,25,44–46] The success of percutaneous PVL repair hinges on proper selection of occlusion devices, which is predicated on the size and shape of the PVL. Because most PVLs are oval in shape, oval occlusion devices may be preferred in most cases. Large PVLs require large occlusion devices. Unfortunately, large occlusion devices increase the risk for prosthetic leaflet impingement, because the discs of the occlusion device can overhang the sewing ring and interfere with valve function. Some authors have suggested that this risk may be alleviated by placing multiple smaller occlusive devices in a large defect.[42] Notably, device manufacturers are developing new devices specifically for PVL, including the Occlutech® PLD Occluder device—the first CE marked device for mitral and aortic valve PVL. The Occlutech® PLD device is currently not available outside of research settings in the United States.

Percutaneous PVL closure has a technical success rate of 77–88% in high-volume centers, with some reporting success rates greater than 95%.[18,25,45,47] Clinically significant success has been reported in 67–77% of cases. Peri-procedure complications, including tamponade, device embolization, stroke, and prosethetic damage, have been reported in around 10% of cases. Mortality has been reported in approximately 1% of cases. Late embolization of occlusive devices has also been reported, but is rare.[48,49]

## Access for percutaneous PVL repair

Percutaneous PVL repair is performed from multiple access points: retrograde via the femoral or radial artery, antegrade via femoral vein (with trans-septal access), or via transapical (TA) access.[42] The specific access site and approach is chosen on a case-by-case basis with consideration for the location of the defect, location of the prosthesis as well as other anatomical considerations, multiple patient-specific issues, and operator experience.

Closure of aortic PVL is typically performed via the retrograde arterial approach from the femoral artery access.

Mitral PVL closure is technically more challenging than aortic PVL closure. The location of the PVL along the mitral annulus determines the optimal approach for the procedure. If the PVL is close to the atrial septum, it may be difficult to engage the defect via the femoral venous-trans-septal approach. Even if the defect can be crossed via a femoral venous-trans-septal approach, additional retrograde arterial access may be required to snare the wire in an effort to provide a more stable rail for device delivery. Left ventricular structures (such as trabeculae, papillary muscles, and chordae)

may complicate retrograde engagement of mitral PVL. In some instances, access via a TA approach is required. TA access provides direct engagement of mitral PVL at any location around the mitral annulus.

### Transapical access in the cardiac catheterization laboratory

Transapical (TA) access has been used for diagnostic and therapeutic procedures for over 50 years.[50] TA access was traditionally achieved with direct surgical exposure of the LV apex via a mini-thoracotomy. More recently, percutaneous access of the LV apex has been described for interventional procedures.[51–54] The percutaneous LV access technique was derived from LV puncture-needle catheterization, which was historically used to measure LV pressures in the presence of mechanical aortic and mitral valves. Havranek and Sherry reported a procedure-related mortality of 0.5%, tamponade of 1.4%, and pneumothorax/hemothorax of 2.7% in a cohort of 1150 patients from the literature in patients who received LV puncture via this approach.[55] The larger access sheaths required for interventional use of TA LV access carry increased risk. Pitta and colleagues reported an overall complication rate of 62%, most commonly hemothorax, for patients undergoing interventional procedures via TA approach.[53] In contrast, Jelnin and colleagues reported a much lower complication rate of 7.1% when closure of the LV access site is performed at time of sheath removal.[51]

Interventional TA access is most commonly used for structural interventions involving the mitral valve or as an alternative to femoral access in patients with severe peripheral arterial disease who are undergoing aortic valve interventions. TA access was initially considered an alternative access to the transfemoral (TF) approach for transcatheter aortic valve replacement (TAVR). However, secondary, propensity-matched analysis of early TAVR data have shown an overall increase in morbidity and mortality with TA-TAVR when compared to TF-TAVR.[56] More modern, smaller TAVR delivery systems have increased the number of patients amenable to TF-TAVR, and as a result TA-TAVR has declined in popularity. Although TA-TAVR is not the preferred access site for average TAVR patients with typical valve systems in the United States, use of TA access for the delivery of novel valve systems and indications continues.[57]

The primary indication for TA access may be limited to mitral valve interventions. Navigation of large valve system machinery into the mitral position is technically challenging via either the trans-septal or retrograde-aortic approach. The direct, in-line access to the mitral valve from TA access is attractive for percutaneous mitral valve therapies, and has been the preferred access in many investigational percutaneous mitral valve intervention cohorts.[58–61]

### Transapical access for mitral PVL closure

The current literature regarding prosthetic mitral PVL closure via the TA approach is sparse. Jelnin and colleagues published the largest cohort with 26 patients treated with a TA approach.[51] Of this group, 10 cases used primary intended TA access, six cases were crossovers due to failed arterial or transeptal access, and 10 cases were combined TA and transeptal with the creation of a venous-LV apical rail. Delivery sheaths ranged from 5-Fr to 12-Fr. Of the 22 patients with access sites >5-Fr, 20 were closed with an Amplatzer Duct Occluder. The 5-Fr access sites were not closed with a closure device. Two patients in the overall cohort had procedure-related complications (7.1%). In addition, total fluoroscopy time for primary intended TA access resulted in a 35% decrease compared to conventional arterial or venous access at the same center (27.4 ± 15.6 min compared with a total 42.6 ± 29.9 min). A separate retrospective review by Taramasso and colleagues described a cohort of 17 high-risk patients who underwent TA mitral PVL closure.[62] This group had a procedural success rate of 94%, with similar outcomes to a comparison group of 122 surgically treated patients (68% mitral PVL).

TA access is a potentially preferred technique for mitral PVL closure due its more direct approach, as well as its decreased procedure and fluoroscopy time. Direct puncture of the left ventricular apex still poses risks of complications, including potential for left anterior descending (LAD) coronary artery puncture and bleeding after sheath removal resulting in hemopericardium. Further comparative studies are necessary to determine the optimal approach to mitral PVL closure, however TA access appears to be effective and safe.

### Our approach

Prior to PVL closure, the details of each patient's case are presented at our institutional "Valve Conference." This Heart Team meeting includes cardiac surgeons, interventional cardiologists, and often cardiovascular imaging physicians. PVL cases are discussed along with pre-procedure TAVR and percutaneous mitral valve repair cases. Percutaneous therapy for PVL is our preferred approach for patients with adequate anatomy for transcatheter intervention. However, re-do surgery is sometimes preferred in cases of complicated, extensive PVL—particularly when a large (extending >50% around valve annulus) leak is present. Patients with a history of multiple sternotomies or a hostile chest are typically excluded from surgical consideration. STS scores are routinely calculated and presented with the patient's information so as to offer the optimal therapy to the patient.

The informed consent process includes a detailed discussion of the procedure, including possible complications. Our conversation with the patient pays particular attention to the off-label use of occluder devices. Contraindications to TA include cardiac surgery within 6 weeks, left ventricular thrombus, and left ventricular apical aneurysm. All TA procedures are done with general anesthesia. Percutaneous TA access is an ideal case for the hybrid operating room, where bleeding complications can quickly be addressed with open thoracotomy. After the induction of anesthesia, the anesthesiologist places a dual lumen airway. This allows the anesthesiologist to preferentially deflate the left lung to allow optimal positioning of the left ventricular apex, while allowing preferential ventilation to the right lung. Identification of the left ventricular apex occurs initially with palpation of the left 5th intercostal

space, in the mid-clavicular line. Once the location between the ribs has been palpated, transthoracic echocardiography is used to confirm apical location and a marker is placed on the skin at the site. Coronary angiograms of the left anterior descending artery (or the left internal mammary artery if the patient has had coronary artery bypass graft surgery) are performed with the marker in place (Figure 3). If the marker position is adequately distant from the LAD, apical puncture is performed with a 7 cm micropuncture needle under TTE guidance with the left lung deflated.

A standard micropuncture wire is advanced into the left ventricle (LV) and a standard 5-Fr sheath is placed into the LV cavity and sutured in place to prevent movement. Real-time 3D TEE is critical for identifying the location and size of the defect. In general, an H1 or JR4 catheter may be used to direct an Advantage Glide Wire (Terumo, Somerset, NJ, USA) through the defect (Figure 4). 3D-TEE confirms that the guidewire is passed through the defect and not intravalvular (Figure 5). Once the wire is across the defect, it is exchanged for a stiff 0.035 inch Amplatz wire (Boston Scientific, Natick, MA, USA). Next, a 6-Fr 60cm Torqvue catheter (St. Jude Medical, St. Paul, MN, USA) is advanced over the wire across the defect. Depending on the location of the defect (paravalvular, septal) the Torqvue catheter may need further modification. It is important to note that we typically do not use larger bore access than the 6-Fr Torqvue catheter. All of the devices we typically use from the TA approach are compatible with 6-Fr access, and larger catheters may increase the risk of access site complication.

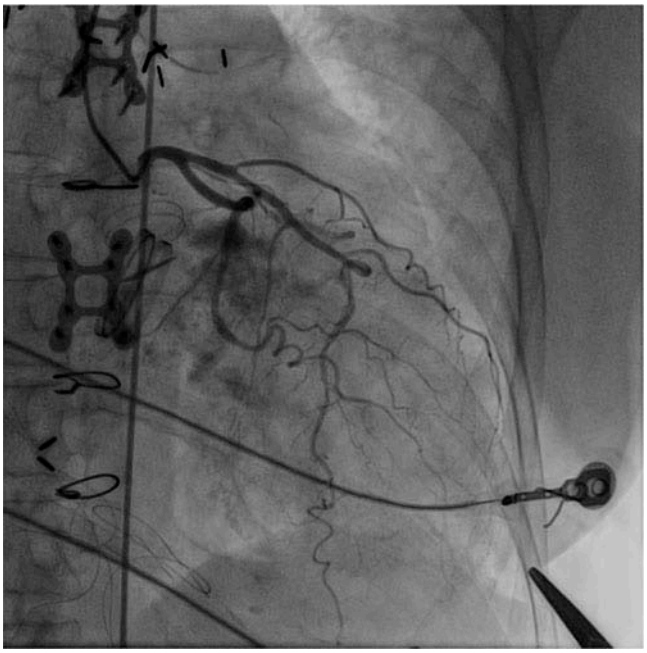

**Figure 3.** Coronary angiography prior to transapical puncture. Once the apex is identified by palpation and transthoracic echocardiography, a marker (hemostat) is placed over the LV apex and coronary angiography is performed. If the course of the left anterior descending artery is adequately distant from the marker, it is safe to proceed with percutaneous transapical puncture.

In the US, there are no FDA approved devices for the treatment of PVL, but St. Jude vascular plugs, septal occluders, and ventricular septal occluders have all been used. The defect is measured with TEE to help select the type and size of occluder device implanted (Figure 1). Once the appropriately sized device is placed across the defect, 3D TEE ensures that there is no further PVL and that the device itself does not interfere with the normal excursion of the valve leaflets or other cardiac structures. Once there is adequate closure of the PVL, the TA access site is sealed with a St. Jude Amplatz Duct Occluder 6/4 (Figure 6). If the patient has multiple premature ventricular contractions, we place a 5-Fr pacing wire in the right ventricle and initiate rapid pacing. Once the ductal occluder is in place, it is released. Although some operators use manual pressure or surgicell for TA closure—particularly when using 5-Fr sheaths, we feel that device-assisted closure of the TA puncture site is safest. There are a number of devices for percutaneous TA closure available in Europe, some with a CE mark.[63] These devices utilize various approaches to secure TA closure, including sutured and suture-less techniques. There are no approved TA closure devices available in the United States. Therefore, we typically use the St. Jude Amplatzer Duct Occluder 6/4 for closure of the 6-Fr TA puncture site. After the closure device is deployed, repeat coronary angiography confirms patency of the LAD, and a left ventriculogram is performed to demonstrate adequate TA closure. When ventriculography is impossible or not preferred—such as in the presence of mechanical aortic prosthesis or chronic kidney disease, TEE is critical in confirmation of adequate TA closure.

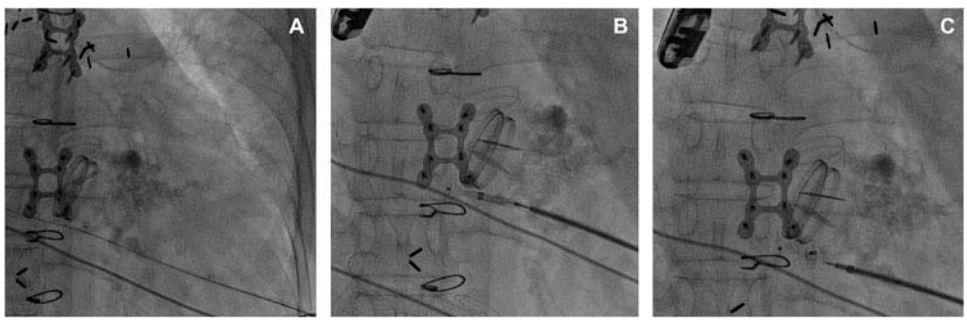


**Figure 4.** Percutaneous transapical mitral paravalvular leak closure. From transapical access, the paravalvular defect is crossed with an Advantage Glide Wire (Terumo, Somerset, NJ, USA) (A) and then exchanged for a stiff 0.035 inch Amplatz wire (Boston Scientific, Natick, MA, USA). After a Torqvue catheter (St. Jude Medical, St. Paul, MN, USA) is advanced over the wire across the defect, the wire is removed and the occlusion device is advanced into the left atrium. The defect is then closed with deployment of the occluder device (B,C) with careful attention made to avoid impinging the valve apparatus or leaflets.

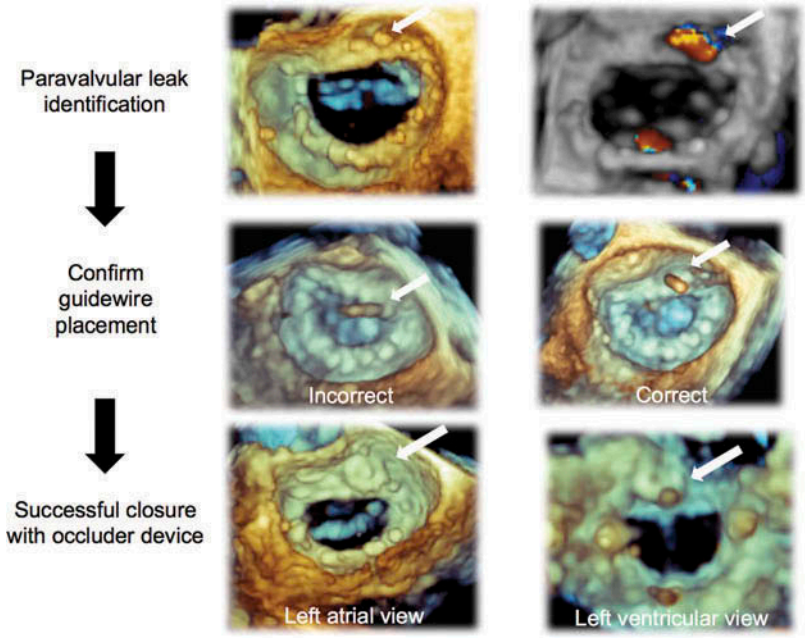


**Figure 5.** Confirmation of guidewire and occluder device location with real-time 3D TEE during percutaneous mitral valve paravalvular leak repair. After identifying the location of the defect (white arrows) on the mitral annulus (top row), 3D TEE confirms correct location of guidewire through the defect (middle row, right). After correct location is confirmed, closure is performed. 3D TEE can assess occluder device placement from both left atrial (bottom row, left) and left ventricular (bottom row, right) views.

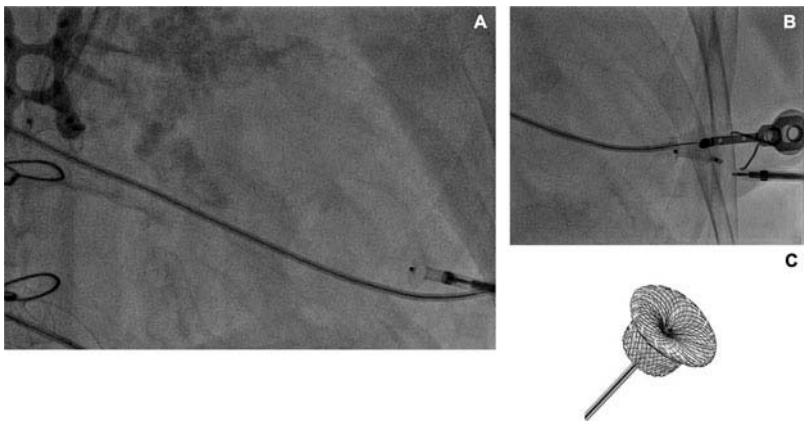


**Figure 6.** Closure of percutaneous transapical puncture site with occluder device. Closure of the transapical access site is achieved with a St. Jude Amplatz Duct Occluder 6/4 (C) (St. Jude Medical, St. Paul, MN, USA) by deploying the device in the apical left ventricle and pulling the disc against the apical wall (A). Ventricular ectopy is common, and some patients require rapid pacing to over-drive PVCs. Once adequate seal of the LV apex is achieved, the device is released (B). A routine ventriculogram is then performed to confirm adequate closure of the ventriculotomy.

Our default TA approach is via percutaneous puncture. We have experienced only one major bleeding complication, which occurred in a Jehovah's Witness patient and was managed with auto-transfusion. We have not had any complications requiring surgical repair or correction. A retrospective/prospective study of our outcomes and complications via TA approach is planned.

## Conclusion

Percutaneous repair of mitral PVL can be performed from various access sites. The transapical approach provides direct access to the entire mitral annulus, simplifies delivery of large-caliber interventional equipment, and limits procedure/fluoroscopy time. Complications associated with transapical access include left anterior descending coronary artery puncture and bleeding following sheath removal. These risks are limited by fastidious technique and device-assisted apical closure.

## Disclosure statement

Atman P. Shah serves as a consultant and proctor for St. Jude Medical/Abbott Vascular. The remaining authors have nothing to disclose.

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