ISSN: 0975-3583,0976-2833 VOL15, ISSUE 07 2024

Device Closure of Paravalvular Regurgitation- A Single-Center Experience from a Tertiary Care Centre in South India

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Abstract

Paravalvular regurgitation/leak (PVL) frequently occurs following prosthetic cardiac valve implantation. The incidence of PVL following mitral valve replacements (MVRs) is 5% to 17% and is about 5% to 10% after aortic valve replacements (AVRs). Symptoms of PVL are either due to heart failure or haemolysis. Surgery for PVL is associated with significant morbidity and mortality. Percutaneous closure of PVLs has emerged as an attractive alternative to surgery. An aortic PVL is closed using less complicated techniques via the retrograde transfemoral approach. Transcatheter closure of mitral PVLs is technically challenging and requires more complex catheter techniques than aortic PVLs. Transoesophageal echocardiogram (TEE) guidance in mitral leaks is mandatory during all stages of the procedure.

In this cohort, one patient had aortic PVL, which was treated using a retrograde transfemoral approach. Four patients had mitral PVLs, and transseptal puncture was done in all four patients. In one mitral PVL patient, the device closure was done using the antegrade transseptal technique. In the remaining three mitral PVL patients, we utilised the arteriovenous loop technique for device closure. Procedural success was noted in four out of five patients. Achieving a mild or lesser severity of PVL at follow-up is key to a good outcome. Residual leak post-closure determines major adverse cardiovascular events (MACE). The degree of the leak at follow-up is independently associated with both MACE and death.

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Introduction

Paravalvular leak (PVL) is a frequent problem following prosthetic cardiac valve implantation [1]. The incidence of PVL following mitral valve replacements (MVRs) is 5% to 17% and is about 5% to 10% after aortic valve replacements (AVRs) [2]. Symptoms of PVL are either due to heart failure or haemolysis [3]. Surgery for PVL is associated with significant morbidity and mortality. Redo operation is unsuccessful because of underlying tissue friability, inflammation, and calcification around PVL [4]. Mild to moderate leaks deteriorate over time; hence, conservative management is not advisable in patients with mild to moderate leaks. The closure of PVL of the percutaneous device was first reported by Hourihan et al. in 1992 [5]. Various techniques of percutaneous device closure of PVL were described in small series [6]. Here, we report our experience in the device closure of PVL.

Materials and methods:

We retrospectively studied the outcomes of consecutive patients who underwent device closure for PVL over the past five years (January 2018 to December 2023) in our institution. Our study also examined the different techniques for Aortic and Mitral PVLs. All patients who underwent device closure were initially evaluated with transthoracic echocardiography (TTE) followed by a transoesophageal echocardiogram (TEE).

This being a retrospective study, data collection included detailed TTE and TEE assessment of PVL and their morphological features in each patient based on hospital records. Cardiac catheterisation findings were also noted. Follow-up data was analysed at their last clinic visit, including the patient's clinical profiles and TTE and TEE studies. "The research was conducted in accordance with the principles outlined in the Helsinki Declaration of 1964 and its later amendments". Data collection was done after the institute's ethics committee approval. Informed consent was obtained from all the participants.

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The interventionist performed TEE on all the patients under general anaesthesia. Heparin was administered at 100 U/kg, and activated clotting time was maintained between 250 and 300 seconds during the procedure.

The Amplatzer vascular plug (AVP) II/III and Amplatzer Duct occluder (ADO) II were used (Figure 1). Post-procedure, all patients underwent a TTE 24 hours after the procedure to check for device position, residual shunt presence, and complications. Procedural success was defined as stable device position on echocardiogram at discharge. All Patients came for their first follow-up at 6 months and yearly, with TTE done at each visit. We describe the case details and techniques of all consecutive patients at our institution.

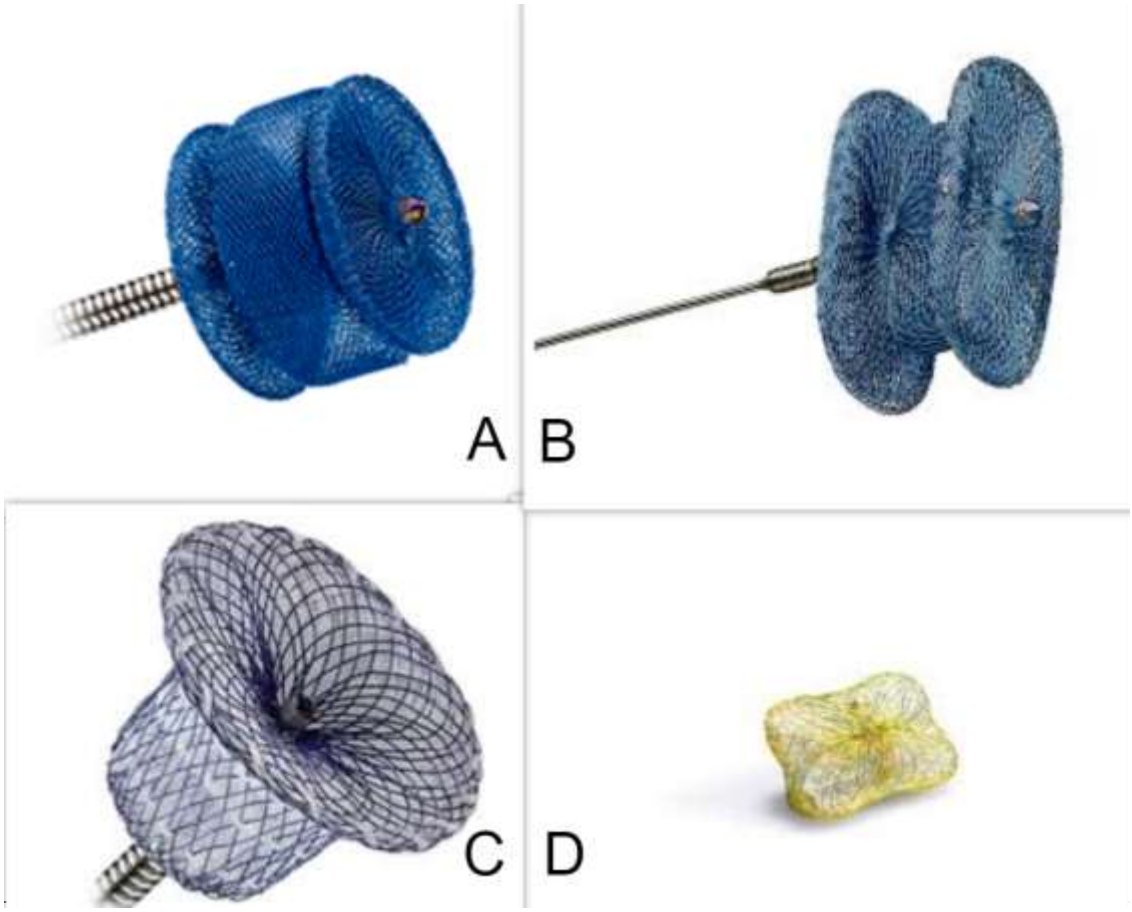

Figure 1: a) Amplatzer vascular plug (AVP) II**, b)** Amplatzer vascular plug (AVP) III, **c)** Amplatzer Duct occluder (ADO) II**., d)** Occlutech PLD occlude

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Case 1:

A 56-year-old male patient, who had been diagnosed to have chronic rheumatic heart disease (cRHD) and had undergone MVR (ball and cage, Starr Edwards valve Prosthesis) and annuloplasty for severe Mitral stenosis (MS) and Tricuspid Regurgitation (TR). The echocardiogram showed a 2x5 mm mitral PVL along the interatrial septum (IAS) at the 10 o'clock position. Mitral PVL device closure using the arterio-venous loop technique was done (figure *2a*-f). An Amplatzer Vascular Plug III (AVP III) 8-4mm device was used. A follow-up echocardiogram at 3 years showed no residual paravalvular leaks, and the device was stable.

Case 2:

A 42-year-old male patient, who had been diagnosed to have cRHD, had undergone dual valve replacement (DVR) (bi-leaflet 25mm St Jude's metallic valve at the mitral position and 19mm St Jude's valve at the aortic position) for severe MS and moderate aortic stenosis (AS). The echocardiogram showed 2mm moderate aortic PVL at the 8 O'clock position between the septal tricuspid leaflet and IAS. Aortic PVL device closure using the retrograde transfemoral technique was done (figure *3a*-c). AVP III 3-6mm was used with no residual leak post-procedure and at 6 months follow-up.

Case 3:

A 25-year-old male patient who had been diagnosed with infective endocarditis in the past had undergone MVR (tilting disc 31mm TTk Chitra metallic valve). The echocardiogram showed moderate Mitral PVL. Device closure was done using the arterio-venous loop

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technique (Figure 4a-d). An AVP II 8x10mm device was used. A follow-up echocardiogram at 6 months showed no residual PVL with a stable device.

Case 4:

A 57-year-old male patient, who had been diagnosed to have cRHD, had undergone MVR (tilting disc, 27 TTk Chitra metallic valve) for severe MS. Echocardiogram showed 2.6mm moderate mitral PVL around 2-3 o'clock position. Mitral PVL device closure was done using the arterio-venous loop technique (figure *5a*-d). AVP III 5-10mm device was used. A follow-up echocardiogram at 12 months showed a stable device with no residual leak.

Case 5:

A 38-year-old male patient, who had been diagnosed to have cRHD, had undergone DVR (ball and cage, Starr Edwards valve at mitral position and bi-leaflet 19mm St Jude's metallic valve at aortic position). The echocardiogram showed moderate mitral PVL along IAS at the 4 o'clock position. PVL device closure using antegrade transseptal technique was done with Amplatzer duct occluder II (ADO II) 10-8mm device. An echocardiogram after 24 hours showed an embolised device in the Left ventricle. Emergent surgical retrieval of the device and paravalvular leak closure were done.

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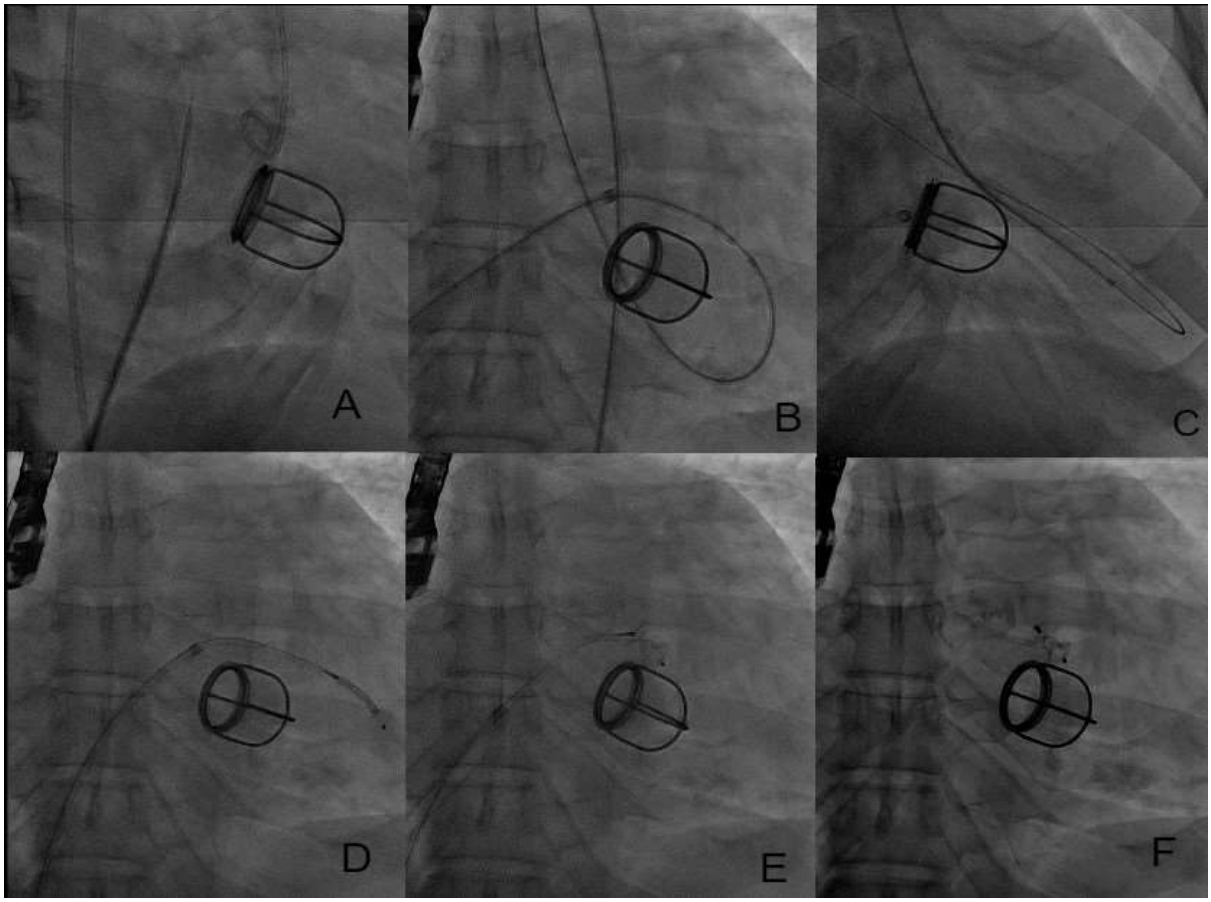

Figure 2: a) Transeptal puncture using Brocken Brough puncture needle under TEE guidance, b) wire snared and exteriorised through femoral venous access creating an arterio-venous loop. c) 8F long sheath in left atrium, defect crossed using 035 guide wire from left ventricle via femoral arterial access. d,e) AVP III device deployment. f) stable device position after deployment

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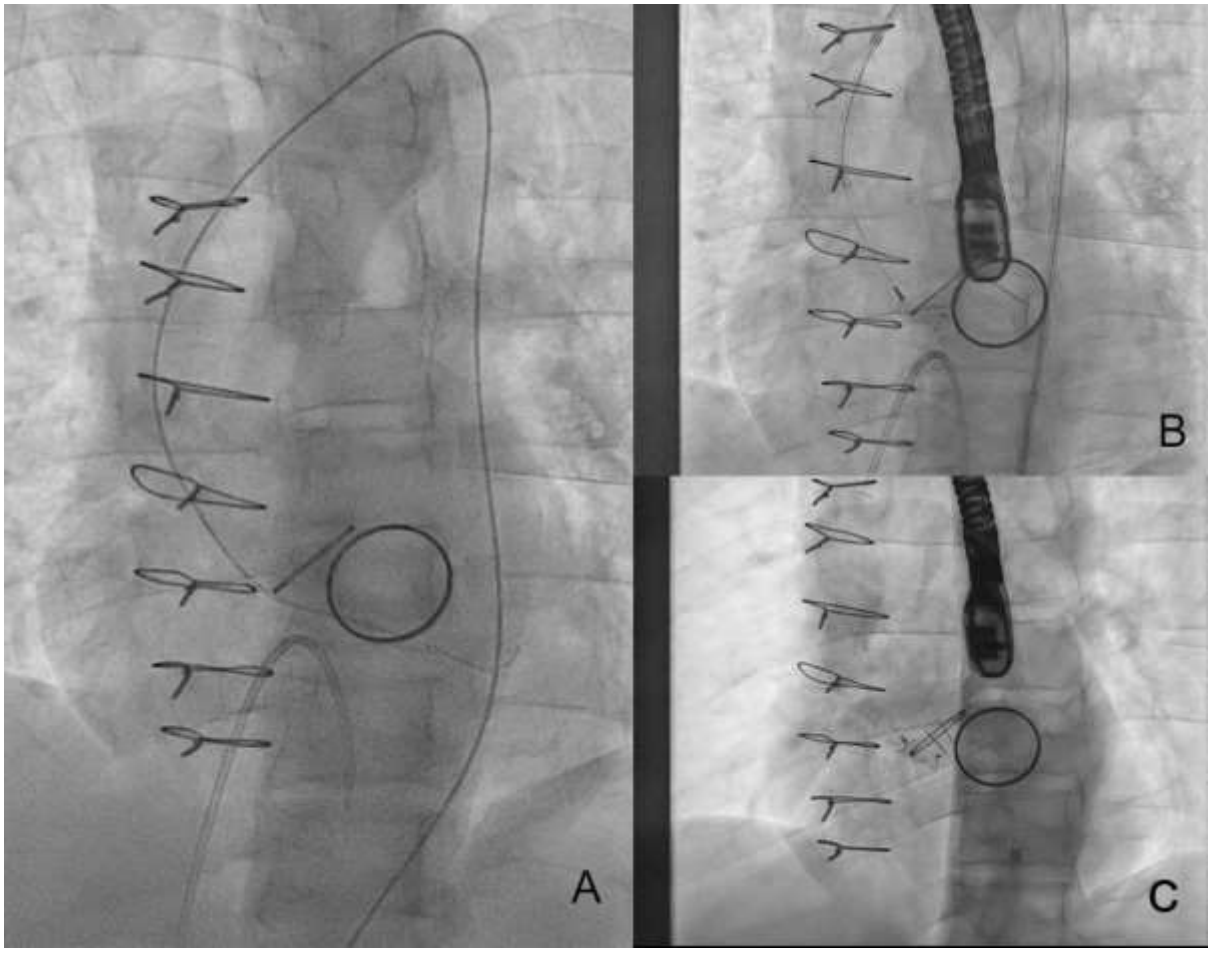

Figure 3: a) PVL defect crossed using 035 guide wire by retrograde transfemoral technique b) AVP III device deployed. c) stable device position after deployment.

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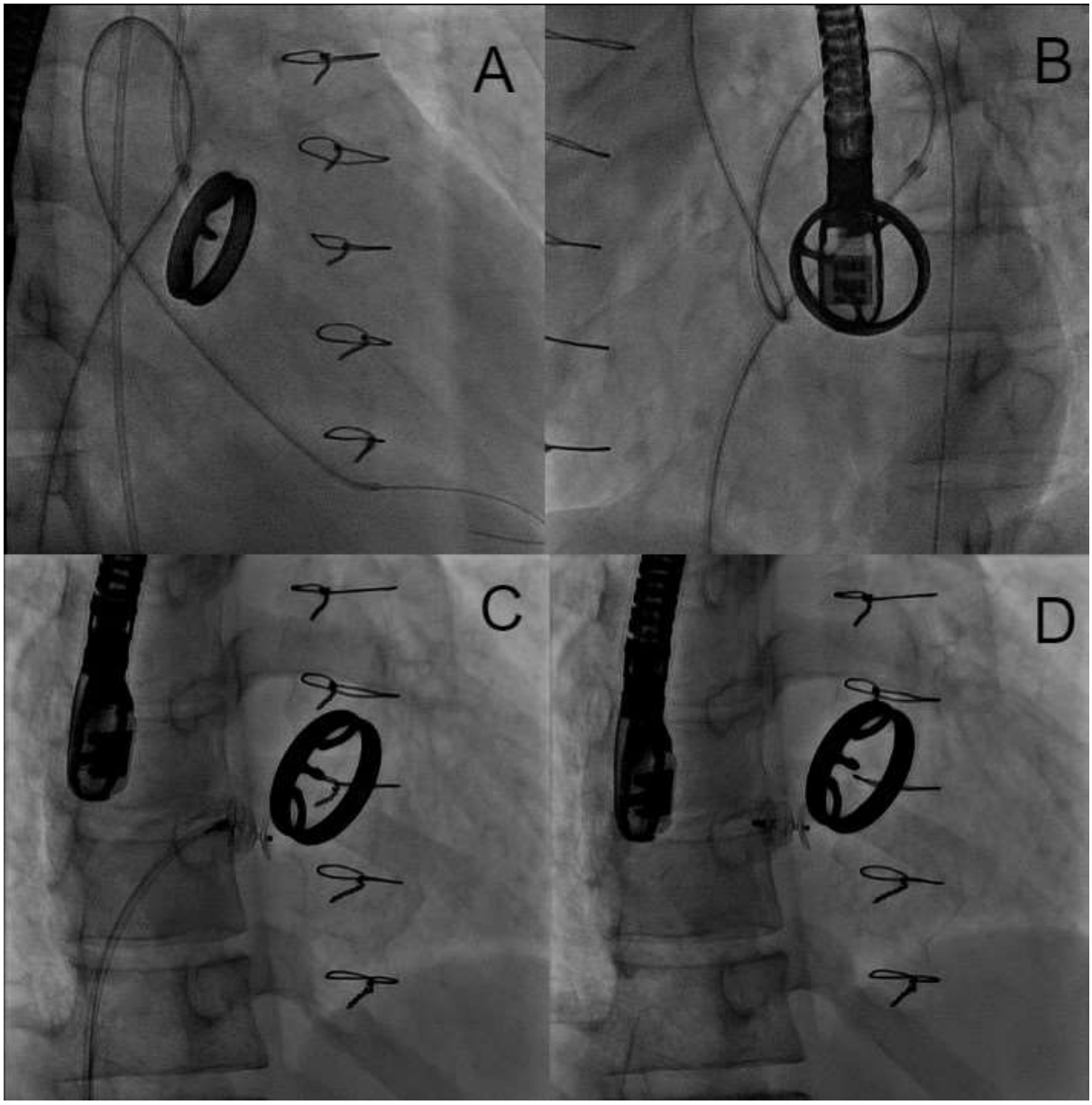

Figure 4: a) Transeptal puncture using Brocken Brough puncture needle under TEE guidance, b) 8F long sheath in the left atrium, defect crossed using 035 guide wire from the left atrium via femoral venous access, wire snared and exteriorised through femoral arterial access creating an arterio-venous loop. c) AVP II device deployment. d) stable device position after deployment.

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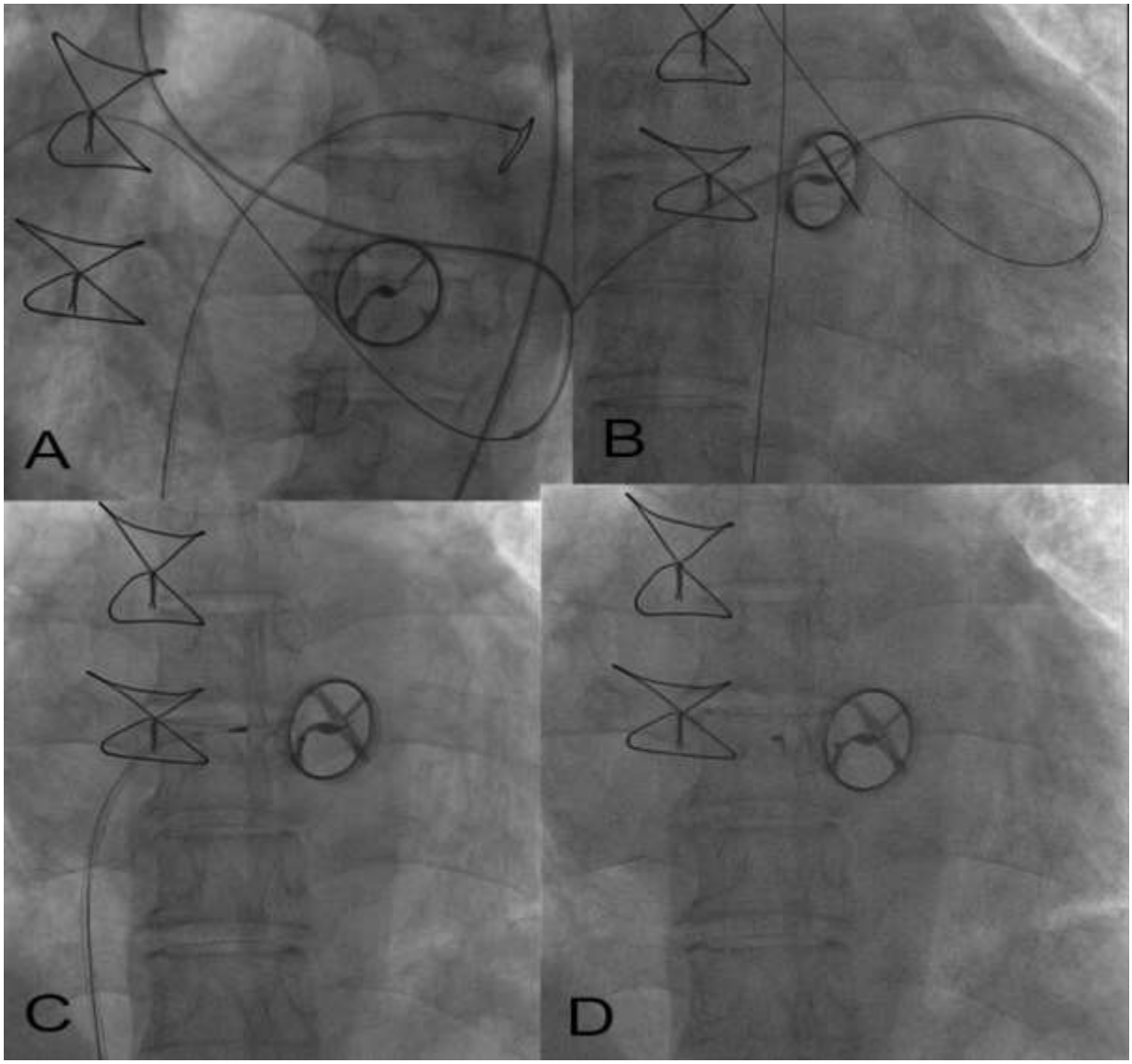

Figure 5: a) Transeptal puncture using Brocken Brough puncture needle, 6F goose neck snare in the left atrium. b) 035 guidewire crossed defect from the left ventricle into left atrium and exteriorised through femoral venous access, creating an arterio-venous loop. c) AVP III device deployment. d) stable device position post-deployment.

Results and outcomes:

All procedures were performed under general anaesthesia and with TEE guidance. TEE guidance was necessary for the transseptal puncture in these patients. One patient had aortic PVL, which was treated using a retrograde transfemoral approach. Four patients had mitral

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PVL, and transseptal puncture was done in all four patients. The device closure was done in one patient using the antegrade transseptal technique. In the remaining three mitral PVL patients, we utilised the arteriovenous loop technique for device closure (Table *1*). The arteriovenous loop approach facilitated our ability to pass the sheath through the shallow angles and the calcified lesions.

In our center, device closure failed in one patient. Procedural success was noted in four patients. The commonly used devices were the AVPII and AVP III, which are potentially better for crescent-shaped orifices. ADO II was used in case 5, which could have been the reason for device embolisation. Access site-related complications are encountered after any interventional procedure but were not encountered in our series.

Table 1: Case and procedure details

	PVL type	TEE guidance	Technique	Device type	Procedural success	Follow up
Case 1	Mitral	Yes	Arterio-venous loop	AVP III	Yes	3 Year
Case 2	Aortic	Yes	Retrograde Transfemoral	AVP III	Yes	6 Month
Case 3	Mitral	Yes	Arterio-venous loop	AVP II	Yes	6 Month
Case 4	Mitral	Yes	Arterio-venous loop	AVP II	Yes	6 Month
Case 5	Mitral	Yes	Antegrade Trans septal	ADO II	No	-

Complications:

There was no procedure-related mortality. Coronary air embolism or cardiac tamponade were not encountered. As the patients were subsequently followed up, other complications, like late embolisation of the device or worsening of valve regurgitation, were not observed.

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Follow-up outcomes:

The study's follow-up period was between 6 months and 5 years (Table 1). All patients who came for follow-up were clinically better and asymptomatic. Echocardiography at follow-up showed the device was stable in all four successful patients. None of them had any signs of erosion.

Discussion:

PVL patients are a high-risk cohort. Surgical reoperation is associated with 30-day in-hospital mortality of 8.8% to 11.5% [7]. Long-term survival after surgical correction of PVLs reported was 30% to 57.8%, 12-year actuarial survival was 39% but freedom from cardiac death was 54% at 12 years. Percutaneous closure of PVLs has emerged as an attractive alternative to surgery. The results of the device closure are comparable with the results from the surgical series, which showed lower morbidity and mortality rates. The American Heart Association 2020 guidelines for valvular heart disease provide level IIa recommendations for percutaneous PVL closure at comprehensive valve centres. A procedural success rate of 80% was achieved in our series which was in accordance with previously reported series (60-90%) [8]. Patients with successful percutaneous PVL closure significantly improved their symptoms, reduced heart failure-related hospitalisation, and lowered rates of mitral valve reoperation. Achieving a mild or lesser severity of PVL at follow-up is key to a good outcome [9].

The size of the arc of valvular dehiscence reflects valvular stability and PVL size and is an important variable in determining the suitability for percutaneous closure. It is best estimated on 3D-TEE. Transoesophageal echocardiogram (TEE) guidance in mitral leaks is mandatory during all stages of the procedure.

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The retrograde transfemoral approach closes an aortic PVL using a less complicated technique. In this technique, defects are crossed using a 0.035-inch 260cm hydrophilic guidewire from the aorta into the left ventricle (LV) through a 5/6 Fr Judkins right (JR) or Multipurpose (MP) diagnostic catheter under fluoroscopic and TEE guidance from femoral arterial access. After crossing the defect, the hydrophilic guidewire is exchanged for the 0.035-inch 260cm super-stiff guidewire through the catheter. Over the stiff guidewire, the delivery sheath is taken across the defect and parked in the left ventricle. An appropriate device is chosen and deployed through the delivery sheath after confirming the stable device position using fluoroscopy and TEE.

Mitral PVLs are technically challenging and requires complex catheter techniques for crossing the PVL and delivering the device. Depending on the location of the defect, different access routes and catheter techniques are used for mitral PVL closure.

Technique 1: The retrograde transfemoral approach is the most used approach for all mitral PVLs. It is commonly used for PVLs located at 6 o'clock on the mitral valve. Defects are crossed using a 0.035-inch 260cm hydrophilic guidewire from the left ventricle (LV) into the left atrium (LA) through a 5/6 Fr Judkins right (JR) or Multipurpose (MP) diagnostic catheter under fluoroscopic and TEE guidance from femoral arterial access. After crossing the defect, the hydrophilic guidewire is exchanged for the 0.035-inch 260cm super-stiff guidewire through the catheter. Over the stiff guidewire, the delivery sheath is taken across the defect and parked in the left atrium. An appropriate device is chosen and deployed through the delivery sheath after confirming the stable device position using fluoroscopy and TEE.

Technique 2: The Antegrade Transseptal approach is used if the PVL is located at 12 o'clock of the mitral valve. The transseptal puncture is done using a Brocken Brough needle under TEE and fluoroscopic guidance from femoral venous access. A lower transseptal puncture is

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preferred in PVL patients. A long sheath is taken across the interatrial septum (IAS) through the puncture site and parked in the left atrium. Defects are crossed using a 0.035-inch 260cm hydrophilic guidewire from the left atrium (LA) into the left ventricle (LV) through a 5/6 Fr Judkins right (JR) or Multipurpose (MP) diagnostic catheter under fluoroscopic and TEE guidance. After crossing the defect, the hydrophilic guidewire is exchanged for the 0.035-inch 260cm super-stiff guidewire through the catheter. Over the stiff guidewire, the delivery sheath is taken across the defect and parked in the left ventricle. An appropriate device was chosen and deployed through the delivery sheath after confirming the stable device position using fluoroscopy and TEE.

Technique 3: Arteriovenous Loop technique: In some patients, an arteriovenous loop through the PVL defect is created to advance the delivery sheath. The transseptal puncture is done using a Brocken Brough needle under TEE and fluoroscopic guidance from femoral venous access. A lower transseptal puncture is preferred in PVL patients. A long sheath is taken across the interatrial septum (IAS) through the puncture site and parked in the left atrium. Defects are crossed using a 0.035-inch 260cm hydrophilic guidewire from the left atrium (LA) into the left ventricle (LV) through a 5/6 Fr Judkins right (JR) or Multipurpose (MP) diagnostic catheter under fluoroscopic and TEE guidance. After crossing the defect, the hydrophilic guidewire is snared out of femoral arterial access using a gooseneck snare, thus creating an arterio-venous wire loop. Over the guidewire loop, the delivery sheath is taken across the defect and parked in the left ventricle. An appropriate device is chosen and deployed through the delivery sheath after confirming the stable device position using fluoroscopy and TEE.

Defects can also be crossed from femoral arterial access, and wire can be snared out of femoral venous access to create an arterio-venous guidewire loop.

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Technique 4: Percutaneous Trans-apical Puncture Approach is used in patients with dual mechanical valve replacement. Closure of mitral PVLs is unsafe via the retrograde or arteriovenous wire loop approaches in such patients. A coronary angiogram is done to delineate the left anterior descending artery. The left ventricle apex is punctured at the appropriate position away from the left anterior descending artery, and a 5/6 Fr short sheath into the left ventricle is placed. Defects are crossed using a 0.035-inch 260cm hydrophilic guidewire from the left ventricle into the left atrium through a 5/6 Fr Judkins right (JR) or Multipurpose (MP) diagnostic catheter under fluoroscopic and TEE guidance. The transseptal puncture is done using a Brocken Brough needle under TEE and fluoroscopic guidance from femoral venous access. A lower transseptal puncture is preferred in PVL patients. A long sheath is taken across the interatrial septum (IAS) through the puncture site and parked in the left atrium. The guidewire in the left atrium is snared out of femoral venous access using a gooseneck snare, creating a guidewire loop between the left ventricle apex and the femoral vein. Over the guidewire loop, the delivery sheath is taken across the defect and parked in the left ventricle. An appropriate device is chosen and deployed through the delivery sheath after confirming the stable device position using fluoroscopy and TEE. Finally, percutaneous transapical access is closed with an Amplatzer duct occluder II (ADO II) device. Taramasso et al. reported good outcomes through the transapical route [10].

The additional incremental benefit of using an Occlutech PLD occluder (GmbH, Jena, Germany) over the AVP-III device was published by Calvert et al. [11]. Transcatheter closure of a Transcatheter PVL is a lower-risk alternative, with a 1% to 2% risk of periprocedural mortality or need for reoperation. The procedural success rate was reported to be around 80%, and the success rate dropped to around 70% for mitral PVL [12]. It was associated with a shorter procedural time and fewer blood transfusions than redo-surgery [13]. PVLs of the MVR are associated with increased MACE. Factors associated

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with PVL occurrence were MVR position, supra-annular AVR, and continuous sutures in the mitral position (41%-67%).

In our center, device closure failed in one patient. Procedural success was noted in four patients. In the literature review, delayed presentation, severe pulmonary hypertension, and the presence of >2 PVLs were described as predictors for failure. Predictors of procedural success described were annual procedural volume and the type of device used. Garcia et al. found that using oblong devices such as the AMPLATZER vascular plug III versus other circular devices was associated with significantly higher procedural success [14]. In countries where AVP-III or PLD are not approved, mitral PVL closure procedures are performed off-label with the AVP-II device. The commonly used devices in our series were the AVP II or AVP III, which are potentially better for crescent-shaped orifices. ADO II was used in case 5, which could have been the reason for device embolisation.

Conclusions:

Percutaneous PVL device closure is an alternative to surgery. Transcatheter closure of mitral PVLs is technically challenging and requires more complex catheter techniques than aortic PVLs. Residual leak post-closure is a crucial factor in determining MACE. The degree of the leak at follow-up is independently associated with both MACE and death.

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List of abbreviations:

PVL - Paravalvular leaks

MVR - Mitral valve replacement

AVR - Aortic valve replacement

DVR - Dual valve replacement

cRHD - chronic rheumatic heart disease

MS - Mitral stenosis

AS - Aortic stenosis

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TR - Tricuspid Regurgitation

IAS - Interatrial septum

AVP III - Amplatzer Vascular plug III

AVP II - Amplatzer Vascular plug II

ADO II - Amplatzer duct occluder II

TEE - Transesophageal echocardiogram

MACE - Major adverse cardiac events

PLD - PLD occlutech occluder

JR - Judkins right diagnostic catheter

MP - Multipurpose diagnostic catheter

LA – Left atrium.

LV – Left ventricle.