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Editorial

Transcatheter closure of paravalvular leaks – How do i do it?

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1. Introduction

Paravalvular leak following mitral and aortic valve replacement is a serious clinical problem, though fortunately rare.[1] Even though immediate post-operative transesophageal echocardiographic studies have identified minute suture leaks in as many as 20%, hemodynamically significant leaks occur only in 1–5% of patients.[2] They are commoner in mitral than aortic positions, but the incidence is highest with the recent transcatheter aortic valve implantations. The causes include improper suturing, undue stress on the suture lines across the annulus, fibrosis or calcification of the annulus which fails to hold the sutures and rarely infections.[3] The patients present with anemia, hyperbilirubinemia, heart failure, or ventricular dysfunction with elevations of pro-brain natriuretic peptide levels.[4,5]

In this issue, Sasikumar et al have reported successful device closure of paravalvular leak following aortic valve replacement after balloon sizing their defects under transesophageal echocardiographic guidance.[6] After balloon sizing, they employed sequential placement of two devices through the same leak through two femoral arterial sheaths. In another article in this same issue, Vinay kumar sharma et al have demonstrated the utility of trans esophageal three dimensional echo while closing the mitral para valvular leak.[7] These two articles show the diversity of the nature of the leaks, presentation, and choice of devices, methods of deployment and guidance of the procedure. In this review, we intend to discuss the magnitude of the problem, justification for closure of paravalvular leak, technical details of the procedure, armamentarium of devices, important do's and don'ts and finally practical tips of successful completion of the procedure.

2. Does paravalvular leak closure really improve survival?

Relatively asymptomatic patients after prosthetic valve replacement surgery diagnosed with paravalvular leaks are commonly followed medically in clinical practice without any interventions.[8] When an aggressive surgical strategy was adopted to close the leaks, there was a clearly documented mortality advantage from 12% in surgical arm compared to 26% in conservative arm, even though patients in conservative arm were less anemic and less symptomatic. The actuarial survival at 1,5 and 10 years following aggressive surgical closure of paravalvular leaks after successful surgery was 98%, 90% and 88%, respectively. In patients followed on conservative approach, the actuarial survival was abysmal at 90%, 75% and 68% in the same observational period.[9]

3. Why not address the paravalvular leaks under vision in a redo surgery?

Even though surgical correction of paravalvular leak seems the most logical option since it is done under direct vision and not image guided, redo surgery has two basic demerits. The operative mortality for redo surgery is higher than the first surgery, and stands at around 14% across all patients.[10] In emergent situations, the mortality increases to 35%. The second problem about the surgery is the recurrence of the paravalvular leak. The annular fibrosis and calcification which caused the occurrence of the paravalvular leak in the first instance will fail to hold the sutures well and will result in recurrence of the paravalvular leak in the same areas. The incidence of paravalvular leak recurrence in the same areas

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after first redo surgery has been reported to be 13% and increases further to 35% after second redo surgery.[11] This makes transcatheter closure an attractive option, however, it is limited by the limited choice of devices, off-label uses of those devices, limited operator experience, challenging anatomy with serpiginous course and crescentic shapes, and challenges posed by very large defects. Every attempt should be made to ensure normal functioning of the prosthesis after device closure of the paravalvular leak. This means a successful procedure helps the patient immensely, but an unsuccessful procedure will risk and worsen the functioning of the mechanical prosthetic valve.[12]

4. Imaging modalities: old and new

The dense metallic artifacts of the valves and annular calcifications obscured echocardiographic images and Doppler evaluations during conventional two dimensional transesophageal echocardiography to adequately quantify the leaks by the conventional color jet width and area criteria. Nevertheless they gave information about the dilatation and function of the left ventricle, location and direction of the leak, flow reversals in pulmonary veins and aortic arch to quantify the hemodynamics. With the advent of three dimensional echocardiogram, exact visualization of the defects, identification of the number, size, shape, orientation and location were improved.[13] Another upcoming imaging modality is the multiphase computed tomography using contrast media, where 16–20 phases of cardiac cycle were acquired with retrospective ECG gating and cyclically displayed to simulate a heart movement at a heart rate of 60 per minute.[12] However, this technology involves ionizing radiation and iodinated contrast load to the patient.

5. Fluoroscopic profiling of the leak

In spite of the tremendous advances in imaging, profiling the defect in an appropriate fluoroscopic plane has remained the key step in the catheterization laboratory. In the past, multiple angiograms were made in conventional orthogonal views to define the leak before closure.[4] The large contrast load in these compromised patients used to decompensate them further. Nowadays, the first angiographic view is guided by the echocardiographic information. If the mitral paravalvular leak is visualized on the most posterior position of the annulus on transesophageal study or located on 6 o' clock position on atrial enface view of volume rendered three dimensional echocardiography, then 90° lateral cranial view will be the most appropriate single projection to visualize the defect. Similarly, if the aortic paravalvular leak is located on the left margin of a parasternal short axis echocardiogram or 3 o' clock position of the aortic enface view of three dimensional echocardiogram, anteroposterior projection is chosen as the first and single angiographic projection to profile the defect (Fig. 1).

6. Sizing the paravalvular leak

In spite of the challenges posed by metallic artifacts in echocardiogram, a commonly followed technique is to freeze frame the widest color Doppler jet on echocardiogram and

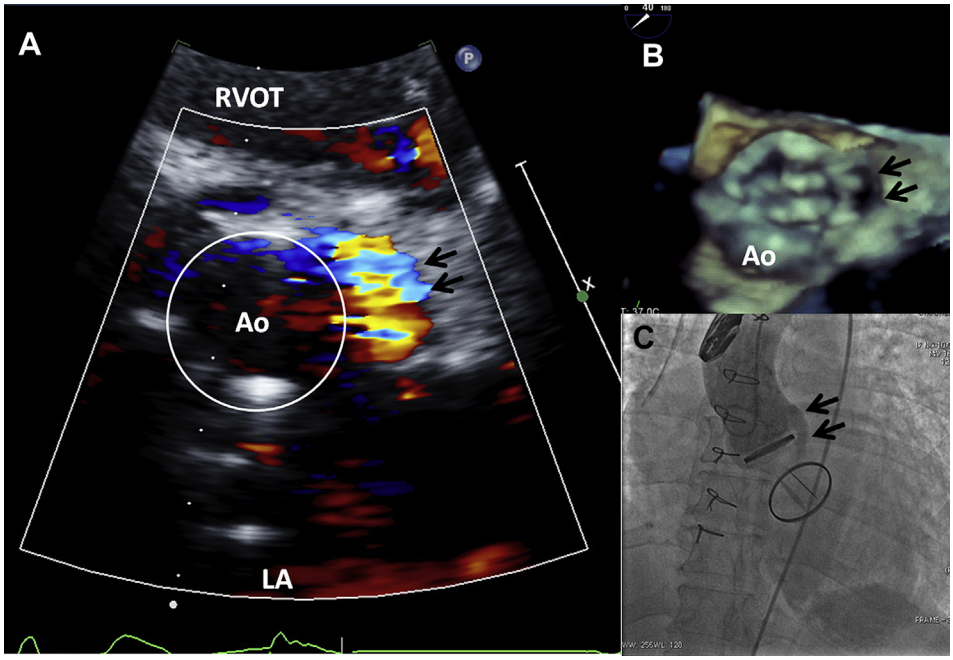

Fig. 1 – Angiographic projection guided by prior echocardiographic assessment. The aortic paravalvular leak is shown with double arrows in 3 o' clock position of the aortic annulus (circular ring) on this parasternal short axis view (A) and confirmed with a volume rendered transesophageal three dimensional echocardiographic aortic enface view (B). Since the defect is on the left side of the prosthesis, ascending aortogram in anteroposterior projection (C) is the single best projection for profiling this defect. RVOT–right ventricular outflow tract; LA – left atrium.

measure the color width. All precautions should be chosen to optimize the two dimensional echo gains and color gains to avoid over or under estimation of the defect size. The newer modalities of imaging using three dimensional echo helps not only in more accurate sizing, but also gives an insight about the varying shapes including crescentic, oval and serpiginous courses (Fig. 2). Balloon sizing using a compliant balloon (AGA sizing balloon, St Jude Medical, MN or Tyshak II balloon, Numed Inc, NY) after crossing the defect has also been widely adopted in the catheterization laboratory. When using this technique, two angiographic projections in orthogonal views are needed since most defects are oval or elongated (Fig. 3).

7. How to cross the defect?

Any paravalvular leak can be crossed antegradely or retrogradely. If a mitral valve leak is crossed from left atrium to the left ventricle, it is antegrade entry. Similarly if an aortic valve is entered from the ascending aorta into the left ventricle, it is retrograde entry. In aortic paravalvular leaks, retrograde entry is the most practical and feasible way. However, in extensive aorto-iliac disease, a transapical access may be needed to gain antegrade entry into the aortic leak from the left ventricle. In mitral paravalvular leaks, the left atrium gets aneurysmally dilated, especially with remodeling after onset of atrial fibrillation. In such cases, antegrade entry into a relatively small defect in the large sea of left atrium will be challenging. In such instances, a Judkins left or right coronary catheter is advanced into the left ventricle from aorta and turned posteriorly toward the mitral annulus to gain a retrograde entry through the mitral paravalvular leak.[4] The left ventricular walls will direct any hydrophilic straight tipped exchange length guide wire (Glidewire, Terumo Inc, Japan or Hiwire, Cook Medical, IN) through the paravalvular leak along the annular edge into the left atrium. The exchange length guide wire is snared through a transseptal sheath placed in the left atrium to get an arteriovenous railroad through the interatrial septum and paravalvular leak. A high and posterior transseptal puncture is desirable using intraprocedural transesophageal echo guidance.

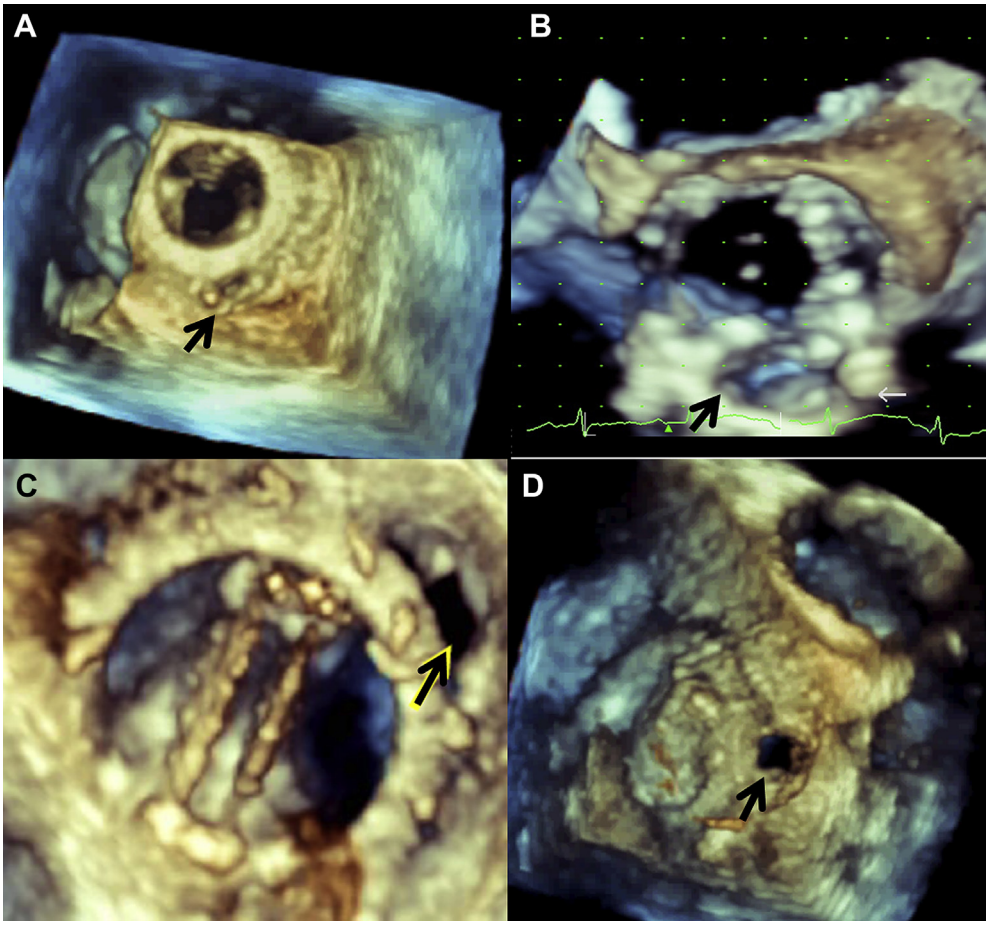

Fig. 2 – Three dimensional echocardiography demonstrating various shapes of leaks. A small circular leak in 5 o' clock posterior position of mitral annulus of a bioprosthesis on atrial enface view (A), a large oval leak in anterior aortic annulus of a single disc mechanical prosthesis on aortic enface view (B), a crescentic large leak on the bileaflet mechanical mitral prosthesis in 2 o' clock position on atrial enface view (C) and a large square shaped leak on another bileaflet mechanical mitral prosthesis in 2 o' clock position on atrial enface view (D) are demonstrated.

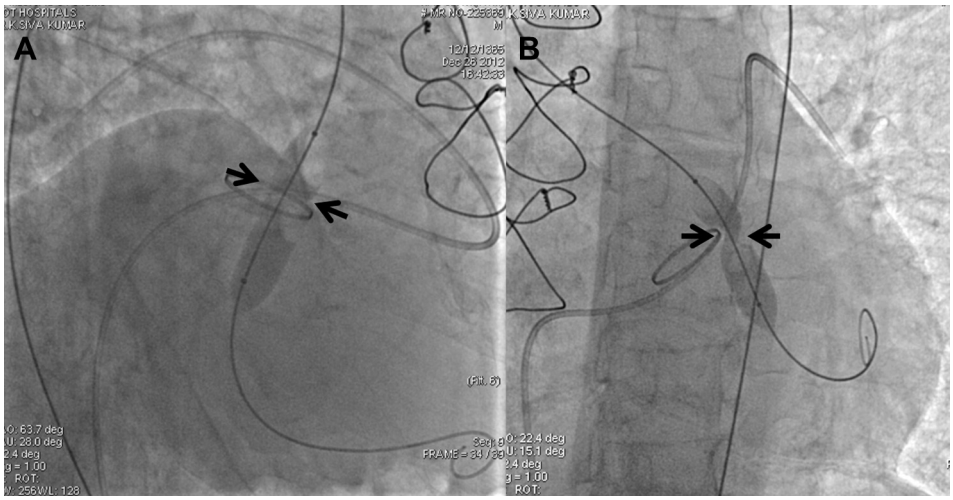

Fig. 3 – Balloon sizing of paravalvular leaks. A compliant balloon filled with diluted contrast is inflated to create a waist at low atmospheric pressures across the paravalvular defect to size the defect. Difference in the waist measurements shown with arrows on orthogonal projections (A: left anterior oblique projection and B: right anterior oblique projection) indicate the oval shape of the defect.

8. How to ensure a prosthetic valve lumen is not crossed by the wire?

An echocardiogram (three dimensional echocardiogram is ideal) at this stage is mandatory to confirm passage of the wire through the paravalvular leak and ensure that the wire is not through the prosthesis (Fig. 4). A careful assessment of the movement of the discs or poppets of the mechanical prosthesis on fluoroscopy is mandatory to avoid a serious mishap of crossing the lumen of the valve. Echocardiographic assessment is the key in mechanical prosthesis without a radio opaque disc (TTK Chitra, TTK Healthcare Ltd, Trivandrum), those without a radio opaque annular ring (St Jude Medical, St Paul, MN) and all biological prosthesis.

9. Choice of devices available for paravalvular leak closure

The most frequently used devices in the past were the muscular ventricular septal occluder or duct occluder devices (St Jude Medical, MN or Lifetech Scientific Inc, Shenzhen). Since the width of the waist of muscular VSD occluder is only 7 mm, if the rigid annular ring of the prosthetic valve is more than 7 mm, the device gets elongated leading to a narrower waist than the original diameter of the device. For the same reason, a duct occluder device (which is only 7 mm long) cannot be used in high profile prosthesis where the annular sewing rings may be broader than 10–12 mm. The newer devices used include circular and oval shaped Amplatzer vascular plugs II and III,

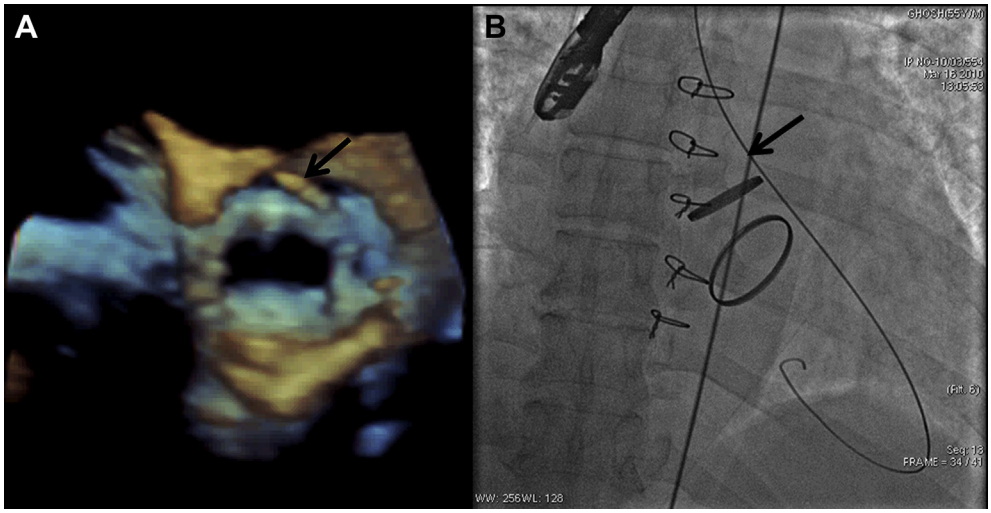

Fig. 4 – Initial guide wire should cross only the paravalvular leak and not the lumen of the valve. Live three dimensional transesophageal echocardiogram (A) and fluoroscopy in an appropriate projection (B) confirm that the guide wire (arrow) has passed only through the paravalvular leak and not the valve orifice.

respectively (St Jude Medical, MN). They are made up of thinner wires with small pore size which form multiple closure layers to provide improved surface contact and aid in faster occlusion. The vascular plug II is freely available in India; however, the plug III is yet to be registered in India. The vascular plug III is oval in shape with one longer and one shorter dimension, specifically made for the oval or crescentic shapes of the paravalvular leaks.[14] The plugs carry the advantage of being suited for even the larger profile leaks which are broader than 10–12 mm and therefore can be used in more varieties of leaks than the duct occluder devices.

10. Hybrid surgical approaches

The key step involved in device closure of paravalvular leak is formation of a wire loop across the paravalvular leak.[4] This is almost considered mandatory for placing the sheath securely across the defect with very rare exceptions.[15] In the presence of mitral valve paravalvular leaks in patients with mechanical aortic prosthesis, such arteriovenous loop is not possible through the aortic prosthesis. Similarly, extensive aortic or aorto-iliac disease may preclude use of this technique. In such cases, a direct transapical access with a small introducer sheath into the left ventricular apex will help in getting an arteriovenous loop after a transseptal sheath is placed in the left atrium (Fig. 5). Even though percutaneous transapical access is feasible and can be closed with a small duct occluder device after completion of the procedure, a limited anterolateral thoracotomy may facilitate better hemostasis.[12]

11. Summary of the key steps to remember

a. A good imaging before the procedure to understand the three dimensional orientation of the defect in relation to the adjacent structures is mandatory. A detailed discussion with the cardiovascular surgeon in combination with

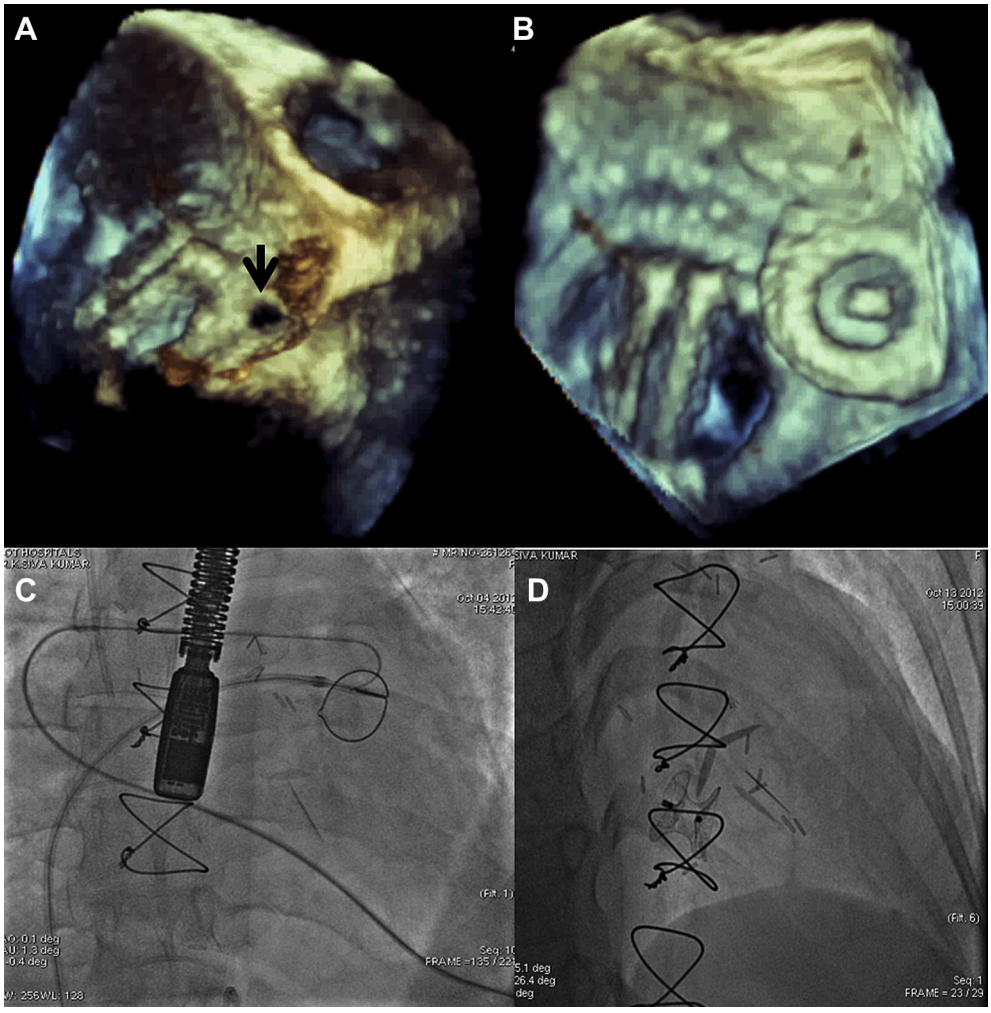

Fig. 5 – Hybrid surgical transapical approach through left anterolateral thoracotomy. A mitral paravalvular leak in 2 o' clock position near the interatrial septum and behind the aortic root shown with an arrow on atrial enface view of transesophageal three dimensional echocardiogram (A). A mechanical aortic prosthesis precludes arteriovenous railroading and so a transapical sheath is inserted. A guide wire from the transapical sheath through the leak is snared by a transseptal snare catheter (C). The stability of the muscular ventricular septal occluder device position is confirmed with three dimensional echocardiogram (B) and fluoroscopy (D). Both the mitral and aortic mechanical prosthesis are bileaflet and have non radiopaque annular rings.

an internet search about the nature of the prosthesis, its profile, its annular ring width, radio-opacity of the annular ring and the discs will facilitate the procedure.

b. After placing an appropriately shaped catheter in close vicinity of the paravalvular leak and crossing with an atraumatic guide wire, the flexible and hydrophilic catheter should be gently advanced across the defect under echocardiographic guidance to ensure normal prosthesis function and fluoroscopic confirmation of normal disc movements.
c. Subsequently, an extra support exchange length guide wire replaces the catheter, the tip of which is either exteriorized to form an arteriovenous loop or coiled in a stable distal chamber.
d. A delivery system sheath with an appropriate length is advanced over this wire without getting kinked; Based on the defect width in different axis, shape, valve profile, the most suited device is chosen and it is delivered through the delivery system. The guide wire may be retained as a buddy to maintain the access through the defect, if the initial crossing was too difficult or the sheath is likely to kink.
e. The positioned device should be analyzed carefully before release for interference with the prosthetic disc movement, unstable position and likelihood of embolization and malposition. If such complications are noted after release of the device, efforts should be taken to snare out the device or surgically retrieve the device.
f. A larger single defect may significantly overhang the defect and cause prosthetic valve disc malfunction; in such cases, placement of smaller multiple devices either simultaneously or sequentially may be more appropriate with less overhanging. Similarly the vascular plugs may overhang less than the occluder devices; Atrial septal occluders have the maximum overhanging.
g. Meticulous follow-up after the procedure should focus on post procedural hemolysis, residual persistent leaks, prosthetic valve dysfunction, additional paravalvular leak through previously missed multiple orifices and persistent symptoms of heart failure.

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