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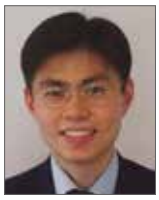
How should I treat a percutaneous posteromedial mitral periprosthetic paravalvular leak closure in a bioprosthesis with no radiopaque ring?



Paul T.L. Chiam[1,2]*, MRCP; Ping-Ping Goh[1], MRCP; Yean-Teng Lim[1,2], MRCP

1. Mount Elizabeth Hospital, Singapore; 2. Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Invited experts: Nicolas M. Van Mieghem[3], MD, PhD; Eric Eeckhout[4], MD, PhD; Ka-Yip Lo[4], MD; Alain Delabays[4], MD

3. Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands; 4. Cardiology Service, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland

CASE SUMMARY

BACKGROUND: A 66-year-old male with a previous mitral valve replacement (Mosaic bioprosthesis) presented with worsening cardiac failure due to a severe mitral paravalvular regurgitation.

INVESTIGATION: Transoesophageal echocardiography showed that the defect was located posteromedially with a 3 mm width. Fluoroscopy showed that the Mosaic bioprosthesis had a radiolucent ring with only three markers to indicate the top of the stent posts.

DIAGNOSIS: Severe posteromedial mitral periprosthetic paravalvular leak in a bioprosthesis with no radiopaque ring.

MANAGEMENT: Percutaneous paravalvular leak closure was performed. Formation of an arteriovenous loop was necessary to facilitate antegrade deployment of an AVP III device. However, embolisation into the left ventricle occurred after device release. The device was snared and, subsequently, a larger AVP III device was successfully implanted.

KEYWORDS: bioprosthesis, embolisation, mitral regurgitation, paravalvular leak, percutaneous, prosthetic valve

PRESENTATION OF THE CASE

A 66-year-old male presented with worsening dyspnoea (NYHA Class III-IV), due to cardiac failure for several months. He had had a mitral valve replacement with a 27 mm Mosaic® bioprosthesis (Medtronic, Minneapolis, MN, USA) nine years before. Transthoracic echocardiography (TTE) and transoesophageal echocardiography (TEE) revealed a left ventricular ejection fraction (LVEF) of 45% and severe mitral regurgitation (MR) due to a paravalvular leak (PVL). The defect was located posteromedially (4 o'clock position on the surgical view) and measured 3 mm at its width **(Figure 1A, Figure 1B)**. The effective regurgitant orifice area was calculated to be 0.4 cm² and the regurgitation volume was 64 ml. The bioprosthetic valve leaflets were well visualised to be functioning normally and not thickened, with satisfactory haemodynamics (mean pressure gradient 7 mmHg). Coronary angiography showed no significant coronary artery disease. A left ventriculogram showed an MR jet located posteriorly and medially **(Figure 2A, Figure 2B)**.

A redo open chest surgery to repair the PVL was offered; however, the patient declined surgical intervention. Hence, a percutaneous option was planned. The procedure was performed under general anaesthesia with TEE and fluoroscopic guidance. Transseptal puncture was performed with a Brockenbrough needle and Mullins sheath. As the initial strategy was to access the PVL antegrade from the left atrial (LA) side, the transseptal puncture was made more cranial and anterior to allow room for catheter and wire manipulation. After several attempts, the PVL was

**Corresponding author: 3 Mount Elizabeth, #08-06, Singapore, 228510 Singapore.*
E-mail: paulchiam@heartvascularcentre.com

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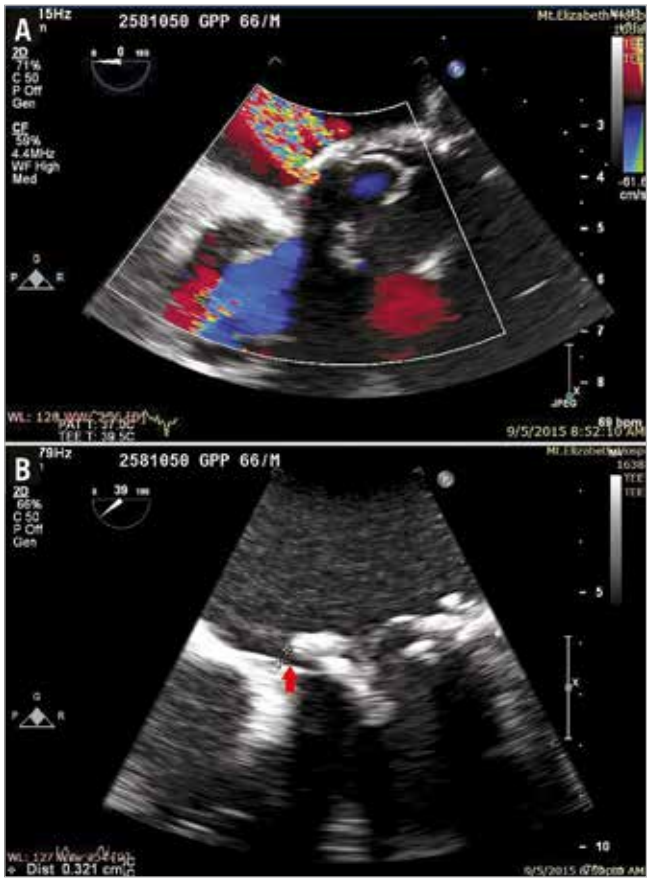

Figure 1. *Pre-procedure TEE. A) TEE image showing severe MR through the PVL. B) TEE image showing the PVL defect (red arrow) measured at 3 mm.*

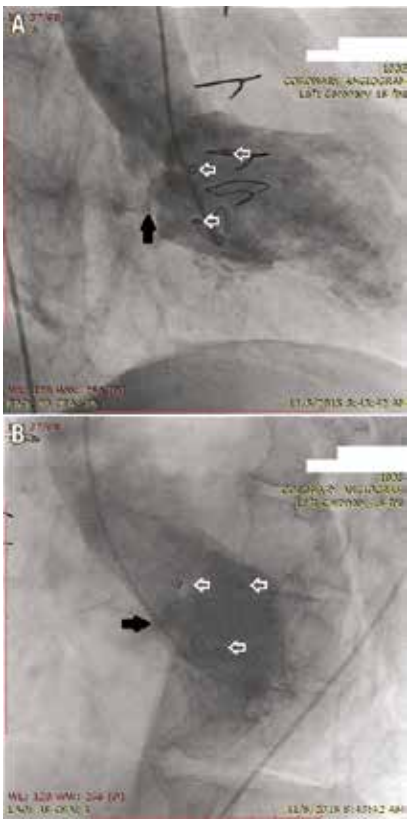

Figure 2. *Pre-procedure LV angiography. A) LV angiography image (RAO cranial view) showing the location of the MR jet (black arrow) and the markers of the stent posts (white arrows). Note the lack of a radiopaque ring. B) LV angiography (LAO view) showing the location of the MR jet (black arrows) and the markers of the stent posts (white arrows). Note the lack of a radiopaque ring.*

crossed with a 4 Fr Cobra catheter (Cordis, Fremont, CA, USA) and a 0.035 inch straight tip Glidewire® (Terumo Crop., Tokyo, Japan), and then a 5 Fr pigtail catheter was placed in the left ventricular (LV) apex **(Figure 3)**. A 260 cm Amplatz Super Stiff™ wire (Boston Scientific, Marlborough, MA, USA) was advanced through the pigtail catheter but the entire system prolapsed back into the LA.

The decision was made to perform retrograde crossing via an access from the femoral artery. The PVL was crossed retrogradely with a 5 Fr AL1 catheter and an angled Glidewire. However, due to the need for the AL1 catheter to be looped back to direct it towards the defect, there was insufficient catheter length to advance it across the PVL. A 15 mm GooseNeck® snare (ev3/Covidien, Plymouth, MN, USA) was then advanced via the femoral vein and the angled Glidewire was snared in the LA and exteriorised, forming a stable arteriovenous (AV) rail **(Figure 4A, Figure 4B)**. A 5 Fr Shuttle® sheath (Cook Medical, Bloomington, IN, USA) was then advanced from the femoral vein across the PVL into the ascending aorta **(Figure 5)**. A 4×8 mm AMPLATZER™ Vascular Plug III (AVP-III) (St. Jude Medical, St. Paul, MN, USA) was positioned across the PVL **(Figure 6)**; due to the lack of a radiopaque sewing ring, only TEE (but not fluoroscopy) was helpful in ascertaining that a disc was on either side of the mitral bioprosthesis. After a stable "tug test", the device was released. Shortly after release, the device was found to have embolised, and was highly mobile in the LV, tumbling back and forth between the mitral valve, the LV apex and left ventricular outflow tract **(Figure 7A, Figure 7B)**.

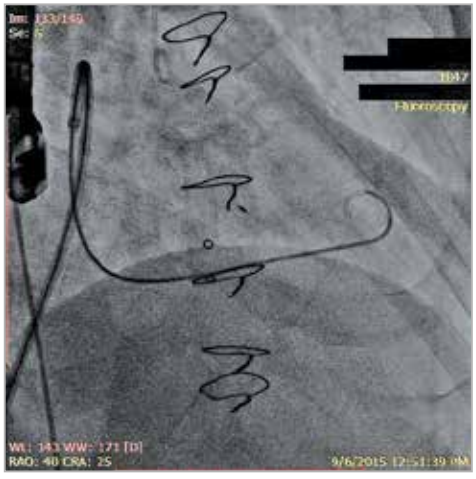

Figure 3. *Fluoroscopy image showing pigtail crossing from LA to the LV apex.*

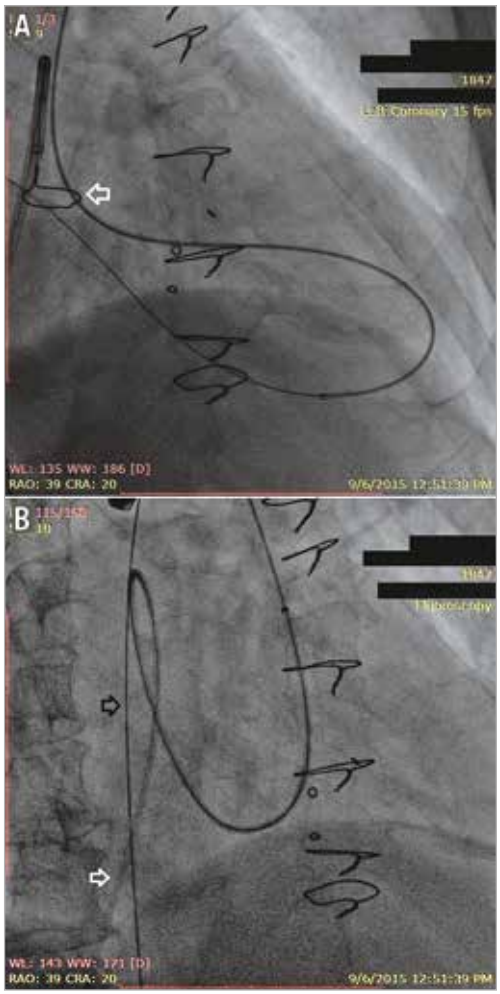

Figure 4. *Intra-procedure fluoroscopic images demonstrating formation of the AV loop. A) Fluoroscopy image showing the AL1 catheter and Glidewire crossing the PVL from the LV side and the GooseNeck snare (arrow) in the LA. B) Fluoroscopy image showing the AV loop (white arrow indicates sheath from the femoral vein and black arrow indicates the Glidewire from the femoral artery).*

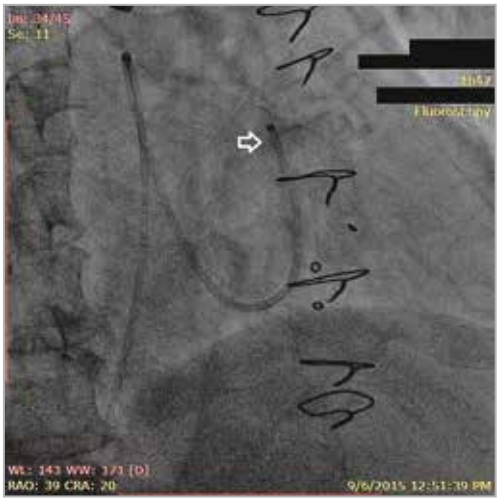

Figure 5. *Fluoroscopy image showing the Shuttle sheath crossing the PVL antegradely into the ascending aorta (arrow).*

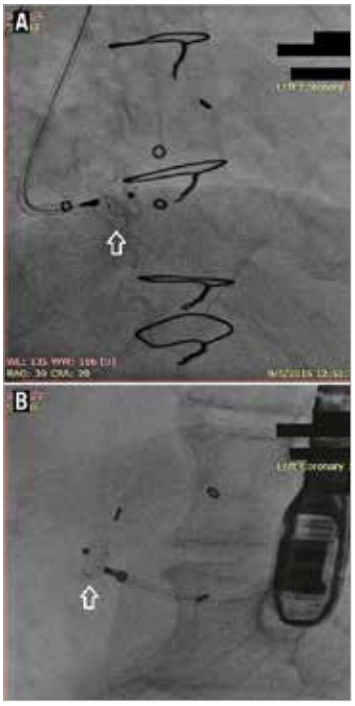

Figure 6. *Intra-procedure fluoroscopic images demonstrating deployment of the AVP-III device. A) Fluoroscopy image (RAO cranial view) showing the AVP-III deployed across the PVL (arrow). B) Fluoroscopy image (LAO view) showing the AVP-III deployed across the PVL (arrow).*

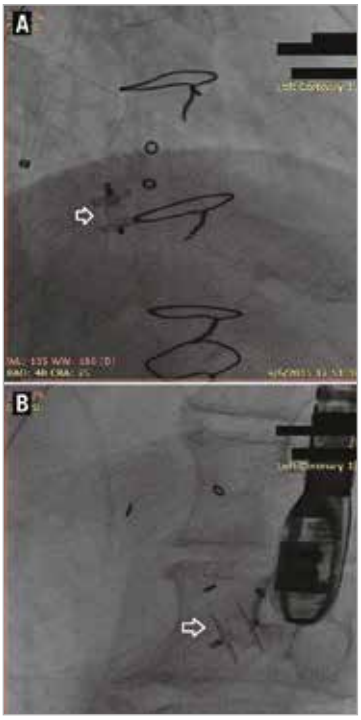

Figure 7. *Intra-procedure fluoroscopic images showing the embolised AVP-III device in the LV cavity. A) Fluoroscopy image (RAO cranial view) showing the embolised AVP-III device (arrow). B) Fluoroscopy image (LAO view) showing the embolised AVP-III device (arrow).*

How would I treat?

Nicolas M. Van Mieghem[3]*, MD, PhD

3. Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands

I would like to take one step back and look at the pre-procedural planning. The patient underwent mitral valve replacement with a 27 mm Mosaic bioprosthesis nine years earlier. By echocardiographic evaluation there is a severe paravalvular leak located posteromedially, 3 mm in size with an effective regurgitant orifice area of 0.4 cm^2 and a regurgitation volume of 64 ml.

A crucial step is to figure out how the bioprosthesis would look under fluoroscopy. An important clinical asset in pre-procedural work-up for a failing bioprosthesis is the "Valve in Valve App" by Vinnie Bapat[1]. The app indeed confirms the absence of a radiopaque ring, but also the presence of fluoroscopic markers on the tip of the three stent posts, about 18.5 mm above the ventricular edge of the bioprosthesis.

I would always complete pre-procedural planning of periprosthetic mitral leaks with a contrast multi-slice computed tomography (MSCT) scan of the heart to obtain unique 3D perspectives to facilitate fluoroscopy guidance. The interatrial septum, the mitral valve apparatus and periprosthetic leaks can be identified by MSCT through double-oblique multiplanar and volume-rendered MSCT reconstructions[2]. An optimal C-arm angulation perpendicular or axial to a given anatomical structure can be simulated; in this case the plane connecting the three radiopaque markers on the Mosaic posts would be the reference. The distance of the Mosaic basal plane relative to the radiopaque markers can also be appreciated in the selected angiographic projection. Simulated angiographic views can be projected in the catheterisation room or even (partially) fused onto the fluoroscopy.

Posteromedial leaks close to the interatrial septum can be tough to wire even with steerable catheters from a transseptal left atrial approach. I would favour a transapical access to minimise catheter and wire manipulations, increase coaxiality and augment per-procedural control.

The embolised plug in the current situation needs to be snared. I would first start by crossing the aortic valve with a 6 or 7 Fr Judkins Right 4 guiding catheter. An Amplatz GooseNeck snare can then be advanced through the guiding catheter and released into the left ventricular outflow tract. I would try to snare the plug in the LVOT and, once fixed against the guiding catheter, withdraw the whole assembly from the groin. A "crossover balloon technique" from the opposite groin can help minimise bleeding and create proper circumstances to close the arteriotomy with one or two suture-based closure devices[3]. I would end the procedure there and plan a second attempt for transapical catheter-based leak closure at a later stage. The type and size of the plug would depend on leak characteristics but I would select a larger size AMPLATZER Vascular Plug III (e.g., 10×5 mm) even though the device embolised in this case because both discs were on the ventricular side of the leak during device release.

Conflict of interest statement

The author has no conflicts of interest to declare.

**Corresponding author: Department of Interventional Cardiology, Thoraxcenter, Erasmus MC, Room Bd 171, 's Gravendijkwal 230, 3015 CE Rotterdam, The Netherlands. E-mail: n.vanmieghem@erasmusmc.nl*

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How would I treat?

Eric Eeckhout[4]*, MD, PhD; Ka-Yip Lo[4], MD; Alain Delabays[4], MD

4. Cardiology Service, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland

In the present volume of the AsiaIntervention journal, Chiam and colleagues report on a failed attempt at percutaneous closure of a mitral paravalvular leak (PVL). After positioning of a 4×8 mm AVP-III at the level of the leak, device embolisation within the left ventricular cavity occurred. We wish to comment on how this complication could have been prevented and treated.

Prevention

Transoesophageal echocardiography (TOE) (in particular 3D acquisition) is key to locating and quantifying the width and extension of the leak in order to judge the feasibility of percutaneous closure and to define the interventional strategy. In the present case, only 2D images (limited to one dimension) are provided, demonstrating a 3 mm gap between the valve and the annulus measured at an angle of 40°. Only 3D TOE can demonstrate the extension of the leak. The colourjet on **Figure 1A** suggests an extension of at least 10 to 15 mm around the annulus. Precise dimensions can be obtained either on greyscale or in a colour 3D data set using a dedicated software **(Figure 8A, Figure 8B)**. In this particular case, suboptimal image acquisition with undersizing of the leak led to an inappropriate strategy with device embolisation as a consequence.

Interventional strategy

The initial strategy was antegrade leak crossing which failed as advancement of a 260 cm Super Stiff wire resulted in the prolapse of the whole system in the left atrium. To prevent this, a few recommendations can be given. First adequate back-up needs to be assured by a dedicated transseptal sheath. Practically, the steerable Agilis™ 8.5 Fr sheath (St. Jude Medical) provides excellent back-up and enables antegrade exploration of the leak for crossing. From the images provided, it seems that the authors may have used this catheter. Second, a 125 cm long Multipurpose catheter (Cordis, Fremont, CA, USA) may be more appropriate **(Figure 9)** as it can be bent at the apex of the left ventricular outflow tract providing

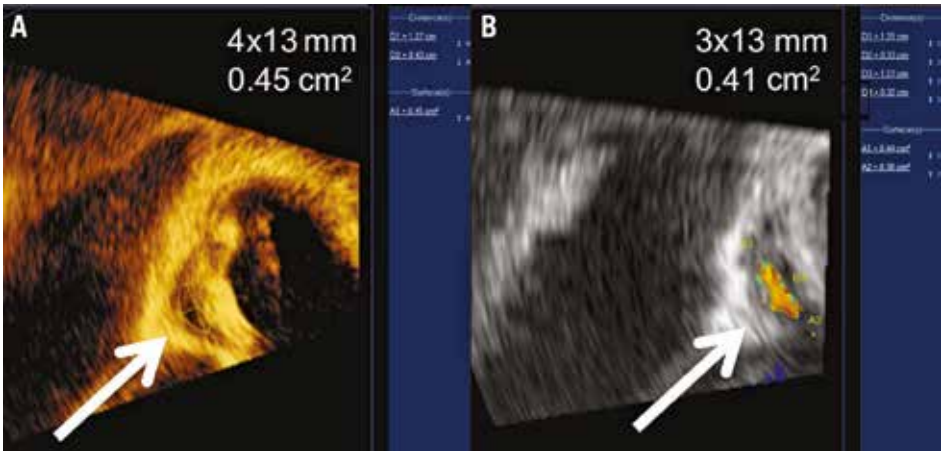

Figure 8. *3D TOE assessment of a paravalvular leak. Assessment using greyscale (A) or colour 3D data set (B) using a dedicated software.*

**Corresponding author: Cardiology Service, Centre Hospitalier Universitaire Vaudois, Rue du Bugnon 21, CH-1011 Lausanne, Switzerland. E-mail: Eric.Eeckhout@chuv.ch*

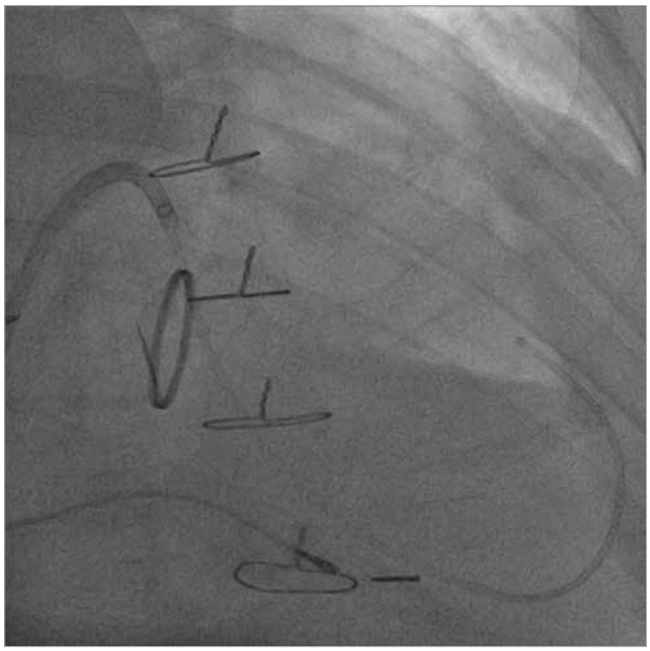

Figure 9. *Bending of a long 6 Fr Multipurpose catheter at the apex of the left ventricle through an Agilis catheter to ensure adequate back-up.*

a longer and more stable working zone to prevent prolapse. Third, new wires specifically for TAVI such as the Confida™ (Medtronic) or Safari™ (Boston Scientific) wires may be preferred to the Amplatz Super Stiff wire as the transition zone between the rigid and soft parts of the wire is more progressive. Even if these recommendations are irrelevant to the final outcome in this case, they are important to simplify a "mostly complex" procedure. Nevertheless, establishing an arteriovenous loop, as an alternative, enabled initial, successful antegrade positioning of a closure device. This approach carries a certain risk, as it exposes the patient to laceration of the native aortic valve during wire and catheter manipulation, partially also because of non-coaxial alignment of the loop across the heart.

Complication management

A 4×8 mm AVP-III device was positioned under echo guidance. Fluoroscopy was not of use because of the presence of a radiolucent ring. Echocardiography (in particular 3D with assessment of any residual leak) is key prior to release of any device. The authors do not provide any images for this part of the procedure but we suspect the presence of a residual leak at this stage. In case of any significant residual leak, the device should be retrieved and a larger or other type of system should be implanted. Once embolised, percutaneous retrieval should be considered, particularly as this implant is relatively small and soft. Through a large 10 Fr arterial sheath, a 6 Fr JR4 guiding catheter may be positioned in the left ventricular outflow tract, and subsequent snaring with an Amplatz GooseNeck snare (15-120 or 20-120 mm) (ev3/Covidien) within the left ventricle should be considered.

Conflict of interest statement

E. Eeckhout and A. Delabays have proctoring contracts with St. Jude Medical. The other author has no conflicts of interest to declare.

How did I treat?

ACTUAL TREATMENT AND MANAGEMENT OF THE CASE

We immediately proceeded to attempt to snare the dislodged AVP-III. The sheath size in the left femoral artery was increased from 6 Fr to 8 Fr. As the device was not in a stable position, but was alternately embolising back and forth from under the mitral valve to the LV apex to the left ventricular outflow tract, it was finally snared after prolonged attempts with a 7 Fr internal mammary shape guide catheter and a 10 mm GooseNeck snare **(Figure 10)**. The device, snare and guide catheter were successfully removed as a unit through the femoral sheath.

The decision was made to proceed with the percutaneous PVL closure. The PVL was again crossed retrogradely in the same fashion, and the Glidewire was snared in the LA and exteriorised to form an AV rail. The 5 Fr Shuttle sheath was advanced from the femoral vein across the defect and into the ascending aorta. The largest diameter available AVP-III (5×10 mm) was selected and deployed across the defect. TEE showed that the two discs were straddling the mitral bioprosthesis, and the MR was reduced **(Figure 11A, Figure 11B)**. After confirming that the device was in a firm and stable position using the "tug test", it was released.

The patient made an uneventful recovery and was discharged from hospital the following day. At one month, he reported that his functional capacity had improved markedly (NYHA II). Echocardiography showed that the AVP-III was in a stable position; LVEF was unchanged at 45% with residual mild MR (effective regurgitant orifice [ERO] 0.2 cm², regurgitant volume 32 ml). Haemoglobin level was stable and there was no evidence of haemolysis.

Discussion

Percutaneous PVL closure is an attractive therapeutic option for patients with periprosthetic paravalvular leaks as it obviates the need for a redo open chest surgery, and is a class IIa recommendation according to current guidelines[4]. An antegrade transseptal or retrograde transarterial approach, or a combination of both could be used for percutaneous mitral PVL closure. A transapical approach allows a more direct access to the PVL and potentially simplifies crossing of the PVL, but this would usually require a mini left thoracotomy in most cases, and adds complexity to the procedure[5,6].

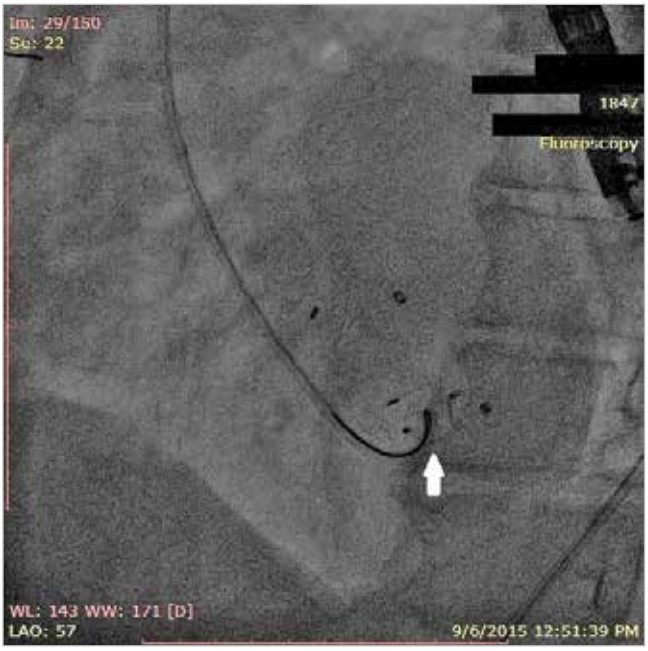

Figure 10. *Fluoroscopy image showing the dislodged AVP-III in the LV and the GooseNeck snare within the internal mammary (IM) guide catheter (arrow).*

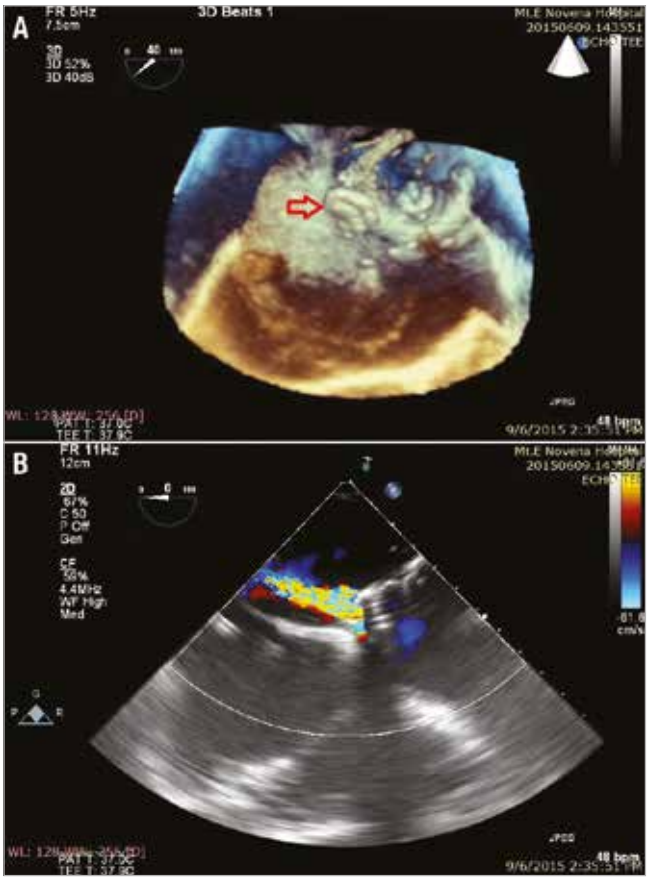

Figure 11. *Intra-procedure 3D TEE and 2D TEE images after final device deployment. A) TEE image showing the AVP-III device disc (arrow) on the LA side (the image is rotated such that the left atrial appendage is on the right of the image). B) TEE image showing a reduced MR jet.*

In our case, the posteromedial location of the PVL defect (4 o'clock on the surgical view from the LA) increased the technical difficulty, making both antegrade and retrograde crossing of the defect very challenging. This was compounded by the lack of a radiopaque sewing ring to act as a marker on fluoroscopy. Although the use of an Agilis steerable catheter could have facilitated antegrade crossing, the main obstacle was the inability to achieve a stable position of the stiff wire to allow subsequent catheter (and delivery system) exchanges. Recognising this, the defect was crossed retrogradely, and wire snaring from the LA side was performed to form a stable and highly supportive AV loop.

Pre-procedure TEE measured the PVL width at 3 mm and this was confirmed on the intra-procedure TEE. Thus, we were initially of the opinion that a 4×8 mm AVP-III device would be sufficient, as the dimensions were of the waist of the device and the larger discs on either side would be larger (8×12 mm). Less oversizing would also theoretically carry a lesser risk of further extending the PVL defect. As the device embolised shortly after release, it was probably undersized, although the possibility that the proximal disc, despite TEE guidance, was not completely in the LA side cannot be excluded. A lack of a radiopaque bioprosthetic ring could have contributed to this complication.

Although early and late device embolisations have been known to occur infrequently, they have mostly occurred with the AMPLATZER Ventricular Septal Defect Occluder, AMPLATZER Duct Occluder or the AVP-II devices (all St. Jude Medical)[7-11], and only rarely with the AVP-III device[6,12]. The AVP-III has been reported to have high success and low complication rates[6,13] due to its oval shape and technical properties, and perhaps could be the device most suited for PVL closures in the majority of cases. Fortunately, in this case, the embolised device was successfully snared despite the technical challenge, as the dislodged device was highly mobile in the LV cavity. Surgical device removal was considered as a back-up option, but that would have entailed conversion to open surgery and a risk of systemic embolisation of the device whilst awaiting transfer.

Our patient experienced significant improvement in functional status despite the residual mild MR. This demonstrates that meaningful clinical benefit can be derived from partial reduction of a PVL, and complete or near complete closure may not be necessary.

Acknowledgements

The authors would like to thank Rena Lim for her assistance with the figure illustrations.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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