CLOSES LEAKS
OPENS OPPORTUNITIES

AMPLATZER™ VALVULAR PLUG III (FORMERLY AVP III)

CLINICAL CASE COMPENDIUM

Abbott

MAT-2212408 v2.0 | Item approved for OUS use only.

TABLE OF CONTENTS

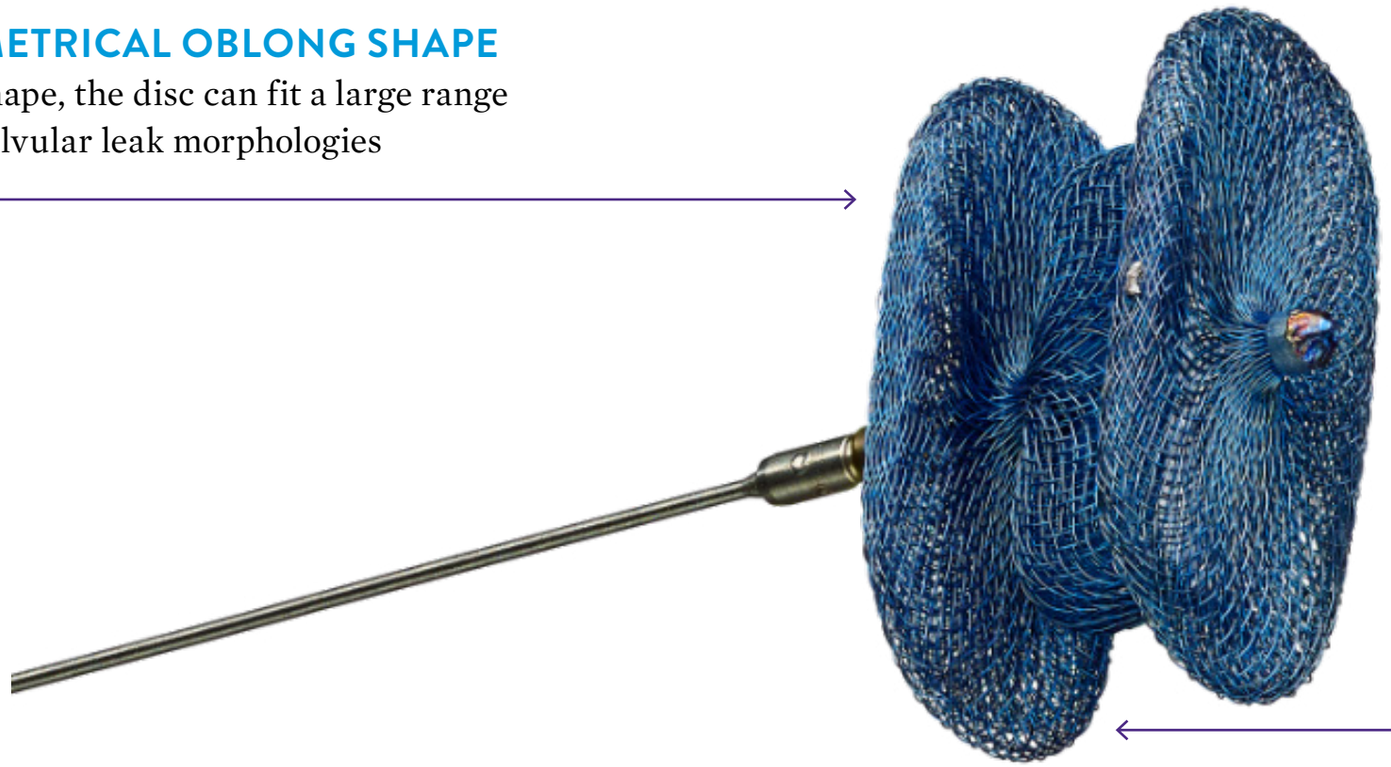
REFERENCES:

1. Calvert et al. Percutaneous device closure of paravalvular leak. Circulation. 2016;134(13):934-944.
2. Garcia et al. Outcomes and predictors of success and complications for paravalvular leak closure: an analysis of the SpanisH real-wOrld paravalvular LEaks closure (HOLE) registry. EuroIntervention. 2017;12(16):1962-1968.
3. Davidavicius G, Rucinskas K, Drasutiene A, et al. Hybrid approach for transcatheter paravalvular leak closure of mitral prosthesis in high-risk patients through transapical access. J Thorac Cardiovasc Surg. 014;148(5):1965-1969.

EVERY DETAIL IS DESIGNED
FOR SUCCESSFUL PVL CLOSURE

ASYMMETRICAL OBLONG SHAPE
In this shape, the disc can fit a large range of paravalvular leak morphologies

DENSE NITINOL WIRE LAYER DESIGN
Additional layers of dense nitinol wire facilitate rapid occlusion



SMALL RETENTION FEATURES
Designed to minimize valve leaflet interference

BUILT ON THE EXTENSIVE AMPLATZER™ LEGACY OF SAFETY AND EFFICACY

- Pioneered transcatheter cardiovascular and peripheral vascular occlusion
- Over 1.25 million Amplatzer devices implanted worldwide[1]
- More than 20 years of clinical experience and global leadership

REFERENCES:

1. Data on File at Abbott

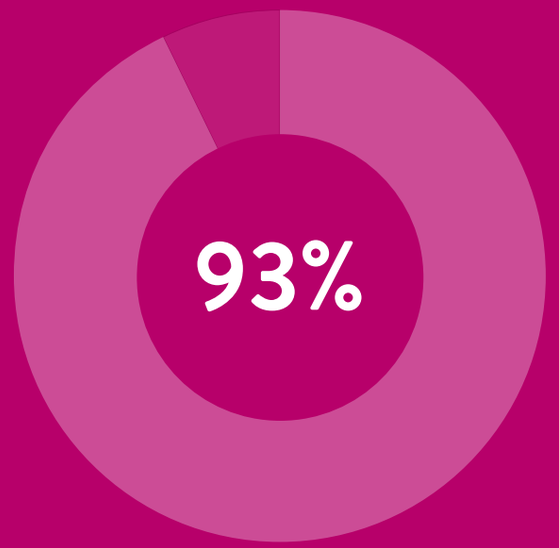
EVERY DETAIL IS DESIGNED
FOR SUCCESSFUL PVL CLOSURE

A SOLUTION TO A KEY ISSUE

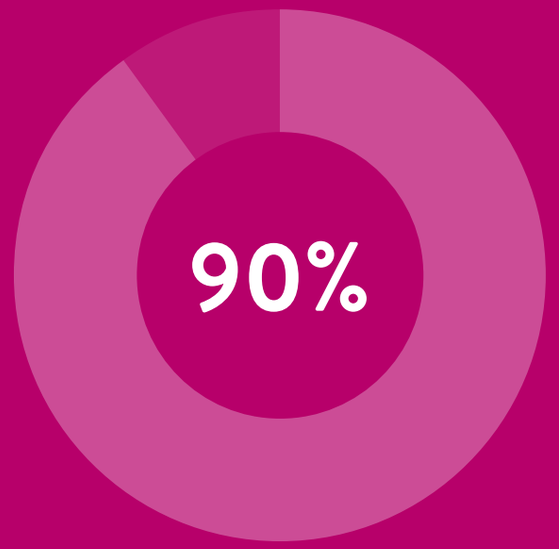
Around the world, paravalvular leaks are a common and challenging problem:

- Paravalvular leaks occur in 7% to 17% of mitral valve replacements (MVRs)
- 5% to 10% of aortic valve replacements (AVRs).[1]

By providing an effective solution to this key issue, the Amplatzer™ Valvular Plug III is improving life quality for an increasing number of patients.[2]



UP TO 93% OF PVL REDUCED TO MODERATE OR LESS.[2,3]



UP TO 90% OF PATIENTS REPORT ONE-CLASS NYHA CLASSIFICATION IMPROVEMENT[2]

REFERENCES:

1. Nietlispach F, Eckstein F, Seeberger M, Osswald S, Kaufmann BA, Reuthebuch O. Closure of apical access site after transapical, transcatheter paravalvular leak closure. Can J Cardiol. 2012;28:516.e5-7.
2. Smolka G, Pysz P, Jasiński M, et al. Multiplug paravalvular leak closure using Amplatzer Vascular Plugs III: A prospective registry. Catheter Cardiovasc Interv. 2016;87(3):478-487.
3. Cruz-Gonzalez I, Rama-Merchan JC, Rodriguez-Collado J, et al. Transcatheter closure of paravalvular leaks: state of the art. Neth Heart J. 2017;25(2):116-124.

LEBANON EXPERIENCE OF **AMPLATZER™ VALVULAR PLUG III (AVP III)**

Dr. Fadi Sawaya
American University of Beirut Medical Center (AUBMC)

ABSTRACT

A 65 year old female patient with history of mechanical aortic and mitral valve replacement presented for severe dyspnea and recurrent admissions for pulmonary congestions. Patient was found to have severe mitral paravalvular leak. We proceeded with successful deployment of AVP III device with no residual regurgitation.

INTRODUCTION

This is the case of a 65 year old female patient with a history of aortic and mitral mechanical valve replacement, atrial fibrillation, anemia, and multiple admissions to the coronary care unit for pulmonary congestion.

CASE PRESENTATION

The patient presented to the clinic complaining of severe dyspnea at rest and upon minimal exertion. Transthoracic echocardiography (TTE) showed an LVEF of 50-54%, trivial aortic paravalvular leak (PVL) with aortic gradients Peak/Mean being 18/9 mmHg respectively, mitral peak/mean gradients 20/5 mmHg with possibility of mitral PVL, and moderate pulmonary hypertension with systolic pulmonary artery pressure (sPAP) 54 mmHg. The patient was recommended to have a transesophageal echocardiography (TEE) for further evaluation of the mitral valve.
TEE showed severe postero-medial acentric PVL with two central jets across the mitral valve.

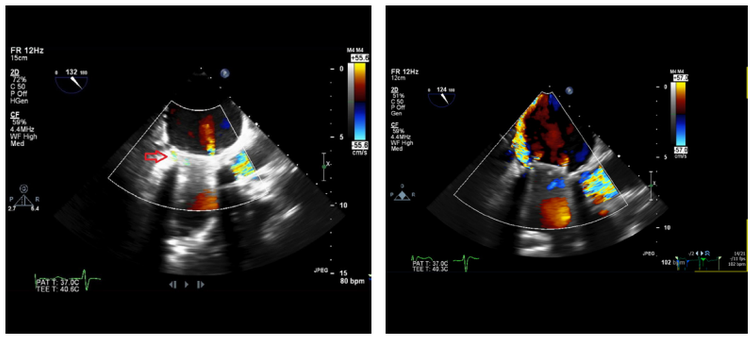


Figure 1

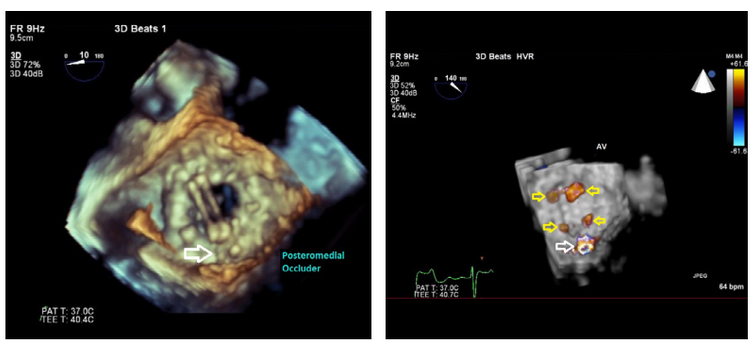


Figure 2

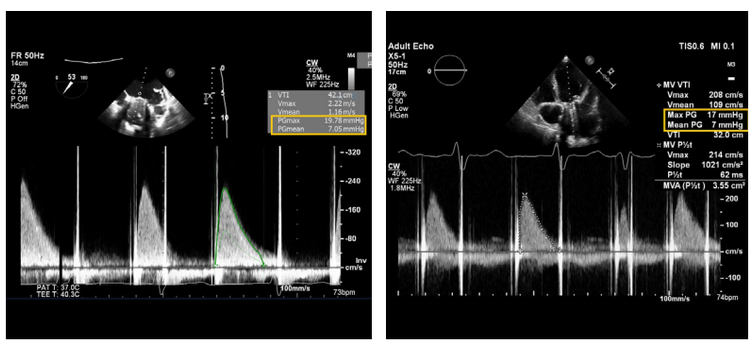


Figure 3

Dr. Fadi Sawaya

CASE DISCUSSION

Patient was admitted to the hospital for PVL closure. The procedure was performed under general anesthesia. 6Fr sheaths were introduced into the right common femoral artery and the left femoral vein under ultrasound guidance with micro puncture. The mechanical aortic valve was crossed using a J-tip guidewire and JR 4 diagnostic catheter. The postero-medial PVL was identified by TEE and cross retrogradely. An Amplatzer™ super stiff guidewire was placed securely across the PVL in the left atrium. The 6Fr was exchanged to Amplatzer Paravalvular occluder (AVP III) delivery sheath over the Amplatzer™ super stiff wire. The AVP III was successfully deployed with no residual regurgitation confirmed by TEE.

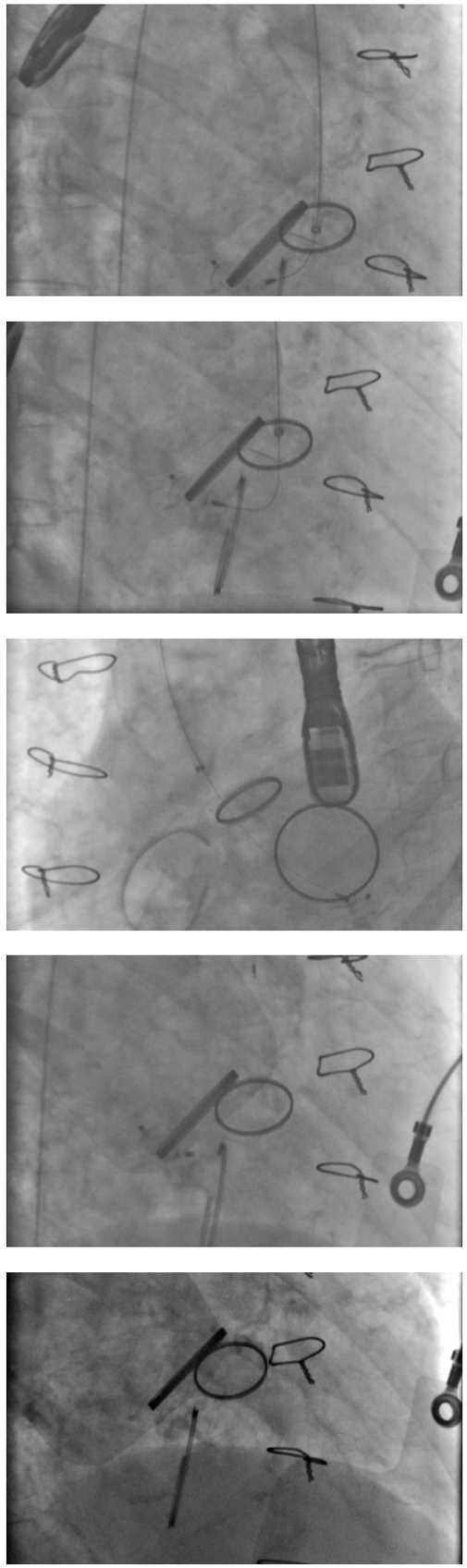


Figure 4

CONCLUSION

Patient is now 2 years post PVL closure. Most recent TTE shows an LVEF of 60-64%, no evidence of aortic or mitral regurgitation. Patient is completely asymptomatic with no hospitalization records.

A COMPLEX PARAVALVULAR LEAK CLOSURE WITH THE AMPLATZER™ VALVULAR PLUG III (AVP III)

Dr. Gerard Martí
Hospital Universitario Vall d'Hebrón.
Barcelona, Spain

ABSTRACT

Transcatheter paravalvular leak closure (TPLC) has proven safety, good procedural, and clinical outcomes. A complex TPLC case is presented in which the combination of multiple Amplatzer vascular plugs and different techniques lead to complete occlusion of the defects. This result was translated into a clinical improvement that is maintained up to two years of follow-up.

INTRODUCTION

TPLC emerged as an alternative to redo cardiac surgery in high risk or non-operable patients. In recent years, it has evolved to a first line therapy due to its proven safety, competitive procedural and clinical results reported in many large series and registries [1,2,]. However, in some complex settings (annular calcification, crescentic or multiple defects, hemolysis at presentation...) these outcomes are more discouraging and strongly related to the grade of residual leaks left [3,4]. Best results are seen in patients in which a complete or almost complete occlusion is achieved. However, the optimal occlusion is often not easily achieved with a single device and a combination of devices and demanding techniques are needed.
The following case shows multiple paravalvular defects in a complex patient that need a combination of Amplatzer™ plugs and techniques to achieve an optimal procedural result. This result was translated into a multidisciplinary clinical improvement that is maintained up to two years of follow-up.

CASE PRESENTATION

A 62-year-old female patient underwent both mitral and aortic mechanical valve replacement for treatment of rheumatic heart valve disease. Two early reoperations were required for treatment of recurrent mitral paravalvular leak. In the last cardiac surgery 8 years ago, a bi-leaflet mechanical mitral valve replacement was performed. Despite well-functioning valves were seen in transoesophageal echocardiography (TEE), a residual severe pulmonary hypertension was early detected. About two years ago, the patient clinically deteriorated to NYHA Class III symptoms. Moderate hemolysis was also detected (LDH>600 U/L, bilirubin 2,2 mgrs./dL and increased reticulocyte count).

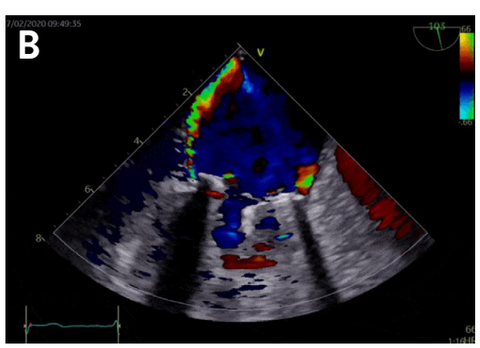


Figure 1:
A) Moderate size oval shaped PVL at 10 o´clock (arrow) and a crescentic large posterior PVL between 4-6 o´clock (braketted arrow).
B) Coanda effect of both PVL.

Dr. Gerard Martí

Moreover, she needed up to four hospital admissions for life-threatening gastrointestinal bleeding episodes with uncountable requirement of packed red cell transfusions. In the second admission, after an extensive work-up, only an ileocecal angiodysplasia was detected as a potential source of bleeding. She was started on long-acting somatostatin analogues from then on. Due to high suspicion of newly recurrent paravalvular leak, a TEE was performed and a severe double paravalvular leak was detected (Figure 1). Pulmonary pressure was estimated over 80 mmHg. After Heart Team discussion, a fourth sternotomy was considered unacceptable for high risk and TPVL was offered.

TPVL procedure was taken under general anesthesia and real time 3D TEE guidance. After a mid-low posterior transeptal puncture, a steerable catheter, Agilis™ (Abbot Medical, US) was placed in left atrium. LA pressure was 24 mmHg with a V wave of 52 mmHg. The lateral leak was crossed with a 0,035 hydrophilic guidewire followed by a 5F multipurpose diagnostic catheter that was placed in left ventricle and exchanged with a Safari wire (Boston Scientific, Marlborough, MA, US). Using a 5F Amplatzer™ 120 cm long delivery sheath (Abbot Medical, US), compatible with the Agilis™ inner lumen, an Amplatzer™ Paravalvular pLUG III (AVP III), 10/5 mm implantation was attempted. However, its deployment led to complete blockage of the mechanical disk despite different positions tested and it had to be removed. The strategy was changed to sequential AVP II 8 mm and AVP II 6 mm implantation.
The first was implanted through the 5F long Amplatzer™ delivery sheath. Keeping the first plug unreleased, the second AVP II 6 mm was implanted through a 4F 90 cm Flexor sheath (Cook Medical, Bloomington, Indiana). After both plugs were released, a mild anterior peridevice residual shunt was judged as not relevant. The crescentic postero-medial leak was treated by the same crossing strategy (Agilis™ –– 0,035 hydrophilic guidewire – diagnostic catheter - Safari wire). Through the same 5F long sheath, the AVP III 10/5 mm that failed in the lateral defect was implanted in the middle of the crescentic leak. Moderate residual leak was seen at both sides of the device. Once again, leaving the AVP III unreleased, two new AVP II 6 mm and 8 mm were placed sequentially through the 4F Flexor long sheath (Figure 2) and a complete closure of the defect was seen on echo. Nevertheless, the residual leak in the lateral defect had worsened to moderate (grade II). We were able to cross the defect with a 5F diagnostic catheter and we deployed an AVP IV 8 mm (Figure 3). LA pressure felt to 12 mm Hg with a V wave to 18 mmHg. After 2.5 hours of procedure and after implantation of six devices (Figure 4) a complete occlusion of both leaks was achieved.

The postoperative period was uneventful, and the patient was discharged two days after. The early follow-up showed clinical improvement (NYHA II symptoms) and complete resolution of anemia and haemolytic pattern. TEE examination at 6 months showed persisting complete occlusion of both mitral PVL mitral and well-functioning mitral and aortic valves. Despite that, pulmonary pressure was estimated around 65 mmHg. Most impressively, after two years of follow-up the patient has not suffered new gastrointestinal bleeding episodes even after early somatostatin analogues discontinuation.

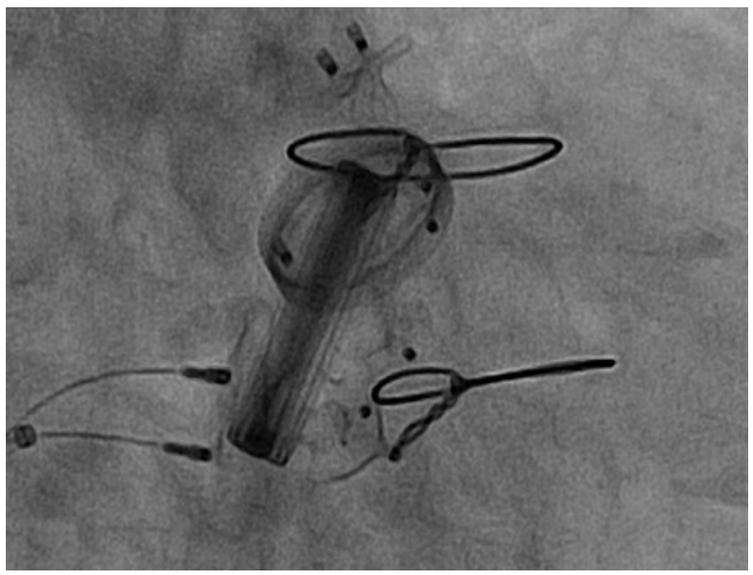


Figure 2: Implantation of the last AVP II device in the crescentic leak. Notice that AVPL III is attached to delivery cable, unreleased.

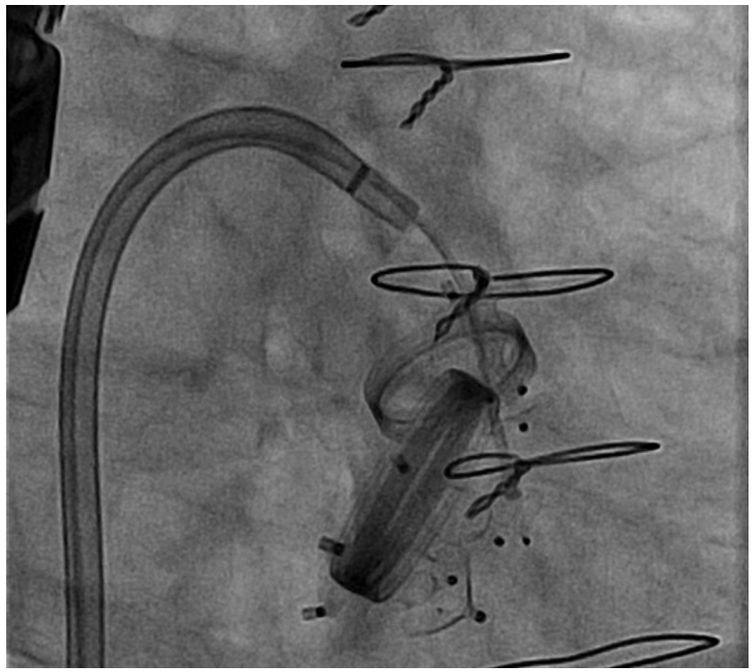


Figure 3: Implantation of the AVP IV through a diagnostic catheter.

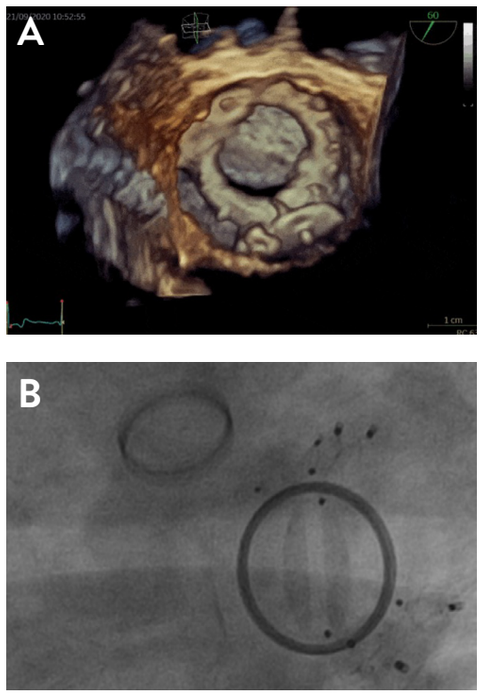


Figure 4:
Six devices implanted and occlusion of both leaks.

All content provided by Dr. Gerard Marti unless otherwise noted.

CASE DISCUSSION

Even moderate (grade II) residual leak has been strongly related to worse clinical outcomes and mortality. Therefore, the main goal of TPVL should be the complete occlusion of all the paravalvular defects detected, especially in those patients presented with hemolysis. However, difficulties in crossing guidewires, catheters and delivery sheaths, inaccurate conformation of the plug inside the defect or interference of the plug with the mechanical disks, make this goal difficult to be accomplished. A wide range of approaches and demanding techniques are available to overcome these limitations [5]. In our case, one of the techniques was the combination of vascular devices. Three Amplatzer vascular plugs (two AVP II and one AVP IV) made possible the complete occlusion of the lateral defect where an AVP III couldn't be implanted because of interference with disk of the mechanical prosthesis. On the other hand, the combination of an AVP III and two AVP II achieved an occlusive result in the complex crescentic posterior leak. When a combination of devices is used, they can be implanted simultaneously or sequentially. The first option demands two independent delivery sheaths. In case of sequential implantation, as in our case, it is recommended to leave the first plug unreleased to avoid its embolization or misplacement during crossing and deployment manoeuvres of the second device. The broad range of sizes and shapes and the competitive delivery sheath compatibilities makes the Amplatzer™ device family an outstanding option.

Interestingly, in our case not only a resolution of anemia was detected but also a complete resolution of gastrointestinal bleeding episodes. The normalization of Hb levels could be explained alone by resolution of hemolysis. The second finding has been linked to an acquired von Willebrand disease similar to such described in aortic stenosis and angiodysplasia. [6]

BIBLIOGRAPHY:

1. Alkhouli M, Zack CJ, Sarraf M, et al. Successful Percutaneous Mitral Paravalvular Leak Closure Is Associated With Improved Midterm Survival. Circ Cardiovasc Interv. 2017;10(12):e005730. doi:10.1161/CIRCINTERVENTIONS.117.005730
2. Ruiz CE, Jelnin V, Kronzon I, et al. Clinical outcomes in patients undergoing percutaneous closure of periprosthetic paravalvular leaks. J Am Coll Cardiol. 2011;58(21):2210-2217. doi:10.1016/j.jacc.2011.03.074
3. Millán X, Skaf S, Joseph L, et al. Transcatheter reduction of paravalvular leaks: a systematic review and meta-analysis. Can J Cardiol. 2015;31(3):260-269. doi:10.1016/j.cjca.2014.12.012
4. Calvert PA, Northridge DB, Malik IS, et al. Percutaneous Device Closure of Paravalvular Leak: Combined Experience From the United Kingdom and Ireland [published correction appears in Circulation. 2016 Nov 1;134(18):e403]. Circulation. 2016;134(13): 934-944. doi:10.1161/CIRCULATIONAHA.116.022684
5. CS, Sorajja P, Booker JD, Hagler DJ, Cabalka AK. Principles of percutaneous paravalvular leak closure. JACC Cardiovasc Interv. 2012;5(2):121-130. doi:10.1016/j.jcin.2011.11.007
6. Van Belle E, Rauch A, Vincent F, et al. Von Willebrand Factor Multimers during Transcatheter Aortic-Valve Replacement. N Engl J Med. 2016;375(4):335-344. doi:10.1056/NEJMoa1505643

CONCLUSION

When treating PVL, it has been proven that optimal procedural results translate into best clinical outcomes. Consequently, complete, or almost complete occlusion of the defects should be pursued ambitiously in every single case. For this purpose, the Amplatzer™ family offers an unique range of shapes, sizes and sheath compatibilities that, used alone or in combination, allows to treat the most challenging anatomies with long standing results.

PERCUTANEOUS PARAVALVULAR LEAK CLOSURE: **ADAPTING DEVICE STRATEGY TO ACHIEVE TECHNICAL SUCCESS**

Wongsakorn Luangphiphat, MD, Alain Delabays MD, Eric Eeckhout, MD, PhD.
Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland.

ABSTRACT

Paravalvular leaks (PVL) after cardiac surgery may occur in up to 15% of patients, with a larger incidence after mitral valve replacement compared to aortic surgery. Common causes of PVL are “healed” - infectious endocarditis, severe annular calcification, redo surgery, suturing technique, frail or lack of tissue. Nevertheless, the cause is often unknown. Most of the patients with PVL are asymptomatic, only 4% to 6% of them present with symptoms; typically, hemolysis and/or heart failure which relates with poor prognosis. Besides redo-surgery, percutaneous PVL closure has emerged as an elegant and less invasive alternative. There are several case reports and series on percutaneous PVL closure.

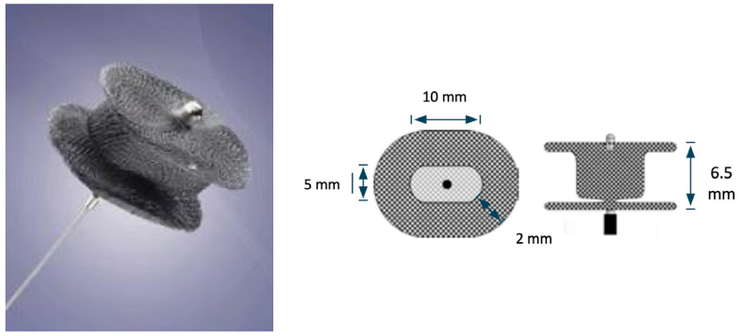


Figure 1: A: Detailed schematic presentation of Amplatzer vascular plug (AVP) III (Abbott Cardiovascular, Plymouth, MN), a rectangular oval shape that fits a wide range of paravalvular leaks (PVL) with dense nitinol wire layer design that facilitates rapid occlusion and small retention features, minimize valve leaflet interference. B: Waist long axis, waist short axis, overhang and plug length of AVP III mm - millimeter.

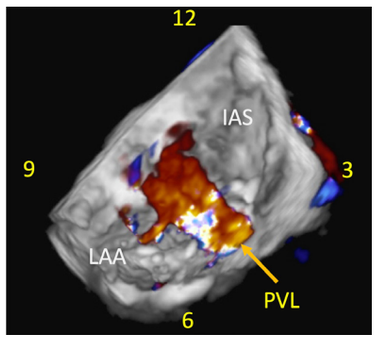


Figure 2: 3D with color Doppler transesophageal echocardiography demonstrating progression of the PVL at 5-7 o’clock. IAS – interatrial septum; LAA – left atrial appendage; PVL – paravalvular leak

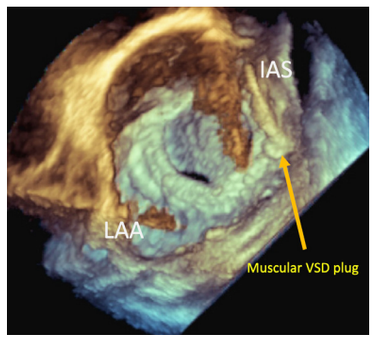


Figure 3: 3D transesophageal echocardiography showing implantation of a 6 mm muscular VSD plug and the blocked leaflet of the mechanical valve. IAS – interatrial septum; LAA – left atrial appendage

These publications have several limitations such as selection bias, limited number of patients and lack of long-term follow-up. Several devices not designed for PVL closure have been used with variable success. The Amplatzer Valvular plug (AVP III) (Abbott Cardiovascular, Plymouth, MN) is a multiple layers of nitinol mesh that is woven tighter than other Amplatzer implants (Figure 1).
It has an elliptical shape that may conform to the crescentic shape of a PVL. Here, we report the case of progression of a mitral PVL 2 years after successful initial closure with an (AVP III) 14/3 mm, which was successfully closed using an AVP III 10/5 mm. The case illustrates that PVL progression may occur over time. It also demonstrates the unique elliptical feature of the AVP III, allowing operators to align the implant in a crescentic shaped PVL.

CASE PRESENTATION

A 63-year-old female patient with a previous history of post-streptococcal rheumatic disease underwent repeated valve replacement surgery over a period of almost 20 years. A combined mitral and aortic bioprosthesis surgery was performed in 1980. The mitral valve was replaced by a new bioprosthesis in 1990 and finally a last combined mitral and aortic valve surgery was undertaken with mechanical valves in 1998.
The patient was addressed to our center in 2020 with a clinical picture of severe hemolysis in relation to a PVL located at the inter-atrial septum at about a 3-4 o’clock position. This PVL could be treated successfully, by a transseptal retrograde approach with an Amplatzer Vascular plug III 14/3 mm.

Dr. Wongsakorn Luangphiphat | Dr. Alain Delabays | Prof. Eric Eeckhout

In 2022, after an uneventful period of almost 2 years, the patient was addressed again to our center with a clinical picture of recurrent and severe hemolysis in relation to a new PVL. Transesophageal echocardiography (TEE) demonstrated progression of the PVL at 5-7 o'clock (Figure 2).

The patient was considered suitable for percutaneous PVL closure. This procedure was again performed under general anesthesia and TEE guidance. After transseptal puncture, a 14F steerable sheath (Oscor Destino Twist, Palm Harbor, FL, USA) was introduced in the left atrium. After careful measurement of the leak, it was decided to implant a 6 mm muscular VSD plug, which despite several manipulations continuously blocked the leaflets of the mechanical valve (Figure 3). The muscular VSD was removed and a second PVL closure attempt was undertaken with the Amplatzer Valvular Plug III 10/5 mm. TEE review indicated a more crescentic shape of the defect. Initial placement of the plug III was suboptimal and non-coaxial (Figure 4) with a persistent residual leak. It was possible to push the device back in the left ventricle and adequate alignment of the plug could be achieved by rotation of the partially deployed device in the left ventricle. This was particularly smooth because of the large 14F steerable sheath facilitated this rotation maneuver. Final TEE images and fluoroscopy demonstrated a nice alignment of the plug III with the previously implanted one and a trivial residual leak (Figure 5-6). The patient could be discharged and improved clinically.

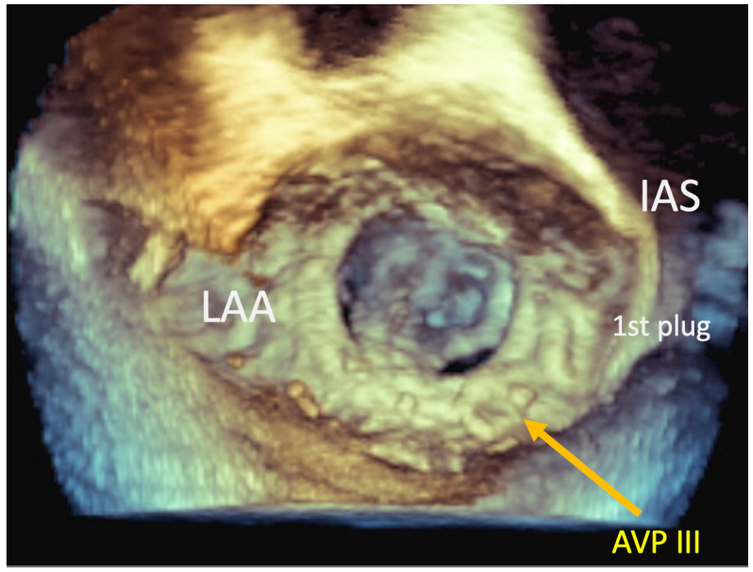


Figure 2: Final 3D transesophageal echocardiography demonstrated a nice alignment of the AVP III with the previously implanted plug III and a trivial residual leak. IAS – interatrial septum; LAA – left atrial appendage; AVP III - Amplatzer™ Valvular Plug III; PVL - paravalvular leak

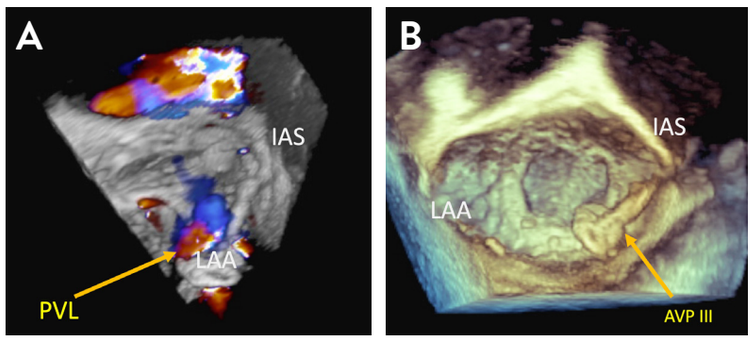


Figure 4: 3D with color Doppler transesophageal echocardiography (A) and 3D transesophageal echocardiography (B) showing after initial placement of the AVP III 10/5 mm was suboptimal and non-coaxial with a persistent residual leak. IAS – interatrial septum; LAA – left atrial appendage; AVP III - Amplatzer™ Valvular Plug III; PVL - paravalvular leak

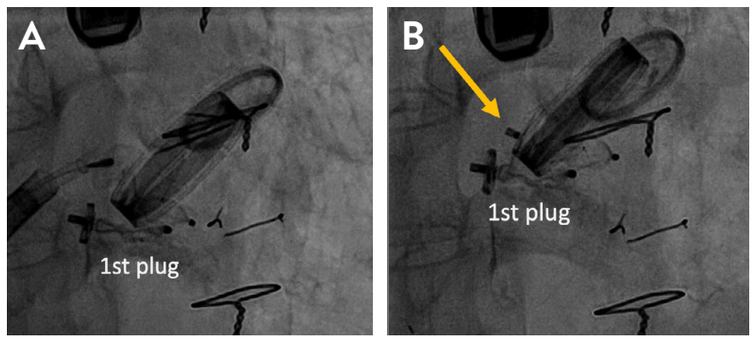


Figure 4: A: Angiogram showing putting the AVP III to fix PVL. B: Proper alignment of the AVP III with the previously implanted one.

CONCLUSION

This case of percutaneous PVL closure has several take-home messages. First, it demonstrates that PVL can progress over time with extension of the leak around the mitral annulus. Second, because of the shadowing of the first implant, quantification of a new leak may be difficult. Therefore, the first closure attempt failed because an inadequate device was chosen. Because a crescent extension of the new leak and the lesser risk of leaflet blockage, an AVP III was implanted. At the initial attempt, the device was not well aligned (with a persistent leak). The third message from this case report is that, because of the unique feature of the Amplatzer Valvular Plug III, this device can be repositioned and rotated within the left ventricle to achieve optimal alignment. The use of a large 14F steerable sheath facilitates this rotation maneuver.

CLOSURE OF A LARGE PARAVALVULAR LEAK **WITH THE AMPLATZER™ VALVULAR PLUG III**

Prof. David Hildick-Smith, Dr. Desham Weerman
Royal Sussex County Hospital, Brighton UK

CASE PRESENTATION

A 76 year old male underwent a St Jude mechanical bileaflet MVR with bypass grafts in 2002. He developed exertional breathlessness in 2008 and was referred for closure of a paravalvular leak in 2010. A pre-procedural transoesophageal echocardiogram showed a crescentic defect just posterior to the origin of the left atrial appendage, in a typical anatomical location.

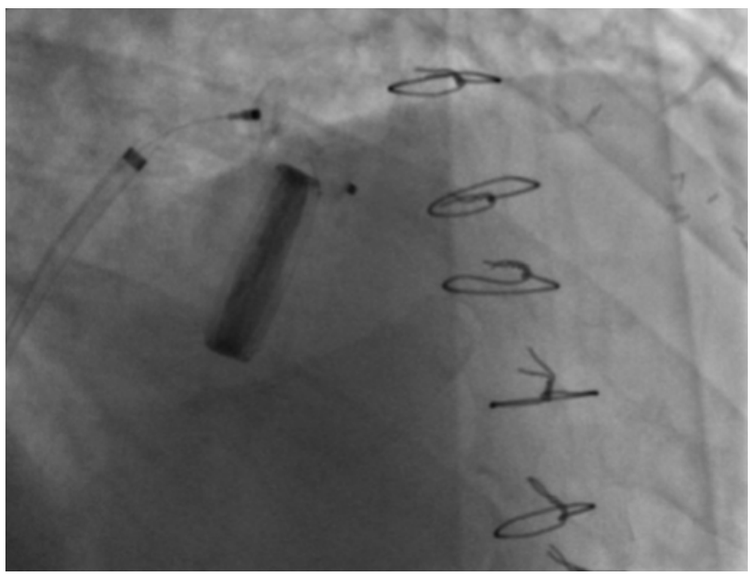


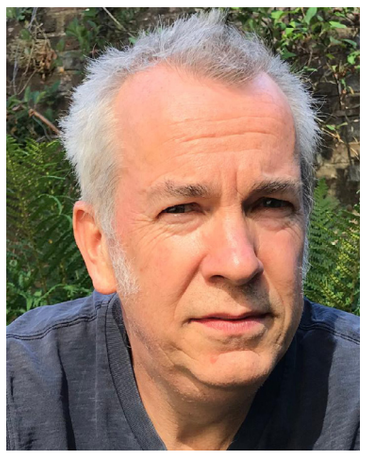
Figure 1: Fluroscopic image of the 1st 5x12mm AVP III device insertion

CASE DISCUSSION

The procedure was performed under general anaesthesia with transoesophageal echo guidance. Venous access was made with an 11F sheath. The pulmonary artery systolic pressure was 55mmHg. A transseptal puncture was made in a mid-fossa slight posterior location and a 71cm medium curve Agilis sheath was advanced into the left atrium. Through this, a multipurpose catheter was directed under echo guidance to the defect and a Terumo glidewire was passed into the left atrium. The multipurpose catheter was passed into the left ventricle and an Amplatzer Superstiff wire was pre-curled and laid around the apex of the left ventricle. After removal of the Agilis catheter a 7F Cook shuttle sheath was introduced over the Amplatzer Superstiff wire into the left ventricle.

The size of the defect strongly suggested that two devices would be needed, as it was over 2cm in length, with resultant severe mitral regurgitation. We therefore removed the dilator of the Cook shuttle sheath and introduced a second wire into the left ventricle.
The shuttle sheath and 11F venous sheath were removed over the two wires and the shuttle sheath was reintroduced over one wire into the venous system and around into the left ventricle. There was minimal ooze at the venous access site which was controlled by brief manual compression.

A 12x5 AVP III device was taken and was passed down the shuttle sheath into the left ventricle. Here it was opened 4cm below the St Jude valve in an RAO cranial projection which profiled the valve perpendicular to the line of view. In this orientation the AVP III was extruded from the catheter fully and was very slowly rotated clockwise until its short axis sat perpendicular to the valve. In this view the device will lie in an optimal position along the line of the defect. This device was deployed and the sheath was removed, leaving the cable in place to avoid risk of embolization with a second device.



Prof. David Hildick-Smith

Dr. Desham Weerman

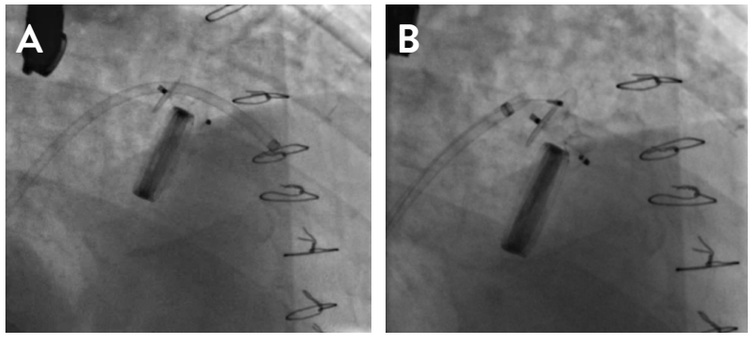


Figure 2: Fluroscopic images showing the deployment (A) of the second 5x10mm AVP III device (B)

The shuttle sheath was then advanced on the second wire, slowly across the defect and into the left ventricle. Fortunately it was on the side of the major part of the defect, rather than squashed against the edge of the defect (50/50 chance). A 12x5mm AVP III device was taken and was deployed in identical manner.
With both devices, the aim was the make sure that the "meat in the sandwich" part of the device occupied the defect, with the "layers of bread" either side. Once both devices were in place the defect was assessed further and there was found to be no regurgitation of note (even small residual defects may cause haemolysis). Both devices were released simultaneously from their cables and the venous sheath removed, and manual compression applied.

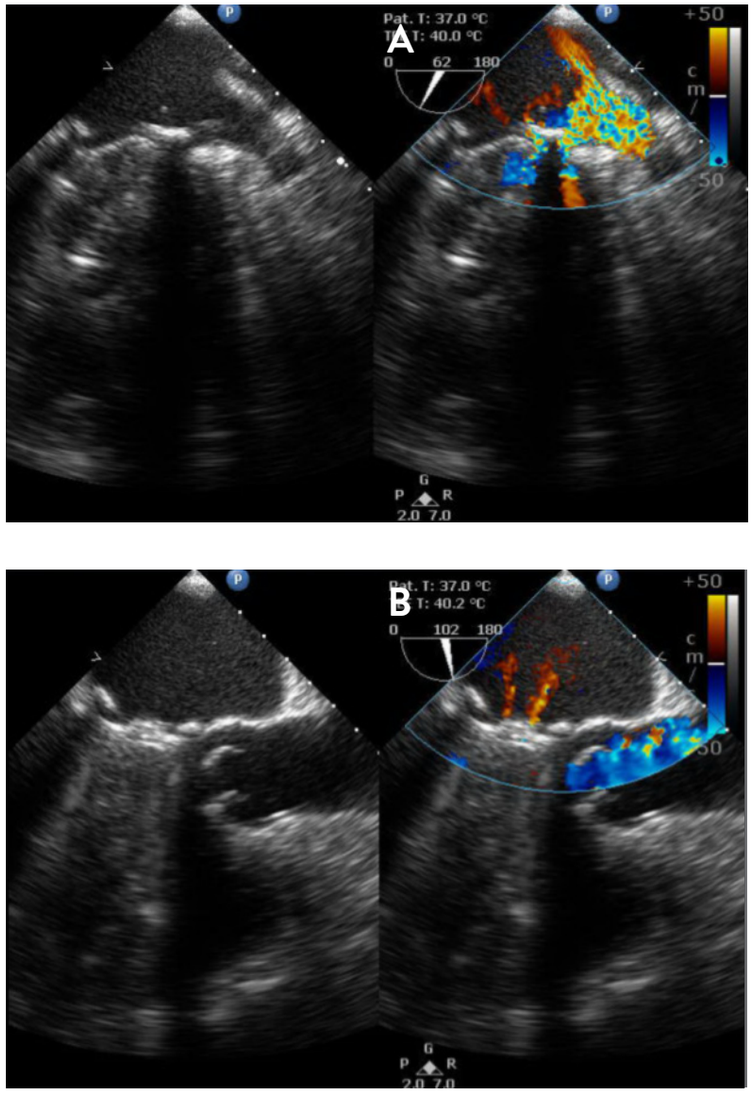


Figure 3:
Pre-procedural Transoesophageal echocardiography and colour doppler (A) showing a large paravalvular leak and following closure (B) with 2 AVP III devices

CONCLUSION

The unique properties of the AVP III device allowed closure of a paravalvular leak following a mechanical MVR, with resolution of the paravalvular leak and an excellent long term result. The patient did well immediately following the procedure, with resolution of his symptoms of breathlessness and was discharged after 24 hours.
He is currently stable (NYHA 1), and his mechanical mitral valve is well seated with no paravalvular leak.

COMPLEX PARAVALVULAR LEAK CASE

Jason Nogic[1] and Patrick A Calvert[1,2]
[1] Department of Cardiology, Royal Papworth Hospital, Cambridge, UK
[2] University of Cambridge, Cambridge, UK

ABSTRACT

Paravalvular leak (PVL) closure following valve replacement represents a minimally invasive therapeutic option for symptomatic patients. We present the case of successful treatment of a patient with ongoing severe PVL surrounding a mitral valve mechanical prosthesis, haemolytic anaemia, and severe ventricular dysfunction despite multiple re-do surgeries and prior insertion of two Amplatzer™ Vascular Plug devices.

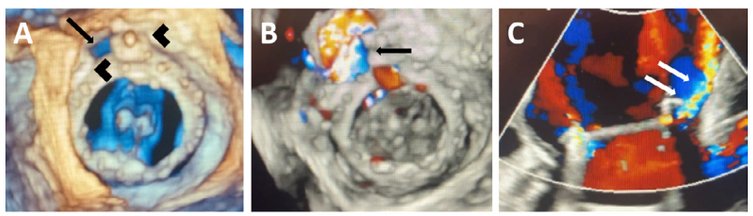


Figure 1:
A) Cross sectional TOE X-plane of mechanical MVR. Severe PVL (black arrow) with previously inserted AVP III and AVP4 devices (black chevrons). B) Colour flow through PVL between the two devices on cross sectional (black arrow) and C) transverse (white arrows plane).

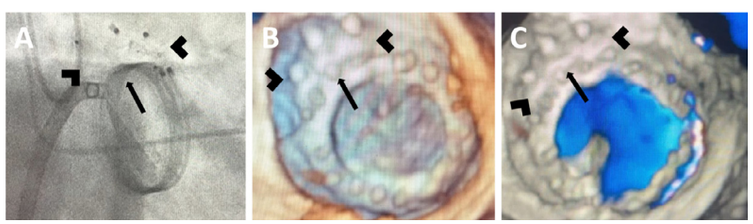


Figure2:
A) Angiographic image of newly inserted AVP III (black arrow) with previously inserted AVP III and AVP4 devices (black chevrons). B) Cross sectional X-plane of newly inserted AVP III (black arrow) and previously inserted (black chevron) C) Colour flow through MV prosthesis showing no residual PVL around newly inserted AVP III (black arrow) and previously inserted AVP III and AVP4 devices (black chevron).

INTRODUCTION

Paravalvular leak (PVL) occurs when there is dehiscence of a prosthetic valve and can occur due to a variety of causes. PVL manifests as heart failure (80% of all presenting symptoms) or intravascular haemolysis (16%) and has a prevalence rate as high as 5-17% of all surgical valves replacements [(1)]. The pathophysiological mechanism of PVL is not well understood, but most likely relates to poor substrate into which the valve is sewn. Misalignment of sewing ring and annulus due to calcification, poor apposition due to the sutures themselves and weakened tissue around the valve due to chronic infection may all be implicated. Re-do surgery remains a high risk option for patients with mortality rates for first, second and third redo surgeries of 13%, 15% and 35% respectively and with each subsequent operation less likely to be successful [(2)].

In experienced centres, percutaneous PVL closure is the treatment of choice. Here we present a complex patient with multiple redo mechanical mitral valve replacement (MVR) following initial infective endocarditis with ongoing severe residual PVL requiring multiple Amplatzer™ closure devices over multiple percutaneous procedures.

CASE PRESENTATION

A 60-year-old male presented for repeat percutaneous PVL closure in the setting of ongoing heart failure and haemolytic anaemia. He had a complex past surgical and procedural history having had his first mechanical MVR at the age of 52y following infective endocarditis. He underwent re-do mechanical MVR replacement within a year due to severe PVL. Despite this second surgery, within a short period of time he required a third re-do mechanical MVR. Some four years later, with ongoing shortness of breath, severe PVL and marked haemolytic anaemia, he was referred from the original cardiothoracic centre to Royal Papworth Hospital for percutaneous closure of PVL. The patient initially underwent percutaneous PVL closure over two separate procedures with an 8x3mm Amplatzer™ Paravalvular Leak III (AVP III) and the second with an 8mm AVP4 device.

Dr. Jason Nogic Dr. Patrick Calvert

Both these procedures were undertaken via a retrograde approach through right femoral artery access due to a heavily calcified atrial septum, making the more conventional anterograde access via transseptal puncture challenging. Despite two separate devices being deployed, there remained a leak between the devices. Given the potential risk of device embolization, it was decided to stage implantation of the third device.

Following initial improvement in symptoms the patient had an ongoing progressive decline with increasing breathlessness. Repeat investigations showed marked haemolytic anaemia with persistently elevated LDH of 1391, albeit lower than previously. Transthoracic echocardiography revealed severe left ventricular systolic dysfunction with an ejection fraction of 35% with transoesophageal echocardiography showing severe residual leak **(Figure 1)**. Following detailed discussion with the patient and procedural planning, implantation of a third AVP between the two previously inserted devices was attempted.

Under general anaesthesia with 3D-TOE guidance, the third percutaneous procedure was undertaken. Access was obtained via the right femoral vein utilizing ultrasound guidance with a ProGlide pre-closure device. Transseptal puncture was undertaken with difficulty using a radiofrequency needle. Although the transseptal puncture was low which increased the difficulty of the procedure, using a JR4 guide catheter within the small curve Agilis™ we were able to cross the hole between the two previously inserted devices with the assistance of 3D-TOE guidance. Initially a 10x5mm AVP III device was deployed, however this interfered with the mechanical valve discs and therefore had to be removed. We then deployed an 8x4mm AVP III device which abolished the residual PVL. **(Figure 2)**

CASE DISCUSSION

Percutaneous paravalvular leak closure is an excellent therapeutic option and has become the default strategy for experienced centres given the now wide availability of purpose-specific devices. Indeed, there is increasing observational evidence that there is significant short-term benefit for the initial approach being percutaneous.

In a retrospective observational study of 163 patients undergoing 189 procedures reported by our group, there was significant mortality and morbidity advantage at 30 days in those undergoing percutaneous closure. Of the 115 patients whose initial treatment was percutaneous closure, 30-day mortality rates were lower than surgery (2 [1.5%] vs 5 [9.3%]; p=0.01) and in-hospital major adverse cardiovascular or cerebrovascular events was also lower (1[0.8%] vs 5 [9.3%]; p<0.01). There was no difference in NYHA functional class between the groups at longest available follow up of 3.4 (IQR: 1.6-6.2) years and no difference in long-term survival (p=0.22) [3].

REFERENCES:

1. Percutaneous Device Closure of Paravalvular Leak: Combined Experience From the United Kingdom and Ireland. Circulation. 2016 Sep 27;134(13):934-44.
2. Genoni M, Franzen D, Vogt P, Seifert B, Jenni R, Kunzli A, et al. Paravalvular leakage after mitral valve replacement: improved long-term survival with aggressive surgery? Eur J Cardiothorac Surg. 2000;17(1):14-9.
3. Giblett JP, Jara T, MacCarthy T, Vibhishanan J, Venuraju S, Garbi M, et al. Transcatheter Versus Surgical Management of Paravalvular Leak: A Single-Center Experience With Purpose-Specific Occluders. JACC Cardiovasc Interv. 2022;15(12):1293-5.

CONCLUSION

This case highlights the efficacy of percutaneous closure of PVL even in apparently very complex cases despite adverse clinical features. Paravalvular leak closure is a safe and well tolerate procedure with significantly reduced risk of peri-procedural complications and death compared to re-do surgery with no difference in long-term survival or symptoms. In the absence of infection or valve instability, percutaneous closure of PVL is the first choice procedure in experiences centres.

INDIAN EXPERIENCE OF AMPLATZER™ VALVULAR PLUG III (3 CASES)

Dr. Y. Vijayachandra Reddy
Senior Consultant, Interventional Cardiologist,
Apollo Mains Hospital, Chennai, India

ABSTRACT

Vascular plugs are ideally suited to close extra-cardiac, high flowing vascular communications. Vascular plugs in general have a lower profile and the newer variants can be delivered even through a diagnostic catheter. These features make them versatile and easy to use. The Amplatzer™ Valvular Plug III is used for closing intracardiac defects including coronary arterio-venous fistula and paravalvular leakage.

INTRODUCTION

Closure of abnormal natural or artificial vascular communications is frequently performed in the catheterization laboratory. Commonly, 2 types of materials are used for closure of vascular communications, which include materials for embolization like coils, gel foam or particles and the various septal/duct occluders. Embolization materials like coils are relatively inexpensive, have a low profile and are easy to deliver; but the release of these materials cannot be secure and the rates of embolism is higher. The occluder devices are expensive, need a relatively larger sheath for delivery and are difficult to deliver in tortuous structures due to their bulkier profiles. However, the duct/ septal occluders can be released in a controlled fashion. The vascular and valvular plugs have features of both embolic materials and occluder devices. They have a relatively low profile and can be released in a controlled fashion. Almost all the published literature with the vascular plugs is with Amplatzer devices [Abbott, Minnesota, USA] 1-5.

CHOOSING THE CORRECT TYPE AND SIZE OF AVP

The choice of device depends on vessel type to be embolized, size of the vessel, quantum of blood flow, approach to the intended site of occlusion and the available landing zone. Amplatzer™ Valvular Plug III (AVP III) is preferred for medium sized, high flow, tubular/elliptical structures where faster occlusion is desired. AVP III seems particularly suitable for closing the paravalvular leaks. We measure the most restrictive diameter along the length of the vascular channel to be closed. It is recommended that a device is chosen that is at least 30-50% larger than the size of the native vessel. The mean device to vessel ratio was 1.4-1.5 in most of the published series. For instance, for a vessel size of 4 mm diameter, a plug with a diameter of 6 mm, and for a vessel of 5 mm a plug with a diameter of 8 mm is generally chosen. The length of the vessel and the available landing zone is also an important determinant of the plug size. An oversized device tends to lengthen significantly across the vessel. Hence, a plug must be chosen that is large enough to ensure complete occlusion, but at the same time does not elongate and protrude into nearby structures.

REFERENCES:

1. Wang W, Li H, Tam MD, Zhou D, Wang DX, Spain J. The Amplatzer vascular plug: a review of the device and its clinical applications. Cardiovasc Interv Radiol. 2012;35:725e740.
2. Tuite DJ, Kessel DO, Nicholson AA, Patel JV, McPherson SJ, Shaw DR. Initial clinical experience using the Amplatzer vascular plug. Cardiovasc Interv Radiol. 2007;30:650e654.
3. Barwad P, Ramakrishnan S, Kothari SS, et al. Amplatzer vascular plugs in congenital cardiovascular malformations. Ann Pediatr Cardiol. 2013;6:132e140.
4. Schwartz M, Glatz AC, Rome JJ, Gillespie MJ. The Amplatzer vascular plug and Amplatzer vascular plug II for vascular occlusion procedures in 50 patients with congenital cardiovascular disease. Catheter Cardiovasc Interv. 2010;76:411e417.
5. Hill SL, Hijazi ZM, Hellenbrand WE, Cheatham JP. Evaluation of the AMPLATZER vascular plug for embolization of peripheral vascular malformations associated with congenital heart disease. Catheter Cardiovasc Interv.2006;67:113e119.

Dr. Y. Vijayachandra Reddy

CASE REPORT 6

38 years old lady with a long history of mitral valve disease and multiple cardiac surgeries (first mitral repair and then 3 mechanical mitral valve replacements at different centres), presented to us with history of dyspnoea on exertion NYHA Class III, along with easy fatigability and palpitation for past 2 months.

She presented to us for 5th cardiac redo surgery versus cardiac transplant. Transesophageal echocardiography revealed a normal functioning SJM mechanical mitral prosthesis in mid LA cavity. The ventricularised LA chamber extended just beyond the fossa ovalis; the functional LA chamber into which the pulmonary veins were draining was relatively small. There was a large defect on the posterolateral side of the mitral valve prosthesis causing severe PVL. There was no valvular mitral regurgitation, and a preserved left ventricular ejection fraction.

PROCEDURE

Given the high risk of 5th redo cardiac surgery (EuroSCORE II: 46 %), the heart team decided to treat her by means of a transapical, transcatheter technique to close the PVL. This procedure was done under general anesthesia, starting with a small left anterolateral thoracotomy to expose the left ventricular apex.
A purse string suture with pledgets was placed, and a needle puncture done to pass a guide wire and place a 30 cm 10 F Cook sheath in left ventricle. Using a telescoped 5F JR diagnostic catheter, the PVL defect was easily crossed with a hydrophilic angled Terumo guidewire which was parked in right superior pulmonary vein.

This was then exchanged to 0.038” Amplatz superstiff guidewire and the Cook sheath was negotiated carefully into the smaller true-left atrium chamber. A 14/5 mm Amplatzer™ Valvular Plug III was deployed (ABBOTT, Plymouth, MN, USA) resulting in almost complete closure of the PVL, leaving only a small regurgitant jet.

The apical puncture site was closed by pre-placed purse string sutures. She made an excellent recovery and was discharged in a stable status. She remains symptom free since discharge.

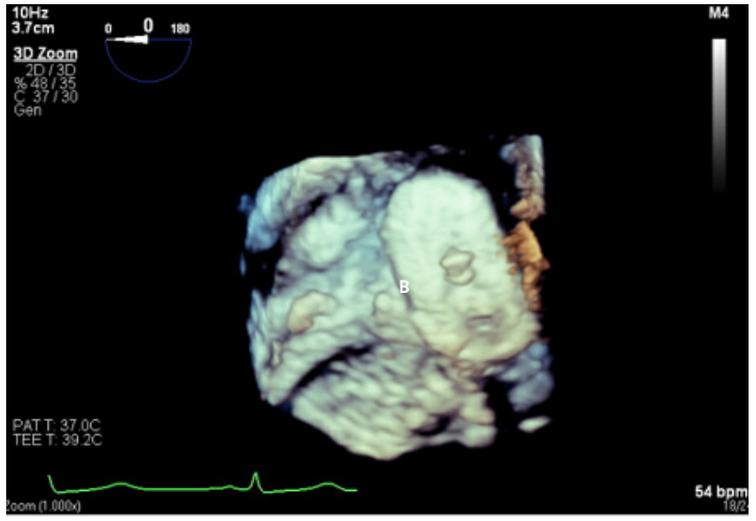


Figure 1: Post-procedure 3D Transesophageal echocardiogram left atrial view showing the AVP III plug with normally functioning mitral valve

CASE REPORT 7

60 years old male patient with mitral valve prolapse (MVP) developed Enterococcal infective endocarditis of the mitral valve and underwent mitral valve replacement surgery with bioprosthetic valve (St Jude 25mm) in 2011. The postoperative course was very uneventful. Echo prior to the discharge showed normal gradient across the tissue prosthesis and there was no PVL. However he developed another episode of staphylococcal infective endocarditis involving the bioprosthetic mitral valve in 2019, needing antibiotics for 6 weeks. Echo showed severe MR and severe PAH. After completion of the antibiotic course he underwent redo-mitral valve surgery with a bioprosthetic valve (Medtronic Mosaic porcine heart valve 25mm).

The surgery was complicated by extensive annular dissection requiring the use of Goretex patch to reinforce and strengthen the annulus. The surgeon had difficulty in approximating the tissue valve to the annulus and had to use Gore-Tex patch to reinforce and strengthen the annulus. TOE on the table showed significant PVL which was accepted as further repair even on reopening was not possible. The surgeon also had to suture close the IAS after attempted trans-septal PVL closure.
Mr. X was discharged on 10th post operative day in a stable hemodynamic condition. One month after the discharge he came back with NYHA class III dyspnea and was in gross CHF. He was treated with diuretics and other decongestive measures. TOE showed severe PVL at 10'o clock position and another smaller PVL at 11'o clock position. He had no clinical or biochemical evidence of hemolytic anemia and there was no evidence of infective endocarditis.

PROCEDURE

It was planned to attempt the PVL closure by retrograde transaortic route. 7F, 100cm, Cook sheath with a 5F 125cm MPA catheter as a telescopic access was passed from right common femoral artery and a 0.035 angled Terumo guide wire was negotiated across the major PVL defect from LV to LA under fluroscopic and 3D TOE guidance. The wire was then positioned in the right upper pulmonary vein and MPA catheter was tracked over the wire into right upper pulmonary vein. The entry of the system through the major PVL defect was confirmed by TOE and fluoroscopy. Intraprocedural shape and size of the defect assessed using 3D TOE. After removing the glide wire and MPA catheter, a 5x12mm AVP III device was delivered through the Cook sheath and the LA end of the device deployed successfully and it was confirmed that the device is caught tightly across the defect by a gentle tug and pull on the device towards the LV and then LV end of the device successfully deployed across the PVL defect.

Final TOE showed normally functioning mitral bioprosthesis, with minimal residual leak around the AVP III plug. The smaller leak was not attempted for closure at this juncture as there was no evidence of hemolytic anemia in the preprocedural evaluation.

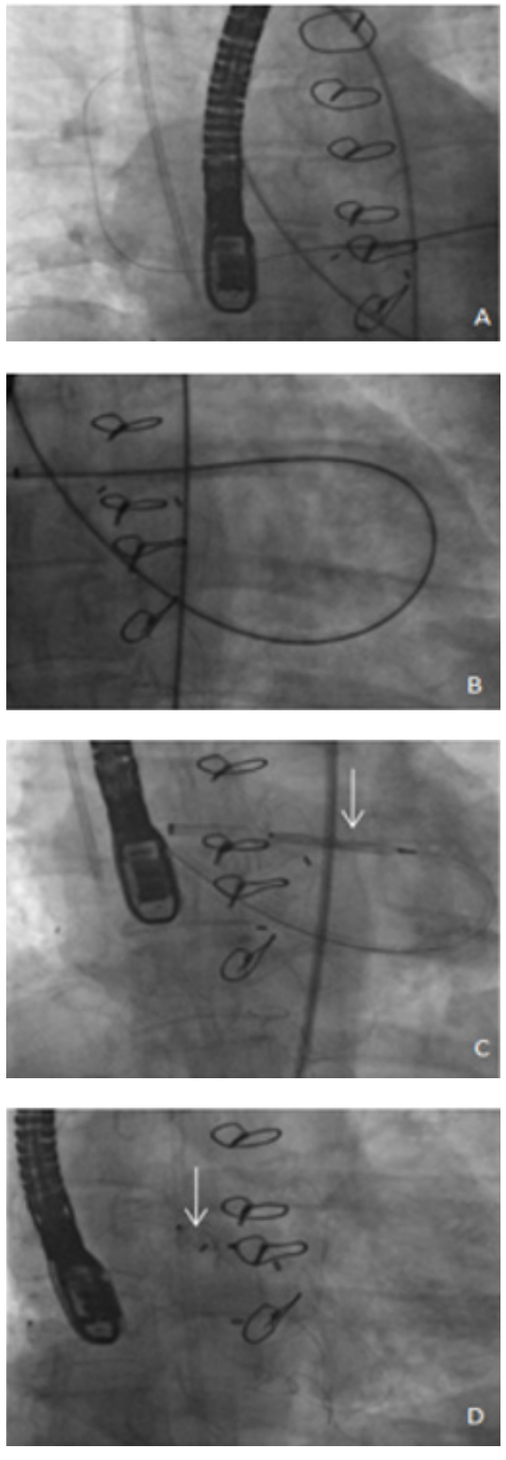


Figure 2 A, B, C and D: Device closure procedure (**A**) Pig tail in LV, glide wire in LULPV (**B**) Delivery sheath in RA (**C**) Device inside the delivery sheath (**D**) Deployed AVP III device across the defect

CASE REPORT 8

62 Years old male patient with aortic bioprosthetic valve (21 mm Medtronic pericardial tissue valve) was admitted with infective endocarditis and heart failure. TEE showed periprosthetic Aortic regurgitation. After initial medical management , he was taken up for PVL closure. Using a telescoped 5F JR diagnostic catheter, the PVL defect was crossed with a hydrophilic angled Terumo guidewire . This was then exchanged to 0.038" Amplatz superstiff guidewire and the Cook sheath was negotiated carefully. A 9/3 mm Amplatzer™ Valvular Plug III was deployed (ABBOTT, Plymouth, MN, USA) resulting in almost complete closure of the PVL, leaving only a small regurgitant jet.

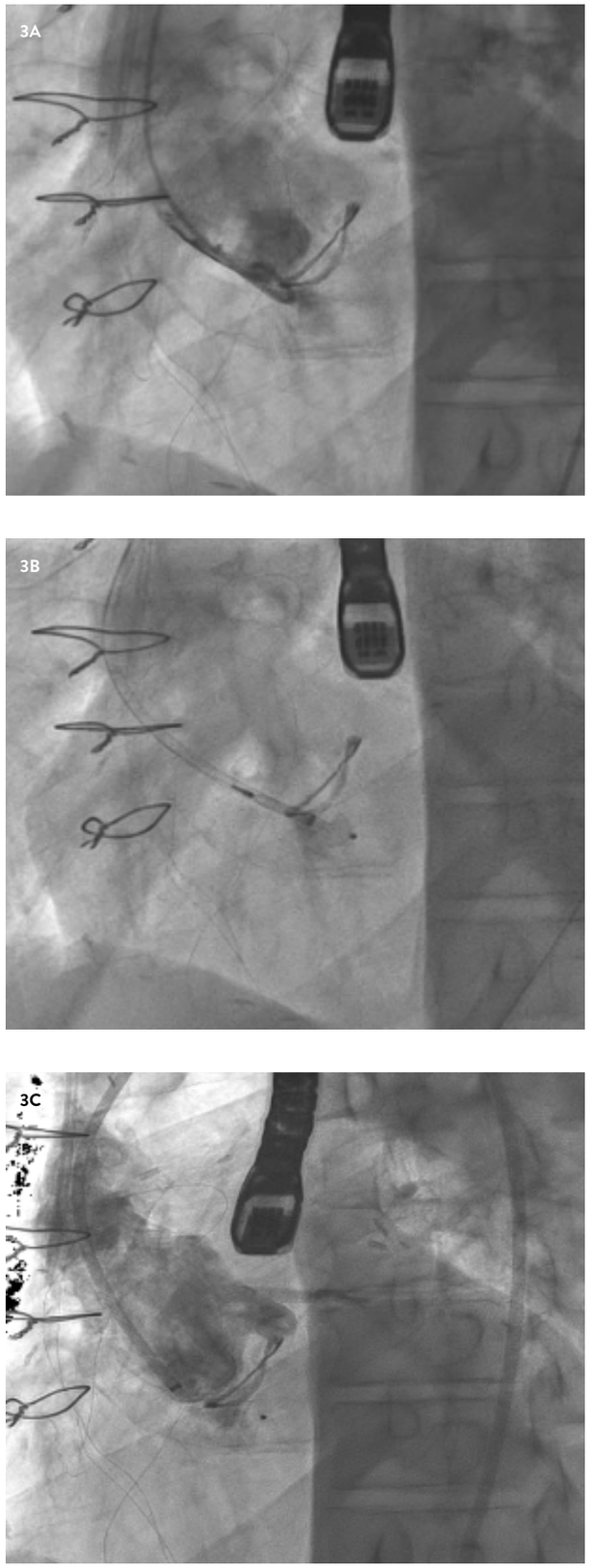


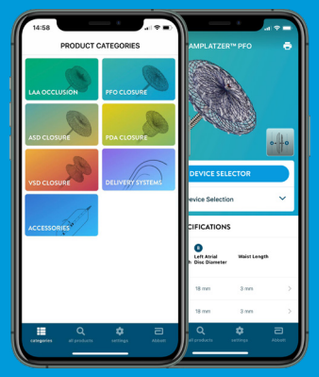
Figure 3: (**3A**) Pre procedural aortogram showing paravalvular leak (**3B**) Delivery catheter with device (**3C**) Post procedural aortogram showing sealed paravalvular leak

CONCLUSION

The Amplatzer™ Valvular Plug III is preferred for medium sized high flow tubular/ elliptical structures, where faster occlusion is desired. It seems particularly suitable for closing paravalvular leaks interventionally.

CASE #7 – INDIA: INDIAN EXPERIENCE OF AMPLATZER™ VALVULAR PLUG III (AVP III)

All content provided by Dr. Y. Vijayachandra Reddy unless otherwise noted.



DOWNLOAD NOW

Download the free Amplatzer™ Portfolio App from your favorite app store.

Download on the App Store

GET IT ON Google Play

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.
Always check the regulatory status of the device in your region. Information provided for Health Care Professionals only. The content herein represents the independent opinions and medical judgement of the contributor(s).

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA

www.structuralheart.abbott

Abbott