Percutaneous Closure of Prosthetic Paravalvular Leaks

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Paravalvular leaks (PVLs) are relatively common after valve replacement. These leaks are usually small and disappear during the follow-up. Symptomatic PVLs occur in 1% to 2% of patients undergoing valve replacement. PVLs causing clinical consequences require surgical intervention. Surgery is considered the gold standard of dehiscence repair. In recent years, the use of percutaneous closure devices for closing PVLs has been proposed as an alternative to surgery. Such techniques are less invasive and can be used in most high-risk patients instead of performing repeat surgery. This article describes how to assess the leak as well as the technical aspects of the procedure.

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KEY WORDS

Paravalvular leak • Percutaneous leak closure

Paravalvular leaks (PVLs) are relatively common after valve replacement. Intraoperatively performed transesophageal echocardiography (TEE) detects regurgitant jets in 17% of cases after aortic valve replacement and in 22% after mitral valve replacement.[1] PVLs are more common in cases of mechanical than bioprosthetic valves.[2] These leaks are usually small and disappear during the follow-up, due to progressing endothelialization of an implanted valve ring and "ingrown" valve prosthesis into the surface layer of the endocardium. Late symptomatic PVLs occur in 1% to 2% of patients undergoing valve replacement[3] and are associated mainly with prosthetic mitral valves.[4] Approximately 60% of these leaks occur within the first 6 months after surgery.[5]

The pathogenesis of PVLs may be associated with many circumstances. They may be the result of the suturing technique used, or associated with the diseased annulus as a result of previous infective

endocarditis (IE) or previous valve surgery. In some cases, PVLs are caused by poor artificial valve ring adhesion caused by massive annulus calcifications.[6] But the most important factor influencing PVL occurrence is IE leading to a paravalvular abscess formation, and its evacuation and leak; such IE requires valve reimplantation and long-term antibiotic treatment.[7]

Small PVLs may not cause any hemodynamic consequences. Yet rapid blood flow through the paravalvular orifice, caused by a large difference in pressure between the heart chambers, could lead to clinically significant hemolysis and severe hemolytic anemia, which requires frequent blood transfusions. Large PVLs are similar to valve insufficiency and lead to an increasing ventricular volume and congestive heart failure (CHF).

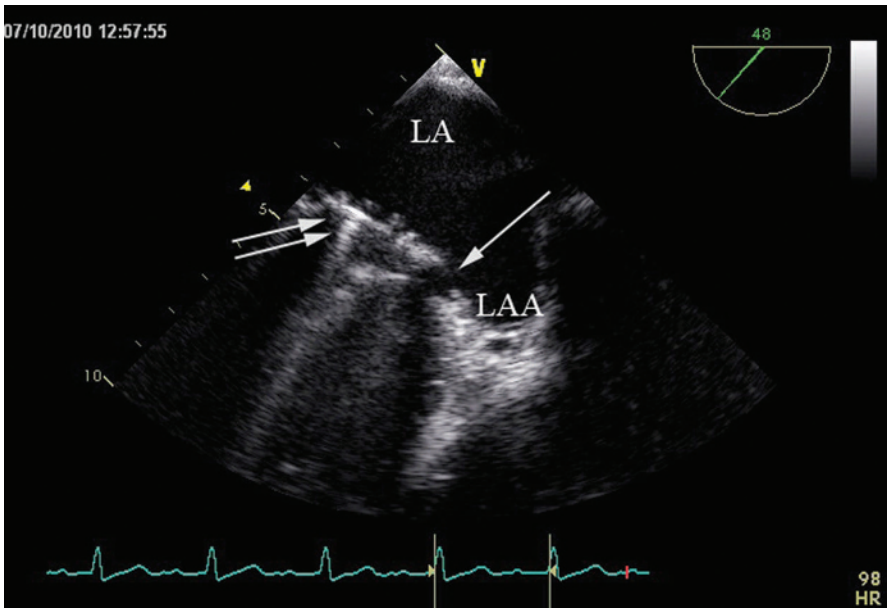

Figure 1. Sample transesophageal echocardiographic image. The prosthetic mitral valve implanted in mitral orifice (*double arrow*) with dehiscence in lateral part of mitral annulus (*single arrow*). LA, left atrium; LAA, left atrium appendage.

PVLs, regardless of their size, cause clinical consequences that require surgical intervention. Surgery is considered the gold standard of dehiscence repair, but reoperation is associated with significant morbidity and mortality rates. Mortality rates in valve reoperations reach approximately 10%.[8,9] Fortunately, repeat valve surgery for PVLs is rarely required and only 5% of patients with PVLs need reoperation.[10,11]

In recent years, the use of percutaneous closure devices for closing PVLs has been proposed as an alternative to surgery. This technique was first reported in 1992 by Hourihan and colleagues,[12] who closed PVLs using Rashkind devices. Since then, despite growing experience with the procedure and a major technical improvement in the occluder family of devices, the method is still not routinely performed and surgical repair is still a gold standard for treating such defects. The long-term clinical outcome of percutaneous closure of PVLs is unknown, so the procedure should be proposed only to patients with a very high or unacceptable risk for reoperation, or to those with severe clinical consequences (eg, severe hemolysis, CHF), who do not agree to undergo repeat surgery. Another aspect of the procedure is lack of specific devices designed for such procedures. All devices that are approved for closing cardiovascular defects (eg, atrial septal defect [ASD], ventricular septal defect [VSD], patent ductus arteriosus) are used off-label for PVL closure. Therefore, patients should be precisely informed of the risks and benefits of off-label device use and should give their informed consent for the procedure.

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Examination

Each patient suspected of PVL should undergo complete transthoracic echocardiography (TTE) and TEE examinations, performed by an experienced cardiologist. Two-dimensional (2D) TTE with spectral and color Doppler imaging is used for diagnosing PVLs. TEE, which has higher resolution and sensitivity for the diagnosis of PVL than TTE, is usually used for assessing the exact location and size of the defect (Figures 1 and 2). The severity of the dehiscence can be defined using the same criteria as those for valvular regurgitation. The parameters measured are the area of the color Doppler regurgitant jet, vena contracta (VC), the magnitude of the proximal isovelocity surface area, and regurgitant volume and fraction. Most authors propose to classify mitral PVLs as moderate when the VC is 3 to 7 mm, and as severe when the VC is $>$ 7 mm, but some authors classify PVLs with VC $>$ 5 mm as severe. For the aortic valve, a PVL with VC $>$ 6 mm is classified as severe.[6] A very careful examination of the leak anatomy and the related structures is a

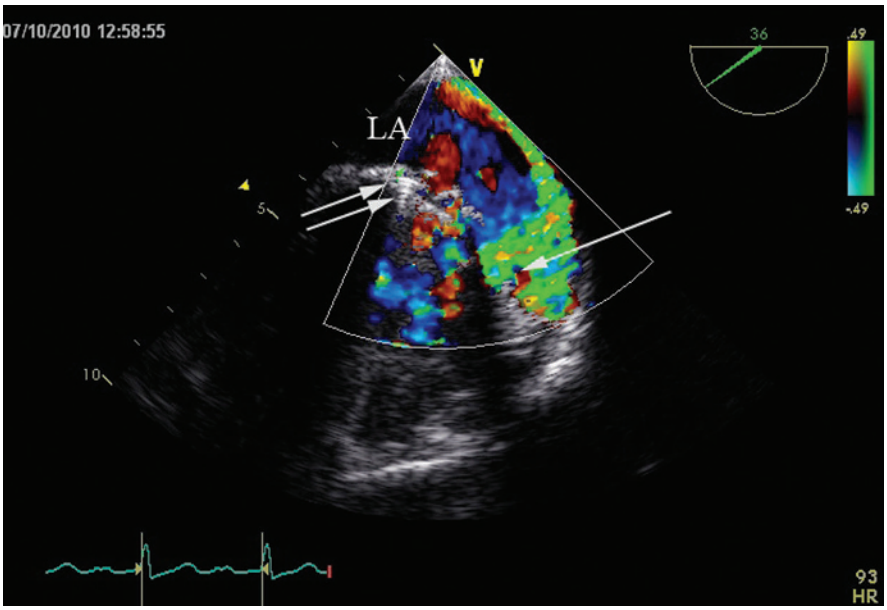

Figure 2. Sample transthoracic echocardiogram with color Doppler imagining. The prosthetic mitral valve (*double arrow*) with paravalvular leak (*single arrow*). LA, left atrium.

critical point for qualifying to the procedure. The defect and its spatial characteristics should be visualized in three-dimensional (3D) anatomy. The best method for this purpose is real-time 3D TEE (RT 3D TEE). It can reveal the exact location, size, and shape of a PVL, which may be round, linear, crescent, or irregular. RT 3D TEE also provides spatial relations of surrounding intracardiac structures, especially the distance from the implanted valve leaflets and a 3D reconstruction of the anatomic view, and aids in choosing the best occluder. The length and diameter of the leak tunnel determine the waist of the device used for closure. The close proximity of the PVL to the prosthetic valve makes it possible for the device disc to interact with valve leaflets. Echocardiography should specify the distance from valve leaflets and aid in choosing the right size of disc.[6,13] Closing PVLs localized next to the artificial valve ring without the tissue rim creates the risk of valve leaflets being covered by a device disc, thus locking them permanently in the closed or open position.

Contraindications include an active infection, especially ongoing IE with the presence of vegetation, or an intracardiac thrombus. Another contraindication to percutaneous closure is a large PVL caused by the rupture of many stitches, which leads to mechanical instability of the prosthetic valve.[14] In all these conditions, valve re-replacement should be performed.

PVL closure procedures are performed in cardiac catheterization laboratories with biplane imaging. RT 3D TEE assists in the assessment of PVLs and guidance of the catheters, and helps in performing a trans-septal puncture and device positioning, as well as in estimating the presence of residual leaks after the procedure. The procedure is performed under general anesthesia and TEE is performed continuously during the procedure. A critical point of the procedure is to visualize the 3D anatomy of the dehiscence and its spatial orientation to the surrounding intracardiac structures and to navigate the guidewires and the catheters. It is difficult to mentally transform a 2D echocardiography or fluoroscopy image on a 3D object. 2D TEE is a sufficiently accurate method for diagnosing and localizing a PVL, but it is not ideal for visualizing an intracardiac catheter. The mobile tip of a catheter with a variable curvature can exit the plane of a 2D TEE sector. A 3D transducer provides exact 3D mapping of the catheter position in relation to the PVL and surrounding intracardiac structures, and it allows the catheter to be guided precisely.[4,15] RT 3D TEE can confirm that the catheter has passed through the orifice of PVL, not through the implanted valve orifice. Blocking mechanical valve prosthesis leaflets caused by a wire or catheter may lead to severe hemodynamic disturbances, because leaflets stay widely open or permanently closed (as in the case of acute severe regurgitation or stenosis). With the use of the RT 3D TEE the entire mitral prosthesis can be seen en face and the PVL orifices can be identified and analyzed. Because of the aortic valve plane, RT 3D TEE images of aortic valve prosthesis are not as informative as those of mitral prosthesis but can still provide valuable information when compared with 2D images.

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The 3D echocardiography does have its limitations, such as a relatively slow (30 frames/s) acquisition rate of 3D imaging or lack of standardized 3D views. However, this technology is in constant evolution and in the near future it will have the potential to be an independent method of visualization during procedures of interventional cardiology. After the procedure,

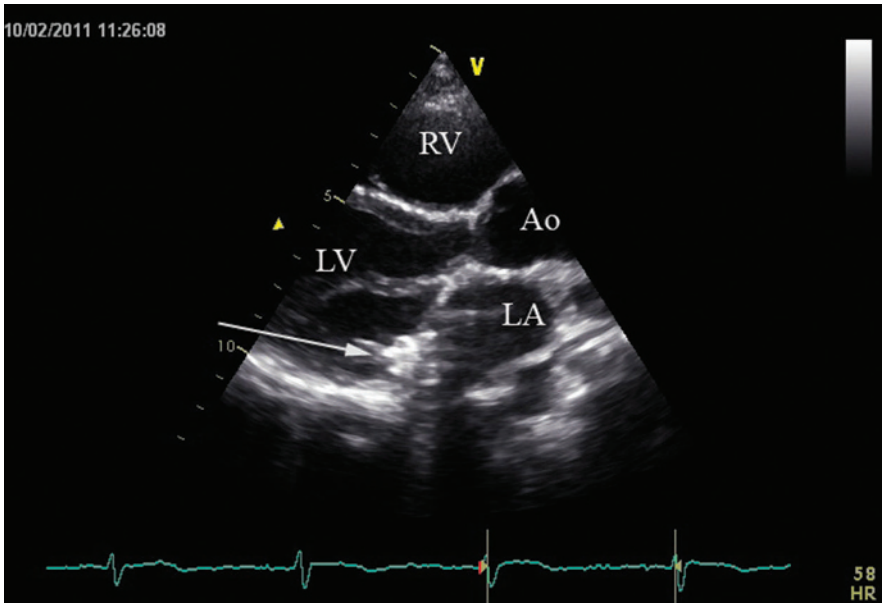


Figure 3. Sample transthoracic echocardiogram, parasternal long axis view. The Amplatzer™ Vascular Plug III (St. Jude Medical, St. Paul, MN) positioned in dehiscence (*arrow*). Ao, aorta; LA, left atrium; LV, left ventricle; RV, right ventricle.

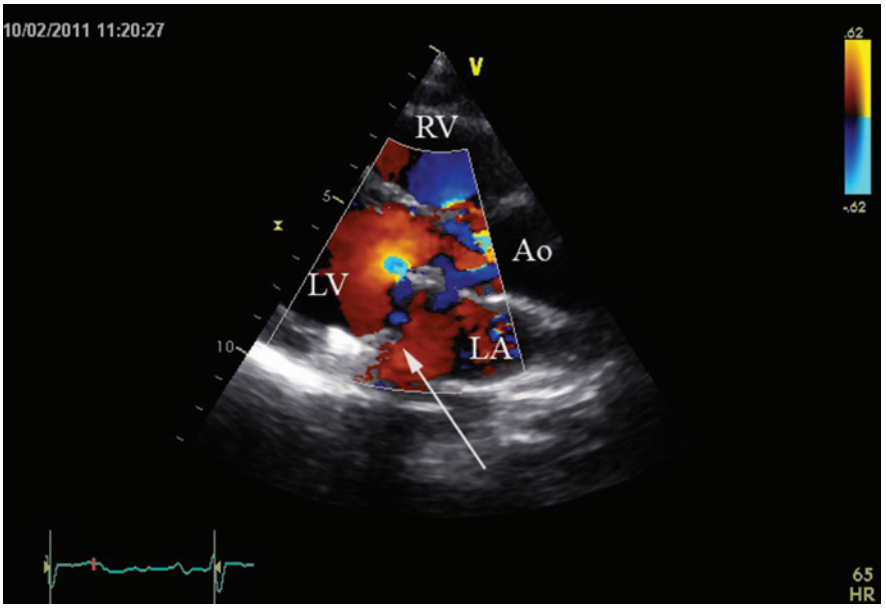


Figure 4. Sample transthoracic echocardiogram with color Doppler imagining, parasternal long axis view. The Amplatzer™ Vascular Plug III (St. Jude Medical, St. Paul, MN) positioned in dehiscence (*arrow*). No paravalvular leak shown in color Doppler imagining. Ao, aorta; LA, left atrium; LV, left ventricle; RV, right ventricle.

RT 3D TEE can confirm the device stability and its interaction with the surrounding structures (eg, mechanical valve leaflets) (Figures 3 and 4).

Procedure

The approach may be anterograde, retrograde, or transapical, depending on the PVL location or whether the patient has implanted both aortic and mitral mechanical prostheses. Mitral PVLs are usually accessed by the anterograde approach. A femoro-femoral or femoro-jugular wire loop must be constructed to deliver the closure device. Closure via an anterograde fashion is made by the trans-septal approach. A trans-septal puncture is performed and the catheter is advanced into the left atrium. Through this catheter a wire is delivered via the defect into the left ventricle and then the catheter is moved into the left ventricle. To enhance the stability, an arteriovenous loop is established (Figure 5). For this purpose, the catheter is advanced through the aortic valve into the left ventricle and the wire from a trans-septal catheter is snared and drawn into it. Then the closure device is delivered and deployed across the PVL through the trans-septal catheter (Figure 6). The retrograde approach is rarely used. In this approach, a guidewire and catheter are delivered across the aortic valve, then the guidewire is advanced through the defect into the left atrium, where it is snared by a trans-septal wire. Using this loop, the delivery sheath can be advanced trans-septally into the left ventricle via PVL. When the leak cannot be accessed with the methods described above, the transapical approach is performed. It is not uncommon, but when the leak cannot be crossed in an antegrade fashion and when there are mitral and aortic prostheses, the leak is crossed via the transapical approach. When the leak is crossed, the delivery sheath can be delivered either antegrade via the trans-septal approach or via the transapical approach. It is a more invasive procedure requiring surgical access to the apex and post-procedural surgical closure of the puncture of the apex.

Aortic PVLs are usually accessed retrogradely. Via the femoral artery and the aorta, the sheath is advanced through the defect into the left ventricle to deliver the occlusion device. When a PVL cannot be accessed in this way, the anterograde approach is used. The sheath is advanced through a femoral vein trans-septally via the left atrium into the left ventricle. Then the guidewire from the sheath is directed through the leak into the aorta, where it is snared.

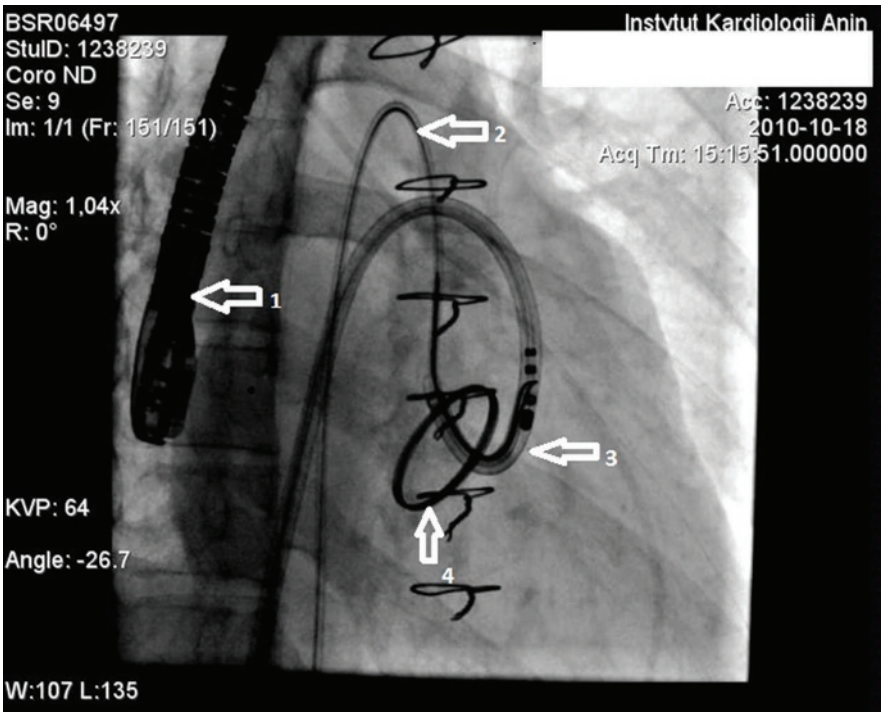
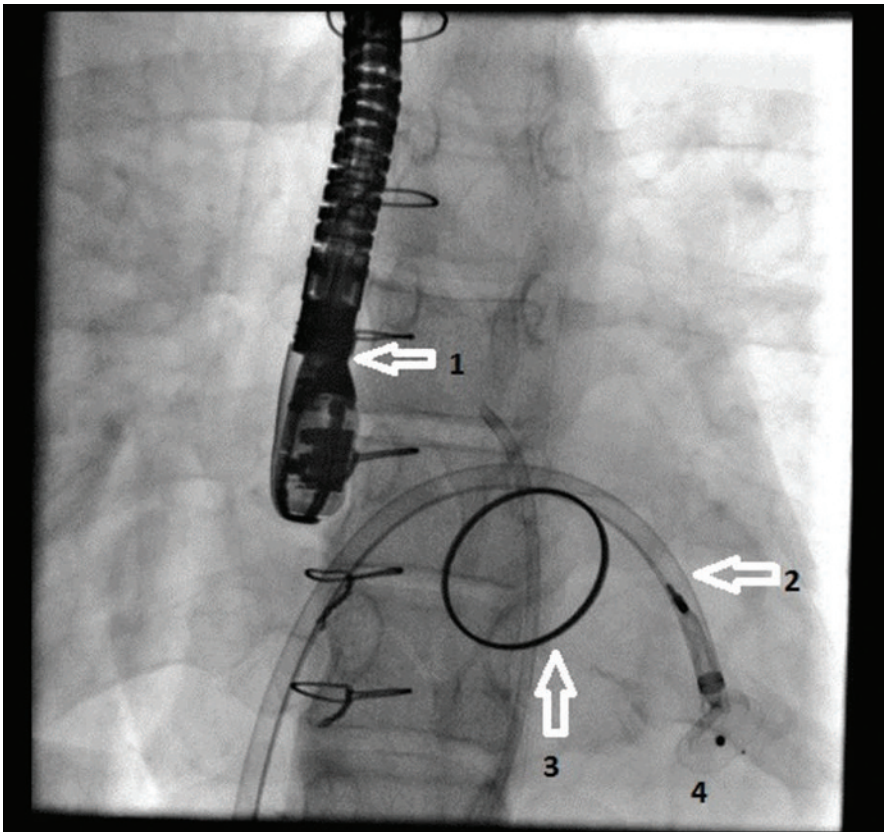


Figure 5. Fluoroscopy shows the femoro-femoral loop. The trans-septal sheath crossing through the paravalvular leak from the left atrium into the left ventricle. The steerable electrode in trans-septal sheath and Amplatzer™ (St. Jude Medical, St. Paul, MN) left catheter with a wire create the loop. Arrows show transesophageal echocardiography transducer (1), arterial catheter (2), trans-septal sheath (3), and ring of implanted mitral valve (4).

Figure 6. Fluoroscopy shows the distal disc opened in the left ventricle. The wire is released. The steerable electrode and the Amplatzer™ (St. Jude Medical, St. Paul, MN) catheter are removed. Through the trans-septal sheath, an Amplatzer™ Vascular Plug III is advanced into the left ventricle. Arrows show transesophageal echocardiography transducer (1), trans-septal sheath, advanced via paravalvular leak into the left ventricle (2), ring of implanted mitral valve (3), and opened distal disc of the Amplatzer™ device (4).



Using such a loop, a delivered sheath can be advanced through a PVL either anterogradely or retrogradely. A transapical approach is used rarely, when a PVL cannot be accessed by the methods described above, or when both mitral and aortic mechanical valves are implanted. During the percutaneous closure of an aortic PVL, it is important to determine the distance from the defect to the coronary artery and aortic valve leaflets. An adequate diameter of the disc should be selected, not to interfere with valve leaflets or with the coronary artery orifice. For this purpose, coronary angiography and aortography are required.

Currently, all devices applied for PVL closure are used off-label. In earlier studies of the Rashkind double umbrella devices, Gianturco coils, and dumbbell coils were used for PVL closure.[12,16] Currently, the most commonly used device is one of the Amplatzer™ (St. Jude Medical, St. Paul, MN) family of vascular plugs. The Amplatzer™ occluders include five devices specially designed for closing ASDs (Amplatzer™ Septal Occluder), muscular and membranous VSDs (Amplatzer™ Muscular VSD Occluder), persistent ductus arteriosus (Amplatzer™ Duct Occluder and Vascular Coils), and Amplatzer™ Vascular Plug. Different shapes, and waist and disc diameters, allow an appropriate device to be chosen for different types of defects. It is very important to choose the right dimension of the device waist. Oversized devices placed in the leak orifice can aggravate the tension and radial forces in the adjacent tissues and increase the dehiscence. Undersized devices may result in a large residual leak or device instability. No less important is the diameter of the disk. A disc that is too large in diameter creates a possibility of overlap with

mechanical valve leaflets and may block their movement. A disc that is too small does not cover the leak orifice and will cause device dislodgment. Another major advantage of the Amplatzer devices is that they can be removed through the sheath when the effect is unsatisfactory (eg, large residual leak, unstable position, interference with valve prosthesis).

Balloon-sizing of the leak orifice can be helpful but is rarely used because overflowing balloon carries the risk of defect expansion. On the other hand, round balloons are not suitable to estimate oval or crescent defects. Thus, the diameter of device waist is selected according to TEE measurements.

All the occluders mentioned above have different types of discs and waists and different disc-to-waist ratios. The ASD and patent foramen ovale occluders have large disc diameters and carry a high risk for interference with artificial valve leaflets. Conversely, the muscular VSD occluder and Amplatzer duct occluder have small discs and wide waists, and are appropriate for closing defects localized just next to the artificial valves. Currently, the best for PVL closure is Amplatzer Vascular Plug III with oval-shaped discs and waist.

In some cases, complete PVL closure requires implantation of two devices: for example, in the case of residual leak after first occluder implantation or simultaneous implantation of two devices with small discs (instead of one large device) to avoid interference with artificial valve leaflets.

Results

The ultimate success of the procedure is estimated at 60% to 90%, and there is a need for repeat intervention in up to 40% of cases.[17] The procedure was successfully used for closing not only paramitral and para-aortic leaks but also for paraprosthetic aorto-right ventricular leaks caused by a fistulous communication between the sinus of Valsalva and the right ventricular chamber.[2] The best results of occluding are achieved in patients with small or medium (< 5 mm), single, circular PVLs, with a distance of at least some millimeters from the valve ring. Hein and colleagues[5] reported that, in 95% of patients qualified for the procedure, occluders were implanted with a success rate of approximately 50%, which was described as total occlusion of the leak. There were no procedure-related deaths.

The devices used do not always seal leaks completely. Larger defects may require more than one device.[14] Such a procedure increases the risk for device dislodgement, embolization, and interference with prosthetic leaflets. But in most cases, the failure of the procedure is determined by the inability to deliver a device or device interference with the surrounding structures. Not without significance is the fact of relatively high rates of occluder dislodgment.[18,19] Published data have shown that successful closure for the first device deployment is achieved in about 82% to 100% of cases, but in some patients it was necessary to change a device two or three times during the procedure to obtain total PVL closure.[20]

Complications include residual leaks, device dislodgment, blocking valve leaflets, or thrombus formation (mainly on the disc in the left atrium).[21,22] Some complications are related to the transfemoral approach and trans-septal puncture. Residual leaks are common, in up to 45% of cases, and may not cause serious hemodynamic consequences, but may worsen pre-existing hemolysis. Increasing postprocedure hemolysis is related to high velocity paravalvular jets or high velocity flow rates through the occluder wire mesh, causing mechanical fragmentation of erythrocytes. Slight hemolysis usually disappears after the endothelialization of device wires is completed, which usually lasts approximately 6 months.[5] Persistent severe anemia needs repeated blood transfusions. Late device dislodgement after percutaneous closure of a paramitral leak has also been reported.[19]

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Two months after the procedure, TEE performed in a patient with severe hemolysis and deep anemia, revealed the device dislodgement in the left atrium, which was successfully removed surgically. Another serious complication during the procedure is the perforation of the cardiac wall leading to pericardial effusion and tamponade. But the most serious, although fortunately rare complication, is IE of the prosthetic valve and implanted device. This complication usually is treated surgically with prolonged subsequent antibiotic treatment.

The percutaneous closure of PVLs with Amplatzer occluders is feasible, but there is a need for engineering a device designed specifically for PVL closure. Because of the close proximity of PVLs to implanted valves and their leaflets, the devices should be shaped appropriately. Depending on the PVL, 3D anatomy and PVL distance from the valve implanted, the device discs should be round

or oval, and should be low in profile in order not to block valve leaflets after a disc is positioned and opened. Furthermore, because of the left ventricle contractility, the changing PVL diameter depending on the phase of LV contraction and forces generated by muscle acting on the device, the device should be made of a material capable of conforming to the dynamic morphology of the defect. It should also provide enough stability regardless of the contractility and pressure gradient across the cardiac chamber.[4]

Conclusions

A lack of specially designed devices and a technically difficult procedure requiring significant experience result in these procedures being performed rarely. But with the development of technology and increasing use of transcatheter methods, the procedure may soon substitute for surgical treatment in most cases. ■

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MAIN POINTS

- Paravalvular leaks (PVLs) are relatively common after valve replacement. PVLs are more common in cases of mechanical rather than bioprosthetic valves; these leaks are usually small and disappear during the follow-up.
- Recently, the use of percutaneous closure devices for closing PVLs has been proposed as an alternative to surgery. However, despite growing experience with the procedure and a major technical improvement in the occluder family of devices, the method is still not routinely performed.
- Currently, all devices applied for PVL closure are used in an off-label fashion. The most commonly used device is one of the Amplatzer™ (St. Jude Medical, St. Paul, MN) family of vascular plugs.
- Complications can include residual leaks, device dislodgment, blocking valve leaflets, or thrombus formation.