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Percutaneous Mitral and Aortic Paravalvular Leak Repair: Indications, Current Application, and Future Directions

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Abstract Paravalvular regurgitation (PVR) is a symptomatic or asymptomatic complication after surgical valve replacement. It may be related to calcification, infection or tissue friability and occurs in 5 % to 17 % of surgical implanted heart valves. Reoperation is associated with a higher morbidity and mortality than the index procedure. Percutaneous closure of PVR can be an effective and lower risk alternative to reoperation. However, feasibility for percutaneous closure has to be assessed by defining the shape, size and location of the defect. Echocardiography with three-dimensional defect reconstruction is a cornerstone for guiding percutaneous PVR closure. Access for aortic PVR is usually retrograde via the femoral artery and access to mitral PVR either retrograde from the aorta, transvenous-transseptal or transapical. Meticulous planning and prudent procedural execution by experienced operators ensuring no impingement of the prosthetic leaflets leads to a high success rate of percutaneous PVR repair.

Keywords Perivalvular leak · Percutaneous intervention · Aortic valve replacement · Paravalvular regurgitation · Mitral valve replacement · Surgical bioprosthesis · Mechanical valve prosthesis

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Introduction

Paravalvular regurgitation (PVR) results from a communication between two cardiac chambers manifesting as a regurgitant jet, originating between the outer margin of a surgical valve and the native tissue surrounding the prosthesis. Of all implanted surgical prosthetic heart vales, 5 to 17 % will eventually develop PVR [1–4]. The occurrence of PVR may be related to infection [5], calcification [6–9], suture rupture [10–12], suturing technique [10, 11] or tissue friability [9]. The early occurrence of PVR is usually related to technical surgical aspects of the implantation. Clinically significant PVR most often occurs in association with mitral prostheses, less often with aortic, and rarely with pulmonary or tricuspid prostheses [13, 14]. Historically reoperation has been the standard treatment [3, 6, 15]. However, it is associated with higher morbidity and mortality than the index procedure [15–18]. Alternatives to surgical PVR closure, avoiding the risk of re-operation, have been pursued [19, 20]. The first report on percutaneous paravalvular leak closure from 1992 [19] proved, that the principles of percutaneous techniques to close intra-cardiac shunts (e.g., atrial septal defects, ventricular septal defects, patent ductus arteriosus) can be translated to percutaneous PVR closure [14, 19, 21–24, 25••, 26••] (Table 1).

Indications and Planning

Most paravalvular leaks are small, asymptomatic and take a benign course. PVR repair is only indicated, when symptoms occur. As re-operation is often high risk, the first line procedure to address PVR may be percutaneous repair. Patients, who are not candidates for percutaneous PVR closure (e.g., very large defects), should be considered for surgical repair. However, despite re-operation the initial

Table 1 Selected paravalvular leak closure case series

Publication	Device	Location	Access	Outcome	Complications
Ruiz [25••] 2012	Amplatzer Duct Occluder, Amplatzer Muscular VSD Occluder, Amplatzer Vascular Plug II, Amplatzer Septal Occluder	32 mitral 9 aortic 2 mitral and aortic	Retrograde for aortic position Transseptal antegrade or transapical for mitral position	Technical success 86 % Clinical success 77 %	2 device embolization 1 procedure related death 1 iliac artery dissection 2 cardiac perforation
Sorajja [26••] 2011	Amplatzer Septal Occluder, Duct Occluder, Muscular Ventricular Septal Defect Occluder, or Vascular Plug II	90 mitral 25 aortic	11 apical retrograde 25 transaortic 77 transseptal antegrade	Successful closure (≤1+ residual regurgitation) in 77 %	2 device embolizations 5 leaflet impingement 1 Malposition in LV 4 hemothorax
Nietlispach [33] 2010	Amplatzer Vascular Plug III	4 mitral 1 aortic	4 transapical 1 transfemoral	NYHA class fell from 4 (IQR 3 to 4) to 2 (IQR 2 to 3) Technical success 100 % Clinical success 100 %	2 pericardial bleeding 1 leaflet impingement
Cortes [38] 2008	Amplatzer patent ductus arteriosus occluder	27 mitral	27 transseptal	30-day survival 100 % Technical 63 % Clinical success 59 %	2 leaflet impingement 2 thrombi 2 stroke 6 blood transfusion 2 cardiac arrest (successful resuscitation) 1 cardiac perforation
Shapira [50] 2007	Amplatzer occluder	9 mitral 2 aortic	9 transseptal 2 transfemoral retrograde	Technical success 92 % Clinical success 60 %	2 leaflet impingement
Hein [44] 2006	Amplatzer patent ductus arteriosus occluder Amplatzer muscular VSD Occluder	13 mitral 8 aortic	8 transfemoral 13 transseptal or retrograde transarterial	Technical success 95 % Clinical success 70 %	2 leaflet impingement 1 Endocarditis
Pate [14] 2006	Amplatzer ASD occluders Amplatzer PDA occluder Coils	9 mitral 1 aortic	9 antegrade transseptal 1 retrograde transfemoral	Technical success 70 % Clinical success 57 %	1 leaflet impingement 1 device embolization
Hourihan [19] 1992	Raskind umbrella device	4 aortic	4 retrograde transfemoral	Technical success 75 % Clinical success 50 %	2 device embolization

cause for PVR often persists leading to high recurrence rates after repeat surgery.

Patients may present with congestive heart failure, hemolytic anemia or both [7]. In case of heart failure, any reduction in regurgitant volume is anticipated to improve cardiac function. However, if hemolysis is predominant, relief may be uncertain unless there is complete closure of the leak.

Establishing the diagnosis of PVR may be challenging, when associated murmurs are soft and Doppler flow images are obscured by prosthetic material [27]. While mitral PVR creates a pan-systolic murmur heard best at the left sternal border, aortic PVR is appreciated as a high-pitched decrescendo diastolic murmur. The sensitivity and specificity of transesophageal echocardiography (TEE) is higher than transthoracic echocardiography (TTE) to differentiate between transvalvular regurgitation and PVR and to diagnose and quantify PVR. Therefore, the threshold for performing TEE in a symptomatic valve patient with suspected PVR should be low [27, 28]. TEE is the cornerstone for evaluating feasibility and estimating the likelihood of success for paravalvular leak closure [28]. Defects causing PVR are rarely cylindrical holes, but may be crescent, semilunar or oblong [29, 30]. If the defect includes more than 20 % of the sewing ring circumference percutaneous repair is unlikely to be successful. The best results may be achieved in patients with small to medium sized (less than 10 mm), single, circular, paravalvular leaks. Implanting multiple smaller devices into large leaks reduces the risk for leaflet impingement as compared to using a single large device. However, this has to be counterbalanced by the risk for embolization and residual PVR, when using smaller devices. Active endocarditis may result in PVR and is considered a contraindication for percutaneous PVR repair.

Access for Paravalvular Leak Closure

Percutaneous PVR repair can be performed antegrade or retrograde and via venous, arterial or transapical access. Access site selection depends on the location of the prosthesis, the location the defect in relation to the valve, the presence of mechanical valves, operator experience and preference and anatomical peculiarities of the individual patient. The best approach is to be determined on a case-by-case basis.

Aortic Paravalvular Defects

Closure of aortic PVR is mostly performed retrograde from the femoral artery. The small diameter of the radial artery restricts suitability for PVR repair as it limits device size and delivery system profile.

An angled or straight hydrophilic guidewire is advanced through the leak using a steerable catheter (e.g., Glidecath, Judkins Right, Multipurpose). Before exchanging the hydrophilic wire by an exchange length extra-support wire (e.g., Amplatz extra-stiff) it has to be ascertained by fluoroscopy and/or TEE, that the wire is actually crossing the paravalvular leak and not positioned transvalvular. Evaluation of the shape and size of the defect may be performed by balloon sizing or echocardiography. The size and type of device determines the diameter of the delivery catheter needed, which is placed across the leak railed by the stiff exchange length wire. After withdrawing the wire and introducer, and before the device is loaded onto the delivery catheter, it has to be ensured, that there is no air in the system. Air entrapment in the system may also occur after loading the device onto the catheter, because of the vacuum created when pushing the occluder through the delivery system. Before final release of the PVR occluder the free motion of the prosthetic leaflets should be documented as well as the stable anchoring of the device within the defect and the reduction of the regurgitant jet.

Mitral Paravalvular Defects

Closure of mitral PVR is more challenging than aortic and is mostly performed using a femoral transvenous-transeptal approach. Transvenous-transeptal access includes puncture of the inter-atrial septum. While transseptal puncture may be performed with fluoroscopy only, we recommend using TEE or intracardiac ultrasound [31], because it markedly reduces the associated risks (cardiac perforation, pericardial effusion and tamponade). If the paravalvular leak is close to the atrial septum, a transseptal approach through the superior vena cava or a retrograde approach from the femoral artery, aorta and left ventricle has been used. Retrograde access for mitral PVR repair may be complicated by left ventricular structures (e.g., trabeculae, papillary muscles, chordae). Snaring and externalization of the guide wire creating a complete arteriovenous circuit may be necessary to maintain stability and allow device advancement from either the arterial or the venous side. Due to the sometimes acute angle when engaging mitral PVR leaks from a femoral approach, the use of a deflectable sheath [32••] (e.g., Agilis™, St. Jude Medical, MN, USA) may facilitate crossing the defect.

An alternative access for mitral PVR repair is the transapical approach [25••, 26••, 33•]. This approach allows the most direct engagement of mitral paravalvular leaks irrespective of defect location. Although often performed with a surgical incision with limited exposure of the left ventricular apex, fully percutaneous transapical PVR leak closure can be accomplished with percutaneous puncture with or without closure of the left ventricular apex [34]. Various devices

have been used for this indication [35] and a number of dedicated percutaneous apical closure devices are currently under development and clinical investigation. A fully percutaneous transapical approach requires careful planning of the puncture site of the skin and the apex for which three-dimensional computed tomography (CT) reconstructions may be helpful. The puncture has to be aligned with the defect but has to spare the lung parenchyma, the coronary arteries and the papillary muscles. This can be ascertained by ultrasound, fluoroscopy, simultaneous coronary angiograms or overlaying the CT images and the live fluoroscopy. However, as long as the safety and efficacy of percutaneous apical closure devices [34, 36] is not thoroughly established, we generally favor an open apical approach.

Imaging

Echocardiography

Angiography is of limited value to determine the degree, location and shape of the PVR defect [19]. Today three-dimensional TEE guidance [37] (Fig. 1) is the cornerstone imaging modality for PVR assessment and closure [38–40]. Color Doppler imaging allows localization of the regurgitant jet and assessment of its severity [28] (Fig. 1). Injecting saline through the catheter and observing the bubbles on TEE can be helpful for engaging the defect. However, when acoustic shadowing is a concern, aortography or ventriculography may still be helpful adjuncts. TEE is also useful to locate the optimal region of the interatrial septum for the transseptal puncture, introduce the wire and guide through the defect, correctly deliver the device, quickly identify possible complications (e.g., thrombi or leaflet impingement) and document the result of the procedure. By facilitating access to the leak, probing and device delivery, it reduces procedure duration, injected contrast volume and radiation exposure. We do not advise transthoracic echocardiography for PVR closure guidance.

Surgeons have a unique perspective with respect to valvular anatomy, typically viewing the mitral valve from a left atrial approach. Consequently echocardiographers routinely display and describe the mitral valve as if viewed from the left atrium. When looking at the mitral valve, the aortic valve is displayed on top with the mid anterior leaflet (A2) at 12 o'clock. The mid posterior leaflet (P2) is at 6 o'clock. The left atrial appendage and the anterolateral commissure are at 9 o'clock and the inter-atrial septum with the posteromedial commissure at 3 o'clock. The typical posterior-anterior anatomic or left anterior oblique end-on fluoroscopic view displays the mitral ring as though seen from the left ventricle. Consequently the echo view and fluoroscopic views are mirrored and upside down views of each other. It is useful for the interventionalist to understand and utilize the echocardiographers' terminology. On occasion displaying the echo image so as to correlate with the apical view of the mitral ring can be very helpful.

Similarly, the aortic valve from the surgeons view is described with the non-coronary cups between 7 and 11 o'clock, the left coronary cups between 11 and 3 o'clock and the right coronary cusp between 3 and 7 o'clock. The mitral-aortic fibrous continuity corresponds to 12 o'clock in both the mitral and aortic clock.

Computed Tomography

Three-dimensional reconstructions from CT have become an asset to diagnosis and planning of percutaneous interventions in structural heart disease [41–43]. Four-dimensional reconstructions from ECG-gated helical multiple phase CT acquisitions can simulate the cardiac cycle and render detailed paravalvular leak assessments. With the corresponding software the reconstructions may be overlaid onto the live fluoroscopy during the procedure. When rotating the c-arm, the CT image will equally be angulated [43]. This way radiolucent landmarks can be visualized which facilitates localization and crossing of the leak. However, performing a CT for planning of paravalvular leak closures increases total radiation exposure and contrast media volume and artifacts from dense structures as the surgical valve prosthesis may reduce image quality and information.

Sizing

For proper device selection, the size, location and shape of the defect need to be defined. The size and the hemodynamic effects of closure can be assessed by test balloon occlusion [19, 44]. For small leaks, a coronary angioplasty balloon may be used and for large defects a peripheral or sizing balloon [44]. The mostly relied on imaging modality to assess the defect size, however, is three-dimensional TEE (Fig. 1). Reconstructions from pre-procedural CT scans can also render valuable defect measurements, provided there are negligible artifacts from the surgical prosthesis material.

Device Selection

In the first percutaneous PVR repair [19] reported in 1992 the Raskind umbrella device was successfully deployed. Initially this device was intended for closure of patent ductus ateriosus [45, 46] and was also used for defects in collateral channels, aortopulmonary windows and venous connections [45, 47]. Its modification was successfully deployed in atrial and ventricular septal defects and in patent foramen ovale [46, 48, 49].

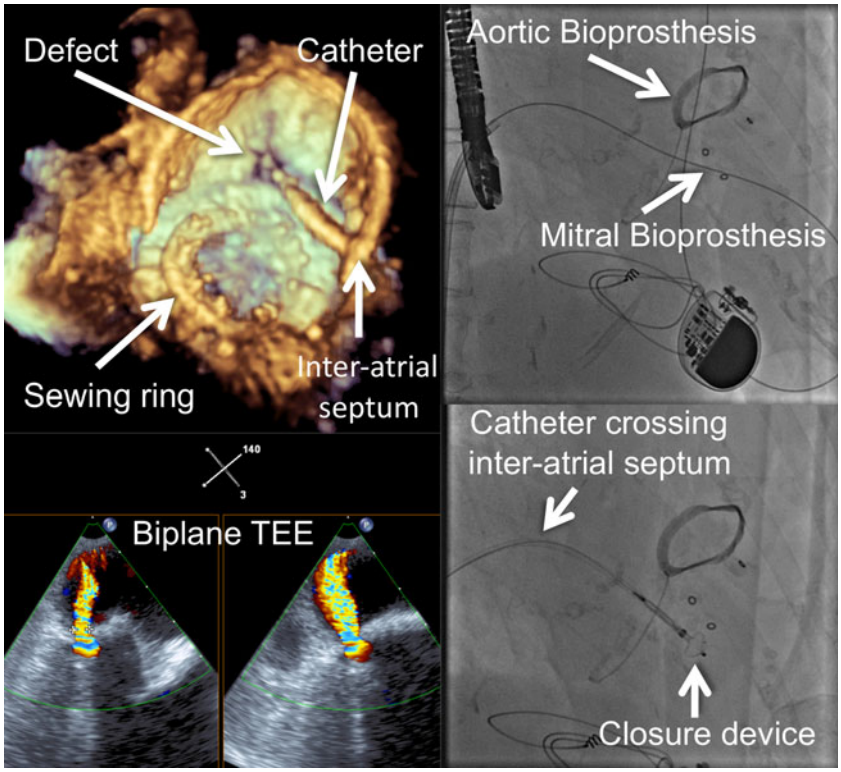

Fig. 1 Imaging guidance for percutaneous paravalvular leak repair. Transesophageal echocardiography (TEE) (*upper left* and *bottom left*) is essential for planning and performing percutaneous paravalvular leak repair. TEE helps to quantify (*bottom left*) the defect and guides the catheter and delivery system to the defect (*upper left*). After placing a wire through the defect (*upper right*), the delivery system with the device is advances through the leak for stepwise deployment (*bottom right*)

Today, most PVR repairs are performed with Amplatzer devices [14, 25••, 26••, 38, 50] (St. Jude Medical, St. Paul, MN, USA). The devices are either cylindrical (Amplatzer Septal Occluder, Amplatzer Muscular VSD Occluder, Amplatzer Duct Occluder, Amplatzer Vascular Plug II and IV) or oval shaped (Amplatzer Vascular Plug III). While the Amplatzer Vascular Plug consists of one single, cylindrical body (diameters 4−16 mm), the Amplatzer Vascular Plug II comprises of three cylindrical discs with the same diameter (diameters 3−22 mm). The Amplatzer Vascular Plug III is oval shaped and adjacent to the center body are two discs, each forming a 2 mm rim (center body from 4×2 mm to 14×5 mm). The Amplatzer Duct Occluder has a cylindrical body with one adjacent rim (waist 4 −14 mm) and the Amplatzer Muscular VSD Occluder has a cylindrical waist with two adjacent rims (waist diameter 4−18 mm). Other occluders previously used for PVR repair are the CardioSEAL Clamshell device (Nitinol Medical Technologies, Boston, MA, USA), the Gianturco-Grifka vascular occlusion device (Cook Cardiology, Bloomington, IN, USA) and different coils (Cook, Bloomington, IN, USA).

Selection of the most appropriate device and size for PVR repair is critical for its success. As most PVR leaks are not cylindrical, the oval shape of the Amplatzer Vascular Plug III may better fit crescent shapes. Large defects may warrant large occluders, however, the discs of large occluders may easily overhang the sewing ring especially of mechanical valve prosthesis thereby increasing the risk for prosthetic leaflet impingement. Placing several smaller devices can overcome this risk, because the smaller disks are less likely to overhang the sewing ring.

Complications

The risk for emergent surgery and for death as a complication of percutaneous PVR repair is 1–2 % [14, 21, 38, 44].

The most common complication associated with PVR repair is bleeding [38], which may occur at the access site [38], intrapericardial [26••, 38] or manifest as hemothorax [26••]. The transvenous approach to mitral PVR repair includes transseptal puncture, which is associated with the risk for cardiac perforation [26••, 38] and tamponade.

Adequate anticoagulation should be monitored, to avoid clot formation [38] on the wire and delivery system with the risk of systemic and cerebral embolization [38].

Impingement of the prosthetic leaflets [26••, 33•, 38, 44, 50] may be detrimental [44] and can be avoided by proper device selection [33•, 44]. Embolized closure devices [19, 25••, 51] may be snared [19, 25••]; but on occasion may necessitate unplanned surgery [51, 52] depending on localization and feasibility for percutaneous recapture.

Local access site infections or endocarditis [44] are rare complications of PVR repair. Contrast induced renal injury should be rare as the procedure can generally be performed with little or no contrast.

Future Directions

Transcatheter therapies are the natural evolution of structural heart disease interventions. The safety and efficacy of percutaneous PVR repair has never been compared to re-operation in a randomized trial, although published case series and comparisons to historical cohorts suggest that percutaneous repair is an effective and lower risk alternative. After the initial experience with various percutaneous devices [14, 19], the development of purpose-specific occluders [33•] will be an important step toward individualizing percutaneous PVR repair. Real-time multimodality imaging techniques, that combine fluoroscopy, echocardiography and CT, will further facilitate the execution of these challenging and complex procedures. The use of dedicated percutaneous apical closure devices will allow safe access and exit for a fully percutaneous apical approach to paravalvular leaks and will reduce the need for the more complex transvenous-transseptal approach for mitral PVR repair.

Conclusion

Percutaneous repair of paravalvular leaks can be an effective, lower risk alternative to re-operation, when performed by experienced operators in symptomatic patients with a feasible defect anatomy. Proper planning and execution including multimodal imaging guidance will lead to successful percutaneous PVR repair.

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- •• Of major importance

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