Closure of prosthetic paravalvular leaks: a long way to go

Carlos E. Ruiz¹**, Howard Cohen¹, Raquel Del Valle-Fernandez², Vladimir Jelnin¹, Gila Perk³, and Itzhak Kronzon³

¹Division of Structural and Congenital Heart Disease, Department of Interventional Cardiology, Lenox Hill Heart and Vascular Institute of New York, 130 East 77th Street, Black Hall Building, 9th Floor, New York, NY 10075, USA
²Hospital Central de Asturias, Oviedo, Spain
³New York University School of Medicine, New York, NY, USA

Introduction

Cardiac valve replacement, albeit a well-established and safe procedure, is associated with a significant risk of complications. Symptomatic paravalvular leak (PVL) is a significant post-operative complication of cardiac valve replacement. The prevalence of this complication along with the long-term significance of asymptomatic leaks remains unknown. When these patients develop worsening heart failure or severe haemolysis that requires multiple transfusions from paravalvular regurgitation, the current recommendation is for closure of the leak. The recommended approach has been surgical closure until transcatheter techniques were introduced by Hourihan et al.¹ There have been significant innovations in occlusive devices over the past 20 years; however, there are no specifically designed device(s) for the treatment of PVLs. Percutaneous device closure of PVLs has become an attractive alternative to surgical closure. This has further been enhanced by the ability to integrate multimodal imaging modalities that have helped to define the pre-operative anatomy as well as to plan and guide the percutaneous closure procedure, resulting in improved outcomes.

Imaging techniques

Since no single imaging modality has the capability to provide all the crucial information that is required for percutaneous closure of PVLs, in our centre we utilize an integrated multiple imaging modalities within a bi-plane cardiac catheterization laboratory. The following modalities assist in the assessment and guidance of percutaneous closure of PVLs.

Echocardiography

Echocardiography is a multifaceted tool used for the diagnosis, quantification, and guidance of treatment of paravalvular prosthetic valve leaks.

Diagnosis

Two-dimensional (2D) echocardiography with spectral and colour Doppler flow images are frequently used for the non-invasive diagnosis of PVLs. Transthoracic echocardiography (TTE) in various imaging planes obtained from the parasternal, apical, subxyphoid, and suprasternal windows helps to define the site of the leak (Figure 1A). However, the jet of prosthetic valvular and/or PVL may be overshadowed by the prosthetic valve, thus underestimating the degree of leak or obscuring it completely. On the other hand, transoesophageal echocardiography (TEE) provides higher resolution and sensitivity for the diagnosis. With the transducer in the oesophagus, behind the left atrium, the mitral paravalvular regurgitant jet is no longer obscured by the prosthetic mitral valve (Figure 1B).

The severity of the leak can be defined by the same criteria used to define the valvular regurgitation² severity. These include the area of the colour Doppler regurgitant jet in the proximal chamber (e.g. the mitral regurgitant jet in the left atrium), the narrowest diameter of the leak jet (vena contracta), the magnitude of the proximal isovelocity surface area, and the regurgitant volume and fraction obtained by spectral Doppler volumetric methods.
Three-dimensional (3D) real-time (RT) TEE is currently commercially available. It can address the shortcomings of 2D echocardiography and demonstrate the exact number, sites, sizes, and shape (round, linear, crescent, irregular) of the PVLs. With the use of the 3D zoom modality, the entire mitral prosthesis can be seen en face and the PVL orifices identified and analysed (Figure 1C). The full volume modality (which is not RT acquisition) allows the demonstration of Doppler colour flow through the leak site, as well as normal and abnormal flow patterns through the valve (Figure 1D). Because of the aortic valve plane, 3D RT TEE images of aortic valve prosthesis are not as effective as those of mitral prosthesis but can still provide valuable information when compared with 2D images.

It is recommended that the mitral prosthesis images be presented in the ‘surgical view’. By image rotation, and assuming a mitral ring in the shape of a clock, the aortic valve is brought to a position at the top of the mitral ring (i.e. at 12 o’clock) and thus allowing the atrial appendage to assume a position at approximately 9 o’clock (Figure 2). The location of the leak is described according to its location on this ‘clock’. In our experience, the majority of mitral PVLs occur between 3 and 9 o’clock (posterior more than anterior).

Figure 1  Echocardiographic evaluation of mitral ring dehiscence. (A) Parasternal long-axis view from a transthoracic echocardiogram (TTE) demonstrating mitral annuloplasty ring dehiscence. The posterior aspect of the ring is seen and appears to be possibly separated from the elevated native mitral annulus. (B) Two-dimensional transoesophageal echocardiographic image, obtained at 0°. The ring is clearly dehisced, appearing in the middle of the mitral annulus. (C) Real-time three-dimensional image obtained using the 3D zoom mode. The mitral ring is viewed en face, from the left atrial perspective. The dehisced segment is clearly seen, its shape, size, and location easily defined. (D) Image obtained using full volume, colour Doppler acquisition. Significant mitral regurgitation is seen originating from around the ring (‘para-ringular’) through the dehisced segment. LA, left atrium; LV, left ventricle; RV, right ventricle.

Figure 2  Surgical view of the mitral valve. A 3D zoom mode acquisition of a mitral annuloplasty ring. The image is rotated such that the aortic valve is positioned at 12 o’clock, making the left atrial appendage at 9 o’clock. This allows defining the position of a dehisced segment relative to this imaginary clock (in this case, shown at 7 o’clock).

Guidance and monitoring of percutaneous paravalvular leak closure procedure

The TEE probe is positioned at the beginning of the procedure and remains there throughout its course. Real-time 2D and 3D images are obtained at various stages. We found the 3D images especially useful for the imaging of the wires, catheter, and the closure devices.

Two-dimensional TEE provides high-resolution images with relatively high frame rate. However, since they move in three planes (Figure 3A), the entire length and
extent of the catheters, especially their tips, often cannot be accurately assessed. Although 3D imaging has a lower frame rate, the entire intracardiac portion of all the catheters can be visualized. This facilitates the assessment of the anatomical relation between the catheter tips, the target site, and the surrounding anatomical structures (Figure 3B). The operator can then visualize the advancement of the catheter tip toward the PVL orifice, avoiding the prosthetic valve orifice (Figure 4).

The size and shape of the leak orifice guides the selection of the closure device. The device itself can be visualized by RT 3D TEE, and when deployed, its exact location and shape can be appreciated (Figure 5). At this point, colour Doppler study is repeated with special attention to...
residual leak at the repaired site, along with other possible sites. The possibility of interference with prosthetic function is also assessed by colour Doppler (for new prosthetic regurgitation) and spectral Doppler which can assess any possible device-induced stenosis. Once these deployment parameters are considered successful, the device can be released and the catheters removed.

At the end of the procedure, TEE is used to assess segmental and global wall motion, the presence of residual valvular or PVL, and any possibility of intracardiac clot and pericardial effusion.

**Multiphase-gated CT angiography**

The ability to acquire ECG-gated CT angiography (CTA) combined with volume rendering (VR) reconstruction and new post-processing software allows obtaining 3D/4D images for a detailed evaluation and display of the cardiac anatomy and function. This is especially important when considering structural cardiac interventions, as the spatial-temporal relations may not be as evident from conventional 2D images. We currently recognize retrospective ECG-gated CTA with multiphase reconstruction as an essential tool in the evaluation of these complex defects. This imaging modality assists in determining the exact location of the PVLs, as well as the shape, trajectory, and size.

**Cardiac CT angiography acquisition protocol**

ECG-gated CTA is performed prior to the intervention in all patients who are scheduled for transcatheter PVL closure (except those with clinical contraindications). The acquisition protocol in these patients is similar to the standard protocol used for coronary artery evaluation; helical acquisition with retrospective ECG-gated reconstruction of multiple phases and similar timing, contrast volume, and ejection rate. The most significant difference regarding the coronary protocol is the number of reconstructed series: for cardiac interventions, we reconstruct at least 16 phases (maximum 20) which are equally spaced, and therefore in 6.25% RR-interval increments (or 5% increments if 20 phases are reconstructed).

This multiphase reconstruction allows four-dimensional (4D) reconstruction (time factor) and display, which helps simulate actual heart movements. Dynamic anatomic interrelations, which are critical in the evaluation process of percutaneous interventions, can therefore be evaluated.

**CT angiography post-processing**

We use the ‘Aquarius’ workstation by TeraRecon, Inc. (San Mateo, CA, USA) for CTA post-processing due to its excellent performance and VR capabilities (this allows VR reconstruction of sets of up to 10 000 DICOM images). After the 16–20 phases are reconstructed, they are cyclically displayed to simulate heart movements at approximately 60 bpm (the speed of display can be modified). Volume rendering presets are adjusted using contrast subtraction from the heart chambers to allow for an optimal visualization of the cardiac anatomy (including the leak) and the prosthetic valves (Figure 6). Once the volume of the heart is displayed in movement, it can still be rotated, sliced, and the presets modified to best analyse any structure in ‘real time’. Artefacts from dense structures (such as prosthetic valves or extensive calcification) may limit PVL size.
estimation; however, with increased experience, review of the images in motion will improve reliability.

Initial experience with four-dimensional CT angiography guidance for paravalvular leak intervention

Crossing the leak with the guidewire may be a challenge in some patients, especially those that are serpiginous. The advantage of 3D–4D when compared with 2D CTA is precise identification of the leak in relation to surrounding cardiac structures. This relation can be analysed from many point of views, since whole-volume information can be displayed in various angulations.

To facilitate the use of 4D-CTA guidance in the catheterization laboratory, an additional computer monitor was placed for the 4D set display, adjacent to the fluoroscopy screens. Initially, the CTA set was reconstructed using contrast subtraction from the chambers to locate the leak. Next, we required ‘marking’ (or precise identification) of the leak position in the three spatial axes. Since a specific tool for this purpose was unavailable, we used a surrogate tool that was originally designed to perform 3D measurements. With this tool, the leak was marked in colour and carefully adjusted from several positions and multiple views. This ensured that the ‘mark’ remained in place at the leak location despite rotating and angulating the heart volume. Then, once the leak had been adequately marked, the initial volume render preset was switched to a specifically designed preset that emulates the appearance of the fluoroscopy image, which we refer to as ‘fluoro-like’ (Figure 7). Finally, the juxtaposed display of the fluoroscopy image and the CTA image (in this fluoro-like view) allowed for simultaneous view in the same angulations. Hence, the position of the marker in the CT set can be extrapolated to the real life, fluoroscopic image that enables the operator to locate the leak at any view.

This image integration in our experience has significantly shortened the length of time to cross the PVLs with the
guidewires using the CTA data and to confirm the degree of occlusion and lack of interference with the prosthetic valve by the occlusion devices using the RT-3D TEE.

Transcatheter techniques

The transcatheter closure of a prosthetic PVL can be technically challenging. As they tend to be lengthy and performed with TEE, the majority are done under general endotracheal anaesthesia. A successful procedure mandates that the appropriate imaging studies be performed and analysed beforehand. A meticulous strategy is undertaken with a willingness to change approach in mid-course if the initial plan is proving to be unsuccessful. In all our patients, we perform pre-operative 4D CTA to precisely determine the size and location of the defect(s) to be treated (vide supra). It is not uncommon for the patient to have more than one defect. The 4D-CTA images are displayed in the catheterization laboratory and the location of the defect is then marked on the computer (Figure 7) allowing the operator to then ‘aim’ for the defect with an exploring guidewire. Real-time 3D TEE (RT-3D TEE) is also critical to help guide the procedure and to assess the results once a device has been deployed. The RT-3D TEE can determine whether or not the exploring guidewire is ‘through the defect’ or ‘through the valve’. In addition, with mechanical prostheses, it is common for the patient to have haemodynamic deterioration when the wire is through the valve. It is therefore imperative to haemodynamically monitor the patient very carefully. The approach chosen may be antegrade, retrograde, or trans-apical depending on the location of the leak and whether or not the patient has both an aortic and mitral mechanical prostheses. All procedures are performed with systemic anti-coagulation.

Aortic paravalvular leaks

Aortic PVLs are most commonly located posterior in the non-coronary cusp and then in the left coronary cusp. These defects can be easily crossed retrograde with an angled or straight hydrophilic guidewire, supported by an appropriate catheter that will direct the wire toward the defect. Once the defect is crossed, the support catheter is then advanced across the defect and a sturdy support wire with a soft tip (Lunderquist or Amplatzter) (AGA Medical, MN, USA) is advanced into the left ventricle. Careful precautions should be taken when advancing enough wire, to avoid excess wire that can lead to perforation. Once the sturdy wire is in place, an appropriate French size delivery sheath is introduced into the left ventricle to deliver the occlusion device. The distal end of the device is deployed below the aortic valve being cautious not to entangle any of the mitral apparatus. The device is then pulled back into the defect. If an Amplatzter ventricular septal defect (VSD) is being employed, the proximal end of the device is deployed just above the defect being exceedingly careful to avoid impingement on the left main orifice, if the defect is in the left coronary cusp.

On occasion, an aortic PVL will be impossible to cross retrograde. This may be crossed antegrade via transseptal access to the left ventricle. Once access to the left atrium is achieved, the left ventricle is entered via standard technique. We commonly use a balloon-tipped pulmonary artery monitoring catheter that will take a 0.35 inch guidewire. An exchange length 0.35 hydrophilic guidewire is then directed toward and across the PVL and into the descending aorta. The guidewire is then snared and exteriorized through the femoral artery sheath. A continuous rail is thus created from the right femoral vein, across the inter-atrial septum, into the left ventricle, and across the aortic PVL and finally exteriorized through the femoral arterial sheath. Care must be taken not to have a tight loop in the left ventricle, as this can cause severe mitral regurgitation by entrapping the anterior leaflet of the mitral valve. This may lacerate the mitral valve resulting in acutely severe or fatal mitral regurgitation. Having an exteriorized continuous rail outside the body allows for full control and advancement of the delivery sheath across the defect retrograde, with the defect then closed in the manner described above. The defect can also be closed antegrade with advancement of the delivery sheath across the inter-atrial septum, into the left ventricle, and ultimately across the PVL.

A trans-apical approach may be necessary in the presence of prosthetic mechanical mitral and aortic valve replacements, or when the aortic PVL cannot be crossed retrograde or antegrade. The location for the apical approach is guided by the 3D CTA with the puncture toward the apex and between the two papillary muscles, away from any major epicardial vessel. The puncture is performed with a Cook micro-puncture needle (Cook Medical Inc., Bloomington, IN, USA) under fluoroscopic guidance. The micro-puncture 0.018 inch guidewire is advanced into the left ventricle and a Cook micro-puncture 5 F catheter is inserted (Cook Medical Inc., Bloomington, IN, USA). The PVL can then be crossed with a hydrophilic guidewire with a short Berenstein catheter for direction and support. In case that the catheter will not follow the guidewire across the defect, the catheter shall be withdrawn and a glide catheter then advanced across the defect. An exchange length guidewire is at that time advanced into the descending aorta and exteriorized as described above. Following this, an appropriate sized delivery sheath can be deployed across the defect, followed by the delivery of the closure device, most typically an Amplatzter PDA or Amplatzter muscular VSD device (AGA Medical, MN, USA). The trans-apical approach is invariably performed in post-operative patients with surgery being remote. This makes pericardial tamponade less likely, but does not completely obviate this possibility. We have ‘closed’ the trans-apical puncture using several different techniques. We used balloon occlusion with the sheath withdrawn following by removal of the balloon when the activated clotting time has normalized. We have also reported the closure of the defect using coils and closure of the tract using Surgiflo (Ethicon360, USA). Most commonly, we have closed the trans-apical access site using a 6 mm Amplatzter PDA (AGA Medical, MN, USA) device (Figure 8).
Mitral paravalvular leaks

Mitral valve PVL repair is more complex than aortic PVL repair, as these leaks may be more difficult to reach and cross. Rarely, the retrograde approach with a guidewire and support catheter delivered across the aortic valve, and the wire then directed retrograde across the mitral paravalvular defect using a modification of the ‘Shirey technique’, can be used. The long glide-wire is then snared in the left atrium via transseptal...
Table 1  Published case reports on transcatheter paravalvular leak closure

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Age</th>
<th>Symptoms</th>
<th>Valve</th>
<th>Device</th>
<th>Deployment</th>
<th>Residual leak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moore et al.</td>
<td>2000</td>
<td>M</td>
<td>Haemolysis</td>
<td>Mitral</td>
<td>Gianturco coil</td>
<td>Successful</td>
<td>No</td>
</tr>
<tr>
<td>Eisenhauer et al.</td>
<td>2001</td>
<td>F</td>
<td>CHF</td>
<td>Mitral</td>
<td>Gianturco-Grifka vascular occlusion device</td>
<td>Successful</td>
<td>No</td>
</tr>
<tr>
<td>Moscucci et al.</td>
<td>2001</td>
<td>M</td>
<td>Haemolysis</td>
<td>Mitral</td>
<td>2 coils</td>
<td>Successful</td>
<td>Yes, Flipper coil placed successfully 3 months later</td>
</tr>
<tr>
<td>Kort et al.</td>
<td>2004</td>
<td>M</td>
<td>Haemolysis + CHF</td>
<td>Mitral</td>
<td>Amplatzter Duct Occluder</td>
<td>Successful</td>
<td>Yes. CHF resolved</td>
</tr>
<tr>
<td>Pate et al.</td>
<td>2004</td>
<td>M</td>
<td>CHF</td>
<td>Mitral</td>
<td>Amplatzter septal occluder</td>
<td>Successful</td>
<td>No. CHF resolved</td>
</tr>
<tr>
<td>Hijazi et al.</td>
<td>2004</td>
<td>M</td>
<td>Haemolysis + CHF</td>
<td>Mitral</td>
<td>Amplatzter muscular VSD + custom-made</td>
<td>Successful</td>
<td>Yes, from multiple other areas of suture rupture</td>
</tr>
<tr>
<td>Webb et al.</td>
<td>2005</td>
<td>M</td>
<td>CHF</td>
<td>Aortic</td>
<td>Flipper coils failed. Amplatzter Duct Occluder</td>
<td>Successful</td>
<td>No</td>
</tr>
<tr>
<td>Feldman et al.</td>
<td>2006</td>
<td>M</td>
<td>CHF</td>
<td>Aortic</td>
<td>Amplatzter Duct Occluder</td>
<td>Successful</td>
<td>No</td>
</tr>
<tr>
<td>Dussailant et al.</td>
<td>2006</td>
<td>M</td>
<td>CHF</td>
<td>Aortic</td>
<td>Amplatzter Duct Occluder</td>
<td>Successful</td>
<td>No. CHF resolved</td>
</tr>
<tr>
<td>Momplaisir et al.</td>
<td>2007</td>
<td>M</td>
<td>CHF</td>
<td>Aortic</td>
<td>Amplatzter septal occluder</td>
<td>1st device migrated. Larger device successful</td>
<td>Trivial</td>
</tr>
<tr>
<td>Hildick-Smith et al.</td>
<td>2007</td>
<td>M</td>
<td>CHF</td>
<td>Aortic</td>
<td>Amplatzter muscular VSD occluder</td>
<td>Successful</td>
<td>No</td>
</tr>
<tr>
<td>Sivakumar and Shahani</td>
<td>2007</td>
<td>M</td>
<td>Haemolysis</td>
<td>Mitral</td>
<td>Amplatzter septal occluder</td>
<td>Successful</td>
<td>No</td>
</tr>
<tr>
<td>Ussia et al.</td>
<td>2007</td>
<td>M</td>
<td>Haemolysis + CHF</td>
<td>Mitral</td>
<td>Amplatzter muscular VSD</td>
<td>Successful</td>
<td>Tiny. Dislodgement 2 months later</td>
</tr>
<tr>
<td>Bhindi et al.</td>
<td>2008</td>
<td>M</td>
<td>Haemolysis</td>
<td>Aortic</td>
<td>Amplatzter muscular VSD</td>
<td>Successful</td>
<td>Improvement in haemolysis and symptoms</td>
</tr>
<tr>
<td>Lasorda and Mohsin</td>
<td>2008</td>
<td>M</td>
<td>Haemolysis</td>
<td>Mitral</td>
<td>Amplatzter ductal occluder</td>
<td>Successful</td>
<td>Yes (1–2+)</td>
</tr>
<tr>
<td>Nikolic et al.</td>
<td>2009</td>
<td>M</td>
<td>CHF</td>
<td>Mitral</td>
<td>Amplatzter muscular VSD</td>
<td>Successful</td>
<td>Mild</td>
</tr>
</tbody>
</table>

* m, months; M, male; F, female; CHF, congestive heart failure; VSD, ventricular septal defect; ?, not described in the paper.
access and exteriorized through the right femoral vein as described above. This wire is then used as a rail to insert the delivery sheath across the defect in an antegrade fashion with the closure device deployed as described. The antegrade approach is utilized more commonly to cross mitral PVLs, with the above process reversed. The leak is crossed via transseptal access using a Mullins sheath (Medtronic Inc., Minneapolis, MN, USA), a glide-wire (Terumo Medical Corp., Somerset, NJ, USA), and a support catheter (typically a Berenstein catheter or JR 4). Once across the leak, the wire is passed into the descending aorta, snared, and then exteriorized (Figure 9). The leak can then be closed antegrade as described above.

It is not uncommon that the leak cannot be crossed in an antegrade fashion. When this occurs or when there are mitral and aortic prostheses, the leak is crossed via the trans-apical approach (Figure 10). Once the leak is crossed, the wire is snared in the left atrium and exteriorized through the Mullins sheath. The delivery sheath can then be delivered either antegrade via the transseptal approach or via the trans-apical approach. The former is preferable as this eliminates the need for a larger trans-apical delivery sheath. Sometimes, however, the antegrade approach is not possible due to the position of the defect and the trans-apical approach is required. The technique utilized is the same as described above, except that the PVL involves the mitral and not the aortic valve. The trans-apical access site is closed as described above.

**Clinical results**

The acute and long-term results of percutaneous closure of prosthetic PVLs remain unknown. Over the past several years, only a few small series of patients (less than 30 cases) and several case reports have been published (Table 1). Furthermore, due to the lack of specifically designed devices for this application, a great variety of devices have been used.

To the best our knowledge, Hourihan et al. \(^1\) were the first to report a series of four patients who underwent transcatheter aortic PVL closure with a Rashkind double-umbrella device (USCI angiographics, CR Bard, Billerica, MA, USA), paving the way to these new procedures. The report also included the results on four other patients with valvular leaks. Closure was finally not attempted in one of the patients with PVL because the defect was considered crescent-shaped and unsuitable for the device to close; this patient died during surgical repair. The other three patients received one device each. Closure was successful and complete in two patients; the first patient was in NYHA I class 32 months post-repair and the other underwent subsequent surgery for an associated PVL in mitral position resulting in death during the operation. The fourth patient had an aortic leak and an aorta-to-right ventricular fistula. Initial closure was left with a residual shunt and the patient developed oliguria and haemolysis over the first hours post-procedure. An X-ray demonstrated migration of the device to the pulmonary artery 12 h post-intervention with correction of the haemolysis. In the catheterization laboratory, the device was retrieved and replaced with a larger one, which also migrated intra-procedure to the pulmonary artery. After successful removal, a third device was successfully placed and the patient remained asymptomatic 21 months later.

This first experience already highlights some of the difficulties later confirmed in subsequent studies: anatomical characteristics of the defect may preclude closure, there may be residual shunt and a need for reoperation, and haemolysis may be (at least temporarily) aggravated because of the high-velocity jet crossing through the device.

Pate et al. \(^2\) attempted PVL closure in 10 patients (9 mitral and 1 aortic leaks). In two patients, the leak could not be crossed and in one the device could not be deployed because of interference with the prosthesis; in the other seven patients, the device was successfully deployed. Four new procedures were performed at follow-up, three of them due to residual shunt: a device could be successfully deployed in the patient with initial interference with the valve, but residual leak persisted; complete occlusion with a second device was obtained in two other cases; the last patient required urgent surgery because of dislodgement of the initial device during the second procedure. Overall, in five patients, the leak was completely occluded; in two
there was residual leak, in two no device was implanted because of failure to cross the defect, and one needed urgent surgery due to device dislodgement. Interestingly, both patients requiring transfusion prior to intervention remained transfusion-dependant, despite complete and partial occlusion of the leaks, respectively. There was one retroperitoneal haemorrhage reported. Devices used were Atrial Septal Occluder (ASO) and Patent Ductus Arteriosus (PDA) occluder (Amplatzer, AGA Medical, MN, USA) in the initial procedures and coils (Cook, Bloomington, IN, USA) in repeated procedures.

The series by Hein et al. included 21 patients (13 mitral and 8 aortic PVL) in which Amplatzer ASO, PDA, or muscular VSD occluders were used. Deployment was successful in 95% of the patients and there was one procedural failure due to inability to cross a mitral leak. Of note, five of the initial devices had to be replaced for smaller ones because of interference with the prosthetic valve (two cases), unstable position, or significant distortion. Three patients required a second procedure because of residual leak with haemolysis, with complete resolution or relevant reduction of the haemolysis achieved (two and one patients, respectively). Reported post-procedural complications included: endocarditis that led to death in one patient, valve surgery because of persistent severe haemolysis in two patients, and surgery because of device interference with the valve in one patient. At the end of the observation period (14 ± 12 months), significant shunt was reported in 45% of the patients and event-free survival (including freedom from death, re-operation, stroke, transcatheter re-intervention, and residual shunting) was 50%.

In 2007, Sorajja et al. reported their experience in the percutaneous treatment of 19 leaks in 16 patients using the Amplatzer ASO or PDA devices. Indications for closure were congestive heart failure in 15 patients and haemolysis requiring transfusion in 5 cases (some patients had both). As previous reports, these patients had been rejected from surgery because of excessive surgical risk (Parsonnet 39 ± 7). Successful deployment with mild or no residual shunt was finally achieved in 81% of 21 separate percutaneous attempts. In one case, the defect could not be crossed. Two patients had successful closure of a PVL but significant regurgitation persisted through additional leaks; in one patient, regurgitation recurred adjacent to the device and underwent a second successful procedure; finally, in one patient, only an undersized device could be deployed and moderate residual regurgitation persisted. The only significant periprocedural event was a haemothorax in a patient, in which a trans-apical approach was used. Nevertheless, four deaths were reported during follow-up (3.1 ± 2.6 months): a sudden death 4 weeks after the procedure, two due to progressive heart failure and one due to pneumonia.

Finally, the longest series to date is the one by Cortés et al., which includes 27 patients with mitral leaks. Despite they focus on the use of TEE to define the leak and to guide the procedure, they exhaustively report complications in the first month. In 10 patients, the procedure was abandoned because it seemed impossible to cross the defect. This was in two of the three patients with PVL in the lateral internal region of the ring and in three of the six patients with anterior or lateral external leaks. Nevertheless, 83% of posterior leaks were successfully closed. Adverse events included: ventricular arrhythmia requiring electric shock in one patient, transient asystole because of aortic prosthesis compromise by the guidewire in one case, five cases of bleeding with one case of worsening haemolysis requiring transfusion, two cerebrovascular accidents, and one case of mild pericardial effusion due to perforation (which resolved spontaneously over time). Transoesophageal echocardiography identified intra-auricular thrombi in two patients and residual septal defect post-transseptal puncture in one patient. There were no deaths in the first month post-procedure. At follow-up (1 month), regurgitation had improved in 8/17 successfully treated patients and clinical status in 59% of the device-implanted patients, compared with improvement of only 1 of the 10 non-device-implanted patients.

Our group recently reported (ESC 2009) our experience on 27 closure attempts (20 mitral and 7 aortic leaks) performed on 18 patients. All aortic leaks were approached retrograde from the aorta, 13 mitral leaks were approached antegrade through a transseptal puncture, and 7 exclusively retrograde (5 from the aorta and 2 through a trans-apical puncture). Success rate, defined as successful deployment without valve dysfunction and no major complications, was 100% on the aortic valve and 82% on the mitral valve. Five patients with initial success (three with mitral and two with aortic leaks) required six new procedures due to additional leaks, and success of these new procedures was 50%. Overall mitral success rate (including first and repeated procedures) was therefore 75% and overall aortic success rate was 86%. Procedural failures were due to inability to cross the leak with the wire or the guiding catheter in five patients and interference of the device with the opening of the valve in one patient. Complications included a successfully retrieved device that embolized during the procedure to the aorta, one case of no flow-limiting femoral dissection and a haemothorax after trans-apical puncture (before device closure of trans-apical access) that required drainage. In our more recent experience with over 50 consecutive patients including 14 procedures done by trans-apical approach, we have had one death due to cardiac tamponade and one emergency surgery for a patient in whom the guidewire became entrapped in a serpiginous aortic PVL with an inability to extract the wire during the percutaneous procedure.

**Summary**

It is clear that transcatheter PVL closure is a complex and technically demanding intervention. The complicated anatomy of the defect precludes successful crossing in some patients, and device interference with the valve prohibits device deployment in others. Furthermore, the lack of specifically designed devices to close these varied and complex defects, in part, explains the
somehow low rates of procedural success when compared with other percutaneous interventions. Nevertheless, the periprocedural rate of adverse events appears to be acceptable for such high-risk symptom limited patients. In the majority for whom redo surgery is of exceedingly high risk, symptoms, and outcomes can be improved by percutaneous close of the PVL. There may be a need for repeated procedures due to residual leak, new leak development, and late dislodgement of the device with leak recurrence as it has been previously reported.17,26,27

Transcatheter closure of PVL seems to be an attractive alternative for these patients, but in reality we still have a long way to go and further efforts will be required to improve outcomes.

Conflict of interest: C.E.R.: Consultant and educational grant recipient from Philips, Consultant and educational grant recipient from TeraseRecon, Proctor for AGA, Consultant and Equity—Medtronic-CoreValve. H.C.: Consultant and equity—CardiacAssist Inc., Educational Grant—Abbott Vascular, Consultant and speaker honoraria—Medtronic. I.K.: Honoraria, Philips, Research grant GE.

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