



Clinical update

Percutaneous paravalvular leak closure: chasing the chameleon

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Paravalvular leak (PVL) occurs after both surgical and transcatheter valve replacement/implantation. It can lead to haemolysis, heart failure and may increase the risk of endocarditis. Percutaneous closure has significantly less morbidity than re-operation and is therefore often the therapy of choice. Percutaneous PVL closure can make an important difference for patients and can improve patient prognosis. These procedures can be intricate and larger case series and research is needed to further develop and improve these procedures.

Keywords Paravalvular leak • Valvular heart disease • Percutaneous closure

A 56-year-old woman with previous aortic and mitral valve replacement and redo double valve replacement 20 years later, presented with a severe mitral paravalvular leak (PVL). Despite heart failure symptoms (NYHA III) and the need for repetitive blood transfusions due to haemolysis, she was treated medically for 5 years before undergoing transapical PVL closure.¹ Five years after the procedure, the patient remains in NYHA I without need for further blood transfusions.

This case illustrates the often dramatic effect treatment of PVL can have both for symptomatic relief and to improve prognosis. These procedures are probably underperformed, and may address unmet clinical needs for patients with valvular heart disease.

Paravalvular leaks: aetiology, indication, and outcome

Paravalvular leaks can occur after (i) surgical valve replacement, (ii) surgical valve repair, or (iii) after percutaneous valve implantation. It is important to differentiate between the three clinical settings, since aetiologies, time points of occurrence, treatments and prognoses differ. Paravalvular leaks can cause haemolysis and/or symptoms of heart failure and may increase the risk of endocarditis. The

indications for treatment of PVL include symptomatic patients with heart failure or haemolysis and possibly in some patients with endocarditis. There are conflicting data on whether mild-to-moderate paravalvular regurgitation affects prognosis and should be addressed in an asymptomatic patient, but evidence of ventricular decompensation (e.g. progressive LV enlargement or declining ejection fraction) associated with PVL should be approached in the same way as asymptomatic regurgitant lesions for native valvular disease (Table 1). Mild PVL after surgical valve replacement in standard risk patients has a benign course,^{2,3} which is also found for transcatheter valves in intermediate to high-risk patients undergoing transcatheter valve implantation (TVI).⁴ However, in high surgical risk patients with multiple co-morbidities, even mild PVL in randomized trials was associated with increased 2-year (and longer) mortality after treatment with transcatheter valves.^{5,6}

Precise quantification of PVL can be difficult (which is particularly true for PVL after percutaneous valve implantation). Multimodality imaging including echocardiographic, computed tomography and magnetic resonance imaging is helpful in such cases.

Success rates for PVL closure are variable in different reports. Aortic leaks are easier than mitral to treat and have higher success rates. Acute procedure success definitions are not standardized but can be categorized into *technical* (successful delivery of a PVL

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Table 1 Absolute and relative indications for paravalvular leak closure

	Absolute indications	Relative indications
Haemolysis d/t PVL	x	
Symptoms of heart failure d/t PVL	x	
Risk of endocarditis		x
Asymptomatic mild/moderate PVL		x
Mild/moderate PVL with declining LVEF	x	
Mild/moderate PVL with progressive LV enlargement	x	
Mild/moderate PVL after TAVI		x

d/t, due to.

closure device without interference with the valve prosthesis), *procedural* (technical success and ≥ 1 grade regurgitation reduction), and *clinical* success. Following device implantation residual PVL is usually simply classified as none, mild, moderate or severe. After device implantation PVL may decrease or resolve over a period ranging from hours to months, which complicates the assessment of procedural success. In a recent meta-analysis of 12 reports including 362 patients, technical and procedural success rates were 86.5% and 76.5%, respectively.⁷ Procedural success was associated with lower follow-up cardiac mortality (OR 0.08, 95% CrI 0.01–0.9), fewer surgical reinterventions (OR 0.08, 95% CrI 0.01–0.4) and improvement in congestive heart failure or haemolysis compared with failed interventions. For closure of aortic PVLs technical and procedural success rates were 86.9% and 84.1%, respectively. Two-thirds of treated PVLs were in the mitral position, with technical and procedural success rates of 82.3% and 73.3%. Twelve per cent of these mitral PVL closures were done with a transapical approach, with a success rate of 100%, compared with success rates of 78.4% with antegrade transseptal, and 66.4% with retrograde transaortic approaches. These differences in success rates, however, do not allow concluding one approach to be better than the other and access should be chosen individually in each patient.

There is a substantial learning curve for PVL closure procedures, with significantly decreased complication rates and improved acute success after the first 50 cases at a single center.⁸

The main procedural complications during PVL closure are device embolization, interference with prosthetic valve leaflets, air-/thrombo-embolism, or bleeding complications. Embolized devices can be snared and retrieved percutaneously in most cases. If interference with prosthetic leaflets occurs, the device must be retrieved, repositioned, or exchanged for another device. Interference with prosthetic valve leaflets can occur after the device is unscrewed from the delivery cable and is no longer retrievable. In this situation, the device needs to be pushed or pulled either with the use of a snare or a biptome. For transseptal procedures, pericardial effusion is a potential complication. If a transapical procedure is chosen, haemothorax can be seen and may require drainage, but rarely requires open surgical intervention.⁹ In case of aortic PVL closure, coronary ostial obstruction can theoretically occur and may be

difficult to treat by percutaneous approaches, but the occurrence is anecdotal. Another rare complication is type A dissection caused by sheath manipulation in the aortic arch, not specific to PVL closure procedures.

Long-term outcome data after percutaneous PVL closure are scarce. A study on 126 patients¹⁰ showed a 3-year cardiac mortality of 9.5%. While the degree of residual paravalvular regurgitation predicted symptom-status (e.g. patients with residual moderate PVL did not show symptomatic benefit), it was not a predictor of survival. On the other hand, persistence of haemolytic anaemia was associated with worse survival. A smaller series reported similar outcomes¹¹ with a cardiac mortality of 8% after 18 months and symptomatic benefit in >70% of treated patients.

It is important to recognize that the prognosis, as reported in available studies, reflects the high-risk nature of the treated patients in the early experience. In one study, the 3-year survival was reported to be 65%¹⁰ and 12-year survival was 35%¹² in a larger series of patients.

A word of caution is needed when interpreting data on PVL closure, since they are descriptive, retrospective, and comprise rather limited numbers of patients. Many reports characterize acute procedure success, defined as successful device implantation, without showing clinical success, or longer-term mortality.¹³

Given the intricacy of the procedures in often high-risk populations, and the possibility for conventional re-operation in many patients, an interdisciplinary heart-team approach is advisable.

Devices for percutaneous paravalvular leak closure

Requirements for an ideal PVL closure device are (i) the ability to conform to the often serpiginous course of the defects, (ii) retrievability and repositionability, (iii) deliverability through small bore sheaths/catheters, (iv) low risk of embolization, (v) complete closure after implantation, and (vi) the ability to implant several devices next to each other (*Figure 1*). The devices currently used all are retrievable and repositionable consisting of a woven (more or less dense) nitinol mesh, with some filled with polyester (*Table 2*).

Only very few purpose-specific devices exist. In the USA, there are no devices approved for the indication of PVL closure. The Amplatzer Vascular Plug III (AVP III; St Jude Medical, St Paul, MN, USA)⁹ and the Occlutech PVL device (PLD; Occlutech, Jena, Germany)¹⁴ are specifically designed for PVL closure. The AVP III (*Figure 1*) is a nitinol-based device with an elliptical lobe that adapts to the often crescent-shaped defects. The lobe is covered by two discs on each side protruding from the lobe by only 2 mm, in order to reduce the risk of interference with mechanical valve leaflets. The lobe comes in nine sizes ranging from 4 × 2 to 14 × 5 mm and fits through a 4French to 7French sheath. The PLD comes either in a square or rectangular shape, while one disc is slightly larger than the other. The lobe of the square device is round (ranging from 4 to 7 mm) or consists only of a 'connector' between the two discs. The lobe of the rectangular device is elliptical (different sizes from 4 × 2 to 18 × 10 mm) or again only consists of a connector. The PLD requires a 6French to 10French sheath.

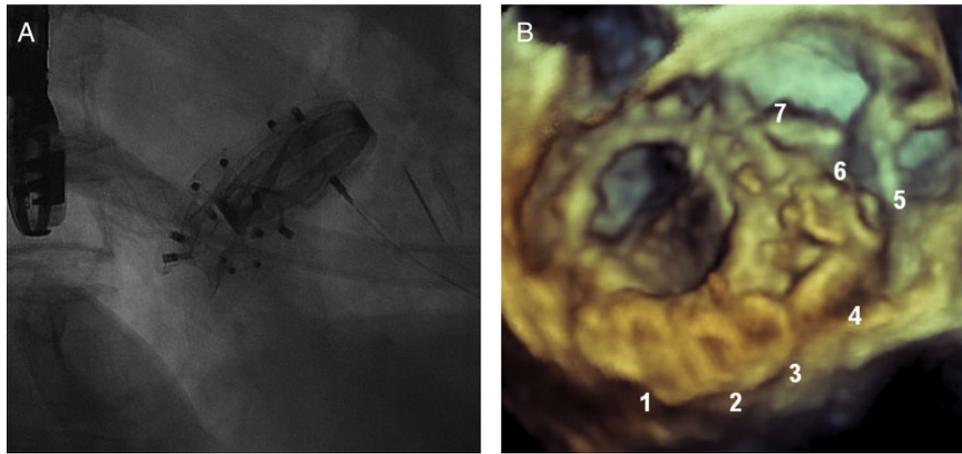


Figure 1 (A) Deployment of several Amplatzer Vascular Plug III devices in a large mitral paravalvular leak (fluoroscopic image). (B) Deployment of several Amplatzer Vascular Plug III devices (numbered 1–7) in a large mitral paravalvular leak (3D transoesophageal echocardiographic image).

Table 2 Devices frequently used for paravalvular leak closure

Device	Range of lobe size (mm)	Disc extends lobe by (mm)	Required sheath size (F)	Special considerations
Amplatzer Duct Occluder	5–12	4–6	5–7	Device length 5–8 mm
Amplatzer Duct Occluder II	3–6	6	4–5	Double disc device in 4 or 6 mm length
Occlutech PDA Occluder	3.5–14	5.5–10	6–8	Lobe is conical with the proximal end 1.5–4 mm larger
Amplatzer Musc. VSD Occluder	4–18	5–8	5–9	Waist length 7 mm
Amplatzer Septal Occluder	4–38	12–16	6–12	Left atrial disc is larger than right atrial disc
Figulla Flex II ASD Occluder	4–40	10–14	7–12	Left atrial disc is larger than right atrial disc
Amplatzer Vascular Plug II	3–22	0	4–7	Workhorse for large defects
Amplatzer Vascular Plug III	4 × 2–14 × 5	2	4–7	Little risk of interference with mechanical valve leaflets
Amplatzer Vascular Plug 4	4–8	N/A	4F diagnostic catheter	Suited for small PVLs (e.g. after TAVI)
PLD SQUARE W	4–7	9–10	6–7	Distal disc is 1–2 mm larger than proximal disc
PLD SQUARE T	N/A	11.5–17	6–7	No lobe, only a connecting twist. Distal disc is 1–1.5 mm larger than proximal disc
PLD RECTANGULAR W	4 × 2–18 × 10	9.5–18.5	6–10	Distal disc is 1.5–2 mm larger than proximal disc
PLD RECTANGULAR T	N/A	13–21 mm	6–9	No lobe, only a connecting twist. Distal disc is 1.5–2 mm larger than proximal disc

All Amplatzer devices are from St Jude Medical (St Paul, MN, USA), all other devices from Occlutech (Helsingborg, Sweden).

PDA, patent ductus arteriosus; Musc. VSD, muscular ventricular septal defect; ASD, atrial septal defect; PLD, paravalvular leak device; W, waist; T, twist.

A variety of different Amplatzer or ‘Amplatzer-type’ devices are used, such as VSD occluders, Vascular Plug II and 4, duct occluders. These devices may have advantages in certain situations: e.g. the smaller AVP 4 can be deployed through a 4French diagnostic

catheter and can be the device of choice if accessing the leak with a larger sheath would present a problem; the Vascular Plug family is made of a very thin and densely woven nitinol mesh, allowing conforming to a variety of shapes. The VSD occluder comes in sizes up

to 18 mm and allows closure of large defects, however, the disc protrudes the waist by 4 mm on each side, thereby increasing the risk of interference with mechanical leaflets.

Device choice depends on the shape of the defect, the type of prosthetic valve (mechanical or biological), the access and whether it is planned to use a single or multiple devices.

For a small crescent shape leak, a purpose-specific device is used most of the times. On the other hand, a large crescent shape leak can either be treated with one large device (e.g. a VSD occluder), or multiple purpose-specific devices (Figure 1). In case of a round PVL (e.g. after mitral valve repair, see below), a VSD occluder would be the device of choice (Figure 2). If the leak is long tunnel shaped with a large central cavity, the AVP II may be a good choice.

If multiple devices are deployed sequentially, an additional wire (anchor wire or safety wire) can be left next to the deployed device (e.g. a 0.018" V18-wire (Boston Scientific), or a 0.035" glide wire or an extrasupport coronary guidewire, depending on the size of the defect) in order not to be obliged to rewire the defect several times. This requires that the delivery sheath is upsized by at least one French size.

Another important technical challenge is the selection of a delivery catheter to be used in conjunction with a specific closure device in an individual patient. The delivery catheter must be able to cross the leak, and be of sufficient length and calibre to accommodate the chosen closure device. Equipment compatibility tables have been published.¹⁵

Different aetiologies and anatomical factors dictate the use of different treatment strategies and approaches.

Paravalvular leaks after surgical valve replacement

Suture dehiscence is the most frequent mechanism of PVL after initial successful surgical valve replacement and may occur years after the index surgery. It can occur due to patient factors (severe

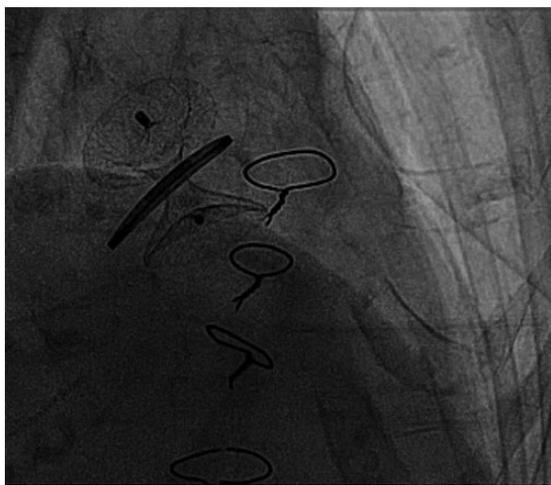


Figure 2 Closure of a paravalvular leak after surgical valve repair with one large VSD occluder.

calcification, fragile tissue), endocarditis, or suboptimal suturing during surgery. The risk of PVL increases with the use of a mechanical heart valves, when compared with bioprosthetic valves.¹⁶ The incidence of relevant PVL after valve surgery is reported to be ~1% in aortic and 2.2% in mitral cases.¹⁷ After 11 years of follow-up, the incidence of aortic PVL was increased to 4% (mechanical valve) and 2% (bioprosthetic valve), whereas mitral PVL increased to 17% (mechanical valve) and 9% (bioprosthetic valve).¹⁶ While aortic PVL are typically less complex to close, percutaneous closure of mitral PVL's can be technically intricate.

Although much less frequent, pulmonary¹⁸ and tricuspid¹⁹ PVL can also be closed percutaneously using analogous techniques.

Re-operation is usually not the treatment of choice, as it has a higher in-hospital mortality when compared with percutaneous PVL closure (9.3% vs. 0%, OR 8.95, CI 1.8–13; $P = 0.05$). Perioperative complications are less frequently observed in percutaneously treated patients (infection, stroke, and myocardial infarction; 6.5% vs. 0%).¹²

For procedural orientation, aortic leaks should be described according to the proximity of the respective cusp (right, left, and non-coronary cusp), whereas the mitral leaks are typically described on a clock-scale from 1 to 12 o'clock, with 12 o'clock facing anterior (to the aortic valve) and 3 o'clock facing towards the atrial septum, as seen on a typical 3D TEE left atrial 'surgeons view'. An alternative to the clock-face approach is the simple 'anatomic approach', which is less dependent on cardiac rotation: with this method a mitral leak is described to be (i) anterior or posterior and (ii) medial or lateral, or (iii) a combination thereof (e.g. posteromedial). Anatomical structures are taken as a reference: the aortic valve is anterior of the mitral valve, the left atrial appendage is anterolateral and the atrial septum is medial.²⁰

Approach to aortic paravalvular leaks

Aortic PVL's can be closed via retrograde femoral access and in local anaesthesia in most cases. The leak is typically crossed with a diagnostic Amplatzer left 1 (AL1), right Judkins (JR4), or Multipurpose (MP) catheter and the use of a 0.035" hydrophilic wire. Once the defect is wired, it is critical to ensure a paravalvular position of the wire. This can be done by moving the X-ray in an angle that the wire can be identified as outside of the prosthetic valve either 'en face' or parallel to the valve (Figure 3). In case the prosthetic valve is mechanical, tactile feedback and the motion pattern of the wire will tell the operator whether the wire is positioned para- or transvalvular.

Once correct wire position is confirmed, the diagnostic catheter is advanced over the hydrophilic wire into the left ventricle. This wire and the catheter are then replaced by a support wire [e.g. Backup Meier (Boston Scientific, Marlborough, MA, USA), Amplatz Superstiff (Boston Scientific) or Amplatz Extrastiff (Cook Medical, Bloomington, IN, USA)] unless a device is chosen that can be advanced directly through the diagnostic catheter (in which case no support wire is needed).

Over the stiff wire an appropriately sized catheter or sheath is advanced through which the occluder can then be deployed. In case of a mechanical bioprosthesis, proper opening and closing of the valve leaflets is checked on fluoroscopy (in a perfectly perpendicular view to the valve leaflets; Figure 4) and/or TEE. Then the device is

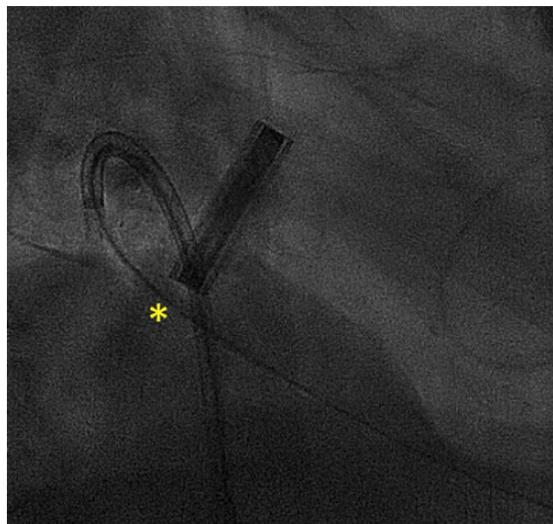


Figure 3 The Agilis sheath in the left atrium allows wiring difficult paravalvular leaks. A perfectly perpendicular view separating the wire (*) and the valve prosthesis is important to identify a correct paravalvular course of the wire.

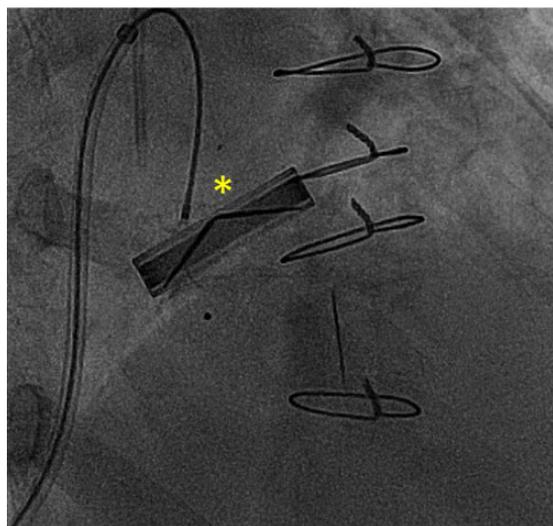


Figure 4 A perfectly perpendicular view to the valve leaflets allows for evaluation of valve function during PVL closure.

released. The result can be assessed by an aortogram, TEE and/or a bedside transthoracic echocardiogram. The aortic regurgitation index (ARI) can help to assess the haemodynamic changes after PVL closure. The ARI calculates as $[(BPd - LVEDP)/BPs] \times 100$. The lower the ARI, the more severe the aortic regurgitation. An ARI of <25 has been shown to go along with worse prognosis.²¹ The value of the ARI is questionable, since it is influenced by other parameters unrelated to the severity of regurgitation (e.g. arterial resistance and arterial stiffness).²²

Given location of these devices in the aortic sinuses, confirmation of patency of coronary arteries is recommended (i.e. aortography or echocardiography). If needed, further devices are deployed in the same manner.

Approach to mitral paravalvular leaks

Access can be antegrade (transvenous, transseptal), transapical, or (rarely) retrograde from the femoral artery. These procedures are most often done under general anaesthesia and with guidance by transoesophageal echocardiography (TEE). Both, two- and three-dimensional TEE are helpful for intra-procedural imaging.

Although technically more complex, we prefer the antegrade approach as default, due to its least invasiveness with fast postprocedural recovery of patients. Typically, a low transseptal puncture is beneficial, while a steerable sheath together with a catheter (e.g. an MP catheter) facilitates wiring the defect, even if the defect is medial (close to the septum) (Figure 3). 3D TEE further helps guiding the wire through the defect and can confirm correct wire position. The small diagnostic catheter is then advanced over the wire in the left ventricle and replaced by a support wire. The steerable sheath is replaced by a delivery sheath or catheter. Advancing a delivery sheath or catheter through the defect can be difficult, particularly in medial defects. Some operators prefer to establish a V-A-wire loop by snaring the wire in the aorta and externalizing it through the femoral artery. While it is not the most frugal approach, it will eventually allow passing the sheath through shallow angles and calcified lesions. It is also possible to puncture the LV apex and snare and externalize the wire to create a supportive, coaxial rail, but this method is demanding and adds some risk.²³

The chosen device is then implanted by retracting the sheath. In any case, it is worthwhile to keep a small diameter 'buddy' or 'safety' wire in the left ventricle next to the device, in order not to be obliged to rewire the defect several times, in case further devices are needed.

Another option is the use of a transapical access coming along with two potential advantages⁹: the access allows (i) easy steering of the wire at every location on the mitral annulus and (ii) wiring the defect occurs in the direction of the regurgitant jet.

Transapical access can be done either by a surgical cut-down to the apex or by a direct transcutaneous puncture of the apex. In the latter case, caution needs to be exercised not to puncture the left anterior descending artery. In case of doubt, it is recommended to do a selective coronary injection.

Once the apex is punctured, a sheath (e.g. 4French) is inserted and a steerable catheter (e.g. MP or Judkins right) is advanced. Probing the defect with a hydrophilic wire is done under TEE-guidance. Over the wired defect, a proper-sized sheath for the device chosen is advanced and the device deployed.

Closure of the apical access site is surgical in case a surgical cut-down was performed. If a transcutaneous puncture was conducted, there are two options: (i) the sheath can be pulled and the apex observed on echocardiography for a while to ensure proper 'self-compression' of the myocardium⁹ or (ii) an Amplatzer occluder can be delivered over the sheath to the apical puncture site (e.g. a VSD occluder or a PDA occluder; Figure 5).^{1,24} The latter method is probably overall safer, even with smaller sheaths (e.g. 6F and smaller).

Paravalvular leaks after surgical valve repair

A 78-year-old patient in heart failure classes III–IV was referred due to recurrent severe mitral regurgitation. Fourteen years ago she had undergone mitral valve repair with quadrangular resection of the posterior leaflet and implantation of an annuloplasty ring. The reason for her recurrent severe mitral regurgitation was found to be a PVL.

In case a quadrangular leaflet resection was performed (typically in conjunction with implantation of an annuloplasty ring), the excision extends all the way to the annulus. Then the two parts of the respective leaflet are sutured and the annulus needs to be plicated. If the suture holding the annulus becomes dehiscent, a true PVL can occur. Although this is a rare clinical picture, it is important to differentiate it from other forms of recurrent mitral regurgitation after previous mitral valve repair (e.g. a dehiscent annuloplasty ring). Therapies of the different entities vary fundamentally: e.g. PVL closure in case of a truly PVL, MitraClip in case of a dehiscent

annuloplasty ring with recurrent central MR, a valve-in-ring procedure for recurrent valvular mitral regurgitation.

Paravalvular leak closure in this setting is best done antegrade as described above and a generously oversized occluder can be implanted (e.g. VSD occluder), since there is no risk of interfering with a prosthetic leaflet (Figures 2 and 6).

Paravalvular leaks after percutaneous valve implantation

Paravalvular leaks are significantly more frequent after percutaneous TVI than after surgical valve replacement. With the use of balloon-expandable valves (as opposed to self-expanding valves), even mild PVLs may have a negative effect on survival in high-risk patients.^{4–6}

When compared with earlier generation valves, PVLs are dramatically reduced with current percutaneous heart valves: moderate

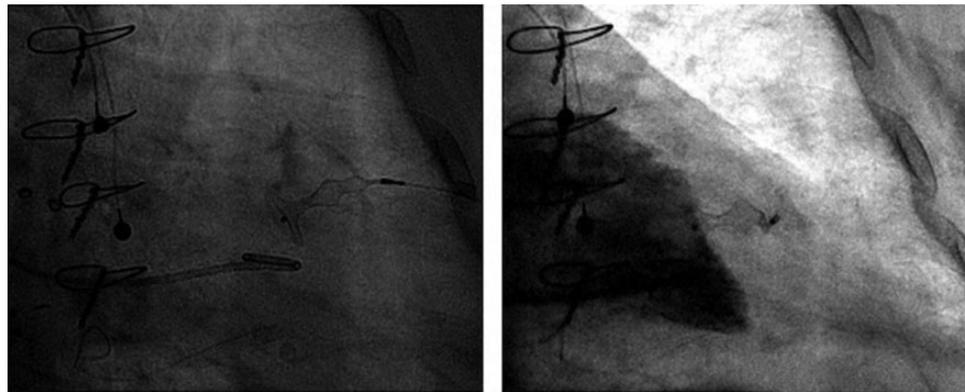


Figure 5 Percutaneous closure of the apical access site using a VSD occluder. Left: VSD occluder is still attached to the delivery cable. Right: occluder has been released from the delivery cable. A contrast injection to the left ventricle confirms haemostasis.

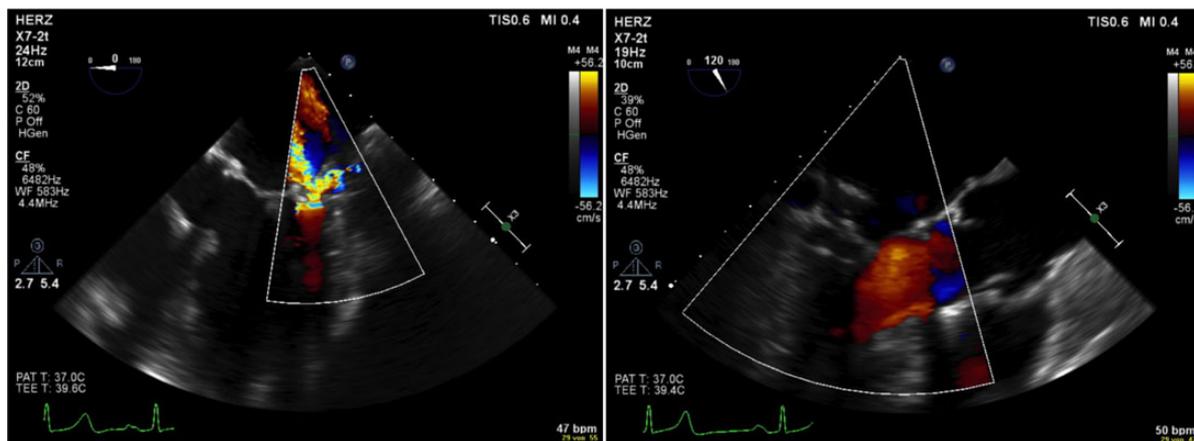


Figure 6 A true paravalvular leak after quadrangular mitral leaflet resection is diagnosed on TEE (left; consider the vena contracta of the regurgitant jet at the level of the annulus) and closed with one single device resulting in disappearance of the regurgitation (right).

and severe PVLs occur in ~3–4%, and even fewer with next-generation transcatheter aortic valve implantation (TAVI) devices.

Quantification of PVL after TAVI can be difficult, since several regurgitant jets often co-exist. Echocardiography is most frequently used for semi-quantitative assessment. Doppler assessment of the descending aorta may be one of the best indices of AR severity in this setting. Holodiastolic flow reversal in the descending Ao identifies more than mild AR with a sensitivity of 86% and rules out significant AR with specificity 92%.²⁵ Alternatively, precise measurement of regurgitant volume by magnetic resonance imaging offers an excellent imaging tool in this setting, while haemodynamic or angiographic assessments have limitations and are only used intraprocedurally.

Due to the variability of echocardiography assessments, PVL can either truly or appear to improve (or disappear), remain unchanged, or worsen over time.^{26–28} Commonly, there is a reduction in PVL acutely in the initial several minutes or hours after the index TAVI. Much less common is the appearance of delayed worsening of PVL after TAVI resulting in symptoms and requiring closure. Several mechanisms for PVL after TVI exist. Percutaneous PVL closure is needed only when PVL is associated with recurrent or persistent heart failure, progressive LV chamber enlargement, or haemolysis.

In case of PVL due to a too low implantation of the valve, a valve-in-valve procedure will resolve the leak (by extending the sealing skirt). In case of mal-apposition of the valve to the annulus, a post-dilatation of the valve can improve the leak (at the potential price of a slightly higher stroke rate, as suggested by Hahn *et al.*).^{29,30} Percutaneous PVL closure can be considered if the leak is due to a large calcification pushing against the valve frame. In this situation, aggressive post-dilatation may carry the risk of annular rupture, and PVL closure can be carried out. In a large single centre study, the need for percutaneous PVL closure after TVI with a balloon-expandable valve emerged in 1.5% of cases.³¹

Typically, Vascular Plug 4-devices (AVP 4) or coils are used for this purpose.^{32–34} The AVP 4 can be delivered through a diagnostic catheter using a retrograde transfemoral access (e.g. an 8 mm Amplatzer Vascular Plug 4 passes through a 4French diagnostic catheter). In the previously mentioned study,³¹ aortic PVL closure after TAVI was associated with a lower success rate (60% success) when compared with PVL closure after aortic SAVR (100% success). One reason for the lower success rate seems to be the difficulty to advance the delivery sheath through the defect in TAVI cases, due to the sandwiched residual native valve leaflets and the necessity to cross the bioprosthetic valve stent. The authors further identified the amount of calcification to be a significant predictor of success. Success rates are higher in some smaller series.³²

Conclusions

Paravalvular leak remains an infrequent but clinically very important problem after both surgical and transcatheter valve replacement. Percutaneous closure has significantly less morbidity than re-operation and represents the first line of treatment for most patients with PVL and clinical indications for closure. Dedicated devices and larger case series are needed to further develop and improve these procedures. With a reasonable success rate and a low rate of complications, PVL closure can make an important difference

for patients and can improve patient prognosis. Such procedures are intricate and an experienced team is advised.

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