



## Přehledový článek | Review

## Management of paravalvular leaks

Marian Branny, Jaroslav Januška, Libor Škňouřil, Bronislav Holek,  
Miroslav Dorda, Libor Gajdůšek

Oddělení kardiologie, Kardiocentrum, Nemocnice Podlesí, a. s., Třinec, Česká republika

## INFORMACE O ČLÁNKU

## Historie článku:

Došel do redakce: 2. 5. 2012

Přepřeván: 26. 5. 2012

Přijat: 28. 5. 2012

Publikován online: 2. 6. 2012

## Keywords:

Artificial valve

Paravalvular leak

Percutaneous closure

## Klíčová slova:

Paravalvulární leak

Perkutánní uzávěr

Umělá chlopeč

## ABSTRACT

Paravalvular leaks (PVL) occur in 5–17% of patients who underwent aortic or mitral valve implantation. The patients who have a paravalvular leak mostly present with heart failure, hemolytic anaemia, or both. The gold standard for treatment of severe symptomatic paravalvular leaks is reoperation, which is, nevertheless, associated with increased morbidity and is not always successful. Because of frequent patient morbidity and increased risk of reoperation, there is a trend to favor the less invasive approach of initial percutaneous closure without another sternotomy. The percutaneous approach requires implantation of specially dedicated occlusive devices and a choice of three different access sites: antegrade approach through femoral vein with transseptal puncture, retrograde approach through femoral artery and transapical approach. PVL closure is a complex and technically demanding intervention with a success rate between 40–90% and an acceptable rate of adverse events. In a group of patients with a high risk of redo surgery the percutaneous closure of PVL can lead to improving symptoms and outcomes.

## SOUHRN

Paravalvulární leaky (PVL) se vyskytují u 5–17 % pacientů, kteří podstupují náhradu aortální anebo mitrální chlopně. Nemocní s paravalvulárním leakem nejčastěji mají projevy srdečního selhání, hemolytické anemie anebo kombinace obou. Zlatým standardem léčby hemodynamicky závažných, symptomatických paravalvulárních leaků je reoperace, která je však spojena s vyšším rizikem komplikací a není vždy úspěšná. Časté komplikace a vyšší riziko reoperací vedly k novému trendu preference méně invazivních postupů, perkutánních uzávěrů leaků jako metody první volby. Perkutánní přístup zahrnuje implantaci speciálně určených okluzivních systémů do místa leaku, a to třemi různými přístupy: antegrádním, cestou femorální žíly spolu s transseptální punkcí, retrográdním cestou femorální tepny a transapikálním. Uzávěr PVL je komplexním a technicky náročným výkonem s očekávanou mírou úspěšnosti 40–90 % a akceptabilní mírou nežádoucích příhod. Ve skupině pacientů s vysokým rizikem opakovaného chirurgického výkonu perkutánní uzávěr PVL může vést ke zlepšení symptomů a dlouhodobých výsledků.

© 2012, ČKS. Published by Elsevier Urban and Partner Sp. z o.o. All rights reserved.

## Introduction

Paravular leaks (PVL) are the most common significant complication after the surgical valve replacement despite their well-established and safe methodology. PVL are mostly related to tissue friability, calcification, infection,

but also surgical techniques. The overall incidence of PVL is 5–17%, they are more frequent in mechanical valves compared to bioprosthetic valves. PVL is also more common in mitral valves than aortic valves. The high overall incidence is based on the transesophageal echocardiography (TEE) data and also includes small, non-significant

jets. The presence of clinically relevant PVLs that need to be repaired is 1–5% among the patients with artificial valves [1–5].

## Symptoms and clinical findings

The patients with significant PVL mostly suffer from symptoms of heart failure or hemolytic anaemia [or both]. When the patient develops a worsening of shortness of breath, legs swelling or he/she requires multiple transfusions, there is common recommendation for the closure of the leak.

## Laboratory tests and echocardiography

Patients without hemolysis do not have any specific abnormalities in laboratory tests. In contrast, patients with hemolysis, especially with asymptomatic hemolysis, have reduced hemoglobin levels, elevated lactate dehydrogenase activity (LDH), changed reticulocyte counts and bilirubin levels, as well as reduced haptoglobin concentrations.

The diagnosis is based on echocardiography findings. The transthoracic echo (TTE) is often difficult to assess because the pictures are obscured by calcium and sewing ring of the artificial valves. The overshadowing of the PVL by mechanical valves can lead to completely overlooking or underestimating the PVL. The gold standard is a transesophageal echocardiography (TEE), which offers us a higher resolution and sensitivity for the diagnosis. When we insert the TEE probe to the oesophagus, behind the left atrium, the position of the probe allows us to get a better picture and the paravalvular jet is no longer obscured by the prosthetic valve. The severity of the leak is defined by the same criteria as are used for the quantification of valvular regurgitation [6]. There are also well-known and accepted indirect criteria which suggest the significance of aortic PVL, such as reverse diastolic flow in descending aorta, short pressure half time (PHT), increasing peak of transvalvular gradient, lack of left ventricular end-diastolic diameter (LVEDD) reduction after surgical aortic valve replacement (SAVR). Similar indirect criteria of significant mitral PVL are as follows: mean gradient > 5 mmHg, the prosthetic velocity time integral (VTI) to left ventricular outflow tract (LVOT) – VTI ratio > 2.5, tricuspid regurgitation velocity > 3 m/s. Major progress in TEE in terms of PVL imaging has been 3-dimensional reconstruction. The three-dimensional (3D) real-time TEE can better recognize PVLs morphology (numbers, sizes, shape) and the relation to the other heart structures. 3D TEE can also help during the transcatheter PVLs closure as guidance and monitoring of the procedure.

## Treatment

### Open heart surgery

Surgical repair has been the standard treatment of the PVLs, but it is usually associated with significant morbidity and mortality. Moreover, surgery may not be successful

since the original anatomical problems persist. Because of these issues, there is a strong interest in minimally invasive percutaneous techniques that may allow successful treatment of paravalvular regurgitation without another sternotomy [7–12]. Because of frequent patient morbidity and increased risk of reoperation, there is a trend to favor the less invasive approach of initial percutaneous closure. Surgical repair is reserved for patients in whom percutaneous repair cannot be performed or is contraindicated (e.g., active endocarditis, significant dehiscence involving more than one fourth of the valve ring). Surgical treatment is also the first choice when PVL is connected with dysfunction or instability of the prosthetic valve, need for by-pass surgery (coronary artery by-pass graft – CABG) and infectious endocarditis.

### Catheter based treatment

The percutaneous approach requires implantation of specially dedicated occlusive devices and choice of the access site. There are three options: first femoral vein and transseptal puncture mostly for treatment of mitral PVL, second femoral artery for retrograde approach for closure of aortic and also mitral PVLs. Finally, there is the transapical approach which requires minor thoracotomy or direct puncturing of left ventricle for treatment of mitral PVL. Despite the different access site the main

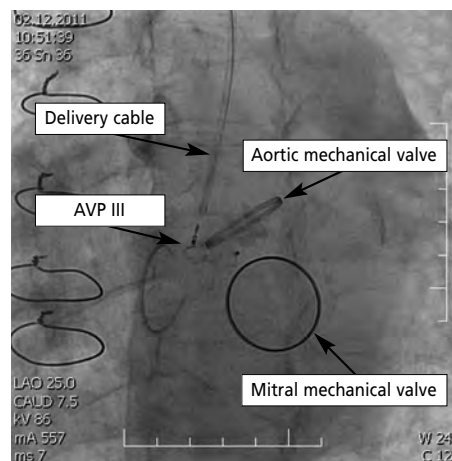


Fig. 1 – The Vascular plug III with delivery cable in process of closure aortic PVL.

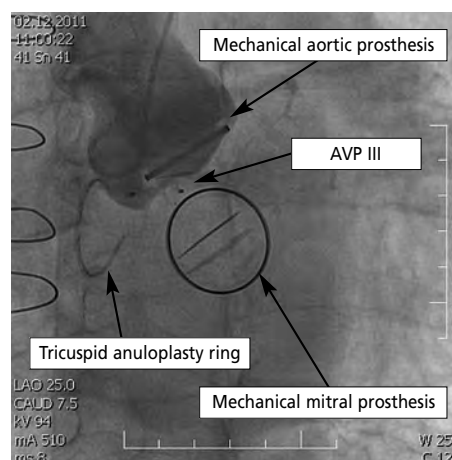
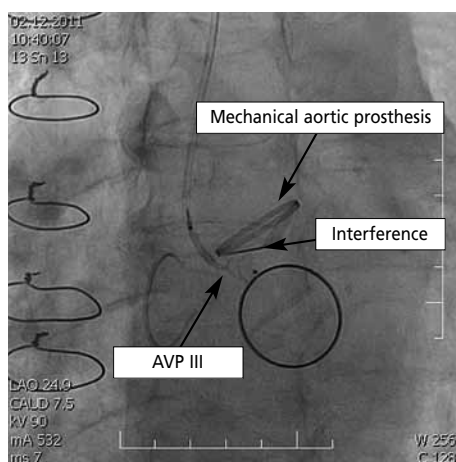


Fig. 2 – The Vascular plug III after releasing from delivery cable with a close relation to the aortic valve disc without any consequences to the function of the prosthesis. Successful PVL closure.



**Fig. 3 –**  
The Vascular  
plug III is in  
contact with disc  
of mechanical  
aortic prosthesis.  
This position  
of the Vascular  
plug is incorrect  
and needs  
to be changed.

principles of the percutaneous closure of PVL have been the same. At the beginning of the procedure it is essential to move closer to PVL canal with well fitting catheter, then pass through the canal with the guidewire and place the guidewire to the appropriate heart chamber. The next step is crucial – the guiding catheter should pass the canal and then the dedicated occluder is deployed. The selection of the occluder device is based on the shape of PVL canal. In crescent-shaped PVL elipsoid AVP III could be the appropriate option (Fig. 1, 2). On the other hand, round-shaped PVL can be closed by persistent ductus arteriosus (PDA) or ventricular septal defect (VSD)-dedicated occluders. A very important issue is to choose the proper size of the device. This is determined by the PVL canal diameters as well as by the distance to the artificial valve. Especially in case of mechanical prosthetic valves there is a risk of interference between the occluder device and the discs of the prosthesis (Fig. 3). There are several technical issues which could made the procedure demanding. The first issue is the localization and morphology of PVL track which made serious difficulties to engage and cross it by the guidewire. The next problem is to pass the guidewire through the narrow, winding PVL canal between the calcified annulus and the sewing ring. It is helpful to use telescopic coaxial system coexisting with Judkins right 4 or Amplatz left 2 7Fr guiding catheter and multipurpose 5Fr 125 cm long catheter and exchange-length, extrasupport, angled, hydrophilic 0.035-inch wire. In most cases, these systems allow catheters to cross PVL canal without excessive force.

The transapical approach can be an alternative in mitral PVL cases. It could be done as a first method of choice or as a second procedure in terms of a failed attempt using the percutaneous transfemoral route. Transapical

procedure should be performed in the hybrid operation room. The procedure is performed under general anesthesia by lateral minithoracotomy or direct percutaneous puncture of the apex. The rationale for using the transapical approach is based on the absence of needs for transeptal puncture and challenging navigation in the left atrium. Moreover, there is a pure advantage of direct access to the valve. The experience with transapical PVL closure is limited even in the high volume structural heart disease centers, however in most cases the procedural success rate is high [13].

## Complications

Complications of PVL closure procedure are the following: cardiac tamponade, access site bleeding, thromboembolic complication, embolisation of the device and the malfunction of the prosthetic valve due to interference with the occluder device [14].

There are not very much data regarding the efficiency of transcatheter PVL closure procedure. The long-term results of percutaneous closure of prosthetic PVLs remain unknown. Mostly the published data are based on the small numbers of patients and short-term results. In most publications the procedural success rate was between 50 and 90% (Table 1).

## The Cardiocenter Podlesi Hospital data

Our group has had experience of eight closure attempts (two mitral and six aortic leaks) performed on seven patients. All aortic leaks were approached retrogradely from the aorta, the both mitral leaks were approached antegradely through a transeptal puncture. Six leaks have been successfully closed. Both procedural failures, one aortic and one mitral, were due to interference of the device with the open disc of the valve. One of these patients underwent a repeated procedure with a different type of device with the final procedural success. The complications occurred in one patient with embolisation of the device to the descending aorta. The device was successfully retrieved by the lasso catheter.

## Summary

There is no doubt that transcatheter PVL closure is a complex and technically demanding intervention. The challenging anatomy of the PVLs canal rules out success-

**Table 1 – Published series of patients on transcatheter paravalvular leak closure.**

Author	No of leaks	Year	Valve	Device	Procedural success	Residual leak
Hein [15]	21	2006	13 mitral, 8 aortic	ASD, VSD, PDA	95%	10%
Sorajja [16]	19	2007	NA	ASD, PDA	81%	5%
Pate [17]	10	2006	9 mitral, 1 aortic	ASD, PDA, coil	50%	40%

ASD – atrial septal defect; NA – not available; PDA – patent ductus arteriosus; VSD – ventricular septal defect.

ful crossing in some patients, and device interference with the valve prohibits device deployment in others. Because of the lack of specific devices for closing these complex defects, there is a lower rate of procedural success compared to other percutaneous interventions. On the other hand, the periprocedural rate of adverse events appears to be acceptable for such high-risk symptom limited patients. In group of patients with a high risk of redo surgery the percutaneous closure of PVL can lead to improving symptoms and outcomes. It should be calculated with the needs for repeated procedures due to residual leak, new leak development, and late dislodgement of the device with leak recurrence. Transcatheter closure of PVL seems to be a promising alternative for these patients, but, honestly, we still have a long way to go before we improve the outcomes.

## References

- [1] O'Rourke DJ, Palac RT, et al. Outcome of mild periprosthetic regurgitation detected by intraoperative transesophageal echocardiography. *J Am Coll Cardiol* 2001;38:163–6.
- [2] Movsowitz HD, Shah SI, et al. Long-term follow-up of mitral paraprosthetic regurgitation by transesophageal echocardiography. *J Am Soc Echocardiogr* 1994;7:488–92.
- [3] Rallidis L, Moyssakis IE, et al. Natural history of early paraprosthetic regurgitation: a five-year follow-up. *Am Heart J* 1999;138:351–5.
- [4] Dávila-Román VG, Waggoner AD, et al. Prevalence and severity of paravalvular regurgitation in the Artificial Valve Endocarditis Reduction Trial (AVERT) echocardiographic study. *J Am Coll Cardiol* 2004;44:1467–72.
- [5] Vongpatanasin W, Hillis LD, Lange RA. Prosthetic heart valves. *N Engl J Med* 1996;335:407–16.
- [6] Zoghbi WA, Chambers JB, Dumesnil JG, Foster E, Gottdiener JS, Grayburn PA, et al. Recommendations for evaluation of prosthetic valves with echocardiography and doppler ultrasound: a report from the American Society of Echocardiography's Guidelines and Standards Committee and the Task Force on Prosthetic Valves, developed in conjunction with the American College of Cardiology Cardiovascular Imaging Committee, Cardiac Imaging Committee of the American Heart Association, the European Association of Echocardiography, a registered branch of the European Society of Cardiology, the Japanese Society of Echocardiography and the Canadian Society of Echocardiography, endorsed by the American College of Cardiology Foundation, American Heart Association, European Association of Echocardiography, a registered branch of the European Society of Cardiology, the Japanese Society of Echocardiography, and Canadian Society of Echocardiography. *J Am Soc Echocardiogr* 2009;22:975–1014.
- [7] Hourihan M, Perry SB, Mandell VS, et al. Transcatheter umbrella closure of valvular and paravalvular leaks. *J Am Coll Cardiol* 1992;20:1371–7.
- [8] Moore JD, Lashus AG, Prieto LR, Drummond-Webb J, Latson LA. Transcatheter coil occlusion of perivalvular mitral leaks associated with severe hemolysis. *Catheter Cardiovasc Interv* 2000;49:64–7.
- [9] Eisenhauer AC, Piemonte TC, Watson PS. Closure of prosthetic paravalvular mitral regurgitation with the Gianturco-Grifka vascular occlusion device. *Catheter Cardiovasc Interv* 2001;54:234–8.
- [10] Moscucci M, Deeb GM, Bach D, Eagle KA, Williams DM. Coil embolization of a periprosthetic mitral valve leak associated with severe hemolytic anemia. *Circulation* 2001;104:E85–6.
- [11] Sorajja P, Cabalka AK, Hagler DJ, et al. Successful percutaneous repair of perivalvular prosthetic regurgitation. *Catheter Cardiovasc Interv* 2007;70:815–23.
- [12] Nietlispach F, Johnson M, Moss RR, et al. Transcatheter closure of paravalvular defects using a purpose-specific occluder. *J Am Coll Cardiol Interv* 2010;3:759–65.
- [13] Nietlispach F, Johnson M, et al. Transcatheter closure of paravalvular defects using a purpose-specific occluder. *JACC Cardiovasc Interv* 2010;3:759–65.
- [14] Bairaktaris A, Haas NA, et al. Pitfalls in catheter-based interventions to treat paravalvular leaks. *J Thorac Cardiovasc Surg* 2008;136:1076–7.
- [15] Hein R, Wunderlich N, Robertson G, Wilson N, Sievert H. Catheter closure of paravalvular leak. *EuroIntervention* 2006;3:318–25.
- [16] Sorajja P, Cabalka AK, Hagler DJ, Reeder GS, Chandrasekaran K, Cetta F, Rihal CS. Successful percutaneous repair of perivalvular prosthetic regurgitation. *Catheter Cardiovasc Interv* 2007;70:815–23.
- [17] Pate GE, Al Zubaidi A, Chandavimol M, Thompson CR, Munt BI, Webb JG. Percutaneous closure of prosthetic paravalvular leaks: case series and review. *Catheter Cardiovasc Interv* 2006;68:528–33.