



EDITORIAL COMMENT

Percutaneous closure of prosthetic paravalvular leaks – Should it be considered the first therapeutic option?☆



Encerramento percutâneo de *leaks* periprotésicos – deve ser considerada como a primeira opção terapêutica?

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Paravalvular leak (PVL) is one of the most common complications of surgical implantation of mechanical or biological valve prostheses and, more recently, with percutaneous valve replacement. Its incidence ranges, according to the series, between 2 and 10% for aortic valves and 7 and 17% for mitral valves.^{1,2}

Although most patients with PVL have few or no symptoms and are accordingly treated conservatively, some leaks can lead to an unfavorable clinical outcome, including heart failure (HF), hemolytic anemia or death.

It is now accepted that PVLs should be closed if associated with hemolytic anemia, congestive HF, worsening left ventricular function or progressive left ventricular dilatation.

The severity of the regurgitant jet(s) is not as important as the clinical repercussions of regurgitation. For this reason, even PVLs with mild or moderate regurgitation on echocardiographic criteria should be treated if they are associated with hemolysis, HF, or progressive left ventricular dilatation.³

Following transcatheter valve replacement, intermediate-risk patients with mild PVL usually have a benign clinical course, but mortality is higher in patients at higher risk and with comorbidities at two-year follow-up.^{4–6}

Medical treatment is merely palliative, and until recently the only option for patients with clinical indication for PVL closure was surgical correction. Various closure techniques have been described, including direct suturing and placement of autologous tissue or patches, but all these options have high failure rates, ranging from 12 to 35%. In-hospital mortality is also high, particularly in cases of reintervention, such as the 12–37% seen in a series of 618 surgical reinterventions by Echevarria et al.⁷

The first percutaneous PVL closure was reported by Hourihan et al.⁸ in 1992, and since then several small series have been published. In a recent meta-analysis including 362 patients, the procedural success rate was 76.5%, and procedural success was accompanied by lower cardiac mortality during follow-up (odds ratio [OR]: 0.08, 95% confidence interval [CI]: 0.01–0.9), fewer surgical reinterventions (OR: 0.08, 95% CI: 0.01–0.4) and improvements in HF and hemolytic anemia.⁹ The 30-day incidence of major adverse events (death, myocardial infarction, stroke, major bleeding and urgent surgery) is less than 10%, which compares favorably with surgery.¹⁰ Embolization of closure devices is a rare complication and very few cases of late embolization have been reported.¹¹

Closure of aortic PVLs is usually technically simpler, with only one access route, and echocardiographic support is not as crucial as with the mitral valve, for which various access routes can be used (antegrade transseptal, retrograde transaortic and transapical) and for which the assistance of imaging techniques other than angiography, such as three-dimensional transesophageal echocardiography, is essential. New modalities have recently been developed,

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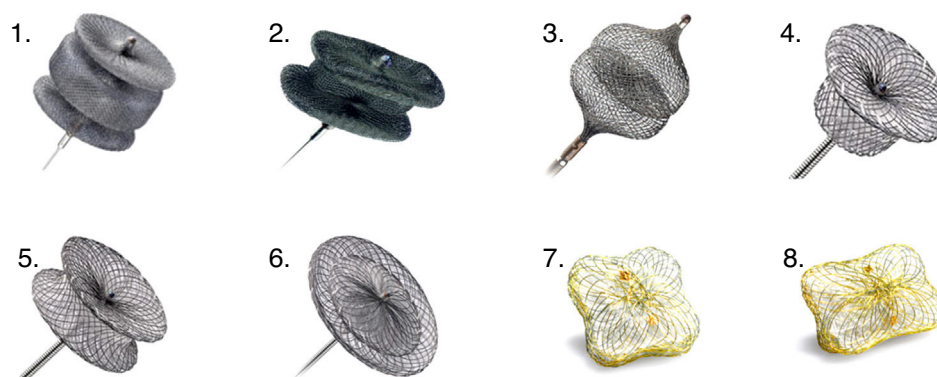


Figure 1 Examples of devices used for percutaneous paravalvular leak closure: (1) Amplatzer Vascular Plug II; (2) Amplatzer Vascular Plug III; (3) Amplatzer Vascular Plug IV; (4) Amplatzer Duct Occluder; (5) Amplatzer Muscular VSD Occluder; (6) Amplatzer Septal Occluder; (7) Occlutech PLD (square); (8) Occlutech PLD (rectangular).

integrating images with fusion technology (tomography, angiography and echocardiography), such as Philips Medical Systems' HeartNavigator and EchoNavigator.¹² Certain locations of mitral PVL, particularly medial or septal, are extremely challenging, for which steerable sheaths such as the Agilis NxT (St. Jude Medical) or an arteriovenous loop may be useful, and in some cases the best option could be a transapical approach.

Another factor that is crucial to success in these procedures is operator experience; complications decrease and success rates rise as the operator gains experience.¹³ This experience should be concentrated in a reference center and in an operator trained in structural cardiac intervention.

With regard to the devices used for PVL closure, the choice is determined by what is available in a given center and a particular country, and is also influenced by the operator's experience with specific devices in other types of structural intervention. Some case series deal with a single device, as in the series by Cruz-González et al. with the Amplatzer Vascular Plug (AVP) III (St. Jude Medical), in which success rates were over 90%.¹⁴ However, most series are based on more than one device. The most popular is the AVP II (St. Jude Medical), which has been approved by the US Food and Drug Administration.¹⁴ The sizes most often used are between 8 mm and 12 mm for the AVP II, which is round in shape and thus permits the implantation of more than one device. Furthermore, it makes more sense to implant multiple small devices rather than a single large one, since this is more likely to result in complete closure and less likely to interfere with the prosthetic valve.¹⁰

In cases of PVL following transcatheter aortic valve implantation, the device most often used is the AVP IV, but success rates are lower (around 60%), mainly due to difficulty in cannulating the leak. New devices have recently been developed that are specifically designed for PVLs, such as the Occlutech PLD¹⁵ (which comes in rectangular and square forms), but their use is currently limited to small series (Figure 1).

The series by Azevedo et al.¹⁶ published in this issue of the *Journal* presents the experience of a single center treating different types of patients with mechanical and biological valves, aortic and mitral PVL, and a variety of devices. The results are generally good and are consistent with larger previously published series. Given the small

numbers of patients treated in each Portuguese center, it is important to establish prospective, multicenter national registries that collect information systematically, to shed more light on this therapeutic alternative.

It would be difficult to perform studies specifically designed to provide evidence on which to base future recommendations on this subject, but it is clear that the good results of percutaneous PVL closure compared to the surgical alternative already make it the first-line treatment for clinically relevant PVL.³

Conflicts of interest

The author has no conflicts of interest to declare.

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