



## Case Report

# Paravalvular leak closure with off-label devices: a valuable resource

Emilio Herrera<sup>1,a</sup>, Alberto Navarro<sup>1,b</sup>, Julián Vanegas<sup>2,c</sup>, Juan C Ortiz<sup>1,2,d</sup>

Received: August 1, 2023  
Accepted: October 19, 2023  
On line: December 2, 2023

### Affiliation of the authors

<sup>1</sup> Cardiology Section, Department of Internal Medicine, Universidad de Antioquia, Medellín, Colombia.  
<sup>2</sup> Department of Cardiology, Hospital Alma Mater de Antioquia, Medellín, Colombia.  
<sup>a</sup> Physician; <sup>b</sup> fellow in Cardiology; <sup>c</sup> cardiologist; <sup>d</sup> fellow in interventional cardiology; <sup>e</sup> echocardiographer; <sup>f</sup> interventional cardiologist.

### Correspondence

Emilio Herrera.  
Tv 32 C 74D-33 Apto 304 Ed Portal de Alameda. Medellín, Colombia

### E-mail

emilio.herrera@udea.edu.co

### Funding

Self-financed

### Conflicts of Interest

The authors declare no conflict of interest.

### Cite as

Herrera E, Navarro A, Vanegas J, Ortiz JC. Cierre de parafuga valvular con dispositivos *off-label*: un recurso valioso. Reporte de caso. Arch Peru Cardiol Cir Cardiovasc. 2023;4(4):184-187. doi: 10.47487/apcyccv.v4i4.302.



This work is licensed under a Creative Commons Attribution 4.0 International License.

## ABSTRACT

We present the case of a patient with a paravalvular leak of mechanical prosthesis in aortic position. Due to a recent previous surgery, it was decided to perform a percutaneous repair to reduce perioperative risk. This was done under an off-label indication using a device designed for ventricular septal defect (VSD) closure. The procedure was successful and without complications in the follow-up.

**Keywords:** Heart Valve Disease; Cardiac Valve Prosthesis; Aortic Valve Insufficiency (source: MeSH-NLM).

## Introduction

Valvular heart disease remains common. In industrialized countries, degenerative origin is more common, while in those in the developing world, rheumatic origin is more prevalent. In most cases where valvular heart disease progresses to severe forms, valve replacement therapy is required, mostly through surgical means and, more recently, also percutaneously<sup>(1)</sup>. In the United States, approximately 60,000 prosthetic heart valves are implanted annually, and between 5 and 17% of these may develop some degree of paravalvular insufficiency due to multiple mechanisms. Reintervention has been the standard therapy for many years; however, it is not without risks, and in this regard, percutaneous repair can be a reasonable alternative<sup>(2,3)</sup>.

## Case report

54-year-old male, with a history of aortic valve replacement with a bioprosthesis in 2008; replacement with Medtronic #25 mechanical prosthesis in 2022 due to structural deterioration. A bicameral pacemaker was implanted due to complete atrioventricular (AV) block. In the course of 2022, he experienced prosthesis thrombosis successfully treated with pharmacological fibrinolysis. Anticoagulated with warfarin according to international normalized ratio (INR).

Admitted due to a clinical presentation over the past 3 weeks characterized by dyspnea progressing with minimal exertion, associated with lower limb edema and orthopnea. Clinical examination: weight 56 kg; height 168 cm; blood pressure 107/57 mmHg; pulse 74/min; respiratory rate 16/min; oxygen saturation 95% on room air. Notable findings include a valvular click and absence of a cardiac murmur. Presence of grade I symmetric lower limb edema. No other significant findings noted. Initial examinations revealed unremarkable blood biochemistry (no evidence of hemolysis) and INR within target range. Electrocardiogram showed complete left bundle branch block (LBBB) due to pacemaker stimulation.

A transthoracic echocardiogram was performed, showing a left ventricular ejection fraction (LVEF) of 30%; severe central aortic valve prosthesis insufficiency with maximum velocity: 2.58 m/s, acceleration time: 67 m/s and integral ratio: 0.48. Aortic root dilatation: 41 mm. The rest of the parameters were within normal limits.

The evaluation was complemented with a transesophageal echocardiogram, revealing a dilated left ventricle with an LVEF of 30% and diffuse hypokinesia, with normal-sized atria. TAPSE: 17 mm. The mitral valve showed two jets of mild central insufficiency. The aortic mechanical prosthesis with a 21 mm annulus, without pannus with normal hemidisc opening, a maximum gradient of 37 mmHg, and a mean gradient of 18 mmHg. Paravalvular leak is observed between the 9 and 12 o'clock positions towards the mitroaortic continuity (**Figure 1**), with a flow length of 19 mm, covering 25% of the circumference, and an anatomical defect measuring 9x6 mm. Vena contracta: 10 mm, and hemi-pressure time: 190 ms. Pulmonary systolic arterial pressure (PSAP): 49 mmHg.

In the clinical context of acute heart failure, associated with the described paravalvular leak on echocardiography, in a patient with two previous cardiac surgeries, it was decided to proceed with percutaneous repair of the defect.

The repair was performed under cardiovascular anesthesia, preceded by an aortogram and with 3D transesophageal echocardiography. Findings were confirmed. The defect was crossed using a hydrophilic guide to the left ventricle. A device for closure of the interventricular communication #8 was advanced (off-label indication). Positioning was confirmed by echocardiography and fluoroscopy and released without complications (**Figure 2**). In-room echocardiography showed a

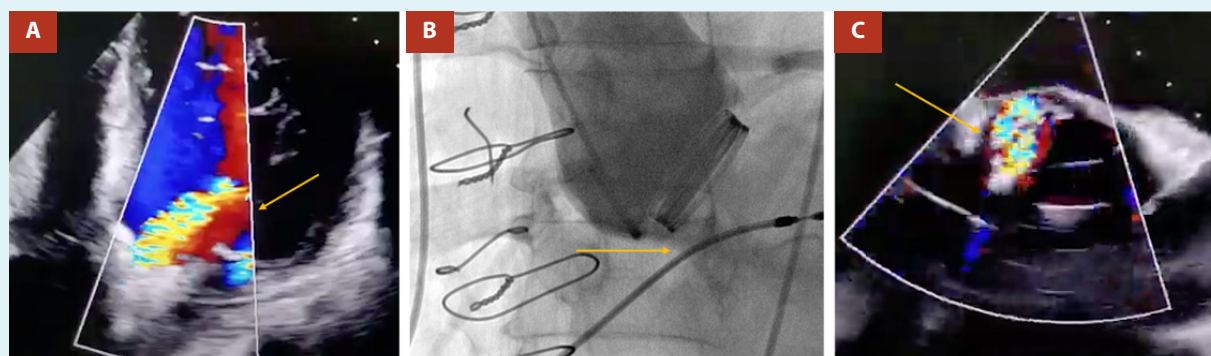
significant decrease in the degree of insufficiency. The patient is discharged 48 hours after the procedure, asymptomatic. Follow-up at 10 weeks reveals good clinical condition; New York Heart Association (NYHA) functional class I.

## Discussion

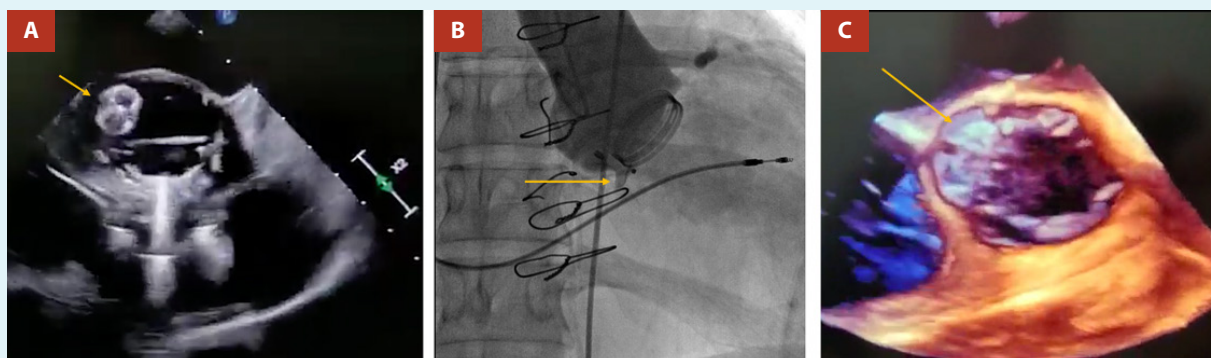
Paravalvular leaks can occur after valve repair or replacement (open or percutaneous). Although even mild leaks can have a poor long-term prognosis, treatment is usually indicated when they cause ventricular compromise (dilatation-dysfunction), heart failure, hemolysis, and in the context of endocarditis<sup>(4)</sup>. The patient under discussion had severe compromise of ventricular function associated with clinical heart failure.

In valve replacement, the most common cause of paravalvular leak is usually suture dehiscence. This can occur due to patient-related factors such as friable and highly calcified tissue or external factors such as the presence of endocarditis and suture technique. Dehiscence is more common in mechanical valves than in bioprostheses and usually in the mitral position (around 80% of cases). More than two-thirds occur in the first year after valve repair, similar to the presented case. In these patients, surgical reintervention has been shown to have a high mortality rate compared to percutaneous closure.

Diagnosis is often challenging. The patients have mild murmurs that vary according to the position and trajectory of the regurgitant jet. Color Doppler evaluation may be compromised by artifacts generated by mechanical valves and valve annulus calcifications. Transesophageal echocardiography is often necessary for a definitive diagnosis. In our patient, the



**Figure 1.** Pre-procedure images. **A)** Transthoracic echocardiogram, five-chamber apical view, color Doppler showing aortic regurgitation jet (yellow arrow), **B)** Cinefluoroscopy demonstrating contrast leakage with closed prosthetic discs, outside the prosthesis. **C)** Transesophageal echocardiogram, short-axis view, color Doppler revealing paravalvular leak (yellow arrow).



**Figure 2.** Multimodal post-procedure image. **A)** Transesophageal echocardiogram, short-axis view, **B)** Cinefluoroscopy, and **C)** 3D echocardiogram of the prosthetic aortic valve, showing the Amplatzer-type device (yellow arrow) in position at the site of the paravalvular leak.

mechanism and severity of insufficiency were determined with transesophageal echocardiography, and the findings were confirmed with cinefluoroscopy.

The use of 3D echocardiography is recommended for assessment, as the shape of the regurgitant jet is often irregular (usually crescent or rectangular-oblong), as is its course. Quantifying the severity of the paravalvular leak can be challenging; in color Doppler, a 'garden hose' image may be seen, where small orifices fill the entire outflow tract of the left ventricle, without there being severe regurgitation. On the other hand, the acoustic shadow and other artifacts from mechanical valves may underestimate the severity of the regurgitant jet. Aortogram, computed tomography (CT) (more recently, CT fused with fluoroscopy), cardiac magnetic resonance, and intracardiac echocardiography are other available tools to address cases that generate doubt<sup>(5,6)</sup>.

Currently, there is not a significant offering in terms of devices created exclusively for this purpose; most are used off-label. The most commonly used devices are from the Amplatzer family for closure of septal defects. Available in various sizes, they are generally chosen slightly larger than the defect to ensure complete occlusion, taking care not to exceed the inner edge of the valve frame and interfere with the opening and closing mechanism of the prosthesis, as this complication can be very serious<sup>(7)</sup>. Once the closure device is positioned, it is confirmed by imaging and the degree of residual regurgitation is assessed, as was done in our case.

Follow-up imaging is recommended, mainly at 6 months, to assess device stability, effectiveness of closure and residual leakage. Clinical improvement is seen in 67-76% of patients<sup>(8)</sup>. Complications are potentially serious and include device embolization, interference with prosthetic valve discs, thromboembolism or air embolism, cardiac tamponade and bleeding. Other complications, such as aortic dissection and obstruction of coronary ostia, are less frequent.

Although there is limited data on long-term prognosis after closure, residual leakage does not seem to be a good predictor of survival but may generate symptoms. On the other hand, hemolysis appears to be a marker of mortality. In this regard, when the goal is to improve heart failure, any reduction in regurgitant volume is favorable for the patient. Conversely, if closure is indicated for hemolysis, the goal should be complete closure of the defect. Some series have reported survival rates close to 86% at 18 months and 64% at 5 years<sup>(9,10)</sup>.

### Ethical aspects

We declare that the authors have obtained the patient's consent.

### Author contributions

EH: Writing - Original Draft, Writing - Review & Editing and Project Administration. AN: Supervision, Visualization and Writing - Review & Editing. JV: Resources (images), Writing - Review & Editing. JCO: Conceptualization and Writing - Review & Editing.

## References

1. H Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. ESC/EACTS Scientific Document Group. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* 2022;43(7):561-632. doi: 10.1093/eurheartj/ehab395.
2. Ruiz CE, Hahn RT, Berrebi A, Borer JS, Cutlip DE, Fontana G, et al. Paravalvular Leak Academic Research Consortium. Clinical Trial Principles and Endpoint Definitions for Paravalvular Leaks in Surgical Prosthesis. *Eur Heart J.* 2018;39(15):1224-45.

3. Sorajja P, Bae R, Lesser JA, Pedersen WA. Percutaneous repair of paravalvular prosthetic regurgitation: patient selection, techniques and outcomes. *Heart*. 2015;101(9):665-73. doi: 10.1136/heartjnl-2014-306270.
4. Rihal CS, Sorajja P, Booker JD, Hagler DJ, Cabalka AK. Principles of percutaneous paravalvular leak closure. *JACC Cardiovasc Interv*. 2012;5(2):121-30. doi: 10.1016/j.jcin.2011.11.007.
5. Lancellotti P, Pibarot P, Chambers J, Edvardsen T, Delgado V, Dulgheru R, et al. Recommendations for the imaging assessment of prosthetic heart valves: a report from the European Association of Cardiovascular Imaging endorsed by the Chinese Society of Echocardiography, the Inter-American Society of Echocardiography, and the Brazilian Department of Cardiovascular Imaging. *Eur Heart J Cardiovasc Imaging*. 2016;17(6):589-90. doi: 10.1093/ehjci/jew025.
6. Ribeiro HB, Orwat S, Hayek SS, Larose É, Babaliaros V, Dahou A, et al. Cardiovascular Magnetic Resonance to Evaluate Aortic Regurgitation After Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol*. 2016;68(6):577-585. doi: 10.1016/j.jacc.2016.05.059.
7. Nietlispach F, Maisano F, Sorajja P, Leon MB, Rihal C, Feldman T. Percutaneous paravalvular leak closure: chasing the chameleon. *Eur Heart J*. 2016;37(47):3495-3502. doi: 10.1093/eurheartj/ehw165.
8. Cruz-González I, Luengo-Mondéjar P, Trejo-Velasco B, Núñez-García JC, González-Ferreiro R, Moreno-Samos JC, et al. Percutaneous Closure of Mitral Paravalvular Leak: Long-Term Results in a Single-Center Experience. *J Clin Med*. 2022;11(16):4835. doi:10.3390/jcm11164835
9. Sorajja P, Cabalka AK, Hagler DJ, Rihal CS. Long-Term Follow-Up of Percutaneous Repair of Paravalvular Prosthetic Regurgitation. *J Am Coll Cardiol*. 2011;58(21):2218-24. DOI:10.1016/j.jacc.2011.07.041
10. Kumar R, Jelnin V, Kliger C, Ruiz CE. Percutaneous Paravalvular Leak Closure. *Cardiol Clin*. 2013;31(3):431-40. doi: 10.1016/j.ccl.2013.05.004.