



EDITORIAL COMMENT

Introduction of percutaneous treatment for mitral regurgitation in Portugal[☆]



Introdução em Portugal da reparação percutânea da insuficiência mitral

Eduardo Infante de Oliveira

Serviço de Cardiologia, Hospital de Santa Maria, Centro Hospitalar Lisboa Norte, Instituto de Fisiologia, Faculdade de Medicina, Universidade de Lisboa, Lisboa, Portugal

Mitral regurgitation (MR) is the second most common valvular disorder in Europe.¹ Its diagnosis, classification and treatment are standardized by the joint guidelines of the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery (ESC/EACTS).² Surgical repair is the reference treatment,² but around half of patients with severe MR are denied surgery³ due to advanced age, ventricular dysfunction or other comorbidities or contraindications. There is thus a clear need for less invasive alternatives. In the last twenty years, various percutaneous devices have been developed, and many concepts and approaches have been tested, including direct and indirect annuloplasty, the NeoChord valve repair device, right ventricular remodeling, leaflet plication, and percutaneous valve replacement. However, to date only one device has progressed beyond the stage of randomized clinical trials⁴ and been recommended by regulatory bodies^{2,5,6}: the MitraClip system (Abbott Vascular, Menlo Park, CA, USA). This device reproduces percutaneously the Alfieri surgical technique, in which a double-orifice valve is created by plicating the mid segments of the anterior and posterior leaflets. The MitraClip has a complex delivery mechanism by which, via a transseptal approach, one or more cobalt chromium clips are implanted to bring together the mid segments (A2 and P2 scallops) of the valve leaflets. Over 20 000 MitraClip procedures have been performed worldwide.

The EVEREST I and II trials in the USA included a pilot stage to evaluate safety and feasibility, a registry of patients at high surgical risk, and a randomized trial comparing MitraClip therapy with conventional surgery,^{4,7–9} and were followed by the REALISM continued access registry. In October 2013 the US Food and Drug Administration (FDA) approved use of the MitraClip in patients with symptomatic degenerative MR and high surgical risk,⁵ while in Europe the device received CE Mark approval in March 2008. Its use has grown exponentially, mostly in patients with functional MR, advanced age and high surgical risk. The ACCESS-EU registry (Phase I and II) included around 1000 interventions.

In the 2012 ESC/EACTS guidelines on the management of valvular heart disease, the MitraClip was given a class IIb recommendation for symptomatic functional or degenerative MR in patients judged inoperable or at high surgical risk.² The technique has thus, despite its limitations, overcome various hurdles in the evaluation process and has won its place in clinical practice.

In Portugal the first MitraClip procedure took place on January 9, 2013 at Hospital de Santa Maria (Figure 1), and others followed at Hospital de Santa Marta and Hospital de Vila Nova de Gaia. This was relatively late compared to other European countries, five years after the device received CE Mark approval and in the same year as its approval by the FDA. Its growth has been slow but steady: in the first half of 2015 around a hundred procedures were performed in the Iberian Peninsula, about 20% of them in Portugal. The results presented by Cacela et al. in this issue of the *Journal*¹⁰ reflect real-world experience and are comparable to those of large European registries, including the

[☆] Please cite this article as: Infante de Oliveira E. Introdução em Portugal da reparação percutânea da insuficiência mitral. Rev Port Cardiol. 2015;34:525–527.

E-mail address: e.infante.de.oliveira@gmail.com



Figure 1 The team responsible for the first MitraClip implantation in Portugal.

international Transcatheter Valve Treatment Sentinel Pilot Registry¹¹ and the German TRAMI registry.¹²⁻¹⁴ The three Portuguese centers are expected to participate in the important international RESHAPE-HF 2 trial, confirming the consistent quality of their work in this area. The primary aim of this randomized trial is to assess the impact of the MitraClip on mortality and rehospitalization for heart failure in patients with severe symptomatic functional MR compared to optimal standard of care therapy. It has the potential to bring about profound changes in the treatment of patients with impaired systolic function and secondary MR.

Percutaneous valvuloplasty to treat MR is now a real solution for carefully selected patients who are considered inoperable or at high surgical risk. It requires allocation of significant resources, including the creation of multidisciplinary teams, but it is the only treatment option for a considerable number of patients. Percutaneous valve replacement may appear a simpler and more widely applicable solution, but it affects the subvalvular apparatus and ventricular geometry, increases the aggressiveness of the procedure and has all the limitations of implanting a biological valve in mitral position. I believe that the future will see the simultaneous development and growth of techniques of percutaneous repair, percutaneous valve replacement and minimally invasive surgery. Such diversity of therapeutic options will widen the range of candidates for treatment, all of which will have a role to play.

Conflicts of interest

The author has no conflicts of interest to declare.

References

1. Iung B. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J.* 2003;24:1231-43.
2. Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur J Cardiothorac Surg.* 2012;42:S1-44.
3. Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J.* 2007;28:1358-65.
4. Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med.* 2011;364:1395-406.
5. Center for Devices and Radiological Health. *Recently-Approved Devices - MitraClip Clip Delivery System - P100009.* Center for Devices and Radiological Health.
6. Percutaneous mitral valve annuloplasty | Guidance and guidelines | NICE. NICE. Available from: <https://www.nice.org.uk/guidance/ipg352>
7. Feldman T, Wasserman HS, Herrmann HC, et al. Percutaneous mitral valve repair using the edge-to-edge technique: six-month results of the EVEREST Phase I Clinical Trial. *J Am Coll Cardiol.* 2005;46:2134-40.
8. Feldman T, Kar S, Rinaldi M, et al. Percutaneous mitral repair with the MitraClip system: safety and midterm durability in the initial EVEREST (Endovascular Valve Edge-to-Edge REpair Study) cohort. *J Am Coll Cardiol.* 2009;54:686-94.
9. Mauri L, Foster E, Glower DD, et al. 4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation. *J Am Coll Cardiol.* 2013;62:317-28.
10. Cabela D, Fiarresga A, Branco L, et al. Terapêutica percutânea da insuficiência mitral: experiência inicial com o dispositivo MitraClip. *Rev Port Cardiol.* 2015;34(9):515-24.
11. Nickenig G, Estevez-Loureiro R, Franzen O, et al. Percutaneous mitral valve edge-to-edge repair: in-hospital results and 1-year follow-up of 628 patients of the 2011-2012 Pilot European Sentinel Registry. *J Am Coll Cardiol.* 2014;64:875-84.
12. Baldus S, Schillinger W, Franzen O, et al. MitraClip therapy in daily clinical practice: initial results from the German transcatheter mitral valve interventions (TRAMI) registry. *Eur J Heart Fail.* 2012;14:1050-5.

13. Wiebe J, Franke J, Lubos E, et al. Percutaneous mitral valve repair with the MitraClip system according to the predicted risk by the logistic EuroSCORE: preliminary results from the German Transcatheter Mitral Valve Interventions (TRAMI) Registry. *Catheter Cardiovasc Interv.* 2014;84:591–8.
14. Eggebrecht H, Schelle S, Puls M, et al. Risk and outcomes of complications during and after MitraClip implantation: Experience in 828 patients from the German TRAns catheter mitral valve interventions (TRAMI) registry. *Catheter Cardiovasc Interv.* 2015.