

# Percutaneous mitral valve repair: the beginning of the end or the end of the beginning?

Alec Vahanian\*, Dominique Himbert, Eric Brochet  
and David Messika-Zeitoun

Address: Hôpital Bichat, 46 rue Henri Huchard, 75018 Paris, France

\* Corresponding author: Alec Vahanian (alec.vahanian@bch.aphp.fr)

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## Abstract

The new percutaneous mitral valve repair techniques are at an early stage. Preliminary series show that they are feasible; however, they need to be further evaluated in comparison with contemporary treatment to accurately assess their efficiency. Potential applications may benefit high-risk patients after thorough evaluation.

## Introduction and context

Mitral regurgitation (MR) represents more than 30% of native valve disease [1-3]. The good results of surgery, particularly valve repair, set a high standard for future percutaneous valve intervention [4-6]. However, in current practice worldwide, surgery is denied in many patients with severe valvular heart disease and symptoms [7] and mitral valve repair is not always used or feasible [8,9]. In addition, surgical risk remains high in a significant percentage of contemporary patients who are elderly and have comorbidities [3].

## Recent advances

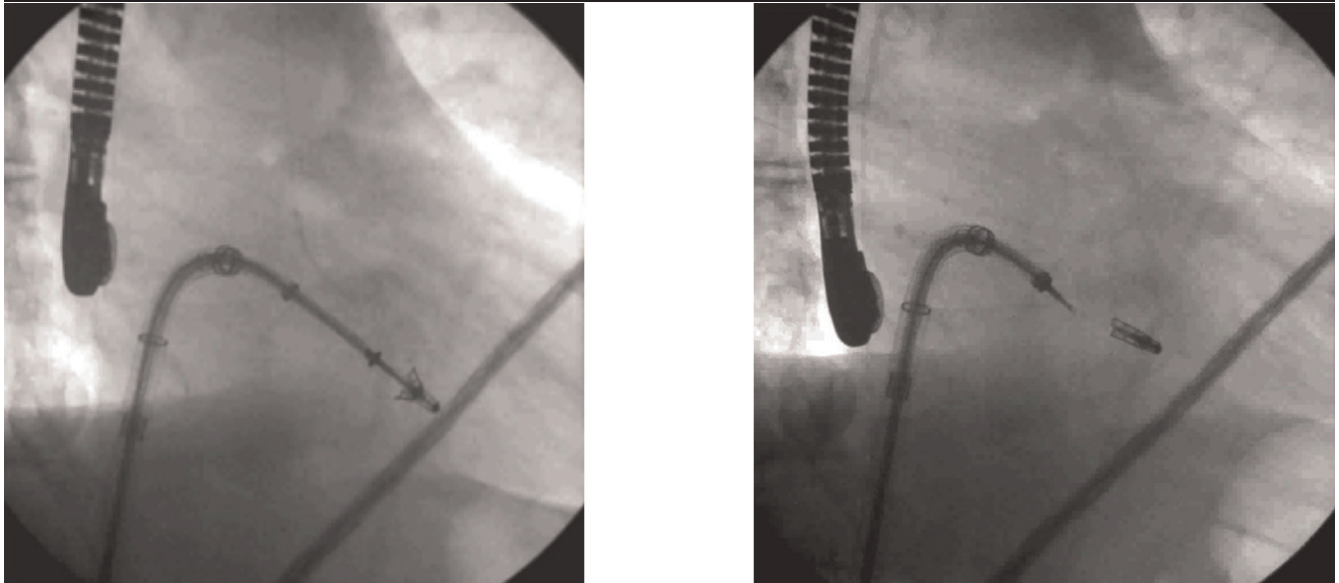
Two main techniques can be used for percutaneous mitral valve repair: the edge-to-edge technique and prosthetic ring annuloplasty. The edge-to-edge technique mimics the surgical Alfieri procedure, which creates a double mitral orifice by means of a few stitches securing the two leaflets together in their midpart [10]. This technique can be performed percutaneously using a clip (MitraClip®; Evalve, Inc., Menlo Park, CA, USA) made of cobalt-chromium alloy and covered with polyethylene terephthalate [11]. Another design involved the use of one or more sutures deployed via a catheter-based device. The technique requires general anaesthesia and a transseptal approach with continuous fluoroscopic and transoesophageal echographic guidance to catch the

leaflets at their coaptation point [12] (Figure 1). These constraints mean that the technique is initially difficult to learn and will limit its dissemination.

Current clinical experience is focused almost exclusively on the clip technique (MitraClip) in 500 patients [13,14] because the development of the other, suture-based device has been abandoned [15]. In the initial EVEREST (Endovascular Valve Edge-to-Edge Repair Study) registry including 107 patients, severe MR was of degenerative origin in around 80% of patients. Success rate and procedure time improved steadily with experience. Sixty-four percent of patients were discharged from hospital with a clip and MR of less than grade 2/4, and the procedure did not induce mitral stenosis [14-17]. The procedure was well tolerated and 98% were free from any complication in the expert centres involved in the study. After 36 months, 66% of patients who underwent a successful procedure were free from death, mitral valve surgery, and MR greater than grade 2/4 [14]. Preliminary studies also report satisfactory outcomes in patients at high risk or in functional MR subsets.

Limitations of the edge-to-edge technique can be anticipated: this technique, in isolation, does not address the problem of annulus dilatation, which has been shown to increase the risk of secondary residual

**Figure 1. Percutaneous mitral valve repair: edge-to-edge technique using a clip (MitraClip; Evalve, Inc., Menlo Park, CA, USA)**



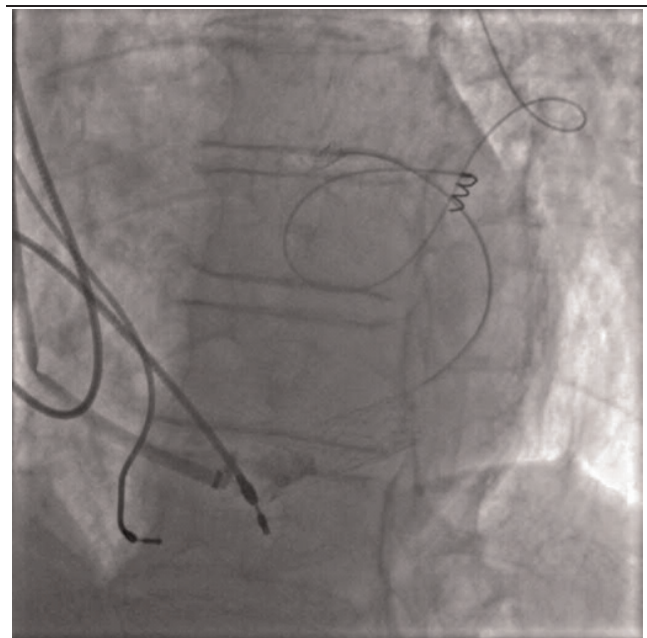
Left panel: Right anterior oblique view. The clip is opened in the left ventricle, just below the mitral valves under transoesophageal echocardiographic guidance. Right panel: Right anterior oblique view. The clip is closed at the coaptation point of the mitral valves and then released. Images courtesy of Peter Block.

regurgitation. In degenerative MR, its use will probably be restricted to a limited percentage of patients. Residual regurgitation carries the risk of insidious development of left ventricular dysfunction.

Prosthetic ring annuloplasty is key in most cases of surgical valve repair; data show that the diameter of the mitral annulus can be reduced by inserting a constraining device in the proximate coronary sinus [18]. Several devices are under investigation: the Carillon device (Cardiac Dimensions Inc., Kirkland, WA, USA) uses a nitinol wire with proximal and distal anchors [19]; the Viacor device (Viacor, Inc., Wilmington, MA, USA) leads to a decrease in anteroposterior diameter through the application of pressure on the midportion of the posterior leaflet by using several rigid elements placed in a plastic sleeve [20]. These two devices can be withdrawn if efficacy is not satisfactory or if the circumflex artery is compromised. In the Monarc device (Edwards Lifesciences LLC, Irvine, CA, USA), self-expanding stents are joined via a bridge that contracts after 6 weeks [21]. All of these devices have had several technical modifications over time.

Prosthetic ring annuloplasty is easier to perform than the edge-to-edge technique and requires a catheterisation of the coronary sinus through the jugular vein and the delivery of the devices under fluoroscopic guidance (Figure 2).

**Figure 2. Percutaneous mitral valve repair: edge-to-edge technique using a suture (Mobius; Edwards Lifesciences LLC, Irvine, CA, USA)**



A left anterior oblique view of a clinical case of coronary sinus prosthetic percutaneous annuloplasty is shown. The device is positioned in the coronary sinus. A proximal stent is deployed in the proximal part of the coronary sinus, and the distal stent is deployed in the distal part of the coronary sinus. A constraining bridge connects the two stents.

The preliminary results obtained in around 200 patients with functional MR suggest that the feasibility ranges from 40% to 80% and that safety is satisfactory (83% of implanted patients are event-free at 90 days). After 2 years, preliminary studies show that 80% of the patients survive and most of them experience functional improvement. Data on efficacy are more limited and show a trend toward reduction of the degree of MR. In addition, up to 30% of patients had some degree of circumflex cinching, but this led to adverse events in only a few cases [19-21].

The coronary sinus approach also has potential limitations. The long-term benefits of mitral valve repair in functional MR are debated [22]. The ring inserted into the coronary sinus is localised to the posterior half of the annulus, where surgeons usually use undersized and complete rings [23]. The coronary sinus is 1 or 2 cm away from the atrioventricular groove on the atrial side, and this may also decrease the efficacy [24]. Finally, there is a potential risk of cinching the circumflex artery whilst crossing the coronary sinus [25,26]. This requires noninvasive anatomic evaluation before the procedure by using computed tomography imaging [25,26].

Several other devices and techniques are currently being investigated experimentally or tested in humans for the first time: 'direct' annuloplasty (such as transventricular suture-based annuloplasty or subannular annuloplasty), and 'mitral cerclage' annuloplasty, in which ventricular remodelling using either transpericardial ventricular remodelling with anchoring pads on either side of the ventricle or a combination of anchors placed in the coronary sinus and the atrial septum allows a tensioning cable to be placed across the left atrium, applying tension to reduce the septal lateral dimension. Finally, the first experiments on percutaneous valve replacement have also been performed.

### Implications for clinical practice

The data we have on these new techniques are still limited and suffer from a number of methodological limitations. A lot of questions are still pending: more clinical data are needed to accurately assess efficacy, safety, and durability. The EVEREST II randomised study comparing the percutaneous edge-to-edge technique with surgery will be presented soon and further safety and efficacy studies are to be conducted with percutaneous annuloplasty. It is essential to know whether secondary intervention, either percutaneous (including resynchronisation) or surgical, will be feasible. Imaging guidance using three-dimensional transoesophageal echocardiography will improve the performance of the edge-to-edge technique. Overall, it is unlikely that these

new percutaneous techniques will reproduce the current results of surgical valve repair; however, they may play a role in patients with contraindications to or high risk for surgery. This concerns a large population and may have a great clinical impact [27].

### Abbreviations

EVEREST, Endovascular Valve Edge-to-Edge Repair Study; MR, mitral regurgitation.

### Competing interests

The authors declare that they have no competing interests.

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