






# Case series of late complications after transcatheter mitral annuloplasty using Cardioband and surgical treatment options

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## Abstract

**Background:** Treatment of functional mitral regurgitation using transcatheter techniques such as the Cardioband annuloplasty device (Edwards Lifesciences) has gained wide acceptance in the recent years. However, complications of such devices are rarely reported.

**Methods:** Here, we present a case series involving two patients with dislocation of the Cardioband device and discuss the surgical management.

**Results:** In the former the valve was re-repaired by surgical implantation of an annuloplasty ring, and in the latter the valve had to be replaced due to severe damage of the mitral valve annulus. Both patients had an uncomplicated course and were discharged to rehabilitation Center.

**Conclusion:** Dislocation of the Cardioband devices can be successfully managed by surgical approaches. Depending on the extent of damage to the mitral valve annulus, the valve could be re-repaired or should be replaced.

## KEYWORDS

cardioband, mitral valve insufficiency, mitral valve repair, mitral valve replacement

## 1 | INTRODUCTION

Minimally invasive transcatheter-based mitral valve (MV) interventions are highly relevant treatment options for inoperable and elderly high-risk patients.<sup>1</sup> The treatment of functional mitral regurgitation (FMR) depends mostly on the annular reduction of the MV. Cardioband (Cardioband™ Edwards Lifesciences) is one such transcatheter device that has been in the market since 2016, and there are various publications that vouch for the safety and efficacy of this device.<sup>2-4</sup>

We report here a case series involving two patients who developed severe recurrent mitral regurgitation (MR) several months after therapy with Cardioband due to subsequent dislocation of implanted anchors, and we describe the different surgical managements.

In accordance with the local guidelines of the ethics commission, no ethical application was needed. Institutional Review Board approval or consent statement was not required.

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## 1.1 | Case reports

### 1.1.1 | Patient 1

A 71-year-old multimorbid male patient was admitted to our center due to severe FMR. He had undergone coronary artery bypass grafting in 2006 and coronary angioplasty with stent placements in 2016.

Taking his comorbidities into consideration and to avoid high-risk redo-surgery, a percutaneous transcatheter mitral valve repair was performed using the Cardioband device (Cardioband™ Edwards Lifesciences) (Figure 1A). Postimplantation transthoracic echocardiogram (TTE) revealed a successful reduction of MR (Figure 1B). The mean MV gradient was recorded to be 2 mmHg and an expected mild iatrogenic left-to-right shunt was observed due to septal puncture.

A 6-month follow-up TTE showed a mild MR with still intact device but steeply elevated posterior mitral leaflet (PML) due to traction on secondary chordae. Ten months after the initial procedure, the patient was readmitted due to recurrent dyspnea and clinical signs of cardiac decompensation. Transesophageal echocardiography (TEE) revealed a shifted Cardioband at the margin of the PML resulting in severe MR (Figure 1C), as well as a new moderate aortic valve stenosis and tricuspid valve regurgitation. A surgical revision was initiated, as the conservative medical therapy showed limited success. The patient underwent redo-surgery with cardiopulmonary bypass. The intraoperative inspection showed an abridged Cardioband, especially on the posterior leaflet in the area of the P2 segment. Ten among the thirteen implanted anchors could be gently unscrewed without causing annular damage. The remaining three were left in situ, as they were deeply anchored in the surrounding annular tissue. Subsequently, a complete annuloplasty repair was performed using an Edwards Physio II ring (32 mm) (Figure 2). We opted for reconstruction after careful intraoperative evaluation of the anatomical condition and due to a reduced left ventricular function (left ventricular ejection fraction: 40%; left ventricular end diastolic diameter: 66 mm).

In addition, the patient underwent an aortic valve replacement (SJM Trifecta Aortic Valve) as well as reconstruction of the tricuspid valve (physio ring tricuspid 32 mm; Edwards Lifesciences). Postoperatively, the patient was hemodynamically stable under moderate dosage of inotropes. The subsequent course was complicated due to a symptomatic bradycardia with intermittent ventricular tachycardia episodes, thereby requiring implantation of a prophylactic implantable cardioverter-defibrillator. The patient improved gradually and was discharged 1 week after surgery. A postoperative TTE control after 6 months showed patency of the valves with mild MR.

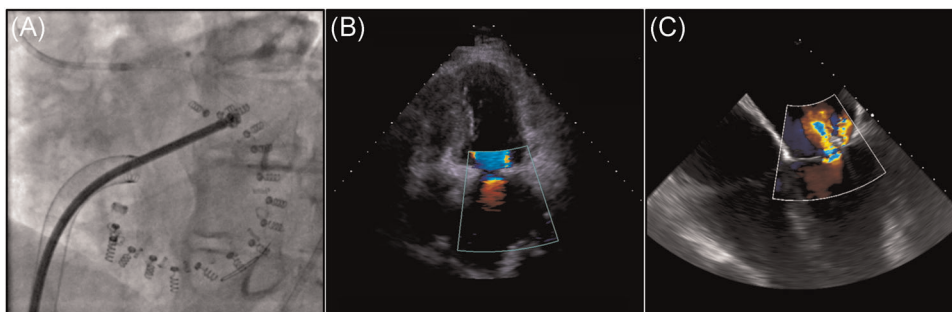
### 1.1.2 | Patient 2

A multimorbid 76-year-old male patient presented with severe FMR. His comorbidities included atrial fibrillation, hypertension, and adiposity as well as chronic renal failure and reduced ejection fraction.

After heart team discussion, the patient underwent Cardioband implantation. During the procedure, an iatrogenic circumflex artery occlusion was observed and consequently treated with implantation of drug-eluting stent (Figure 3A). TTE showed a mild MR with a rigid PML and a gradient of maximum 4/mean 1.5 mmHg (Figure 3B).

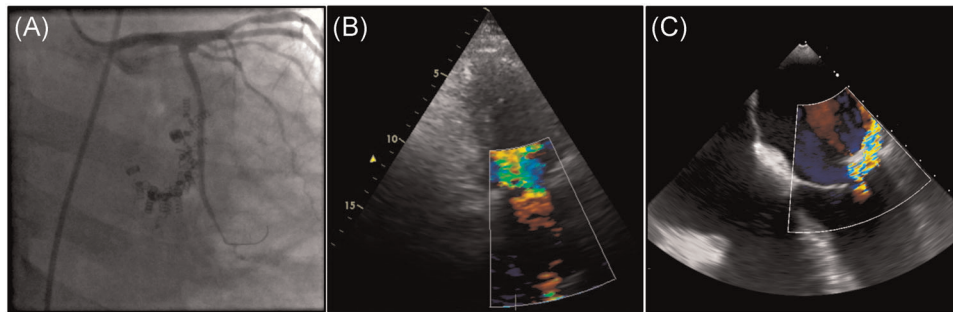
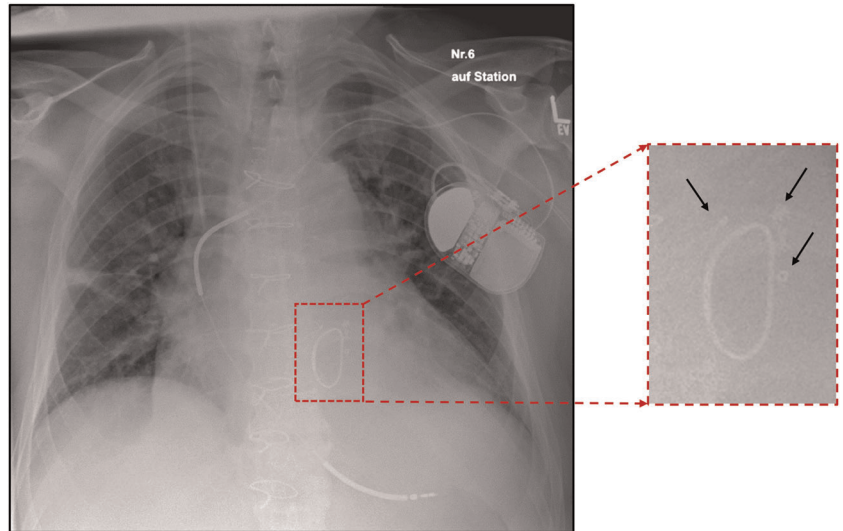
Eight months after the primary procedure, the patient was readmitted to hospital with dyspnea (NYHA-III), weight gain, and peripheral edema. TTE revealed moderate MR but no dysfunction of the Cardioband. Despite further intensive medical treatment, the symptoms persisted. TTE after 12 months revealed dislocation of the Cardioband resulting in severe MR (Figure 3C).

The patient underwent a high-risk operation requiring cardiopulmonary bypass. Intraoperatively, it was seen that the shear forces of the central Cardioband anchors located in the region of PML (specially across the P2 segment) caused extensive damage of the annulus (Figure 4A,B). Therefore, a repair was not possible, resulting in new implantation of biological MV (Medtronic Hancock 29 mm). As the previously implanted stent in the circumflex artery showed good patency, we abstained from an additional surgical intervention.



**FIGURE 1** The course of the first patient: angiogram in the left anterior oblique projection during the implantation of Cardioband showing the 16 anchors (A). Two-dimensional (2D) transthoracic echocardiogram showing a four-chamber view and color-flow Doppler of the mitral valve (MV) on the first postinterventional day demonstrating mild mitral regurgitation (B). 2D transesophageal echocardiography with a four-chamber view and color-flow Doppler of MV after 12 months showing severe regurgitation jets, one central and other near the dislocated Cardioband (C)

**FIGURE 2** Chest X-ray of the first patient. Chest X-ray in the anteroposterior view showing the remaining three Cardioband anchors after the surgical revision and implantation of the annuloplasty ring



**FIGURE 3** The course of the second patient: angiogram in right anterior oblique view with caudal angulation after the implantation of Cardioband with 16 anchors and drug-eluting stent placement in the circumflex artery (A). A 2D transthoracic echocardiogram image showing two-chamber view and color-flow Doppler of the mitral valve on the first postinterventional day demonstrating mild mitral regurgitation (MR) (B). Two-dimensional transesophageal echocardiography with four-chamber view and color-flow Doppler of the mitral valve after 12 months showing severe recurrent MR with dehiscence of the Cardioband (C)

The patient was stable with moderate inotropic support and could be successfully weaned from ventilator 12 h after surgery. Due to third-degree atrioventricular block, the patient received a DDD pacemaker. He was discharged with a good condition after 2 weeks. Echocardiography control after 6 months confirmed patency of all valves.

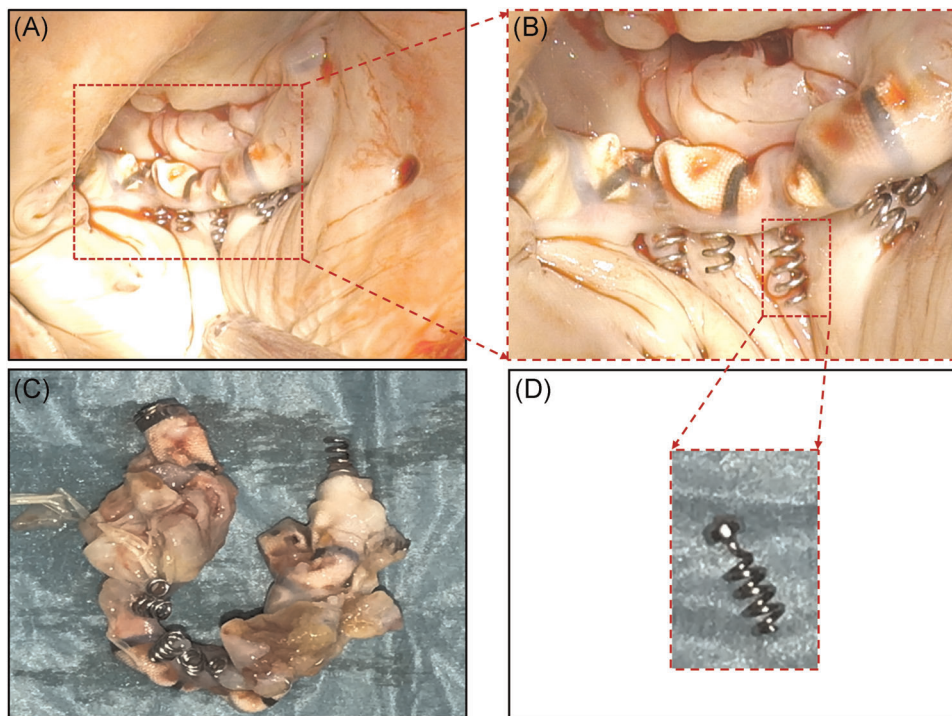
## 2 | DISCUSSION

In this report, we present two patients with late severe recurrent MR after Cardioband annuloplasty due to loosening of the anchor mechanism and subsequent tear of the Cardioband out of the annular tissue. Furthermore, we show two different treatment modalities for these patients. In general, repair of the MV with Cardioband annuloplasty has been reported to have good success rates. A multicenter study with 1-year follow-up of 60 patients who underwent Cardioband repair is published by Messika-Zeitoun et al.<sup>4</sup> They reported about anchor disengagement in 10 patients (17%); however, the time of occurrence was immediately after the implantation. Furthermore, six patients among those (10%) required further interventions to

correct the significant device insufficiency, but procedural details were not disclosed. Another report published by Carrel et al. described mitral valve replacement after cardioband dehiscence.<sup>5</sup>

With regard to our cases, we like to emphasize two aspects. First, postprocedural echocardiography and 6-month follow-up recorded no severe MR. Therefore, it can be assumed that in both the cases, the anchor disengagement appeared in the later stage, which accentuates the importance of careful re-evaluation in the first year even after successful postimplantation results. Second, the surgical strategy to re-repair the mitral valve should depend primarily on the extent of annular destruction. The Cardioband anchors should be unscrewed carefully when possible or left in situ to minimize the annular damage. Here, we show that successful reconstruction of the valve with surgically implanted annuloplasty rings is possible even after dehiscence of Cardioband, thereby achieving an effective leaflet coaptation and improved long-term results. However careful decision-making is of utmost importance when it comes to treatment options (repair vs. replacement).

Currently, the selection of the interventional treatment method (Cardioband, Mitraclip, etc.) for patients with MR depends mainly on expert consensus. Analogous to the TAVI procedure, development of



**FIGURE 4** Cardioband in situ: intraoperative image of the mitral valve and the dehiscent Cardioband at P2 level (A and B) with the dislocated anchors. The removed Cardioband with the anchors (C). One of the removed anchors (D)

established treatment pathways, especially after complications, is necessary for optimal results in interventional MR treatment. This will enable to select the most suitable and appropriate intervention method.

#### CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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