

EDITORIAL COMMENT

Leaflet Injuries After Percutaneous Edge-to-Edge Repair



A Challenge to Avoid*

Francesco Maisano, MD

Percutaneous mitral leaflet repair is one of the safest procedures in structural interventions, even when applied to very high-risk patients (1). Blossom et al. (2) report a case of torrential mitral regurgitation (MR) occurring after edge-to-edge transcatheter repair, a rare but important event that has somehow been under-reported in the medical literature for a number of reasons: it is rare, it is difficult to diagnose and handle, and until now, it is not well understood.

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Exactly 10 years ago, in an apparently routine working day, I was first confronted with the unexpected: a massive MR following an apparently successful MitraClip (Abbott Vascular, Santa Clara, California) implantation in a patient with secondary MR with an ejection fraction below 15% and torrential secondary MR at baseline. Following an otherwise uneventful grasping and clip closure, an immediate total resolution of the MR was observed. An echocardiography revealed a smoke effect, a sign with multiple possible interpretations. Mitral stenosis was excluded (the residual valve opening area was above 3 cm²), and the image was interpreted as the consequence of low-cardiac output and the abolition of the washing effect of the regurgitant jet into the left atrium. Soon

after, it was realized that the patient had developed severe afterload mismatch with low arterial pressure. For that reason, the anesthesiologist supported the patient with multiple doses of epinephrine. Finally, the patient responded with recovery of left ventricular function, which was shortly associated with severe systemic hypertension. Recurrent severe MR was observed, initially interpreted as the consequence of the increased afterload. Soon after, the systemic pressure decreased, but the pulmonary pressure increased significantly, with persistent severe MR. For the first time, technicians were confronted with the scenario of an intraprocedural leaflet perforation following catheter-based edge-to-edge repair (Figure 1) requiring immediate surgical bailout.

A few months previously, a commissural clip entanglement was encountered in an elderly patient with degenerative MR requiring open heart correction. After an uneventful valve replacement, the patient died a few days later of multiorgan failure due to frailty and comorbidities.

A RARE COMPLICATION THAT TRANSFORMS A LOW-RISK INTO A HIGH-RISK SCENARIO

It was learned that, although the MitraClip is usually safer than surgery, some complications may transform a simple procedure into a nightmare.

The first report of leaflet damage following percutaneous edge-to-edge repair was from the case of a patient who had undergone surgery in the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) trial (3). Few other case reports of leaflet injuries are present in the medical literature (3-8). More recently, data from the core laboratory events of the EXPAND (A Contemporary, Prospective Study Evaluating Real-world Experience of Performance and Safety for the Next Generation of MitraClip Devices) study revealed

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From the Department of Cardiac Surgery, University of Zurich, Zurich, Switzerland.

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that leaflet injuries occurred in a minority of cases: 4 of 1,030 patients (0.04%) (F. Asch et al., EURO PCR online course, personal communication, 2020). It must be noted that the site-reported frequency was slightly higher (11 of 1,030 patients [1%]), but the core laboratory could not confirm the diagnosis. Notably, of those 4 events, 3 were associated with the use of the recently released longer clip arm device (MitraClip XTR). A recent report from Praz et al. (9) described 2 cases of leaflet injury in an early multi-center experience with the XTR system, all requiring conversion to open heart surgery due to hemodynamic instability.

WHAT TO DO?

Leaflet injuries are difficult to diagnose. The initial step is to choose between a leaflet injury or residual MR due to residual lack of leaflet coaptation. Leaflet damage should always be suspected in cases of residual or worsening severe MR and worsening of the hemodynamic status. In the absence of residual primary lesions, residual severe MR is seen in patients with annular dilation (defined as annulus-to-leaflet mismatch [10,11]). To confirm leaflet injury, ad hoc imaging and multiplanar color comparison images could be necessary.

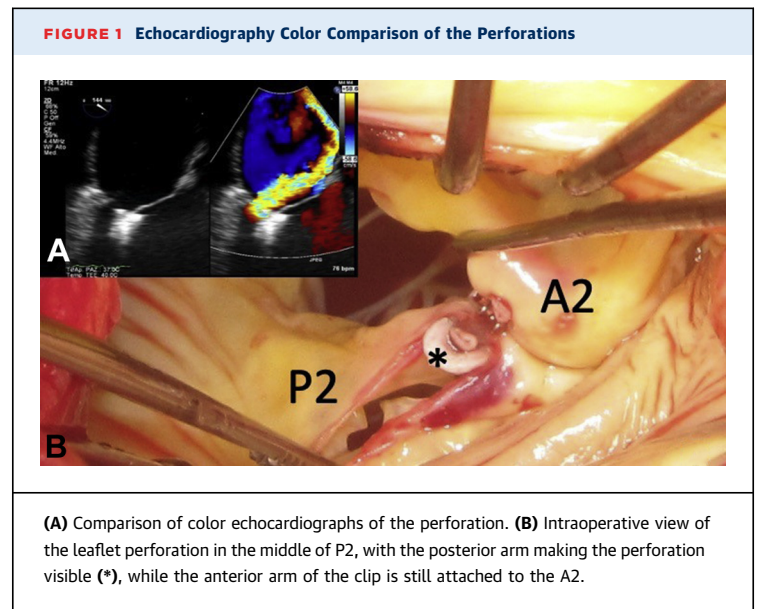
Once leaflet damage has been correctly diagnosed, the most definitive solution for patients experiencing leaflet injuries is open surgical repair or replacement (3), although replacement in some cases could be prohibitive. Conservative treatment is rarely possible unless leaflet injury is minimal. On most occasions, the hemodynamic consequences are not compatible with a delay in treatment. Rarely, an additional clip implantation can solve the issue, due to the lack of available tissue to grasp. However, the Pascal valve repair system (Edwards Lifesciences, Irvine, California) has solved for a damaged leaflet after a MitraClip XTR implantation attempt (6).

Another option, available only in cases of leaflet perforation, is deployment of vascular plugs (5). Although this solution can be extremely effective for solving the issue acutely, it can be complicated by hemolysis or delayed embolization. Therefore, it should be adopted with careful patient selection and preferably in cases of otherwise inoperable patients.

Finally, as suggested by Blossom et al., inoperable patients can be stabilized with advanced life support and referred to transplantation (2).

HOW TO PREVENT LEAFLET INJURIES

Leaflet injuries can be prevented by patient selection, device selection, and procedural care. In most cases,



leaflet tears occur in patients with extreme anatomies. Tissue fragility can be present, particularly in elderly and frail patients. Special care must be taken in patients with calcified annuli and thin leaflets. Severe tethering of the leaflets is also a possible risk factor for leaflet injuries. In that case, the tension on the tissue imposed by the device can cause a tear. The presence of annulus-to-leaflet-mismatch increases the stress acting on the leaflets. This was early demonstrated for the surgical Alfieri technique (12) and more recently confirmed from studies adapted to percutaneous leaflet repair (13,14).

Annuloplasty prior to leaflet repair could mitigate the risk under these conditions. Also, the selection of a shorter arm device (MitraClip NTR) could be preferable in these cases to reduce the longitudinal stress on the leaflets. Due to its nature (a memory alloy device), the Pascal platform could reduce the risk due to its intrinsic flexibility, although this assumption must be confirmed by clinical data.

Finally, leaflet injuries can be prevented by careful manipulation during grasping and closure of the clip arms in MitraClip. A common maneuver for the MitraClip is to push the clip delivery system toward the ventricle during clip closure to reduce the pressure on the leaflets from the tip of the clip arms.

CONCLUSIONS

Leaflet injuries transform a low-risk procedure into a challenging scenario. This complication should be known, prevented, and eventually managed carefully, using all the possible tools available, according

to patient presentation and characteristics, ranging from conservative treatments to the most definitive solutions including heart transplantation.

AUTHOR DISCLOSURES

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ADDRESS FOR CORRESPONDENCE: Prof. Francesco Maisano, Cardiac Surgery, University of Zurich, Pestalozzistrasse 3/5, CH 8091 Zürich, Switzerland. E-mail: francesco.maisano@uzh.ch.

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