

EDITORIAL COMMENT

Prevent, Identify, and Manage Complications to Keep Percutaneous Mitral Repair Procedures Safe*



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Avoiding and treating complications is a fundamental duty for any surgeon, but coping with complications is not always an easy task. In this issue of *JACC: Case Reports*, Shah et al. (1) report a case series of different complications that occurred during MitraClip (Abbott Vascular, Santa Rosa, California) procedures (1). Complications can be the consequence of inappropriate patient selection, inadequate device handling, or intra-procedural decision making, but they can also occur after a successful implant.

COMPLICATIONS DUE TO INAPPROPRIATE PATIENT SELECTION

Patient selection is key to achieving good outcomes. This has been best demonstrated by the opposite outcomes in 2 similarly designed trials on functional mitral regurgitation (MR), which produced infinite debates (2,3). Anatomic and clinical factors strongly influence the outcomes of percutaneous treatment.

The double orifice repair relies on mitral valve opening reserve, which can be impaired in patients with rheumatic or other inflammatory disease. The ongoing inflammatory disease may also induce evolution of the gradients. Shah et al. (1) report 1 case of increasing gradient after MitraClip implantation. This patient showed a pre-procedural gradient of

3 mm Hg, although the commissures were not fused and the leaflets did not look thickened. After clip implantation, there was residual MR and a gradient of 8 mm Hg. This outcome was considered acceptable, but in the follow-up, the patient remained symptomatic with increasing gradient and required open surgical treatment.

The issue of the acceptable threshold for intra-procedural gradient is debated. Failure to reduce the mean left atrial pressure is associated with ongoing symptoms (4), and it can be caused by residual regurgitation but also to increased gradients. When there is doubt, gradients could be assessed under fast pacing to evoke subclinical stenosis.

Greater effort should be made to achieve a compromise between MR reduction and increase of gradients: continuous pressure monitoring is now incorporated in last-generation leaflet repair technologies.

As an alternative to surgery, catheter-based replacement can be enabled by electrosurgical ablation of the tissue bridge (5).

ACCESS COMPLICATIONS

A wrong transseptal puncture can lead to intra-procedural challenges, and punctures outside of the fossa can induce tamponade. Tamponade was reported in 1.1% of patients in ACCESS-EU (A Two-Phase Observational Study of the MitraClip System in Europe) and in 1.8% in the TRAMI (German Transcatheter Mitral Valve Interventions) registry (6). Transesophageal echocardiography (TEE)-guided puncture mitigates but does not abolish the risk. Tamponade can occur in the case of a misleading TEE image: for example, in the presence of pacemaker lead artifacts. If a lead lies on the fossa, the surgeon can be fooled by a false image of tenting and push the

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**ABBREVIATIONS
AND ACRONYMS****MR** = mitral regurgitation**TEE** = transesophageal
echocardiography

needle in a wrong position. It is recommended to check the fossa anatomy before needle maneuvers and to follow needle position thoroughly during the manipulations. In presence of floppy septum, uncontrolled movements of the transseptal system toward the roof of the left atrium or the appendage may provoke lesions. Delayed tamponade can also occur in the case of posterior punctures (often needed to gain height). The transseptal-related complication reported by Shah et al. (1) is also not uncommon. Thrombi can be seen before or immediately after transseptal puncture and advancement of the delivery system. The root cause can be either local to or dislodgement of thrombotic material from the iliofemoral venous compartment. The first event can be prevented by administration of heparin (2,000 IU, up to half the dose planned to reach the working activated clotting time) right after the venous access puncture. The value of administering heparin before puncture could even be stronger for less experienced surgeons who require longer times and multiple attempts before locating the intended puncture location. Mobilization of thrombotic material from the venous system can be avoided only by ad hoc imaging, to be carried out in patients with a history of venous thromboembolic disease. In case thrombi appear on the tip of the catheters, careful aspiration is sometimes efficacious.

Venous access complications are also not uncommon, ranging from hematomas, bleeding, and—in the worst-case scenario—large fistulas. Echocardiography-guided puncture is today recommended to avoid complications.

**COMPLICATIONS RELATED TO DEVICE
HANDLING AND INTRAPROCEDURAL
DECISION MAKING**

MitraClip involves the manipulation of large-bore catheters within the left atrium. The device has been designed to be retrievable; however, careful handling is necessary to avoid mechanical complications.

Shah et al. (1) report a case of single leaflet attachment (SLA). The rate of SLA in the initial experience was 9% (7), and it decreased in the more recent registries to 2% (6). SLA is usually due to improper implantation (insufficient leaflet insertion in the clip) and is higher in patients with degenerative mitral regurgitation and extreme anatomies. Alternative leaflet events are less frequent, including tears and perforations (difficult to diagnose and to treat) or

other lesions (distortions, leaflet or chordal entanglement, chordal ruptures, etc.).

To prevent leaflet events, TEE guidance is key. Any movement should be guided by TEE to avoid complications like leaflet entanglement or perforations. A proper transseptal puncture location is key to achieving a coaxial approach and enough height to facilitate grasping. Coaxiality also improves control of the clip during the maneuvers, whereas fluoroscopy can be used to avoid clip rotations (and asymmetric grasping). TEE can assess leaflet insertion (there are different methods) but also to identify other predictors of delayed detachment. As an example, in the presence of newly directed jets or increased regurgitation after temporary clip closure, asymmetric implant should be ruled out. Asymmetry induces distortions difficult to correct and can be associated with delayed leaflet rupture.

Before clip release, the decision to accept or to modify the grasp is based on a multifactorial algorithm including TEE and hemodynamic guidance. The judgment requires a true team effort involving the surgeons, imager, and anesthesia team. TEE is used to assess leaflet insertion (for durability), symmetry of implantation, residual MR, and gradient. Continuous monitoring of the left atrial pressure could implement the information from Doppler echocardiography (4).

SLA can usually be treated with additional clip implantations, whereas other leaflet events are more difficult to correct.

LATE EVENTS

Device-related adverse events are rare after 6 months from the index procedure (8): they include endocarditis and, as mentioned, rare cases of increasing gradients.

The authors report a case of endocarditis post-MitraClip requiring open surgery, with a dismal outcome. Asmarats et al. (9) found only 12 cases in a systematic review on the topic. Patients were at high risk (EuroSCORE II 45%), the most common microorganism was *Staphylococcus aureus*, and surgical management was the most common solution. The mortality associated with the infective endocarditis overall was 42%. Proper sterility and careful handling of the implantable devices is important, together with an institutionally driven prophylactic antibiotic regimen.

Although the MitraClip remains a low-risk procedure, its safety strongly depends on prevention,

prompt diagnosis, and management of eventual complications in a team effort.

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REFERENCES

1. Shah MA, Dalak FA, Alsamadi F, Shah SH, Qattee MB. Complications following percutaneous mitral valve edge-to-edge repair using MitraClip. *J Am Coll Cardiol Case Rep* 2021;3:370-6.
2. Obadia JF, Messika-Zeitoun D, Leurent G, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. *N Engl J Med* 2018;379:2297-306.
3. Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med* 2018;379:2307-18.
4. Kuwata S, Taramasso M, Czopak A, et al. Continuous direct left atrial pressure: intra-procedural measurement predicts clinical response following MitraClip therapy. *J Am Coll Cardiol Interv* 2019;12:127-36.
5. Lisko JC, Greenbaum AB, Guyton RA, et al. Electrosurgical detachment of MitraClips from the anterior mitral leaflet prior to transcatheter mitral valve implantation. *J Am Coll Cardiol Interv* 2020;13:2361-70.
6. 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 Transcatheter Mitral Valve Interventions (TRAMI) registry. *Catheter Cardiovasc Interv* 2015;86:728-35.
7. 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.
8. Feldman T, Kar S, Elmariah S, et al. Randomized comparison of percutaneous repair and surgery for mitral regurgitation: 5-year results of EVEREST II. *J Am Coll Cardiol* 2015;66:2844-54.
9. Asmarats L, Rodriguez-Gabella T, Chamandi C, et al. Infective endocarditis following transcatheter edge-to-edge mitral valve repair: a systematic review. *Catheter Cardiovasc Interv* 2018;3:583-91.

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