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EDITORIAL COMMENT

Clip It, Cut It, and Then Replace It

ELASTA-Clip for Failed MitraClip*

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Mitral regurgitation (MR) is the most common heart valve disease worldwide and vastly undertreated (1). Transcatheter edge-to-edge repair with the MitraClip (Abbott Vascular, Santa Clara, California) is currently approved by the U.S. Food and Drug Administration for primary MR (when surgical risk is prohibitive) and for secondary MR. With these indications, more than 100,000 MitraClips have been implanted worldwide. MitraClip was invented on the basis of the concept of the Alfieri stitch to achieve the best results in the A2-P2 location. Mitral valve anatomy is complex, and not all anatomies are optimal for MitraClip placement. In the TVT (Transcatheter Valve Therapy) Registry, about 15% of MitraClips were placed in A1-P1 or A3-P3 locations (2). In addition, the presence of mitral leaflet calcification (20%) and mitral annular calcification (35%) may affect procedural success. In a national sample, a total of 6.5% patients had grade 3+ or 4+ MR post-procedure, and 26% had grade 2+ MR (2). In the COAPT trial of patients with secondary MR, 7.4% had grade 3+ or 4+ residual MR at 30 days (3). Significant residual MR after MitraClip implantation is associated with increased mortality and heart failure hospitalizations and worse quality of life (4,5).

Residual MR after MitraClip can be treated in multiple ways: 1) repeat MitraClip implantation can be performed if the transvalvular mean gradient and valve area permit; 2) commissural MR can be treated with plugs (6); 3) intraclip MR can be treated with the Amplatzer Vascular Plug or Amplatzer Duct Occluder (St. Jude Medical, St. Paul, Minnesota) (7); 4) investigational transcatheter annular reduction therapies can be undertaken; or 5) cardiac surgery can be performed. Unfortunately, many patients with significant residual MR are not eligible for these options, because of a high mitral diastolic gradient, the anatomic location of residual MR, or prohibitive risk of cardiac surgery. Transcatheter mitral valve replacement (TMVR) is an emerging solution for patients with MR and is currently being investigated in multiple trials. However, the creation of a bridge between the anterior and posterior leaflets with a MitraClip has eliminated, to date, the option of TMVR.

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In this issue of *JACC: Cardiovascular Interventions*, Lisko et al. (8) describe a novel transcatheter approach to solve this issue: electrosurgical laceration and stabilization of failed MitraClip(s) (ELASTA-Clip). Transcatheter electrosurgical techniques were used to lacerate the anterior mitral leaflet, resulting in a central orifice and a posterior leaflet with attached MitraClip(s). This facilitated the placement of a Tendyne TMVR device (Abbott Vascular) through transapical access, pinning the posterior leaflet and retained MitraClip(s) between the myocardium and new valve. First described by Sorajja et al. (9) in a single patient in 2019, ELASTA-Clip followed by TMVR was performed successfully in this single-center study in 5 patients with prohibitive surgical risk. An intra-aortic balloon pump was placed preemptively in each case for hemodynamic support. The median duration from laceration to TMVR was

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20 min, and the median duration of the whole procedure was 205 min. There were no deaths, left ventricular outflow tract obstruction, need for emergent cardiac surgery, or strokes during the procedure. Two patients had hemothorax during the hospital stay requiring surgical intervention. Echocardiographically, there was no central MR; however, 2 patients had mild to moderate paravalvular leaks (PVLs) at discharge. These PVLs progressed to moderate at 30 days in both patients. At 30 days, all patients were alive; 4 were living independently and 1 remained in a rehabilitation facility. One patient had a stroke (although its relationship to the mitral procedure was unclear), and 1 had significant bleeding after a fall on therapeutic anticoagulation, requiring thoracentesis.

With expanding indications and an increasing number of MitraClips implanted, viable and broadly applicable solutions to tackle residual MR are needed. ELASTA-Clip is a welcome new tool and offers a possible solution in patients with residual or recurrent MR after MitraClip implantation. Using their experience in transcatheter electrocautery techniques (10), the investigators have developed a promising solution to convert the double orifice into a single orifice. For operators who are experienced in the BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent coronary artery obstruction) and LAMPOON (intentional laceration of the anterior mitral leaflet to prevent left ventricular outflow obstruction) techniques, this novel method will likely be replicable and achievable. Development of dedicated devices will make it even more feasible.

As with every new technique and procedure, there is a learning curve and unknowns. There are multiple factors that need to be considered before it can be more broadly applied in clinical practice. In the present study, transapical access led to complications in 2 patients. Although the Tendyne valve has specific characteristics that may favor ELASTA-Clip, it will be interesting to see if one of the transseptal TMVR devices can achieve similar results with pinning of the posterior leaflet and MitraClip(s). The impact of retained MitraClip(s) on the long-term function of the subsequently placed bioprosthetic valve and risk for thrombosis due to extra hardware in the mitral position must be determined with longer follow-up and a larger sample size. The new iterations of the MitraClip with longer and wider clip arms may also affect the feasibility of this approach and the risk for damage to adjacent cardiac structures. How the size, shape, and function of the left ventricle affect the feasibility and complications of this approach also warrants further study.

A cautionary note was the occurrence of moderate PVLs in 2 of 5 patients at 30 days. Very plausibly, the investigators attribute this to undersizing of the mitral valve prostheses rather than retained MitraClips. Given the changes in the mitral orifice area and dimensions resulting from breaking the anterior-posterior tissue bridge, algorithms for valve sizing in TMVR may need to be adjusted when ELASTA-Clip is planned. Experience will determine how predictable these geometric changes (and their implications for proper valve sizing) may be.

Initially, as experience grows and potentially adverse consequences are identified, the procedure should be limited to patients who are at prohibitive risk for cardiac surgery and mitral valve replacement. Potential candidates must be carefully evaluated to ensure that all criteria for successful TMVR (e.g., valve sizing, risk for left ventricular outflow tract obstruction) are met. At this juncture, these restrictions will limit the number of potential candidates for ELASTA-Clip, but as the procedure becomes more predictable and reproducible and as TMVR devices and sizing evolve, the number of candidates for this approach to address significant residual or recurrent MR after MitraClip could substantially increase.

ELASTA-Clip offers a novel approach to facilitate TMVR for significant residual MR after MitraClip. If and when this technique is perfected, it may influence how clinicians think about applying their toolbox to the treatment of MR. Given the low procedural risks associated with MitraClip placement, one may decide to attempt MitraClip implantation first, even if valve anatomy is less than ideal, anticipating that it could be clipped and then cut and replaced if residual MR is significant. Although randomized trials involving this technique are difficult to envision at this stage, a multicenter registry of these cases among a core group of operators and institutions will be instrumental to shorten the learning curve, understand potential complications, inform technique innovation, and facilitate the sharing of best practices.

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