State of the Art of Transcatheter Mitral Annuloplasty: Present and Future

An appraisal of current and upcoming devices for direct and indirect transcatheter annuloplasty procedures.

BY SHINGO KUWATA, MD, PHD, AND FRANCESCO MAISANO, MD

Mitral annular remodeling with mitral valve (MV) annuloplasty is the most commonly performed technique to surgically treat mitral regurgitation (MR) and is frequently encountered in clinical practice. Surgical MV annuloplasty is the gold standard to treat degenerative MR. This technique works well because an undersized annuloplasty ring increases leaflet coaptation length and reduces structural strain on valvular tissue in functional MR (FMR).[1] During surgical MV repair, annuloplasty is performed either alone or in conjunction with artificial chords, leaflet resection or augmentation, closure of perforations or clefts, and edge-to-edge repair. Transcatheter approaches to annuloplasty would be needed if transcatheter mitral repair is to reach its full potential. Transcatheter MV annuloplasty is the most surgical-like alternative option to treat MR in high-risk patients.

With the availability of transcatheter mitral annuloplasty, CT has become an essential imaging tool in defining patients' anatomy and eligibility for mitral annuloplasty. Because it offers a comprehensive assessment of the real three-dimensional anatomy, CT allows assessment of the MV anatomy as well as the surrounding structures. In certain preprocedural evaluations, there is a need to identify the target zone of the implant; assess the angle between aortic valve and the MV plane; measure the distance between the coronary artery, coronary sinus (CS), and the valve annulus; and evaluate the risk of injury to surrounding structures. It is also occasionally necessary to obtain detailed measurements of the target zone to implant the ideal annuloplasty device.

Different annuloplasty devices complete the wide spectrum of repair technologies, but only limited clinical data are available at this time. Heart teams dedicated to transcatheter mitral therapies should become expert in selecting solo annuloplasty or a combination procedure to improve outcomes and increase the number of patients who are potentially eligible for transcatheter mitral therapies.

INDIRECT TRANSCATHETER ANNULOPLASTY DEVICES

Indirect annuloplasty devices are based on the anatomic proximity of the CS to the posterior mitral annulus. This approach is particularly attractive because the cannulation of the CS is an easy and reproducible venous access technique.[2]

The Carillon mitral contour system (Cardiac Dimensions, Inc.) (Figure 1A) is the only indirect device that has obtained CE Mark approval. There have been several modifications of the device to improve its safety and efficacy, as

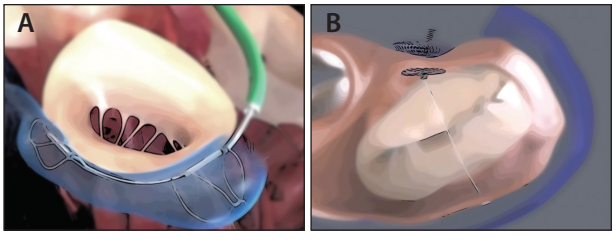

Figure 1. Clinical devices used for indirect transcatheter mitral annuloplasty. Carillon mitral contour system* (A); the Arto system (B). *CE Mark approved.

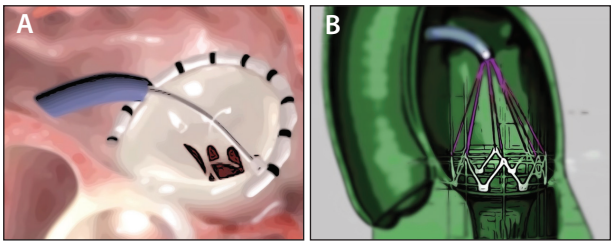

Figure 2. Clinical devices used for antegrade direct annuloplasty. Cardioband mitral system* (A); the Iris device (B). *CE Mark approved.

initial results with this approach have not been satisfactory mainly due to suboptimal efficacy and the risk of delayed complications.[3-6] The Arto system (MVRx, Inc.) (Figure 1B) is another indirect transcatheter system for treating FMR. The mechanism of the device consists of a suture that connects interatrial-septal and CS anchors. This suture is tensioned to shorten the anteroposterior diameter of the mitral annulus, thereby improving mitral leaflet coaptation and reducing FMR.[7]

Anatomic assessment of the CS, coronary artery, and mitral annulus relationship is crucial before considering the use of these devices due to the risks of coronary artery compression and device dislocation.

DIRECT ANNULOPLASTY DEVICES

The Cardioband mitral system (Edwards Lifesciences) (Figure 2A) is the closest transcatheter device to a surgical prosthetic ring. A surgical-like, adjustable Dacron band is deployed on the atrial side of the posterior mitral annulus from lateral trigone to medial trigone by a transseptal approach.[8,9] A clinical study of Cardioband has shown the safety and efficacy of the device during the 6 months following treatment.[10] Cinching of the implanted Cardioband significantly reduced the annular septolateral dimension and MR and also showed significant improvement in functional status after 6 months.

The Iris device (Millipede, Inc.) (Figure 2B) is being developed as a catheter-delivered complete ring device that mimics surgical annuloplasty via a transseptal approach. The ring is anchored to the annulus, resulting in size adjustment of the annulus. Although only small clinical experiences exist as of now, the devices have shown no interference with electrical conduction nor trouble with anchoring, according to previous report.

The Mitralign percutaneous annuloplasty system (Mitralign, Inc.) (Figure 3A) allows for retrograde placement of MV annular pledgeted sutures to achieve annular size reduction. The pledgets are placed and cinched on the mitral annulus, thus reducing annular circumference.[11] Nickenig et al have reported initial 6-month safety and clinical outcome results of 71 patients using the Mitralign system.[12] The procedure significantly reduced anteroposterior and septolateral dimensions and also induced reverse left ventricular remodeling. The Mitralign system has received CE Mark approval to treat FMR but is not available for sale in the United States.

Amend (Valcare Medical) (Figure 3B) is a different transcatheter MV annuloplasty ring with a semirigid, D-shaped ring, which is delivered via transapical approach. It is designed to stabilize the mitral annulus, reduce the septolateral dimension of the native valve, improve leaflets coaptation, and reduce MR.[13]

The AccuCinch system (Ancora Heart, Inc.) (Figure 3C) has a different concept, with spaced anchors in the basal left ventricular subannular space to reduce the basal left ventricle and mitral annular dimensions.[14]

CONCLUSION

Patients with severe MR who are very ill and cannot undergo conventional surgical intervention can successfully be treated with transcatheter intervention. The long-term durability and effectiveness of annuloplasty devices remain unclear, requiring additional study of larger patient cohorts with longer-term follow-up to definitively determine the future of this class of devices.

Surgical experience has shown that recurrence of MR after valve repair is higher in the absence of concomitant annuloplasty.[15] In selected cases, such as in those with a

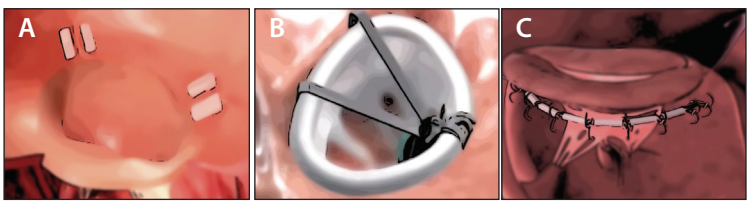

Figure 3. Clinical devices used for retrograde direct annuloplasty. Mitralign percutaneous annuloplasty system* (A); Amend annuloplasty ring (B); AccuCinch system (C). *CE Mark approved.

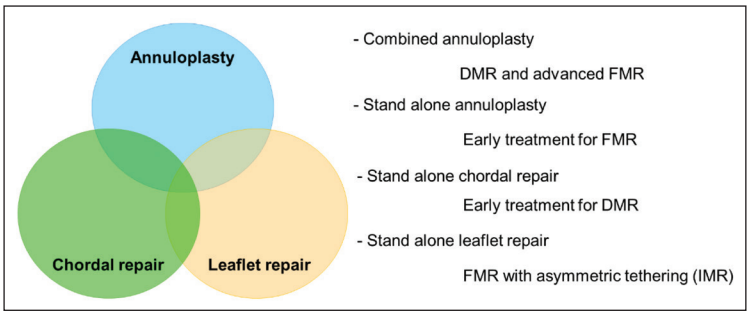

Figure 4. Complementary role of transcatheter intervention. DMR, degenerative mitral regurgitation; IMR, ischemic mitral regurgitation.

high risk of recurrence, transcatheter annuloplasty should be considered as a first-line procedure because a major advantage of this approach is maintaining the potential for future open intervention. Specific algorithms with detailed indications will be required to guide the optimal treatment for each patient (Figure 4). Simplified algorithms to define the complementary role of the different solo or combined transcatheter mitral therapies are also needed. The role of the combination of different repair devices (leaflet or chordal plus annular repair) has to be defined in selected patients. In a few years, this safe and low-commitment approach may drive a shift toward earlier intervention for MR in heart failure patients. ■

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Shingo Kuwata, MD, PhD
University Heart Center Zurich
University of Zürich
Zürich, Switzerland
Cardiology Department
St. Marianna University School of Medicine
Kanagawa, Japan
shingo.k.571019@gmail.com
Disclosures: None.

Francesco Maisano, MD
Division of Cardiovascular Surgery
University Hospital Zürich
Zürich, Switzerland
francesco.maisano@usz.ch
Disclosures: Consultant for Abbott Vascular, Edwards Lifesciences, Medtronic; cofounder of 4Tech.