Editorial

Direct annuloplasty: where are we at and where are we heading?

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Mitral annular dilatation plays an important pathophysiologic role in patients with both primary and secondary mitral regurgitation (MR). Traditional treatment with surgical mitral annuloplasty (SMA) serves to restore the size and shape of the mitral annulus, maintain long-term annular reduction and provide functional annular support. SMA is a well-established adjunctive tool, in addition to plication, resection, etc., for primary MR and improves the durability of the repair (1). The clinical benefit of SMA in the treatment of secondary MR is much less certain, continually debated and likely dependent on the pathology involved (i.e., ischemic versus non-ischemic) along with anatomic selection criteria (e.g., degree of tethering, leaflet angles, tenting area and inter-papillary muscle distance) (1).

Since the advent and ultimately, the success of transcatheter edge-to-edge repair (TEER), there has been interest in expanding the transcatheter mitral toolbox (TMT) with "surgical-like" techniques/devices, such as annuloplasty, chordal replacement and/or complete valve replacement for the treatment of symptomatic MR. The interest in increasing the breadth and depth of the TMT is driven primarily by the desire to: (I) improve durability and efficacy of stand-alone TEER and, (II) shift towards treating moderate- and lower-risk patients; however, unless the device(s)/procedure(s) can be reliably reproduced, carry a favorable safety profile and, provide short and long-term outcomes similar to surgical treatment options, this shift will not occur.

At present there are many manufacturers with devices under various stages of development competing to stack the TMT. Intense efforts are currently being applied towards transcatheter direct annuloplasty devices (TDAD), whereby a ring (partial or complete) is implanted into the mitral annulus in a manner similar to surgery. Once implanted, the rings are then designed to reduce the annular dimensions to mimic a surgical reduction annuloplasty. The two leading contenders for TDAD are both transfemoral-transseptal systems. The first system introduced was the Cardioband incomplete annuloplasty ring (Edwards Lifesciences, Nyon, CA, USA) (2). The system works with implantation of individual anchors around the mitral annulus (from lateral to medial) guided by fluoroscopy and trans-esophageal echocardiography. Once anchors are secured into the annulus, the incomplete ring is "cinched down" to achieve annular reduction. Despite early enthusiasm, published one-year results (in sixty patients) were somewhat disappointing, with acute procedural success rates of only 68%, more than 30% of patients with moderate or more MR and many patients requiring re-intervention within the one-year follow-up (2). Additional reports indicated approximately 6% of patients experienced coronary artery injures as a result of anchor interaction during deployment and/or contraction.

As of this publication, the manufacturer has abandoned further development of this system for the mitral valve in lieu of these findings and is slated to be redesigning the implant. The second contender for a TDAD is the Millipede annuloplasty ring (Millipede Inc., Santa Rosa, CA, USA) which is a semi-rigid complete (closed) ring. In its original description, the ring carries eight retractable and adjustable helical anchors which are inserted into the mitral annulus under direct visualization with the aid of an integrated intra-cardiac echo. Once the anchors are secured, sliding collars are "actuated" to reduce the distance between adjacent anchors. In this manner, the reduction annuloplasty is "customizable" to the final annular dimensions based on the patient specific needs. A total of seven patients have been treated to date (surgical and by transcatheter

delivery) with initial promising results (100% with MR of 1+ or less at 30 d) and favorable safety profile (3). An early feasibility study is underway and further data regarding reproducibility, safety and efficacy are eagerly awaited.

To date, other unique and "out of the box" transcatheter approaches for mitral annular reduction have been formulated and, in some cases, clinically tested [e.g., indirect annuloplasty, annular plication (Mitralign, Tewksbury, MA, USA), ventriculoplasty (Accucinch, Santa Clara, CA, USA); apical annuloplasty delivery (AMEND, Herzlyia Pituach, Israel), etc.]. None so far have reached the safety and reliability bar set forth by regulatory agencies before heading towards assessment as part of a pivotal trial to determine efficacy (4). Furthermore, as none of these approaches mimic an established surgical treatment option, they are unlikely to succeed and currently do not warrant an exhaustive discussion at this time.

In the decades to come, we will look back at this time period as the early era of transcatheter therapy for mitral valve interventions. This is a phase of intense design and device development followed by redesign and redevelopments. As such, the established TMT is currently light with only the TEER device(s). TDAD are poised to take hold as the technology matures. In the years to come we will see increasing device iterations and clinical data demonstrating reproducibility and safety. Additionally, we will see a plethora of clinical trials with TDAD utilized in isolation and/or in conjunction with other TMT devices in efforts to customize treatment options based on the pathologic anatomy present. Many uncertainties remain as to who they will benefit and how, as well as the indications for the intervention. It is certain that novel devices or technologies will continue to surface in this ever-complicated patient and anatomic landscape.

Ultimately, the currently suggested clinical questions, in evaluating the role for TDADs, include:

(I) In patients with primary MR at prohibitive risk for surgical repair, does addition of TDAD to TEER result in improved durability of the MR reduction? Does it lead to survival benefit?

(II) In patients with primary MR at moderate-risk for surgical repair, is addition of TDAD to TEER non-inferior to surgical treatment with respect to symptom improvement, freedom from MR, and overall survival? What about in low-risk patients?

(III) Which anatomic functional mitral regurgitation (FMR) subgroup clinically benefits from catheter-based annuloplasty reduction in addition to guideline-directed medical therapy?

(IV) In patients with FMR with COAPT like clinical and anatomic criteria, is catheter-based annuloplasty additive or non-inferior to TEER?

(V) Can TDAD provide additive benefit to TEER in Mitra-FR subgroup of patients?

(VI) In atrial FMR, can TDAD lead to superior MR reduction *vs.* TEER alone?

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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