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Percutaneous repair of Mitral Valve Repair – the newer options

Muhammad Hafizullah

Cardiology Department, Lady Reading Hospital, Khyber Medical University Peshawar-Pakistan

Address for Correspondence:

Dr.Muhammad Hafizullah

Professor,

Department of Cardiology Lady Reading Hospital & Vice Chancellor Khyber Medical University, Peshawar - Pakistan

Email:mhu5555@gmail.com

Mitral valve apparatus is a complex and pathology of anyone of mitral valve annulus, leaflets, papillary muscle, chordae tendineae, LV, or left atrium (LA) can all produce or contribute to Mitral regurgitation (MR). 1MR is a common valvular disease, being present in 24% of adults with valvular heart disease and in 7% of the population \geq 75 years of age in the West. $^{2.3}$ In the EuroHeart survey, degenerative and functional etiologies accounted for 61% and 7%, respectively 2 . However, local data supports rheumatic disease at a greater prominence (up to 50%) in the developing world but this has a low probability of repair. $^{4-6}$ Patients presenting with symptomatic severe MR or asymptomatic severe MR with left ventricular (LV) dysfunction or enlargement require intervention - being surgical in a majority of cases. 7 Efforts have been underway to treat severe degenerative MR with mitral valve repair (MVRe) as against mitral valve replacement (MVR) as it produces superior outcomes. $^{8.9}$

Last decade witnessed strides of developments in the field of percutaneous repair of mitral valve targeting leaflets (percutaneous leaflet plication, percutaneous leaflet coaptation, percutaneous leaflet ablation), the annulus (indirect: coronary sinus approach or an asymmetrical approach; direct: true percutaneous or a hybrid approach), the chordae (percutaneous chordal implantation), and the LV (percutaneous LV remodeling). 10

Percutaneous Leaflet Plication (Edge-to-Edge Leaflet Repair): This is based on the surgical Alfieri technique 11 , which approximates the anterior and posterior leaflets together with a suture, creating a "double orifice". This reduces MR by re-establishing leaflet coaptation. This technique is most suitable for degenerative MR, although it can be employed in functional MR. MitraClip system employs a steerable catheter via transseptal access to deliver a clip to the anterior leaflet and posterior leaflet. The safety and feasibility study (EVEREST I) showed that procedural success was achieved in 74% with <1% in-hospital mortality. At 1-year, freedom from death, MV surgery or MR $>\!2+$ was 66%. 12,13 MitraFlex, deploys a clip to the leaflets via the transapical route, is undergoing pre-clinical testing. The major limitation is that the basic surgical technique is used with annuloplasty, as results without annuloplasty have been suboptimal. 14

Leaflet Ablation: Radiofrequency energy is delivered to the leaflet(s) to cause fibrosis or reduced motion through structural and functional alteration. This technology is designed to target degenerative MR. Thermocool irrigation ablation electrode is a radiofrequency ablation (RFA) catheter that gains access retrogradely into LV. It has been tried in animal models with limited success. ¹⁵ Limiting factor being uncontrolled scarring and fibrosis from RFA.

Indirect Annuloplasty: This approach mimics surgical annuloplasty rings, which are commonly used for repair of both degenerative and functional MR. These percutaneous devices might thus offer an alternative for those patients at excessive surgical-risk or who do not require another concomitant cardiac surgical procedure. ¹⁶

Coronary Sinus Approach (CS Reshaping): This involves implantation of devices within

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the CS which push the posterior annulus anteriorly reducing the septal-lateral dimension of MA. Carillon Mitral Contour System, consisting of self-expandable nitinol distal and proximal anchors connected by a nitinol bridge, is placed in the great cardiac vein and proximal CS via a catheter-based system. A feasibility study showed modestly reduced septal-lateral dimension and MR.¹⁷ These devices shrink the MA only indirectly by traction on the LA wall. The annulus might in fact continue to dilate, reducing device effectiveness. There is potential risk of these devices compressing a coronary artery. It has been demonstrated that a diagonal or ramus branch crossed between the CS and MA in 16% of patients, whereas it was between 64% and 80% for the left circumflex artery. 18,19

Asymmetrical Approach: This uses the proximity of CS to Mitral annulus to reshape MA and exert force on a portion of LA or right atrium, resulting in asymmetrical forces. The aim is to reduce septal-lateral dimension and decrease MR. Further device development, however, has been abandoned. ²⁰

Direct Annuloplasty using Percutaneous Mechanical Cinching Approach: This reshapes MA directly approaching MA from either side. Sutures or some other device are implanted onto the MA itself and used to directly "cinch" the MA. Mitralign device and Accucinch Annuloplasty System have been used to cinch posterior annulus circumferentially from trigone to trigone with improvement in MR. These technologies might be able to address the potential limitations of the indirect annuloplasty method and can be most useful for functional MR.

Direct Annuloplasty employing Percutaneous Energy-Mediated Cinching Approach: Heat energy is applied to MA, causing its scarring and shrinkage. QuantumCor, ReCor Mitralign and Accucinch devices have been used with variable success and await further trials. 21

Direct Annuloplasty using Hybrid Approach: An annuloplasty ring is implanted surgically and can be subsequently adjusted via transseptal access if MR recurs or worsens. The Adjustable Annuloplasty Ring is implanted surgically and can be adjusted with a mechanical rotating cable, whereas the Dynamic annuloplasty Ring System which recently had FIM results, is adjusted with radiofrequency energy.²²

Chordal Implantation: Synthetic chords or sutures are implanted either from transapical or transseptal approach and anchored onto the LV myocardium at one end, with the leaflet at the other. The length of the chord is then adjusted to achieve optimal leaflet coaptation and reduce MR. There are 3 devices currently in development: the transapically delivered MitraFlex and NeoChord devices, and the transapical-transseptal route Babic device. Limitations are residual leaflet prolapse (artificial chords too long) or leaflet restriction (chords too short) and residual MR and device thrombus formation. 1,23

Percutaneous MVR: Despite the armamentarium available to surgeons surgical MVRe is not possible or fails, and MVR is required. ²⁴ In the future, the new technology of percutaneous MVR might prove to be an attractive alternative in a selected group of patients with a low probability of successful repair. There are 3 devices in development - Endovalve-Herrmann prosthesis, Lutter prosthesis and CardiAQ prosthesis. They are in pre-clinical development and considering the complexities involved with this approach, further improvements will be required before clinical testing. ²⁵

The experience dictates that annuloplasty is the mainstay technique employed for functional MR and leaflet repair for degenerative MR. No single percutaneous technique is going to be successful in all patients requiring intervention for MR. A combination of percutaneous techniques will most likely be needed if results comparable to surgery are expected. In addition, it has to be borne in mind that certain pathologies (rheumatic, endocarditic, inflammatory, and so forth) are often not repairable hence limited role for current age percutaneous techniques. Therefore, current percutaneous options might be useful only in a selected patient pool.

The field of percutaneous transcatheter MVRe is expanding exponentially. Of the current techniques available Percutaneous edge-to-edge leaflet repair has been shown to be noninferior to surgery in randomized trials. Most other technologies—including various direct and indirect annuloplasty and LV remodeling devices—have achieved first-in-man results or are in pre-clinical testing. Most likely a combination of these technologies will be required for satisfactory MVRe. The need for a cautious approach to percutaneous MVRe is further emphasized by the excellent results of surgical repair and the low perioperative mortality. ²⁶ Even with current techniques and development, for many patients repair is not possible hence MVR will be required. Although there are significant challenges, several percutaneous MVR prototypes are already in development and may see further refinement in technique and claim higher success rate.

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