

# Transapical beating-heart mitral valve repair using a cordal implantation device— are we ready to open our minds?

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Mitral valve (MV) disease is one of the most prevalent of heart valve disorders in the world with about 2% of the population living with significant mitral regurgitation (MR) (1). Degenerative MR is the most common indication for MV surgery in North America (2). Although surgical repair or replacement remains the most common intervention on the MV, minimally invasive and percutaneous options are emerging as viable alternatives in select patient populations. This is fuelled by the rapid evolution and success of transcatheter therapies on the aortic valve.

Gammie *et al.* (3) report the first-in-human clinical experience of a transesophageal echocardiography (TEE)-guided transapical beating-heart MV repair using a preformed expanded polytetrafluoroethylene (ePTFE) knot implantation device (Harpoon TSD-5). Eleven patients with severe degenerative MR due to posterior leaflet prolapse who were at low-risk for conventional surgery underwent beating-heart MV repair. The group reports 100% procedural success rate with an average of  $3.6 \pm 0.7$  (3-5) ePTFE artificial cords implanted. The total procedure time averaged  $108 \pm 30$  minutes and the total time the introducer was in the ventricle averaged  $38 \pm 14$  minutes. There were no perioperative mortality, strokes, myocardial infarctions, or conversions to open surgery. There were two in-hospital adverse events: both patients required a subxiphoid window at days 5 and 13 for a delayed pericardial effusion. One other patient required re-operation at postoperative day 72 for recurrent symptomatic severe MR, which was due to one ePTFE cord being untied from the apical epicardial pledget. Eight patients had trace or no MR and three had mild MR at the completion of procedure. At 30 days, two patients had moderate MR, five had mild MR, and four

had trace or no MR. There was evidence of early (30 days) ventricular remodeling with an 11% and 18% decrease of end-diastolic dimension and volume, respectively. There was also a significant decrease in LA volume and mitral annular dimension. The authors conclude that the Harpoon TSD-5 device enabled less-invasive beating-heart image-guided transapical MV repair with 100% procedural success and safe and reliable reduction of MR.

This report represents an extremely important step towards minimally invasive MV repair and will likely become an important addition to our repertoire of techniques and options for MV surgery. The procedural results with 100% success rate and no complications are encouraging. One of the major advantages of this procedure is that it is performed in a beating heart, which allows titration of the cord lengths using TEE to an anatomically and physiologically accurate length. With the advent of such novel technology in low-risk patients, the bar for perfection remains very high since traditional MV surgery has excellent results.

In the evaluation of this and any new technologies regarding MV repair, there should remain a vigilance to postoperative surveillance since a very steep learning curve is expected. In this first-in-man series, the authors note that 1 patient required a reoperation for recurrent symptomatic severe MR at 72 days due to 1 cord becoming untied from the apical epicardial pledget in addition to a ruptured native edge cord to A2. This early reoperation represents the early learning curve associated with a new technology and a wider applicability should overcome this limitation.

Secondly, transcatheter MV technologies including Harpoon, NeoChord, and the Mitraclip all utilize

amelioration of MR without annular stabilization. During surgical MV surgery, a complete or partial ring prosthesis is implanted after leaflet resection or neochords are implanted. The surgical dogma has noted that long-term outcomes are predicated by a ring annular stabilization. It is possible that transcatheter MV surgery, which does not include a ring or band, may have recurrence in the long-term if the annular dimension increases. In the early experience with the Harpoon device, there was some progression of MR from no patients having moderate MR and three with mild at the end of the procedure to two moderate and five mild MR at 30 days. With only four patients followed up to 6 months, these patients will need to be followed longer to answer this speculation. It is feasible that a combination of transcatheter techniques (e.g., the Valtech trans-septal annuloplasty band used concomitantly with Neochord) will be used in those with annular dilation.

The third point to discuss is the use of new technology in patients considered low-risk for traditional surgery. The current expectation in a low-risk population is to obtain near perfect and durable results with minimum risk as can be obtained with conventional surgery. With the use of this disruptive technology, results will need to be scrutinized carefully and with not only early, but also long-term results.

Despite these early limitations, these results are encouraging and hold promise for yet another advancement in the treatment of MV primary disease. The MV is a complex apparatus, which will require a plethora of MV repair techniques. As this technique and the device improve, the Harpoon TSD-5 has the potential to become an important component of the MV surgeon's armamentarium.

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