

The potential of transapical beating-heart mitral valve repair with neo-chordae

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Comment on: Gammie JS, Wilson P, Bartus K, *et al.* Transapical Beating-Heart Mitral Valve Repair With an Expanded Polytetrafluoroethylene Cordal Implantation Device: Initial Clinical Experience. *Circulation* 2016;134:189-97.

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Transapical beating heart mitral valve (MV) repair with an expanded polytetrafluoroethylene (PTFE) chordal implantation device, proofs excellent initial clinical experience in patients suffering from mitral regurgitation (MR) due to degenerative MV disease with isolated posterior leaflet prolapse, as recently reported by Gammie and colleagues (1).

This innovative operation allows for MV repair without the use of cardiopulmonary bypass (CPB) and its associated risk factors. The concept has initially been introduced by a group from the Mayo clinic in 2009 in an acute animal model—although using a different device, the so called NeoChord DS1000 (2). This device in contrast is used to grasp the leaflet, to pierce it with a dull needle, and eventually to pull a PTFE chord through the prolapsing segment of the MV leaflet. To finish the procedure this long PTFE suture is then tied with a girth hitch knot, which eventually re-suspends the free edge of the leaflet under normal filling conditions at the optimal length by fixation on the left ventricular apex. The procedure, similar to the Harpoon device, is fully echocardiographically guided. Successful first in man application occurred in 2010 with a subsequent proof of concept study in a total of 30 patients examined during the TACT trial (3,4).

Gammie and colleagues used the same operative concept via an off pump transapical access, however a different application device. The so called Harpoon device uses a

slightly different mechanism for fixation of PTFE sutures on the diseased MV leaflet: it perforates the respective MV segment from the ventricular side and anchors the PTFE suture, which resumes in its preformed knot configuration as soon as it is deployed on the atrial side of the leaflet (1). The preformed knot functions as a locking and fixation mechanism on the prolapsing segment of the MV once it is deployed. Subsequently after fixation on the LV apex it is used to resuspend the leaflet. Similar to the NecChord device, a fixation of the suture on the apex is performed at the ideal length under normal filling conditions leaving no or only trace residual MR (1).

The clinical interest and the interest of the cardiovascular community in this new operative concept, using either of the two available devices, has recently been increasing especially since results show to be stable over time (5,6). NeoChord Inc. has reported relatively high patient numbers reaching a total of more than 500 treated patients by now (personal communication).

The Harpoon device however entered the clinical arena with first in man application well behind the NeoChord DS1000. Its excellent results however are equally promising. Gammie and colleagues report a 100% procedural success rate in a series of eleven patients with posterior leaflet prolapse and severe MR. The immediate postprocedural grade of MR was reported to be trace. These results remained fairly stable over time with a mean grade of MR

of only mild at 1 month follow-up (1). The investigators found evidence for early ventricular remodeling with significantly decreased end-diastolic left ventricular and left atrial volumes (1). There was no stroke, no death, no early MV reoperation and no blood transfusion within 1 month. Only one patient underwent successful re-repair for recurrent severe MR at postoperative day 72. Out of the total of 11 patients, six patients showed stable results over the first 6 months, which highlights the potential of this approach—especially since NeoChord has been shown to reach excellent 5-year outcome in three selected patients who were included in the early phase of the TACT trial. All three of these patients remained stable over a period of 5 years with mild residual MR (6).

When comparing the Harpoon device to the NeoChord DS1000 device, the biggest advantage of the Harpoon system may be the use of a sheath on the left ventricular apex which allows for easy, repeat access into the left ventricle. In addition the implantation process facilitating the end-effector, which stabilizes the prolapsing segment of the leaflet, and the very quick application of the PTFE suture, seemed to be especially handy. Also the Harpoon device does not grasp and thus fix the leaflet within the device; it simply stabilizes the prolapsing segment with calculated force and thus less risk of potential tissue damage. The downside of the Harpoon device however is that once a suture has been deployed, it cannot be retrieved and must stay in place, even when it has no effect on the pathology whatsoever. Despite these relatively minimal drawbacks, Gammie *et al.* successfully confirmed the concept of transapical beating-heart MV repair without the use of CPB, which represents a significant step forward in the field of minimal invasive mitral repair.

Patient selection however is key for this innovative operation. Irrespective of the overall patient clinical status and their associated operative risk, morphological criteria must be followed in order to reach a successful outcome. Since the technique only allows for isolated chordal replacement, the target pathology is degenerative MR with the presence of a MV prolapse. Albeit a complex lesion might be susceptible to isolated chordal replacement, patients with an isolated posterior MV prolapse represent the optimal target population thus far. Gammie *et al.* confirmed this by treating only those patients with isolated PML prolapse. Nevertheless, with growing experience application for isolated anterior leaflet prolapse or even commissural disease is conceivable, with however inferior results compared to isolated PML pathology—this has

already been shown in clinical application of the NeoChord device (5). Furthermore the creation of an edge to edge repair seems to be a potential repair strategy (addressing ischemic MR) with for transapical mitral chordal repair; however it is not yet well defined.

Next to the minimal invasive nature of this approach, the potential of an early operation in patients with degenerative MR already at the time of no or only mild annular dilatation and a limited degree of left ventricular remodelling, eliminating MR might lead to an overall change in the course of the disease, meaning that an early operation with isolated neochordal replacement may have the potential to prevent subsequent open heart surgery downstream. Although there is no data yet at all underlining this point of view, the Harpoon as well as the NeoChord concept challenges the standards of MV repair. It is not just that open surgical repair in patients with isolated prolapse might be replaced by a transapical beating heart chordal repair approach, but even more so that the Carpentier principles of mitral repair are at the center of attention. As per Carpentier, three principles need to be followed in MV repair surgery: (I) establish a normal leaflet motion; (II) establish an area of coaptation; and (III) perform an annuloplasty (7). It is known that standard surgery applies and follows all three principles, either performed through a minimal invasive access or a conventional sternotomy, with excellent short- and long-term outcome (8,9). Nonetheless it is unknown, if an annuloplasty is a “must” in the presence of only a mildly dilated MV annulus. The question remains if an early operation establishing a normal leaflet mobility and a normal area of coaptation will be sufficient as stand-alone therapy. In other words, what is the outcome of patients undergoing MV repair without annuloplasty?—This cannot be answered based on current literature. Therefore prospective randomized trials, such as the RECHORD trial (comparison of the NeoChord procedure with standard of care open heart surgery), will have to answer this question (10). Depending on the outcome of this trial, which has just started enrolling patients, a paradigm shift in modern mitral repair may be possible.

In conclusion, the paper by Gammie and colleagues on the transapical beating-heart MV repair with implantation of neo-chordae nicely underlines the ongoing trend towards less invasive mitral repair. It represents a significant step towards a fully percutaneous approach, which will further decrease the operative risk and increase patient comfort. Facing the significant clinical need in valvular heart disease as well as the substantial investments made in innovative

surgical and interventional techniques, it may only be a matter of time until comparable-to-surgery treatment options for a substantial number of patients will be available on a regular basis—to the understanding of the authors, the Harpoon and the NeoChord device only represent an intermediate step towards percutaneous repair. However, more real world data is needed to reveal the real potential of this new approach.

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Footnote

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

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