Platelet Function Testing in Clinical Practice – Experience and Views from Europe and the US

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Mitral Valve Regurgitation

Off-pump Transapical Mitral Valve Repair with Implantation of Neo-chordae

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Abstract
The authors present a case report of a mitral valve repair procedure featuring beating-heart, sternal-sparing implantation of neo-chordae. The 73-year-old female patient had severe mitral regurgitation (MR) pre-operatively, but no MR post-operatively and at 30-day follow-up. The patient was enrolled in the Transapical artificial chordae tendineae (TACT) trial sponsored by NeoChord Inc.

Keywords
Neo-chordae, NeoChord, mitral valve repair

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Mitral valve regurgitation (MR) is frequently induced by degenerative mitral valve (MV) disease and leads to leaflet prolapse. Therefore, valve repair is a well-proven surgical technique with excellent long-term outcomes.\(^1\)\(^-\)\(^5\) The risk of declining left ventricle (LV) function or LV enlargement and the development of atrial fibrillation or severe pulmonary hypertension due to chronic volume overload will lead to earlier surgical intervention in the non-elderly population.\(^6\)

In the attempt to provide a less invasive surgical approach to mitral valve repair (MVR), the concept of transapical beating-heart implantation of neo-chordae, using the NeoChord DS 1000 device (NeoChord Inc., Minnetonka, MN, US), has been developed and proven in acute and chronic animal studies and the first clinical experiences have been reported.\(^7\)\(^-\)\(^9\) In this article we illustrate the feasibility and applicability of this new technique in clinical use in humans.

Materials and Methods
We performed transapical beating-heart MVR off-pump through a small left lateral mini-thoracotomy. The major selection criteria were isolated, symptomatic, severe MR due to isolated prolapse of the posterior leaflet with no, or only mild, annular dilatation. Institutional ethics committee approval and written informed consent were obtained.

Patient
The patient was a 73-year-old woman with severe MR due to degenerative MV disease with posterior leaflet prolapse. The patient was in New York Heart Association functional class II to III heart failure. Intra-operative transoesophageal echocardiography (TOE) confirmed that the isolated leaflet was prolapsed mainly in the P2 segment. The mitral annulus was normal at <40 mm.

NeoChord DS 1000 Device
Three key features represent the technical characteristics of the device (see Figure 1):

- a grasping mechanism on the tip of the device to capture the prolapsing leaflet;
- a fibre optic-based device monitor to certify successful leaflet grasping; and
- a semi-dull needle for puncturing and fixing the neo-chord to the leaflet and for subducting the implanted neo-chord extracardially.

Surgical Technique
Standard anaesthesia was performed through a left-lateral mini-thoracotomy in the sixth intercostal space (5 cm small incision), a transapical access to the MV was established and two standard purse-string sutures were placed on the apex.\(^10\) In addition, a temporary epicardial pacing wire was placed on the left ventricle. A safety net was prepared for emergency cardiopulmonary bypass.\(^11\) Using 2D and 3D echocardiographic guidance, the NeoChord DS 1000 device was inserted into the beating heart and advanced through the MV into the left atrium (see Figure 2). Posterior leaflet grasping was achieved with expandable jaws on the tip of the device (see Figure 1). Effective leaflet capture was confirmed by observing the four fibre optic monitors of the device. After leaflet puncture with the device needle and subsequent deployment of a 4-0 polytetrafluoroethylene suture (Gore-Tex®; WL Gore and Associates Inc., Flagstaff, AZ, US), the device was retracted and a girth hitch knot was secured to the leaflet. After determining adequate neo-chord length with TOE guidance, the neo-chordae were secured to the apex using a French-eye needle and additional felt pledgets. After final TOE evaluation, the apex was closed with the purse-string sutures, the pericardium partially adapted and a chest tube inserted. The left-lateral mini-thoracotomy was closed in a routine fashion. Afterwards, the patient was transferred to our recovery room for early extubation.
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Results

Successful transapical beating-heart MVR was performed. Acute procedural success with complete elimination of MR was achieved. A total of three neo-chordae were implanted. The fast-track anaesthesia concept was used. The post-operative intubation time was 55 minutes. The post-operative course was uneventful. Pre-discharge and four-week follow-up echocardiographic examinations showed no MR (see Figure 3).

Discussion

Transapical beating-heart implantation of neo-chordae is a novel surgical procedure for performing MVR in patients with severe MR. The goal of this procedure is to decrease the invasiveness of the current gold-standard MVR and to avoid the risks of cardiopulmonary bypass and aortic cross-clamping.

The rationale of this new and modern approach aims towards correction of MR before the development of heart failure. Due to this assumption, off-pump MVR might be a promising treatment option.

Our initial clinical experience shows the feasibility and safety of this unique concept and novel operation. Particular attention needs to be given to the number and length of implanted neo-chordae. Also, identification of the prolapsing valve segment is fundamental. For this purpose skilled intra-operative echo guidance is indispensable and a close interdisciplinary approach is therefore vital. Continuing clinical evaluation of this novel procedure is needed to evaluate MVR with chordal replacement as a stand-alone technique.

In conclusion, transapical off-pump implantation of neo-chordae in cases of MV regurgitation is feasible. Based on our early experience we believe the NeoChord procedure merits additional study to further investigate additional applications and long-term results.
