Transapical beating heart mitral valve repair with the NeoChord system: early outcomes of a single-center experience

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Abstract

Introduction: *Trans-apical beating heart off-pump mitral valve (MV) repair is a novel surgical technique for treating mitral regurgitation (MR) caused by degenerative flail/prolapse (DLP).*
Aim: *To present early outcomes of a single-center experience with transapical beating heart mitral valve repair with the NeoChord system.*
Material and methods: *Thirty-seven patients with severe symptomatic MR were treated with the NeoChord technique between September 2015 and December 2018 (78% men; mean age: 62.3 ±13.4 years). We evaluated standard cardiac surgery perioperative complications as well as those related to the NeoChord technique as well as early surgical success as defined by the reduction of MR to less than moderate by implantation of at least 2 neochordae.*
Results: *During this series we had no hemodynamic instability due to bleeding or arrhythmia. There were no transapical technique-related adverse events such as a leaflet perforation or tear, a major native chord rupture, which would require implantation of a new chord, ventricular apex rupture, or left atrial perforation. There were no major adverse events including death, stroke or acute myocardial infarction. Nine (24%) patients developed an episode of perioperative atrial fibrillation. We were able to conclude the operation in 98% of our patients with less than moderate MR. One (2%) patient had moderate MR at the conclusion of the operation.*
Conclusions: *Trans-apical off-pump MV repair with the NeoChord system is a safe, minimally invasive procedure, with few minor complications. In well-selected candidates it provides successful treatment of degenerative MR. Results are anatomy dependent, so preoperative patient selection is crucial.*

Key words: *mitral valve insufficiency, mitral valve, mitral valve repair, mitral valve prolapse.*

Introduction

Significant mitral regurgitation (MR) affects approximately 2% of the total population and 9% of the population older than 75 years old [1]. In the majority of degenerative mitral valves the regurgitation is caused by flail segment either from a rupture or elongation of chords. Surgical mitral valve (MV) repair is the current treatment of choice for degenerative flail/prolapse (DLP) [2]. Minimally invasive mitral valve surgery has become a routine procedure in many leading institutions [3, 4]. Gammie *et al.* [5]. recently published report on isolated mitral valve surgery based on the Society of Thoracic Surgeons Adult Cardiac Surgery Database. There were 87 214 isolated primary mitral operations performed during 2011–2016 in the United States with less invasive operations in 23% of these patients. Concurrently,

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robot-assisted approaches were used in 12% of patients. Although there has been a small increase in the percentage of cases performed in a less invasive manner, there seems to be a plateau in enthusiasm for these approaches in many centers. Comparatively, leading centers can achieve impressive results with on-pump MV surgery with mortality of 0.1%, a success rate of 99.9%, and median hospital stay of 6 days [6]. However, in the real world STS database group, the DLP repair rate was approximately 80% with a mortality of 1.2%, a stroke rate of 1.1% and prolonged ventilation at 6.1%.

Trans-apical beating heart off-pump MV repair is a novel surgical technique to treat mitral valve prolapse without concomitant annuloplasty [7, 8]. The main benefits of this approach are MV repair under physiological conditions and avoidance of cardiopulmonary bypass (CPB), providing the potential for lower perioperative complications rates. However, limited data regarding early surgical results and the initial learning curves are available [8–11]. Therefore, we report a single-center series of consecutive patients treated using the trans-apical chordal replacement technique.

Aim

The objective of this study was to present the early outcomes of the single-center experience with transapical beating heart mitral valve repair with the NeoChord system.

Material and methods

This is an analysis of prospectively collected data from 2015 to 2018 in 37 patients with severe symptomatic MR treated with NeoChord technique. Our patients' mean age was 62.3 ±13.4 years (nine of them were older than 75). These were predominantly men (78%). Patients were considered suitable for trans-apical chordal implantation if severe MR was present due to prolapse or flail of 1 leaflet and had the potential for good coaptation without requiring a prosthetic annuloplasty. We evaluated the early surgical success of the procedure as well as standard cardiac surgery perioperative complications and those related directly to the NeoChord technique.

Preoperatively, all patients underwent a transthoracic (TTE) as well as trans-esophageal (TEE) echocardiography with 3D reconstruction to confirm the mechanism and severity of MR along with the suitability for NeoChord implantation. Preoperative and follow-up images were obtained using the iE 33 machine (Philips Medical Systems, Andover, Massachusetts). Intra-operative TEE views were obtained the using EPIQ 7 system (Phillips, Eindhoven, NL) and the trans-esophageal X7-2t Live 3D xMATRIX array transducer.

The MR severity was described according to the EACVI recommendations for the assessment of native valvular regurgitation [12]. Severe MR was diagnosed based on complex qualitative and quantitative criteria, including an evaluation of color flow regurgitant jet, vena contracta width, convergence zone, signal of regurgitant jet in continuous wave Doppler, an effective regurgitant orifice area (ERO) and regurgitant volume. The left ventricle (LV) morphology and function were assessed routinely.

Operative technique

Echo-guided trans-apical implantation of artificial chordae on a beating heart with the NeoChord DS 1000 system is a novel technique designed to treat degenerative MR. It was the first trans-apical repair technique approved by the EMA for patients with MR due to prolapse or leaflet flail. After institutional approval all patients signed informed consent, which entailed the current state of the art for mitral repair, surgical risks, known clinical results, and alternative approaches. We used the NeoChord DS1000 system (NeoChord, Inc., St. Louis Park, MN, USA) to restore normal leaflet motion under real-time two (2D)- and three (3D)-dimensional trans-esophageal echocardiographic (TEE) guidance. With this technique, chordal implantations and length adjustments are possible without the use of CPB. The detailed technique used by our team has been published [13].

Outcome definitions

Early surgical success was defined as the reduction of MR to less than moderate by implantation of at least 2 neochordae. Safety measures included standard cardiac surgery and perioperative complications. Major adverse events were death, stroke, and acute myocardial infarction (AMI). Minor events included wound infection, preoperative atrial fibrillation (AF) episode, acute renal failure, pericardial or pleural effusion, blood transfusions and surgical

re-exploration for bleeding. Additional complications considered were related to the NeoChord technique and included a leaflet perforation or significant leaflet tear, native chord rupture, ventricular apex rupture, and left atrial perforation, which all would have resulted in hemodynamic instability, due to bleeding or arrhythmia, or acute LV dysfunction, all requiring implementation of CPB.

Statistical analysis

Descriptive statistics for quantitative data were presented as mean ± standard deviation or median and range. Qualitative data were shown as counts and percentages.

Table I. Patients' characteristics (n = 37)

Variable	Value
Age [years]	62.3 ±13.4
Male gender, *n* (%)	29 (78)
EuroSCORE II	0.92 (0.56–3.73)
Arterial hypertension, *n* (%)	20 (54)
COPD, *n* (%)	2 (5)
Preoperative creatinine [mg%]	0.97 (0.61–1.8)
Leaflet pathology, *n* (%):	
Posterior	35 (95)
Anterior	2 (5)
Type of pathology, *n* (%):	
A (isolated central posterior leaflet prolapse P2)	25 (67.6)
B (multiple prolapsing segments)	8 (21.6)
C (commissural involvement, anterior leaflet)	4 (10.8)
Cardiac structure/function:	
LVEF (%)	65 (45–70)
LVEDD [mm]	56 (40–71)
LVESD [mm]	42 (34–49)
LA [mm]	43 (33–57)
TRPG [mm Hg]	32 (13–68) in 4 patients > 50

Data are expressed as mean and SD, median and range (min., max.) or percentage; COPD – chronic obstructive pulmonary disease, LVEF – left ventricular ejection fraction, LVEDD – left ventricular end-diastolic diameter, LVESD – left ventricular end-systolic diameter, LA – left atrium, TRPG – tricuspid regurgitation peak gradient.

Results

Patients' baseline characteristics

Baseline clinical characteristics and preprocedural basic echocardiographic data are described in Table I. Operated patients were low in surgical risk with a mean EuroSCORE II of 0.92%. The predominant pathology was posterior leaflet prolapse and/or flail of the posterior leaflet P_2 segment.

Procedure characteristics

All procedures were performed by the same surgeon and echocardiographer in the cardiac operating room. Single lumen intubation and general anesthesia were used in all patients. Cardiac access was achieved in the majority of patients (in 2–3 cases it was the 6th, but never the 4th) through the fifth intercostal space just lateral to the nipple. In all patients the apical purse string suture technique was a double U perpendicular 3-0 Prolene Teflon pledget suture. After the completion of neochordae implantation all Gore-tex sutures were passed through additional Teflon at the cardiac apex pledgets. The median procedure time was 115 min. The number of chords implanted were as follows: 28 (76%) patients 3–4 chords, 4 (11%) patients 2 chords, in 4 (11%) patients 5 chords and in 1 (3%) patients 6 chords. In 90% of patients we were able to conclude the operation with trace, trace to mild or mild MR. In 3 (8%) patients the MR was mild to moderate and in 1 (2%) patient moderate. The median length of stay in the ICU was 32 h. Patients were discharged after a median postoperative hospital stay of 7 days. Surgical results are summarized in Table II.

Major and minor perioperative complications

There were no major adverse events including death, stroke or AMI. Nine (24%) patients developed a peri-operative AF episode. Two patients developed pleural effusions and 2 patients had superficial local would infection with only 1 patient requiring blood transfusion.

Procedure-related issues

There were no NeoChord technique-related safety issues such as leaflet perforation or significant leaflet tear, or major native chord rupture, which would require implantation of a new chord, ventricular apex rupture, or left atrial perforation. All of these

Table II. Surgical results

Parameter	Value
Implanted chords per patient	3 (2–6)
Number of implanted chords:	
2	4 (11)
3	20 (54)
4	8 (22)
5	4 (11)
6	1 (3)
Last 10 cases	3.5 (2–5)
Operative time [min]	115 (65–175)
Troponin T [ng/ml]	268 (73–811)
Blood loss [ml]	300 (100–1280)
Last 10 cases [ml]	200 (100–400)
Difference between admission and discharge hemoglobin values [g%]	1.7 (0–3.9)
ICU length of stay [h]:	
Total	32 (22–100)
< 24	17 (46)
24–48	15 (40)
> 48	5 (14)
Post procedure length of stay [days]	7 (4–17)

Data are expressed as median and range and percentage.

Table III. Intra- and perioperative events (n = 37)

Parameter	Value
Surgical complications, *n* (%):	
Surgical revision for bleeding	0
Conversion to conventional surgery	0
Apex bleeding or rupture	0
Major events, *n* (%):	
Death	0
Stroke	0
AMI	0
Minor events, *n* (%):	
Pericardial effusion	0
AF episode	9 (24)
Pleural effusion	2 (5)
Wound infection	2 (5)
Acute renal failure	0
Blood transfusion	1 (2.5)

Data are expressed as percentage. AF – atrial fibrillation, AMI – acute myocardial infarction.

would have resulted in conversion to conventional heart surgery. We observed no acute LV dysfunction requiring implementation of CPB or hemodynamic instability due to bleeding or arrhythmia. Intra- and perioperative events are shown in Table III.

Transapical approach (troponins, ECG)

We had no significant problems related to the transapical approach. Due to surgical implantation through the ventricular apex, troponin T release was observed in all patients (median: 268 pg/ml). In some patients we observed transient changes of the ST segment. No patient was diagnosed with perioperative AMI according to the standard definitions.

Blood loss

Since the procedure requires a mini-thoracotomy and a trans-apical puncture without a dedicated sheath there is a potential for blood loss. Even with the purse strings tightened on tourniquets during chord implantation there was continuous back bleeding around the device and through the channel for the needle. The amount of blood loss is associated with the time the NeoChord device is inserted inside the LV as well as the number of chords needed to be implanted. For this reason a cell saver device was used routinely to recover blood loss, which was auto-transfused. Overall the median blood loss for the procedure was 300 ml or approximately 100 ml per chord. In last 10 patients this was reduced to a median of 200 ml with 3.5 chords per patient (60 ml per chord). After auto-transfusion the median drop of hemoglobin of 1.7 g% for the series was observed.

Discussion

The classic surgical mitral valve repair was described by Carpentier and involved a quadrangular resection of a leaflet prolapsing/flail segment with/without a sliding valvuloplasty, followed by a ring annuloplasty [14]. Replacing diseased chordae tendinae

with PTFE sutures was first described by Frater *et al*. [15]. Neo-chordal replacement was later popularized by David *et al*. [16]. To simplify this technique, Oppel and Mohr used pre-measured PTFE loops [17]. Neochordae implantation has provided excellent short- and long-term results. Falk *et al*. showed that PTFE chord implantation created a significantly longer coaptation line and larger mitral orifice area when compared with the resection technique [18]. The modified Chitwood "haircut technique" supported P2, using chord bearing leaflet tissue "flaps" or PTFE neochordae [19]. The "respect rather than resect" approach has changed surgical thinking and repair strategies for posterior leaflet prolapse. Instead of focusing on the site of resection, our goal is to preserve and remodel the posterior leaflet to create the best surface of coaptation possible [20]. A generally accepted principle of MV repair operations has been that a mitral annuloplasty is required to increase the area of leaflet coaptation, which leads to improved durability. Nevertheless, preliminary data by Kiefer *et al*. [21] revealed that the lack of an annuloplasty ring does not lead to ongoing annular dilatation and does not induce recurrent MR. A study by Maisano *et al*. showed that 20% of patients referred for a repair do not require annular downsizing [22]. This patient group should benefit from less invasive repair approaches such as trans-apical chordal implantation with the NeoChord device. In order to become the "first choice" treatment for DLP the procedure needs to be as safe, effective, and as durable as a traditional repair.

Our initial experience with trans-apical chordal implantation using the NeoChord device proves that the procedure can be performed with minimal patient risk. Early safety outcome results in our cohort show that the risk of major complications, as well as fatal events, requiring conversion to open surgery is minimal. There were no major adverse events or conversions in our group. Yet the risk still exists, but probably it is more related to the learning curve and patient selection as previously shown by Colli *et al*. [9]. This is at least comparable to contemporary series of MV repair patients [5, 23]. There were no strokes in our cohort. Patients with higher risk for perioperative stroke could have benefited from this approach. But this needs to be proven in randomized studies.

Avoidance of cardiopulmonary bypass is one of the potential advantages of this approach, especially for patients with coronary artery disease, advanced aortic atherosclerosis, obstructive pulmonary disease, and kidney failure. Moreover, procedural times are shorter, especially when compared to the other minimally invasive procedures needing CPB [23]. Median operative time in our series was 115 min. The trans-apical approach has been considered more invasive than the trans-femoral/ trans-septal approach because of the need for thoracotomy and surgical management of the apex incision. Our data show that even without a sheath this approach can be safe, but requires obligatory use of a cell-saver device. Only 1 (2.7%) patient in our cohort required a blood transfusion. In comparison sternotomy-based surgery operations require transfusions in approximately 10–20% of patients, but can be dependent on the institutional protocols [23]. Postoperative AF incidence was comparable with the conventional approach. We observed AF in 9 (24%) patients, whereas it was 26% in the DLP group from the STS database [5]. The length of ICU stay and postoperative hospital stay was not significantly different from the conventional approach group. Unfortunately, length of stay has been affected by local standards (delay in transfer home or rehabilitation unit).

Successful placement of at least 2 chords was feasible in all our patients. This compares favorably to data from the TACT trial [8] as well as the initial experience from Padua and Vilnius surgical groups [9] as well as a multicenter experience [24]. Procedural times and techniques have improved significantly over time and may have been related to bio-simulator training as well as increased experience with proctoring [25]. This device enables the team to practice the procedure multiple times before clinical application. In 90% of our patients we were able to conclude the operation with trace, trace to mild or mild MR. In 3 (8%) patients it was mild to moderate and moderate in 1 (2%) patient. This proves that in well-selected patients it is possible to achieve comparable early results to the overall population with a concomitant annuloplasty. From the STS database Gammie showed either moderate or severe MR was 3.2% at discharge for mitral repair patients who had degenerative leaflet prolapsed [5]. Thus, our initial results show safety and technique feasibility as well as the potential for restoration of the proper mitral valve function in selected patients. More follow-up data are needed in order to optimally select patients for the potential of a durable result [26].

Conclusions

Transapical off-pump mitral valve repair with the NeoChord system is a safe, minimally invasive procedure, with few minor complications. In well-selected candidates it allows for successful treatment of degenerative mitral regurgitation. Results are anatomy dependent, so preoperative patient selection is crucial. Patients require adequate long-term follow-up in order to determine the durability of this approach.

Conflict of interest

Two authors disclose proctoring for NeoChord. Others authors declare no conflict of interest.

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