

Is trans-apical off-pump neochord implantation a safe and effective procedure for mitral valve repair?

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ABSTRACT

Objective: Trans-apical off-pump mitral valve repair is a new minimally invasive surgical technique for the correction of mitral regurgitation caused by mitral leaflet prolapse. The purpose of this study is to evaluate, using clinical and echocardiographic follow-up data, the mid-term results of patients undergoing this procedure.

Methods: A total of 26 patients diagnosed with severe mitral regurgitation underwent mitral valve repair with trans-apical off-pump neochord implantation using the NeoChord device at our hospital from July 2015 to July 2017. All patients were examined by transthoracic and transesophageal echocardiography. Eighteen (69.2%) patients had type A anatomy, 4 (15.4%) had type B anatomy, and 4 (15.4%) had type C anatomy. Preoperative, intraoperative, and postoperative demographic, echocardiographic, and clinical data were collected.

Results: The patients' age ranged from 33 to 76 years (mean: 56±10.1 years). The average preoperative EuroSCORE II was 1.04±0.7%. Acute procedural success was achieved in 25 (96.15%) patients. There was only 1 early death (30-day mortality rate: 3.8%) due to postoperative low cardiac output syndrome. Transthoracic echocardiography examinations revealed trivial/mild mitral regurgitation in 87.5% of the patients and moderate regurgitation in 12.5% of the patients. During the follow-up period, transthoracic echocardiography examinations revealed trivial/mild mitral regurgitation (MR) in 14 (58.3%) patients. Six (25%) patients presented with moderate MR and 4 (16.7%) patients had severe MR. At the 30-month follow-up, freedom from residual severe MR was 78.8%±10.3% and freedom from reoperation was 87.5%±6.8%.

Conclusion: Trans-apical off-pump mitral valve repair with neochord implantation may be a suitable treatment option in patients with isolated posterior mitral valve leaflet prolapse. (*Anatol J Cardiol* 2019; 22: 00-00)

Keywords: mitral regurgitation, mitral valve prolapse, neochord

Introduction

Primary mitral regurgitation (MR) is caused by an abnormality of one or more components of the valve apparatus. This is in contrast to secondary MR, which is caused by adverse left ventricular remodeling from cardiomyopathy or coronary artery disease. Mitral valve (MV) repair is preferred over MV replacement due to the following advantages: preservation of ventricular function, lower operative mortality, better long-term survival, and avoidance of anticoagulation (1-3). Most of the MV pathologies involve the posterior leaflet or annulus and can usually be repaired using standard valve repair techniques (4). The use of artificial neochordae made of expanded polytetrafluoroethylene

(ePTFE) sutures has been proposed as a safe and effective surgical procedure for repairing the prolapsed and flail leaflet of the MV (5). In recent years, minimally invasive MV surgery has been proven to be an effective alternative to the conventional approach for managing MR in patients with low perioperative morbidity and short-term mortality (6, 7). Trans-apical off-pump MV repair with neochord implantation (TOP-MINI) using the NeoChord Delivery System (DS) 1000 device (NeoChord, St. Louis Park, MN) is a new MV repair option that uses the principle of chordal replacement and enables trans-apical beating heart off-pump MV repair (8). The purpose of this study is to evaluate, through clinical and echocardiographic follow-up, the mid-term results of using the Trans-apical NeoChord DS 1000 device for MV repair.

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Accepted Date: 26.08.2019 **Available Online Date:** 04.10.2019

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DOI:10.14744/AnatolJCardiol.2019.17055



Methods

Patient selection

This is a retrospective study including 26 patients with a diagnosis of severe MR who underwent MV repair with TOP-MINI using the NeoChord DS1000 device at Sakarya University Training and Research Hospital between July 2015 and July 2017. All patients were examined by transthoracic and transesophageal echocardiography (GE Vivid S70N-GE Vingmed Ultrasound AS, Horten, Norway). All the operations were carried out by the same surgeon, cardiologist, and anesthesia team using standard surgical methods. The study protocol was approved by the Local Ethics Committee (No.71522473/050.01.04/9, Date: 24/05/2019). The study was conducted in accordance with the principles of the Declaration of Helsinki. Surgical intervention on the MV was made in accordance with preoperative transthoracic and 3D transesophageal echocardiography (TEE) mitral insufficiency grading, the anatomy of the diseased segments of the MV, and the intraoperative evaluation of the valve by the surgeon and cardiologist. The mitral insufficiency was graded echocardiographically as trivial, mild, moderate, and severe (9). The inclusion criterion was severe degenerative MR due to posterior, anterior, or both the MV leaflets' prolapse and/or flail. The exclusion criteria consisted of the presence of active endocarditis, marked annular dilation, severe left ventricular dysfunction, and unsuitable MV anatomy (heavily calcified leaflets, leaflet perforation, significant leaflet tethering). According to the preoperative extension of the diseased segment of the MV assessed by the 3D TEE, the following anatomical types were described; Type A: flail/prolapse limited to P2 segment, Type B: multi-segment disease involving P1–P2 or P2–P3 or P1–P2–P3, and Type C: anterior leaflet disease, bileaflet disease, pericommissural disease, or presence of calcifications of the annulus or leaflet (10, 11). Eighteen (69.2%) patients had type A anatomy, 4 (15.4%) had type B anatomy, and 4 (15.4%) had type C anatomy.

All patients were informed about the potential risks of the procedure and each patient provided written informed consent to undergo the TOP-MINI procedure. Preoperative, intraoperative, and postoperative demographic, echocardiographic, and clinical data were collected.

Operative technique

The trans-apical off-pump NeoChord implantation was performed under general anesthesia with single-lung ventilation in a standard cardiac surgery operating room. The patients were placed in a supine position with a 30-degree right lateral rotation of the thorax. Access to the left ventricle was achieved through a left anterior mini-thoracotomy in the fifth intercostal space. The left ventricle access location was identified by 2D-TEE imaging using gentle digital palpation, approximately 2–3 cm lateral to the true LV apex. Apical access was secured with 2 concentric, round purse-string sutures using large custom-made, rectangu-

lar Teflon pledgets and 2-0 non-absorbable sutures. Under TEE imaging, 4/0-Gore-Tex (W. L. Gore&Associates, Inc., Flagstaff, Arizona, USA) neochordae were implanted on the free margin of the prolapsing segment of the leaflet and secured at a defined length on the LV apex. The procedure was then repeated until at least 2 or 3 neochordae were implanted in the leaflet. Once the implanted neochordae were pulled out of the apex of the heart, the optimal length was adjusted under TEE guidance. To achieve the optimal length of the neochordae, optimal pressure was applied by pulling them until it was evident that the MR jet disappeared on the echocardiograph. Once the optimal length of the neochordae was determined, each neochord was securely fixed to the apex of the heart with epicardial pledgets. After partial closure of the pericardium, a pleural drain was inserted and the mini-thoracotomy was closed in a standard fashion.

Follow-up

All patients were evaluated with TTE before hospital discharge (1st follow-up) and in the mid-term (2nd follow-up). Mid-term follow-up was obtained at an average of 29±6 months. Echocardiographic findings were recorded in the computer database of the hospital. All patients were given anticoagulant treatment with warfarin sodium for 3 months after the surgery and permanently if they had atrial fibrillation (AF) or other mechanical valves. Follow-up data were analyzed using cardiology and cardiac surgery outpatient follow-up notes, primary care and institutional computer-based databanks, and telephone interviews.

Statistical analysis

All statistical analyzes were performed using the SPSS Version 25.0 (SPSS Inc., Chicago, IL, USA). Data were presented as frequencies and percentages for categorical variables and medians or means with standard deviations for continuous variables. Late survival and freedom from residual severe MR and reoperation were estimated using the Kaplan-Meier survival analysis.

Results

The patients' demographic data and preoperative characteristics are presented in Table 1. The patients' age ranged from 33 to 76 years (mean: 56±10.1 years), and the occurrence of MV prolapse was less frequent in females than in males (8 patients; 30.8%). Nine patients (34.6%) were in the New York Heart Association (NYHA) functional class of III-IV. The mean preoperative LV ejection fraction was 59%±3.1%. The average preoperative EuroSCORE II was 1.04%±0.7%. Eleven patients (42.3%) had mild tricuspid regurgitation (TR) and 1 patient had moderate TR. All of the patients had presented with severe, symptomatic MR and were undergoing medical treatment.

The operative data have been summarized in Table 2. Acute procedural success was achieved in 25 (96.15%) patients. One

Table 1. Clinical characteristics of all patients

Variables	(n=26)
Age, years (mean±SD)	56±10.1
Male sex, n (%)	18 (69.2)
EuroSCORE II (%)	1.04±0.7
Associated diseases, n (%)	
Hypertension	11 (42.3)
Diabetes mellitus	7 (26.9)
Chronic obstructive pulmonary disease	6 (23.1)
Peripheral vascular disease	2 (7.7)
Coronary artery disease	3 (11.5)
Previous cardiac operations, n (%)	
Coronary artery bypass graft	2 (7.7)
Preoperative AF, n (%)	8 (30.8)
NYHA III-IV, n (%)	9 (34.6)
Preop LVEF % (mean±SD)	59±3.1
LVEDD, mm (mean±SD)	52.19±4.33
SPAP, mm Hg (mean±SD)	33.8±8.16
Mitral valve anatomy*, n (%)	
Type A	18 (69.2)
Type B	4 (15.4)
Type C	4 (15.4)
TR, n (%)	
No	6 (23.1)
Trivial	8 (30.8)
Mild	11 (42.3)
Moderate	1 (3.8)

Data are presented as mean value±standard deviation or the number of patients (percentage). *Type A: flail/prolapse limited to the P2 segment, Type B: multi-segment disease involving P1–P2 or P2–P3 or P1–P2–P3, and Type C: anterior leaflet disease, bileaflet disease, peri-commissural disease or presence of calcifications of the annulus or leaflet. LVEDD - left ventricular end-diastolic diameter, LVEF - left ventricle ejection fraction, NYHA - New York Heart Association, SPAP - systolic pulmonary artery pressure, TR - tricuspid regurgitation

patient underwent conversion to conventional MV replacement because of leaflet damage induced by the device. Fragile leaflet tissue was observed during the open surgery, which might have contributed to the inability to deploy the neochordae and subsequent damage to the leaflet. Three neochordae were implanted in 12 patients (46.2%), 4 in 7 patients (26.9%), and 5 in 1 patient (3.8%). The mean procedure duration time was 133±15.2 minutes and the mean time till extubation was 3.3±0.9 hours.

The early complications after neochord implantation are presented in Table 2. There was only one early death (30-day mortality rate: 3.8%) due to postoperative low cardiac output syndrome. New-onset AF developed in 5 patients (19.2%) and was medically resolved in all patients except one. Two patients (7.7%)

Table 2. Operative and postoperative data

Variables	(n=26)
Neochordae implanted	
2	6 (23.1)
3	12 (46.2)
4	7 (26.9)
5	1 (3.8)
Operative time, minutes	133±15.2
Mechanical ventilation time, hours	3 (2-5)
ICU stay, days	2.11±0.65
Hospital stay, days	6.11±2.12
Early (<30 days) complications	
In-hospital mortality	
Cardiac	1 (3.8)
Inotropic support >24 hours	2 (7.7)
New-onset postoperative atrial fibrillation	5 (19.2)
Pleural effusion requiring drainage	1 (3.8)
Reoperation for bleeding	1 (3.8)
Stroke	1 (3.8)
Superficial wound infection	1 (3.8)
Pulmonary complications	3 (11.5)
Prolonged mechanical ventilation	1 (3.8)

Data are presented as mean±SD or the number of patients.
ICU - intensive care unit

required inotropic support for more than 24 hours. The mean intensive care unit and hospital stays of patients were 2.11±0.65 days and 6.11±2.12 days, respectively. Twenty-five patients were discharged from the hospital in a good clinical condition. At discharge, transthoracic echocardiography examinations revealed trivial/mild MR in 87.5% of the patients and moderate MR in 12.5% of the patients.

Mid-term follow-up was obtained in 24 patients at an average of 29±6 months postoperatively [the median (IQR) follow-up time was 28 (20–46) months]. During follow-up visits, transthoracic echocardiography examinations revealed trivial/mild MR in 14 (58.3%) patients. Six (25%) patients presented with moderate MR and severe MR developed in 4 (16.7%) patients. One patient was treated medically and the other 3 patients were treated with MV replacement. One of them experienced a new native chordal rupture at the anterior leaflet that led to reoperation after 20 months of initial repair. Echocardiographic data and the distribution of residual MR according to the anatomical type of MV are given in Table 3.

At the 30-month follow-up, freedom from residual severe MR was 78.8%±10.3% and freedom from reoperation was 87.5%±6.8% as shown in Figure 1 and 2.

Table 3. Echocardiographic findings of patients after trans-apical neochord implantation

MV anatomical type	Discharge residual MR				Follow-up residual MR			
	Trivial	Mild	Moderate	Severe	Trivial	Mild	Moderate	Severe
A (n=16)	11 (45.8)	4 (16.7)	1 (4.2)	0	8 (33.3)	4 (16.7)	3 (12.5)	1 (4.2)
B (n=4)	0	3 (12.5)	1 (4.2)	0	0	2 (8.3)	1 (4.2)	1 (4.2)
C (n=4)	1 (4.2)	2 (8.3)	1 (4.2)	0	0	0	2 (8.3)	2 (8.3)
N	12 (50)	9 (37.5)	3 (12.5)	0	8 (33.3)	6 (25)	6 (25)	4 (16.7)

Data are presented as the number of patients (percentage). MR - mitral regurgitation, MV - mitral valve

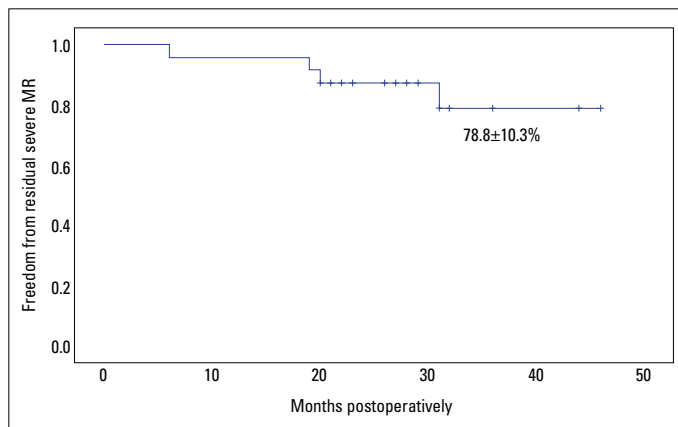


Figure 1. The Kaplan-Meier analysis of freedom from residual severe mitral regurgitation (MR) for all patients

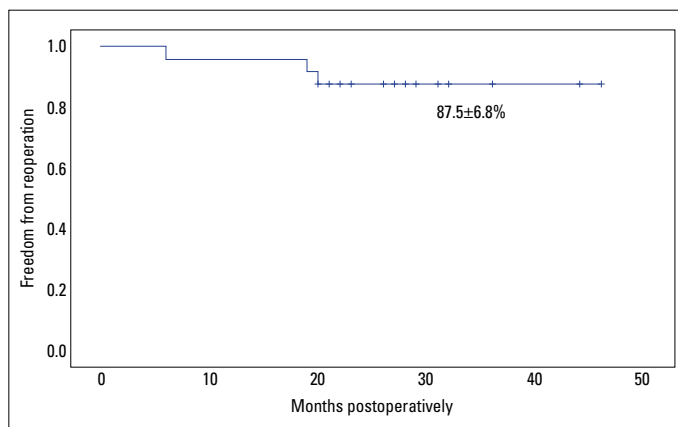


Figure 2. The Kaplan-Meier analysis of freedom from reoperation for all patients

Discussion

The reported advantages of MV repair over replacement are undeniable. Compared to valve replacement, MV repair provides better postoperative left ventricular function and greater freedom from endocarditis, thromboembolic events, and anticoagulant-related hemorrhage (2, 4, 12, 13). Because of these reasons, MV repair has become the method of choice for surgical correction of MR. Although several surgical repair

procedures have been used to correct leaflet pathologies in the previous decades, no specific technique has emerged as a predominant method in the present day (5, 14, 15).

The most simple and common MV lesion, the prolapse of the posterior leaflet, can be treated with leaflet resection or neochordae replacement with excellent short- and long-term results (16). In an era of respect rather than resect, most of these cases are repaired with artificial neochordae of the prolapsed P2 segment. The goal of this approach is to preserve the leaflet tissue to maintain the coaptation surface and to correct the prolapse by using artificial neochordae without performing leaflet resection (17). The primary goal of minimally invasive MV surgery is to avoid median sternotomy-related complications such as mediastinitis and nerve injuries. In addition, it decreases the incidence of adverse outcomes due to extracorporeal circulation. The TOP-MINI using the NeoChord DS 1000 device enables resuspension of a prolapsed segment under physiological conditions on a beating heart without having to perform cardiopulmonary bypass and encounter its potential risks of morbidity and mortality (18). Trans-catheter MV treatment should be discussed by the cardiac team in symptomatic patients who are at high surgical risk or are inoperable (19). In our center, close cooperation between the cardiac surgeons and cardiologists helps to determine the timing of the operation and the management strategy for each patient.

In our series consisting of 26 consecutive cases that underwent TOP-MINI using the NeoChord DS 1000 device, acute procedural success (APS) was achieved in 25 (96.15%) patients. At discharge transthoracic echocardiography examinations revealed trivial/mild MR in 87.5% of the patients and moderate MR in 12.5% of the patients. During follow-up, severe MR occurred in 4 (16.7%) patients and reoperation was needed in 3 (12.5%) patients. The estimation of Kaplan-Meier survival analysis was $78.8\% \pm 10.3\%$ and $87.5\% \pm 6.8\%$ respectively, considering freedom from residual severe MR and freedom from reoperation.

TOP-MINI using the NeoChord DS 1000 device for type A MV regurgitation has shown promising results (18, 20). In our study, a majority of the patients (69.2%) had type A MR, which is the most recommended group for NeoChord DS 1000 device. Although the mid-term results are inferior to type A lesions,

the technique can also be applied for patients presenting with prolapse of the anterior mitral leaflet (Type C) and bileaflet prolapse or multi-segment prolapse of the posterior leaflet (Type B and C) (21). There were 4 patients with type B and 4 patients with type C MR in our series. The rate of re-intervention for trans-apical neochord failure during the follow-up period was (3/24, 12.5%) higher than the value reported by Colli et al. (22) (4/49, 8.2%). This may be because the number of type B and C patients in our study were higher than the patients in their study (8/26, 5/49 respectively) (22). Colli et al. (23) reported procedural success in 206/213 (96.7%) patients. There were 82 (38.5%) patients with type A, 98 (46%) with type B, and 33 (15.5%) type C anatomy (23). A multi-center study recently reported excellent procedural success rates, including 96.7% of patients demonstrating mild or reduced residual MR prospectively and 98%±1% 1-year survival and freedom from composite endpoints at a value of 84%±2.5% (20).

The TACT (Trans-apical Artificial Chordae Tendinae) study has played a major role in the development of the TOP-MINI procedure. Patients with anterior or bileaflet MV prolapse were excluded from the TACT study. APS was achieved in 26/30 (86.7%) patients and at the 30-day follow-up, 17 patients maintained an MR grade of ≤+2. (18). We have observed that MV morphology is a determining factor in minimizing residual MR. As seen in the TACT study, patient selection should be done optimally and with care, considering MV pathology and the mechanism of MR. Patients with isolated posterior leaflet prolapse, especially P2, and only limited annular dilatation seem to be the best sample group for this procedure. The TOP-MINI procedure can be applied in other patients with high comorbid factors when conventional surgery is complicated by comorbidities.

Implantation of multiple neochordae on the prolapsing segment may help in distributing the tension, providing a more stable coaptation area, and reducing the risk of leaflet-chordae dehiscence (24, 25). As confirmed in other studies, a prolapsing posterior leaflet segment that is too wide and too high may require the application of more than 2 or 3 neochordae (10, 23). In a study by Rucinkas et al. (11), one patient with 2 neochordae developed recurrent MR at the 30-day follow-up. Our technique in trans-apical implantation of neochordae evolved with a learning curve. Firstly, we deployed 2 neochordae on the prolapsing segment to reduce MR in some cases. Upon the recurrence of MR in these patients, we deployed more than 2 neochordae for each patient to minimize the load per neochord. In the last 10 patients, a minimum of 3 neochordae was applied. When the number of neochordae needed to correct the regurgitation was achieved, they were placed under tension using direct echocardiographic guidance. It is very important to make the adjustment of the neochord length under TEE guidance in a controlled stepwise approach.

Since the NeoChord DS 1000 device offers limited access through a left anterior mini-thoracotomy, the reoperation usu-

ally goes smoothly. In our study, 3 patients were re-operated easily through conventional on-pump surgery with no additional surgical risk. During the reoperation, there were no pericardial adhesions, except in the area around the apex of the left ventricle. Therefore, in selected patients who do not want conventional surgery, we can use trans-apical neochordae to give them another chance in the future with no additional surgical risk.

The use of a mitral annuloplasty ring has become routine in mitral valve repair procedures for degenerative MV disease, and the lack of it has been identified as a risk factor for the failure of mitral valve repair (16, 26). We believe that early correction of severe MR before excessive annular dilatation may significantly alter the course of the disease and reduce the failure rate of trans-apical neochord implantation. In patients who have excessive annular dilatation, we recommend the use of conventional on-pump surgery.

Study limitations

This study had several limitations. Firstly, the small patient population and the retrospective nature of this study did not allow us to draw a satisfactory conclusion about the effectiveness of our procedure. Moreover, the follow-up periods were limited in some cases. Further clinical studies are needed to appreciate the safety and efficacy of performing trans-apical neochord implantation for severe MR.

Conclusion

Due to the decreased invasiveness and the effective reduction of MR with low operative risk, trans-apical off-pump MV repair with neochord implantation using the NeoChord Delivery System (DS) 1000 device may be a suitable treatment option in patients with isolated posterior MV leaflet prolapse, especially in the P2 segment with limited annular dilatation. The long-term durability of the neochord procedure remains to be proved.

Conflict of interest: None declared.

Peer-review: Externally peer-reviewed.

Authorship contributions: Concept – S.S., İ.K., C.K.; Design – S.S., İ.K., C.K.; Supervision – S.S., İ.K., C.K.; Fundings – None; Materials – S.S., B.Ö., H.S.; Data collection &/or processing – S.S., B.Ö., H.S.; Analysis &/or interpretation – S.S., İ.K., C.K.; Literature search – S.S., İ.K., C.K.; Writing – S.S., H.S., C.K.; Critical review – S.S., İ.K.

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