

Original Article

The first four cases of successful NeoChord procedure in mainland China

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BACKGROUND: Transapical off-pump NeoChord procedure is a novel minimally invasive surgical repair of degenerative mitral regurgitation (MR). Here, we report the first four cases of NeoChord procedure in patients with mitral valve prolapse in mainland China.

METHODS: Four patients, aged 86, 84, 80 and 60 years, with severe MR due to posterior middle scallop prolapse (P2), underwent transapical off-pump artificial chordae implantation on April 9 and 10, 2019. The procedure was performed by left mini-thoracotomy under general anaesthesia and guided by 2D and 3D dimensional transoesophageal echocardiography (TEE).

RESULTS: Mitral valve repair via NeoChord procedure was successfully performed with implantation of 3 artificial chordae in the first patient and 3, 2, and 3 artificial chordae in the following patients, respectively. Intraoperative TEE and pre-discharge transthoracic echocardiography (TTE) showed only mild to moderate MR of these four patients and no postoperative complications were noted. There were no changes of TTE finding between one-month follow-up and pre-discharge.

CONCLUSION: The successful NeoChord procedures in four Chinese indicate that the valve repair using the NeoChord system for Chinese population is feasible.

KEY WORDS: Mitral regurgitation; Mitral valve repair; NeoChord system

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INTRODUCTION

Surgical mitral valve repair (MVR) is considered as the gold standard treatment for chronic severe mitral regurgitation (MR) due to leaflet prolapse.^[1] Conventionally, MVR is performed in the patients in cardioplegic arrest to allow exposure of the mitral valve. However, some elderly or high-risk surgical patients cannot tolerate surgical thoracotomy, which reduces the opportunities of these patients to receive effective treatments.^[2] In the era of growing percutaneous treatments for valvular heart disease, the transapical NeoChord repair procedure was emerged to offer an alternative option to conventional surgeries for the treatment of high-risk surgical patients.^[3] The procedure of NeoChord system could be performed on a beating heart under direct transoesophageal echocardiography

(TEE) guidance and allows restoration of normal leaflet motion.^[4] With this technique, chord implantation and adjustment of their length is possible without the use of cardiopulmonary bypass. Recently published clinical studies have confirmed early safety and efficacy of this procedure. As a well-recognized cardiovascular intervention center, we can perform transcatheter aortic valve implantation.^[5] We have successfully completed 12 mitralclip procedures and the first two cases of mitral valve repair by Arto system in Asia. Herein, we describe the first four cases of NeoChord procedures in patients with severe MR in mainland China.

CASES

Patient 1

An 86-year-old man with significant chest tightness

and short of breath was admitted to the hospital for acute exacerbation of heart failure. New York Heart Association (NYHA) class of this patient was IV and he received percutaneous coronary intervention (PCI) procedure five years ago. This patient also had chronic obstructive pulmonary disease (COPD) with pulmonary function tests indicating mild obstructive ventilation dysfunction. Echocardiography (TTE, 2D/3D TEE) revealed slightly thickened mitral leaflets. Because of ruptured tendinous chords, segment P2 of the posterior leaflet regurgitated into left atrium during mitral valve closure and severe single-jet, eccentric MR was noted. Clinical and echocardiographic information of this patient is summarized in Table 1.

Patient 2

This patient was an 84-year-old man who was admitted to the hospital for recurrent dyspnea. He had a history of hypertension and coronary heart disease and NYHA class was IV. Echocardiography (TTE, 2D/3D TEE) showed posterior mitral leaflet thickening, and part of the leaflets (P2 segment) prolapsed into the left atrium during mitral valve closure. Severe multiple-jet could be seen on the mitral valves during systolic period, which run along the anterior lobe and atrial septum. Clinical and echocardiographic information of this patient is summarized in Table 1.

Patient 3

This patient was an 80-year-old woman with recurrent chest tightness. She had a history of coronary artery disease but without hypertension or diabetes. NYHA class of this patient was III. Echocardiography (TTE, 2D/3D TEE) confirmed severe prolapse of the segment P2 of the posterior leaflet due to ruptured tendinous chords. Severe multiple-jet, eccentric MR was noted which run along the left atrial side of the atrial septum. Clinical and echocardiographic information of this patient is summarized in Table 1.

Patient 4

This patient was a 60-year-old man without significant

past medical history. Echocardiography (TTE, 2D/3D TEE) revealed severe eccentric MR due to prolapse of segment P2 of the posterior leaflet caused by rupture of tendinous chords. A cord-like structure could be seen at the apex of the posterior leaflet to move with the opening and closing of the leaflet. Severe multiple-jet, eccentric MR was detected. Clinical and echocardiographic information of this patient is summarized in Table 1.

Procedure

Procedures were performed under general anaesthesia in a hybrid catheterization lab with the capability of cardiopulmonary bypass. All the processes were guided by 2D/3D TEE. Echocardiographic images were displayed on multiple monitors and can be clearly seen by the surgical team. The patient was placed in slight right lateral position to facilitate access to the apical area. Real-time 3D TEE confirmed the mechanism of MR (Figure 1A). After the apex was located by transthoracic echocardiography (TTE), a small incision which was 4 cm in length was performed in the 5th intercostal space. Following the opening of pericardial sac, the site of access to the left ventricle (2–3 cm posterolaterally from the apex) was identified by ultrasound. Apical access was secured with purse strings and felt pledgets. After NeoChord system was inserted, the tip of the instrument was manipulated through the mitral valve at the site of leaflet prolapse under 2D/3D TEE guidance (Figure 1B). Once the device crossed the MV, the prolapsing leaflet was grasped which was then punctured with the instrument needle after full capture was confirmed by fibre optic. The hooked needle was pulled back, and then a loop and two ends of an artificial chord were pulled out. The leaflet was released and a hitch knot fixed the artificial chordae on the leaflet after passing the ends of the chord through the loop. The device was withdrawn under 2D/3D TEE guidance to avoid any damage to the native MV apparatus and was reloaded to implant more neo-chordae. Three artificial chordae were implanted in the first patient and 3, 2, and 3 artificial chordae were implanted in the following patients, respectively. The free ends of all the artificial chordae were passed through

Table 1. Patients' demographics and preoperative echocardiographic data

Patient	ID	Age (years)	Gender	NYHA	CAD	COPD	Hypertension	Diabetes	LVEF (%)	LVEDD (cm)	MR grade	Leaflet involvement	Leaflet prolapse
Patient 1	10659216	86	Male	IV	Y	Y	N	N	51.1	5.06	Severe	P2	Y
Patient 2	10800079	84	Male	IV	Y	N	N	N	68.0	4.26	Severe	P2	Y
Patient 3	11297740	80	Female	III	Y	N	N	N	72.7	5.41	Severe	P2	Y
Patient 4	03145944	60	Male	II	N	N	N	N	72.3	4.77	Severe	P2	Y

NYHA: New York Heart Association; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction (%); LVEDD: left ventricular end-diastolic diameter; MR: mitral regurgitation.

a single felt pledget. Artificial chordae lengths were adjusted using 2D/3D TEE and finally anchored at the LV apex using pledgeted sutures (Figure 1C). TEE was then performed to determine MR to test the effect of chords implantation (Figure 1D). Finally, the pericardial sac was sutured, with a drain inserted into the pleural space and the thoracotomy was closed in a standard fashion.

RESULTS

All four operations were successful. Three artificial chordae were implanted in three male patients, while two chordae were implanted in the female patient. In all male patients, after the artificial chordae were anchored to the epicardium, intraoperative TEE with colour Doppler showed all of them only have a mild MR (Table 2). And in the female patient TEE showed a moderate MR (Table 2). Postoperative drainage was no more than 300 mL and the duration of stay in an intensive care unit of all four patients was only 1 day. Patient 1 and patient 3 developed transient atrial fibrillation (AF) after procedure, but spontaneously converted. Postoperative course was uneventful in all four patients with no adverse events including blood transfusion, pacemaker insertion,

stroke, prolonged ventilation, or reoperation. All patients were discharged from hospital in good clinical condition and pre-discharge TTE confirmed left ventricular ejection fractions (LVEF) were normal in all patients and a significant acute reduction of MR from severe to mild or moderate (severe-to-moderate only in female patient) were achieved that were no change from intraoperative TEE findings (Table 2).

Table 2. Effect of NeoChord implantation and 1-month follow-up results

Variables	Patient 1	Patient 2	Patient 3	Patient 4
ID	10659216	10800079	11297740	03145944
MR				
Preoperative	Severe	Severe	Severe	Severe
Intraoperative	Mild	Mild	Moderate	Mild
Pre-discharge	Mild	Mild	Moderate	Mild
One-month follow-up	Mild	Mild	Moderate	Mild
LVEF (%)				
Preoperative	51.6	68	72.7	72.3
Pre-discharge	40.9	73.5	66.1	57.3
One-month follow-up	53.7	61.4	64.6	55.7
LVEDD (cm)				
Preoperative	5.06	4.26	5.41	4.77
Pre-discharge	4.82	4.08	5.20	4.88
One-month follow-up	5.30	3.69	4.93	5.06
Complications				
Pre-discharge	Transient AF	N	Transient AF	N
One-month follow-up	N	N	N	N

MR: mitral regurgitation; LVEF: left ventricular ejection fraction (%); LVEDD: left ventricular end-diastolic diameter; AF: atrial fibrillation.

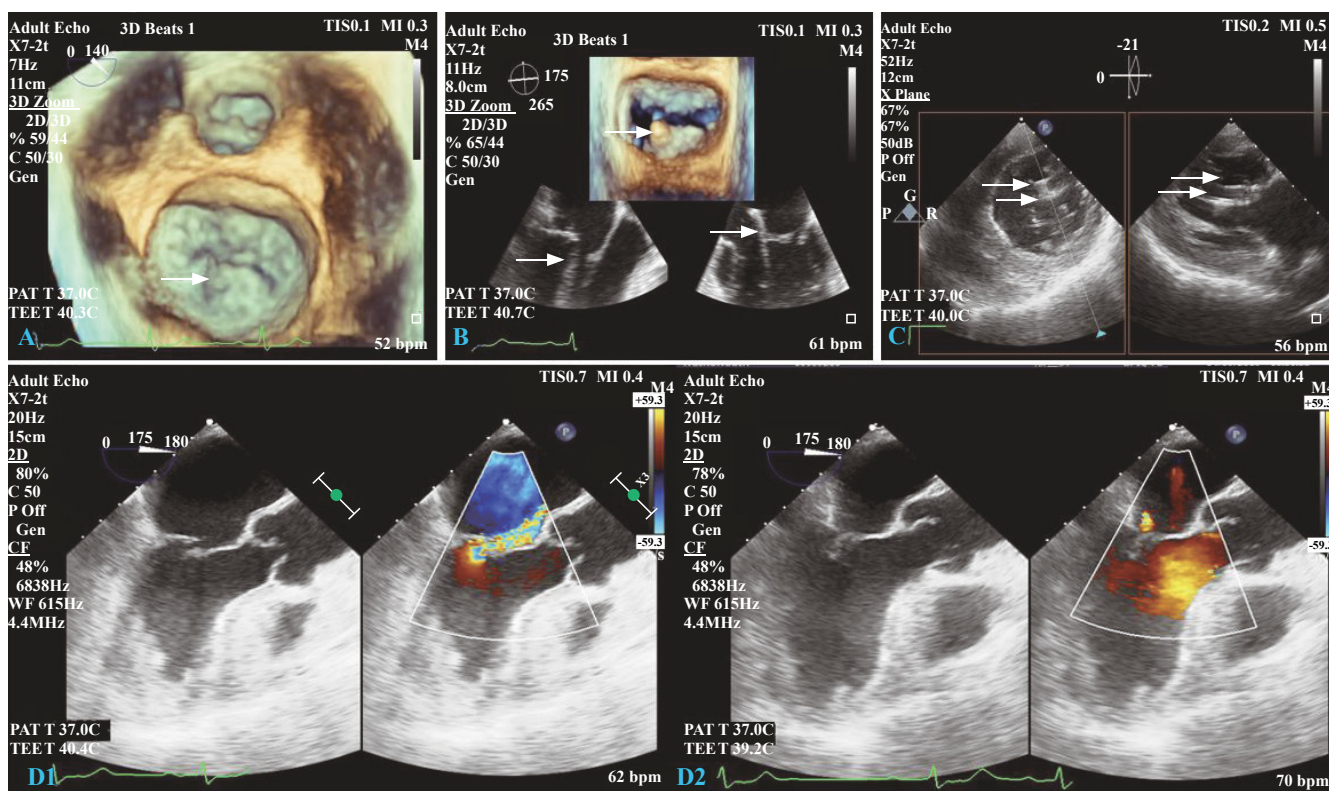


Figure 1. Three-dimensional transoesophageal echocardiography of patient 1. A: Posterior leaflet prolapse involving the P2 segment (arrow); B: 3D TEE view of the mitral valve from the left atrial perspective (“surgeon’s view”); the delivery system of NeoChord located at the prolapsing P2 segment (arrows); C: The procedure results displayed by the transgastric 2-chamber views; the NeoChord pathway could be seen from near the left ventricular apex to the mitral valve (arrows); D: Images of colour Doppler of TEE; D1: Before the procedure; D2: After the procedure.

At 1-month follow-up, MR of these 4 patients was graded as mild, mild, moderate and mild, respectively. All patients reported no cardiac-related symptoms or complications (Table 2).

DISCUSSION

Mitral valve repair by surgical treatment is a routinely performed procedure, especially for patients with posterior leaflet pathology. However, the decision of patients to undergo surgery is often delayed because the valve disease may be asymptomatic or may develop mild symptoms in early stage. Once severe symptoms occur, many people are already in an advanced age and the risk of surgery increases significantly, which makes many patients be no longer able to tolerate the surgeries. The long-term survival rate (6.3%) of patients with severe MR decreases by 6.3% every year.^[6] With increasing of age, volume overload gradually leads to cardiac remodeling and may cause atrial fibrillation, pulmonary hypertension and heart failure. Some epidemiological investigations revealed that over 10 years 63% patients developed atrial fibrillation and symptomatic heart failure, while at 10 years of diagnosis of severe MR, 90% patients die or require surgical treatment.^[6] Therefore, how to stratify the risks and decide timing of surgery are very important and somewhat challenging.

The NeoChord system as a transcatheter mitral valve repair technology provides us a promising alternative to open-heart MVR in patients with severe degenerative MR. This procedure allows for artificial chordae implanted to a mitral leaflet on a beating heart guided by echocardiography without the use of cardiopulmonary bypass.^[7] The method is safe, effective and reproducible as demonstrated in animal studies^[8,9] and clinical^[10,11] studies. To date, the largest published series includes 213 patients from Italy, Germany, Lithuania and Poland. The successful placements of 2 or more neochordae were achieved in 206 (96.7%) patients. At 1-year follow-up, overall survival was 98%±1% and MR was absent/trace in 60 (31.4%) patients, mild in 84 (44%) patients, moderate in 32 (16.7%) patients, and severe in 15 (7.9%) patients. The majority of the patients experienced both a reduction in MR severity and an improvement in the NYHA functional classes.^[12] Recently, a long-term follow-up study was reported by 6 patients at 5 years. Successful repairs were achieved in 5 out of 6 patients. Two patients had to undergo reoperation for recurrent MR at three and sixteen months post-procedure. The remaining three patients were followed up at a period

of 5 years and were observed to have complete freedom from recurrent MR ≤2+.^[13] The author observed all three failure could be attributed to poor patient selection and suggested that patients with isolated posterior leaflet prolapse, in particular P2, with only limited annular dilatation, will be the best target population for this procedure which was confirmed by current literature.^[3,14]

CONCLUSION

In this study, we report the first four cases of the NeoChord procedure in mainland China. The reasonable selection of patients and overcoming the learning curve will significantly improve clinical results and accelerate the worldwide adoption of this new therapeutic procedure with significant benefits for patients.

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Ethical approval: This study protocol was approved by ethical committee of the Second Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China.

Conflicts of interests: The authors declare that they have no competing interests. The funders had no role in the design, conduct, analysis, or interpretation of data or in writing the manuscript.

Contributors: JAW, XBL, ZXP, MJK, FG, LY, WH, MY performed the procedure. JBJ, KDR, LHW, XPL, and XPL evaluated these patients for NeoChord system. XBL and LHW wrote the manuscript. JAW revised and edited the manuscript. All authors read and approved the final manuscript.

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