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Original Article

Initial experience with percutaneous edge-to-edge transcatheter mitral valve repair in a tertiary medical center in Taiwan

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Abstract

Background: The transcatheter edge-to-edge mitral valve repair, using MitraClip, has been a safe and effective treatment for severe mitral regurgitation (SMR) in the westerners. However, the therapeutic results of the MitralClip in Taiwan remained elucidated.
Methods: Patients with symptomatic SMR were evaluated by the heart team. For those with high or prohibitive surgical risks, transcatheter mitral valve repair was performed in hybrid operation room. During procedure, continuous hemodynamic monitoring was conducted. Transthoracic echocardiography (TTE), blood tests, and six-minute walk test (6MWT) were performed before and 1-month after surgery.
Results: A total of 20 patients (73.4 ± 11.1 years, 85% male) with a mean Euroscore II of 13.2 ± 17.7% and a mean STS score of 8.7 ± 9.0% for mortality were enrolled. After a mean procedural time of 239 ± 95 min, an average of 1.8 ± 0.7 clips were used in each procedure. The procedural successful rate was 95% to achieve mild residual mitral regurgitation. Cardiac output was increased from 3.6 ± 0.9 to 4.6 ± 1.4 ($p = 0.008$) and V-wave of left atrial pressure declined from 24.4 ± 9.8 to 19.3 ± 7.1 ($p = 0.030$) immediately during the index procedure. There was no peri-procedural death, myocardial infarction, stroke or any events requiring emergent cardiac surgery. All patients experienced significant improvement in heart failure symptoms. The 6-min walk distance increased from 219.6 ± 118.4 m to 279.1 ± 111.6 ($p = 0.04$) at 1 month. The echocardiogram further showed significant improvements of mitral regurgitation, pulmonary artery systolic pressure, and the left ventricular end-diastolic volume.
Conclusion: Trans-catheter edge-to-edge mitral valve repairs are safe and effective in Asians with symptomatic SMR, regarding the improvements of clinical symptoms and exercise capacities. MitraClips is also associated with reverse remodeling of pulmonary hypertension and left ventricular size in patients with SMR.

Keywords: Mitral regurgitation; Transcatheter mitral valve repair

1. Introduction

More than 10% of the subjects, aged≥ 75 years have moderate to severe mitral regurgitation,[1] resulted from prolapsing leaflets or rupture chordae (degenerative mitral regurgitation, DMR), or as a consequence of annulus dilatation or abnormal left ventricular function (functional mitral regurgitation, FMR). Patients with symptomatic mitral regurgitation, if left untreated, would experience progressive heart

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failure, and the 5-year mortality rate could be as high as 50%.[2] Although mitral valve repair or replacement is the standard treatment for DMR, only 49% of them have received surgery in European heart survey.[3] For those with DMR and advanced age or FMR, the mitral valve surgery may carry high or even prohibitive risks.

The transcatheter edge-to-edge mitral valve repair, using MitraClip (Abbott Vascular, Menlo Park, CA, USA), has been suggested as an alternative of mitral valve therapy for patients with moderate to severe symptomatic DMR in the Endovascular Valve Edge-to-Edge Repair Study (EVEREST II).[4,5] Moreover, MitraClip has also been proposed the survival advantages over medical treatment in the inoperable patients.[6,7] Given one of the major determinants for the procedural success of MitraClip is the mitral valve area, the use of MitraClip to treat mitral regurgitation in Asians may be with challenges when Asian's hearts are smaller than the Western's.[8,9]

In the present study, we reported the initial experience of using MitraClip in Taiwan to demonstrate the feasibility of trans-catheter mitral valve repair for severe mitral regurgitation (SMR). We also showed the hemodynamic and echocardiographic influences of MitraClip in these patients.

2. Methods

2.1. Study participants

Subjects with heart failure and SMR were eligible for this study. All patients would undergo a standard diagnostic workup, including history taking, physical examinations, functional capacity assessments by the New York Heart Association (NYHA) classification and 6-min walk test, transthoracic and transesophageal echocardiogram, diagnostic coronary angiography, and right heart catheterizations for preoperative evaluation. The heart team would disclose the surgical risks and discuss with the patients for the treatments for SMR. Patients undergone trans-catheter mitral valve repair were enrolled in this analysis. The investigation conformed to the principles outlined in the Declaration of Helsinki. A written informed consent approved by our institutional review board was obtained from each subject before enrollment.

2.2. Study protocol

In addition to the pre-operative evaluations, patients would undergo repeated assessments for functional capacity and cardiac performance by transthoracic echocardiogram at 1, 3, 6, and 12 months after the index procedure. Blood tests at fasting were also obtained for the measures of hemoglobin, serum creatinine, and N-terminal pro-B type natriuretic peptide (NT-proBNP) levels. All participants were followed in the clinics or by telephone contact every month for a year.

2.3. Echocardiographic measurements

All patients received a comprehensive Doppler and M-mode transthoracic echocardiography according to the recommendations of American Society of Echocardiography.[8,10] Left ventricular end diastolic and systolic volume (LVEDV and LVESV), and left ventricular ejection fraction were measured by biplane Simpson's method. The regurgitant volume, vena contracta and effective regurgitant orifice of mitral regurgitation were also calculated.[11] The left and right atrial length and transverse major and minor axis were measured from the apical four-chamber view.[8] The severity of mitral regurgitation was then graded as mild (grade 1), mild-to moderate (grade 2), moderate- to severe (grade 3), or severe (grade 4) accordingly. The measurements of mitral valve area (MVA), the flail gap, flail width, coaptation length and coaptation height were obtained by transesophageal echocardiogram (TEE).[4]

2.4. Transcatheter mitral valve repair

The procedure was conducted under general anesthesia with the guidances of fluoroscopy and TEE in a hybrid operative room. During the procedure, pulmonary artery pressure and cardiac output were continuously recorded by Swan–Ganz catheter. In brief, MitraClip was introduced into left atrium after the transseptal puncture to grasp the leaflets and minimize the regurgitation.

Procedural success was defined as a successful implantation of one or more clips to immediately reduce mitral regurgitation of less than grade 2.[12] Procedure related complications of myocardial infarction, stroke, transient ischemic attack, major bleeding and major vascular complications were recorded according to Valve Academic Research Consortium (VARC) and VARC-2 definitions.[13]

2.5. Statistical analysis

Means, standard deviations, and percentages were used to describe the characteristics of the study population. Paired t-test was used for the comparison of pre- and post-procedure hemodynamic and echocardiographic changes. Because of the skewed distribution, NT-proBNP was taken log transformation prior to the statistical analysis. Non-parametric independent t-test was used to compare the baseline characteristics between groups. Statistical significances were set at $P < 0.05$ and all statistical analyses were carried out using SPSS 15.0 (SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Patient characteristics

A total of consecutive 20 patients (73.4 ± 11.1 years, 17 men) treated with MitraClip were included in this analysis. The baseline characteristics were displayed in Table 1. The patients were characterized by high surgical risk (median Euroscore II of 13.2% and median STS score of 8.7% for mortality), and multiple morbidities. The surgeon declined to conduct surgical repair or replacement due to prior open-heart surgery (4 patients), severe lung disease (4 patients), disabled

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