Application of special surgical instruments in transaortic septal myectomy for the treatment of hypertrophic obstructive cardiomyopathy

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Abstract

Background and aim: High technical difficulty has stimulated further studies regarding improving myectomy approaches and reducing the difficulty of myectomy. This study aimed to evaluate the efficacy and repeatability of transaortic septal myectomy with the aid of special surgical instruments for the treatment of hypertrophic obstructive cardiomyopathy (HOCM). Methods: Between March 2016 and March 2019, 168 HOCM patients (83 males, mean 56.8 $\pm$ 12.3 years) were included who underwent isolated transaortic septal myectomy with the aid of special surgical instruments. Intraoperative, in-hospital and follow-up results were analyzed. The incidence of major adverse events per surgeon was compared. Results: Nine (5.4%) patients received immediate repeat surgery. Surgical mortality was 0.6%. Five (3.0%) patients developed complete atrioventricular block and required permanent pacemaker implantation. The median follow-up time was 6 months. No follow-up deaths occurred with a significant improvement in New York Heart Association functional status. The maximum gradients decreased sharply from the preoperative value (11.5 $\pm$ 7.4 mmHg vs. 94.4 $\pm$ 22.6 mmHg, $p<0.001$). The median degree of mitral regurgitation fell to 1.0 (vs. 3.0 preoperatively, $p<0.001$) with a significant reduction in the proportion of moderate or more regurgitation (1.2% vs. 57.7%, $p<0.001$). In addition, no significant difference was found among six surgeons with varied operation volume regarding the incidence of major adverse events (p=0.739). Conclusions: The transaortic septal myectomy with the aid of special surgical instruments achieved favorable and reproducible results, and thus may be a promising treatment option for HOCM.

2.1 Patients

Between March 2016 and March 2019, consecutive HOCM patients aged [?] 18 years who underwent septal myectomy with the aid of special surgical instruments in this center were reviewed. Inclusion criteria were the maximum LVOT gradients [?] 50 mmHg at rest or with provocation and presence of severe limiting symptoms refractory to maximum pharmacologic therapy with non-vasodilating β-blockers and/or calcium channel blockers. Exclusion criteria included: (1) organic mitral valve (MV) lesions (rheumatic, degenerative, ischemic, infective, and mitral annulus calcification); (2) previous valvular surgery; (3) LVOT obstruction secondary to hypertensive heart disease or severe aortic stenosis; (4) concomitant coronary artery disease requiring bypass grafting; (5) concomitant modified Maze procedure; and (6) concomitant obstruction of right ventricular outflow tract requiring enlargement. Patients who underwent septal myectomy via the transseptal approach through right atrium or via the left atrial approach through interatrial sulcus were also excluded.

2.2 Preoperative evaluation

Preoperative transthoracic echocardiography (TTE) examination was performed to define (1) the location and magnitude of any left ventricular pressure gradient, both at rest and with provocation; (2) the distribution and severity of myocardial hypertrophy; (3) MV anatomy and function; (4) the presence of mitral subvalvular anomalies including abnormal chordae tendineae attached to the ventricular septum or free wall (false cords), fibrotic and retracted secondary chordae inserted on the anterior mitral leaflet body, and papillary muscle (PM) abnormalities (hypertrophy, and direct insertion into the anterior mitral valve leaflet); and (5) the presence of intrinsic MV disease including lesions of mitral leaflets and mitral annulus. Resting LVOT velocity was measured by continuous-wave Doppler of the outflow tract from an apical window, and the resting LVOT pressure gradient was estimated by using the modified *Bernoulli* equation (i.e., gradient $= 4v^2$, where v = peak LVOT velocity). In patients with resting LVOT gradients < 30 mmHg, maneuvers such as the Valsalva maneuver and stand-to-squat were frequently used. In addition, cardiac magnetic resonance was frequently used to measure basal septal thickness and for characterization of PM morphology and location within the left ventricular cavity, PM thickness, and PM mobility.

2.3 Study protocol

This study protocol was approved by the ethics committee of Zhongshan Hospital Fudan University and was consistent with the *Declaration of Helsinki* . All included patients signed an informed consent approved by the ethics committee. Data collection was performed by trained staff (two people). The trained staff, however, were not informed of the purpose of this study.

Baseline and surgical characteristics, and perioperative results were obtained from our institutional database and were reviewed using a standard data collection form. Patients were regularly followed up at 3 and 6 months following surgery, respectively, and thereafter at 6-month intervals. Follow-up data were obtained by a clinic visit, WeChat, or telephone. In addition, the incidence of major adverse events per surgeon was calculated and compared. The details of baseline characteristics, surgical characteristics, perioperative results, follow-up results, and major adverse events are shown in the additional file 1.

2.4 Surgical procedures

Operations were guided by intraoperative transesophageal echocardiography (TEE), with particular attention paid to ventricular septal anatomy as well as thickness, MV anatomy as well as function, and mitral subvalvular anatomy. The patient was put in the reverse *Trendelenburg* and left lateral decubitus position. Under general anaesthesia, the heart and ascending aorta were exposed by a median incision with sternotomy, and cardiopulmonary bypass with ascending aortic and right atrial cannulation was established with a left ventricular vent placing via the right superior pulmonary vein. Through a low oblique aortotomy approximately 7-10 mm above the right coronary ostium, the aortic valve leaflets were pulled up to gain access to the outflow tract, the hypertrophic cardiac muscle, anterior MV leaflet, and mitral subvalvular apparatus. A head lamp and loupe magnification were used to achieve better inspection of the left ventricular cavity. Special surgical instruments (as shown in Figure 1) were used during the resection. Scalpel resection was usually started at the nadir of the right cusp, 5 mm below the aortic valve and extending leftwards to the left trigone. The area of septal excision was lengthened beyond the bases of PMs and toward the apex of the heart. The depth of resection was up to 50% of the basal thickness of the septum. The excision of the hypertrophic muscles as a whole mass was required. In addition, mitral subvalvular anomalies were also corrected, including false cords cutting, retracted secondary chordae cutting, and hypertrophic PM release and/or resection. After resections were completed, the bases of the PMs should be seen by looking through the incision of the aortic root. And then, the outflow tract, mitral and aortic valves were carefully and thoroughly reexplored.

TEE was used after weaning off bypass to measure the maximum gradients and the severity of MR following myectomy. A repeat procedure was immediately performed if there was residual LVOT obstruction and/or residual moderate or more MR or if a ventricular septal defect or a left ventricular free wall rupture was observed. Residual obstruction was defined as a maximum gradient following myectomy > 30 mmHg.

2.5 Statistical analysis

Statistical analysis was performed with the SPSS statistical package version 22.0 (SPSS Inc., Chicago, IL, USA). Categorical data were expressed as frequency distributions and single percentages and were compared between groups using *Fisher's* exact test if the expected frequency was < 5 or the *chi-square* test. Normally distributed continuous variables were expressed as the mean $\pm$ standard deviation and were compared between groups using an independent-samples t -test; non-normally distributed continuous variables were expressed as median and interquartile range (IQR) and were compared between groups with the *Wilcoxon* rank sum test. A two-sided p -value less than 0.05 was considered statistically significant.

3. Results

3.1. Study population

A total of 208 adult patients who met the inclusion criteria were reviewed. Forty patients were excluded due to concomitant valvular heart disease requiring surgery (27 patients), concomitant Maze procedure (3 patients), concomitant enlargement of right ventricular outflow tract (2 patients), and undergoing septal myectomy via transseptal approach through right atrium (8 patients), which left 168 eligible patients for data analysis. There were 83 male patients and 85 female patients with a mean age of 56.8 +- 12.3 years. The baseline characteristics are listed in Table 1. Despite the fact that 39.9% of the population had a history of hypertension, it was not deemed severe enough to be the primary cause of ventricular hypertrophy. Nine (5.4%) patients underwent previous alcohol septal ablation. Atrial fibrillation and right bundle branch block were recorded in 14 (8.3%) patients and 4 (2.4%) patients, respectively. All patients manifested severe limiting symptoms, such as dyspnea, angina-like chest pain and syncope, with New York Heart Association (NYHA) functional class III and IV in 86.3% of the population.

TTE examination revealed a mean maximum LVOT gradient of 94.4 +- 22.6 mmHg with a mean interventricular septal thickness of 18.3 +- 3.1mm. Systolic anterior motion (SAM) was observed in all patients, of whom 97 (57.7%) were diagnosed with moderate or more MR. Importantly, midventricular obstruction was recorded in 7 (4.2%) patients. Mitral subvalvular anomalies were identified in 45 (26.8%) patients, including false cords (11 patients), fibrotic and retracted secondary chordae (29 patients), and PM abnormalities (13 patients).

All patients underwent transaortic septal myectomy with a mean aortic cross-clamping time of 36.0 +- 8.1 minutes (median, 35.0 min). 45 (26.8%) patients received mitral subvalvular procedures in addition to myectomy, including false cords cutting (11 patients), fibrotic and retracted secondary chordae cutting (29 patients), and M release and/or resection (13 patients).

3.2 Intraoperative results

The immediate repeat procedure was recorded in 9 (5.4%) patients. Of them, 5 patients were identified as residual LVOT obstruction or moderate or more MR due to inadequate initial septal myectomy, and underwent a "more" extended myectomy in terms of depth and length and/or leftward direction from the left ventricular free wall toward the MV according to TEE findings (4 patients) and received transaortic mitral valve repair using the "edge-to-edge" technique (one patient); another 2 patients underwent repair of a left ventricular free wall rupture due to free wall rupture; and the remaining 2 patients underwent repairs of septal defect and aortic right valve due to iatrogenic perforation, respectively.

TEE examination showed that the maximum LVOT gradients following myectomy fell to 10.8 +- 6.3 mmHg with the interventricular septal thickness of 13.8 +- 2.1 mm, both of which were significantly lower than the preoperative values ($p<0.001$). No residual obstruction was recorded. SAM was observed in 16 (9.5%) patients, of whom one was identified as moderate MR. No instances of more than moderate MR were observed.

3.3 In-hospital outcomes

One patient died of cerebral hernia on the fourth day postoperatively, which may be associated with acute cerebral infarction, and surgical mortality was 0.6%. Five (3.0%) patients developed complete atrioventricular node block and required permanent pacemaker implantation. Note that of the 5 patients, 3 had right bundle branch block prior to surgery. Another 4 (2.4%) patients developed new-onset atrial fibrillation, but all the 4 patients returned to sinus rhythm following electrical cardioversion. A total of 167 patients were discharged, and the median length of postoperative hospital stay was 6 days. The other postoperative complications are listed in Table 2.

3.4 Follow-up results

A total of 161 (95.8%) patients received a follow-up visit with a median duration of 6 (6-13) months. During the follow-up periods, the clinical manifestations disappeared, and no deaths or re-interventions were observed. As shown in Figure 2, NYHA functional class significantly improved from the preoperative values, with no patients being class III or IV.

TTE examination at the latest follow-up showed the maximum LVOT gradients were significantly lower than the preoperative values (Figure 3). Three patients were identified as residual obstruction with the maximum gradients of 34 mmHg, 39 mmHg, and 42 mmHg, respectively. However, the 3 patients did not receive repeat surgery or alcohol septal ablation. As summarized in Table 2, moderate MR at the latest follow-up was recorded in 2 (1.2%) patients with no symptoms, which was significantly lower than the preoperative value (1.2% vs. 57.7%, $p<0.001$). There were no cases of severe MR at follow-up. Note that one patient who developed iatrogenic septal perforation intraoperatively was found to have one 2-mm asymptomatic ventricular septal defect during follow-up. The patient was categorized as NYHA class I, and dynamic evaluation was continued.

3.5 Incidence of major adverse events per surgeon

Six surgeons (total number of procedures during the three-year period of 72, 36, 23, 14, 13, and 10, respectively) have completed 168 transaortic septal myectomy procedures. A total of 11 major adverse events were recorded, including surgical death (one patient), complete atrioventricular block (5), residual obstruction (3), and moderate residual MR (2). As shown in Table 3, no significant difference was found among all surgeons regarding the incidence of major adverse events ($p=0.739$).

Discussion

In the 1960s, Morrow et al have reported transaortic resection of a small amount of muscle from the proximal ventricular septum, a technique generally described as classic Morrow operation. Over the next decades, myectomy has evolved from the classic Morrow operation to a more extended septal myectomy guided by preoperative cardiovascular magnetic resonance and intraoperative TEE [15-18]. High technical difficulty, however, limited clinical application of the extended septal myectomy procedure. In 2015, Ferrazzi et al proposed the transaortic secondary chordae cutting in addition to a shallow septal myectomy for the treatment of HOCM [8]. It was reported to be associated with favorable results [8, 19]. However, such an approach remained controversial because the secondary chordae maintains ventricular geometry and enhances wall thickening, which may be helpful in the presence of left ventricular dilation and systolic dysfunction [20]. In this study, with the aid of special surgical instruments, transaortic septal myectomy was performed in 168 patients with HOCM and drug refractory symptoms. Favorable results were achieved, including a low surgical mortality (<1%) with no occurrences of deaths or re-interventions at follow-up, a significant improvement of quality of life with recovery from symptoms and NYHA functional class I and II, an effective relief of LVOT obstruction, and a reliable reduction of MR. The observed good survival and a significant improvement in NYHA functional status coincided with an effective relief of LVOT obstruction and a reliable reduction of MR, which confirmed the safety and efficacy of transaortic septal myectomy with the aid of special surgical instruments in the treatment of symptomatic HOCM.

In this series including 168 transaortic myectomy procedures with the aid of special surgical instruments, the mean duration of aortic cross-clamping was 36.0 +- 8.1 minutes (median, 35.0 min), which was significantly lower than the value (median, 68 min) reported from a famous and experienced myectomy center in the same country[21]. The reason for this difference may be that the application of special surgical instruments may be beneficial in reducing the technical challenges of myectomy and shortening operation time.

Note that 7 HOCM patients in this series suffered from midventricular obstruction and underwent transaortic septal myectomy with the aid of special surgical instruments. Favorable results suggested that the application of special surgical instruments made it easy to remove the myocardium at the base of PMs, even to extend to the apex of the left ventricle. The surgical comfort of the operator is essential for a myectomy surgeon, especially for an inexperienced myectomy surgeon. These may attribute to the small operational radius of the special instruments. Moreover, the application of special surgical instruments is beneficial for an adequate length of septal excision, which is extremely important to surgical effect [14].

In addition, six surgeons with greatly varied operation volume have completed 168 myectomy procedures. Favorable results were achieved, and no significant difference was found among six surgeons regarding the incidence of major adverse events, which suggested that the application of special surgical instruments during transaortic septal myectomy may be a promising treatment option for HOCM, with good and reproducible results.

Complete atrioventricular block, left ventricular free wall rupture, aortic valve injury and iatrogenic septal perforation were the main complications of septal myectomy. In the present cohort, the incidence of pacemaker implantation (3.0%) was greater than expected based on other large series [22, 23]. This elevated incidence was attributed to the excessive subaortic resection to the side of the noncoronary valve when the incision beginning just to the right of the nadir of the right aortic sinus was made. More than 41.0% of patients developed complete left bundle branch block after myectomy, which allowed the adoption of conservative surgical strategies in patients with preoperative right bundle branch block. In this series, left ventricular free wall rupture, a rare complication after myectomy, occurred in 2 (1.2%) patients, and was successfully treated under cardiopulmonary bypass and cardioplegic arrest with a double-armed 3-0 polypropylene suture with a pledget placed in a horizontal mattress fashion, similar to the technique described to control a stab wound to the heart in close proximity myectomy to a coronary artery. Left ventricular free wall rupture may be associated with excessive subaortic resection to the mitral anterior commissure when the incision that began just to the right of the nadir of the right aortic sinus was made. Although abnormal papillary muscles were corrected, left ventricular free wall rupture was indicated via operative exploration to not be associated with the excision of muscle bundles. In principle, aortic valve injury and iatrogenic septal perforation were prone to occur in young patients with small aortic roots and old patients without severe septal hypertrophy, respectively. In this series, ventricular septal perforation occurred in one female patient aged 70 years with a preoperative septal thickness of 17.0 mm. Although the perforation was repaired using a bovine pericardium patch, a residual ventricular septal defect was observed during follow-up and may be associated with the thin myocardium surrounding of the perforation and the small patch that was not large enough to extend beyond the edge of the perforation at a certain distance.

This study had some potential limitations. First, this was a single-center, single-armed observational study with a limited sample size, which may have influenced the generalizability of the results. Second, only a minor part of patients received cardiac magnetic resonance imaging, as it did not serve as a regular examination modality in the early times at our institution. Third, a functional capacity assessment tool, such as the 6-minute walking test, and a quality of life assessment tool, such as the SF-36 questionnaire, were not utilized in this study. Finally, the duration of follow-up was relatively short. It needed longer observation to confirm our findings.

Conclusion

The application of special surgical instruments may contribute to reducing the technical difficulty of myectomy. Transaortic septal myectomy procedure with the aid of special surgical instruments achieved favorable and reproducible results, and thus may be a promising treatment option for HOCM.

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Figure Legend

Figure 1. Special surgical instruments .

Special surgical instruments include long surgical forceps (the left) and long arm surgical scissors (the right).

Figure 2. Pre- and post-operative NYHA functional class.

P<0.001, NYHA functional class prior to myectomy vs. NYHA functional class at the latest follow-up.

Figure 3. Pre- and post-operative maximum LVOT gradients.

The values of the red line represent the mean maximum gradients. LVOT, left ventricular outflow tract.

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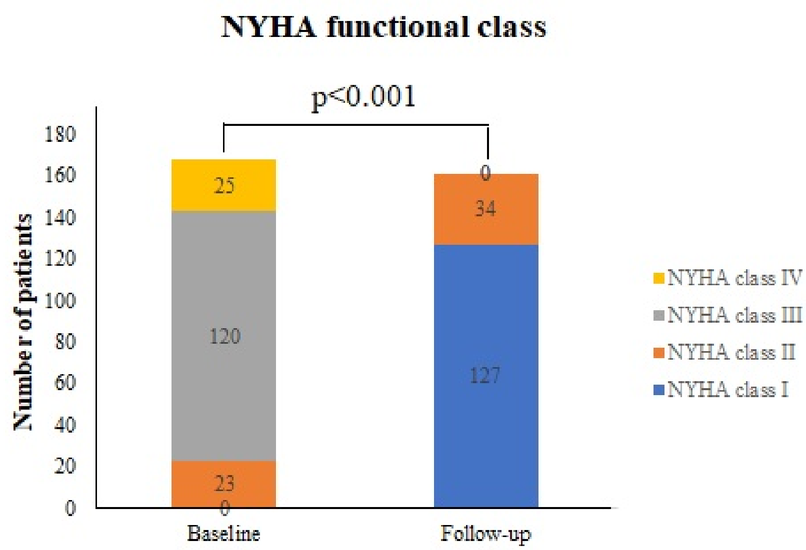
NYHA functional class
p<0.001
Number of patients
180
160
140
120
100
80
60
40
20
0
25
120
23
0
34
127
Baseline
Follow-up
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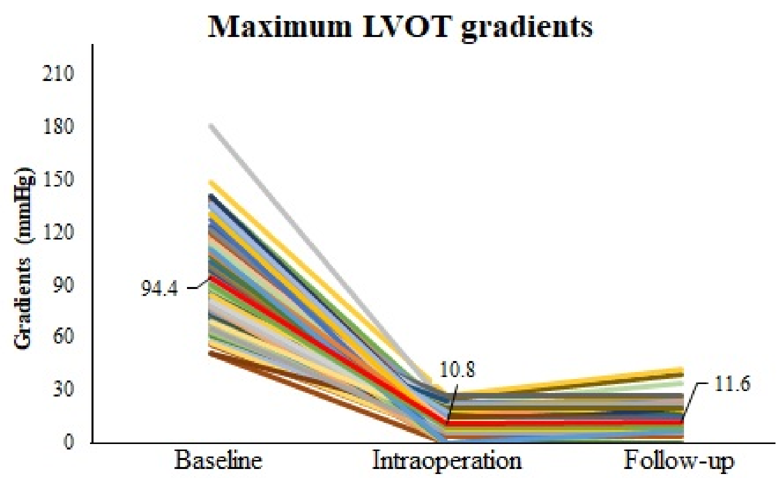
NYHA class III
NYHA class II
NYHA class I


Maximum LVOT gradients
Gradients (mmHg)
210
180
150
120
90
60
30
0
94.4
10.8
11.6
Baseline
Intraoperation
Follow-up