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Minimally Invasive Versus Full Sternotomy Septal Myectomy for Hypertrophic Cardiomyopathy

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SUMMARY

Objective: Septal myectomy remains the gold-standard for the treatment of patients with hypertrophic obstructive cardiomyopathy (HOCM) refractory to medical therapy. There have been few reports of minimally invasive approaches. This study compared a minimally invasive septal myectomy performed at our institution with the traditional full sternotomy approach.

Methods: Patients receiving a stand-alone septal myectomy were retrospectively reviewed from November 1999 to December 2016 (n=120). Patients were stratified by surgical approach: traditional full sternotomy (FS: n=34), and mini-sternotomy (MS: n=86). Preoperative and perioperative variables were compared as well as follow-up symptomatic and echocardiographic outcomes.

Results: Both groups had a significant decrease in NYHA class heart failure symptoms ($p < 0.001$). At a mean follow-up time of 2.0 ± 3.4 years, postoperative NYHA class distribution was similar between MS and FS ($p = 0.684$). Follow-up resting left ventricular outflow tract (LVOT) gradient was also similar between MS and FS ($11 \text{ mm Hg} \pm 15$ vs $9 \text{ mm Hg} \pm 13$, $p = 0.381$). Perioperatively, MS was not significantly different from FS in median cardiopulmonary bypass time (81 min vs. 78 min, $p = 0.101$), but had a slightly longer median cross clamp time (39 min vs. 35 min, $p = 0.017$). Major complications were similar in the two groups. There was one 30-day mortality in the FS group, but no in-hospital deaths.

Conclusions: Septal myectomy performed using a minimally invasive approach has similar outcomes to the gold-standard operation done through a full sternotomy. It represents a feasible option for patients with HOCM unresponsive to medications.

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Keywords

Septal myectomy; Hypertrophic obstructive cardiomyopathy; hypertrophic cardiomyopathy; Minimally invasive surgery

INTRODUCTION

Hypertrophic cardiomyopathy is a genetic cardiac disease characterized by asymmetric hypertrophy of the left ventricle, with an estimated prevalence of 1 in 500 people [1]. It is represented by a broad range of genetic and clinical features, with outcomes ranging from normal life expectancy with little or no symptoms to heart failure and sudden cardiac death [2, 3]. Approximately two-thirds of patients have an obstructive form of the disease in which there is obstruction of the left ventricular outflow tract (LVOT), conventionally defined as having an instantaneous peak Doppler LVOT pressure gradient of at least 30 mm Hg during rest or provocation [4]. LVOT obstruction represents a predictive factor for more severe symptoms such as dyspnea, angina and syncope, as well as an increased risk of atrial fibrillation, heart failure, and death [5–7].

First-line treatment for patients with hypertrophic obstructive cardiomyopathy (HOCM) consists of oral medications including β -blockers or calcium-channel blockers. However, in patients who are refractory to medical management and have a resting or provokable LVOT gradient of at least 50 mm Hg, a surgical myectomy has been the gold-standard treatment as judged by expert consensus and practice guideline recommendations [4, 8, 9]. The classic Morrow septal myectomy was introduced in 1968 [10–12], and was later modified to extend further into the ventricle [13–15]. The conventional surgical approach for a myectomy is a full median sternotomy, while reports of minimally invasive techniques have been lacking and limited in both size and follow-up [16–21].

For more than a decade, our institution has routinely used a minimally invasive technique utilizing a mini-sternotomy to treat severely symptomatic and drug-refractory patients with HOCM. The goal of this study was to compare the outcomes of patients who underwent a mini-sternotomy (MS) septal myectomy with those treated using the traditional full sternotomy approach (FS).

METHODS

Consecutive patients with hypertrophic obstructive cardiomyopathy undergoing stand-alone septal myectomy at our institution were retrospectively reviewed from November 1999 to December 2016. Patients undergoing concomitant procedures were excluded. The study was approved by the Institutional Review Board of the Washington University School of Medicine, with a waiver of patient consent. Demographic and perioperative clinical data were collected from our institutional Society of Thoracic Surgeons (STS) database, while follow-up, echocardiographic and medication data were obtained by query of our electronic medical record database. A total of 120 patients were included in the study cohort. Patients were divided into two groups based on the surgical approach. The literature search was performed using Pubmed and Google Scholar. The studies were selected based on their

relevance as well as impact as judged by the number of citations and impact factor of the journals.

Surgical Technique

We have previously described our minimally invasive technique via mini-sternotomy in detail [22]. The mini-sternotomy is our preferred approach and all patients who are referred for a septal myectomy are considered for it. The full sternotomy is usually reserved for patients with a significant leftward deviation of the aorta, patients with a prior sternotomy, and those undergoing concomitant surgery requiring a wider exposure such as mitral valve repair/replacement, CABG, or the Cox-Maze procedure for atrial fibrillation.

All patients undergo a preoperative transthoracic echocardiography, coronary angiography, and anesthesia assessment. In addition, intraoperative transesophageal echocardiography (TEE) is used to confirm preoperative findings and to aid in planning the extent of the myectomy. The surgical technique used to perform a minimally invasive septal myectomy involves a skin incision that is made between the second and fourth intercostal spaces in the midline, after which a mini-sternotomy is performed by dividing the sternum from the sternal notch down into the fourth right intercostal space. Cardiopulmonary bypass is established in the standard fashion by direct cannulation of the ascending aorta using a 21F (7 mm) flexible cannula (Edwards Lifesciences Corp, Irvine, CA USA), and right atrial appendage using a flat 3 stage venous cannula (Medtronic, Inc., Minneapolis, MN USA). Antegrade cardioplegia is administered. After the aorta is opened transversely and the aortic valve is visible, a flexible arm retractor with custom-designed retractor blade fixed onto the sternal retraction system (AtriCure, West Chester, OH USA), is used to retract the right cusp of the aortic valve and expose the ventricular septum. If the septum is significantly deviated to the left and cannot be adequately visualized, then we convert to a full sternotomy. A ribbon retractor is placed through the aortic valve and used to retract and protect the anterior mitral leaflet and the subvalvular mitral apparatus from injury, and is bent 90 degrees at its distal extent to prevent injury to the papillary muscles or left ventricle. A #15 blade scalpel is used to perform a septal myectomy beginning 1–2 mm below the aortic leaflet insertion and extending from the nadir of the right cusp of the aortic valve leftward to the commissure between the left and right cusps. The myectomy is then extended down towards the edge of the anterior leaflet of the mitral valve, and carried inferiorly as far as needed to remove all of the obstructive muscle, which is usually down to the mid-papillary muscle level, but can be deeper as defined by the intraoperative TEE. The use of long endoscopic, single-shafted forceps and scissors facilitate the exposure for the myectomy.

Lastly, the outflow tract is inspected for accessory papillary muscles and chords, which when present are excised as they can contribute to the obstruction. The aortic and mitral valves are also inspected to ensure they have not been injured, and the patient is then weaned from cardiopulmonary bypass. TEE is used to assess the post-myectomy LVOT gradient, look for presence of systolic anterior motion of the mitral valve, and to rule out a ventricular septal defect.

Study Design

Twenty-three preoperative and 18 perioperative variables were compared between the groups (Tables 1 and 2) and were chosen based on their clinical significance, after a preliminary analysis of more than 100 variables from our STS database. Complications including pneumonia, mediastinitis, need for intraaortic balloon pump, stroke, reoperation for bleeding, and renal failure requiring dialysis were considered major complications and were individually compared between groups. The overall major complication rate was defined as the aggregate of these complications and compared between groups. Other complications such as ventricular septal defect, post-operative atrial fibrillation, need for pacemaker or an implantable cardioverter defibrillator, or prolonged ventilation were also compared between the groups.

Follow-up

One hundred and ten patients were available for follow-up (92%). Symptoms were evaluated based on the New York Heart Association (NYHA) class determined at the time of their last available visit. Mean follow-up time was 2.0 ± 3.4 years (median 7 months). Postoperative echocardiography was performed in 83% of patients (81% in MS, 89% in FS) available for follow-up (92 patients). Intraoperative echocardiograms and those performed within a month postoperatively were excluded. The most recent available echocardiogram was chosen. Mean echocardiographic follow-up time was 1.7 ± 2.3 years (median 6 months).

Statistical Analysis

The hypothesis of the study is that both approaches would have similar perioperative outcomes including complications, in addition to similar follow-up echocardiographic and clinical outcomes. Echocardiographic endpoints were post-operative resting LVOT gradient, change in LVOT gradient pre-operatively to post-operatively, and the degree of mitral regurgitation. The clinical endpoint was NYHA class symptoms at last follow-up. Continuous variables were expressed as mean $\pm$ standard deviation (SD) or as median with interquartile range. Nominal categorical variables were expressed as frequencies and percentages with outcomes compared using the χ^2 or the Fisher exact test. Ordinal categorical variables were expressed as medians with interquartile range and compared using Mann-Whitney U nonparametric test. Continuous outcomes were compared using the t-test for means of normally distributed continuous variables and the Mann-Whitney U nonparametric test for skewed distributions. The change in NYHA class distribution preoperatively to postoperatively within each group was analyzed using the Wilcoxon Matched Pairs Signed Rank test. The change in resting LVOT gradient preoperatively to postoperatively within each group was analyzed using matched pairs t-test. As-treated analysis was used to compare the two patient cohorts. All data analyses were performed using SPSS 23.0 (IBM Software, Armonk, NY) statistical software.

RESULTS

Preoperative Demographics

A total of 120 patients were included in the study cohort. Thirty-four patients were included in the FS group, and 86 patients were in the MS group. Six patients were originally scheduled for a mini-sternotomy but were converted to a full sternotomy prior to the operative procedure in order to facilitate exposure. These patients were included as part of the FS cohort. Among the 23 preoperative demographics collected (**Table 1**), BMI was greater in the FS group compared to the MS group (36 ± 7 vs. 32 ± 7 , $p=0.005$). However, there were no significant differences between the MS and FS groups when comparing age, gender, number of patients with NYHA class III or IV symptoms, or number of patients with a previous cardiac intervention including previous myectomy, previous percutaneous coronary intervention, previous failed alcohol ablation, and previous pacemaker or ICD implantation. There were also no significant differences in left ventricular ejection fraction, left atrial diameter, septal thickness, number of patients in moderate or severe mitral regurgitation, preoperative medications including beta-blockers, calcium channel blockers and disopyramide, or patients with history of syncope, atrial fibrillation, peripheral vascular disease, chronic lung disease, diabetes or stroke. For the 92 patients with both preoperative and postoperative echocardiograms available, there was no significant difference in resting LVOT gradient between MS and FS preoperatively ($54 \text{ mm Hg} \pm 36$ vs. $48 \text{ mm Hg} \pm 30$, $p=0.381$) (**Figure 1**).

Perioperative Results

Eighteen perioperative variables were compared between the MS and FS groups (**Table 2**). MS was not significantly different from FS in median cardiopulmonary bypass time (81 min [interquartile range 72–91] vs. 78 min [interquartile range 67–87], $p=0.101$), but had a slightly longer cross clamp time (39 min [interquartile range 34–46] vs. 35 min [interquartile range 29–41], $p=0.017$). There were no significant differences between MS and FS in median ICU length of stay (LOS) (24 hrs [interquartile range 22–61] vs 30 hrs [interquartile range 24–74], $p=0.367$), median hospital LOS (5 days [interquartile range 4–7] vs. 5 days [interquartile range 5–8], $p=0.373$), median red blood cell units received intraoperatively (0 units [interquartile range 0–2] vs. 0 units [interquartile range 0–1], $p=0.050$), or postoperatively (0 units [interquartile range 0–1] vs. 0 units [interquartile range 0–0.25], $p=0.651$). There were no iatrogenic ventricular septal defects in any of the groups. Overall major complications were similar between the two groups, and there were no differences between MS and FS when comparing individual major complications. Other complications such as atrial fibrillation, pacemaker implantation, ICD implantation, and prolonged ventilation were similar between the two groups as well. There were no post-operative myocardial infarctions in either group. There was one 30-day mortality in the FS group (MS, 0% [0 of 86] vs. FS, 3% [1 of 34], $p=0.283$), but no in-hospital deaths.

Follow-up Results

The percentage of patients with moderate mitral regurgitation at the time of their last echocardiographic evaluation was similar between MS and FS (9% [6 of 67] vs. 8% [2 of 25], $p=1.000$), with severe mitral regurgitation present in only one patient in the MS group.

For the 92 patients with both preoperative and postoperative follow-up echocardiograms available, there was no significant difference in postoperative resting LVOT gradient between MS and FS ($11 \text{ mm Hg} \pm 15$ vs. $9 \text{ mm Hg} \pm 13$, $p=0.695$) (**Figure 1**). The reduction in the resting LVOT gradient preoperatively to postoperatively was similar between MS and FS ($44 \text{ mm Hg} \pm 34$ vs. $38 \text{ mm Hg} \pm 30$, $p=0.479$). In addition, resting LVOT gradient was significantly reduced following septal myectomy in both groups ($p<0.001$). In terms of the NYHA class distribution (**Figure 2**), MS and FS were similar both preoperatively ($p=0.821$) and postoperatively ($p=0.611$) at the patients' most recent clinical follow-up visit. Both groups saw a statistically significant reduction in NYHA class following surgery ($p<0.001$).

Learning Curve

The outcomes of the first 20 cases of the MS group were compared with the last 20 cases to determine if there is a learning curve associated with the MS approach. The median cardiopulmonary bypass time was significantly longer in the first 20 cases (90 min [interquartile range 81–109] vs. 80 min [interquartile range 73–88], $p = 0.007$), as was the median cross clamp time (47 min [interquartile range 40–59] vs. 37 min [interquartile range 33–40], $p = 0.001$). However, there were no significant differences in any other perioperative or long-term outcomes including complications, blood product use, lengths of stay, post-op gradient, or NYHA class.

DISCUSSION

Over the years, minimally invasive techniques have been introduced for the treatment of various cardiac pathologies, including coronary revascularization and for the treatment of valvular heart disease. These techniques have involved limited access, including mini-sternotomy or mini-thoracotomy. In certain instances, these approaches have shown benefits in terms of hospital or ICU LOS and blood loss [23–25]. With regards to surgical treatment of HOCM, current reports and studies of minimally invasive techniques have been very limited in scope [16–21]. The predominant technique for performing septal myectomy remains a full median sternotomy with a transaortic approach. In practice, the less invasive catheter-based septal alcohol ablation procedure has been offered to patients with HOCM requiring intervention. Although there has been no randomized controlled trials comparing septal myectomy to septal alcohol ablation, several meta-analyses have shown that both procedures provide similar symptomatic improvement and have a similar procedural mortality, but septal alcohol ablation is associated with a greater risk of certain complications such as atrioventricular block and need for a permanent pacemaker [4, 26–29]. Therefore, septal alcohol ablation has typically been reserved for higher risk patients that are not surgical candidates. The development of a surgical technique which provides the same symptomatic relief and complication rate as the gold-standard septal myectomy but in a less invasive manner might be helpful in preventing the patient's perception of the invasiveness of the procedure from influencing the choice between a septal myectomy and septal alcohol ablation when one is not clearly indicated over the other. Therefore, the purpose of this study was to evaluate our experience with a minimally invasive technique for performing a septal myectomy, and compare it with the traditional sternotomy approach.

Our technique involves a mini-sternotomy incision and a transaortic approach utilizing central cardiopulmonary bypass.

Both groups were similar with regards to almost all of the preoperative variables reported, except for BMI. The similarity between the groups is a testimony to the fact that we have not only chosen the low-risk patients for a minimally invasive approach. In fact, over the last decade, all patients referred for a septal myectomy are considered for a mini-sternotomy, unless they have obvious displacement of the aorta on chest xray or CT scan, have had a previous sternotomy, have aortic insufficiency, or have significant mitral regurgitation likely requiring repair. Although BMI has not been a main determinant of our decision making process, the observation that patients who underwent a full sternotomy had a statistically significant higher BMI is interesting and might represent the surgeons' perception of a difficult exposure in more obese patients.

The minimally invasive approach can be done without considerably prolonging operative time. The mini-sternotomy added 4 minutes to the median cross clamp time and 3 minutes to the median bypass time. Although the cross clamp time showed a statistically significant difference, 4 extra minutes were not likely clinically significant given that the rate of complications was similar between the 2 groups. The rate of all complications analyzed, including major complications, was similar between MS and FS. This could account for the similarity in both hospital and ICU LOS between the two groups. In addition, there was zero 30-day mortality in the 86 patients that underwent a mini-sternotomy, indicating the safety of this approach.

Follow-up data showed that patients in both groups were doing similarly well in terms of their NYHA functional class, which is very important from a patient perspective, and what many consider to be the most important outcome variable. Our data revealed that both approaches were equally as effective in relieving the symptoms. Furthermore, hemodynamic parameters obtained through echocardiographic follow-up underscore a similar conclusion. Both the postoperative resting LVOT gradient as well as the percentage of patients with moderate or severe MR were similar between both groups. Regarding the resting LVOT gradient, although both groups showed no differences in the preoperative gradient and postoperative gradient, we also analyzed the reduction (change) in the gradient preoperatively to postoperatively within each group and found that this was not significantly different between MS and FS. As a result, we concluded that both approaches had a similar effect in reducing the resting LVOT gradient.

As mentioned earlier, there have been a few other reports of less-invasive surgical techniques for performing a septal myectomy [16–21], although three of these are case reports [17, 18, 20], and two are case-series with less than 20 patients [16, 19]. A recent similar study by Mazine and colleagues [21] compared 24 patients undergoing stand-alone transaortic septal myectomy through a right parasternal mini-thoracotomy with 26 patients undergoing the same procedure through a median full sternotomy. Their study demonstrated similar clinical and echocardiographic follow-up outcomes between the mini-thoracotomy group and the full sternotomy group. In contrast to our study, their minimally invasive group had a shorter hospital LOS when compared to the sternotomy group. The difference between their study

and our report in terms of hospital LOS results probably arises from a longer median hospital LOS in their sternotomy group as compared to ours (8 days vs. 5 days), rather than from a difference between our minimally invasive approaches, which have a similar median hospital LOS of 5 days. An advantage of our mini-sternotomy approach compared to a right mini-thoracotomy is that it can readily be converted to a full sternotomy if the need arises.

Limitations

This study has several limitations. First, this was a retrospective review which introduces inherent potential biases that could have been possibly avoided if performed in a prospective fashion. However, all data except echocardiographic, medication, and follow-up NYHA class variables were collected prospectively and entered into our STS database, and this is a series of consecutive patients. Secondly, we did not report a comparison of provokable LVOT gradient between the two groups even though preliminary analysis showed no significant difference, as this variable was available in only 39% of patients postoperatively. Thirdly, although this is the largest study in the literature looking at minimally invasive septal myectomy, the sample size is still relatively small and the study might not have detected certain differences between MS and FS than if the sample size was larger. Moreover, the amount of patients was not balanced between the different groups, with the MS cohort having more than double the amount of patients than the FS cohort. This is likely due to the fact that most patients referred for a septal myectomy are initially considered for the minimally invasive approach. In addition, we were limited in terms of the long-term clinical and echocardiographic data. These were not available for all patients, and the duration of the follow-up was relatively short compared to the duration of the study. One of the main reasons for this limitation was that patients with HOCM are referred to us from different parts of the country given the highly specialized nature of the procedure that limits the centers of excellence to a few tertiary care centers. It was therefore difficult to obtain long-term follow-up data from all the patients in the study. Lastly, there was a learning curve associated with the minimally invasive approach as shown by the longer bypass and cross-clamp times when comparing the first 20 cases with the most recent 20 cases. Even though there were no differences in any of the complications or other perioperative and long-term outcomes, all the minimally-invasive septal myectomies at our institution were performed by a single surgeon and hence we are unsure of how our results will translate to other institutions.

Conclusions

In conclusion, the septal myectomy procedure performed in a minimally invasive manner via a mini-sternotomy is an effective approach for the surgical treatment of HOCM and is noninferior to the traditional full sternotomy approach. It hence represents a feasible option for patients with HOCM unresponsive to medications.

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Figure 1:
Preoperative and postoperative resting LVOT gradients for MS and FS. For both groups, LVOT gradient was significantly reduced following septal myectomy ($p<0.001$).

Figure 2:
Stacked bar graph showing the distribution of patients according to their NYHA class preoperatively and postoperatively for both MS and FS.

Table 1.

Preoperative demographics

Variable	MS (n=86)	FS (n=34)	p Value
Age (years)	52 ± 13	53 ± 13	0.798
Female gender	45 (52%)	20 (59%)	0.548
BMI	32 ± 7	36 ± 7	0.005
NYHA class III or IV	70 (81%)	27 (79%)	0.801
Previous cardiac intervention	28 (33%)	14 (41%)	0.401
Previous myectomy	0 (0%)	1 (3%)	0.283
Failed alcohol ablation	5 (6%)	2 (6%)	1.000
Pacemaker implantation	10 (12%)	4 (12%)	1.000
ICD implantation	18 (21%)	8 (24%)	0.807
Previous PCI	4 (5%)	2 (6%)	1.000
LVEF (%)	67 ± 9	68 ± 9	0.645
Left atrial diameter (cm)	4.6 ± 0.8	4.6 ± 0.7	0.931
Septal thickness (cm)	2.2 ± 0.5	2.3 ± 0.6	0.518
Moderate or severe MR	45 (52%)	14 (41%)	0.314
Medications			
β-blocker	71 (83%)	29 (85%)	0.793
Calcium channel blocker	31 (36%)	10 (29%)	0.529
Disopyramide	15 (17%)	7 (21%)	0.794
Syncope	23 (27%)	10 (29%)	0.822
Atrial fibrillation	6 (7%)	1 (3%)	0.672
Peripheral vascular disease	3 (4%)	3 (9%)	0.350
Chronic lung disease	8 (9%)	7 (20%)	0.125
Diabetes	13 (15%)	6 (18%)	0.784
Stroke	3 (4%)	1 (3%)	1.000

Values are n (%) or mean ± SD. ICD = implantable cardioverter-defibrillator, LVEF = left ventricular ejection fraction, MR = mitral regurgitation, NYHA = New York Heart Association, PCI = percutaneous coronary intervention.

Table 2.

Perioperative data

Variable	MS (n=86)	FS (n=34)	p Value
Median Cardiopulmonary bypass time (min)	81 (72-91)	78 (67-87)	0.101
Median Cross clamp time (min)	39 (34-46)	35 (29-41)	0.017
Median intra-op RBC units (IQR)	0 (0-2)	0 (0-1)	0.050
Overall major complications *	7 (8%)	4 (12%)	0.504
Ventricular Septal Defect	0 (0%)	0 (0%)	1.000
Atrial fibrillation	19 (22%)	12 (35%)	0.166
Pacemaker implantation	1 (1%)	1 (3%)	0.488
ICD placement	7 (8%)	2 (6%)	1.000
Prolonged ventilation	4 (5%)	3 (9%)	0.403
Mean post-op RBC units (IQR)	0 (0-1)	0 (0-0.25)	0.651
Median ICU LOS, hrs (IQR)	24 (22-61)	30 (24-74)	0.367
Median hospital LOS, d (IQR)	5 (4-7)	5 (5-8)	0.373
30-day mortality	0 (0%)	1 (3%)	0.283

Values are n (%) or mean $\pm$ SD, or median with interquartile range (IQR).

* Major complications include reoperation for bleeding, need for intraaortic balloon pump, stroke, pneumonia, mediastinitis, and renal failure requiring dialysis. No differences in the individual components were found between the two groups. ICD = implantable cardioverter-defibrillator, ICU = intensive care unit, LOS = length of stay, RBC = red blood cell.