Septal Myectomy With Vs Without Subvalvular Apparatus Intervention in Patients With Hypertrophic Obstructive Cardiomyopathy: A Prospective Randomized Study

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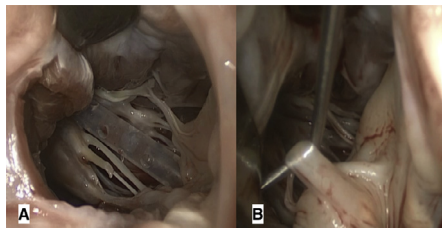
Surgical septal myectomy is a standard treatment option for patients with hypertrophic obstructive cardiomyopathy. Subvalvular abnormalities of the mitral valve might play an important role in residual left ventricular outflow tract obstruction. This randomized study aimed to compare the surgical outcomes of septal myectomy with vs without subvalvular interventions. Between July 2015 and December 2016, 80 eligible patients were randomly assigned to undergo septal myectomy with vs without subvalvular intervention. The peak gradient was 92.3 ± 16.9 and 88.1 ± 15.4 mm Hg, respectively (P = 0.281). The mean septum thickness was 26.8 ± 4.5 and 26.1 ± 4.2 mm, respectively (P = 0.504). Moderate or severe systolic anterior motion syndrome-mediated mitral regurgitation was observed in all patients. There was no residual mitral regurgitation in the group with subvalvular intervention, while 15% of patients in the control group had regurgitation (P = 0.013). Residual systolic anterior motion syndrome was observed in 5% and 27.5% of patients, respectively (P = 0.007). The median postoperative gradient was 13 (interquartile range 9–16) mm Hg and 8 (interquartile range 4–12) mm Hg, respectively (P = 0. 0.019). At the 12-month follow-up, all patients were alive. There were 87.5% vs 77.5%, and 12.5% vs 22.5% of patients categorized as having New York Heart Association functional classes I and II, respectively (P = 0.378). The prevalence rate of residual mitral regurgitation was 10% and 32.5%, respectively (P = 0.010). Concomitant subvalvular intervention during septal myectomy more effectively eliminates left ventricular outflow tract obstruction, providing better freedom from residual mitral regurgitation without clinical benefit 1 year after surgery.

Semin Thoracic Surg 31:424–431

Keywords: Septal myectomy, Hypertrophic obstructive cardiomyopathy



Transaortic view of extended myectomy (a) and preparation for secondary chordae cutting (b).

Central Message

Mitral valve subvalvular apparatus intervention should be carefully addressed in patients with hypertrophic obstructive cardiomyopathy scheduled to undergo surgical septal myectomy.

Perspective Statement

In hypertrophic obstructive cardiomyopathy, the mitral valve subvalvular apparatus plays an important role in systolic anterior motion-mediated left ventricular outflow tract obstruction. Thus, extended myectomy with mitral valve subvalvular apparatus intervention can be considered as the treatment of choice in patients without intrinsic mitral valve disease.

Abbreviations: AV, atrioventricular; CI, confidence interval; CPB, cardiopulmonary bypass; HCM, hypertrophic cardiomyopathy; HOCM, hypertrophic obstructive cardiomyopathy; IVS, interventricular septum; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; LVOTO, left ventricular outflow tract obstruction; MH, mental health; MR, mitral regurgitation; MSA, mitral subvalvular apparatus; MV, mitral valve; NYHA, New York Heart Association; OR, odds ratio; PH, physical health; PM, papillary muscle; QOL (SF-36), quality of life (36-item short form survey); RPR, resection-plication-release; SAM, systolic anterior motion; TEE, transesophageal echocardiography; VSD, ventricular septal defect; 6MWT, 6-minute walking test

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Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of Interest: None declared.

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1043-0679/$–see front matter
https://doi.org/10.1053/j.semtcvs.2019.01.011

BACKGROUND

Hypertrophic cardiomyopathy (HCM) is a genetic disease in adults characterized by a left ventricular wall thickness of ≥15 mm that is not explained solely by loading conditions.[1] Surgical septal myectomy is a standard treatment option for patients with obstructive HCM who are scheduled for septal reduction therapy. The classic Morrow procedure with 2 parallel incisions in the basal septum was criticized for the incomplete resection of the myocardial mass at the midventricular part of the septum; therefore, extended myectomy was proposed.[2] A more extended left ventricular septal myectomy eliminates left ventricular outflow tract obstruction (LVOTO) in most cases of HCM. However, fibrotic anterior leaflet attachment and abnormalities of the papillary muscles (PMs) and secondary chordae may play an important role in HCM patients, and isolated myectomy may not be sufficient in relieving left ventricular outflow tract (LVOT) obstruction and completely eliminating mitral regurgitation (MR).[2–5]

In the present randomized study, we report the surgical outcomes of extended septal myectomy with vs without mitral subvalvular apparatus (MSA) interventions in severely symptomatic patients with obstructive HCM and marked septal thickness.

METHODS

Between July 2015 and December 2016, a total of 110 consecutive patients with hypertrophic obstructive cardiomyopathy (HOCM) underwent surgical myectomy. In the present study, we report the clinical and hemodynamic results of the 80 HOCM patients with marked septal thickness who were randomly assigned to undergo septal myectomy with or without MSA interventions 1 day prior to surgery using a computerized randomization algorithm (ClinicalTrials.gov identifier: NCT02492399). Each of these patients had an LVOTO with a gradient of ≥50 mm Hg at rest and interventricular septum (IVS) thickness ≥20 mm. All patients had been receiving optimal medical therapy with nonvasodilating β-blockers and/or calcium-channel blockers prior to surgery.

Eligible participants were individuals aged ≥18 years with HOCM who met the indications for operation according to the European Society of Cardiology guidelines.[1]

Inclusion Criteria

- Marked septum thickness ≥20 mm measured by echocardiography and/or cardiac magnetic resonance imaging
- Instantaneous peak Doppler LVOT pressure gradient ≥50 mm Hg at rest
- Resting systolic anterior motion (SAM)
- Moderate or severe MR

The inclusion criterion for participating surgeons was an experience of at least 30 septal procedures per year (3 surgeons).

Exclusion Criteria

- Previous alcohol septal ablation therapy
- Organic mitral valve (MV) lesions (rheumatic, degenerative, mitral annulus calcification)
- Abnormalities of the PM such as displacement and direct attachment to the mitral leaflet
- Concomitant valvular heart disease requiring intervention
- Concomitant coronary artery disease requiring bypass grafting
- Atrial fibrillation
- Implanted cardioverter defibrillator

There were no between-group differences in the preoperative characteristics (Table 1).

The Local Ethics Committee approved the study design, and all the patients provided informed consent. The study was conducted in compliance with the Declaration of Helsinki. The CONSORT flow diagram is shown in Figure 1.

The primary endpoint was the residual LVOT gradient after the procedure assessed by direct measurement. The secondary endpoints were residual MR, SAM of the MV, residual LVOT gradient measured by transesophageal echocardiography (TEE) after weaning off bypass, survival, functional capacity, and quality of life 12 months after surgery. The severity of MR was evaluated and defined in accordance with the recommendations of the European Association of Echocardiography.[6]

SURGICAL PROCEDURE

Real-time TEE (Philips iE33, Philips Ultrasound Inc., PA) was performed after the induction of anesthesia for MV lesion estimation and modeling of an adequate length and depth of resection into the LVOT (Fig. 2). The aorta was cross clamped, and cold crystalloid cardioplegic solution (Custodiol HTK Solution, Dr. Franz Köhler Chemie, Alsbach-Hähnlein, Germany) was used for myocardial protection with antegrade root flow. A transverse aortotomy approach for extended septal

Table 1. Baseline Data

	MSA Group, $n = 40$	Control Group, $n = 40$	*P* Value
Age, y	49.6 ± 14.3	52.1 ± 12.8	0.095
Female, *n* (%)	26 (65.0)	23 (57.5)	0.474
NYHA II, *n* (%)	13 (32.5)	10 (25.0)	0.549
NYHA III, *n* (%)	27 (67.5)	30 (75.0)	0.549
LVEF, %	76.2 ± 7.5	72.8 ± 7.5	0.192
LVEDV, mL	57.1 ± 14.6	59.4 ± 17.1	0.546
LVOT gradient, mm Hg	92.3 ± 16.9	88.1 ± 15.4	0.281
IVS thickness, mm	26.8 ± 4.5	26.1 ± 4.2	0.504
Moderate MR, *n* (%)	23 (57.5)	26 (65.0)	0.474
Severe MR, *n* (%)	17 (42.5)	14 (35.0)	0.474

IVS, interventricular septum; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MR, mitral regurgitation; MSA, mitral valve subvalvular apparatus intervention; NYHA, New York Heart Association functional class.

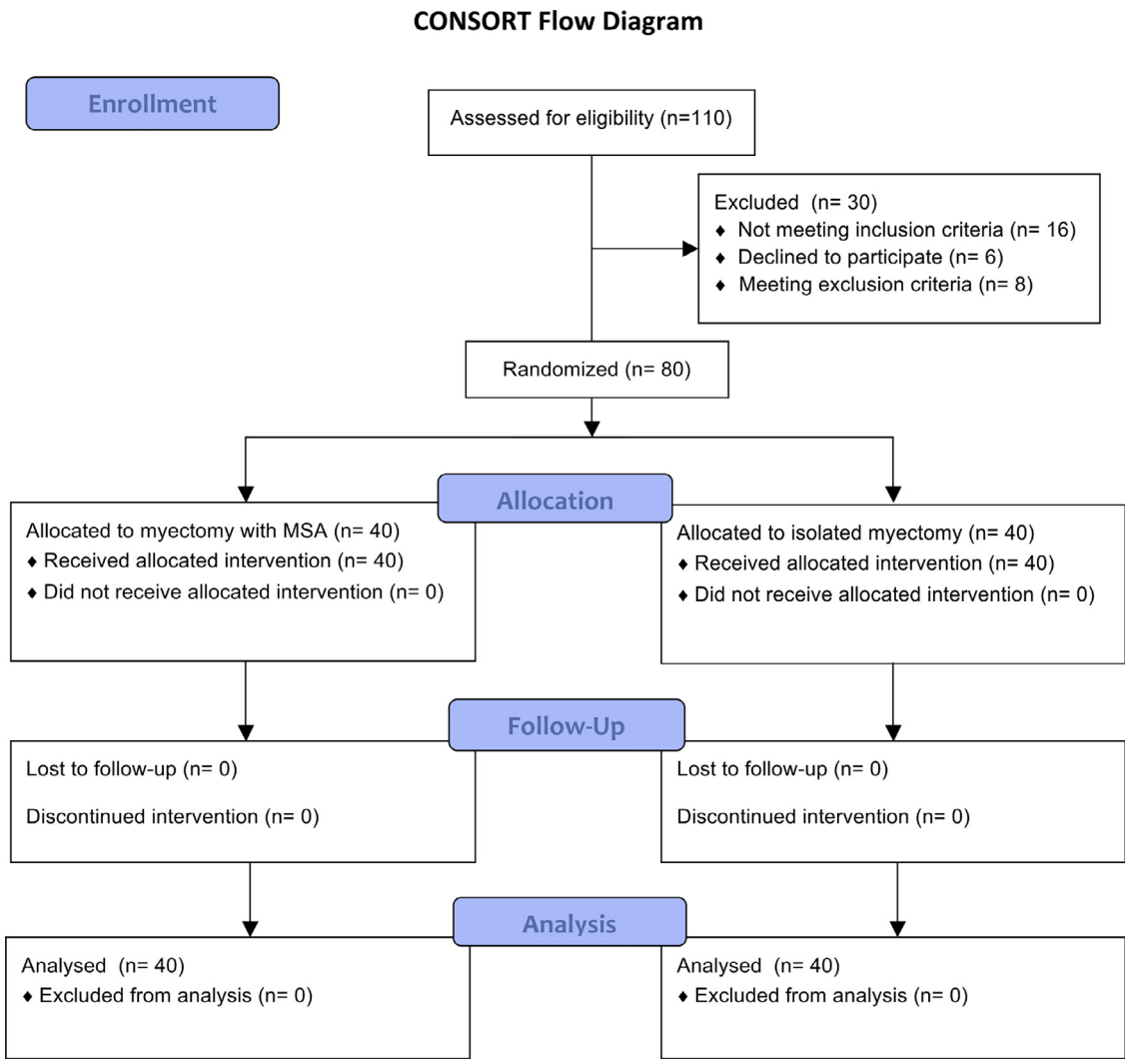

Figure 1. CONSORT flow diagram.

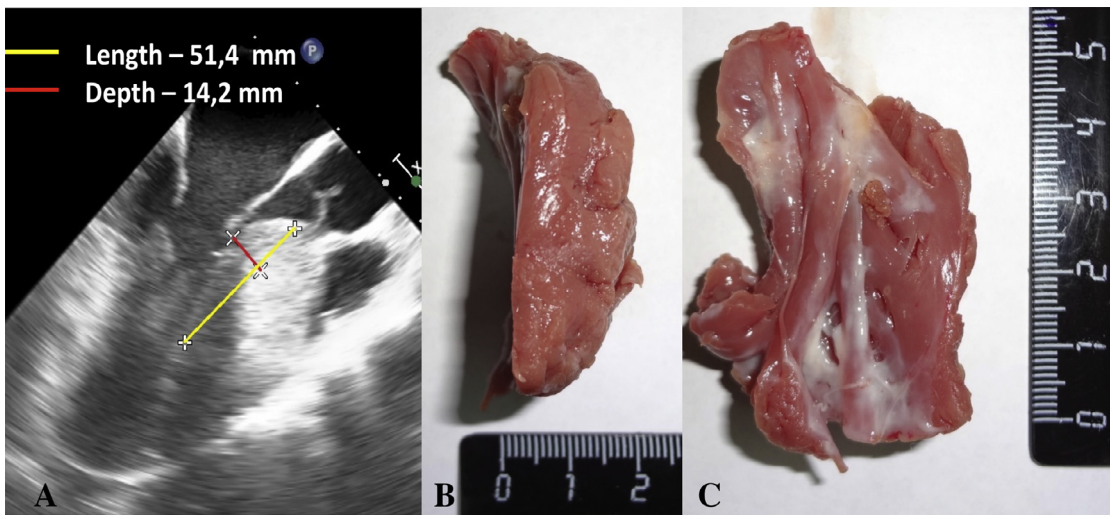

Figure 2. (a) Modeling of an adequate septal myectomy into the left ventricular outflow tract measured by intraoperative transesophageal echocardiography (long-axis view); (b) length and (c) depth of resected myocardium mass.

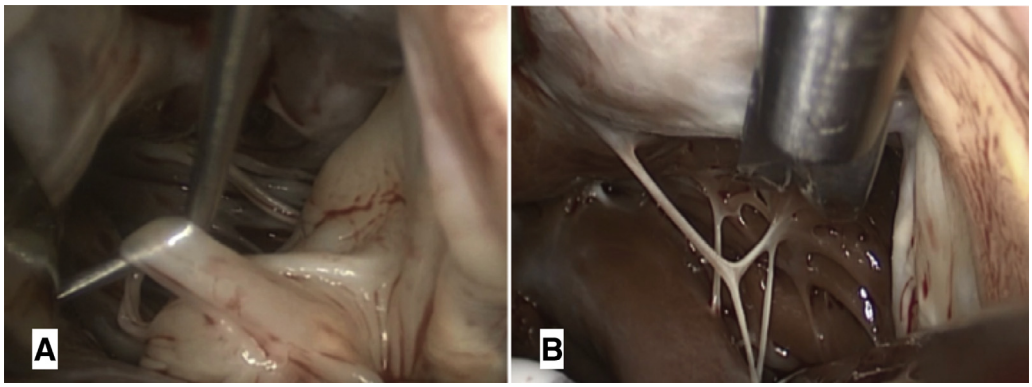

Figure 3. Transaortic intraoperative views: (a) preparation for secondary chordae resection of the anterior mitral leaflet, (b) mobilization of papillary muscle: resection attachments between the free left ventricular wall and papillary muscle.

myectomy, as described by Schaff,[7] was employed in all cases. Subsequently, in the MSA group, transaortic subvalvular apparatus interventions were performed, including retracted secondary chordae cutting (Fig. 3a) and PM release and/or resection (Fig. 3b), as described by Ferrazzi.[4] An intraoperative video of the surgical procedure has been presented elsewhere.[8] Control TEE was performed after the withdrawal of bypass for routine assessment of LVOT hemodynamics. Direct transaortic catheterization of LVOT was used for the measurement of pressure gradients (Fig. 4). The cardiopulmonary bypass (CPB) was reestablished if there was residual moderate to severe MR or if a ventricular septal defect was observed.

PATIENT FOLLOW-UP AND POSTOPERATIVE MANAGEMENT

All patients underwent transthoracic echocardiographic evaluation before discharge. In total, 80 patients were discharged and followed up by cardiologists. After discharge, examinations were scheduled annually. When annual clinic visits were unavailable, follow-up was performed by contact with the referring cardiologist, the patients, or their families. Echocardiograms obtained from outside physicians were reanalyzed at our institution by the most experienced echocardiographers.

Low-dose aspirin was prescribed for 3 months postoperatively for all patients who were in sinus rhythm, as documented by 24-hour Holter monitoring. Patients with a mechanical MV were maintained on lifelong anticoagulation therapy. Nonvasodilating β-blockers were prescribed for all patients after surgery.

Statistical Analysis

All data were collected prospectively. Categorical data were expressed as proportions and continuous variables as mean ± standard deviation or median and interquartile range (IQR) for non-normally distributed data. Proportions were compared using the chi-square test. If the expected frequency was <5, Fisher's exact test was applied. Between-group comparisons of continuous variables were performed using an independent-samples *t* test or the Mann-Whitney *U* test. Logistic regression models were used to determine predictors of reestablishing

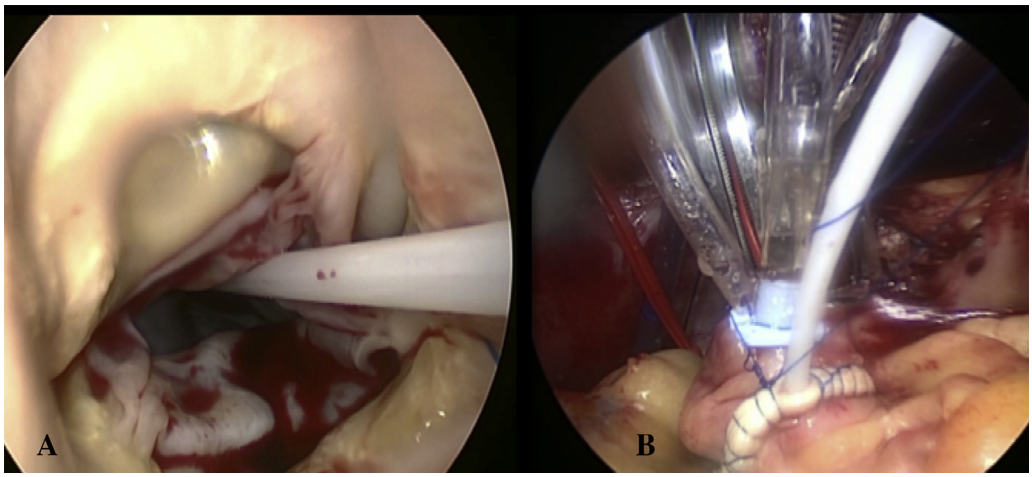

Figure 4. Direct measurement of the left ventricular outflow tract and aortic gradient: (a) catheter inserted through the aortic valve into the left ventricular cavity, (b) aortic root cannula used for direct pressure measurement in the aorta, with the left ventricular catheter passing through the aortic suture line.

Table 2. Intraoperative Data

	MSA Group, $n = 40$	Control Group, $n = 40$	P Value
Secondary chordae cutting, n (%)	40 (100)	–	–
PM mobilization, n (%)	36 (90.0)	–	–
PM longitudinal resection, n (%)	3 (7.5)	–	–
Cardiopulmonary bypass time, min	62.1 ± 14.6	56.8 ± 14.2	0.861
Aortic clamping time, min	45.4 ± 14.1	40.7 ± 13.4	0.157
Direct LVOT gradient, mm Hg	8 (IQR 4–12)	13 (IQR 9–16)	0.019
TEE LVOT gradient, mm Hg	12 (IQR 8–16)	18 (IQR 13–22)	0.028
Residual MR, n (%)	0	6 (15.0)	0.013
Residual SAM, n (%)	2 (5.0)	11 (27.5)	0.007
LVEDV, mL	84.4 ± 19.2	77.3 ± 16.1	0.054
LVEF, %	66.2 ± 7.3	67.4 ± 10.4	0.627
Repeat cross clamping, n (%)	1 (2.5)	7 (17.5)	0.031
MV replacement, n (%)	0	2 (5.0)	0.247
Mass of resected myocardium, g	6.5 ± 2.7	5.8 ± 3.2	0.497
IVS thickness after procedure, mm	15.4 ± 2.3	16.1 ± 3.1	0.841

IQR, interquartile range; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MR, mitral regurgitation; MSA, mitral valve subvalvular apparatus intervention; MV, mitral valve; PM, papillary muscle; SAM, systolic anterior motion; TEE, transesophageal echocardiography.

bypass. Values of $P < 0.05$ were considered statistically significant. Stata/MP for Windows v. 13.0 (StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP) was employed for the statistical analysis.

RESULTS

Mean CPB time was 62 ± 15 and 57 ± 14 minutes in the MSA and control groups, respectively ($P = 0.861$); mean cross-clamp time was not significantly different between the 2 groups (45 ± 14 and 40 ± 13 minutes, respectively, $P = 0.157$). All patients in the MSA group underwent chordal cutting; typically, it was resected from 2 to 6 secondary chordae depending on individual anatomy. In total, 3 of 40 patients (7.5%) with marked PM hypertrophy underwent longitudinal papillary muscle resection in addition to the mobilization technique (Table 2). Invasive measurement after weaning off bypass revealed a significantly higher median LVOT gradient in the control group (13 (IQR 9–16) vs 8 (IQR 4–12) mm Hg, respectively, $P = 0.019$), as well as TEE data (18 (IQR 13–22) and 12 (IQR 8–16) mm Hg, respectively, $P = 0.028$). Control TEE demonstrated a higher incidence of residual (mild) MR ($n = 6$) in the control group (15.0% vs 0%, respectively, $P = 0.013$). Seven patients (17.5%) from the control group and 1 patient (2.5%) from the MSA group required reestablishing bypass due to LVOTO, SAM syndrome, and significant MR ($P = 0.031$). In all these cases, the inadequate initial septal myectomy resulted in residual LVOTO. According to TEE findings, a "more" extended myectomy in terms of septum depth and apical and/or leftward direction from the free left ventricular wall toward the MV has been performed. In 5 patients, MR was resolved to a mild degree after additional myectomy. In 1 young patient from the control group, moderate MR and mild SAM with an acceptable LVOT gradient were allowed. There were 2 patients (5.0%) in the control group who required MV replacements ($P = 0.247$). No MSA intervention was performed in the control group patients who required secondary cross clamping. A summary of the intraoperative data is shown in Table 2. Logistic regression analysis (Supplementary Table 1) was unable to identify independent predictors for reestablishing bypass; nevertheless, the nonperformance of MSA intervention in our cohort was associated with a higher incidence of secondary cross clamping (odds ratio 1.34 [95% confidence interval 1.02–14.51], $P = 0.002$).

There were no occurrences of early death (Table 3). The postoperative systolic LVOT gradient according to TEE was 13.4 ± 5.0 and 16.1 ± 5.2 mm Hg in the MSA and control groups, respectively ($P = 0.205$). Left ventricular end-diastolic

Table 3. Early Adverse Event Rates

	MSA Group, $n = 40$	Control Group, $n = 40$	P Value
Early mortality, n (%)	0	0	–
Complete AV block, n (%)	2 (5.0)	2 (5.0)	1.000
VSD, n (%)	1 (2.5)	0	0.500
Left ventricular wall rupture, n (%)	0	1 (2.5)	0.500
Aortic regurgitation, n (%)	0	0	–

AV, atrioventricular; MSA, mitral valve subvalvular apparatus intervention; VSD, ventricular septal defect.

volume and ejection fraction after the procedure did not differ between the 2 groups. One patient from the control group required urgent surgery in the early postoperative period due to left ventricular wall rupture. The complication was successfully treated. Two patients from each group required permanent pacemaker implantation (5.6% and 5.1%, $P = 0.957$) due to complete atrioventricular node block. There was no new onset of aortic regurgitation in both groups. Several days after surgery, we noted 1 case (2.4%) of 2-mm asymptomatic ventricular septal defect in the MSA group. A dynamic evaluation strategy was employed with a future perspective of percutaneous closure.

A 1-year follow-up was completed in all patients. The survival rate was 100% in both groups. The New York Heart Association (NYHA) functional class showed a significant decrease from the preoperative value in both groups, with no patients in class III or IV and no significant difference between the 2 groups (Table 4). The results of the 6-minute walking test in the MSA and control groups were 432.2 ± 43.1 and 408.9 ± 52.5 m, respectively ($P = 0.847$). The quality of life assessed at 1-year follow-up using the SF-36 questionnaire did not reveal significant between-group differences in all physical health (59.1 ± 4.8 vs 57.7 ± 4.4, respectively, $P = 0.618$) and mental domains (50.4 ± 3.9 vs 51.1 ± 4.1, respectively, $P = 0.391$). During echocardiographic examination, the resting LVOT gradient was 9.1 ± 2.4 mm Hg in the MSA group and 11.5 ± 3.2 mm Hg in the control group ($P = 0.641$). Mild or moderate residual MR was observed in 4 (10.0%) and 13 (32.5%) patients in the MSA and control groups, respectively ($P = 0.027$). There was no severe MR at 1-year follow-up. The patient with iatrogenic ventricular septal defect was categorized as NYHA class I. Dynamic evaluation was continued.

DISCUSSION

The main finding of our study is that MSA intervention during extended septal myectomy allows the reduction of LVOT gradient more effectively in comparison with extended myectomy alone. Moreover, after MSA intervention, we observed a lower incidence of residual MR and SAM syndrome. Nevertheless, extended myectomy with and without MSA intervention effectively eliminates LVOTO immediately after the procedure, thereby relieving heart failure and improving NYHA functional class and the quality of life.

Subvalvular mitral apparatus abnormalities play an important role in LVOTO and should be carefully examined in each case. In a recent study, Ferrazzi et al.[4] clarified the mechanism of hemodynamic improvement, stating that transaortic chordal cutting increases the anterior mitral leaflet annulus ratio, decreases MV tenting area, and as a result moves the MV coaptation zone away from the LVOT in patients with mild septum thickness in comparison with isolated septal myectomy. We believe that the cutting of the thickened secondary chordae attached to the middle part of the anterior leaflet allows the extension of the anterior leaflet's surface. Similar to our findings, some authors[4] demonstrated that the postoperative LVOT gradient was significantly lower in the MSA subset (9 ± 5 vs 13 ± 10 mm Hg, $P = 0.041$).

In contrast, according to Mayo's experience,[3] MV surgery in patients with HCM scheduled to undergo septal myectomy is rarely a necessary procedure, which has been required only in 2.1% of patients without intrinsic MV disease. They also reported that several MV abnormalities did not influence the functional and clinical results if an adequate myectomy is performed. They suggested that additional procedures should be considered for PM abnormalities contributing to LVOTO, emphasizing however that not all PM abnormalities contribute to LVOTO. After MV surgery has been performed, the repair rate was 76.4% (133 repairs and 41 replacements). The regression analysis revealed that MV replacement was significantly associated with late mortality with a hazard ratio of 2.89 (95% confidence interval 1.22−6.82, $P = 0.016$), and they demonstrated the advantage in terms of survival among patients who had MV repair over those who had replacement ($P = 0.002$). The impact of MV replacement on the mortality of HCM patients undergoing concomitant MV surgery was dramatically shown by Vassileva et al.[9] in the analysis of more than a thousand operations with 0% and 11.8% hospital mortality rate after MV repair and replacement, respectively ($P < 0.05$). In a recent randomized study,[10] a better 2-year survival after MV repair over replacement (96.7 ± 3.3% vs 87.2 ± 4.9%, respectively, $P = 0.034$) was demonstrated. Consistent with these reports, MV replacement does not seem to be an

Table 4. Results of the 12-Month Follow-Up

	MSA Group, $n = 40$	Control Group, $n = 40$	P Value
Survival, %	100	100	1.000
NYHA I, *n* (%)	35 (87.5)	31 (77.5)	0.378
NYHA II, *n* (%)	5 (12.5)	9 (22.5)	0.378
Residual MR, *n* (%)	4 (10.0)	13 (32.5)	0.027
LVOT gradient, mm Hg	9.1 ± 2.4	11.5 ± 3.2	0.641
6MWT, m	432.2 ± 43.1	408.9 ± 52.5	0.847
QOL (SF-36), PH	59.1 ± 4.8	57.7 ± 4.4	0.618
QOL (SF-36), MH	50.4 ± 3.9	51.1 ± 4.1	0.391

6MWT, 6-minute walking test; LVOT, left ventricular outflow tract; MH, mental health; MR, mitral regurgitation; MSA, mitral valve subvalvular apparatus intervention; NYHA, New York Heart Association functional class; PH, physical health; QOL (SF-36), quality of life (36-item short form survey).

alternative approach for HCM patients, as previously described.[11,12] Current guidelines[1,5] do not support any MV intervention over the others due to lack of evidence. Ferrazzi et al.[4] concluded that transaortic secondary chordae cutting might reduce the need for MV replacement. In our series, we had to repeat cross clamping more often in the control group and replaced the MV in 2 patients. We suggest that MSA intervention might help in reducing LVOTO, especially in cases whereby myectomy does not guarantee MR elimination due to intrinsic MV disease[3] or is likely to be ineffective due to mild septal thickness.[4,5,7] In our series, we found a higher incidence of SAM, residual MR, and LVOT gradient in the control group. Several techniques have been proposed for MV repair in the HCM subset, including leaflet extension,[13–15] retention,[16,17] plication,[18–20] and subvalvular management.[4,7,19] Typically, the choice of repair technique is surgeon-dependent, especially if bypass is to be reestablished. Nevertheless, the necessity for additional MV procedures during septal myectomy should be carefully assessed. Indeed, all intrinsic MV pathologies should be addressed with the respective MV repair techniques; however, complex leaflet interventions for SAM-mediated MR only appear to be unreasonable. In fact, the extension of the anterior leaflet entails an additional risk of late repair failure due to pericardial patch deterioration or dehiscence. The resection-plication-release (RPR) technique[20] has been proposed for the treatment of redundant anterior leaflet, as it is easier to reproduce than the extension technique. In our study, we did not include patients with organic MV disease and displacement or direct attachment to the mitral leaflet with PM abnormality, which commonly requires PM management. In contrast, we have only observed retraction of the secondary chordae into the anterior mitral leaflet, and we believe that the "RPR" technique would not be applicable for our cohort. Nevertheless, we suggest that the "RPR" technique might be useful for HCM patients with concomitant degenerative MV disease with an elongated anterior mitral leaflet.

Some authors reported acceptable immediate results after using the Alfieri stitch in addition to myectomy in cases of mild IVS thickness and LVOTO without intrinsic MV disease.[21,22] However, the stitch typically required left atrium opening for good exposure, and the durability of a double-orifice MV especially in young patients is questionable. With their adequate experience in the Alfieri technique, Bhudia et al.[23] forewarned that the elimination of SAM after edge-to-edge repair in HCM patients cannot always be achieved, and the lateral portion of the anterior leaflet can be still displaced. Another surgical limitation included the risk of mitral stenosis; furthermore, the Alfieri stitch per se did not prevent residual LVOTO due to inadequate myectomy.[23] Therefore, the Alfieri technique is not the optimal procedure of choice for MV repair in HCM patients.

This study has a few limitations that should be addressed. In particular, this was a single-center study limited by the relatively small sample size and 12-month follow-up period. We included highly selected patients who may not be representative of every patient scheduled to undergo septal myectomy (IVS 26 mm, LVOTO 90 mm Hg, moderate and severe MR without intrinsic MV disease, no concomitant surgeries). However, our results are consistent with those of other investigators. Thus, further studies with larger patient populations and longer follow-up periods are needed to clarify the clinical benefits.

Currently, MV repair with myectomy can be performed safely and effectively. MSA management plays an underestimated role in the hemodynamic normalization in HCM patients, and further studies might determine its significance. We conclude that the MSA should be addressed during septal myectomy. We are also confident to say that adequate septal myectomy per se is sufficient to achieve acceptable results in the majority of HCM patients. Furthermore, MSA intervention in HCM patients with MV subvalvular abnormalities without intrinsic MV disease can be considered as the intervention of choice. However, we did not investigate the clinical benefit of adding MSA intervention to septal myectomy; the primary endpoint was the true LVOT gradient after the procedure. Nevertheless, MSA intervention is an effective, reproducible technique associated with a low secondary cross-clamping rate.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found in the online version at doi:10.1053/j.semtcvs.2019.01.011.

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