

INPLASY PROTOCOL

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None declared.

INTRODUCTION

Review question / Objective: To investigate whether septal resection combined with subvalvular repair is safe and effective in patients with hypertrophic obstructive cardiomyopathy. What are the advantages over other surgical procedures?

Septal myectomy and subvalvular repair in hypertrophic cardiomyopathy, a systematic review and pooled analysis

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Review question / Objective: To investigate whether septal resection combined with subvalvular repair is safe and effective in patients with hypertrophic obstructive cardiomyopathy. What are the advantages over other surgical procedures?

Condition being studied: Currently, there are very limited reports on septal resection combined with submitral valve repair. We hoped to conduct a systematic review of this combined procedure by pooling and analyzing relevant studies that have been published so far.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 February 2023 and was last updated on 27 February 2023 (registration number INPLASY202320116).

Rationale: Extended septal myectomy is currently the gold standard for the treatment of hypertrophic cardiomyopathy. However, some patients still have residual left ventricular outflow tract obstruction and mitral regurgitation after operation. Controversy exists as to whether the mitral

valve should be treated concurrently. There is also controversy regarding the method of intervention for mitral valves that require treatment. So we want one of the interventions for the mitral valve: submitral valve repair.

Condition being studied: Currently, there are very limited reports on septal resection combined with submitral valve repair. We hoped to conduct a systematic review of this combined procedure by pooling and analyzing relevant studies that have been published so far.

METHODS

Search strategy: We selected relevant studies published before December 2022, by searching PubMed, Cochrane, Embase, Web Of Science, FDA.gov, and ClinicalTrials.gov. No language restrictions. We used the following combined text and MeSH terms: (((((((((((Insufficiency, Mitral Valve) OR (Valve Insufficiency, Mitral)) OR (Mitral Valve Regurgitation)) OR (Regurgitation, Mitral Valve)) OR (Valve Regurgitation, Mitral)) OR (Mitral Regurgitation)) OR (Regurgitation, Mitral)) OR (Mitral Valve Incompetence)) OR (Incompetence, Mitral Valve)) OR (Valve Incompetence, Mitral)) OR (Mitral Incompetence)) OR (Incompetence, Mitral)) OR (Mitral Insufficiency)) OR (Insufficiency, Mitral)) OR ("Mitral Valve Insufficiency"[Mesh])) AND (("Cardiomyopathy, Hypertrophic"[Mesh]) OR (((((((Cardiomyopathies, Hypertrophic) OR (Hypertrophic Cardiomyopathies)) OR (Hypertrophic Cardiomyopathy)) OR (Cardiomyopathy, Hypertrophic Obstructive)) OR (Cardiomyopathies, Hypertrophic Obstructive)) OR (Hypertrophic Obstructive Cardiomyopathies)) OR (Hypertrophic Obstructive Cardiomyopathy)) OR (Obstructive Cardiomyopathies, Hypertrophic)) OR (Obstructive Cardiomyopathy, Hypertrophic))).

Participant or population: Number of people included in the study (N=692), average age (53.0±14.8), male 350/653(53.6%), hypertension

39/100(19.0%), Atrial Fibrillation158/628 (25.2%), NYHA Class III/IV 541/692(78.2%), Beta/Ca²⁺ Blockers387/406(95.3%), Family History44/162(27.2%).

Intervention: Septal myectomy combined with submitral repair.

Comparator: No comparator.

Study designs to be included: Retrospective studies and randomized controlled studies.

Eligibility criteria: (1) patients with clinically symptomatic hypertrophic obstructive cardiomyopathy. (2) Myectomy combined with submitral valve repair was performed.

Information sources: By searching PubMed, Cochrane, Embase, Web Of Science, FDA.gov, and ClinicalTrials.gov.

Main outcome(s): The average Cardiopulmonary bypass time was 44 ± 14.8minutes and aortic clamping time was 64.7 ± 22.2minutes. The average follow-up time was 39.6 ± 36.3months, and completion rate was 98.6%. Compared with baseline levels, left ventricular outflow tract gradient (83.6 ± 32.2 mmHg vs 11.0 ± 7.8 mmHg, p<0.01), maximum interventricular septal thickness (22.5 ± 5.1mm vs 14.7 ± 5.5mm, p<0.01), III/IV mitral regurgitation (351/692 vs 17/687, p<0.01), and SAM (215/229 vs 11/229, p<0.01) were significantly improved. AML-annulus ratio was (0.49 ± 0.14 vs 0.60 ± 0.12, p<0.01) and tenting area was (2.72 ± 0.60 cm² vs 1.95 ± 0.60 cm², p<0.01), suggesting that the mitral valve junction is far away from the left ventricular outflow tract. 26(6.2%) patients required permanent pacemaker implantation for complete atrioventricular block. 7 patients received ICD implantation due to 24-hour ECG showing non-sustained tachycardia (n=4) and family history of sudden death (n=3). 14 (2.1%) patients were in New York Heart Association functional class III/IV, significantly improved compared with preoperative (541/692 vs 14/680, p<0.01). 8 patients had mild aortic regurgitation.

Additional outcome(s): During the follow-up period, 10 patients died, and the causes of death included: chronic respiratory failure (n=1), congestive heart failure (n=6), and renal failure (n=3). There were 4 unplanned reoperation: one patient was re-admitted for mitral annuloplasty and posterior leaflet plication due to the residual left ventricular outflow tract gradient mitral regurgitation (n=1), Endocarditis (n=1), repair of aortic perforation (n=1), repair of ventricular septal perforation (n=1).

Data management: Two researchers independently reviewed and screened to extract relevant study population baseline data, including patient number, age, sex, medication history, New York Heart Association functional class, ICD implantation, and related surgical history. Abnormal papillary muscle and chordae found during operation and treatment techniques, preoperative and postoperative echocardiographic indicators, including left ventricular diastolic diameter, ejection fraction, interventricular septal thickness, maximum left ventricular outflow tract pressure gradient, mitral Valve regurgitation degree, pacemaker implantation. Perioperative mortality, reoperation rate during follow-up period, New York heart function class.

Quality assessment / Risk of bias analysis: MINORS was used to assess the risk of bias and quality of the included studies.

Strategy of data synthesis: Systematic review was performed using Review Manager 5.4 (Nordic Cochrane Center, Copenhagen, Denmark). Continuous are reported as mean \pm SD; categorical variables are reported as frequencies (percentages). Student t-test for comparisons on continuous variables and chi-square or Fisher exact test for dichotomous variables. All statistical tests were 2-sided with a level set at 0.05 for significance. The results were analyzed using SPSS 25 software (IBM Corp, Armonk, NY, USA).

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Language restriction: No language restriction.

Country(ies) involved: China.

Keywords: Hypertrophic cardiomyopathy; Mitral valve insufficiency; Subvalvular repair; Septal myectomy.

Contributions of each author:

Author 1 - Ming-Yang Song - designed the research study; data analysis; assessment and results; wrote the manuscript; editorial changes in the manuscript; read and approved the final manuscript.

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