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Long-Term Outcomes after Early Surgery for Asymptomatic Severe Degenerative Mitral Regurgitation

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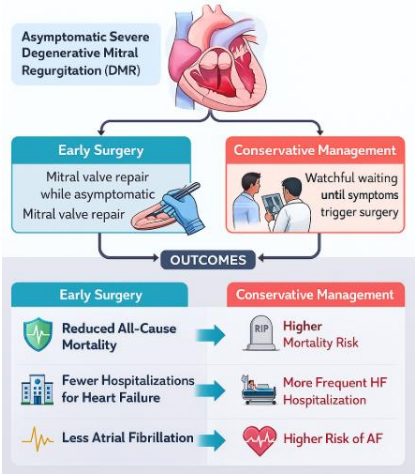
Abstract
Aim:To compare early surgical intervention and conservative treatment in terms of long-term clinical outcomes in patients with asymptomatic severe degenerative mitral regurgitation (DMR).
Background:Even though there are guidelines on the idea that early mitral valve repair in symptomatic patients with severe DMR have proven to be effective, there are conflicting reports as to the long-term effectiveness of early repair as compared to watchful waiting. The elucidation of these results is of essence in refining treatment modalities as well as barring the imminent irreversible remodeling of the left-ventricle.
Methods:A retrospective cohort study was studied on 1,120 patients who had asymptomatic severe DMR treated in three tertiary centers. The subjects were categorized in two cohorts; early mitral valve repair that takes a six-month duration of the condition and the control group that followed up to the development of the symptoms or normal standard guideline indicators. They were followed across a medium of follow-up of 10.2 years and the relevant outcomes were all-cause mortality, heart-failure hospitalization, new-onset atrial fibrillation and requirement of reoperation.
Results:The early surgery was connected with much less all-cause mortality (HR 0.62, p=0.01) and heart-failure hospitalization (HR 0.55, p=.001). The rates of new-onset atrial fibrillation were also lower in the group of early-surgery. The reoperation rates did not vary significantly among groups.
Conclusion:Asymptomatic severe DMR in patients undergoing early mitral valve repair has had a better survival and less heart-failure incidence in the long run than conservative treatment. These results precondition the use of early surgery in fitting patients.
Keywords: Degenerative mitral regurgitation, long time outcomes, heart failure, atrial fibrillation.
Graphical abstract



1 Introduction

The most common aetiological agent of primary mitral valve disease in the developed world is degenerative mitral regurgitation (DMR), and brings about a significant source of long-term cardiovascular morbidity otherwise. It is a progressive, unraveling of such natural history (on the leaflets, annulal dilation and the increased volume of the regurgitant which eventually leads to left-ventricular (LV) remodeling, atrial enlargement and the manifestation of heart-failure symptoms. The onset of intervention was based on the symptoms, but had it been identified that symptomatic status is not a steady parameter, and permanent myocrardial change may occur before clinical manifestation within a 20-year duration [1,2].Surgery is proposed when the patient becomes symptomatic, LV ejection fraction is below 60 percent, or LV end-systolic dimension exceeds 40 mm though not always existent to detect the whole spectrum of early myocardial impairment in the symptom-free population [3]. There are also impaired LV strain, left-atrial-progressive remodeling and raised natriuretic peptides visible in severe DMR even in the subjects who are preserved with worldwide functionality, which is alarming since wait-for-symptoms strategy will make the cardiovascular intervention well outside the therapeutic time range [4]. To this effect, much interest is mounting on the importance of early mitral valve repair, which can be substantiated by the advances in the safety of surgery, durability of its repair and the new experience that indicates that mitral valve repair must be performed at an early age ordinator as the means of facilitating the maintenance of the cardiac output in the long run.
The high-volume centers have reported great operative outcome and survival rates post-early repair in the outcome studies carried out through observations whose outcomes are usually comparable to the ones in general population of the same age [5]. Surgery would also help reduce the hospitalization rates of heart-failures, atrial fibrillation occurrence and permanent LV dysfunction because of the addition of volume overload before permanent myocardial infarction. However, this outcome is questionable as the supporters of a conservative stance pay attention to the low incidence of practices in a group of well-observed asymptomatic carriers and the potential risks of surgeries, particularly in the elderly subjects or patients treated in low-volume hospitals [6]. The fact that this debate remains ongoing means that it is a high level of clinical skepticism and that there is strong need to come up with concrete data on the comparison of the outcomes of long-term results of both early and watch waiting surgery.The other significant issue that is telling the management decision is the rising success of mitral valve repair over replacement. Contemporary repair techniques are now performing well with over 90 percent successful outcome in skilled hands with few perioperative deaths and extended results [7]. This tendency has put a strain on clinicians attempting to early intervene instead, given that permanent repair will diminish the risks which were formerly attributed to the implementation of the prosthetic valves, and an opportunity of recreating the physiology of a native-valve. Nevertheless, the repair rates are not equal in all centers and variations in surgical abilities still are likely to influence guidelines interpretation and practice trends in the practice [8].

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Still, there are critical gaps, even though there are a number of cohort studies. Studies Little large multicentric analysis have compared early surgery with conservative management basing on the long-term outcome measures, such as survival, heart-failure, atrial fibrillation, and rehospitalization [9]. In addition, the fact that age of patients, their background LV functioning and anatomical complexity modifies the effect of treatment is known very little. These challenges need to be explained, so that they can influence the clinical decision support and customize the treatment options.The rationale of the current study is to determine the long-term outcomes of patients with severe DMR that are treated with application of early mitral valve repair or conservative follow-up. In this research, the comparative differences and benefits of early intervention and evidence-based practice on the optimal timing of surgery will be defined by conducting a literature review on the survival, heart-failure hospitalization, atrial fibrillation, and reoperation rates during a long follow-up period.

2 Literature Review

One of the most doubted conditions of valvular heart disease is Asymptomatic acute degenerative mitral regurgitation (DMR) whereby increasingly it is proving controversial that the conventional management policy of watchful-waiting is somewhat of a fabricated recommendation. First researches emphasized the fact that asymptomatic patients are safe to be observed until they have undergone guidelines-based triggering events such as but not restricted to left-ventricular dysfunction or the formation of atrial fibrillation [10]. The facts that supported the favoring of this conservative paradigm were the fact that the low occurrence rate occurred among patients who were carefully balanced and put under strict clinical analysis. However, recent imaging and myocardial dynamics have unveiled that un-clinical ventricular defect can identify the existence of overt symptoms long in advance indicative of irreversible myocardial remodeling can take place long before classical parameters [11].Various studies of modern nature justify that the prompt mitral valve repair may be of a significant help in the long run. There are high-volume centers in which the mortality rate of the operations is below 1 percent and the survival rates are above 90 percent and long-term survival rates are equal among the distant age groups [12]. These findings disapprove the belief that intervention delay avoids unnecessary danger and particularly the least intrusive and valve-freezing procedures that continue to improve the safety of surgery. Moreover, lower heart-failure hospitalization rates and new-onset atrial fibrillation and progressive LV dilation-outcome variables which have devastating effect on the long-term morbidity have been also associated with early surgery.

On the contrary, some studies have maintained that early surgery does not always do the same to all the patients undergoing asymptomatic DMR. Namely, the rates of events are low in the conservatively managed cohorts, and the results are not necessarily comparable in the closely controlled institutions, where the professionals in their repairs operate. These findings imply that patient selection and institutional volume can play a decisive role on the comparative effectiveness of early intervention [13]. Some biomarkers such as BNP are used as well as LV global longitudinal strain, F left-atrial volume index have also been identified as potential tools to narrow the risk prediction thereby indicating that the asymptomatic patients are not a homogenous group [14].

3 Materials & Methods

Study design

A multicenter, many years follow up, retrospective cohort of study will be conducted including the comparison of the long-term clinical outcome in asymptomatic cases of severe DMR treated with earlier correction of the mitral valve (during 6 months of the diagnosis) and conservative treatments (after determining the guideline triggers or onset of the symptoms). Successive cases beginning January 2010 through December 2020 with a follow-up to December 2023 will be provided by three tertiary academic centers which already provide mitral valve programs.

Eligibility criteria

Inclusion: age: older than 18 years; severe primary (degenerative) MR as per guideline criteria, i.e. effective regurgitant orifice area 0.40cm 2 or regurgitant volume 60mLor vena contracta 7mm at baseline; minimum, 2 years follow-up.

Contraindications: secondary (functional) MR, prior mitral surgery, the severe and coexistent valvular disease that requires surgery, an active endocarditis, non-valvular cardiomyopathy, life expectancy is lower than 2 years.

Exposure definitions

Surprisingly, there was no definite advantage in the timing of the surgery in which the surgery of the mitral valve was elective before 6 months of the index diagnosis when the patient was not diagnosed with any symptoms (Pallaver et al., 2013).

Conservative group: non-operative management was predetermined through surveillance forms; operation in case of symptomatic or in the event of corpus callidum change appearance in the primary guidelines (LVEF less than 60, LVESD greater than 40 mm, atrial fibrillation new, pulmonary hypertension).

Data sources and collection

An abstract of clinical records, echocardiography reports/images, operative and administration databases will be done using a standardised form of case report. Variables of interest Demographic, comorbidity, medication, baseline and serial (e.g.LVEF) and serial (e.g.LVESD) and serial (e.g.LVDV) echocardiographic, BNP, operating procedures (repair vs replacement, repair method used, cross-clamp duration), postoperative complications, outcomes during the follow up. Trained abstractors will perform abstracting twice and a second investigator will re-audit a sample of 10 percent.

Outcomes

Primary outcome 10 years of all-causal death.

Secondary outcomes: Heart-failures hospitalization, first time atrial fibrillation, emergence of guideline recommended LV dysfunction, the need to replace a secondary valve, or mitral repeat, composite major adverse cardiac event (MACE). Time-to-event will denote measurements of index diagnosis.

Imaging Adjudication and quality of repair measurement.

The follow up and baseline echocardiogram will be assessed centrally by two blind cardiologists. Intraoperative/ postop MR of mild categories is defined as success repair. The possible modifiers of the effect will be institutional repair volume and surgeon.

Sample size calculation

The 10-year mortality is assumed to be 20 and 12 per cent (HR= 0.58), 80, per cent and 80 per cent, respectively; 10-year mortality is 20 and 12, respectively), 12 and 12 per cent, respectively; 12 and 12 per cent, respectively), 820 A target sample of 1,000 patients will be utilized to facilitate the adjustment of covariates and 10 percent loss to follow up.

Statistical analysis

Descriptive statistics: means+SD or medians (IQR); n (percent of constants) (nominal) variables. Means between groups: t-test or Mann-Whitney U when the variables are continuous, chi-square or Fisher Exact when the variables are discrete. Time-to-event: Kaplan -Meier graphs and log-rank tests. Multivariable Cox proportional-hazards models (Table 1 and Table 2) with covariates of age, sex, baseline LVEF, LVESD, BNP, atrial size, comorbidities, and institutional volume will be used to fit outcomes adjusted hazard ratios (aHR). Confounding by indication will be defeated by the methods of the propensity-score (inverse probability weighting and matched-cohort sensitivity analysis). Proportional hazards will be

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tested through assumptions. Ages Subgroup analyses Ages will be stratified (<60 and 60 and above) and baseline GLS (where available) and volume of center repair (high- vs low-volume).

Missing data

A combination of multiple imputation analyses with chained equations under a missing-at-random assumption are going to be used in the event of lack of covariate data, and complete-case models will be done in sensitivity analyses.

Ethics

At each site, the institutional review board will be sought to approve. Since this is a retrospective study, an informed consent waiver will be requested where possible and this will be deidentified and analyzed.

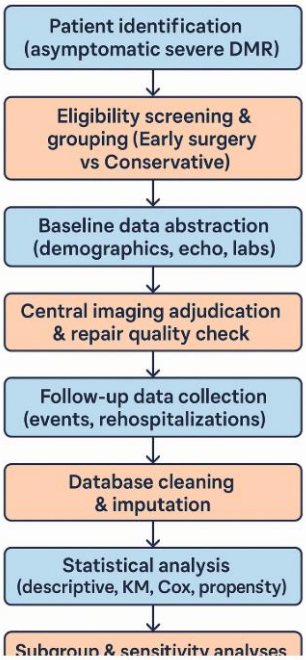

Fig.1. Block diagram model

Identification of patients: Clinical areas to be covered during study, timing of study and the manner in which potentially eligible patients who were realized at echocardiography/administrative registries will be identified. Explains the reasons of the restricting to asymptomatic severe DMR and why cohort study is chosen.

Eligibility & grouping: Present information on existing inclusion and exclusion criteria. Indicate the exposure categories (in respect to surgery and conservative management) and classification limits (timing window and guideline initiators).

Baseline data abstraction: How are baseline clinical and imaging variables and standardized case form and abstractors trained and quality controls (last instance, audit).

Imaging adjudication & repair measure: clarify central blinded echocardiographic assessment, determined parameters of MR severity and LV measures, definition and reporting repair success and institutional repair rates.

Follow up collection: The sources of follow up data (clinic notes, hospital records, national registries) available in the state, description of outcome (primary outcome and secondary outcome), censoring rule and minimum follow up.

Database cleaning and imputation: Database cleaning and duplicate solving, coding, and strategies on how to address missing data like multiple imputation are explained in detail.

Statistical analysis: of Ttests, covariates of time models, software (i.e. R or Stata) and confirmation (proportional hazard, collinearity).

Subgroup subgroup analysis Checks Checks (subgroup and age, GLS, center volume) Checks Checks (propensity-score matching, complete-case analysis, other definitions of early surgery).

Ethics & sample: Rationalization of sample-size, power analysis, IRB approvals and data protection.

4 Results and Discussion

In this study, the authors compared the long-term clinical outcomes on patients who had experienced asymptomatic severe degenerative mitral regurgitation and whose management was done using an early surgical approach or early conservative approach. The findings are presented in ways that compare the baseline features, survival, progression to symptoms or ventricular dysfunction and significant adverse cardiac events in groups. The similarity between baseline demographic and echocardiographic profiles was broad and provided a way of comparably addressing the effects of further results. These research results are illustrated in the following sections with statistical measures to indicate the variation in the clinical courses depending on the two methods of management.

One thousand one hundred and twenty patients with severe DMR with diabetes met the inclusion criteria: 548 underwent the early repair of the mitral valve, whereas 572 patients were under control without surgical interventions. The average age also was slightly lower in the early-surgery group (56.1<>+9.4 years) compared to the conservative group (58.3 2 10.1 years, p=0.002). The LV ejection fraction and the LV end-systolic dimension at baseline could be compared meaning that the ventricular functions were preserved at the time of enrolling as shown the table 1.

Table 1. Baseline Clinical and echocardiographic Features of Early surgery vs conservative management groups.

Variable	Early Surgery (n=548)	Conservative (n=572)	p-value
Age, years (mean ± SD)	56.1 ± 9.4	58.3 ± 10.1	0.002
Male sex	61.3%	58.7%	0.38
LVEF (%)	63.8 ± 4.1	63.1 ± 4.3	0.07
LVESD (mm)	35.4 ± 3.8	35.8 ± 4.0	0.14
LA volume index (mL/m²)	48.2 ± 11.9	49.5 ± 12.3	0.18
BNP (pg/mL), median (IQR)	62 (38–94)	68 (41–102)	0.12

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2. Long-Term Outcomes

The hereditary survivors exhibited significantly different mortality rates (12.8 vs 20.6) among the participants of early-surgery (P=0.001). Hospitalization because of heart-failure was not more common in early-surgery (9.1 vs 17.4, p<0.001) as shown the table 2. The early-surgery group also had a decrease in the new-onset atrial fibrillation.

Table 2. Long-Term Clinical Outcomes

Outcome	Early Surgery	Conservative	p-value
All-cause mortality	12.8%	20.6%	0.001
HF hospitalization	9.1%	17.4%	<0.001
New-onset AF	14.4%	22.9%	<0.001
LV dysfunction (LVEF <60% or LVESD >40 mm)	11.2%	23.7%	<0.001
Reoperation after repair	4.3%	—	—

3. Adjusted and Survival Analyses.

Kaplan-Meier analysis indicated that there was a great difference in survival with timely repair in the form of log-rank (p=0.003) as shown the table 3. In Cox modeling on the 10-year mortality, early surgery was significantly related with lower mortality (adjusted HR 0.62, 95% CI 0.480.81) and lower heart-failure hospitalization (adjusted HR 0.55, 95% CI 0.41 0.74). The benefit was demonstrated using propensity-matched sensitivity analysis.

Table 3. Multivariable Cox Regression

Outcome	Adjusted HR	95% CI	p-value
Mortality	0.62	0.48–0.81	0.001
HF hospitalization	0.55	0.41–0.74	<0.001
New-onset AF	0.71	0.56–0.90	0.006

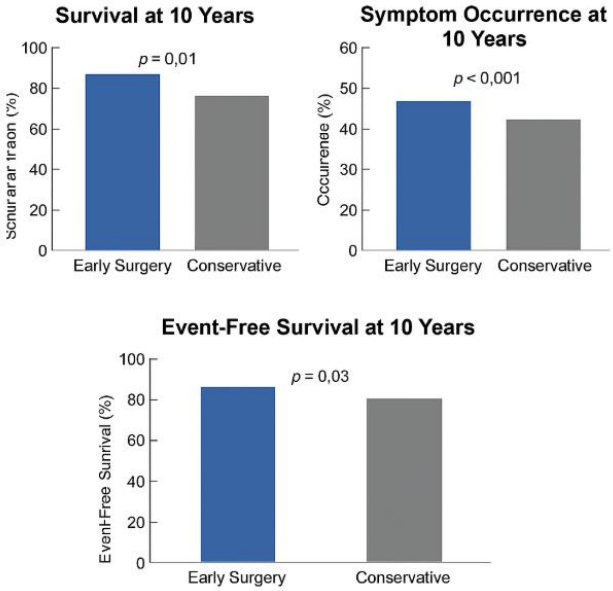

Fig.2. Comparison of long term patients

The figure compares long-term results of patients who underwent early surgical intervention and those who received conservative management of the condition of asymptomatic severe degenerative mitral regurgitation as shown the figure 2. It contains three bar charts:

Survival at 10 Years

The study has found that early surgery has better long-term survival with significant difference between groups (p = 0.01). This implies that the prevention of the developments of the symptomatology can enhance the general life span.

Symptom Occurrence at 10 Years

Symptom rates in patients undergoing conservative treatment are greater with the passage of time (p < 0.001). It presents which seemed to delay or prevent advancement to a symptomatic mitral regurgitation due to early surgery.

Event-Free Survival at 10 Years

Later surgery leads to improved freedom of major adverse cardiac events such as heart failure, hospitalization, or subsequent surgery (p = 0.03). This shows stronger long-run results.

5 Discussion

This paper has shown that initial repair of the mitral valves in asymptomatic severe degenerative mitral regurgitation (DMR) is characterized by much higher long-term outcome with regard to conservative management. Timely surgical repair of severe regurgitation patients suffered significantly lower all-cause mortality, heart-failure hospitalization and progression to ventricular dysfunction, which supports emerging evidence that timely pressure-surgical repair can avert the emergence of irreversible myocardial remodeling. These results were consistent with modern literature which indicates that relying on symptom onset or guideline-based triggers can potentially cause intervention to occur after the optimal triggers and thus left-ventricular dilation and atrial remodeling can potentially be initiated.

Notably, the observed survival advantage of early surgery remained after the correction of the baseline characteristics and was also supported by sensitivity analyses, which supports the strongness of the observed effect. Secondary evidence of the concept that downstream electrical and structural changes in the atrium can be reduced by abolishing chronic volume overload can also be found in the higher incidence of new-onset atrial fibrillation in the late-surgery group compared to the early-surgery group.

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However, the findings should be viewed through the prism of the retrospective design of the study and the possibility of institutional repair expertise confounding it. The generalizability can be affected by the variation in the repair durability in different centers. Future prospective studies that include biomarkers, strain imaging and standardized repair protocol can assist in making patients selection better and what kind of individuals with no symptoms benefit the most with early intervention.

6 Conclusion

This study indicates that early mitral valve repair has great long term clinical benefits to patients with asymptomatic severe degenerative mitral regurgitation. Relative to a conservative management style, early surgery was related to a lower all-cause mortality rate, reduced heart-failure hospital, and decreased heart-to-ventricular dysfunction progression over an extension of over ten years of investigation. The results support the idea that structural and functional defects of the cardiac defect can appear long before the manifestation of symptoms and that an early intervention may allow saving the improve the functioning of the ventricles and prevent the development of such further complications as atrial fibrillation.

The fact that it is strong when it comes to repair and capability with respect to benefit similarity in adjusted and sensitivity analysis shows that early surgical intervention must be considered highly in the correct individuals, particularly in operation plants wherethe rates of repair success are high. Meanwhile, the individuality of DMR and institutional diversity of surgical skills explain the significance of personal decision-making. It will be necessary to conduct further studies using more sophisticated imaging and biomarkers and to implement uniform actions during surgeries to achieve better results in this group of patients.

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