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Impact of Preservation of Mitral Valve Apparatus on Outcomes of Prosthetic Mitral Valve Replacement for Severe Mitral Valve Regurgitation

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Abstract

Objectives: To assess the impact of valve pathology on the outcome of the modified preservation of the mitral valve apparatus during mitral valve replacement. **Hypothesis:** Preservation of mitral valve apparatus will improve outcomes of prosthetic mitral valve replacement for severe mitral valve regurgitation. **Methods**: This prospective analytic cohort study included 100 patients in two main groups: 50 patients with rheumatic mitral valve disease (group A) and non-rheumatic (group B): B1:25 patients with ischemic mitral lesions and B2:25patients with selected degenerative valve lesions admitted between 1st March 2022 and 28th Feb. 2024 at one but a good flow rate-center. All patients had modified preservation of the mitral apparatus during prosthetic mitral replacement. Additionally, Group B1 had bypass grafts to diseased coronary arteries. Group B2 had chordal transposition, folding or reattachment. **Results**: Pre-operative data did not show significant differences between groups ($p > 0.05$) but the smoking index was much higher in group B. Intraoperative Trans-Esophageal Echocardiography showed free mobility of prosthetic leaflets, left ventricular outflow tract free of any obstruction and freedom from any valve-related complications in the groups. Cross-clamp and recovery times were shorter in group A ($p = 0.0001$) & early mortality of 2patients. Group B: post-operative inotrope requirements were significantly larger; three died after failure of weaning from the intra-aortic balloon pump. Three others needed a coronary angiogram and stenting due to the occlusion of one of the grafts 3 and 7 months after surgery. One in group A and another in group B died after thrombo-embolic events. Improved left ventricular functions were reported 6, 12 and 24 months after surgery. Left ventricular and atrial dimensions were reduced among all patients. Mean follow-up period =

34 + 7.5 months. **Conclusions**: This technique is feasible and reproducible for rheumatic and selected cases of non-rheumatic valve lesions due to freedom from mid-term reoperation, preserved ventricular functions and acceptable value-related complication rates.

Keywords

Preservation of Mitral Apparatus during Mitral Replacement, Intra-Operative TEE during Mitral Replacement, Mitral Replacement for Degenerative Mitral Valve Lesions, Mitral Replacement for Rheumatic Mitral Lesions, Mitral Replacement for Ischemic Mitral Lesions

1. Introduction

Mitral valve disease can be due to diverse etiologies, e.g., rheumatic, degenerative, or ischemic heart disease [1] [2]. Rheumatic heart disease remains the most common lesion of cardiac valves worldwide, as it affects approximately 41 million people. In 2013, rheumatic heart disease led to worldwide mortality of 275,100 patients [2]. The prevalence of degenerative lesions increases with age: 2% in people more than 60 years but 10% in people above 70. Degenerative mitral valve lesions account for 60 to 70% of all mitral valve surgeries in developed countries but a much lower percentage in developing countries. Deaths due to coronary artery disease peaked in the mid-1960s. These days, it is the leading cause of death worldwide [3].

Early mortality after mitral valve replacement without preservation of the valve apparatus was 10.4%. Conventional mitral valve replacement even with preservation of the posterior mitral leaflet is associated with a higher rate of postoperative low cardiac output syndrome [3]. Functionally the mitral valve apparatus is producing "annulo-ventricular continuity" [4].

David and his colleagues in 1984 described mitral valve replacement with preservation of both leaflets. Modifications were added to prevent preserved tissues from affecting prosthetic valve function and to ensure an adequate size of the prosthesis preventing left ventricular outflow tract obstruction [5].

Echocardiography and magnetic resonance imaging have made significant contributions to clarifying the mechanisms that progressively worsen mitral valve lesions [6].

Lack or disturbed valve leaflets-coaptation can be due to:

- Left ventricular remodeling owing to severe myocardial infarction,
- local involvement of the papillary muscles,
- Annular dilatation [7].

In others, the abnormal valve structure leads to functional deterioration of the left ventricle because of dilation and, eventually, to ventricular dysfunction. Changes in left ventricular geometry and in the various components of the mitral valve resulting in the functional anatomy of non-ischemic mitral regurgitation [8]

[9].

There is still controversy about the best surgical approach, particularly regarding whether to replace or repair the diseased valve, the type and size of prosthesis to be used in mitral replacement for severe rheumatic and/or severe non-rheumatic mitral valve disease with preservation of the mitral valve apparatus [10].

2. Materials and Methods

This prospective cohort study included 100 patients divided into two main groups: 50 patients with isolated rheumatic mitral valve disease (group A) and non-rheumatic group B (50 patients): 25 patients with ischemic mitral disease (group B1) and 25 patients with severe degenerative mitral valve lesions (group B2).

Sample Size: Sample size formula

$N = Z^2 P (1 - P)/e^2$

N = sample size,

P = population size.: incidence of severe mitral valve disease indicating surgery = 33%, Incidence of repairable mitral valve with regurgitation = 55%.

e = Margin of error (percentage in decimal form)

z = z-score, the z-score is the number of standard deviations a given proportion is away from the mean. The 95% Confidence Interval for the sample proportion (p) of 0.5.

The estimated sample size was 94 patients, we added 6 patients to minimize the error so, Total Number = 100 patients.

Ethical Considerations

The Institutional Review Board (IRB) and Ethics Committee (EC) approved the study, and informed consent from each patient has been obtained. We considered informed consent, voluntary participation, confidentiality, anonymity, potential for harm, and results communication.

Patients were operated upon between 2021 and 2023 at cardiothoracic surgery departments in Suez Canal University Hospitals, Ismailia, Egypt.

Participants were fully informed about the research, including its purpose, procedures, risks, and benefits, before making an informed decision about participation.

Participation was voluntary, with participants having the right to withdraw from the study at any time without penalty.

Confidentiality and Anonymity: We are protecting the privacy of participants by keeping their personal information confidential

All patients had on-pump modified preservation of the mitral apparatus during mitral valve replacement. In addition, ischemic mitral valve lesions indicated coronary artery bypass surgery and degenerative valve lesions mostly indicated repair of the subvalvular apparatus.

Inclusion criteria of patients for mitral valve replacement according to the guidelines [11]

Replacement is indicated when repair cannot restore competence safely. Mitral

valve:

Replacement may be necessary if therapy with diuretics does not relieve symptoms, but it should be performed only in patients who have severe limiting symptoms.

1- Rheumatic mitral valve disease: (repair is not durable and replacement is preferred.)
   leaflet thickening, fibrosis, and calcification.
   Sub-valvular fusion and/or shortening
   Combined severe mitral valve stenosis and regurgitation
2- Degenerative mitral valve disease
   Leaflets are calcified (especially anterior leaflets and commissures).
   Annular calcification
   Complex bi-leaflet pathology.
3- Ischemic mitral regurgitation
   Tethered leaflets and marked left ventricular remodeling

Papillary muscle dysfunction due to elongated, infarcted or incompletely ruptured papillary muscle.

Exclusion Criteria

- Previous mitral repair
- Infective endocarditis
- Dilated cardiomyopathy with ejection fraction < 40%: patients have systolic dysfunction and may or may not have overt symptoms of heart failure. Echocardiography provides an objective assessment of ventricular size, function, and any associated valvular abnormalities.
- Mild or moderate mitral regurgitation.
- The mitral valve apparatus with heavy calcification, fibrosis, fusion or ruptured components of the apparatus.

The selected surgical technique

Femoral Doppler ultrasound can determine groin vessel size. Patients with large vessels are suitable for peripheral cannulation and for robotic or anterolateral thoracotomy. In patients with small groin vessels (e.g., <0.9 cm), we favor partial sternotomy.

The left atrial approach: mitral valve inspection then, we incise any fused commissures towards the valve annulus, and fused or thickened chordae are mobilized. The anterior leaflet was incised from its middle; the incision continued to the annulus; the middle was selected for incision as it is devoid of chordal attachment. Ticron sutures 2/0 with pledges (non-absorbable, polyester braided sutures) were bitten from the annulus thence; those were passed from the bottom to the tip of the leaflet. Lastly, each suture was anchored to the bi-leaflet mitral prostheses (St. Jude bi-leaflet low-profile prostheses were used in all patients. The posterior leaflet was preserved by leaflet-plicating sutures. The prosthetic mechanical valve was placed perpendicularly to the original mitral valve orifice. Modifying techniques such as chordal transposition, folding or reattachment can be mandatory if the left ventricular function is already marginal. A surgeon should modify

or trim chordae only if they are causing obstruction or interfering with prosthesis function.

Modifications were made to:

- prevent the preserved tissue from interfering with prosthetic valve function,
- implant an adequate-sized valve and
- prevent left ventricle outflow tract obstruction.

Statistical analysis:

Data was fed to the computer and analyzed using IBM SPSS software package version 24.0. (Armonk, NY: IBM Corp).

We used the mean values and the standard deviation and estimated the P value

Qualitative variables and their association among groups were studied by applying the Chi-square test and the Fisher Exact test. Quantitative variables among both groups were compared by applying an independent samples t-test. $P < 0.05$ values mean statistically significant results.

3. Results

The etiology of the valve dysfunction was:

1- rheumatic in group A: 50 patients,

2-Coronary artery disease evaluated with preoperative coronary angiography in group B1: 25 patients.

3-Degenerative mitral valve lesions were diagnosed in 25 patients (group B2). Group A: 27 men and 23 women. Group B: 29 men and 21women.

The Mean age was 48.5 + 4.8 years.

Table 1. Pre-operative patient characteristics.

Feature	Group A	Group B1, B2	P value
Number of patients	50	25, 25	…
Range of age in years	33 - 66	40 - 71	➢ 0.05
Mean age in years	51 + 5.84	52 + 6.92	➢ 0.05
Sex: male/female	27/23	29/31	➢ 0.05
Smoking index: pack. year	17.13 + 1	28.26 + 2.3	0.039*
Diabetes Mellitus: Type 1	2 (4%)	4 (8%)	➢ 0.05
Type II	7 (14%)	8 (16%)	
Hypertension	12 (24%)	16 (32%)	➢ 0.05
Dyslipidemia	11 (22%)	14 (28%)	➢ 0.05
Atrial Fibrillation, arrhythmia	18 (36%)	15 (30%)	➢ 0.05
NYHA class III	38 (76%)	40 (80%)	➢ 0.05
IV	12 (24%)	10 (20%)	
History of rheumatic Fever.	50 (100%)	11(22%)	➢ 0.05
Coronary artery disease by angiography	0	30 (100%)	➢ 0.05

*Means: statistically significant finding.

There were 12 patients in group B and 9 (18%) diabetic patients in group A (Table 1).

Each had only one arterial bypass graft, either the left or the right internal mammary artery as a bypass graft besides the venous grafts.

For myocardial ischemia with valve lesions, the following steps were added:

Left internal thoracic artery to left anterior descending coronary artery bypass grafts were done in 23 patients.

The right internal thoracic artery to the right coronary artery bypass graft was done in 11 patients.

The saphenous vein graft to the posterior descending artery was performed in 23 patients and 17grafts to the marginal branch. Total graft number was 90 grafts (Table 2).

Table 2. Intra-operative data.

Finding	Group A (rheumatic valve)	Group B (non-rheumatic valve)	P value
Mean cardiopulmonary bypass-time (minutes)	75.5 + 3.8	94.9 + 4.9	0.0001*
Mean cross-clamp time	52.8 + 6.2	69.5 + 3.6	0.0001*
No. of grafts	0	90	0.0001*
Range of grafts/patient	0	1 - 3	0.0001*
Sub valvular corrections %	20% (10 patients)	30% (18 patients)	0.003*
Abnormalities by TEE	0	3	0.0001*
Need for intra-aortic balloon-pump	3	7	0.002*
High doses of inotropes	8	15	0.0038*
Temporary pacemaker	4	7	0.0047*
ICU stay-days	2 + 1.6	3.5 + 4.5	0.0042*
In-Hospital stay-days	5.5 + 2.1	7.8 + 2.7	0.0031*

*Means: statistically significant finding.

Table 3. Pre-operative, 6 and 24-month post-operative echocardiographic-findings.

Mean	Preoperative clinical		6 months-postop		24 months postop		P value
	Group A	Group B	Group A	Group B	Group A	Group B	Pre/postop
EF %							
At rest	45.5 + 4	43.9 + 1.1	54.5 + 6.39	53.5 + 3.7	64.8 + 4.7	6.5.3 + 1.8	0.0001*
Exercise	49.8 + 2.5	46.2 + 3.4	59.8 + 2.6	59.2 + 4.2	68.1 + 3.1	69.3 + 1.7	0.0001*
FS %	28.2 + 2.3	26.8 + 1.7	33.9 + 4.2	32 + 3.8	35.1 + 1.3	34.8 + 2.6	0.0001*
LVEDD mm	55.2 + 2.5	58.3 + 4.2	51.2 + 1.1	54.1 + 1.3	52 .2 + 2.1	53 + 3.5	0.00019*
LVESD mm	44.7 + 2.8	49.8 + 5.1	43.6 + 2.4	46.2 + 3.2	42.1 + 2.2	45 + .3.1	0.003*

*Means: statistically significant finding. EF: ejection fraction, FS: Fractional Shortening, LVEDD: left ventricular diastolic diameter, LVESD: left ventricular end systolic diameter.

Table 4. Complications one year after surgery.

Features	1 to 6 months postop,		7 to 24 months postop.		P value
	Group A	Group B	Group A	Group B	
Thrombo-emboli & death	1 (2%)	0	0	1 (2%)	0.125
Mortality	1 (2%)	3 (6%)	1 (2%)	1 (2%)	0.0003*
Bleeding	1 (2%)	0	0	1 (2%)	0.0634
occluded grafts	0	2 (4%)	0	1 (2%)	0.0002*
Wound infection	2 (4%)	3 (6%)	0	0	0.153
Endocarditis	1 (2%)	0	0	0	0.0047*
Total complications	6 (12%)	8 (17%)	1 (2%)	4 (7%)	0.004*

*Means: statistically significant findings.

If papillary muscle elongation or rupture was found, Gore-Tex artificial chordal replacement was performed.

Pre-operative clinical data did not show any significant differences between the groups ($p > 0.05$), except for the smoking index which was much higher in group B.

The cross-clamp and recovery times were shorter in group A ($p < 0.05$) & early mortality of 2 patients. The intra-operative TEE examination showed free mobility of the leaflets of the prosthetic valve without any limitations. Also, it did not show any degree of left ventricular outflow tract obstruction or any valve-related complications in both groups (Table 2)

Post-operative inotrope requirements were significantly larger in group B, only one postoperative mortality had been reported. Marked improvement in systolic and diastolic left ventricular functions was reported by echocardiographic parameters-6, 12 and 24 months after surgery. Left ventricular and atrial remodeling were noticed among both groups. There was no post-operative left ventricular posterior rupture or obstructive mechanical valve dysfunction among groups. NYHA classification, diabetes and/or hypertension and other vital data were reported and analyzed. They showed non-significant differences (Table 1).

TTE and TEE during follow-up showed that left ventricular end-systolic diameter, left ventricular end-diastolic diameter, ejection fraction, fractional shortening, left atrial diameter and inter-ventricular septal thickness of group A were significantly improved and corrected compared to those of group B (Table 2, Table 3).

In group B, three died due to failure of weaning from the intra-aortic balloon pump. Two others needed a coronary angiogram and stenting due to thrombotic occlusion of one of the grafts 3 months and one on the 7th month after surgery. One in group B and another in group A developed thrombo-embolic complications and died, two suffered excessive bleeding due to anticoagulant overdose, additionally, 5 had wound infection, one had endocarditis that had been medically

controlled (Table 4).

Improved systolic left ventricular functions were reported 6, 12, and 24-months after surgery. Left ventricular and atrial dimensions were reduced among the groups. (Table 4). Mean follow up period = 34 +/− 7.5 months

4. Discussion

Principles for MVR with preservation of mitral valve apparatus according to Guideline Statement (Both ACC/AHA & ESC/EACTS): During mitral valve replacement, preservation of the sub-valvular apparatus is recommended whenever technically feasible to preserve left ventricular functions [11] [12].

To avoid the need for redo surgery we used prosthetic valves in this relatively young group of patients (The Mean age was 48.5 + 4.8 years). There were perioperative teaching classes to educate patients in Arabic about all information about anticoagulants.

Mitral replacement with preservation of the valve apparatus is a promising approach to perform percutaneous or minimally invasive mitral valve replacement with the modified preservation of the native valve apparatus.

Selective preservation of the subvalvular apparatus is of major value whenever it is anatomically and functionally feasible. The benefit of mitral leaflet chordal preservation during mitral valve replacements depends on preserving functional chord-papillary continuity [13].

All patients with severe valvular heart disease being considered for valve intervention should be evaluated by a multidisciplinary team, with either referral to or consultation with a Primary or Comprehensive Valve Center as the university cardiac center [14].

Severe mitral regurgitation can be indicated by a flail leaflet, ruptured papillary muscle (s), large central jet or eccentric jet reaching the posterior left atrial wall, large flow convergence zone, systolic flow reversal through pulmonary veins, regurgitation-volume > 60 ml [15].

Mitral replacement gives results better than mitral repair as regards recurrence of mitral regurgitation in the following situations where TTE shows one or more of the following features:

1- Tenting area > 2.5 cm^2,

2- Coaptation distance > 1 cm, 3- Rear veil coaptation angle > 45^0. With TEE: 1- Ring > 37 mm, 2- Tenting area > 1.6 cm^2. Severe central jet, complex jets, local remodeling parameters of the left ventricle, inter-papillary distance > 20 mm, rear-fibrous papillary distance > 40 mm lateral wall motility –abnormality: akinesia, basal dyskinesia, severe dilation of left ventricle end-diastolic diameter > 65 mm, end-diastolic volume > 140 ml, sphericity index $\geq$ 0.7, restrictive filling pattern.

These features were applied as inclusion criteria to decide on mitral valve replacement throughout the current study.

Thresholds for intervention now are lower than they were previously because

of the availability of more durable treatment options and lower procedural risks [16].

- Maintenance of left ventricular geometry
- Prevention of LV dilatation and dysfunction
- Better early and late survival rate.

Included patients had the following features:

- Chordae are soft, mobile and minimally calcified.
- Chordae are not excessively shortened or fused.

Intact chordae from the non-infarcted papillary muscle are preservable.

- The papillary-chordal0leaflet unit is intact
- Mitral annular calcification with leaflet calcification can be preserved as long as it does not compromise prosthetic valve seating.

Ejection fraction decreases by 4% after non-conservative surgical correction of mitral valve regurgitation [16] [17]. After preservation of valve apparatus and correction of ischemic left ventricular wall dysfunction, the ejection fraction was raised by about 10% in the current study.

In the most complex, high-risk settings, survivals after repair or replacement were similar in several studies [17]. Researchers also reported that Ischemic mitral regurgitation was further subdivided into three mechanisms of regurgitation: 1) ruptured papillary muscle, 2) infarcted papillary muscle without rupture, and 3) functional regurgitation.

Patients with elongated and infarcted but un-ruptured papillary muscles were classified as having infarcted papillary muscles. Patients with isolated functional mitral regurgitation had normal papillary muscles, chordae, and leaflets; however, the leaflets failed to coaptate, and echocardiograms frequently demonstrated restricted leaflet motion [18].

Researchers in Boston observed that replacement provided a more durable correction of mitral regurgitation regardless of the underlying pathological mitral valve lesions and there was no significant difference between-groups in clinical outcomes. Practice guidelines recommend consideration of chordal-sparing replacement for patients with severe ischemic mitral regurgitation that is causing limiting symptoms despite the best available medical therapy and, possibly, cardiac resynchronization [19]. Clinical studies have suggested that repair is associated with lower perioperative mortality, whereas replacement provides better long-term correction with a lower risk of recurrence (an important consideration, since recurrence of mitral regurgitation confers a predisposition to heart failure, atrial fibrillation, and readmission) [20]. We found that it reduces postoperative mortality and morbidity as this technique improves the left ventricular functions

The natural history of severe functional ischemic mitral regurgitation suggests that surgery, at least in the case of severe MR (4+), is the best option for improving survival. However, there is no agreement concerning the benefits of surgery in patients with mild (2+) or moderate (3+) regurgitation. Until recently, it was recommended that complete coronary revascularization alone be performed, without mitral valve surgery, since the latter had a negative effect on the surgical results.

Other researchers demonstrated that the 10-year survival of patients with coronary disease and moderate ischemic mitral regurgitation who underwent coronary bypass alone was lower than that of a group of patients who did not have mitral insufficiency (53% versus 75%) [21]. Researchers reported that the Kaplan-Meier survival estimates at 1, 3, and 5 years were similar between mitral valve repair-group and valve replacement-group. Logistic regression revealed poor survival was associated with old age (>75 years), preoperative renal insufficiency and low left ventricular ejection fraction (< 30%) [22]. This agrees with the current study.

The rate of complications after replacement for rheumatic valve disease is lower than replacement and correction of myocardial ischemia or degenerative lesions and all are acceptable. There are non-significant statistical differences between the pathology-based groups as regards the outcome including the one year-survival and reoperation rates.

This technique preserves left ventricular function by maintaining an annular-papillary connection and avoiding left ventricular deformation [23].

Mitral valve replacement with modified preservation of leaflets with added revascularization or subvalvular corrections when indicated, is a feasible and reproducible procedure. BI leaflet preservation successfully prevents postoperative decrease in LVEF in comparison with preservation of the posterior leaflet alone. Moreover, posterior-leaflet-only preservation yields excellent results in terms of LV diameter [24]. Lillihie and his colleagues reported that the method of preserving the continuity of papillary muscles and chordae tendineae annulus was that thein 14 consecutive patients who required mitral valve prostheses. Twelve patients (86 per cent) survived the procedure and have had an uneventful recovery.

None of the patients developed the "low output" syndrome in their early postoperative period. There have been no additional deaths in the follow-up period after hospital discharge [25].

Limits of this study

We reported mid-term outcomes. We can continue follow up to get ten-years (long-term) outcomes .Kindly, you can express this meaning as you see.

5. Conclusion

Modified preservation of the mitral valve apparatus during prosthetic mitral valve replacement for rheumatic, degenerative or ischemic mitral valve disease is feasible and reproducible. We report freedom from mid-term reoperation, with acceptable value-related complication rates as well as reduced left ventricular and atrial dimensions. Mitral valve replacement with preservation of both leaflets and sub-valvular apparatus carries the advantages of both mitral repair and mitral replacement.

Participants (Authors)

All authors contributed to the study conception and design. Material preparation,

data.

Collection and analysis were performed by Hamdy. D. Elayouty, Hassan Salah. Hassan and Hamed, M. Sami. The first draft of the manuscript was written by Ahmed Hamdy. Elayouty. All authors commented on previous versions of the manuscript. All authors approved the final manuscript. *All Authors* equally *contributed* to finalizing this article and agree to submit the article to your Journal.

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Statement of Data Availability

Data Available on Request: The data underlying this article will be shared at a reasonable request to the corresponding author.

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Conflicts of Interest

There is not any conflict of interest at all.

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