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Mitral Valve Repair with Flexible Versus Rigid Annuloplasty Device in Degenerative Mitral Regurgitation

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ABSTRACT

Background the most common clinically presented valvular heart disease is mitral regurgitation (MR). Mitral valve repair is considered the surgery of choice for mitral regurgitation.

Objective: The aim of the current work was to evaluate the early result of mitral repair with flexible and rigid annuloplasty devices in degenerative mitral regurgitation.

Patients and Methods: This prospective study included a total of 64 patients with degenerative mitral regurgitation undergoing surgery for mitral valve repair with either a flexible or rigid annuloplasty device, attending at Department Cardiothoracic Surgery, Zagazig University Hospitals. This study was conducted between September 2017 and June 2020. We evaluated all patients after 6 months of surgery.

Results: According to early mortality there were 2 patients in flexible group, and 1 patient in rigid one with no significant differences. There were also no significant differences according to failure of repair.

Conclusion: It could be concluded that in spite of type of annuloplasty devices used, the early outcomes of mitral valve repair with rigid or flexible device show good results in our prospective study, but there were statistical differences between both groups regarding postoperative left ventricular dimension and function.

Keywords: Mitral regurgitation, Degenerative**,** Annuloplasty device and ventricular.

INTRODUCTION

Mitral valve disorders are the second-most common clinically significant form of valvular heart diseases in adult. Mitral Valve regurgitation occurs with high percentage as part of degenerative changes in the aging process. In industrialized nations, degenerative mitral valve diseases represent 2% to 3% [(1)].

Myxomatous degeneration of the mitral valve, also called floppy mitral valve, Barlow disease, or mitral valve prolapse, is the most common cause of mitral regurgitation. Most studies stated that mitral valve prolapse is a genetic connective tissue disorder [(2)].

Surgical treatment of mitral regurgitation is one of the following choice Mitral valve repair or replacement. The choice of procedure depends on skills of surgeon, surgical anatomy and nature of mitral valve intraoperative and also indication of surgery [(3)].

One of the most critical point in mitral valve repair is Trans Esophageal Echocardiography (TEE) which good data about anatomy and pathophysiology of mitral valve, including details of the valvular pathoanatomy and the mechanism, origin, direction, timing, and severity of the regurgitant leak [(4)].

Mitral valve repair has better survival, preservation of ventricular function and decreased thromboembolic complications compared to mitral valve replacement for mitral regurgitation (MR) [(5)].

According to the choice of surgeon, there are different types of annuloplasty devices are present today, rigid, semirigid and flexible annuloplasty device. Any device can be used [(6)].

Both rigid and flexible annuloplasty devices have similarly good results in degenerative mitral valve prolapse. Flexible rings have the advantage of allowing the base of the heart to contract, whereas rigid rings are more resistant to central leakage in patients with left ventricular (LV) dilation. In patients with functional MR, the net advantages of the complete rigid ring exceed those of the flexible ring [(7)]. Many studies carried out on the two techniques for management of mitral regurge each technique has some advantages over the other [(8)].

The aim of the current work was to evaluate the early result of mitral repair with flexible and rigid annuloplasty devices in degenerative mitral regurgitation, and to show which of them is more useful for mitral valve repair in patients with non-ischemic mitral regurgitation.

PATIENTS AND METHOD

This prospective study included a total of 64 patients with degenerative mitral regurgitation undergoing surgery for mitral valve repair, attending at Department Cardiothoracic Surgery, Zagazig University Hospitals. This study was conducted between September 2017 and June 2020.

Ethical Consideration:

The study was approved by the Institutional Review Board (IRP) and an approval of the study was obtained from Zagazig University Academic and Ethical Committee. A written signed consent was obtained from all the study participants.

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The included Patients were randomly allocated using computer generated numbers into two groups; **Group A (flexible group)** consisted of 32 patients underwent mitral valve repair with flexible band and **Group B (rigid group)** consisted of 32 patients underwent mitral valve repair with rigid band.

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The mean ages of flexible and rigid group were (45.2±10.2) years and (46.4±10.3) years, respectively**.** All patients were operated upon and followed up by the same group of surgeons.

Patients **included** in this study were adult patients who have moderate to severe degenerative mitral regurgitation.

Patient **excluded** from the study were those with significant mitral valve stenosis, those who required aortic or pulmonary valves surgery and patients with septic foci.

All patients were evaluated through thorough history taking, detailed clinical examination, investigations as chest X-Ray (CXR), echocardiography, cardiac catheterization if needed, and routine preoperative laboratory tests.

Surgical technique:

After the induction of anesthesia, transesophageal echocardiography (TEE) was performed in all patients. All procedures involved cardiopulmonary bypass with bicaval cannulation and systemic mild hypothermia. The mitral valve was exposed through a left atriotomy. After assessing the whole mitral apparatus, quadrangular resection or triangular exclusion of the prolapsed posterior leaflet was performed. Chordal reconstruction using expanded polytetrafluoroethylene (ePTFE) sutures was performed for prolapse of the anterior mitral leaflet. A flexible or rigid annuloplasty device was applied for ring annuloplasty after measuring the intertrigonal distance and height of the anterior leaflet. Repaired MV was routinely assessed using intraoperative transesophageal echocardiography after weaning from cardiopulmonary bypass.

Data collected as operative time, cardiopulmonary bypass time for mitral valve repair, Intraoperative evaluation of mitral valve repair by trans-esophageal echocardiography and follow up data as, postoperative hemodynamic evaluation, Postoperative neurological evaluation, Postoperative Echocardiographic evaluation of mitral valve repair before discharge of patients.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Data were tested for normal distribution using the Shapiro Walk test. Qualitative data were represented as frequencies and relative percentages.

Chi square test ($\chi 2$) to calculate difference between two or more groups of qualitative variables. Quantitative data were expressed as mean ± SD (Standard deviation). Independent samples t-test was used to compare between two independent groups of normally distributed variables (parametric data). P value < 0.05 was considered significant.

RESULTS

According to demographic data of patients, there was no significant differences between both groups. There were no significant differences regarding of mitral regurgitation (**Table 1**).

Table (1): Demographic criteria, pathology and etiology of mitral valve regurgitation.

		Flexible group (n =32)	Rigid group (n = 32)	P value
Age (years)		45.2±10.2	46.4±10.3	0.3185
Gender	Male	15 (46.9%)	17 (53.1%)	0.5523
	Female	17 (53.1%)	15 (46.9%)	
Pathology	Prolapse of AMVL	17 (26.6%)	14 (21.9%)	0.495
	Prolapse of PMVL	15 (23.4%)	18 (28.1%)	

P< 0.05%= significant difference

Preoperative echocardiographic data, as presented in **table 2** shows no significant difference between both groups regarding Ejection fraction (EF), Left Ventricular end diastolic diameter (LVEDD), tricusped regurgitation (TR) and Left atrial diameter (LAD).

Table (2): Preoperative data echocardiography.

		Flexible band (n =32)	Rigid band (n =32)	P value
Ejection fraction	Mean ±SD	58.44 ± 10.59	56.45 ± 12.17	0.368
Left ventricle (LVEDD)	Mean ±SD	60.56±10.41	62.78 ± 9.22	0.368
Tricuspid	No	10 (15.6%)	8 (12.5%)	0.5970
	Mild	5 (7.8%)	7 (10.9%)	
	Moderate	2 (3.2%)	3 (4.8%)	
	Moderate to Severe	9(14.1%)	6 (9.3%)	
	Severe	6 (9.3%)	8 (12.5%)	
LAD	Mean ±SD	48.86±8.14	50.52±7.21	0.340
PHT	Mean ±SD	45.84±21.41	47.34±13.93	0.616

P< 0.05%= significant difference.

Table (3): Operative data in both groups.

		Flexible band group (n =32)	Rigid band group (n =32)	P value
Technique of repair	Annuloplasty and artificial chordae with gore tex suture	17 (26.6 %)	14 (21.9%)	0.4992
	Annuloplasty and quadrangular resection of p2	8 (12.5%)	10 (15.6%)	
	Posterior Leaflet triangular exclusion of p2	7 (10.9%)	8 (12.5 %)	
Types of annuloplasty device	Teflon band 32	6 (9.3 %)	-	-
	Pericardial band 30	10 (15.6 %)	-	-
	Pericardial band 32	14 (21.9 %)	-	-
	Cosgroov Edward band 30	2 (3.2 %)	-	-

P< 0.05%= significant difference.

There was no significant difference between groups regarding technique of repair. The most common technique of repair used in flexible and rigid groups was annuloplasty and artificial chordae with Gore Tex suture (12.5%, 15.6%) respectively. There were different sizes of annuloplasty devices among flexible group patients. the most common device used was pericardial band 32 (21.9%). The only used rigid device was carpentier edwards ring (100%).

According to concomitant surgery, the most common concomitant surgery among flexible group and rigid group is tricuspid valve repair with no significance of differences (**Table 4**).

Table (4): Concomitant surgery among studied patients.

		Flexible band group (n = 32)	Rigid band group (n =32)	χ^2	P value
Tricusped Valve repair	NO	10 (15.6%)	8 (12.5%)	0.797	0.3719
	Annuloplasty ring 32	8 (12.5%)	10 (15.6%)		
	Elgabryannuloplasty technique	8 (12.5 %)	6 (9.4%)		
	Devage annuloplasty	6 (9.4 %)	8 (12.5%)		

There was significant difference between groups regarding post-operative degree of EF, MR and LV ($p<0.05$) while there was no significant difference between groups regarding post-operative Pulmonary hypertension (PH), TR and LAD ($p >0.05$) (**Table 5).**

Table (5): Postoperative echocardiography follow up.

		Flexible band group (n = 32)	Rigid band group (n = 32)	P value
Degree of MR	No	8 (12.5%)	3 (4.7%)	0.001*
	Mild	7 (10.9%)	16 (25%)	
	Trivial	15 (23.4%)	10 (12.6%)	
	Mild to moderate	2 (3.2%)	3 (4.7%)	
Ejection fraction	Mean ±SD	59.43 ± 9.04	53.48± 9.81	0.001*
Left ventricle (LVEDD)	Mean ±SD	50.24±10.33	55.00 ± 10.57	0.001*
Tricuspid	No	6 (9.4%)	5 (7.8%)	0.1393
	Mild	9 (14.1%)	10(12.6%)	
	Trivial	16 (25%)	15(23.4%)	
	Moderate	1 (1.5%)	2 (3.2%)	
LAD	Mean ±SD	49.72±7.17	50.54±25.77	0.6752
PHT	Mean ±SD	33.94±11.32	35.52±9.51	0.452

P< 0.05%= significant difference.

In terms of complications the flexible band group had a higher rate of failure to repair, neurological complications and death while the rigid band group had a higher rate of re exploration for control of bleeding **(Table 6).**

Table (6): Complications rate.

		Flexible band group (n = 32)	Rigid band group (n = 32)	P value
Failure of repair		2(3.2%)	1 (1.5%)	0.495
Neurological complication	Lt sided hemiparesis	1 (1.5%)	Zero (0%)	0.125
	Brain stem infarction	1 (1.5%)	Zero (0%)	
Bleeding and reexploration		2 (3.2%)	3 (4.7%)	0.436
Death	After 2 days from bleeding	1 (1.5%)	1 (1.5%)	0.125
	After 7 days from brain death	1 (1.5%)	0 (0%)	

P< 0.05%= significant difference.

DISCUSSION

The proper procedure for surgical management of mitral regurgitation is mitral valve repair in comparison to mitral valve replacement. All Previous surgical studies stated that mitral valve replacement has higher rate of mortality and thromboembolic complication than mitral valve repair [(7)].

The corner stone of our study was intraoperative transesophageal echocardiography. It helped us to revise the echocardiographic data of the patient, evaluate the pathology of the mitral valve and evaluation of repair of mitral valve after weaning from cardiopulmonary bypass for possibility of failure of repair and replacement of mitral valve.

Mitral valve repair was done in all patients - in this study - by annuloplasty in both groups with specific technique according to pathology of mitral valve apparatus. In flexible group, quadrangular resection of p2 was done in 8 patients (12.5%),, artificial chordae with gore tex suture was done in 17 (26.6 %), and Posterior Leaflet triangular exclusion was done in 7 patients (10.9%) and but In rigid band group, artificial chordae with gore tex suture was done in 14 (21.9%), quadrangular resection of p2 was done in 10 patients (15.6%), Posterior Leaflet triangular exclusion was done in 8 patients (12.5%).

In study done by **chang *et al.* [(9)],** a rigid ring group mitral valve repair was done with Segmental resection of Leaflet in 154 patients (82.4%), new chordae formation with PTFE sutures in 43 patients (23%), Chordae shortening in 12 patients (6.4 %), Commissurotomy in 6 patients (3%) and Chordae transfer in 2 patients (1%). In flexible ring group, mitral valve repair was done with Segmental resection of Leaflet in 129 patients (80.4%), New chordae formation with PTFE sutures in 40 patients (23.5%), Chordae shortening in 9 patients (5.3 %), commissurotomy in 3 patients (1%) and Chordae transfer in one patient (0.6 %). Mitral repair with artificial chordae was used in all cases besides mitral annuloplasty ring in 95%, in study performed by **Maselli *et al.* [(10)]**. In study performed by **salvador *et al.*[(11)],** mitral repair with artificial chordae was used in all cases besides mitral annuloplasty in 99.7%.

Our study shows that early failure of repair and re operation of Mitral Regurgitation were lower in the Rigid group, but this difference was statistically insignificant. Among 32 patients who required repair

with flexible annuloplasty device, (3.2 %) of patients need reoperation, the cause of recurrence of MR was dislodgment of artificial chordae from papillary muscle due to inappropriate surgical technique.

In study performed by **Chang *et al.*[9],** reoperation and recurrence of MR were higher in the Duran ring group, but this difference was not statistically significant. There were 8 patients who required reoperation, the cause of reoperation in 2 patients was dilated mitral annulus due to abnormal shape of the Duran ring, that caused in improper annular fixation. In study performed by **Kanemitsu *et al.*** [6], mortality rate and freedom from reoperation were not significant. The causes of reoperation in three patients were recurrent leaflet prolapse in two and leaflet sclerosis in one.

No Intraoperative mortality was found in our study.

As regards early mortality (with 30 days of operation) in our study, in flexible band group, 2 cases died (3.2%), 1 case mortality at second day postoperatively occurred due to bleeding, 1 cases mortality at 7th day postoperatively occurred due to hypoxic brain death. but in rigid band group, 1 case died (1.5 %) at 7 day postoperatively occurred due to bleeding.

In study performed by **Kuntze *et al.*** [12], early mortality was 1.4 % due to Congestive Heart Failure (2.5 %). Also in study performed by **Salvador *et al.*** [11], early mortality was 1% all related to low cardiac output.

CONCLUSIONS

It could be concluded that in spite of type of annuloplasty devices that were used, the early outcomes of mitral valve repair with rigid or flexible device show good results in our prospective study, but there were statistical differences between both groups regarding postoperative left ventricular dimension and function.

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