

# Research Journal of Pharmaceutical, Biological and Chemical Sciences

## Mitral Valve Repair With Flexible Band Hemodynamic Advantages Versus Rigid Band In Mitral Regurgitation.

Mamdouh El Sharawy, Mostafa A. El Newihy, Mohamed F. El Gabry, Mahmoud M. Abd Rabo, and Sameh E . Saeed\*.

Department Of Cardiothoracic Surgery, Zagazig Faculty Of Medicine Egypt.

### ABSTRACT

Mitral valve annuloplasty is a proper technique for mitral valve repair . There are three types of annuloplasty devices: the rigid, semi rigid and the flexible annuloplasty devices. To assess the early result of mitral repair with flexible and rigid band and which technique is superior to the other. This study carried out in the period between September 2017 and June 2019 on 106 patients who underwent mitral valve repair, patients randomly allocated into two groups a flexible band group and rigid band group each group 53 patients. All patients evaluated after 3-6 months to assess the progress of the repair procedure. The mean age of flexible band group and rigid band group were  $(48.24 \pm 10.15)$  years and  $(50.44 \pm 10.39)$  years, respectively. There was no significant difference between groups regarding failure of repair, neurological complications, bleeding, and death. Regarding mortality, 6 (5.6%) cases died among flexible band group compared with 4 (3.8%) cases among rigid band group. Flexible band annuloplasty shows a better outcome regarding left ventricular function and dimension. Rigid band annuloplasty has a lower failure rate.

**Keywords:** mitral valve repair, annuloplasty devices, left ventricular function

<https://doi.org/10.33887/rjpbcs/2019.10.6.6>

*\*Corresponding author*

## INTRODUCTION

All over the world, the most common clinically presented valvular heart disease is mitral regurgitation (MR). Any changes or pathology that affect the normal anatomy of the leaflets and sub-valvular apparatus causes mitral regurgitation (organic MR), any pathology that affects the left ventricular geometry can cause functional MR (1).

Coronary artery disease, dilated cardiomyopathy, mitral valve prolapse, and myxomatous valve disease are the most popular causes of mitral regurgitation, but rheumatic valve disease, mitral annular calcification, infective endocarditis, congenital anomalies, connective tissue disorders, cardiac trauma, and endocardial lesions are less popular disorders that lead to MR (2).

Severity of mitral regurgitation is in opposite relation to its prevalence. The prevalence of trivial mitral regurgitation is 70 % in normal persons, but mild MR represents 19% of the population. Also, moderate or severe MR represents 1.9% and 0.2%, respectively, mitral valve prolapse (MVP) represents 0.6–2.4 % (3).

The most important factor in mitral valve repair is Trans esophageal echocardiography (TEE) because it gives us broad image about anatomic and pathophysiology of mitral valve apparatus, it also gives enough information about direction, timing, and severity of the regurgitate leak. (4).

Mitral valve repair is the most appropriate choice for MR. It gives better results than mitral valve replacement in form of survival, ventricular function and thromboembolic complications (5).

The basic part of mitral valve repair is Annuloplasty. Regarding Carpenter's concepts, an annuloplastic device is important for (I) restoring the size and shape of annulus; (II) preventing more annular dilatation; and (III) providing annular support (6).

Many types of annuloplasty devices are present today, rigid, semi-rigid and flexible rings. Any ring can be used according to the choice of surgeon. Many studies were carried out on the two techniques for management of mitral regurgite, each technique has some advantages over the other (7,8).

In this study we are trying to show which of them is more advantageous for patients in our hospital.

## PATIENTS AND METHOD

The study is a comparative randomized controlled study, carried out in zagazig university hospitals, cardiothoracic surgery department, and Essen University hospitals, Germany on 106 patients with mitral valve regurgite undergoing mitral valve repair, patients will be allocated randomly into two groups according to a table of random numbers at the time of the operation.

Group A : patients will be subjected to mitral valve repair with flexible band ,

Group B : patients will be subjected to mitral valve repair with rigid band.

Patients included in this study are those who has - moderate to severe or severe - Ischemic, Degenerative, Rheumatic, or Congenital mitral regurgitation.

Patient excluded from the study are those with significant mitral valve stenosis, and those who require aortic or pulmonary valves surgery.

After approval of the IRP Committee, and a written consent from all patients, patients were subjected to preoperative history taking, clinical examination, investigations as CXR, echocardiography, cardiac catheterization if needed, exclusion of septic foci and routine preoperative laboratory tests.

**Surgical technique:**

Trans esophageal echocardiography (TEE) was performed in all patients after the induction of anesthesia. All operations were done through a median sternotomy with bicaval cannulation. Cardiopulmonary bypass was done with mild systemic hypothermia (32°C). Myocardial protection was done by antegrade blood cardioplegic solution. The size of annuloplasty device was selected according to the intertrigonal distance. Mitral annuloplasty devices were implanted with 2-0 Ethibond interrupted horizontal mattress sutures. According to the underlying pathology, another operative technique has been used. After weaning from cardiopulmonary bypass, Mitral repair was reevaluated by using Trans esophageal echocardiography. The techniques of mitral valve repair and concomitant operations are shown in Tables 3.

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.

Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD, the following tests were used to test differences for significance; difference and association of qualitative variable by Chi square test (X<sup>2</sup>).

**RESULTS**

Demographic criteria of the patients nearly similar between both groups but regarding pathology and etiology of mitral regurgitation, the commonest cause in the flexible band group is degenerative while in rigid band group is ischemic, dilated annulus is the commonest pathology in rigid and flexible band group. Demographic criteria, pathology and etiology of mitral valve regurgitation demonstrated in table 1.

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

		Flexible group n=53	Rigid group n=53	P value
age		48.2±10.2	50.4±10.3	0.3185
gender	Male	25(47.2%)	28(52.8%)	0.5523
	Female	28(52.8%)	25(47.2%)	
Causes of mitral regurgitation(MR)	Ischemic	19(17.9%)	25(23.6%)	0.499
	Degenerative	22(20.7%)	19(17.9%)	
	Rheumatic	10(9.4%)	9(8.5%)	
	Congenital	2(1.9%)	0(0%)	
pathology	Dilated annulus	19(17.9%)	25(23.5%)	0.499
	Prolapse of AMVL	12(11.3%)	10(9.4%)	
	Prolapse of PMVL	10(9.4%)	9 (8.5%)	
	Restricted PMVL	10(9.4%)	9 (8.5%)	
	Cleft mitral valve leaflet	2 (1.9%)	0 (0%)	

P< 0.05%= significant difference.

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

**Table 2: Preoperative data echocardiography.**

		Flexible band	Rigid band	P value
Ejection fraction	M±SD	60.00 ± 10.59	58.45 ± 12.17,	0.368
	Range	32-71	30-70,	
Left ventricle(LVEDD)	M±SD	60.56±10.41	64.78 ± 9.22	0.368
	Range	45-83	48-82	
Tricuspid	No	7 (6.7%)	10 (9.4%)	0.5970
	Mild	15 (14.1%)	20 (18.9%)	
	Moderate	13 (12.3%)	8 (7.5%)	
	Trivial	0 (0%)	3 (2.8%)	
	Moderate to severe	2(1.9%)	4 (3.8%)	
	Severe	13 (12.3%)	8 (7.5%)	
LAD	M±SD	53.86±8.14	47.52±7.21	0.340
	Range	37-73	35-70	
PHT	M±SD	48.84±21.41	46.34±13.93	0.616
	Range	Normal-90	30-78	

P< 0.05%= significant difference.

There was no significant difference between groups regarding technique of mitral valve repair between two groups. The most common technique of repair used among flexible and rigid band groups was annuloplasty only ( 17.9% , 23.5% ) respectively .There were different sizes of bands among flexible band group patients. the most common band used was pericardial band 32 ( 43.4% ). The only used rigid band was Carpentier-Edwards Ring (100%).

The most common concomitant surgery among flexible group is tricuspid valve repair (29.2%), but among rigid group is CABG (Coronary Artery Bypass Graft) (26.4%) with no significance of differences between two groups shown in table 3.

**Table 3: Operative data in both groups**

		Flexible band group	Rigid band group	P value
Technique of repair	Annuloplasty	19(18.9 %)	25(23.5%)	0.4992
	Annuloplasty and artificial chordae with gortex suture	12 (11.3 %)	10(9.4%)	
	Annuloplasty and closure of cleft with interrupted suture	2 (1.9 %)	0 (0%)	
	Annuloplasty and quadrangular resection of p2	8 (7.6%)	6 (5.6)	
	Posterior Leaflet triangular exclusion	2 ( 1.9%)	3 (2.9 %)	
	Annuloplasty and excision of fibrous peel	10 (9.4 %)	9 (8.5%)	
Types of bands flexible band group	Teflon band 32	18(33.9 %)	-	-
	Pericardial band 30	10(18.9 %)	-	-
	Pericardial band 32	23(43.4 %)	-	-
	Cosgroov Edward band 30	2(3.8 %)	-	-
Tricusped repair	NO	22 (20.8 %)	30(28.3%)	0.3719
	Annuloplasty ring 30	0 (0%)	3 (2.8%)	
	Annuloplasty ring 34	0 (0%)	5 (4.7%)	
	Elgabryannuloplasty technique	18 (16.9 %)	10 (9.4%)	
	Devage annuloplasty	13 (12.2 %)	5 (4.7%)	
CABG	No grafts	31 (29.2%)	25(23.5%)	0.5074
	Single graft	10 (9.4%)	8 (7.5%)	
	Three grafts	6 (5.7%)	10(9.4%)	
	Four grafts	6 (5.7%)	10(9.4%)	
ASD closure	No closure	51 (48.1%)	53 (50%)	0.845
	Closure with pericardial patch	2 (1.9%)	0 (0%)	
Other	No	51 (48.1%)	53 (50%)	0.845
	Ligation of PDA	2 (1.9%)	0 (0%)	

There was significant difference between groups regarding post-operative degree of EF and LV while there was no significant difference between groups regarding post-operative Pulmonary hypertension (PH) , TR,MR , and LAD (p >0.05). table 4

**Table 4: Postoperative echocardiography follow up.**

		Flexible band group	Rigid band group	P value
Degree of MR	No	8 (7.5%)	0 (0%)	0.337
	Mild	19 (17.9%)	30 (28.3%)	
	Trivial	25 (23.6%)	20 (18.9%)	
	Mild to moderate	1 (0.95%)	3 (2.8%)	
Ejection fraction	M±SD	59.43 ± 9.04%	45.48±11.81%	0.000*
	Range	39-70	25-70	
Left ventricle (LVEDD)	M±SD	50.24±10.33	60.00 ± 10.57	0.000*
	Range	35-84	40-77	
Tricuspid	No	10 (9.4%)	12 (11.3%)	0.1393*
	Mild	29 (27.3%)	31(29.2%)	
	Trivial	13 (12.3%)	7 (6.7%)	
	moderate	0 (0%)	3 (2.8%)	
LAD	M±SD	49.72±7.17	50.54±25.77	0.6752
	Range	35-65	32-66	
PHT	M±SD	33.94±11.32	35.52±9.51	0.452
	Range	20 - 65	25-55	

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. As shown in table 5.

**Table 5: Complications rate**

		Flexible band group	Rigid band group	P value
Failure of repair		2(1.8%)	1 (.95%)	0.495
Neurological complication	Lt sided hemiparesis	2 (1.9%)	Zero (0%)	0.125
	Brain stem infarction	2 (1.9%)	Zero (0%)	
Bleeding and re-exploration		2 (1.9%)	5 (4.7%)	0.436
Death	after 2 days	2 (1.9%)	Zero (0%)	0.074
	after 5 days	Zero (0%)	2 (1.9%)	
	after 7 days from HF	2 (1.9%)	Zero (0%)	
	Death after 7 days from cardiac ischemia	Zero (0%)	2 (1.9%)	
	Death after 10 day	2 (1.9%)	Zero (0%)	

P< 0.05%= significant difference.

### DISCUSSION

Mitral valve repair is the proper method for functional regurgitation in comparison to mitral valve replacement. Previous surgical teachings have traditionally focused on the high mortality rate associated with mitral valve replacement. (9).

Regarding age, The mean ± SD ages of flexible band group and rigid band group were (48.24 ± 10.15)years and (50.44 ± 10.39) years, respectively, which is nearly similar to the study performed by Chang et al, showed that the mean age of patients was 50.3 ±16.0 years in flexible group and 49.4±1.53 years in rigid group(10). But, in study done by Spoor et al, the mean age of patients was 63.5 ± 9.4 years in flexible group and 50 ± 10.3 in rigid group (9) .

Regarding patient gender, in our study, in flexible band group, 28 were females (52.8 %) and 25 were males (47.2%) but in rigid band group male was 28 (52.8 %) to 25 were females (47.2%) . In a study performed by Chang et al, there was 54.7 % of patients male and 45.3 % of patients female in flexible group, there was also 55.9% of patients male and 44.1% of patients were female in rigid group (10) . According to Spoor et al, females represent in 45 % flexible group and 49 % in rigid group ( 9 ) , this two previous studies are similar to result of our study ,but in study performed by David et al and Salvador et al, there were predominance of male patients 72% and 71.2% respectively ( 11 , 12) .

In this study the most common pathology of MR was dilated annulus due to dilated left ventricle (45.3%) , 26.4% of cases of MR repaired with rigid annuloplasty devices with non-significant incidence of recurrence of significant MR .

In our study, mitral valve repair was done in all patients by annuloplasty in both groups with or without specific technique according to pathology of mitral valve apparatus. In flexible group, quadrangular resection of p2 was done in 8 patients (7.6%) , annuloplasty only was done in 19 patients ( 17.9%), artificial chordae with gortex suture was done in 12 (11.3 %) , excision of fibrous peel was done in 10 patients ( 9.4%) , Posterior Leaflet triangular exclusion was done in 2 patients (1.9%) and closure of cleft with interrupted suture was done in 2 patients ( 1.9%) . but In rigid band group , annuloplasty only was done in 25 patients ( 23.5%) , artificial chordae with gortex suture was done in 10 (9.4%) , quadrangular resection of p2 was done in 6 patients (5.8%), Posterior Leaflet triangular exclusion was done in 3 patients (2.9%) and excision of fibrous peel was done in 9 patients ( 8.5%) .

In study was done by Chang et al , in Carpentier 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 Duran 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 %) (10).

In study performed by Maselli et al , mitral repair with artificial chordae was used in all cases besides mitral annuloplasty ring in 95% (13) . In study performed by Salvador et al , mitral repair with artificial chordae was used in all cases besides mitral annuloplasty in 99.7% (12) . According to Kuntze et al , mitral repair was done in all patients with artificial chordate beside mitral annuloplasty ring , complete in 73.1% and incomplete ring in 26.1 (14) .

In our study, regarding early morbidity occurred in our patients, among rigid band group 5 (4.7%) cases were re explored compared with 2 (1.8%) cases among flexible band group. also there was neurological complications in form of 2 cases with left sided hemiparesis and 2 cases with brain stem infarction among flexible band group but no neurological complication among rigid band group.

In a study performed by Kuntze et al, early morbidity was re exploration for bleeding in 3.6%, postoperative renal failure was 2.1 % required dialysis, postoperative stroke in 1.7% (14). also in study done by Salvador et al ,early morbidity was re exploration for bleeding was 34% renal failure 9.6% , heart failure was 24% , post-operative stroke 10% (12).

This study was designed to compare the short-term results between rigid and flexible bands. Reoperation and recurrence of MR were lower in the Rigid ring group, but this difference was statistically insignificant. Among 53 patients who required repair with flexible band, 2 patients need reoperation, the cause of recurrence of MR in 2 patients was dislodgment of artificial chordae from papillary muscle due to inappropriate surgical technique.

In our study, The most critical points in for mitral repair are proper surgical skills intraoperative trans esophageal echocardiographic evaluation .a . It seemed that annuloplasty with a rigid band might prevent the

recurrence of MR with prevention of elongation of the anterior-posterior diameter of the mitral valve. That is more common in MR due to dilated annulus in dilated left ventricle.

In study performed by Chang et al , reoperation and recurrence of MR were higher in the Duran ring group, but this difference did not reach statistical significance. Among 8 patients who required reoperation, the cause of recurrence of MR in 2 patients was the elongation of the anterior-posterior diameter of the mitral annulus because of the morphologic deformation of the Duran ring, which resulted in the inability to achieve annular fixation; however, it is unclear why the recurrence and reoperation rate is higher in the Duran ring group (10) . In study performed by Kanemitsu et al , freedom from reoperation agreed with the findings of other studies of MV repair for MR. The causes of reoperation were recurrence of MR in three patients (caused by recurrent leaflet prolapse in two and leaflet sclerosis in one), hemolysis in two patients (caused by residual MR in one and recurrent MR caused by leaflet prolapse), endocarditis in one patient, mitral stenosis due to calcification of the leaflets in one patient, and unknown cause in one patient( 8).

In our study, There were no statistical clinical differences between the rigid and flexible band group, regarding postoperative pulmonary hypertension and left atrial dimension ,but There were statistical differences between them , regarding postoperative left ventricular dimensions, early postoperative left ventricular dimensions were reduced ,also left ventricular function was significantly improved in flexible band group more than rigid one.

Change et al , showed that Mitral valve annuloplasty with both bands showed good short term clinical results. There were no statistical differences between the Carpentier ring and the Duran ring, and follow-up echocardiography demonstrated that both early postoperative left ventricular dimensions were significantly reduced and that left ventricular function was significantly improved in both groups (10) .

### CONCLUSION

Mitral valve repair with a flexible annuloplasty device have a higher rate of developing recurrent mitral regurgitation (MR) requiring reoperation than rigid group. The use of a rigid annuloplasty device appears to reduce the need for repeat surgical procedures.

Mitral repair shows better early results in our prospective randomized study in both group. There was no difference between the rigid and flexible bands in terms of left atrial dimensions , but There were statistical clinical differences between both bands according to postoperative left ventricular function and left ventricular dimensions which was significantly improved in flexible group .

### REFERENCES

- [1] Maisano F, Redaelli A, Soncini M, Votta E, Arcobasso L, Alfieri O. Anannular prosthesis for the treatment of functional mitral regurgitation:finite element model analysis of a dog bone-shaped ring prosthesis. Ann Thorac Surg. (2005);79:1268–1275.
- [2] Issamismail and axel haverich : pathology and classification of mitral valve disease ; in Robert S. Bonser Domenico Pagano,AxelHaverich (2011) , Mitral Valve Surgery.
- [3] lung B, Baron G, Butchaert EG, et al., ( 2003) : A prospective survey of patients with valvular heart disease: the euro heart survey
- [4] on valvular heart disease. Eur Heart J(2003). 24:1231-1243.
- [5] Enriquez-Sarano M, Avierinos JF, Messika-Zeitoun D, Detaint D, Capps M, Nkomo V, Scott C, Schaff HV, Tajik AJ. Quantitative determinants of the outcome of asymptomatic mitral regurgitation. N Engl J Med . (2005); 352:875–883
- [6] KANEKO T et al. Mitral Valve Repair , Evolution and Revolution 1923–2013 .Circ J(2014); 78:560 – 566.

- [7] Wan, S., Lee, A. P. W., Jin, C.-N., et al . The choice of mitral annuloplastic ring-beyond “surgeon’s preference”. *Annals of Cardiothoracic Surgery*( 2015) , 4(3), 261–5.
- [8] Jensen MO, Jensen H, Levine RA , et al . saddle shaped mitral valve annuloplasty rings improve leaflet coaptation geometry.*JThorac Cardiovascular surg* (2011) , 142:697-703
- [9] Kanemitsu, H., Okada, Y., Sakon, Y., et al . long term outcomes of mitral valve repair with the duran flexible ring. *Journal of Cardiac Surgery* (2015) , 30(4), 333–337. 7
- [10] Martinus T. Spoor, MD; Amy Geltz, RN et al . Flexible versus non flexible mitral valve rings for congestive heart failure. *Circulation* (2006) ;114: I-67-I -71 .
- [11] Chang BC, Youn YN, Ha JW, Lim SH, Hong YS, Chung N . Long-term clinical results of mitral valvuloplasty using flexible and rigid rings: a prospective and randomized study. *J Thorac Cardiovasc Surg* ( 2007) ; 133:995 – 1003.
- [12] David TE, Ivanov J, Armstrong S, et al.: A comparison of outcomes of mitral valve repair for degenerative disease with posterior, anterior, and bileaflet prolapse. *J Thorac Cardiovasc Surg* (2005) ;130:1242–1249.
- [13] Salvador L, Mirone S, Bianchini R, Regesta T, Patelli F, Minniti G, Masat M, Cavarretta E, Valfrè C . A 20-year experience with mitral valve repair with artificial chordae in 608 patients. *J Thorac Cardiovasc Surg* (2008) . 135(6):1280-7.
- [14] Kuntze T, Borger MA, Falk V, Seeburger J, Girdauskas E, Doll N, et al. Early and mid-term results of mitral valve repair using premeasured Gore-Tex loops (‘loop technique’). *Eur J Cardiothorac Surg* (2008) ; 33:566 – 572
- [15] Maselli D, De Paulis R ,Salica A et al . Anew method for artificial chordae length in mitral valve repair .*J Thorac Cardiovasc Surg* (2007) . 134 :454-9.