Flexible or rigid ring in mitral annuloplasty—do the results differ?

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Received: 5 January 2020 / Revised: 23 May 2020 / Accepted: 1 June 2020 / Published online: 27 August 2020
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Abstract

Introduction Mitral valve annuloplasty has evolved over the decades since its introduction and Carpentier played a major role in developing the technique. Mitral valve repair is preferred over replacement for severe primary mitral regurgitation, as it restores normal life expectancy when successful and does not require lifelong anticoagulation. There is an ongoing debate regarding the choice of ring for mitral valve annuloplasty—rigid or flexible. At present, the choice of ring is based on the availability of the ring and left to the surgeon's discretion.

Methodology This is a retrospective study conducted at a tertiary referral centre.

Aim To compare the outcomes of mitral valve repair annuloplasty with flexible and rigid rings. The hospital records of 112 patients who underwent mitral valve annuloplasty between January 2010 and December 2014 at our hospital were studied. All patients were followed up for 5 years. The rigid and flexible groups were compared for left ventricular (LV) size regression and the presence of mitral regurgitation (MR).

Results One hundred and eight patients had no progression of mitral regurgitation at 5-year follow-up, compared with the immediate postoperative period. The choice of the ring (rigid and flexible) did not affect the recurrence of mitral regurgitation. At 5-year follow-up, three patients (2 patients in the rigid group and 1 patient in the flexible group) had 3+ MR. One of the two patients in the rigid group had poor functional status and underwent mitral valve replacement (MVR). The other two patients (one in the rigid group and one in the flexible group) with 3+ MR had class II NYHA symptoms and were on medical follow-up. The left ventricular internal diameter diastolic (LVIDD) measured 59.1 mm in the flexible ring group and 56.76 mm in the rigid group preoperatively and these values reduced to 48.4 mm and 47.3 mm, at 5-year follow-up respectively. The mean left ventricular internal diameter systolic (LVIDS) size regression at 5 years was 4.5 ± 6.09 mm in the flexible ring group and 3.2 ± 7.17 mm in the rigid ring group and the difference is not statistically significant (p value 0.314). The mean LVIDD size regression at 5 years was 10.62 ± 6.57 mm in the flexible ring group and 9.38 ± 9.29 mm in the rigid ring group and the difference is not statistically significant (p value 0.408).

Conclusion The choice of rigid or flexible ring did not have a marked difference on the outcome of mitral valve annuloplasty at midterm follow-up.

Keywords Mitral valve · Repair · Annuloplasty · Flexible · Rigid

Introduction

Mitral valve annuloplasty has evolved over the decades since its introduction, and Carpentier played a major role in developing the technique [1]. Mitral valve repair is preferred over

valve replacement for severe primary mitral regurgitation, as it restores normal life expectancy when successful and does not require lifelong anticoagulation [2]. The survival after mitral valve repair for primary mitral regurgitation far exceeds the survival with any other modality of treatment [3].

The technique of repair used depends on the mechanism of mitral regurgitation. Mitral valve annuloplasty combined with leaflet procedures is considered the golden standard for mitral valve repair to prevent further dilatation of annulus [4, 5]. There is an ongoing debate regarding the choice of ring for mitral valve repair—rigid or flexible [6]. At present, the choice of ring is based on the availability of the ring and surgeon's discretion [6, 7].

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Methodology

This is a retrospective study conducted at a tertiary referral centre. The hospital records of 112 patients who underwent mitral valve repair annuloplasty between January 2010 and December 2014 at our hospital were studied.

Data was collected retrospectively from hospital records. Institutional technical advisory committee and the institutional ethics committee clearances were obtained before commencing the study.

Inclusion criteria All patients with primary mitral regurgitation who had undergone mitral valve repair at our institute between January 2010 and December 2014 were included.

Exclusion criteria Patients with ischemic mitral regurgitation and also those who underwent a concomitant procedure along with mitral valve repair were excluded.

Operative strategy

Fifty cases were performed using superior septal approach and sixty-two by using the left atrial approach. Valve was exposed with the aid of three annuloplasty sutures—one at P2 and one in each of the trigones. After segmental analysis, leaflet repair and chordal procedures were performed. Once the repair was found to be satisfactory with water test, annuloplasty stitches were completed. The ring used for annuloplasty was sized after filling the left ventricle. We used both flexible and rigid rings according to the surgeon's comfort and based on the availability of the ring.

Water was used to test again once the annuloplasty was complete, to assess the coaptation and the competency of the valve. After weaning from cardiopulmonary bypass (CPB),

the adequacy of the repair was confirmed with trans-oesophageal echocardiography in all the cases. A coaptation distance of more than 5 mm and absence of mitral regurgitation were the criteria used for deeming the repair good and accepting it. Presence of more than mild mitral regurgitation or an eccentric jet hitting the ring was not accepted and they were readdressed on CPB.

Intraoperatively, the mitral valve ring size was assessed by the surgeon using a standard valve sizer specific for a ring type. And the sizing was done after suture placement at the mitral annulus by measuring the intertrigonal distance and anterior mitral leaflet area.

Outcome parameters

LVIDD and LVIDS were collected from preoperative echocardiogram from parasternal long axis view and follow-up echocardiogram at 5 years. The regression in LV dimension and degree of mitral regurgitation was assessed at 5 years.

Follow-up

All patients were followed up for a period of 5 years. All patients operated during the study period who satisfied the inclusion and exclusion criteria were included in the study. Follow-up data was collected from the hospital records in a retrospective manner.

Statistical analysis Descriptive analysis was carried out by computing mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Student's *t* test and paired *t* test were used to study the left ventricular size regression. IBM SPSS version 22 was used for statistical analysis.

Table 1 Demographic and operative data

	Rigid ring group	Flexible ring group	<i>p</i> value
Males	27 (64.2%)	51 (72.8%)	0.457
Females	15 (35.7%)	19 (27.2%)	
Age (years)*	42.3 ± 6.41	45.3 ± 6.82	0.03
Height (cm)*	163.36 ± 9.50	165.13 ± 8.69	0.298
Weight (kg)*	62.76 ± 15.05	62.67 ± 12.12	0.972
Body surface area (kg/m ²)*	1.67 ± 0.26	1.68 ± 0.19	0.771
Leaflet involvement			
PML	38	61	
AML	4	7	
Bi-leaflet	0	2	
Surgical approach			
Superior septal	18	32	
Left atrial	24	38	

*Mean ± SD. PML, posterior mitral leaflet; AML, anterior mitral leaflet

Table 2 Types of rings used for annuloplasty

Rigid rings (<i>n</i> = 42)		Flexible rings (<i>n</i> = 70)	
CE	15	SJM TAILOR	38
PHYSIO II	18		
CG FUTURE	5	DURAN ANCORE	32
PROFILE 3 D	4		

CE, Carpentier-Edwards classic (Baxter Healthcare Corp, Irvine, CA); *PHYSIO II*, Physio II (Edwards Lifesciences, Irvine, CA, USA); *CG FUTURE*, Colvin-Galloway (CG) Future ring (Medtronic Inc., Minneapolis, MN); *PROFILE 3 D* (Medtronic Inc., Minneapolis, MN); *SJM TAILOR* (St Jude Medical, Inc, St Paul, Minn); *DURAN ANCORE* (Medtronic, Inc., Minneapolis, Minn)

Ventricular dimensions in preoperative echocardiogram were compared with the 5-year echocardiogram. Data was also analysed to see the relation between left ventricular dimensions and body surface area with ring sizes. Results were also analysed to look for any difference in reduction of left ventricular sizes for flexible and rigid ring groups. Left ventricular sizes were averaged for the total number of patients.

Results

One hundred and twelve patients were included in the study.

Demographic parameters (Table 1)

The mean age of the patients in the rigid group was 42.3 ± 6.41 years and in the flexible group was 45.3 ± 6.82 years.

The number of males was 78 (69.64%) and females was 34 (30.35%) in the study population. In the rigid group, 27 (64.2%) were males and 15 (35.7%) were females. In the flexible group, 51 (72.8%) were males and 19 (27.2%) were females.

Rigid rings were placed in 42 patients and flexible rings in 70 patients (Table 2, Fig. 1). Sixty-eight of the flexible rings

used were implanted from trigone to trigone as partial annuloplasty rings. Ninety-nine cases required posterior mitral leaflet (PML) procedures with annuloplasty; eleven cases with anterior mitral leaflet (AML) involvement were corrected with neochordae or perforation closure with annuloplasty. Two patients had bi-leaflet involvement. One patient required reoperation for haemolysis on postoperative day five.

Out of the 112 patients operated, 39 patients (13 in the rigid group and 26 in the flexible group) had no mitral regurgitation (MR), 51 patients (20 patients in the rigid group and 31 patients in the flexible group) had 1+ MR and 22 patients (9 patients in the rigid group and 13 patients in the flexible group) had 2+ MR in the immediate postoperative echo.

At 5-year follow-up, 3 patients (2 patients in the rigid group and 1 patient in the flexible group) had 3+ MR. One of the patient in the rigid group with 3+ MR had NYHA class III symptoms and required mitral valve replacement (MVR). Two patients (one in the rigid group and one in the flexible group) with 3+ MR had NYHA class II symptoms and were on medical follow-up. One patient in the rigid group developed mitral stenosis and underwent MVR. Forty patients (16 patients in the rigid group and 24 patients in the flexible group) had only 1+ MR and fifty patients (15 patients in the rigid group and 35 patients in the flexible group) had no MR at 5-year follow-up (Table 3).

Ventricular size regression

There was statistically significant reduction in LVIDD and LVIDS at 5-year follow-up compared with preoperative values in both rigid and flexible groups (Table 4).

Left ventricular size regression was similar in both the groups at 5-year follow-up (Table 5). The mean LVIDS size regression at 5 years was 4.5 ± 6.09 mm in the flexible ring group and 3.2 ± 7.17 mm in the rigid ring group and the difference is not statistically significant (*p* value 0.314). The mean LVIDD size regression at 5 years was 10.62 ± 6.57 mm in the flexible ring group and 9.38 ± 9.29 mm in

Fig. 1 Ring sizes used for annuloplasty

Table 3 Severity of mitral regurgitation at follow-up

Severity of mitral regurgitation	Number of patients with each ring (immediate postoperative period)		Number of patients with each ring (at 5-year follow-up)	
	Rigid	Flexible	Rigid	Flexible
No MR	13	26	15	35
1+ MR	20	31	16	24
2+ MR	09	13	8	10
3+ MR	0	0	2	1

MR, mitral regurgitation

the rigid ring group and the difference is not statistically significant (p value 0.408). Ventricular size was near normal at 5 years. According to the American Society of Echocardiography, the normal LVIDD for men is between 42 and 59 mm and for women is between 39 and 53 mm. The left ventricle is considered to be mildly dilated when LVIDD ranges from 60 to 63 mm in men and 54 to 57 mm in women and is moderately dilated when LVIDD is between 64 to 68 mm in men and 58 to 61 mm in women. The left ventricle is severely dilated when LVIDD is ≥ 69 mm and ≥ 62 mm in men and women, respectively. [8]

Discussion

The mitral annulus is a dynamic structure which changes its shape depending on the phase of the cardiac cycle [9]. The saddlehorn height of the valve increases during systole and helps reduce the stress endured by the leaflet [10]. This led to the development of flexible rings by Duran, to maintain the dynamic changes in the shape of the annulus [11]. On the other hand, the classic Carpentier ring which is rigid reshapes the annulus and prevents it from dilating [12, 13]. The conclusion from most of the studies performed on the choice of rings is quite conflicting and this has left the surgeon with little choice but to go by personal preference based on experience rather than evidence. This prompted us to evaluate the data we had at our institution to reach a consensus on the choice of rings based on

evidence. As LV diameter is an established marker of sudden cardiac death independent of ejection fraction, we measured the left ventricular dimensions and compared them between flexible and rigid ring groups [14]. LV internal diameter seemed to represent outcome more credibly than ejection fraction.

Chang et al. compared the Carpentier-Edwards rigid ring and flexible Duran annuloplasty ring in their prospective randomised trial of 363 patients. The left ventricular dimensions were significantly decreased in both groups after a mean follow-up period of 46 months. There was no difference in the long-term echocardiographic results between the 2 groups. However, the reoperation rate was higher with the Duran ring group [15]. Our present study gives similar results with significant regression of left ventricular sizes to near normal range at 5 years with no difference between rigid and flexible rings.

Shahin et al. in their randomized study comparing the Carpentier-Edwards rigid Classic and semi-flexible Physio rings found that patients who received the Classic ring had 16% more mortality than those who received the Physio ring, at follow-up [16]. The overall mortality in their operated patients seems to be high at a mean follow-up period of 4 years, though this was statistically insignificant. There was no mortality in the 112 patients in our study at 5-year follow-up.

An animal study by Dagum et al. in six sheep used radiopaque markers to measure three-dimensional coordinates fluoroscopically, after implantation of a partial flexible ring and a complete flexible ring. They observed that the annulus remained fixed with both the partial and complete flexible rings [17]. This is in

Table 4 Comparison of mean LVIDD and LVIDS sizes preoperatively and at 5-year follow-up

	Preoperative (mean $\pm$ SD)	At 5-year follow-up (mean $\pm$ SD)	p value
Flexible ring			
LVIDS (mm)	36.48 $\pm$ 5.55	32.7 $\pm$ 6.64	< 0.001
LVIDD (mm)	59.1 $\pm$ 7.72	48.47 $\pm$ 6.64	< 0.001
Rigid ring			
LVIDS (mm)	35.02 $\pm$ 7.57	31.80 $\pm$ 5.89	< 0.001
LVIDD (mm)	56.76 $\pm$ 11.17	47.38 $\pm$ 6.82	0.006

LVIDD, left ventricular internal diameter diastole; LVIDS, left ventricular internal diameter systole

Table 5 Comparison of mean left ventricular size regression between flexible and rigid annuloplasty groups

	Flexible ring (mean $\pm$ SD)	Rigid ring (mean $\pm$ SD)	<i>p</i> value
LVIDS (mm)			
Preoperative	36.48 $\pm$ 5.55	35.02 $\pm$ 7.57	0.243
At 5-year follow-up	32.7 $\pm$ 6.64	31.80 $\pm$ 5.89	0.874
Left ventricle size regression (difference between LVIDS at 5 years and preoperative value)	4.5 $\pm$ 6.09	3.2 $\pm$ 7.17	0.314
LVIDD (mm)			
Preoperative	59.1 $\pm$ 7.72	56.76 $\pm$ 11.17	0.194
At 5-year follow-up	48.47 $\pm$ 6.64	47.38 $\pm$ 6.82	0.407
Left ventricle size regression (difference between LVIDD at 5 years and preoperative value)	10.62 $\pm$ 6.57	9.38 $\pm$ 9.29	0.408

LVIDD, left ventricular internal diameter diastole; *LVIDS*, left ventricular internal diameter systole

contrast to the studies which have stated that flexible rings preserve the dynamicity of the annulus better than rigid rings [4].

Bogachev et al. in their study compared flexible band with complete semirigid ring in 171 patients with degenerative mitral valve disease. At serial echocardiographic examinations, only the flexible band group showed significant LV remodeling. There were no inter-group differences in overall survival, freedom from cardiac-related death, and follow-up LV remodeling. Their study showed the superiority of the flexible posterior band over the semirigid complete ring in terms of freedom from recurrences of significant and/or severe MR and risk of MV reoperation [18]. This contradicts the study by Chang et al. who demonstrated higher reoperation rate with the flexible Duran ring [15]. Our study did not reveal an increased rate of reoperation with either ring but showed similar LV regression following annuloplasty with either ring.

Literature search yielded mixed results regarding the choice of rings for mitral valve annuloplasty. Our study finds that there is no difference between the flexible and rigid rings in result in terms of LV regression and mitral regurgitation recurrence at 5-year follow-up. Mean ventricular dimensions reverted to normal values (of the general population) in both the rigid and flexible groups. It is perhaps the durability of the repair and freedom from mitral regurgitation rather than the choice of ring that may influence the LV remodeling.

Conclusion

Rigid ring or flexible ring does not have marked effect on the outcome of mitral valve annuloplasty at midterm follow-up.

Limitations

This is a retrospective study and is not a prospective blinded study. It was not a single operator-based study and the

preferences and results might have been different for each of the surgeons. This might have affected the results. This aspect has not been looked into. The type of ring used depends on the surgeon's choice and availability of the ring. A blinded randomised control trial would have been more desirable. The sample size is only 112 in our study and the follow-up period is only 5 years. Long-term follow-up with larger sample sizes may reveal the durability of each type of repair and provide more insight into the topic.

Funding Nil

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The Institutional Ethical committee clearance has been obtained (IEC No. 1232 on 17th Aug, 2018).

Informed consent As this is a retrospective study design based on hospital records, the need to obtain informed consent has been waived off.

Ethics statement regarding human and animal rights There was no infringement of human or animal rights in this study.

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