



OUR EXPERIENCE OF MITRAL VALVE REPAIR IN A PREDOMINANT RHEUMATIC POPULATION USING A SEMIFLEXIBLE ANNULOPLASTY RING (CE PHYSIO 2 ANNULOPLASTY RING).

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ABSTRACT **Background:** Annular dilation is the most typical finding in Mitral regurgitation and annuloplasty with a prosthetic ring is common to various techniques described in literature Mitral valve repair in rheumatic heart disease possesses various technical difficulties with no general consensus on the ideal annuloplasty ring. This study describes our experience and results with a semirigid annuloplasty ring (CE physio II ring) in a predominant rheumatic population. **Methods:** This is a retrospective study using data including 23 patients who underwent mitral valve repair at Vardhman Mahavir Medical College and Safdarjung hospital, New Delhi, between July 2018 to April 2022. Patients were followed up to a mean of 19.3 10.6 months with a minimum follow-up period of 6 months. **Results:** The mean age was 30.5 15.3 years. The majority of patients, 78.3% (18) had rheumatic heart disease. 82.6% (19) of patients belonged to NYHA class I/II. The results in our study with CE physio II ring are excellent with 91.3% patients free from significant MR (grade 2). 72% of the patients had improved or preserved Left ventricular function with a decrease in mean LVEF by 2.4% which was statistically insignificant ($P>0.05$). There was 0 operative or early mortality in our study. **Conclusions:** The semiflexible CE physio II ring provides excellent results in both short and midterm outcomes in terms of freedom from recurrence of significant MR with preservation of left ventricular function.

KEYWORDS : Mitral valve repair, Semiflexible ring annuloplasty, CE physio II ring

INTRODUCTION

Mitral valve (MV) repair has now become the treatment of choice for isolated mitral regurgitation (MR) and is preferred to prosthetic valve replacement. MV repair offers better preservation of Native valve functions and left ventricular function without the need for anticoagulation. Carpentier's first described his approach to MV repair in 1968¹, the techniques have since evolved but the principle of ensuring good coaptation without systolic anterior motion (SAM) is common to all.

Modern MV reconstruction is associated with low operative morbidity and mortality and has also been shown to improve left ventricular (LV) function² and increased long-term survival in MR, secondary to a range of pathologies. Up to 95% of degenerative mitral valves can be repaired with current techniques, but only 75% of the patients with rheumatic mitral valve disease are amenable to repair³.

The Carpenters Edward ring has long been used for Mitral valve repair procedures and various report published since mid -the 90s has consistently demonstrated good short and midterm results⁴. The CE Physio II ring is the next generation of semi-flexible Annuloplasty rings, which are designed to accommodate the changing pathology, particularly the anterior leaflet and to prevent SAM. Its double saddle design maximises the distribution of stress across the reconstructed MV and aids in remodelling.

Out of numerous reports of MV repair, only a few have addressed the range of pathologies causing Mitral regurgitation, and the majority are limited to degenerative or ischemic aetiologies. Repair of rheumatic mitral Regurgitation poses special challenges, which include mixed lesions, diseased sub-valvular apparatus and no consensus for the patient selection for repair vs replacement. Our study is one of the very few, if not the only, describing the results of the Semirigid

Annuloplasty ring (CE II Physio ring) in the repair of MV in a predominant rheumatic population.

MATERIAL AND METHODS

Patient population and indications

This is a retrospective study including 23 patients who underwent MV repair, at Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, between July 2018 to April 2022. The median age was 26 years (6-61 years). The male-to-female ratio was 5:18. The underlying pathology was rheumatic in a majority of patients (19). [Table 1] Severe MR was an indication for surgery. The selection of repair vs replacement was based primarily on intra-operative findings. Statistical analysis of the data was done using SPSS (Statistical Package for Social Sciences) software (version 21, Chicago, IL, USA) and Microsoft Excel.

Preoperative evaluation

All patients underwent transthoracic Echocardiography to determine the aetiology and severity of MR. Quantitative parameters such as effective regurgitant orifice area (EROA 0.40 cm²), a regurgitant fraction (50%), and vena contracta width (0.7) were used to assess the severity of MR. Left ventricular ejection fraction (LVEF) was calculated by the biplane Simpson method. All patients over 40yrs of age underwent coronary angiography before surgery.

Operative technique

Intraoperative trans-oesophageal echocardiography was performed in all cases. Surgery was undertaken through a median sternotomy and cardiopulmonary bypass (CPB) was established via aorto-bicaval cannulation. Cardiac arrest and cardio-protection were achieved through moderate hypothermia and cold-blood cardioplegia. The MV was exposed either through a longitudinal incision after developing the interatrial groove or through the transeptal approach.

Operative techniques included resection of the prolapsing valve segment, leaflet reconstruction, cuspal thinning, cummisuroplasty, cleft repair and remodelling with the annuloplasty ring. Where appropriate, neo-chordae were used. A horizontal mattress suture with CV- 5/6 polytetrafluoroethylene (PTFE; Gore-Tex suture; W.L. Gore & Associates, Inc, Flagstaff, AZ, USA) was initially placed through the fibrous thickened part of the appropriate papillary muscle. Both ends of the suture were then passed through the prolapsing scallop 3–5 mm from the free edge of the leaflet from the ventricular side to the atrial side. Additional PTFE sutures were implanted as appropriate to the number of prolapsing scallops. After sizing of the anterior leaflet, a semiflexible annuloplasty ring (CE Physio II, Edwards Lifesciences, Irvine, CA, USA) [figure 1] was implanted with interrupted 2/0 Ethibond sutures (Ethicon, Inc, Somerville, NJ, USA). Valve competency was subsequently tested by injecting cold saline into the LV across the valve. [Figure 2] With the LV full, the neo-chordae were adjusted to ensure good leaflet coaptation. Before the left atrium was closed, the MV leaflets were observed to be bulging with appropriate areas of coaptation and no residual regurgitation or prolapse.



Figure 1: CE Physio II semiflexible annuloplasty ring

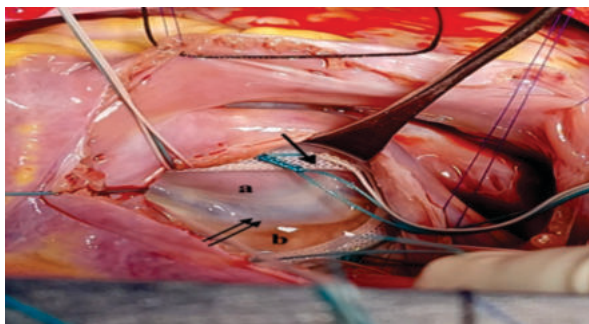


Figure 2: Intraoperative Image

Intraoperative image showing good coaptation of mitral valve leaflets (as shown by double arrow) using saline test, post mitral valve repair using CE physio II annuloplasty ring (shown by bold arrow) ; a- anterior mitral leaflet , b- posterior mitral leaflet Transeptal approach of mitral valve exposure though right atrium.

Postoperative care and follow-up

Postoperatively patients were started on antiplatelet and Vit K antagonist. Vit K antagonist was continued for 3 months with Target INR 2.5 which was then discontinued, and Patients were kept on antiplatelets only. Patients with atrial fibrillation were kept on Vit K antagonist on a lower dose with target INR of 2.0. A postoperative echo was performed before the discharge with advice to follow up after 1 week. Subsequent follow-ups were done after 1 month and every 6 months subsequently. Follow-up echo was advised at 1 month and then every 6 months subsequently.

Table 1 Demographics and preoperative characteristics

Sl.No.	Preoperative characteristic	N (n=23)
I	Gender	
1	Male	5 (21.7%)
2	Female	18 (78.3%)
II	Median Age in years	26 (6-61) years
II	Mean Age in years	30.5 15.3 years
III	Presenting symptoms	
1	Shortness of breath	23
2	Palpitation	20
3	Chest pain	10
4	Tiredness	18

IV	Preoperative NYHA class	
	I/II	19 (82.6%)
	III/IV	4 (17.4%)
V	Comorbidities	
1	Diabetes mellitus	3
2	Arrhythmia	5
3	COPD	2
4	CVA	1
5	CAD	1
6	Thyroid disorder	1
VI	Aetiology	
1	Rheumatic	18 (78.3%)
2	Degenerative	3 (13.0%)
3	Ischemic	1 (4.35%)
4	Infective Endocarditis	1(4.35%)
VII	Preoperative echocardiography	
	LV function (54.9 9.2 %)	
	Normal	16 (69.6%)
	Mild dysfunction	5 (21.7%)
	Moderate dysfunction	2 (8.7%)
	Severe dysfunction	0

RESULTS

The 23 patients included in this study were followed up for a mean of 19.310.6 (6-41) months with a minimum follow-up period of 6 months. The mean age was 30.5 15.3 (6-61) years. The most common presenting complaints were shortness of breath (23) and palpitation (20) followed by tiredness (18) and chest pain (10). 82.6% (19) patients were NYHA class I/II while 17.4% (4) patients were NYHA class III/IV on admission. The majority of the patients, 78.3% (18), had rheumatic heart disease while 13% (3) patients had degenerative pathology. Atrial fibrillation (5) was the most common comorbidity followed by Diabetes Mellitus (3) and COPD (2). Preoperatively, 69.5% (16) patients had normal LV function while 21.8% (5) and 8.7% (2) patients had mild and moderate dysfunction respectively. Mean LVEF was 54.9 9.2%. (Table 1)

Neochordea insertion was the most common procedure done in 13 patients followed by cuspal thinning (8), cummisuroplasty (8), and leaflet reconstruction (6). Ring Annuloplasty alone was done in 4 patients. TV repair (4) was the most common concomitant procedure followed by LA myxoma excision (2) and Av repair (1). (table 2)

In our study Mitral valve repair with semirigid Annuloplasty ring (CE physio II ring) showed excellent results with 56.5% of patients having none (6) or trivial (7) on postoperative transthoracic echocardiography while 34.8% (7) patients had mild MR. 2 patients had moderate MR on postoperative echocardiography while 1 patient had severe MR on postoperative Echocardiography, who underwent reoperation with Mitral Valve replacement on a postoperative day 2. On Follow up Echocardiography, 56.5 % of patients had none (5) or Trivial (8) MR while 34.8 % of patients had mild MR(8). LV function was well preserved postoperatively with a decrease in mean LVEF on follow-up by 2.5% which was non-significant (p<0.05).

Reexploration was done in 2 patients out of which 1 was for bleeding and 1 patient was converted to MVR on postoperative day 2 as post-operative transthoracic echo showed moderate-severe MR. There was no incidence of Sepsis, Multiorgan dysfunction syndrome (MODS), Acute kidney injury (AKI), Cerebrovascular accident (CVA) or death. (Table 3)

Table 2: Operative Characteristics

SL No.	Operative characteristic	N(n=23)
I	Urgency of Surgery	
1.	Elective	19 (82.6%)
2.	Urgent	4 (17.4%)
3.	Emergency	0
II	Concomitant procedures	
1	Tricuspid valve Repair	4
2	Aortic Valve Repair	1
3	LA Myxoma Excision	2
4	CABG	0
III	Mitral valve Procedures	
1	Neochordae insertion	13 (56.5%)

2	Cusp thinning	8 (34.8%)
3	Leaflet reconstruction	6 (26.1%)
4	Commisuroplasty	8 (34.8%)
5	Cleft repair	4 (17.4%)
6	Papillary muscle splitting	3 (13.0%)
7	Ring Annuloplasty alone	4(17.4%)
IV	Median Annuloplasty ring size	28

Table 3: Postoperative Characteristics and Follow-up

SL No.	Post-operative characteristic	N(n=23)
I	Mortality	0
II	Complications	
1	Reexploration	2
2	Sternal rewiring	0
3	Wound infection	3
4	Sepsis	0
5	MODS	0
III	Mean Post-operative stay	10. 5.5 days
III	Median postoperative stay	9 days
IV	Post op -Mitral regurgitation	
1	None	6 (26.1%)
2	Trivial (0)	7 (30.4%)
3	Mild (+1)	7 (30.4%)
4	Moderate (+2)	2 (8.7%)
5	Severe (+3)	1(4.4%)
V	Follow-up Mitral regurgitation	
1	None	5 (21.7%)
2	Trivial (0)	8 (34.8%)
3	Mild (+1)	8 (34.8%)
4	Moderate (+2)	1 (4.35 %)
5	Severe (+3)	1 (4.35 %)
VI	Post-op LV function (54.3 8.2. %)	
1	Normal	14 (60.8%)
2	Mild dysfunction	6 (26.1)
3	Moderate dysfunction	2 (8.7%)
4	Severe dysfunction	1 (4.4%)
VII	Follow-up LV function (52.5 8.9 %)	
1	Normal	16 (69.9%)
2	Mild dysfunction	4 (17.4%)
3	Moderate dysfunction	2(8.7%)
4	Severe dysfunction	0
VIII	Post op Mean gradient	2.7 1 mm hg
IX	Follow-up Mean Gradient	2.4 0.6 mm hg
X	Follow up NYHA class.	
	I	20(86.4%)
	II	2(13.6%)

DISCUSSION

The first surgical intervention on the mitral valve was performed as a blind commissurotomy for a patient in the extremis by E.C. Cutler in 1923⁵. The patient suffered with rheumatic heart disease, a common aetiology of interest in mitral valve surgery. In the current era of prosthetic mitral valves, surgeons have been sceptical about the long-term outcomes of mitral valve repair vs mitral valve replacement, especially in the subset of rheumatic heart disease. On the other hand, replacement of the diseased mitral valve with a prosthetic valve is associated with the risks adherent to anticoagulation and suboptimal preservation of ventricular function leading to reduced survival⁶⁻⁷. Poor compliance with an anticoagulation regime, growth, and teratogenicity associated with the use of Vitamin K antagonists in pregnancy remain important issues in young patient populations, especially in developing countries.

The pioneering work on MV repair was accomplished in the 1970s through the achievements of Alain Carpentier¹⁸⁻¹¹. Alain Carpentier's method of quadrangular resection of posterior leaflet prolapse, transfer of chordae to other prolapsed segments and rigid annuloplasty to correct annular dilatation emerged as the most successful and reproducible means of correcting MR. Developed through autopsy and pathology studies of the mitral valve, Carpentier's method of mitral valve repair aimed to restore normal dimensions to the mitral valve and apparatus⁹, a so-called anatomic approach is known as "French correction"¹¹.

With the improvement in the imaging technique, the dynamic structure

and function of mitral valve came to light. This led to the development of functional correction of Mitral Regurgitation by Lawrie and colleagues, which they referred to as the "American Correction"^{9, 12-14}. The primary principle around which this repair was developed is "respect not resect". The "American Correction" relies on flexible annuloplasty ring and artificial chordae, also known as Neochordae, to correct prolapse and realign leaflets with sparing of Mitral valve leaflets and chordae¹⁴⁻¹⁵.

The most typical finding in MR is annular deformity and annuloplasty with a prosthetic ring corrects annular dilatation and allows remodelling to take place. The range of annuloplasty rings available today, from rigid to semirigid to flexible is quite extensive. The lack of consensus on the features of a durable and effective device makes the clinical decision of choosing an ideal ring more difficult. However, a balance needs to be struck between the rigidity of the design which can aid in the remodelling process, and the flexibility of the ring which preserves the dynamic function of the mitral annulus. The detrimental effects of systolic anterior motion (SAM) of the anterior mitral leaflet, the impact on left ventricular function and the diastolic gradients across the mitral valve must be considered while choosing between annuloplasty devices.

Mitral valve repair for rheumatic heart disease is technically more demanding and has a potentially high failure rate as compared to repair of degenerative disease, mitral valve repair is still considered an optimal surgical strategy as compared to mitral valve replacement. Although there is no consensus on the reparability of the mitral valve in rheumatic heart disease, several predictors have been described based mainly on AML length and mobility¹⁶⁻¹⁷. Indexed Anterior mitral leaflet (AML) length and the bending angle of anterior mitral leaflet have been described as strong predictors of reparability by Gupta et al¹⁶ and Fu JT et al¹⁷ respectively.

This study reports the early and midterm outcomes of MV repair using a semirigid annuloplasty ring (CE physio II ring, Edwards Lifesciences, Irvine, CA, USA) in a predominant rheumatic population. CE physio II ring is a semirigid Annuloplasty ring with selective flexibility and rigidity in different planes and locations, aiming to optimize remodelling while allowing some degree of movement at the annulus. The anterior rigidity aids in remodelling while the posterior flexibility helps in preserving cardiac motion. The saddle shape of these rings is a better fit for structures around the mitral annulus.

In our study, we report zero operative as well as early mortality rates which are similar to rates reported by Dillon J. et al¹⁷, 1% and 0% in rheumatic and degenerative subsets respectively. Kumar AS et al, however, have reported higher mortality rates, 4%, however, their study included a substantially larger cohort of patients with the majority of patients, 64%, in NYHA functional class III/IV as compared to 17.4% in our study¹⁸. At the mean follow-up of 19.3 10.6 months, most of our patients (91.3%) were free from significant MR (grade 2). Kurosawa H. et al¹⁹ and Vohra et al²⁰ have reported similar results, 96.6% and 87% respectively, using the Carpentier Edward physio I ring and Carpentier Edward Physio II ring respectively. However patient cohort in both these studies comprised mainly of degenerative aetiology. Similar results have also been reported by Ananthanarayanan C et al (89.2%), Dillon J. et al (89.5%), and Kumar AS et al (70%) using various techniques of mitral valve repair in a predominantly rheumatic population¹⁸⁻²⁰. In patients with Barlow disease, Jouan et al described a 9.8% recurrence rate of moderate or severe MR²². In our study, 13.1 % of patients developed moderate or severe MR in the early postoperative period, however on follow-up echocardiography it reduced to 8.7%.

We were unable to show an overall improvement in LV function in our study. This is not unexpected in surgery for mitral regurgitation, given the overestimation of LV ejection fraction due to pathological offloading through the regurgitant valve, preoperatively. However, the majority of patients, 72%, had preserved or improved LV function on follow-up echocardiography and the decrease in mean LVEF by 2.4% was statistically non-significant (p<0.05). The majority of our patients, 20 (90.1 %), were NYHA class I in their last recorded follow-up. We also observed an acceptable gradient across the mitral valve with a mean gradient of 2.4 0.6 mm hg. There were no cases of SAM, which could be attributed to either the surgical technique or the novel design of the Carpentier Edward Physio II ring²¹.

Several randomised control trials (RCTs) and retrospective studies have studied the relative merits and demerits of different annuloplasty ring available currently while focussing on whether the theoretical and echocardiographic differences correlate with clinical outcomes. Shahin et al in a prospective randomised study involving 96 patients, compared the classic CE rigid ring with the semiflexible physio CE ring and found a 16 % decrease in mortality in the semiflexible group at a mean follow-up of 5.1 years. This difference was statistically insignificant but can be considered clinically important²³. Another retrospective study by Sidiki et al involving 306 patients comparing long term outcomes of the Semirigid CE Physio ring and rigid CE classic ring showed comparable long term outcomes²⁴. Sidiki et al in the same study recommended artificial chordal implantation (Neochordae) instead of chordal shortening²⁴. In a large RCT involving 356 patients, Chang et al. compared a rigid Carpentier ring to the Duran flexible ring²⁵. The study showed similar short-term and long-term outcomes in echocardiographic performance, 10-year actuarial survival and 8-year freedom from recurrence.

Our study is a retrospective study, which has investigated the early and mid-term outcomes of a single annuloplasty ring at one centre. No direct comparison has been made between different types of rings thus this study is not ideal to make informed clinical decisions on the choice of ring and further studies are required to define the 'gold standard' annuloplasty ring. In our study, the semiflexible CE Physio II ring has shown promising early and midterm outcomes. Although the patient cohort is relatively small, this is the first study to report operative data using the new CE Physio II ring in a predominant rheumatic population.

CONCLUSION

The semiflexible CE physio II ring annuloplasty is a safe and effective method of MV remodelling without inducing major early complication of SAM, Left ventricular outflow tract obstruction with encouraging early and midterm outcomes in terms of recurrence of MR, preservation of LV function and overall mortality in a predominant rheumatic population. However, its performance in long term needs to be further evaluated

Declarations

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