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Mitral Valve Repair with a Biodegradable Annuloplasty Ring for Mitral Regurgitation

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Keywords
Biodegradable ring, annuloplasty, mitral regurgitation

Abstract

Objective: We aimed to evaluate the effectiveness of the mitral valve repair procedure using biodegradable ring implantation to treat severe mitral valve regurgitation.

Method: Between May 2007 and 2009, 20 patients without mitral stenosis underwent mitral valve repair using biodegradable annuloplasty ring. Preoperative, postoperative 7th day, 3rd month, 6th month, and 1st-year echocardiographic data of 20 patients were collected retrospectively and statistically analyzed with Chi-square and Student T-tests. 10- and 15-year results of 10 patients were available and the follow-ups were evaluated.

Results: At follow-up, transthoracic echocardiography revealed no or trivial regurgitation. Although there was an increase in the mean gradient during the early postoperative period (7th days and 3rd months), there was no statistically significant difference in the mean gradient between the preoperative and late postoperative period (6th month and 1st year). Mean gradients were 3.48±0.64, 2.72±0.31, 2.62±0.25, and 2.58±0.21 mmHg, respectively at 7th days, 3rd months, 6th months, and 1st year. Increased preload due to mitral regurgitation resulted in larger left ventricular end-diastolic volume (LVEDV) and left ventricular end-systolic volume (LVESV) preoperatively of 194.42±21.39 ml (range, 245.00 to 165.00 ml) and 94.23±36.59 ml (range, 203.35 to 52.80 ml) respectively. The decrease in mean LVEDV and LVESV at 1 year was statistically significant, 130.40±11.04 ml (range, 145.00 to 115.00 ml; $p<0.001$) and 64.21±13.20 ml (range, 80.08 to 40.25 ml; $p<0.001$), respectively. Additionally, left ventricular ejection fraction (LVEF) reaches the preoperative value (%51.15±14.04) in the 6th month (%51.58±7.32), although there is a decline in the early postoperative period (%47.11±11.22 on 7th day and 46.35±8.03 in 3rd month). Long-term outcomes(10-15 years) were similar to those in the late-postoperative period(1st year). One late death occurred.

Conclusion: Annuloplasty using biodegradable mitral ring has shown desired late post-operative outcomes with particular advantages compared to traditional annuloplasty rings.

Introduction

Mitral valve repair is a more preferred method than prosthetic valve implantation in patient groups such as ischemic or degenerative mitral valve regurgitation, Barlow's disease, rheumatic origin mitral insufficiency, and congenital mitral valve disease. Ring annuloplasty during the surgical repair of mitral regurgitation significantly increases the success of valve repair.[1,2] For this purpose, rigid and semi-rigid rings are used for ring annuloplasty. The recurrence of mitral regurgitation after implanting these rings was investigated in the long term.[3,4] Studies have shown that the mitral annulus is not a fixed structure, and it shrinks with each ventricular systole, contributing to the left ventricular workload. This contribution was found to disappear with rigid ring implantation. Additionally, rigid ring annuloplasty to be performed in the pediatric patient group will not be able to follow the mitral annulus, which will expand with growing age. For this reason, deterioration in the mitral valve structure will occur. These problems were tried to be overcome with the method using biodegradable material.[5,6] In this method, the aim is to create scarring in the mitral annulus and shrink the annulus after the inflammation thanks to the biodegradable ring. Since there is no rigid structure holding the annulus from the outside, it was predicted that the annulus would continue its physiological movements and would not prevent growth in the pediatric population. The first implantations of biodegradable rings in the pediatric population have had successful results[7,8]. In the next period, the biodegradable ring was also used in the adult patient group.

Patients and Methods

In this study, the results of mitral annuloplasty operations using the biodegradable ring in adult patients with advanced mitral regurgitation were examined. Operations were performed at Maltepe University Cardiovascular Surgery Department between May 2007 and May 2009. Transthoracic and transesophageal echocardiography of all patients were performed by the same physician, using the Vivid 7 Dimension (General Electric Healthcare Systems, Milwaukee, WI, USA) echocardiography device in the cardiology department. A transthoracic echocardiography examination was performed in the left lateral decubitus position by the guidelines of the American Society of Echocardiography. Left ventricular end-diastolic and end-systolic volume calculations were made in millimeters with the help of three-dimensional echocardiography, using the program installed in the echocardiography device. Mitral regurgitation was calculated with PISA (Proximal Iso Surface Area) method in the preoperative period. In this way, ERO (Effective Regurgitant Orifice area, cm2) and RV (Regurgitant Volume, milliliter) calculations were made. The calculations were repeated preoperatively and postoperatively (7th day, 3rd month, 6th month, 1, 10 and 15-years). The gradient formed on the mitral valve in the postoperative period was measured with CW Doppler (Continuous Wave Doppler) and the "mean" gradient was recorded. In addition, patient data in terms of tissue valve incompatibility, stenosis in the repaired valve, thrombus formation, pannus, rhythm changes in the heart, bleeding, infection, and stroke were investigated throughout clinical follow-up. The Chi-square test and Student-T test were used as statistical methods. $P<0.05$ was considered statistically significant. The data in this study was analyzed with the SPSS 15.0 program. The mean age of the study group, which included 20 patients with mitral ring implantation, was 47.35 ± 13.13. Seventeen of the patients were male and 3 were female. The (Body Mass Index) BMI of the patients was 25.89 ± 2.66 and their classification according to New York Heart Association (NYHA) was 2.3 ± 0.75. The preoperative EuroSCORE values of the patients were 80% low risk (0-3 points), and 20% moderate risk (4-6 points).

Results

Two patients had ring implantation in both the mitral and tricuspid valves. As an additional surgical procedure; coronary bypass in 2 patients, chordal transfer in 4 patients, repair with Alfieri method in 1 patient, PFO/ASD closure in 1 patient, P2 chordae resection in 8 patients, and aortic valve homograft implantation in 1 patient were performed. The numbers of rings used were 30.45 ± 3.76. Cross clamp time was 34.05 ± 9.62

minutes and cardiopulmonary bypass time was 51.25 ± 16.21 minutes. The amount of drainage from the patients was 472.50 ± 236.46 milliliters. The extubation time was 4.95 ± 2.23 hours. The length of stay in the intensive care unit was 1.70 ± 1.17 days.

Echocardiographic Evaluation Results

The main pathology in all patients included in the study was advanced mitral regurgitation. In the transthoracic echocardiographic examinations performed in the preoperative period, the ERO value was calculated as 0.44 ± 0.11 cm2 and 54.42 ± 11.18 ml. In the postoperative period, it regressed to the degree of trace or mild in the quantitative evaluation. While a moderate decrease was observed in the left ventricular ejection fraction values in the early postoperative (first 90 days) period, this decrease tended to improve in the later period. (**Figure 1, Table 1**). There was a statistically significant decrease between the LVEF values measured in the preoperative period and the early postoperative period (7th day, 3rd month) (Table 1). In the late postoperative period (6th month and 1st year) and long-term (10-15 years), there was a statistically significant increase in LVEF compared to the early postoperative period (**Table 1**).

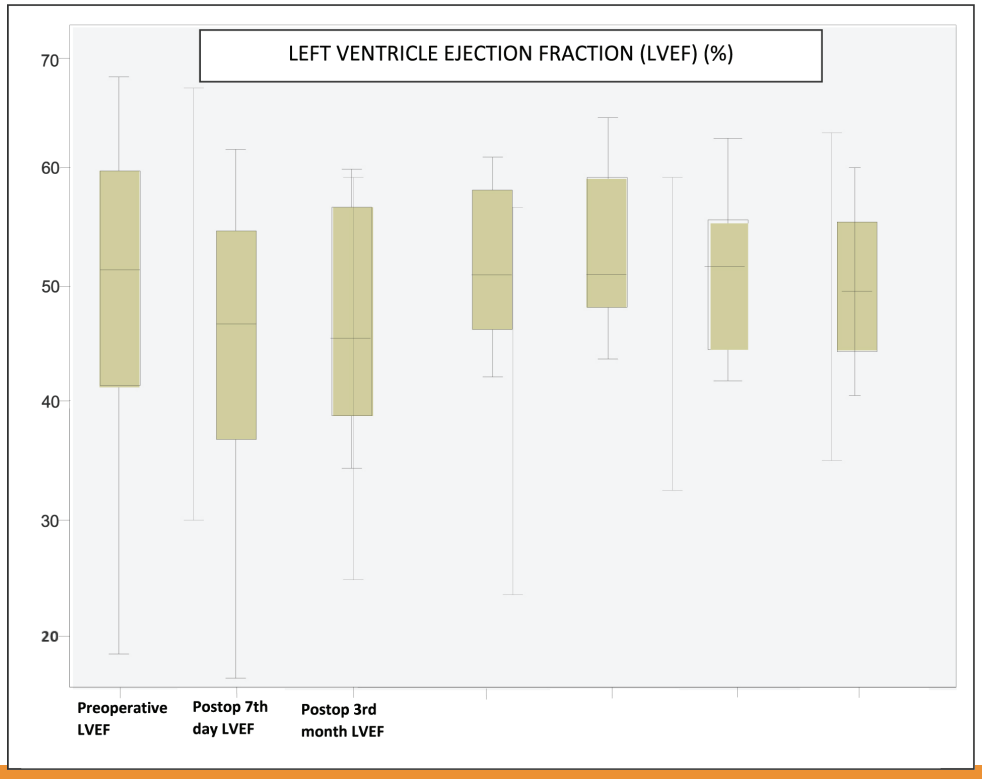

Figure 1. Left Ventricular Ejection Fraction Values as a Percentage

Table 1. Left Ventricle Ejection Fraction Values (Preoperative-Postoperative Period)

	N	Minimum	Maximum	MEAN	P value
PREOPERATIVE LV EJECTION FRACTION (%)	20	17	68	51,15 ± 14,04	
POSTOP LV EJECTION FRACTION 7th DAY (%)	19	16	62	47,11 ± 11,22	<0,001
POSTOP LV EJECTION FRACTION 3rd MONTH (%)	17	34,00	60,00	46,35 ± 8,03	0,08
POSTOP LV EJECTION FRACTION 6th MONTH (%)	17	41,00	62,00	51,58 ± 7,32	0,001
POSTOP LV EJECTION FRACTION 1st YEAR (%)	10	43,00	65,00	51,10 ± 7,38	0,10
POSTOP LV EJECTION FRACTION 10th YEAR (%)	10	41,00	63,00	51,38 ± 7,32	0,18
POSTOP LV EJECTION FRACTION 15th YEAR (%)	10	40,00	60,00	49,36± 7,22	0,05

In the postoperative follow-up of the patients, a significant decrease was observed in the left ventricular volume. This decrease was detected in both end-diastolic volume and end-systolic volume (**Figures 2 and 3, Table 2**).

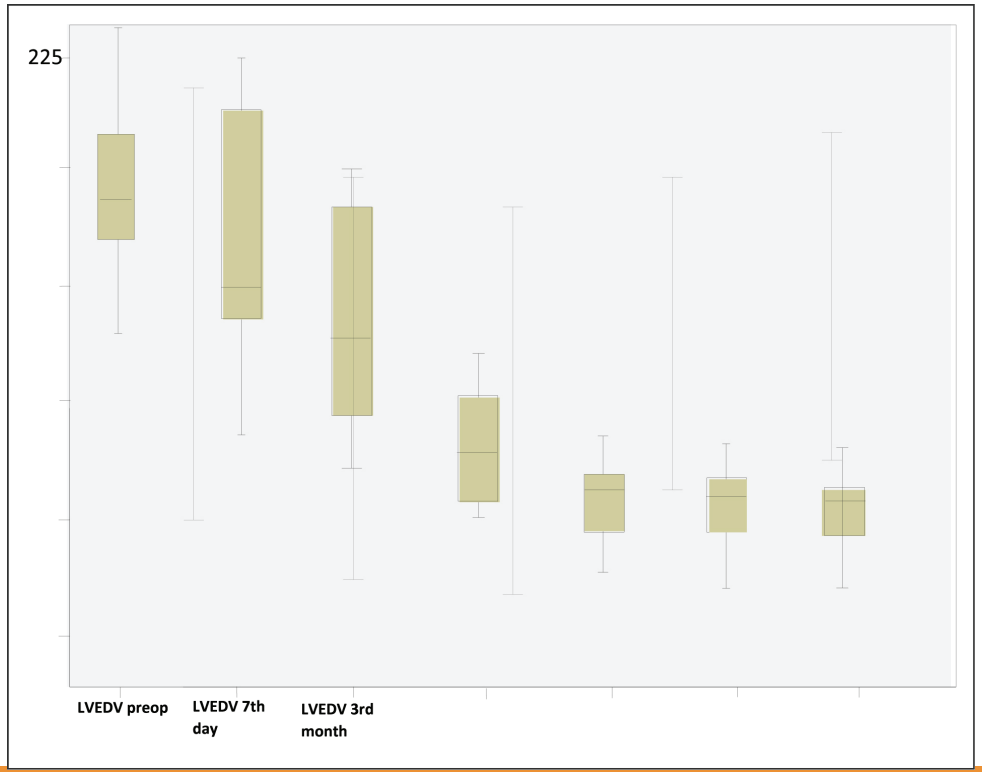

Figure 2. Preoperative and Postoperative Period Left Ventricle End-diastolic Volume (LVEDV) (milliliters)

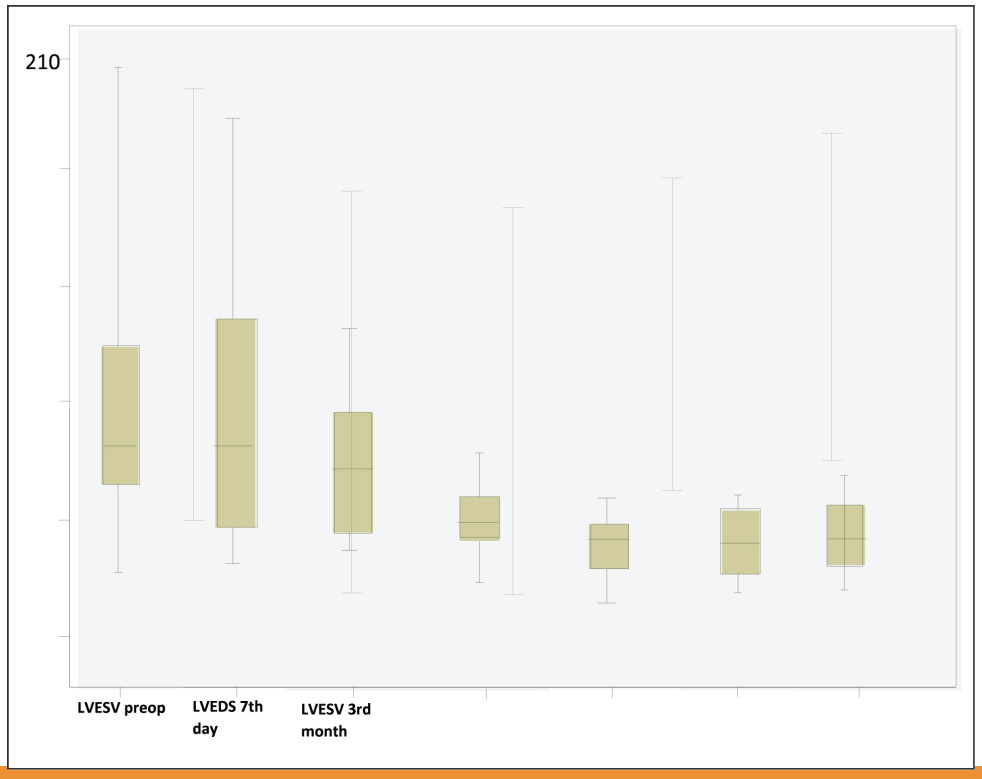

Figure 3. Preoperative and Postoperative Period Left Ventricle End-systolic Volume (LVESV) (milliliters)

Table 2. Left ventricle end-diastolic and end-systolic volumes

	Total N	Maximum	Minimum	Mean	Standard Deviation
LV ENDDIASTOLIC VOLUM PREOP	20	245,00	165,00	194,42	21,39
LV ENDDIASTOLIC VOLUM POSTOP 7th DAY	20	225,00	145,00	174,42	21,39
LV ENDDIASTOLIC VOLUM POSTOP 3rd MONTH	17	205,00	140,00	159,37	17,14
LV ENDDIASTOLIC VOLUM POSTOP 6th MONTH	17	160,00	125,00	141,18	10,60
LV ENDDIASTOLIC VOLUM POSTOP 1st YEAR	10	145,00	115,00	130,40	11,04
LV ENDDIASTOLIC VOLUM POSTOP 10th YEAR	10	142,00	110,00	128,00	12,07
LV ENDDIASTOLIC VOLUM POSTOP 15th YEAR	10	142,00	110,00	126,00	10,01
LV ENDSISTOLIC VOLUM PREOP	20	203,35	52,80	94,23	36,59
LV ENDSISTOLIC VOLUM POSTOP 7th DAY	20	189,00	56,55	94,34	32,67
LV ENDSISTOLIC VOLUM POSTOP 3rd MONTH	17	125,40	60,00	85,42	19,26
LV ENDSISTOLIC VOLUM POSTOP 6th MONTH	17	91,20	47,50	68,88	14,61
LV ENDSISTOLIC VOLUM POSTOP 1st YEAR	10	80,08	40,25	64,21	13,20
LV ENDSISTOLIC VOLUM POSTOP 10th YEAR	10	81,02	43,70	65,07	12,10
LV ENDSISTOLIC VOLUM POSTOP 15th YEAR	10	85,08	44,25	67,21	13,25

In the transthoracic echocardiography performed in the preoperative period, no gradient was detected on the mitral valve to indicate the formation of stenosis. However, transthoracic echocardiography performed in the early postoperative period revealed a mild to the moderate gradient on the mitral valve. This gradient formation gradually decreased in the late postoperative period and returned to normal levels at the end of 1 year. There was no significant difference in 10- and 15-years. (**Figure 4 and Table 3**).

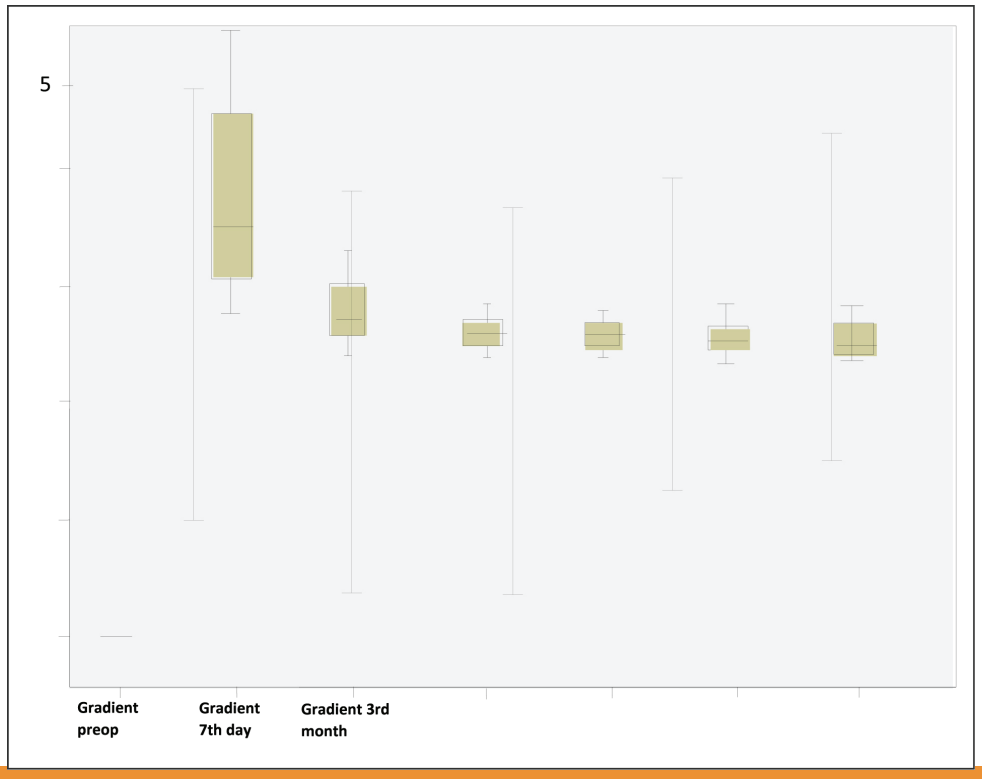

Figure 4. Gradient values on the mitral valve in the preoperative and postoperative period (mm Hg)

Table 3. Gradient values on the mitral valve in the preoperative and postoperative period

	Total N	Maximum	Minimum	Mean	Standard Deviation
PREOP GRADIENT on the VALVE (mmHg)	20	,00	,00	,00	,00
POSTOP 7th DAY GRADIENT on the VALVE (mmHg)	20	5,80	2,90	3,48	,64
POSTOP 3rd MONTH GRADIENT on the VALVE (mmHg)	17	3,20	2,40	2,72	,31
POSTOP 6th MONTH GRADIENT on the VALVE (mmHg)	17	2,90	2,30	2,62	,25
POSTOP 1st YEAR GRADIENT on the VALVE (mmHg)	10	2,80	2,30	2,58	,21
POSTOP 10th YEAR GRADIENT on the VALVE (mmHg)	10	2,90	2,30	2,50	,17
POSTOP 15th YEAR GRADIENT on the VALVE (mmHg)	10	2,95	2,35	2,42	,20

Mitral regurgitation greater than or equal to +2 developed during the follow-up period in 3 patients. Mitral regurgitation regressed in the serial ECHO controls of the 2 patients. The other patient was re-operated for mitral valve replacement. Late death occured in 3 patients during the follow-up period. 2 of them were due to non-cardiac events, carcinoma. Cardiac-related death occurred in one patient due to complications caused by arrhythmia. During the follow-up periods, the 10-year and 15-year survival rate were 90% and 90%, respectively.

Discussion

Mitral valve repair techniques have shown promising results with lower operative mortality, avoidance of anticoagulation, better preservation of left ventricular function, and the possibility of the continued growth of the valve in young children[9]. An annuloplasty ring has been used frequently for mitral valve repair since the late 1960s when the first generation human rigid mitral valve ring was introduced. The annuloplasty ring is sutured onto the native annulus to correct dilatation, consolidate the valve repair, improve leaflet coaptation during systole, and remodel the shape of the mitral valve. Traditional annuloplasty rings may cover the needs of the adult population, but it brings about suboptimal valve repair in pediatric patients. In addition, the classic annuloplasty ring used in the pediatric group has

two major drawbacks directly related to the ring. These drawbacks are exposure to foreign material causing a risk of fibrous tissue overgrowth, which may have an impact on valve function and restricted potential for native annular growth[10].

Kalangos biodegradable annuloplasty ring (Bioring SA, Lonay, Switzerland), commercially available in sizes 16 to 36 mm. This biodegradable ring has a curved C-shaped segment of poly-1,4- dioxanone polymer colored with a blue dye, which makes it only a partial ring. The ring is attached at both ends with a needle-holding extension suture (2/0 monofilament polyvinyl). The ring is implanted into the posterior annulus using the suture extension and fixed at the anterior and posterior trigones of the mitral valve. It represents a new concept owing to its biodegradable properties and enables us to apply a unique intra-annular implantation technique. This ring encircles the entire length of the posterior segment of the mitral valve, as well as commissural areas, and supports the posterior annulus from trigone to trigone[11]. Although the ring does not encircle the entire annulus, this can be considered acceptable because the results of posterior annuloplasty have been suggested to be equivalent to circumferential annuloplasty.

The semi-rigid structure of the ring enhances leaflet coaptation at the time of implantation and permits mobility of the mitral valve annulus during the cardiac cycle, yet it does not interfere with the motion of the posterior annulus and the leaflets. The gradual biodegradation of the ring induces annular fibrosis and ensures optimal annular reinforcement and satisfying results in the midterm. Although the concept of mitral-annular biodegradable ring implantation is novel and may raise concerns about the safety of its implantation technique, experimental studies[12,13] have confirmed that Kalangos biodegradable annuloplasty ring does not cause ischemic complications secondary to circumflex coronary artery occlusion[14]. Kalangos biodegradable ring annuloplasty is facilitated by a single continuous suture, unlike the multiple interrupted sutures used in conventional annuloplasty. Hence the implantation time and the aortic cross-clamp time are significantly shorter[11]. This is particularly important in complex mitral valve repairs and concomitant procedures[15,16]. The intra-annular position of the ring prevents contact with the blood, thus, it negates the need for anticoagulation. Moreover, the ring preserves the growth potential of the native mitral and tricuspid annulus. Conventional annuloplasty rings consist of woven, non-degradable prosthetic material that may be a source for the proliferation and colonization of bacteria and may adversely affect the surgical outcome[17,18]. The sub-endocardial implantation of the biodegradable ring prevents direct contact of the ring with the blood circulation; therefore the risk of postoperative infection decreases especially for patients with infective endocarditis. Pektok et al. have indicated this benefit in their study using biodegradable rings in 17 consecutive patients with acute infective endocarditis[19].

Yakub et al. shared their experience regarding the implantation of the biodegradable ring in young children between 2006 and 2011. 68 patients underwent mitral valve repair for congenital mitral valve disease. They divided their patients into two groups, which were 39 patients with biodegradable annuloplasty ring implantation, and 29 patients with non-ring annuloplasty techniques. There was a significant difference between the two groups concerning freedom from mitral valve repair failure (p=0.04) and mitral valve re-operation free survival (p=0.026). Echocardiography follow-up on 24 patients with the biodegradable ring was undertaken to assess the growth of the native annulus. The mean Z-score was noted to undergo normalization at 3 and 5 years, which suggests normal annular growth. This is another advantage of the biodegradable ring in the pediatric population since it permits the growth of the native annulus[20].

We tried to evaluate the early and late results of hemodynamic changes in patients who underwent mitral valve repair with a biodegradable ring, keeping echocardiographic findings in the foreground. The usage areas and results of the biodegradable annuloplasty ring in different patient groups have been previously examined in many studies mentioned above.

With this study, we saw that the advanced degree of mitral regurgitation decreased to a trace or mild degree in the post-op period. Although

LVEF decreases in the early postoperative period (7th day and 3rd month), there is no statistically significant difference in LVEF between the pre-operative and late postoperative period (6th month and 1st year) and long-term (10- and 15-years) as well. This situation was interpreted as the sudden increase in afterload as a result of acute correction of mitral regurgitation. Another important finding was a significant decrease in left ventricular volumes in the post-operative follow-up. This decrease occurred in both end-diastolic volume and end-systolic volume. In addition, no gradient was detected on the mitral valve in the examinations performed with transthoracic echocardiography in the pre-operative period. However, there was a mild to the moderate gradient on the mitral valve in the early post-op period. This gradient formation gradually decreased towards the late post-op period. When the studies with rigid and semi-rigid rings were examined, the continuation of the gradient on the mitral valve during the late postoperative period was an important problem[21,22,23,9]. Therefore, a biodegradable mitral annuloplasty ring might be a potential option to treat severe mitral valve insufficiency.

In the literature, there are studies showing that the long-term results are more satisfactory since the repair surgeries using flexible rings are more physiological repair method[24,25].

In our patient group, the main pathology was advanced mitral regurgitation. It was a male predominant group in the younger age group than the patient population examined in the studies in the literature. It was an interesting result that 2 patients with +2 or more mitral regurgitation in the early post-op period were free of mitral regurgitation in their long-term follow-up. The possible reason is that it is a physiological repair method and that the biodegradable ring interposed intra annularly allows fibrosis and ventricular remodeling.

Conclusion

The biodegradable ring can be implanted successfully to treat mitral regurgitation resulting from various etiologies**.** The more widespread use of this ring is expected with the disclosure of long-term results of ongoing clinical studies.

Fundıng Statement

No funding source

Conflıct of Interest

Authors claim no conflict of interest

Study Limitations

An important limitation of this study is the small number of patients. This may cause to miss some statistically significant values. Depending on the number of cases, data significance that would allow the comparison of case groups such as ischemic and degenerative mitral regurgitation could not be achieved. In addition, the absence of a comparison group like the valve replacement patient group is another limitation.

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