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Research Article

Recurrent Regurgitation Following Complete versus Partial Ring Annuloplasty in Degenerative Mitral Valve Insufficiency

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Abstract

Objectives: The goal of annuloplasty in mitral valve repair is to restore the normal physiologic form and function of native valve, with a recommendation of performing an annuloplasty with the repair. One of the major differences between the types of annuloplasties is the complete versus partial ring. We aimed to determine if the incidence of recurrent mitral regurgitation was affected by the type of annuloplasty used.

Methods: A single institution, retrospective review of 262 patients with degenerative mitral valve disease from 2008-2014 who underwent mitral valve repair with an implanted annuloplasty ring. Patients with documented type of annuloplasty ring, and complete follow up echocardiograms were included. The primary outcome was recurrent mitral regurgitation. Secondary outcomes included 30-day re-admissions and 30-day mortality.

Results: 145 of 254 patients (57.1%) received the complete ring annuloplasty while 108 patients (42.5%) received a partial ring. Recurrent mitral valve regurgitation was present in 20 (13.8%) patients versus 22 (20.37%) in the complete and partial ring, respectively (p=0.164). A multivariate logistic regression analysis was performed that revealed a complete ring was significant in reducing recurrent regurgitation (p=0.038).

Conclusions: Among patients with degenerative mitral valve disease and undergoing mitral valve annuloplasty, the use of a complete ring has a trend toward decreasing recurrent mitral regurgitation compared to a partial ring. When using a multivariable logistic regression analysis to adjust for predefined baseline covariates, there is a significant reduction in recurrent mitral regurgitation using a complete annuloplasty ring. Secondary endpoints of 30-day mortality, 30-day readmission, and overall mortality demonstrate no differences between the types of ring used.

Introduction

Mitral valve dysfunction affects millions of Americans and can be caused by numerous etiologies. The most common form of mitral valve dysfunction is mitral valve regurgitation. When deciding on operative repair, controversy continues to ensue concerning mitral valve repair versus replacement. ACC/AHA guidelines published in 2014 recommended mitral valve repair over a replacement when surgically durable repair possible [1]. The goal of annuloplasty in mitral valve repair is to restore the normal physiologic form and function of native valve, with a recommendation of performing an annuloplasty with the repair [2,3]. Numerous annuloplasty rings are commercially available. Recent studies have attempted to examine the differences of annuloplasty rings in the aspect of ventricular remodeling, ventricular function, and mortality outcomes [4-6]. Numerous minor differences between annuloplasty rings exist; one of the major differences is the complete versus partial ring. With no concise indication of when to use one over the other, surgeon preference prevails.

At our institution we perform mitral valve annuloplasties with both complete and partial annuloplasty rings. The aims of this study were to see whether there was an increased incidence of recurrent mitral regurgitation in one group versus the other. Our hypothesis was that there was an increase in the incidence of recurrent regurgitation in patients that received partial annuloplasty ring compared to patients who received a complete ring.

Materials and Methods

A retrospective review was conducted for patients undergoing mitral valve repair between the dates of January 2008 and December 2014. Permission through the institutional review board was obtained, and patient consent was waived. Use of the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery database was utilized to gather patient information. Patients with documented degenerative mitral valve disease who had undergone mitral valve repair were included in the study.



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A total of 342 patients with degenerative mitral valve disease underwent mitral valve repair. Annuloplasty ring implantation occurred in 337 patients. After complete chart review and post-operative follow-up, 262 patients had a complete documentation of post-operative echocardiograms for documentation of recurrent regurgitation.

Surgical management was conducted by three surgeons, all cases were elective repairs. Ring selection was at the discretion of the operative surgeon at the time of the operation. Documentation of the surgeon's choice was gathered from the operative dictation and confirmed by the patient's medical records.

Pre-operative patient medical conditions and history were collected from the STS database. Thirty-day mortality and 30-day readmission were also part of the completed database documentation. Overall mortality was obtained from the Social Security Death Database Index. Recurrence of mitral valve regurgitation was documented from post-operative echocardiograms. Mitral regurgitation grades were classified by interpreting cardiologists as: trace, mild, moderate, and severe. Recurrent regurgitation was interpreted as moderate, moderate-severe, or severe.

Statistical analysis

We report continuous variables as means (standard deviation) or medians and ranges, and categorical variables as proportions. We used Student's t-test or the Wilcox on rank-sum test to analyze between-group differences, as appropriate. Chi-square or Fisher's exact test was used for categorical variables, including the primary outcomes. Odds ratios of univariate analysis with 95% confidence intervals were reported. Any p-Value under 0.05 was considered significant. Additional analyses were performed with the use of multivariable logistic regression adjusted for predefined baseline covariates including the patient demographics, risk factors, and

Table 1: Pre-operative Patient Demographics (p < 0.05).

	Complete Ring Partial Ring			
	n=145 (%)	n=108 (%)	p-value	
Age	67.4 (±12.4)	62.2 (±12.4)		
Sex (male)	84 (57.9)	75 (69.4)	0.067	
Caucasian	134 (92.4)	103 (95.4)	0.346	
Diabetes	30 (20.7)	9 (8.3)	0.008	
Dyslipidemia	98 (67.6)	54 (50)	0.004	
Hypertension	117 (80.7)	70 (64.8)	0.004	
Renal Failure	1 (0.7)	0 (0)	0.389	
Cerebrovascular	19 (13.1)	6 (5.6)	0.034	
Prior CABG	11 (7.6)	0 (0)	0.004	
Prior Valve	4 (2.8)	2 (1.9)	0.645	
Prior MI	28 (19.3)	8 (7.4)	0.008	
Prior HF	55 (37.9)	27 (25)	0.033	
Arrhythmia	1 (0.7)	5 (4.6)	0.041	
Pre-op EF	46.9(±14.9)	56.2(±6.7)		

CABG-Coronary Artery Bypass Grafting, MI- Myocardial Infarction, HF- Heart Failure, EF- Ejection Fraction.

procedure type. All data analyses were conducted by using the SAS statistical software version 9.4 (SAS Institute, Cary, NC).

Results

Between the patients of degenerative mitral valve insufficiency, pre-operative patient demographics demonstrate statistically significant differences among patients with dyslipidemia (p=0.004), hypertension (p=0.004), prior MI (p=0.004), and subsequent prior CABG (p=0.04). Pre-operative ejection fraction was also statistically significant, favoring patients with an implanted partial ring (Table 1).

Table 2: Comparison of number of procedures, concomitant procedures, and type of concomitant repair performed (p<0.05).

	Complete Ring Partial Ring			
	n=145 (%)	n=108 (%)	p-value	
Number of procedures				
I	26 (17.9)	61 (56.5)	<0.001	
II	43 (29.7)	26 (24.0)	0.341	
III	40 (27.6)	13 (12.0)	0.003	
IV	28 (19.3)	8 (7.4)	0.005	
V	8 (5.5)	0	0.013	
Concomitant Procedures				
AVR	26 (17.9)	5 (4.6)	<0.001	
TVR	60 (41.4)	17 (15.7)	<0.001	
CABG	64 (44.1)	17 (15.7)	<0.001	
COX MAZE	33 (22.8)	20 (18.5)	0.428	
LAAL	48 (33.1)	15 (13.9)	<0.001	
Aortic Root	8 (5.5)	2 (1.9)	0.142	
Mitral Repair				
Annuloplasty	143 (98.6)	84 (77.8)	<0.001	
Sliding Annuloplasty	2 (1.4)	24 (22.2)	<0.001	
Resection	6 (4.1)	36 (33.3)	<0.001	
Commissuroplasty	5 (3.5)	5 (4.6)	0.625	
Cleft Closure	4 (2.8)	6 (5.6)	0.254	
Neochord	51 (35.2)	61 (56.5)	<0.001	
Chordal Transfer	11 (7.6)	11 (10.2)	0.458	
Leaflet				
A1	3	2		
A2	10	7		
А3	1	0		
P1	2	2		
P2	26 (17.9)	69 (63.9)	<0.001	
P3	4	5		
≥2 Anterior	0	0		
≥2 Posterior	5	6		
Bileaflet	9	7		

AVR- Aortic valve replacement, TVR- Tricuspid valve repair, CABG- Coronary Artery Bypass Grafting, LAAL- Left atrial appendage ligation.

Peri-operative

The number of procedures performed and concomitant valves repaired did differ between the groups. The number of surgeries performed in which repair of the mitral valve was the only procedure occurred in only 26 (17.8%) of patients with the complete ring and 61 (56.5%) of patients with the partial ring (p<0.001). Concomitant performed procedures of AVR, TVR, CABG, and LAAL were all statistically significant (p<0.001) between the two groups. AVR was performed in 27 (18.5%) and 5 (4.6%) for complete ring and partial ring groups, respectively. TVR was performed in 61 (41.8%) and 17 (15.7%) for complete ring and partial ring groups, respectively. CABG was performed in 65 (44.5%) and 17 (15.7%) for complete ring and partial ring groups, respectively. LAAL was performed in 48 (32.9%) and 15 (13.9%) for complete ring and partial ring groups, respectively (Table 2).

Along with the focus of annuloplasty and implanted annuloplasty rings, multiple mitral valve repair techniques exist. Though a statistically significant number of annuloplasties and sliding annuloplasty procedures performed differed between the groups, when combined all annuloplasties are accounted for. There were also multiple concomitant mitral valve repair procedures performed along with annuloplasty, with the most commonly performed being a neochord. The repair procedure of neochord was performed in 52 (35.2%) in the complete ring group, and 61 (56.5%) in the partial ring (p<0.001). Leaflet resection was performed in 6 (4.1%) patients in the complete ring compared to 36 (33.3%) in the partial ring (p<0.001). Other procedures performed included commissuroplasty, cleft closure, and chordal transfer, all of which were statistically insignificant. Of the leaflets reconstructed, the P2 leaflet was

Table 3: Post-operative complications.

	Complete Ring	Partial Ring	p-value	
	n=145 (%)	n=108 (%)		
Transfusions	108 (74.5)	42 (38.9)	<0.001	
Average #	3.10 (2.8)	2.38 (3.0)		
ICU admission	145 (100)	108 (100)	NA	
# hours	83.1 (80.6)	54.9 (38.9)		
ICU re-admissions	2 (1.4)	1 (0.9)	0.746	
Complications				
Rebleed	6 (4.1)	1 (0.9)	0.125	
Valve Dysfunction	0	0	NA	
Sepsis	0	0	NA	
Sternal Wound	0	0	NA	
Stroke	2 (1.4)	0	0.222	
Prolonged Ventilation	15 (10.3)	1 (0.9)	0.002	
Pneumonia	1 (0.7)	1 (0.9)	0.83	
DVT	0	1 (0.9)	0.244	
Renal Failure	5 (3.5)	0	0.052	
Dialysis	5 (3.5)	0	0.052	
Pacemaker	0	0	NA	
Atrial Fibrillation	27 (18.6)	22 (20.4)	0.708	

ICU- Intensive care unit, DVT- Deep venous thrombosis (p<0.05).

reconstructed in 26 (17.9%) of the patients in the complete ring group, with 69 (63.9%) patients in the partial ring group (p<0.001). The remaining leaflets, including bi-leaflet repair, was not statistically significant between the two groups (Table 2).

Post-operative

Post-operative complications occurred in both groups. A total of 108 (74.5%) of patients in the complete ring group required a transfusion compared to 42 (38.9%) in the partial ring group (p<0.001). However, of those transfused, the number of units transfused was not statistically different. The length of stay in the ICU was an average of 83.1hours (± 80.6) for the complete ring, versus 54.9 hours (± 38.9) for the partial ring (p<0.001) (Table 3). The only post-operative complication reaching statistical significance was patients requiring prolonged ventilation with 15 (10.3%) patients in the complete ring compared with only 1 (0.9%) patient in the partial ring (p=0.002). The number of patients who developed renal failure and subsequent dialysis was greater in the complete ring, and approached statistical significance (p=0.052) (Table 3).

All post-operative echocardiograms were at least 1 month post-operative and the technique of transthoracic echocardiogram was used. Recurrent regurgitation was present in 20 (13.8%) of patients in the complete ring, compared with 22 (20.4%) in the partial ring group (p=0.164). Thirty-day readmission occurred in 15 (10.3%) patients in the complete ring group, and 7 (6.5%) in the partial ring group (p=0.281). Thirty-day mortality was the same between the two groups, with two patients in each. Overall mortality occurred in 10 (6.9%) in the complete ring, and 3 (2.8%) in the partial ring group (p=0.142) (Table 4).

Further univariate and multivariate analyses were performed to compare patients with no recurrent regurgitation versus those who had a recurrence of regurgitation. Between the two groups, 211 patients did not have a recurrence of regurgitation, and 42 had a recurrent regurgitation. Patient demographics, risk factors, procedures, and repairs were chosen upon the statistical significance of prior analysis between the complete and partial ring groups. In the univariate analysis, no variables exhibited statistical significance when comparing no recurrent regurgitation and present recurrent regurgitation. In multivariate analysis, statistical significance was achieved in patient age (OR 0.41, CR 0.18-0.97, p=0.042), concomitant AVR (OR 4.22, CI 1.23-14.42, p=0.027) and TVR (OR 3.16, CI 1.13-8.80, p=0.027), the use of blood products (OR 2.73, CI 1.12-6.67, P=0.027), mitral repair with neochord (OR 2.527, CI 1.066-5.99, p=0.035) and chordal transfer (OR 4.202, CI 1.27-13.91, p=0.0187), and the use of a complete ring annuloplasty (OR 0.381, CI 0.152-0.952, p=0.038). Age greater than 65 and the use of a complete ring were demonstrated to be associated with no recurrent regurgitation

Table 4: Study outcomes (p<0.05).

	Complete Ring Partial Ring		n value	
	n=145 (%)	n=108 (%)	p-value	
30-day Mortality	2 (1.4)	2 (1.9)	0.766	
30-day Readmission	15 (10.3)	7 (6.5)	0.281	
Recurrent Regurgitation	20 (13.8)	22 (20.4)	0.164	
Overall Mortality	10 (6.9)	3 (2.8)	0.142	

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development after repair. However, concomitant AVR and TVR, and repair with neochord and/or chordal transfer were significant in the development of recurrent regurgitation (Table 5).

Discussion

Discriminating between ischemic and degenerative mitral valve disease continues to play importance in prognostic information, as well as further guidance of treatment [11-13]. Degenerative mitral valve disease most commonly presents as leaflet prolapsed from a torn chordae. However, the spectrum of degeneration can further

Table 5: Univariate and Multivariate Analysis for Recurrent Regurgitation (p <0.05). Univariate and Multivariate results given in odds ratios. Confidence intervals given in parenthesis. Time given in minutes.

	No Recurrent Regurgitation	Recurrent Regurgitation				
	Number (%)	Number (%)	Univariate (CI)	p-value	Multivariate (CI)	P-value
# of Patients	211	42				
Demographics						
Age 65 and older	123 (58)	20 (48)	0.65 (0.33-1.26)	0.2025	0.41 (0.18-0.97)	0.0424
Female	77 (37)	17 (41)	1.18 (0.60-2.33)	0.6256	0.89 (0.39-2.00)	0.7688
Race	199 (94)	38 (91)	0.57 (0.32-1.87	0.3140	1.07 (0.27-4.27)	0.9245
Risk Factors		1		1		1
Diabetes	36 (17)	3 (7)	0.37 (0.11-1.28)	0.1040	0.62 (0.15-2.58)	0.5103
Dyslipidemia	129 (61)	23 (55)	0.77 (0.39-1.50)	0.4410	0.97 (0.43-2.22)	0.9462
Hypertension	153 (73)	34 (81)	1.61 (0.70-3.69)	0.2553	1.87 (0.71-4.89)	0.2025
Cerebrovascular	24 (11)	1 (2)	0.19 (0.03-1.45)	0.0903	0.20 (0.02-2.01)	0.1732
Prior CABG	9 (4)	2 (4)	1.12 (0.23-5.39)	1.0	1.93 (0.28-13.42)	0.5061
Prior MI	32 (15)	4 (10)	0.59 (0.20-1.76)	0.3392	0.70 (0.18-2.68)	0.5992
Prior HF	73 (35)	9 (21)	0.52 (0.23-1.14)	0.0959	0.53 (0.22-1.32)	0.1752
Procedures						
AVR	24 (11)	7 (17)	1.56 (0.62-3.89)	0.3395	4.22 (1.23-14.42)	0.0218
TVR	60 (28)	17 (41)	1.71 (0.86-3.39)	0.1215	3.16 (1.13-8.80)	0.0278
CABG	68 (32)	13 (31)	0.94 (0.46-1.93)	0.8715	2.44 (0.85-7.02)	0.0972
>1 procedure	138 (65)	28 (67)	1.06 (0.52-2.13)	0.8749	0.62 (0.19-2.07)	0.4339
Cross-clamp >121.25	36 (17)	4 (10)	0.51 (0.17-1.52)	0.2214	0.44 (0.05-3.66)	0.4453
Bypass time >146.08	35 (17)	4 (10)	0.53 (0.18-1.58)	0.2470	0.76 (0.09-6.19)	0.7969
Blood products	121 (57)	29 (69)	1.66 (0.82-3.37)	0.1586	2.73 (1.12-6.67)	0.0274
Repair						
Annuloplasty	190 (90)	37 (88)	0.82 (0.29-2.31)	0.7802	0.764 (0.189-3.077)	0.7044
Neochord	88 (42)	24 (57)	1.86 (0.95-3.64)	0.0659	2.527 (1.066-5.99)	0.0353
Chordal Transfer	15 (7)	7 (17)	2.61 (0.99-6.87)	0.0662	4.202 (1.27-13.91)	0.0187
Complete ring	125 (59)	20 (47)	0.63 (0.32-1.22)	0.1643	0.381 (0.152-0.952)	0.0388

AVR- Aortic Valve Replacement, TVR- Tricuspid Valve Repair, CABG- Coronary Artery Bypass Grafting.

One of the first mitral valve repairs was performed over 50 years ago [7]. Since that time, the evolution of mitral valve repair has blossomed to an ever evolving procedural art. In 2014, the ACC/AHA recommended mitral valve repair over replacement whenever surgically durable repair was deemed possible [1]. An annuloplasty is recommended to be performed in every repair, with additional repair procedures as necessary.

The spectrum of mitral valve disease stems from discrete pathologic etiologies. Recent research has identified and continues to further expand the best practices for mitral valve repair depending on the pathology. The three most identified etiologies include ischemic, degenerative, and rheumatoid [8,9]. Rheumatoid occurs most commonly patients with a history of rheumatic fever and subsequent mitral valve disease; this also the least common [8-10].

expand to multiple leaflet prolapsed and annular dilation; all of which can further exacerbate the echocardiography and symptomatology of mitral valve insufficiency.

Principles of mitral valve repair follow two fundamental principles: restore a good surface of leaflet cooptation, and correct for annular dilatation [14]. Multiple techniques have been employed to resect abnormal tissue, or to reconstruct existing tissue with neocord placement or chordal transfer. In either case, the failure to perform an annuloplasty at the time of mitral valve repair is one of the strongest predictors of failure, resulting in recurrent moderate or severe mitral valve regurgitation [15]. Multiple annuloplasty rings have been developed by various manufactures. As not a single ring fulfills the utility to provide the perfect repair, various rings depending on rigidity, flexibility, complete and partial have been developed.

Numerous pre-operative differences existed between the comparison groups. The presence of co morbidities, including diabetes, dyslipidemia, hypertension, cerebrovascular disease, prior CABG, prior MI, prior HF, and prior arrhythmia, were statistically significant. Each co morbidity in itself is a risk factor for additional co morbidities and increased mortality. The influence of these co morbidities on the potential of perpetuating recurrent regurgitation has yet to be explored.

Further differences that deserve to be explored are the differences in concomitant procedures performed. Mitral valve repair was the only procedure performed in over 50% of patients with a partial annuloplasty ring insertion. This is in vast contrast to patients in the complete ring group, where only 17.8% of patients had mitral valve repair as the only procedure performed. Most patients with a complete ring insertion had a total of 2 or 3 procedures performed during the same operation. The most common procedures performed were TVR and CABG, occurring >40% of the cases when a complete ring was inserted, versus 15.7% of the time in the partial ring group. The evident selection bias deserves to be further investigated. Perhaps the structural integrity of the valvular anatomy portrays inherent weakening when multiple valves exhibit clinically significant pathology and the notion of a complete ring would theoretically provide more support in annular integrity and leaflet cooptation. Prior studies have demonstrated a rigid annuloplasty ring does not preserve or influence the left ventricular function when compared with a semi-rigid or flexible annuloplasty ring [16].

Patients with an implanted partial annuloplasty ring exemplify mitral valve repair as the sole procedure performed more frequently then complete ring. Of the patients with a partial ring insertion, additional mitral valve repair techniques were also employed more frequently. Though the differences between annuloplasty and sliding annuloplasty were present in patients between the two groups, the two procedures in themselves involve attention to the annulus and implantation of an annual pasty ring; for this reason, they are combined into one. Further dedicated techniques include leaflet resection and neochord placement. The patients in the partial ring group also demonstrated more P2 leaflet pathology. The P2 leaflet has been shown to be the most commonly affected leaflet, as demonstrated in prior studies [17].

As the patients in the complete ring group presented with more clinical co morbidities and underwent more concomitant surgeries, post-operative complications ensued as predicted. The patients underwent more transfusions and remained in the ICU longer. They experienced more episodes of rebleeding, prolonged ventilation, and renal failure, for which the exact reasons remain unknown. The potential of rebleeding is higher in patients who have undergone a coronary revascularization procedure, as did 44.5% of the patients in the complete ring group, which may account for this difference.

Despite the numerous statistically significant differences between the two groups, there is no difference in primary outcome. However, due to these differences, a multivariate logistic regression analysis was performed. Univariate and multivariate analysis was performed to compare patients of recurrent regurgitation versus no recurrent regurgitation. Age greater than 65 and the use of a complete ring was statistically significant in no development of recurrent regurgitation. This is consistent with the findings of Spiegel stein D, et al, who also

found recurrent regurgitation to be significantly lower in patients who received a complete ring [6]. The multivariate analysis also demonstrated AVR, TVR, neochord repair, and chordal transfer repair as a statistically significant risk factor toward the development recurrent regurgitation. The range of the confidence interval is noticeably wide, most likely due to the power of the study.

There are limitations to this study. First and foremost, it is retrospective in its approach. With statistically significant differences pre-operative conditions, one must take into account the overall health of the given population. Corrections were attempted by performing a logistic regression analysis on the primary and secondary outcomes. Further, peri-operative differences were statistically significant in the concomitant procedures performed. This may be the most influential confounding factor. Regression analysis was also performed taking into account these peri-operative differences. Reasons for use of a complete ring when multiple valves were repaired or replaced during the same operation are unknown, however, one must infer the ring to provide a further structural rigidity. Variability in recording the primary and secondary outcomes exists as diagnosis of regurgitation relies on independent cardiology interpretation. Without strict objective criteria for the inclusion diagnosis of regurgitation, intercardiologist variation exists as what one was called mild, mildmoderate, or moderate regurgitation. Recurrent regurgitation was defined as moderate, moderate-severe, or severe. Variation in interpretation would substantially change the percent recurrent regurgitation due to the small numbers.

In conclusion, multiple available annuloplasty rings for mitral valve repair exist with numerous structural differences, including a complete and partial ring. With the primary endpoint of recurrent regurgitation, univariate analysis demonstrated no differences. However, multivariate analysis demonstrated a statistically significant decrease in recurrent regurgitation in patients undergoing complete ring annuloplasty. Thirty-day mortality, 30-day readmission, and overall mortality demonstrated no differences in univariate or multiple variety analyses. As this study is limited to retrospective analysis, and with no congruency between concomitant procedures performed, a randomized clinical trial is recommended to further evaluate clinical outcomes among the use of various mitral valve annuloplasty rings.

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