



Research Article

REPAIR OF TRICUSPID REGURGITATION: COMPARISON BETWEEN SUTURE ANNULOPLASTY AND RING ANNULOPLASTY: AN AMBISPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Objective and background: We undertook this study to evaluate and compare the outcome of the DeVega suture annuloplasty and ring annuloplasty of Tricuspid valve to find out the better option in the setting of RHD.

Method: A total of 100 (N=100), patients of Rheumatic Heart Disease (RHD) with left heart valve involvement and associated with severe functional Tricuspid Regurgitation (TR) and moderate to severe Pulmonary Artery Hypertension (PAH), operated during last five years were included in our study. Group 1 patient were treated by ring annuloplasty of TV and group 2 were treated by modified de vega suture annuloplasty. Patients were evaluated and analysed retrospectively as well as prospectively followed up to see the difference in outcome between the two groups in terms of the clinical and 2D echocardiography changes.

Result: There was a statistically significant difference in terms of postoperative residual TR and recurrence of TR in both the groups. In group 1 intra operative TEE showed 26(52%) had no TR, 22(44%) had trivial TR, and 2(4%) had mild TR, at immediate postop 24(48%) had no TR, 24(48%) had trivial TR and only 2(4%) had mild TR. Whereas, in group 2, intraoperative TEE showed 3(6%) had no TR, 2(4%) had trivial TR, 38(76%) had mild TR and 7(14%) had severe TR, and at immediate post op before the discharge, 2D echocardiography showed 4(8%) had trivial TR, 30(60%) had mild TR, and 16(32%) had moderate TR, with similar results at 3, 6 and 12 month follow up, with p value of <0.001.

Conclusion: The ring annuloplasty is a better and effective method to treat severe functional TR in the setting of RHD with left heart valve disease, compared to DeVega suture annuloplasty.

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INTRODUCTION

Usually, in a setting of Rheumatic Heart Disease (RHD) with left-sided valvular lesion, severe functional Tricuspid Regurgitation (TR), dilated annulus > 40 mm with borderline Right ventricular (RV) function associated with moderate to severe PAH, we go for TV repair[1,2,3] but the dilemma begins with the method of the repair we choose. Generally we do suture or ring annuloplasty for the repair of Tricuspid Valve. However choosing the repair technique remains controversial [4,5]. Recent studies [4-6] have shown that ring annuloplasty is better option than suture annuloplasty in terms of long term outcome for the repair of TV, especially in patients of RHD. We undertook this study to evaluate and compare the outcome of DeVega suture annuloplasty and ring annuloplasty.

As Per ACC Guidelines 2014, Class I recommendations are – Tricuspid valve surgery is recommended for patients with severe TR [stages C and D- i.e. Symptomatic severe TR with Primary - Flail or grossly distorted leaflets or Functional - Severe annular dilation (>40 mm or >21 mm/m²) and Marked leaflet tethering], undergoing left-sided valve surgery. 2017 ESC guidelines are-In secondary tricuspid regurgitation, adding a tricuspid repair, if indicated, during left-sided surgery does not increase operative risk and has been demonstrated to provide reverse remodelling of the RV and improvement of functional status even in the absence of substantial tricuspid regurgitation.. Ring annuloplasty, preferably with prosthetic rings, is key to surgery for secondary tricuspid regurgitation.

The aim of our study was to provide a clear picture and guidelines in helping the surgeons in high volume centres to choose the better option.

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MATERIAL AND METHOD

Study design-A total of 100 (N=100), patients of Rheumatic Heart Disease (RHD) with left heart valve involvement with severe functional Tricuspid Regurgitation (TR) and moderate to severe Pulmonary Artery Hypertension (PAH), operated during last 05 years from Jan 2011 till 09th Oct 2015 (last follow up data included was of 09th Jan 2016) were included in our study. All the patients with degenerative, organic or congenital TV disease were excluded from the study. Institutional ethics committee approval was obtained and written informed consent was taken from all the patients in the study group.

In all the patients, left heart valve surgery along with Tricuspid valve annuloplasty with either Ring annuloplasty or modified DeVega suture annuloplasty was done. We had divided the study group into two, group 1 with ring annuloplasty and group 2 with modified DeVega suture annuloplasty. In each group we had included 50 (n=50) patients. This study was an ambispective observational study. Patients were evaluated and analysed retrospectively as well as prospectively followed up to see the difference in outcome between the two groups in terms of the clinical and 2D echocardiography changes.

Follow up: The preoperative, intraoperative, immediate post operative (before the discharge) and postoperative follow up clinical and echocardiographic data at 03 month, 06 month and 12 month were collected. Preoperative, intraoperative and immediate postoperative data were available for all the patients in the study group. Postoperatively all the patients were followed up clinically and echocardiographically at least once during the 12 month follow up period.

The data were collected from the ctvs record room, during follow up in opd, in the operation theatre and wards, through contacting the patients telephonically and on social media like whatsapp. Nil mortality was recorded and no redo surgery was needed during the follow up.

Surgical technique (a). Modified De Vega suture annuloplasty: in the modified De Vega's annuloplasty, two separate semicircular sutures with multiple pledgets were used as per standard operating procedure. The diameter of the annulus was reduced to 25-30 mm with an obturator or by using back handles of the Cooley's LA retractor which is equivalent to 28mm valve sizer.(b).

Ring annuloplasty: Carpentier Edwards (CE) classic Tricuspid rigid ring from Edward Lifesciences of size 28-34 mm were used. Ring placement was done in a standard way.

Evaluation: Patients were followed up clinically to evaluate NYHA class and atrial fibrillation status and 2D Echocardiography was done preoperatively and postoperatively with TTE in cardiology echocardiography Lab. The 2D Echocardiography parameters studied were to confirm the aetiology, diagnose the valvular lesions, to exclude degenerative, congenital or organic disease of TV. TR was graded as 0 for no TR, 1 for trivial TR, 2 for mild TR, 3 for moderate and 4 for severe TR as per Colour flow Doppler, 2D, and M mode values like, TR jet velocity and jet area, Right ventricular systolic pressure (RVSP)/ Pulmonary artery systolic pressure PASP, vena contracta (VC) width, IVC diameter, RA/ RV dilatation. The measurement of Pulmonary artery systolic pressure (PASP) for pulmonary arterial

hypertension (PAH) and Tricuspid annular plane systolic excursion (TAPSE) for RV dysfunction along with TV annulus size to show the annulus dilatation and TV leaflets morphology.

Statistical Analysis: All data were sampled retrospectively and prospectively from the clinical data sheets/ Performa and the master chart prepared in Microsoft Excel Sheet (attached in appendix). Statistical analysis done using statistical software STATA 13 IC. Mean and SD were used to describe continuous variables and percentage and frequency were used to describe categorical variables.

't' test was applied for the statistical testing between two groups at baseline for continuous variables and chi square test for categorical variables. The difference in continuous and categorical variable during follow up (measurement at different time periods) between two groups were compared using mixed models, i.e. mixed model was used for comparing repetitive measures over time between two groups.

RESULTS

The baseline characteristics of the patients in two study groups are shown in Tab 1, the mean age in years, (mean+/-SD) of group 1 was 28 (+/-13) compared to 31.7 (+/-12.9) in group 2. In group 1, the sex ratio in freq (%), male were 26(52%) and female were 24(48%) compared to 17(34%) were male and 33(66%) were female in group 2. Mean weight in kg (+/-SD) of group 1 was 43(+/-10) and 45(+/-9.6) in group 2. All the patients (N=100) were of rheumatic heart disease, with severe functional tricuspid regurgitation of grade 4. In group 1, 9(18%) were in NYHA class 2B and 41(82%) in class 3B, and no one was in class 4. In group 2, 49(98%) were in class 3B and 1(2%) in class 4B, with p value of 0.05. In group 1, 30(60%) were found to be in atrial fibrillation (AF), compared to 28(56%) in group 2. As far as valvular lesions are concerned, 32(64%) in group1 and 36(72%) in group 2 were suffering from Mitral Stenosis (MS) predominantly. Mitral Regurgitation (MR) was found to be in 29(58%) in group1 and 27(54%) in group 2. Aortic Stenosis (AS) was found in 2(4%) in group1 and 3(6%) in group 2. Aortic Regurgitation (AR) was also found in 6(12%) in group 1 and 7(14%) in group 2. Mixed lesions involving both mitral as well as aortic valve were found in 6(12%) in group1 and 5(10%) in group 2.

Preoperatively in group 1, PASP in mm of Hg (mean+/-SD) was 58.6(11), and in group 2 it was 58(8) with p value of 0.80 and with 95% CI (56-60). TAPSE in mm (mean+/-SD) in group 1 was 15.7(1.3) and 15.9(1.2) in group 2 with p value of 0.41 and with 95%CI (15.5-16). TV annulus in mm (mean+/-SD) in group 1 was 41.6(3.4) and 40.9(1.5) in group 2 with 95% CI (40.7-41.8). In group 1, LVEF in % (mean+/-SD) was 55.7(7.5), and 55.5(6.3) in group 2 with p value of 0.90 and with 95% CI (54-57).

MVR + TV Repair was done in 30(60%) cases in group 1 and 38(76%) in group 2. DVR + TV Repair was done in 6 (12%) in group 1 and 4 (8%) in group 2. MV Repair + TV Repair was done in 14(28%) in group 1 and in 13 (26%) in group 2. Mean (+/-SD) in minute for aortic cross clamp (AOXL) was 95.3(33.5) and in group 2 it was 88.9(34.5) with p value of 0.34 and with 95% CI (85-98.9). CPB time in min, mean (+/-SD) was 139(39.4) in group 1 and 146.8(45.5) in group 2 with p value of 0.37 and 95% CI (134-151).

Post operative Echocardiography in two groups

Intraoperative TEE post cardio pulmonary bypass (CPB) findings as shown in tab 2 and 3, showed that in group 1, 26(52%) had no residual TR, 22 (44%) had trivial TR, and 2(4%) had residual mild TR, whereas, in group 2 only 3(6%) had no residual TR, 2(4%) had trivial TR, 38(76%) were having mild TR and 7(14%) had moderate residual TR with p value of 0.001. At immediate post op follow up just before the discharge, in the group 1, 24(48%) had no TR, 24(48%) had trivial TR, and 2(4%) had mild TR, whereas, in the group 2, 4(8%) was having trivial TR, 30(60%) had mild TR and 16(32%) had moderate TR with p value of 0.001. At 03 months post op, n= 47 in group 1 and n=46 in group 2 were evaluated. In group 1, 14(30%) had no TR, 23(49%) had trivial TR and 10(21%) had mild TR, whereas, in group 2, 3(6%) had trivial TR, 10(22) had mild TR, 23(50) had moderate TR and 10(22%) had severe TR. At 06 months follow up, in group 1, n= 42 and in group 2, n=43 were available for analysis, in group 1, 16(38%) had no TR, 21(50%) had trivial TR, 5(12%) had mild TR, in group 2, 5(11%) had trivial TR, 10(23%) had mild TR, 14(33%) had moderate TR and 14 (33%) had severe TR with p value of 0.001. At post op 12 month, in group 1, n=45 and in group2, n= 43 were available for analysis. In group 1, 13 (29%) had no TR, 17 (38%) had trivial TR, and 15(33%) had mild TR. In group 2, 1(2%) had trivial TR, 6(14%) had mild TR, 15(35%) had moderate TR, and 21(49%) had severe TR, with p value of 0.001.

Post operative results for TAPSE, PASP and LVEF Refer Tab 4, in the group 1, the mean(+/-SD) value of TAPSE in mm was 15.7(1.3) preoperatively, and 15.8(1.9), 15.6(3.5), 16.6(1.8) at 03 month, 06 month, and 12 month post operative follow up respectively. Compared to group 1, in group 2, the value of TAPSE was 15.9(1.2) preoperatively, and 15.5(2), 15.4(2.4) and 15.5(2) at 03 month, 06 month and 12 month post op follow up respectively with p value of 0.41 at pre op, 0.44 at 03 month post op, 0.65 at 06 month and 0.04 at 12 month post op follow up. The group 1 was showing the PASP value as mean (+/-SD) in mm of Hg, pre operatively and at 03, 06, and 12 month follow up as 58.6(11), 27(6.7), 27(6) and 26.6(6.4) respectively, whereas in group 2, the figures were 58 (8), 32(7.9), 31.7(8.8) and 31.6(6.5) with p value of 0.001 at each follow up period. The changes in LVEF in % with mean (+/-SD) value in two groups at immediate post op period, and at 03 month, 06 month and 12 month follow up were 52.4(9.5), 52(10.7), 51.6(12) and 54.8(8) in group 1 and 50.1(7.3), 51(7.6), 50(7.9), and 51(7) for group 2 with p value of 0.79.

Postoperative Outcome in NYHA Class

All the patients were on diuretics and on digoxin for rate control in postoperative period and both groups had similar rate control. No patients on follow up had PHV thrombosis or IE. As shown in fig 2, at 03 months post op, in group 1, 37(79%) were in class 1B and 10(21%) in class 2B, compared to 34(74%) in class 1B and 12(26) in class 2B in group 2 with p value of 0.68. At 06 months post op follow up, 37(88%) in group 1 were in class 1B, and 5(12%) in class 2B, compared to 34(79%) in class 1B and 9(21%) in class 2B in group 2 with p value of 0.58. At 12 months follow up, 39 (87%) in group 1 were in class 1B and 6(13%) in class 2B, whereas, in group 2, 37(86%) were in class 1B and 6(14%) in class 2B with p value of 0.57.

Table 1 Preoperative Characteristics Of The Study Group

S NO.	PRE OP VARIABLES			
	Demographic Profile	Gp 1	Gp2	p value
1	AGE IN YEARS, MEAN(SD)	28(13.3)	31.7(12.9)	0.20
	WEIGHT IN KG, MEAN(SD)	43(10)	45(9.6)	0.30
2	SEX, FREQ(%)			
	MALE	26(52%)	17(34%)	0.07
	FEMALE	24(48%)	33(66%)	
3	CLINICAL PROFILE			
	NYHA CLASS, FREQ(%)			
	CLASS 2	9(18%)	0(0%)	0.005
	CLASS 3	41(82%)	49(98%)	
	CLASS 4	0(0%)	1(2%)	
AF, FREQ(%)	30(60%)	28(56%)	0.68	
4	RHD, FREQ(%)	50(100%)	50(100%)	1
5	RHD WITH IE, FREQ(%)	-	01(2%)	
6	RHD WITH CCP, FREQ(%)	-	01(2%)	
7	FUNCTIONAL TR, FREQ(%)	50(100%)	50(100%)	1
8	P/TV REPAIR, FREQ(%)		01(2%)	
9	ECHOCARDIOGRAPHIC PROFILE			
	FUNCTIONAL TR, FREQ(%)	50(100%)	50(100%)	1
	SEVERE TR (GRADE 4), FREQ(%)	50(100%)	50(100%)	1
	MS, FREQ(%)	32(64%)	36(72%)	0.69
	MR, FREQ(%)	29(58%)	27(54%)	0.70
	AS, FREQ(%)	2(4%)	3(6%)	0.66
	AR, FREQ(%)	6(12%)	7 (14%)	0.40
	MIXED LESIONS, FREQ(%)	6(12%)	5(10%)	0.18
	PASP IN MM OF HG, MEAN(SD)	58.6(11)	58(8)	0.80
	TAPSE IN MM, MEAN(SD)	15.7(1.27)	15.9(1.2)	0.41
	TV ANNULUS IN MM, MEAN(SD)	41.6(3.4)	40.9(1.5)	0.15
	LVEF IN %, MEAN(SD)	55.7(7.5)	55.5(6.3)	0.90

Nyha= Newyork Heart Association, Af= Atrial Fibrillation, Rhd= Rheumatic Heart Disease, Ie= Infective Endocarditis, Ccp= Chronic Constrictive Pericarditis, Tr= Tricuspid Regurgitation, Pasp= Pulmonary Artery Systolic Pressure, Tapse= Tricuspid Annular Plane Systolic Excursion, Lvef= Left Ventricular Ejection Fraction, Ms/Mr= Mitral Stenosis/Regurgitation, As/Ar= Aortic Stenosis/ Regurgitation

Table 2 Intraoperative Changes In Variables

S no.	Intraoperative variables	Ring	Devega	P value	95% ci
		annuloplasty group (gp-1), n=50	annuloplasty group (gp-2), N=50		
1		RESIDUAL TR, Freq(%)			
	0 (NONE)	26(52%)	3(6%)	0.001	
	1 (TRIVIAL)	22(44%)	2(4%)		
	2 (MILD)	2(4%)	38(76%)		
	3 (MOD)	0	7(14%)		
4 (SEV)	0	0			
2	LVEF in %, Mean(SD)	49.5(7.6)	47(5.7)	0.79	
3	AOXL in Min, Mean(SD)	95.3(33.5)	88.9(34.5)	0.34	85-98.9
4	CPB in Min, Mean(SD)	139(39.4)	146.8(45.5)	0.37	134-151
5	MVR+ TV REPAIR, Freq(%)	30(60%)	33(66%)		
	DVR + TV REPAIR, Freq(%)	6(12%)	4(8%)		
7	MV REPAIR+ TV REPAIR, Freq(%)	14(28%)	13(26%)		

Aoxl= Aortic Cross Clamp Time, Cpb= Cardio Pulmonary Bypass Time, Mvr= Mitral Valve Replacement, Dvr= Double Valve Replacement

Table 3 Postoperative Changes In Tr/Nyha Class And Lvef

Categorical characteristics	STUDY GP(N=100)	Imdt post op		Post op 03 m		06 M		12 M	
		GP 1(n=50)	GP 2(n=50)	GP1 (n=47)	GP2 (n=46)	GP1 (n=42)	GP2 (n=43)	GP1 (n=45)	GP2 (n=43)
	0 (NIL)	24(48%)	0	14(30%)	0	16(38%)	0	13(29%)	0
	1 (TRIVIAL)	24(48%)	4(8%)	23(49%)	3(6%)	21(50%)	5(11%)	17(38%)	1(2%)
	2(MILD)	2(4%)	30 (60%)	10 (21%)	10 (22%)	5 (12%)	10 (23%)	15(33%)	6 (14%)
TR GRADE	3(MOD)	0	16(32%)	0	23(50%)	0	14 (33%)	0	15(35%)
	4(SEVERE)	0	0	0	10(22%)	0	14(33%)	0	21(49%)
	P VALUE		0.001		0.001		0.001		0.001
AF with CVR		28	27	23	22	21	21	17	16
AF with FVR		03	02	01	02	Nil	Nil	Nil	Nil
Paravalvular leak/ PHV thrombosis		Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
	1	-	-	37(79%)	34(74%)	37(88%)	34(79%)	39(87%)	37(86%)
	2	-	-	10(21%)	12(26%)	5(12%)	9(21%)	6(13%)	6(14%)
NYHA CLASS	3	-	-	0	0	0	0	0	0
	4	-	-	0	0	0	0	0	0
	P VALUE		-		0.68		0.58		0.57
LVEF IN %, MEAN(SD)		52.4(9.5)	50.1(7.3)	52(10.7)	51(7.6)	51.6(12)	50(7.9)	54.8(8)	51(7)
	P VALUE								0.79

Nyha= Newyork Heart Association, Tr= Tricuspid Regurgitation, , Lvef= Left Ventricular Ejection Fraction

Table 4 Postoperative Changes in Pasp and Tapse

Numerical characteristics	Pre op		Post op 03 m		06 M		12 M	
	GP 1 (n=50)	GP2 (n=50)	GP 1 (n=47)	GP2 (n=46)	GP1 (n=42)	GP2 (n=43)	GP1 (n=45)	GP2 (n=43)
Tapse in mm, mean(sd)	15.7 (1.3)	15.9 (1.2)	15.8 (1.9)	15.5 (2)	15.6 (3.5)	15.4 (2.4)	16.6 (1.8)	15.5 (2)
P value	0.41		0.44		0.65		0.04	
Pasp in mm of hg, mean(sd)	58.6 (11)	58 (8)	27 (6.7)	32 (7.9)	27 (6)	31.7 (8.8)	26.6 (6.4)	31.6 (6.5)
P value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001

Pasp= Pulmonary Artery Systolic Pressure, Tapse= Tricuspid Annular Palne Systolic Excursion

DISCUSSION

In the setting of rheumatic heart disease, patients undergoing surgery for left heart valve disease with severe Tricuspid Regurgitation (TR) can lead to increased morbidity and mortality. Therefore repair of accompanying TR must be performed at the time of initial valve surgery [7,8,9].

In our institute, as a routine practice, severe TR associated with or without left heart valve disease is usually treated concomitantly with TV annuloplasty. The rheumatic heart disease, involves all the valves. In mitral valve disease, PAH develops which in turn causes the pressure overload of the RV along with the dilatation of the TV annulus. Hence, the correction of moderate to severe TR becomes priority in such setting[7-10]. The uncorrected TR may worsen after mitral valve surgery, leading to right ventricular dysfunction and increase in post operative morbidity. [8,-11] This is the reason why many authors have also suggested the early surgical correction of TR without the gross TV annular dilatation.[5-11]. We generally do TV annuloplasty by either Devega suture annuloplasty or by ring annuloplasty. However, it is not clear which procedure is superior. In this study, we retrospectively and prospectively investigated the outcomes in both the groups.The advantage of using rigid ring over the De Vega's technique is that it is more durable. Especially when there is associated pulmonary artery hypertension, the ring gives far better results. It has been noted that the De Vega's repair gives way to the high pressure and TR [10-12].

Bernal et al. also believed that annuloplasty rings were more effective than the De Vega procedure in preventing late TR after mitral valve repair for RHD [12]. It has also been shown that ring annuloplasty remodels the annulus, decreases tension on suture lines, increases leaflet coaptation, and prevents recurrent annular dilatation, which also favours ring over suture annuloplasty especially in the presence of right heart dilatation and dysfunction [11- 13].

Our study also demonstrated that ring annuloplasty had more efficacies in restoring and maintaining tricuspid valve function, hence decreasing TR effectively immediately after surgery, this result was also duplicated At 3, 6, and 12 month follow up.

Strength of the study

All patients in the study group are of almost similar demographical, clinical and 2 D echocardiography profile. We had intraoperative and immediate postoperative record of all the patients in the study group for data analysis. All the patients were in contact through opd follow up, telephonically and on social media for better follow up. Retrospective and prospective study was combined

Limitations

It was a short term to midterm ambispective observation study with good follow up of both the groups. And more so the no. of patients was just 100.

Research implication and future direction

We need to do more randomised control studies along with long term follow up to prove our point and at the same time, we may include multicenter studies.

Since, we have proven our point to use ring for annuloplasty for better maintaining the annulus shape and preventing recurrence of TR compared to DeVega suture annuloplasty group, we should also investigate the efficacy of other rings like, contour 3D annuloplasty ring, semi rigid and flexible rings like Tri-Ad Adams tricuspid annuloplasty ring, since it is believed that it adapts to the three-dimensional geometry of the tricuspid valve in the time of systole and diastole and it also

causes less conduction defects postoperatively. We should also evaluate flexible and biodegradable rings along with Percutaneous Tricuspid Valve Annuloplasty System (PTVAS). We should also consider TARI (Tricuspid Annuloplasty Ring Index), a novel index for implanting tricuspid ring, which has been proposed by Fujita et al. TARI is the ratio of implanted ring size to BSA. TARI less than 18.9 is better in controlling TR post surgery.[16]

CONCLUSION

The ring annuloplasty is a better and effective method to treat severe functional TR in the setting of RHD with left heart valve disease, compared to DeVega suture annuloplasty, without any impact in any statistically significant increase in CPB and AOXL time or any post operative complication like heart blocks.

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