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Tricuspid valve repair by Devega annuloplasty versus ring annuloplasty in patient with functional TR: A comparative analysis

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Abstract
Aim: To analyse the efficacy of Devega Annuloplasty Versus Ring Annuloplasty in Tricuspid Valve Repair among patient's with Functional TR.
Material and Method: This retrospective study analyzed the medical records of 45 patients (15 underwent ring annuloplasty: Group 1, 30 underwent De Vega annuloplasty: Group 2) who underwent tricuspid valve annuloplasty for significant secondary tricuspid regurgitation and dilatation of right sided cardiac chamber due to left sided valve disease. Intra operative Transesophageal Echocardiography (TEE) and saline infusion tests revealed no more than mild TR. Postoperatively all the patients had routine TTE before hospital discharge (considered as immediate post op period). The recorded patients were followed up till 1 year post-operatively (in the form of another TTE and clinical data sheet) at the time of data collection for this study.
Results: Cardiopulmonary bypass time (minutes) was comparatively more in group 1 as compared to group 2 with statistically significant difference as $p<0.05$. Severe TR was reported among 6.7% and 20% of the subjects in group 1 and 2 respectively with statistically significant difference as $p<0.01$. Overall mortality was significantly high in group 2 (16.7%) as compared to group 1 (6.7%).
Conclusion: It can be concluded from the results of the present study that reconstruction of the tricuspid valve with the Annuloplasty ring is highly recommended.

Keywords: functional TR, ring annuloplasty, De Vega annuloplasty, mortality

Introduction
The current tricuspid regurgitation (TR) clinical and surgical treatment is still under discussion, mostly because the organic disease is rare and almost all cases are classified as secondary [1]. Echocardiographically, 80-90 percent of the population may have Tricuspid valve regurgitation (TR) of minimal to mild grade. There are no morphological changes in the "physiological" TR. A moderate to severe TR with increased prevalence at age is found in 0.8 percent of the population [2]. Patients with a significant TR have a markedly reduced life expectancy, even if the hemodynamic is often well tolerated over a long period of time [3].
Functional tricuspid regurgitation is most commonly caused by pulmonary hypertension and right-ventricular overload caused by left-sided valvular lesion, the right ventricle's chronic volume and pressure load leads to RV dilatation and dysfunction. In the region of the free RV wall, the tricuspid valve annulus dilates septal-lateral in direction. As dilatation increases, the ring of the valve becomes planar / circular results in tricuspid regurgitation. It is strongly recommended that a mild to severe tricuspid regurgitation be controlled surgically so as to obtain early and late clinical results [4]. Because if not corrected, TR may worsen over time leading to sever symptoms and will have negative impact on the functional state and survival [5, 6]. According to AHA/ACC guidelines 2017 update, intervention for TR is indicated in patients with moderate to severe TR with either tricuspid annular dilatation (greater than 4 cm) or Tricuspid index greater than 21 cm/m^2. But the important issue is related to the surgical management of TR, mainly regarding the choice of repair technique in a leaking tricuspid valve [7].
The main TV repair technique is annuloplasty with normal leaflets and chordal structures in the presence of a dilated annulus to reduce the annular size and enhance the surface of the leaflet coaptation. Various anuloplasty techniques such as de Vega annuloplasty and ring annuloplasty [8, 9] have been identified to date. Some surgeons perform de Vega TV annuloplasty due to its user-friendly nature, while others prefer to use an annuloplastic ring because it is safe, effective and reliable [10, 11].
The best method of correcting functional TR is uncertain. McCarthy and colleagues reported that ring annuloplasty was superior to suture annuloplasty in patients with functional TR, but there are many confounding factors, including variable etiologies of left heart disease and lack of standardization of surgical techniques [12]. Hence the present study was conducted to compare the efficacy of Devega Annuloplasty Versus Ring Annuloplasty in Tricuspid Valve Repair among patient's with Functional TR.

Material and Method
This retrospective study was conducted between 20th September 2017 to 30th June 2020 among relevant patients admitted in CTVS Department, SMS Jaipur. This retrospective study analyzed the medical records of 58 patients (21 underwent ring annuloplasty, 37 underwent De Vega annuloplasty) who underwent tricuspid valve annuloplasty for significant secondary tricuspid

regurgitation and dilatation of right sided cardiac chamber due to left sided valve disease. The patient selection criteria were as per the institutional protocol (for all functional severe TR and moderate TR with Tricuspid Index > 21mm/m^2) based on preoperative TTE (Trans-thoracic Echocardiography) findings and the type of procedure was the surgeon's decision. Organic tricuspid valve diseases were excluded. After applying inclusion and exclusion criteria, 13 patients were ruled out for the study. So the final sample comprised of 45 patients.

Patients were divided into two groups, in group (1) (n=15) ring annuloplasty was the procedure of repair and in group (2) (n=30) De Vega annuloplasty was the procedure of repair. Intra operative Transesophageal Echocardiography (TEE) and saline infusion tests revealed no more than mild TR. Postoperatively all the patients had routine TTE before hospital discharge (considered as immediate post op period). The recorded patients were followed up till 1 year post-operatively (in the form of another TTE and clinical data sheet) at the time of data collection for this study.

In the case of De Vega technique, the annulus is gathered in the region of the anterior and posterior leaflet by double layers of polyproline suture. The suture is started near the commissure between the anterior and septal leaflet and pierced along the anterior leaflet. In the region of the commissure between posterior and septal leaflet, the suture is guided by pledget and pierced parallel to the first suture. Now, the annulus is reduced by pulling the two filaments under digital control until tricuspid valve regurgitation is no longer present.

In ring annuloplasty, the prosthetic ring was placed using multiple interrupted pledgeted 2-0 ethibond sutures.

Statistical analysis

Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 24.00 for windows; SPSS inc, Chicago, USA). Difference between two groups was determined using chi square test and the level of significance was set at $p < 0.05$.

Results

Table 1 shows the demographic characteristics among the study population. Female subjects were slightly more as compared to male subjects in both the groups. Most affected age groups were 31-50 years of subjects. 66.7% and 70% of the subjects underwent mitral valve replacement among both the groups. Statistically no significant difference was found among both the groups when compared in relation to demographic characteristics.

Table 1: Demographic characteristics of the study population

Variables	Group 1: Ring annuloplasty		Group 2: De Vega annuloplasty		p value
	N	%	N	%	
Gender					
Male	7	46.7	13	43.3	0.72
Female	8	53.3	17	56.7	
Age Group (in years)					
20-30	4	26.7	9	30	0.18
31-40	5	33.3	14	46.7	
41-50	5	33.3	6	20	
>50	1	6.7	1	3.3	
Concomitant Procedure					
Aortic Valve Replacement	3	20	0	0	0.07
Double Valve Replacement	2	13.3	9	30	
Mitral Valve Replacement	10	66.7	21	70	
Total	15	100	30	100	

Mean±SD cardiopulmonary bypass time (minutes), ICU stay (in days) and hospital (in days) was 111.87±17.24, 2.60±0.74, 6.73±2.02 and 99.10±17.55, 2.5±0.57, 6.33±1.67 in group 1 and 2 respectively. When cardiopulmonary bypass time (minutes) was compared between group 1 and 2, it was found to be statistically significant as $p<0.05$ (table 2).

Table 2: Mean description of cardiopulmonary bypass time and Post-operative parameters

Variables	Group 1: Ring annuloplasty		Group 2: De Vega annuloplasty		p value
	Mean	SD	Mean	SD	
Cardiopulmonary Bypass Time (Minutes)	111.87	17.24	99.10	17.55	0.003*
ICU Stay (in days)	2.60	0.74	2.5	0.57	0.39
Hospital (in days)	6.73	2.02	6.33	1.67	0.32

*: statistically significant

At discharge 2 patents expired in group 2. Mild TR was found in 80% and 60% of the subjects in group 1 and 2 respectively with statistically significant difference. After 1 year of follow up, 3 more subjects expired in group 2 whereas in group 1, only 1 subject was expired. Severe TR was reported among 6.7% and 20% of the subjects in group 1 and 2 respectively with statistically significant difference as $p<0.01$. Overall mortality was significantly high in group 2 (16.7%) as compared to group 1 (6.7%) as shown in table 3.

Table 3: Comparison of tricuspid valve status, redo operation and overall mortality among the study subjects during follow up

Variables	Group 1: Ring annuloplasty		Group 2: De Vega annuloplasty		p value
	N	%	N	%	
Tricuspid Valve Status					
At Discharge					
Trival TR	1	6.7	3	10	0.009*
Mild TR	12	80	18	60	
Moderate TR	2	13.3	6	20	
Severe TR	0	0	1	3.3	
At 1 Year					
Mild TR	10	66.7	11	36.7	<0.01*
Moderate TR	3	20	8	26.7	
Severe TR	1	6.7	6	20	
Redo Operation	0	0	2	6.7	0.14
Overall Mortality	1	6.7	5	16.7	<0.01*

*: statistically significant

Discussion

There is significant debate among surgeons over the appropriate treatment of functional regurgitation. This study evaluated the effectiveness of Devega Annuloplasty Versus Ring Annuloplasty in Tricuspid Valve Repair among Functional TR-patients.

Female subjects were slightly more as compared to male subjects in both the groups. Most affected age groups were 31-50 years of subjects. 66.7% and 70% of the subjects underwent mitral valve replacement among both the groups. Statistically no significant difference was found among both the groups when compared in relation to demographic characteristics in our study. Jai Bhagwan *et al.* [13] also reported similar findings. Gökhan Lafçı *et al.* [14] in their study reported that there was no significant difference in the age, gender, body surface area among the study groups.

ICU stay (in days) and hospital (in days) was approximately similar among the two groups. Statistically significant difference was found among the two groups in relation to cardiopulmonary bypass time (minutes) in our study. Khaled Alnawaiseh *et al.* [15] in their study found that there was no statistically significant difference in the duration of CPB, the mean aortic clamping time, intensive care unit stay and extubation time.

At discharge 2 patents expired in group 2 (De Vega annuloplasty group). After 1 year of follow up, 3 more subjects expired in group 2 whereas in group 1 (ring annuloplasty group), only 1 subject expired. Severe TR was reported among 6.7% and 20% of the subjects in group 1 and 2 respectively with statistically significant difference as $p<0.01$. These results were in accordance with study done by Khaled Alnawaiseh *et al.* [15]. They showed that ring annuloplasty had more efficiencies in restoring and maintaining tricuspid valve function immediately after surgery and also in the long run, which indicates that ring annuloplasty is a more durable method for TR repair. Ring anuloplasty successfully mitigated recurrence of TR and increased the quality of life in patients with rheumatic mitral and aortic valve disease. Bernal *et al.* [16] believed that annuloplasty ring were more effective than De Vega procedure in preventing late TR after mitral valve repair for rheumatic heart disease. A prospective randomized study conducted by Rivera *et al.* [17] of 159 patients comparing De Vega suture with ring anuloplasty showed higher recurrence of moderate and extreme TR in the De Vega community.

Similarly, a study by McCarthy *et al* of 790 patients reported earlier recurrence and progressive rise in moderate and severe TR after De Vega repair compared to ring annuloplasty [12]. A similar small group study in 45 patients by Matsuyama *et al.* [18] showed a 45% recurrence of 2+ to 3+ TR in De Vega compared with only 6% in the Carpentier repair group (p=0.027).

Overall mortality was significantly high in group 2 (16.7%) as compared to group 1 (6.7%) in our study. In their meta-analysis Parolari *et al.* [7] found that ring annuloplasty is also associated with better outcomes, being a protective factor for early mortality and long-term recurrence of TR after surgery. Guenther *et al.* reviewed 717 patients who underwent TV repair with either ring annuloplasty or De Vega suture annuloplasty between 1975 and 2009. The 10-year survival rates after TV repair with either ring annuloplasty or De Vega annuloplasty were 46 ±7%, and 39 ±3% ($p = 0.01$), respectively, and freedom from reoperation after TV repair with the De Vega suture technique was 88% compared with 98% after ring annuloplasty ($p = 0.034$). The authors concluded that TV repair with ring annuloplasty is associated with improved survival and a lower reoperation rate compared to suture annuloplasty [19]. However Sung Ho Shinn *et al.* [20], in their study revealed no difference in early mortality of patients receiving suture annuloplasty versus ring annuloplasty which is in contrast to the results of the present study.

This study is retrospective with the usual limitations of such investigations. No consistently measured echocardiographic data were available to quantify, for example, the height of TV tethering or Hemodynamic parameters on TTE follow-up were not regularly measured and so we could not evaluate the effect of postoperative pulmonary hypertension on TR recurrence. Although recurrences and technological problems are typically encountered in the early recovery periods, longer follow-up time along with large sample size is recommended for a more definitive outcome.

Conclusion

It is concluded from the results of the present study that reconstruction of the tricuspid valve with the Annuloplasty ring is highly recommended because it can be done with low rate of residual insufficiencies, a low reoperative rate and improved long-term postoperative event free survival.

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