

## Concomitant Tricuspid Annuloplasty in Functional Tricuspid Regurgitation: De Vega Suture Annuloplasty versus Ring Annuloplasty Along With Mitral Valve Replacement - A Comparative Study

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**Abstract : Introduction :** Our understanding towards the management of functional tricuspid regurgitation has evolved over time, from being of “benign” neglect to the one with huge prognostic importance. About 30% to 50% of mitral valve disease patients have significant functional tricuspid regurgitation. Functional tricuspid regurgitation when addressed along with left heart pathology is a safe procedure and results in better prognosis. Various methods of tricuspid annuloplasty have been described, the most commonly used being DeVega and Ring annuloplasties. In our present study we have attempted a comparison between the two annuloplasty techniques.

**Material & Methods. :** Patients requiring functional tricuspid annuloplasty along with mitral valve replacement were enrolled and were randomized into two groups to receive either DeVega or Ring annuloplasty. Data from clinical examination, patient symptoms and echocardiography were collected at pre-operatively, pre-discharge, 3 and 6 months post discharge and were statistically analyzed.

**Results :** When compared to DeVega annuloplasty we found that Carpentier Edwards rigid ring annuloplasty gives better freedom from recurrence of tricuspid regurgitation, better control of Pulmonary Arterial Hypertension, more decrease in Right Atrial transverse Diameter, better improvement in Right Ventricular function (TAPSE), better functional status of patients and same mortality percentage. The only downside of using Carpentier Edwards’s rigid ring tricuspid annuloplasty over DeVega Tricuspid annuloplasty is significantly longer operating time

**Conclusions :** For a post-operative period of 6 months the Carpentier Edwards rigid ring tricuspid annuloplasty appears to be superior to DeVega Tricuspid annuloplasty for addressing functional tricuspid regurgitation when done along with mitral valve replacement.

**Key words:** DeVega, Ring Annuloplasty, Functional Tricuspid Regurgitation.

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### I. Introduction

The approach to Functional Tricuspid regurgitation (FTR) has seen a remarkable shift in recent years, from one of “benign” neglect to one of very aggressive intervention, with some centers reporting interventions on the tricuspid valve (TV) in up to 60% patients receiving left sided operations<sup>1</sup>. The concept that FTR would resolve once the left sided lesion is corrected with its attendant fall in pulmonary arterial hypertension (PAH) championed by Braunwald’s robust paper<sup>2</sup> in the 1967 was so popular that Carpentier’s plea in the 1970s to repair the TV in FTR went totally unheeded. It has then been recognized that

1. There is high incidence (30% to 50%) of significant FTR in patients of severe Mitral Regurgitation<sup>3,4</sup> as well as Mitral Stenosis<sup>5,6</sup>
2. Concomitant FTR in Mitral valve pathology carries adverse prognosis, and it is related to the severity of FTR<sup>7</sup>
3. FTR when addressed at the time of mitral valve surgery is a reversible pathology<sup>8</sup>, and if left unaddressed it is a progressive disease.<sup>1,9</sup>
4. TV annuloplasty done at the 1st operation is safe and effective and added no incremental risks<sup>10</sup>

Given the decision to repair the tricuspid valve in FTR along with left heart procedures, the debate still continues as to what type of repair is most feasible? On one hand we have advocates<sup>11,12,13</sup> of tricuspid ring annuloplasty, which cite better outcome and less TR recurrence with ring annuloplasty repair; while on the other hand we have studies<sup>14</sup> which say that results are better with conventional De Vega’s suture annuloplasty. There

are also studies<sup>15,16</sup> which negate the superiority of one technique over the other and state that results are similar with both the annuloplasty techniques.

The two most established and most common tricuspid annuloplasty procedures are DeVega annuloplasty and Ring annuloplasty. With this background and conflicting reports, we plan to embark on a journey to research and find ourselves as to which technique is superior to the other, Tricuspid ring annuloplasty or De Vega suture annuloplasty for functional tricuspid regurgitation!

## **II. Materials & Methods.**

In the Department of Cardio-Thoracic and Vascular surgery in Medical College and Hospital, Kolkata over a period of 18 months from the date of approval given by the Ethical Committee (1 year for data collection and 6 months follow up), the patients requiring mitral valve replacement with tricuspid annuloplasty for moderate or severe functional tricuspid regurgitation (as per AHA guidelines<sup>17</sup>) admitted in the CTVS department were enrolled for the study and randomized into two groups.

- Group A- De Vega suture tricuspid annuloplasty
- Group B- Tricuspid Ring Annuloplasty using Carpentier Edwards Classic Ring
  
- Inclusion Criteria
- All patients requiring mitral valve replacement with
  - Severe Functional TR (AHA guidelines<sup>17</sup> Class 1)
- OR
- Moderate Functional TR with tricuspid annular dilation (AHA guidelines<sup>17</sup> Class IIa)
- OR
- Moderate Functional TR with prior evidence right heart failure (AHA guidelines<sup>17</sup> Class IIa)
- OR
- Moderate Functional TR with pulmonary artery hypertension (AHA guidelines<sup>17</sup> Class IIb)
  
- Exclusion Criteria
- Cases not requiring mitral valve replacement
- Concomitant ischemic heart disease patient
- Case requiring Aortic valve surgery along with mitral valve replacement (DVR)
- Organic Tricuspid regurgitation
- Cases requiring TV augmentation / replacement
- Mitral valve surgery with any other cardiac surgery apart from tricuspid annuloplasty.
- Re-operative cases

A detailed medical and family history and physical examination was performed.

Evaluation by 2D Echocardiography was done at

- Pre-operatively
- Pre discharge
- 3months post surgery
- 6 months post surgery

And the following parameters were noted:

- Freedom from recurrence of tricuspid regurgitation- Defined as the freedom from earliest echocardiographic evidence of moderate or greater tricuspid regurgitation.
- Pulmonary Arterial Hypertension – was estimated in terms of pulmonary arterial systolic pressure.
- Right Atrial Diameter (Transverse)- was measured in millimeters in serial echocardiography in apical 4 chamber view
- Right Ventricle Dysfunction – was estimated by measuring Tricuspid annular plane systolic excursion (TAPSE)
- NYHA functional class was noted by history
- Operative mortality – Defined as death within 30 days of surgery or during the same hospital stay.

## **III. Data Analysis**

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 25.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. A chi-squared test ( $\chi^2$  test) was used for any statistical hypothesis test wherein the sampling distribution of the test statistic was to be tested to disprove the null hypothesis. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test.

Two tailed p values were obtained for both t test for difference in mean and chi square test for difference in distribution.

P<0.05 was considered to be significant to prove the null hypothesis wrong.

#### Operative Technique

After median Sternotomy, thymic dissection and pericardiotomy, cardiopulmonary bypass after heparinisation through bicaval cannulation. Aorta cross clamped and heart arrested through cold antegrade cardioplegia. Mitral valve replacement done either through Left atrial incision or right atrial-septal route; in which case superior and inferior vena cava were snared. Tricuspid annular dilatation check on table. Saline test done on table then plan for tricuspid annuloplasty by either:-

Group A: DeVega tricuspid annuloplasty was done by 3-0 polypropylene running parallel sutures (with 5-6 mm bites), starting on the postero-septal commissure, through the endocardium, and directed around the perimeter of the orifice in a counterclockwise direction reaching the antero-septal commissure. The other parallel suture is placed about 1-2 mm outside the previous one, and finally tied together over pericardium at both the points. (Fig 1)



**Figure. 1** De Vega Suture Annuloplasty Being Done

Group B: After sizing based on the length of the septal segment of the annulus, large U sutures are placed around the annulus and through the ring. The Carpentier Edwards Tricuspid Ring is then implanted using eight to ten polyester stitches starting posteriorly (at the midpoint of the septal leaflet) and then proceeding counterclockwise. The surgeon must pay attention during the placement of stitches to damage the conduction system and to avoid the aortic root at the level of septal and anterior leaflet, respectively. The last stitch is placed above the antero-septal commissure, and the ring is finally parachuted and fixed. (Figure 2)



**Figure 2.** Saline Test After Tricuspid Ring Implantation

Tricuspid regurgitation is then tested with saline loading and if found satisfactory then heart chambers are closed. Then Aortic cross clamp is released Usual weaning from cardiopulmonary bypass, Hemostasis and routine closure of surgical site.

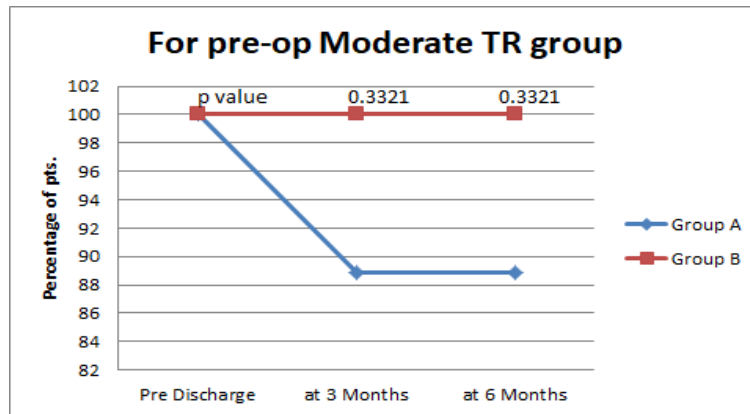
#### IV. Results

In our present study 49 patients were initially enlisted and randomised into 2 Groups A and B.

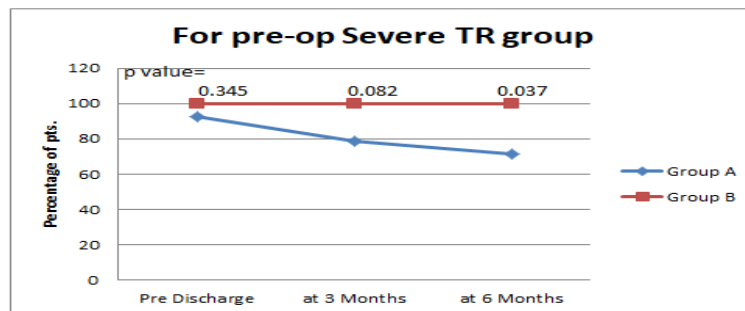
All such patients who were planned for mitral valve replacement and required tricuspid annuloplasty for moderate or greater tricuspid regurgitation were included. (See inclusion and exclusion criteria under "Materials and Methods"). Group A patients were planned to undergo DeVega annuloplasty and Group B were planned for tricuspid ring annuloplasty with Carpentier Edwards rigid ring. There were 2 deaths in group A and 1 death in Group B in the peri-operative period. Also 1 patient from Group B was lost to follow up soon after discharge. A total of 185 echo cardiographic evaluation was carried out for data collection.

In our present study we found that both the Groups were similar in terms of Age and Gender distribution and pre-operative comparable grades of the disease.

We found that there were no statistically significant difference in freedom from recurrence of tricuspid regurgitation at discharge from Hospital, at 3 or 6 months follow up if the patients had moderate tricuspid regurgitation pre-operatively (See Table 1) but with pre-operative severe tricuspid regurgitation at 6 months the freedom from recurrence of tricuspid regurgitation is significantly higher in Group B (Carpentier Edwards ring annuloplasty group) as compared to the De Vega Group. (See Table 2).



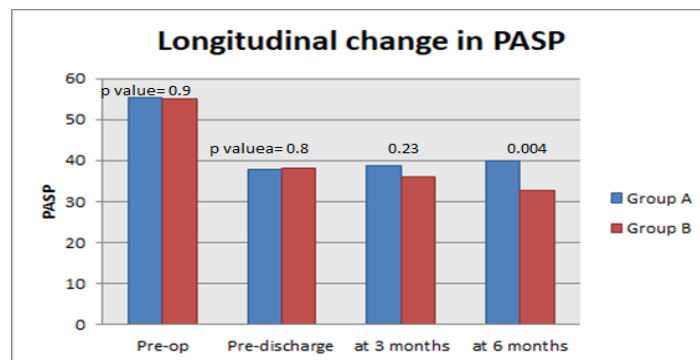
**Table 1.** Freedom from Recurrence of TR for Pre-operative moderate TR group



**Table 2.** Freedom from Recurrence of TR for Pre-operative severe TR group

Though there was a fall in the mean PASPs of both the groups, the difference between them remain statistically insignificant till 6 months of follow up when the distribution as well as the mean of the two groups show a statistically significant difference with better results in ring group. (p values 0.04828 and 0.00476 respectively [See Table 3])

A similar change was seen in Right Atrial Transverse Diameter (p=0.46) (See Table 4)



**Table 3.** Longitudinal Changes in PASPs

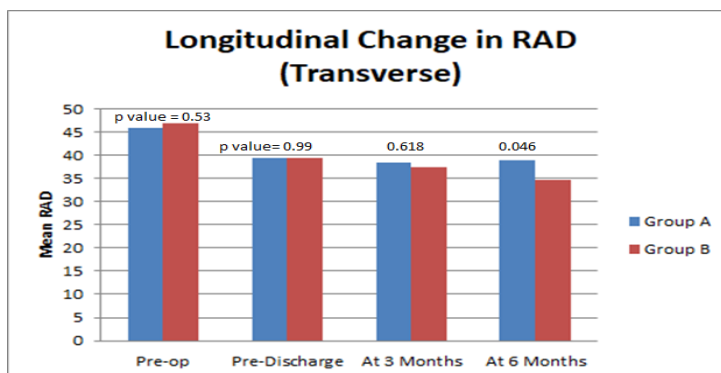


Table 4. Longitudinal Changes in RADs

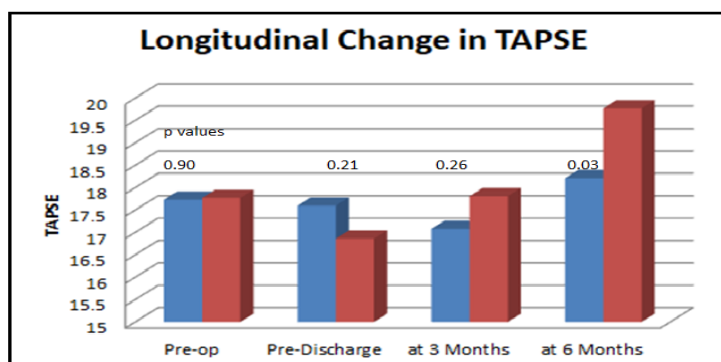


Table 5. Longitudinal Changes in TAPSE

The statistical difference in TAPSE between the two groups reached only at 6 months of follow up; better improvement in ring group. Also to note here is that initially there was a decrease in TAPSE in both the groups at the time of discharge compared to the pre-operative values but then again TAPSE went on increasing.

Both the groups improved in their NYHA class distribution but the difference between the two groups was evident at 6 months of follow up. At 6 months NYHA Class 1 and 2 Patients combined in Group A and B stands out at 52.17% vs 86.36% respectively whereas NYHA Class 3 and 4 Patients combined in Group A and B stands out at 47.82 vs 13.63% respectively..

In our study the peri-operative mortality was 8.33% in DeVega annuloplasty group and 4.34% in Carpentier Edwards ring annuloplasty group. The result was statistically insignificant.

In our study the mean cardiopulmonary bypass time was  $57.65 \pm 8.850$  minutes in DeVega annuloplasty group vs  $64.09 \pm 8.76$  minutes in Carpentier Edwards annuloplasty group.

Also the mean aortic cross clamp time of Group A and Group B were  $44.91 \pm 5.91$  minutes and  $48.90 \pm 6.67$  minutes respectively. The differences in result for both aortic cross clamp time and cardiopulmonary bypass time were statistically significant.

## V. Discussion.

Surgical repair is being increasingly applied now for addressing FTR, a condition for which primarily arises from left heart failure as the result of myocardial or valvular dysfunction, leading to right ventricular (RV) enlargement and asymmetric tricuspid annular dilation.

### Better Freedom From Recurrence Of Ftr With Ring Annuloplasty:

Rivera et al<sup>13</sup>(2010)reported that at 45 month follow-up, the De Vega group demonstrated a greater recurrence of moderate and severe TR (34% of patients) compared with the Carpentier-Edwards group (10% of patients)

McCarthy et al (2004)<sup>18</sup> found that Regurgitation severity increased more rapidly over time with the De Vega procedure at up to 8 years follow-up, whereas regurgitation severity was relatively stable across time with the Carpentier-Edwards ring. At 1 month, prevalence of 3+ or 4+ TR was similar among all groups (15% Carpentier Edwards ring, and 14% De Vega). Late worsening of TR was seen was observed to be associated not only with patient factors but also by the type of annuloplasty. De Vega's annuloplasty showed considerable late worsening of TR.

Matsuyama et al (2001)<sup>19</sup> reported that at 40-month follow-up, moderate and severe TR developed in 45% (13 in 28 patients) of patients in the De Vega group compared with 6% (1 in 17) of patients in the Carpentier-Edwards group.

Roshanali et al<sup>20</sup> (2010) reported that the incidence of severe residual TR was 16% and 28% in De Vega group and 8% and 14% in the ring annuloplasty group after 1 week and 1 month postoperatively respectively.

Chikwe J. et al<sup>10</sup> (2015) reported that Freedom from moderate Tricuspid regurgitation at 7 years was  $97 \pm 2\%$  in ring annuloplasty group versus  $91 \pm 3\%$  in only mitral valve repair group and type of annuloplasty ring had no significant influence on residual or recurrent TR. Probably this is the best result for ring annuloplasty compared to other studies.

Navia et al<sup>11</sup> in 2010 reported at the American Association for Thoracic Surgery meeting that by 5 years, TR had increased only slightly to 12% for isolated rigid prosthesis annuloplasty but was progressively greater for all other annular procedures (flexible prosthesis 16%, De Vega 24%, and Peri Guard 44%, and 19% for the Kay procedure).

Basel et al<sup>12</sup> in 2010 reported lower rate of recurrence in Ring annuloplasty compared to De Vega annuloplasty.

Chang et al. (2008)<sup>21</sup> found recurrence-free survival of De Vega's suture repair to be 71.9%.

No Superiority In Terms Of Failure Of Annuloplasty/ Recurrence Of Tr

Giamberti et al<sup>15</sup> in 2011 reported no significant difference in outcome between annuloplasty and ring repair for TR at 5 years of follow up.

A.N. Khallaf et al<sup>22</sup> (2016) found difference in tricuspid regurgitation at discharge and at 1 year follow up was insignificant statistically between DeVega and Carpentier Edwards ring annuloplasty groups.

Ghanta et al<sup>16</sup> (2007) also reported no statistical differences in the mean TR or prevalence in TR between the two groups at a mean follow up of 3 years.

Carrier et al<sup>23</sup> (2004) reported freedom from repair failure was similar between De Vega's and Carpentier Edwards ring annuloplasty ( $95 \pm 3$  and  $94 \pm 3\%$ , respectively).

Morishita et al<sup>24</sup> (2002) found that the 15-year freedom rate from reoperation was 91.6% and concluded that De Vega's annuloplasty was an effective and reliable procedure for the treatment of TR.

Our result of freedom from regurgitation in DeVega group falls close to that of Roshanali et al<sup>20</sup>, Rivera et al<sup>13</sup> and Matsuyama et al<sup>19</sup>. We achieved 100% freedom from TR in Carpentier Edwards ring annuloplasty group, results very close to that of Carrier et al<sup>23</sup> and Chikwe J. et al<sup>10</sup>. but may be the duration of follow up is too less to comment on this. Many patients in Group A had mild TR but that was not taken into account when counting freedom from recurrence of TR. These results when projected over a longer follow up period may prove to be significant!!.

#### Review Of Literature For

##### a) PASPs and RAD

Chikwe J. et al (2015)<sup>10</sup> showed improvement in the longitudinal PASPs over a follow up period of 5 years and reports that in patients who underwent MVR and tricuspid annuloplasty, pulmonary artery pressures improved such that at midterm follow-up, pulmonary artery pressures were as low as those in patients who underwent MVR only ( $p = 0.97$ ). For right atrial area they reported that in patients who underwent MVR repair and tricuspid annuloplasty, right atrial size decreased to the point that at midterm follow-up, right atrial size was the same as in those patients who underwent MVR only ( $p = 0.50$ ).

The correction of Tricuspid regurgitation soon after surgery causes a decrease in RA pressure and an immediate decrease in RA diameter. The further decrease in RA size or area is due to remodeling and hence slow decrease in RA diameter occurs thereafter.

##### b) RV dysfunction

Our finding was similar to that of Chikwe J et al<sup>10</sup> (2015) where they noted "RV dysfunction initially deteriorated postoperatively in both groups (both  $p < 0.001$ ). This change was more marked in the tricuspid annuloplasty group, in whom the rate of post-operative RV dysfunction before discharge was almost 70%. During follow-up, however, recovery of RV function occurred more rapidly in the tricuspid annuloplasty group, and by 5 years post-operatively, the proportion of patients with normal RV function was similar in both groups" while comparing Mitral Valve Repair vs Mitral Valve Repair along with Tricuspid ring annuloplasty.

Desai et al.<sup>25</sup> (2013) reported sustained improvement in RV after mitral valve surgery with concomitant tricuspid repair.

c) Functional class

Tang et al.<sup>26</sup> (2006) reported NYHA class 3 and 4 symptoms were reported in 20% of patients that underwent ring annuloplasty vs. 25% in patients who underwent suture annuloplasty. Matsuyama et al.<sup>19</sup> (2001) reported no significant difference in NYHA class between DeVega suture annuloplasty and Carpentier Edwards ring annuloplasty at 40 months of follow up. Dreyfus et al.<sup>1</sup> also noted in 2005 that performing an annuloplasty results in improved NYHA functional class and prevents progression of TR, which occurs when tricuspid annuloplasty is not performed

d) Mortality rate

Statistically similar mortality was noted by Chikwe J et al<sup>10</sup>, Rivera et al.<sup>13</sup> and Carrier et al<sup>23</sup> Roshanali et al<sup>20</sup> also reported an operative mortality of 4.8%.

Sarralde et al (2010)<sup>14</sup> had a mean follow-up was 16 years and reported a reduced rate of late mortality in the patient group who underwent De Vega's suture repair of the TV, compared with ring annuloplasty.

e) Cross clamp and Cardiopulmonary bypass time

In our study we had significantly longer cross clamp and cardiopulmonary bypass time in rigid ring group. A. N. Khallaf et al.<sup>22</sup> also reported longer operating time in ring annuloplasty group. Tang and colleagues<sup>26</sup> also reported longer cross clamp time but similar cardiopulmonary bypass time.

## VI. Conclusion

We may conclude by stating that for a post-operative follow up period of 6 months, the Carpentier Edwards rigid ring tricuspid annuloplasty appears to be superior to DeVega Tricuspid annuloplasty technique, for addressing functional tricuspid regurgitation, when done along with mitral valve replacement, but with significantly more operating time.

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