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# Comparative Study of Three Techniques of Repair for Severe Functional Tricuspid Valve Regurgitation

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## ABSTRACT

**Background:** The optimal technique for repair of functional tricuspid valve regurgitation (FTR) remains uncertain. Various modalities of annuloplastyhave been used to repair such pathology, including rigid or flexible rings (complete or incomplete), sutures, and bands.

**Aim of work:** The goal of this study was to compare the outcome of tricuspid valve (TV) repair by pericardial band, Dacron band and Carpentier ring in patients with left sided valve surgery.

**Patients & Methods**: This study was conducted from October 2016 to December 2019 and included 123 patients with functionally severe tricuspid regurgitation secondary to left-sided valve diseases (isolated mitral valve disease or combined mitral and aortic valve disease).Those patients were operated at Zagazig University Hospitals and Nasser Institute. We randomized patients into three groups according to the method used for management of tricuspid regurgitation. There were 41 patients in each group. Repair of TV was performed using Carpentier-Edwards Physio Tricuspid annuloplasty ring in group (A), Dacron band in group (B), and pericardial band in group (C). As, there was one mortality in each group, only 40 patients were enrolled in statistical analysis for each group.

**Results:** There was no significant difference between the three groups regarding the preoperative findings including age, sex, BMI, NYHA functional class and preoperative echocardiography findings. Duration of ward stay was longer in the pericardial group. Postoperatively, there was significant reduction in the mean pulmonary artery systolic pressure (PASP) and right ventricular dimension in the three groups, and notably evident in group (A).

**Conclusion:** Using semi-rigid (Carpentier-Edwards Physio Tricuspid annuloplasty ring) or flexible ring (Dacron band) or pericardial strip are good options in the repair of functional tricuspid valve regurgitation. However, Carpentier ring placement is s consistent with improved RV remodeling and is likely to improve the right ventricular efficiency and a favorable result.

**Keywords:** Tricuspid valve (TV), Tricuspid regurgitation (TR), Dacron band, pericardial band

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## INTRODUCTION

The most common pathology affecting tricuspid valve is functional tricuspid regurgitation (FTR) resulting from annular dilatation, which occurs in close association with right ventricular dilatation and dysfunction as well as pulmonary hypertension seen with left-side valve pathologies (1). Various techniques have been used for repairing the tricuspid annulus. The ideal technique to repair the tricuspid valve (TV) remains undefined. To repair such pathology, multiple annuloplasty modalities are used nowadays, including rigid or flexible rings (complete or incomplete), sutures and bands (2). Although the De Vega technique has been widely used, most surgeons have switched to annuloplasty bands or rings to reduce the incidence of failure of TV repair and better long-term results (3). Currently, there is no agreement that one annuloplasty technique is superior to the other (4).

**Aim of the work.**

The goal of this study was to compare the outcome of TV repair by Carpentier ring, Dacron band and pericardial band with left sided valve surgery (isolated mitral valve surgery or combined mitral and aortic valve surgery).

## PATIENTS AND METHODS

This randomized controlled study was conducted in Zagazig University Hospitals and Nasser Institute for research and treatment in the period from October 2016 to December 2019 for 123 patients with severe functional tricuspid regurgitation. We had a written informed consent from patients to engage in the current study. The department of cardiothoracic surgery, and the Institutional Review Board (IRB), Faculty of medicine, Zagazig University, approved all procedures. The research was carried out in compliance with the World Medical Association's Code of Ethics (Helsinki Declaration) of human-related studies.

All patients had surgery for left side valve lesions either mitral valve or mitral plus aortic valve surgery with concomitant tricuspid repair for associated severe FTR. These patients were computer-generated numbers randomly assigned into three groups according to the method used in management of tricuspid regurgitation. There were 41 patients in each group. TV repair was performed using Carpentier-Edwards Physio Tricuspid annuloplasty ring (Group A), Dacron band (Group B), and pericardial band (Group C). Each group had one case of mortality and so each group included 40 patients for follow-up and analysis.

**Inclusion criteria**: FTR grade 4 (severe) as evaluated by echo with moderate to severe pulmonary hypertension associated with lesions of left-sided heart valves that need repair/replacement(isolated mitral valve surgery or combined mitral and aortic valve surgery).

**Exclusion criteria:** organic TV disease, patients with ischemic cardiac disease requiring CABG and patients with prior history of cardiac surgery.

All patients in this study assessed as follows: preoperative medical history including age, sex, presence or absence of atrial fibrillation (AF) and NYHA functional class.

Prior to surgery, all patients underwent 2D Doppler echocardiography with an appropriate evaluation of TV anatomy and regurgitation severity. Severity of TR was estimated in four grades using Doppler color and systolic flow in the inferior vena cava or hepatic vein as grade 1+ (mild); grade 2+ (moderate); grade 3+ (moderate to severe) and grade 4+ (severe). In addition, ejection fraction (EF), right ventricular end diastolic dimension (RVEDD), right atrial diameter, and pulmonary artery systolic pressure (PASP) were assessed.

Surgical approach: In all patients, median stornotomywas done and cardiopulmonary bypass was established with bicavalcannulation.

Myocardial Protection was done by antegrade cold blood cardioplegia with systemic cooling to 28C and topical cooling using ice. Left sided valvular lesions were surgically managed by replacement or repair. The cavae were snared and a right atriotomy was done to show the tricuspid valve after closing of the left atrium, deairing, and elimination of the aortic cross clamp. Evaluation of the degree of TR was regularly done by intraoperative transesophageal echocardiography (TEE) before CPB.

In group A patients, tricuspid repair was done using the Carpentier-Edwards Physio Tricuspid annuloplasty ring. According to the surface area of the anterior leaflet and/or the septal annulus length,ring size was established and decreased by 1-2 sizes. An annuloplasty ring was fixed with 9–12 stiches of 2/0 ethibond suture, which were positioned from beyond the anteroseptal commissure to the middle of septal leaflet.

In group B, Dacron band annuloplasty was done using a strip of Dacron tube graft designed according to the intraoperative evaluation of the the surgeon where annuloplasty ring sizer used with width of 3–4 mm and a length of 5 to 7 cm.The Dacron band was delimited around the ring seizer's two notches to decide its length after sizing of the septal leaflet and with six to nine U shaped eithbound sutures, Dacron band was fixed to the TV annulus from anteroseptal commissure to posteroseptal commissure.

Group C, repair was performed using pericardial band. Autolgus pericardial strip about 10-12 cm in length and 5-8 mm in width was harvested and fashioned according to the size needed using annuloplasty ring sizer. Interrupted U shaped (2-0) ethibond sutures were taken extended from antroseptal to postroseptal commissure and passing from annulus to pericardium strip then on atrial surface of band and fixed to the TV annulus.

Assessment of efficacy of tricuspid repair done by; a- Saline test before right atrium closure; b- TEE after weaning of CPB.

We collected immediate postoperative data regarding inotropic support, length of ICU stays, ward stay, re-exploration and need for pacemaker.

All groups have been followed up for clinical improvement (NYHA functional class) and echocardiography at one month and one year postoperatively.

**Statistical analysis**

Data were analyzed using IBM SPSS Statistics for Windows (Version 23.0, Armonk, NY: IBM Corp). Mean ± SD was used to express quantitative data, while median (range) & number (percentage were used for qualitative data were.For comparing between more than two groups,analysis of variance **(ANOVA)** testwas used for variables with normal distribution, followed by least significant difference test (LSD to detect significance among groups. Percentage of categorical variables was matched by Chi-square test. All tests were two sided. P-value < 0.05 was counted significant, and p-value ≥ 0.05 was counted insignificant.

## RESULTS

There was no statistical significance difference between the studied groups regarding age, sex, preoperative NYHA functional class, preoperative atrial fibrillation (AF) and preoperative echocardiographic findings (table 1, 2).

**Table 1:** Preoperative data

| Item | Group A (n=40) | Group B (n=40) | Group C (n=40) | $\chi^2$ | P-value |
|---|---|---|---|---|---|
| **Age ( years):**<br>**Mean ±SD.**<br>**Range** | 47.01±11.77<br>29 – 62 | 45.6±10.87<br>26- 66 | 44.43±13.12<br>24-64 | f=0.467 | 0.628 |
| **Sex:**<br>**Male**<br>**Female** | 17(42.5%)<br>23 (57.5%) | 22 (55.0%)<br>18 (44.0%) | 19 (47.5%)<br>21 (52.5%) | 1.26 | 0.53 |
| **Dyspnea: NYHA Class**<br>• **II**<br>• **III**<br>• **IV** | 6(15.0%)<br>24(60.0%)<br>10(25.0% | 2 (5.0%)<br>19(47.5%)<br>19(47.5%) | 9(22.5%)<br>21(52.5%)<br>10(25.0%) | 9.1 | 0.058 |
| **Atrial fibrillation (AF)**<br>•—**Absent**<br>•—**Present** | 18(44.0%)<br>22(55.0%) | 19 (47.5%)<br>21(52.5%) | 26(65.0%)<br>14(35.0%) | 4.1 | 0.128 |

*SD = Standard Deviation, NYHA Class = New York heart association functional class*

**Table 2:** Preoperative echocardiographic data.

| Item | Group A (n=40) | Group B (n=40) | Group C (n=40) | F value | P-value |
|---|---|---|---|---|---|
| **Grade of TV** | 4 | 4 | 4 | | |

| | | | | | |
|---|---|---|---|---|---|
| **regurgitation** | | | | 0 | 0 |
| **PASP:**<br>**Mean ±SD**<br>**Range** | 61.02± 6.79<br>40-70 | 62.45± 6.15<br>55-72 | 62.91±7.8<br>60-80 | 0.791 | 0.4559 |
| **E F %:**<br>**Mean ±SD.**<br>**Range** | 51.91±6.5<br>40-60 | 52.82±6.15<br>44-60 | 52.93±6.83<br>40-60 | 0.31 | 0.734 |
| **RVEDD:**<br>**Mean ±SD.**<br>**Range** | 3.74±0.39<br>2.9-4 | 3.84±0.41<br>2.9-4.2 | 3.9±0.52<br>3-4.2 | 1.33 | 0.269 |
| **RT atrial dimension:**<br>**Mean ±SD.**<br>**Range** | 4.6±0.71<br>4-5 | 4.5±0.68<br>4.5-5 | 4.7±0.73<br>4.2-5.5 | 0.8 | 0.45 |

*TV = Tricuspid Valve, PASP = Pulmonary systolic artery pressure, EF = Ejection fraction, RVEDD = Right ventricular end diastolic dimension.*

There was no statistically significant difference between the 3 investigated groups regarding intraoperative data including type of associated other valve surgery, aortic cross clamp time, bypass time and degree of residual TV regurgitation post TV repair ( table 3).

**Table 3:** Operative data

| Item | Group A (n=40) | Group B (n=40) | Group C (n=40) | F | P-value |
|---|---|---|---|---|---|
| **MV repair/ replacement**<br>**MV + AV replacement** | 26(65%)<br>14(35%) | 30(75%)<br>10(25%) | 28(70%)<br>12(30%) | $\chi^2$=<br>0.95 | 0.621 |
| **ACC Time(min):**<br>• **Mean ±SD**<br>• **Range** | 89.2 ± 24.72<br>60- 150 | 88.7 ± 23.45<br>60-125 | 86.9± 26.82<br>40-145 | 0.093 | 0.91 |
| **Bypass Time(min):**<br>• **Mean ±SD**<br>• **Range** | 128.5±40.6<br>90-220 | 125.7±38.5<br>85-175 | 126.5±39.8<br>70-180 | 0.053 | 0.948 |
| **Degree of TV regurge by TEE post repair:**<br>• **No regurgitation**<br>• **Minimal regurgitation**<br>• **Mild regurgitation** | 14 (35.0%)<br>26 (65.0%)<br>0 (0%) | 15 (37.5%)<br>21(52.5%)<br>4(10.0%) | 18 (45.0%)<br>20 (50.0%)<br>2 (5.0%) | 5.48 | 0.242 |

*MV = mitral valve, AV = aortic valve, ACC = Aortic Cross Clamp, TV = tricuspid valve, TEE = trans-esophageal echocardiography*

In the Pericardial group, the re-exploration due to bleeding, ICU stay, and dosage of inotropic support was higher than other two groups, but difference was not statistically significant. However, duration of ward stay was significantly longer in pericardial band group in comparison to the other two groups. (table 4).

**Table 4:** In-hospital postoperative data

| Item | Group A (n=40) | | Group B (n=40) | | Group C (n=40) | | F value | P-value | LSD |
|---|---|---|---|---|---|---|---|---|---|
| **ICU stay:(day)**<br>• **Mean ± SD**<br>• **Median**<br>• **Range** | 3.3 ± 0.9<br>3<br>2 - 5 | | 3.5±1.2<br>3<br>2 - 5 | | 3.8 ± 1.1<br>4<br>2 - 6 | | 2.19 | 0.12 | |
| **Wards stay:(day)**<br>• **Mean ± SD**<br>• **Range** | 5.4 ± 1.3<br>6 - 8 | | 5.6±1.6<br>6 – 8 | | 7.9 ± 2.4<br>6-10 | | **23.13** | **0.000**** | 0.54[1]<br>**0.0002*[2]**<br>**0.0002*[3]** |
| | **No** | **%** | **No** | **%** | **No** | **%** | **$\chi^2$** | **P-value** | **--** |
| **Re-exploration due to bleeding:**<br>• **No**<br>• **Yes** | 38<br>2 | 95.0<br>5.0 | 39<br>1 | 97.5<br>2.5 | 35<br>5 | 87.5<br>12.5 | 3.48 | 0.175 | --- |
| **Inotrope:**<br>• **Low dose**<br>• **High dose** | 29<br>11 | 72.5<br>27.5 | 26<br>14 | 65.0<br>35.0 | 19<br>21 | 47.5<br>52.5 | 7.76 | 0.1 | |

*Data is shown as number (percentage) or mean ± standard deviation, LSD: Least significant difference. Chi-square $\chi^2$ and Anova -F test was used. Bold values are statistically significant at p<0.05.P1: Carpentier Group versus Dacron Group, P2: Carpentier versus Pericardial Group, P3: Dacron Group versus Pericardial Group.*

There was significant improvement of NYHA functional class in the three groups one month and one year postoperatively (Table 5).

**Table 5:** NYHA class among studied groups in preoperative and post-operative (one month) and follow up (oneyear) periods.

| Item | Carpentier Ring group (n=40) | | Dacron Band group (n=40) | | Pericardial Band group (n=40) | | $\chi^2$ | P-value |
|---|---|---|---|---|---|---|---|---|
| | No | % | No | % | No | % | | |
| **Pre-operative NYHA:** | | | | | | | | |
| • **II** | 6 | 15.0 | 2 | 5.0 | 9 | 22.5 | 7.9 | 0.094 |
| • **III** | 24 | 60.0 | 19 | 47.5 | 21 | 52.5 | 9.1 | 0.058 |
| • **IV** | 10 | 25.0 | 19 | 47.5 | 10 | 25.0 | 2.05 | 0.35 |
| **Post-operative NYHA (1month):** | | | | | | | | |
| • **II** | 0 | 0 | 1 | 2.5 | 2 | 5 | 1.8 | 0.406 |
| • **III** | 6 | 15.0 | 5 | 12.5 | 6 | 15 | 0.74 | 0.688 |
| • **IV** | 2 | 5.0 | 3 | 7.5 | 2 | 5 | 0.44 | 0.801 |
| **Follow up NYHA (1 year):** | | | | | | | | |
| • **II** | 0 | 0 | 1 | 0 | 2 | 5 | 2.31 | 0.31 |
| • **III** | 2 | 5.0 | 2 | 5.0 | 1 | 2.5 | 2.31 | 0.31 |
| • **IV** | 0 | 0 | 0 | 0 | 0 | 0 | | |

*NYHA= New York Heart Association*

There were no statistically significant differences between the studied groups regarding residual TR during follow up.14 patients have no regurgitation; 25 patients have minimal regurgitation, and six patients have mild regurgitation (Table 6).

**Table 6:** post-operative follows up of Tricuspid valve status (one month) & (one year) among studied groups

| Item | Group A (n=40) | | Group B (n=40) | | Group C (n=40) | | $\chi^2$ | P-value |
|---|---|---|---|---|---|---|---|---|
| | No | % | No | % | No | % | | |
| **Echo after one month:** | | | | | | | | |
| • **No regurgitation** | 18 | 45.0 | 17 | 42.5 | 21 | 52.5 | 2.3 | 0.68 |
| • **Minimal regurgitation** | 21 | 52.5 | 20 | 50.0 | 18 | 45.0 | | |
| • **Mild regurgitation** | 1 | 2.5 | 3 | 7.5 | 1 | 2.5 | | |
| **Echo after one year:** | | | | | | | | |
| • **No regurgitation** | 18 | 45.0 | 16 | 40.0 | 20 | 50.0 | 1.54 | 0.81 |
| • **Minimal regurgitation** | 20 | 50.0 | 21 | 52.5 | 19 | 47.5 | | |
| • **Mild regurgitation** | 2 | 5.0 | 3 | 2.5 | 1 | 2.5 | | |

*Data is shown as number (percentage). Chi-square $\chi^2$ is used. Bold values are statistically significant at p<0.05.*

All patients especially in group A showed significant decrease in PASP and significant regression in right ventricular dimension in postoperative follw up echocardiography (Table 7).

**Table 7 :** Echo parameters pre and after one year among studied groups

| Item | Group A (n=40) | Group B (n=40) | Group C (n=40) | F value | P-value | LSD |
|---|---|---|---|---|---|---|
| **RVEDD pre (cm)** | | | | | | |
| • **Mean ± SD.** | 3.56±0.51 | 3.68±0.43 | 3.72 ± 0.39 | 1.39 | **0.252** | |
| • **Range** | 2.8 - 4 | 2.9 – 4.2 | 3 – 4.2 | | | |
| **RVEDD follow up (cm)** | | | | | | |
| • **Mean ± SD.** | | | | | | **0.000*[1]** |
| • **Range** | 2.82 ± 0.17 | 3.31±0.11 | 3.3 ± 0.14 | **758.6** | **0.00001*** | **0.000*[2]** |
| | 2.5 – 3.5 | 2.8 – 4 | 3 – 4 | | | 0.69[3] |
| **P^** | **0.000*** | **0.000*** | **0.000*** | | | |
| **PASP pre:(mmHg)** | | | | | | |
| • **Mean ± SD.** | 61±8.2 | 62.12±9.3 | 63.16±7.2 | 0.68 | **0.508** | |
| • **Range** | 50-70 | 55 - 72 | 60 – 80 | | | |
| **PASP follow up (mmHg)** | | | | | | **0.000**[1]** |
| • **Mean ± SD.** | 43.7±6.85 | 51.81±6.87 | 52.13 ± 7.43 | **16.21** | **0.000*** | **0.000*[2]** |
| • **Range** | 30 - 52 | 40 - 60 | 40 - 60 | | | 0.58[3] |
| **P^** | **0.000*** | **0.000*** | **0.000*** | | | |

*RVEDD= Right Ventriculr End Diastolic Diamter, PASP= Pulmonary Artery Systolic Pressure. Data is shown as mean ± standard deviation. LSD: Least significant difference. Anova test -F , Bold values are statistically significant at p<0.05.*

## DISCUSSION

Functional tricuspid regurgitation (FTR) is usually observed in the lack of any detectable pathology of the tricuspid valve either leaflets or chordae, in conjunction with left-sided valve disease (5).

The most common form of tricuspid valve (TV) pathology is functional tricuspid regurgitation (TR) and tricuspid intervention is more frequently recommended and has become an increasingly relevant area of research (2).

The basis of surgical therapy for FTR is tricuspid annuloplasty, which promotes the coaptation of leaflets by correcting annular dilatation and restoring annular geometry. Suture, ring, and band annuloplasty techniques are the primary surgical procedures used to conduct tricuspid annuloplasty. Suture annuloplasty techniques decrease the size of the tricuspid annulus with a perpetual suture allowing the annulus to be cinched (6).

FTR was traditionally treated with the classic De Vega annuloplasty but has since progressed after the advent of prosthetic tricuspid annuloplasty (7).

Autologous pericardium tricuspid annuloplasty is a useful option for repair in patients with significant TR. This procedure produces a durable, reproducible annuloplasty of the tricuspid valve (8).

Ring annuloplasty based on autologous pericardium tissue has proven remarkable clinical efficacy for the treatment of tricuspid regurgitation. It reveals comparable beneficial effects to Edwards-MC3 annuloplasty during a short-term follow-up time and outperforms the commonly used De Vega annuloplasty (9).

Jabbad and his colleagues compared pericardial strip for repair of FTR with ring annuloplasty (Carpentier semi rigid ring + CarbomedicsAnnuloflex ring) technique and they concluded that annuloplasty using the pericardial strip is a simple inexpensive, reproducible and effective technique, which has results comparable to ring annuloplasty (12).

In our series, we compared short-term outcome of TV repair using three methods (Carpentier ring, Dacron band, and pericardial strip).To our knowledge, this study was the only one comparing these three modalities of TV repair.

One year postoperatively, follow up revealed competent TV in 54 patients (45%) and ≤ 1+ residual TR in the remaining patients with no significant difference between the three groups in this respect.

Significant postoperative reductions in PASP and RVEED were observed in the three groups. However, the Carpentier group showed statistically significant reductions in PASP and RVEED compared to the other two groups.

Many articles supported our results in this report. Gatti and his colleagues compared band TV annuloplasty (B-TVA) with ring TV annuloplasty (R-TVA) for functional TR. Six different tricuspid annuloplasty system types were used: three flexible bands, one traditional rigid ring and two rigid three-dimensional rings. They reported that both were effective in TV repair but the use of ring annuloplasty showed complete right heart reverse remodeling over time more than band annulopasty (15).

Nosair et al. (2020) compared the outcome of TV repair associated with mitral valve surgery using rigid 3D rings (contour 3D or MC3 ring) versus prosthetic fashioned bands (Dacron or PTFE). They reported no statistical significance difference in the instant post-operative duration regarding the degree of improvement of TR, PAP and NYHA class between both groups. However, in long-term follow-up and the need for re-intervention, rigid 3D rings showed substantial improved performance (13).

Wang and his collaborators conducted a systematic study and a meta-analysis of comparative studies to test flexible band ring versus rigid ring for TV annuloplasty for short and long-term survival and TR recurrence. They concluded that both rigid ring and flexible bands are effective choices for restoring TV regurgitation, but by

repair with rigid rings, TR rates are steadier and TR recurrence for long-term follow-up could be less than repair with flexible bands (14).

The outcome of FTV repair using flexible band versus rigid ring was comparable in the study conducted by Ali, However, in the ring group, recurrence of moderate or moderate to severe TR in follow up was more than in the band group, with no statistically significant difference (16).

In a significant patient cohort done by Navia and his colleagues, including 2277 patients who underwent TV procedures for FTR and used different techniques in repairing rigid rings annuloplasty (Standard, Carpentier–Edwards ring or 3-dimensional, EdwardsMC3) were superior to other techniques regarding early outcome and recurrence of TV regurgitation (11).

Patients had excellent results with returning to their average life expectancy following TV repair for FTR. Repair by rigid or semi-rigid tricuspid annular brace showed superior durability when compared to suture and flexible band repair procedures (10).

## LIMITATION

Larger prospective randomized trials with longer follow up periods are needed to validate these findings and assess the improvement in patient survival.

## CONCLUSION

Using semi-rigid (Carpentier-Edwards Physio Tricuspid annuloplasty ring) or flexible ring (Dacron band) or pericardial strip are good options in the repair of functional tricuspid valve regurgitation. However, Carpentier ring placement is s consistent with improved RV remodeling and is likely to improve the right ventricular efficiency and a favorable result.

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