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Technique and Interim Outcomes of Surgical Tricuspid Valve Repair Modalities in Adults: A Prospective Randomized Clinical Study

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Abstract

Background: Tricuspid regurgitation (TR), which is hemodynamically significant, can cause severe symptoms and has a poor prognosis, especially in patients who also have concurrent left sided valvular pathology.

Aim of Study: This research endeavored to study the feasibility and short-term results of different surgical techniques in the repair of tricuspid valve regurgitation in adults.

Patients and Methods: This single center, prospective, multi-arm, parallel, randomized, controlled, triple blinded, study was conducted for all patients operated for Tricuspid valve regurgitation in scope of concomitant mitral valve replacement at our university hospital during the study period. Patients were randomly stratified into 3 equal groups: Group A (De-Vega Annuloplasty, n=25), Group B (Segmental Annuloplasty, n=25), and Group C (other valvuloplasty techniques; Kays's repair n=8, pericardial strip annuloplasty n=8 and ring annuloplasty n=9). All cases were assessed pre-operatively and post-operatively at 2 weeks, 3 months and 6 months.

Results: Included were 75 patients (64% females) with a mean age of 46.86±7.3 years. Two cases (8%) in group A required repetition of the repair due to suboptimal result (*p*=0.018) while 1 case (4%) with pericardial strip annuloplasty repair was repeated due to moderate TR upon TEE.

Replacement with porcine prosthesis following a failed repair was done in one case (4%) in group A and One case (4%) in group C who underwent a pericardial strip annuloplasty.

There was no statistical difference as regards the mechanical ventilation times in hours while the length of ICU stay was significantly longer in group B (d.f=2, F=4.54, *p*=0.014).

There was a significant improvement of the NYHA class among the operated patients. Group B has the most significant improvement of the NYHA class as compared to the other groups. There was no statistically significant difference as regards mortality.

There was a statistically significant improvement of the LV and RV function as well as reduction of left atrial and left ventricular dimension among the studied groups. The RVSP has a significant drop among the groups and duration of follow-up.

Logistic regression analysis was used to identify positive predictors of repair failure were Tricuspid annular diameter >40mm in cases without ring annuloplasty (0.042), severe preoperative TR (*p*<0.001), and pre-operative heart failure (*p*=0.037).

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List of Abbreviations:

TR : Tricuspid regurgitation.
TEE : Transesophageal echocardiography.
NYHA : New York Heart Association.
LV : Left ventricle.
RV : Right ventricle.
RVSP : Right ventricular systolic pressure.
CT : Computed tomography.
CMR : Cardiac magnetic resonance imaging.
EROA : Effective regurgitant orifice area.
RVol : Regurgitant volume.
TAD : Tricuspid diastolic annular diameter.
CCT : Cross clamp time.
BT : Cardiopulmonary bypass time.
MACEs : Major Adverse Cardiac Events.
SD : Standard deviation.
ANOVA : One-Way Analysis of Variance test.
HSD : Tukey's Honest Significant Difference.
CI : Confidence interval.
BMI : Body mass index.
LVEF : Left ventricular ejection fraction.
LVEDD : Left ventricular end diastolic dimensions.
LVESD : Left ventricular end-systolic dimension.
RVEDD : Right ventricular end diastolic dimension.
TAPSE : Tricuspid annular plane systolic excursion.
ICU : Intenstive care unit.
INR : International normalization ratio.
SVT : Supraventricular tachycardia.
COVID : Corna Virus disease.
IQR : Interquartile range.
P-TAP : Autologous pericardial strip.
R-TAP : Prosthetic ring annuloplasty.
LAD : Left atrial diameter.

Conclusion: An early failure rate of Devega annuloplasty was higher than other techniques like pericardial strip annuloplasty. However, no failures were recorded in the segmental annuloplasty and the tricuspid ring repairs in our group of patients recording the least failure rate.

Key Words: Tricuspid – Annuloplasty, Tricuspid repair – Devega – Segmental tricuspid – Pericardial strip annuloplasty – Tricuspid ring.

Introduction

IT is now well established by European, American, and Japanese guidelines that conservative management of more than mild functional Tricuspid regurge (TR) is no longer amenable and treating the mitral valve alone does not cure the Reassociation of Functional TR with mitral valve, aortic valve or both was found to increase the mortality and early-late adverse outcomes **[1]**.

Assessment of TR needs clinical assessment as well as multimodality imaging via echocardiography, computed tomography (CT), as well as cardiac magnetic resonance imaging (CMR) **[1,2]**.

Guidelines provided a trustworthy definition of severe TR that complied with quantitative, semi-quantitative, and qualitative standards. The definition of the quantitative measurement cut-points effective regurgitant orifice area (EROA) $\geq$0.40cm^2 and regurgitant volume (RVol) $\geq$45ml was agreed upon with a notable diastolic annular diameter (TAD) of >40mm, or more than 21mm/m^2 in the apical four-chamber view **[3]**.

Despite the major advances in tricuspid annuloplasty rings and even new transcatheter devices, the optimal method of management of this pathology remains controversial. A Myriad of surgical TV repair techniques were proposed. Suture based annuloplasty techniques include Devega and modified Devega repairs, segmental (Antunes') and modified segmental repairs, Modified semicircular constricting annuloplasty (Sagban's), and edge to edge and clover leaf repairs (Alfieri's). While ring annuloplasty techniques include autologous pericardial strip, Dacron band, and ring bases repairs. Combinations and sub-valvular repair have been novelly reported **[1-3]**.

This research endeavored to study the feasibility and short-term results of different surgical techniques in the repair of tricuspid valve regurgitation in adults.

Patients and Methods

This single center, prospective, multi-arm, parallel, randomized, controlled, triple blinded, study (clinical superiority design) was conducted for all patients operated for Tricuspid valve regurgitation in scope of concomitant mitral valve replacement at the Department of Cardiothoracic surgery, Cardiothoracic and Vascular Surgery Center (CVSC) of Mansoura University, Egypt from September 2017 to January 2021.

Eligible were (75) consecutive patients who underwent TV repair with concomitant cardiac mitral procedures who were adult patients with TR of all encountered pathologies requiring repair. Redo cardiac patients except previous tricuspid repair and-patients with poor ventricular functions and pulmonary hypertension were included. Excluded were patients with infective pathology that requires replacement, Redo tricuspid valve repairs, pregnancy, and refusing the enrollment in the study.

Patients were randomized and numbered using computer generator software into three arms (at a ratio of 1:1:1 and block size of three). The patients were allocated sequentially to the study arms in chronological order as per the generated sequence. Triple blindness was adopted as the randomly generated concealed list was kept by the chief resident of the department, Triple blindness was adopted (Participant, Care Provider, Investigator, and Outcomes Assessor were masked).

Patients were randomly stratified into 3 equal groups: Group A (De-Vega Annuloplasty, n=25), Group B (Segmental Annuloplasty, n=25), and Group C (other valvuloplasty techniques; Kays's repair n=8, pericardial strip annuloplasty n=8 and ring annuloplasty n=9). All cases were assessed preoperatively and postoperatively at 2 weeks, 3 months and 6 months.

All patients received their preoperative and intraoperative settings according to the standards of open cardiac surgery. All cases were operated via full median sternotomy. After finishing mitral surgery first, cross-clamp removal and on a beating heart, the right atriotomy was done while snaring vena cavae. The valve was intraoperatively assessed anatomically using visualization and inspection of the leaflets as well as the measurement of the tricuspid annulus using a ruler.

In group A, a typical DeVega procedure (single pledgeted 2/0 Ethibond sutures from the posteroseptal to the anteroseptal commissure with a pledget at each end). Two sequential sutures were placed in this fashion in a clockwise direction through the annulus and tightened. (Fig. 1-A).

In group B, the first stitch of pledged-supported 2-0 Ethibond suture was placed in the region of the septal commissure to protect the coronary sinus from injury. The subsequent stitches were positioned in a counter- clockwise fashion. The interrupted stitches follow the line that marks out the tricuspid ring and were placed until the zone of the anteroseptal commissure was attained. In general, 5 or 6 stitches were required to be placed to finish the annuloplasty. The first suture was passed in a counter-clockwise direction as a circular stitch from the posterior-septal commissure to the middle of the anterior leaflet. Deep bites are taken every 5 to 6mm into the endocardium and fibrous ring at the junction of the TA and RV free wall. The second limb of the first suture was run parallel to and 1 to 2mm outside the previous suture in the same counter-clockwise direction. At the middle of the anterior leaflet, both sutures were put through a second teflon pledget. The two sutures were then tightened and tied, creating a purse string effect to shrink the length of the anterior and posterior segments of the TA and provide sufficient leaflet coaptation. (Fig. 1-B).

Group C was a mosaic group that included 3 techniques. Autologous pericardium ring annuloplasty was started at the commissure of coronary sinus and septal leaflet and continued counterclockwise through the commissure of anterior and posterior leaflets. The second suture was started at the commissure of anterior and septal and continued clockwise to commissure of anterior and posterior leaflets. The size of the TA was adjusted according to desired annular diameter. Subsequently, fresh autologous pericardium tissue strip was sewed to the tricuspid annulus and parachuted then the sutures were tied. (Fig. 1-C).

Kay's technique involved annulorrhaphy of the posterior segment. The resultant perpendicular forces on the TA in Kay's repair obliterate the posterior tricuspid leaflet. The first arm of the support suture was placed along the posterior annulus. The second arm of the support suture finalized the pledgeted mattress. Ring annuloplasty was performed by choosing right size of the ring by measurement of the distance from the antero-septal to postero-septal commissures (i.e., the surface of the anterior leaflet) and the ring was then inserted using eight to ten 2-0 Ti-cron stitches starting posteriorly (at the midpoint of the septal leaflet) and then proceeding counterclockwise. (Fig. 1-D).

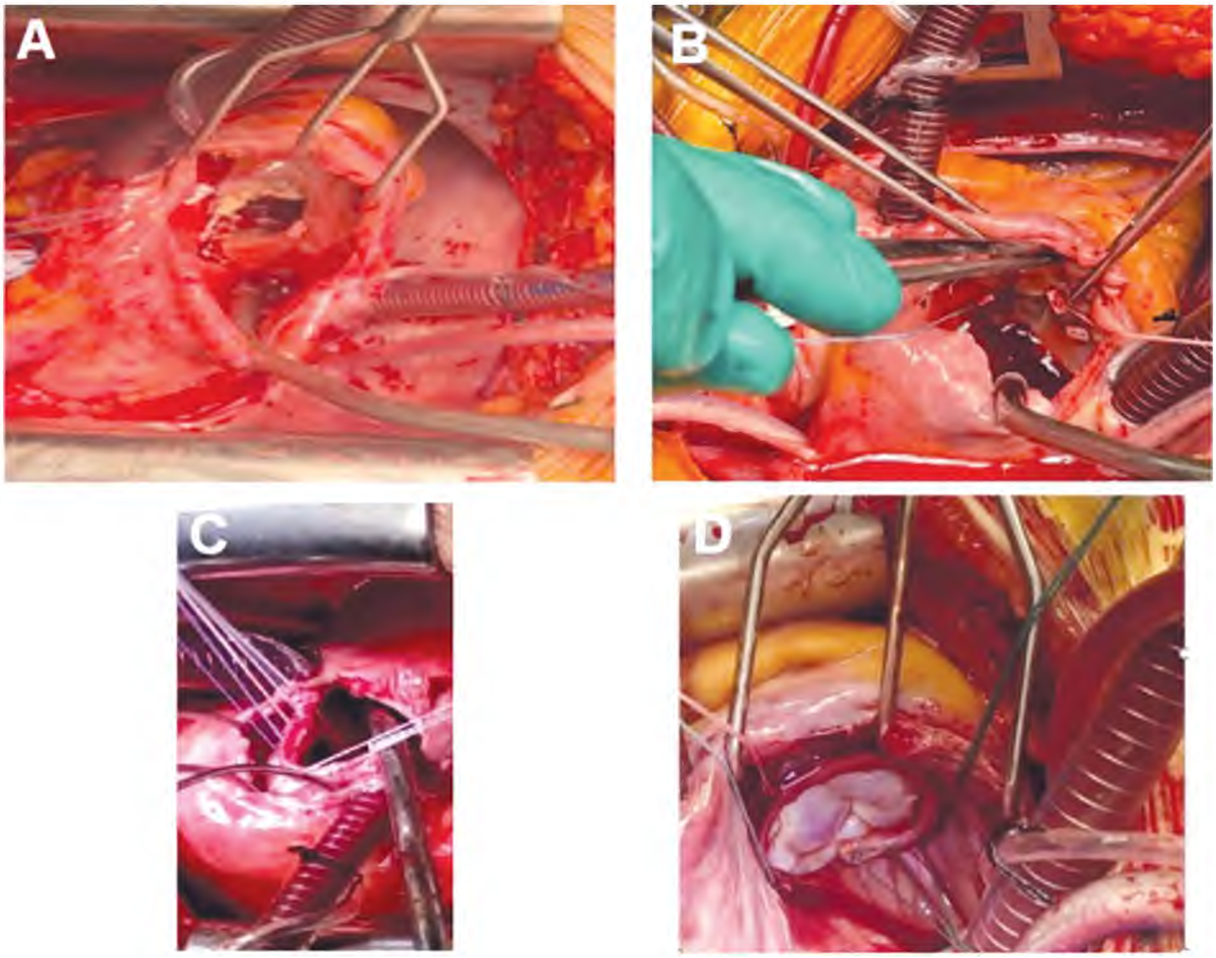

Fig. (1): Operative picture of tricuspid valve annuloplasty. (A) Devega repair, (B) Segmental repair, (C) Pericardial strip annuloplasty, (D) Ring annuloplasty.

All patients received standard post-operative care for cardiac surgery.

In the 3 groups during the repair, a 31 or 33mm Carpentier-Edwards valve sizer was introduced to avoid the unintentional formation of tricuspid stenosis by an overzealous correction or the orifice should be able to admit 2.5 to 3 finger breadths tightly through the valve, or a 30-mm Hegar sizer may be used before tying prevent over correction leading to iatrogenic tricuspid stenosis. The valve was re-tested using pressurized saline injection under direct vision.

Outcome measures:

Primary Outcome measure was intraoperative and early postoperative include repair failure measured by the degree of tricuspid regurgitation by echocardiography (None/ trace – mild – moderate – Severe).

Secondary outcomes included: Need for Pacemaker placement, Hospital morbidity and mortality at 30 days, Cross clamp time (CCT) and cardiopulmonary bypass time (BT), Ventilation time in hours, ICU stay in days, Hospital stay in days. Post-operative echo was done to verify the success of the repair and Post-operative patient symptoms were reassessed regarding dyspnea according to NYHA class.

Post-operative complications anticipated included: Major Adverse Cardiac Events (MACEs), respiratory complications, deep sternotomy wound infections, Need for surgical re-exploration, Arrhythmias, Readmission and reoperation within 30 days.

Follow-up:

Follow-up was done at 2^{nd} week, 3 months, and 6^{th} months, post-operatively using clinical examination and echocardiography.

Statistical analysis:

The data were tabulated and analyzed using IBM SPSS software package version 24.0 (IBM Inc., Chicago, IL, USA). Qualitative data were depicted using number and percentage. Quantitative data were designated using interquartile range, mean, standard deviation (SD).

Pairwise Comparison between distinct groups concerning categorical variables were checked using Chi-square test ($\chi 2$-test). When more than 20% of the cells expected count less than 5, correction for chi-square was conducted using Fisher's exact test or Monte Carlo correction. For normally distributed data, comparison between two independent populations were done using *t*-test. For abnormally distributed data, the Mann-Whitney Z test and Wilcoxon signed ranks tests were used.

Comparison between the 3 groups or different follow-up times regarding the quantitative data with parametric distribution was done using the One-Way Analysis of Variance test (ANOVA). Tukey's Honest Significant Difference (HSD was used to assess the significance of differences between pairs of group means follow-up to one-way ANOVA.

The confidence interval was set to 95% and the margin of alpha error accepted was set to 5%. So, the *p*-value was considered significant as the following: $p>0.05$: Non-significant, $p\leq 0.05$: Significant, and $p<0.01$: Highly significant. Survival analysis and freedom from moderate to severe TR and dyspnea of NYHA class III or more were tested and displayed using time to event Kaplan Meier curves. Binary Logistic regression was done to discover the independent predictors of tricuspid repair failure.

Results

Included were 75 patients (64% females) with a mean age of 46.86±7.3 years (24-59) years. Group A patients underwent De-Vega Annuloplasty (n=25), Group B patients underwent Segmental Annuloplasty (n=25), and Group C patients underwent other valvuloplasty techniques (n=25 (8 cases of Kay's repair or bicuspidization, 8 cases of pericardial strip annuloplasty and 9 cases of ring annuloplasty).

Demographic data of the studied cases are mentioned in Table (1). Our results show group B had significantly older patients compared to the group A and group C ($p=0.0003$ and $p<0.00001$ respectively). Group A vs Group B: Diff=8.3400, 95%CI=3.4603 to 13.2197, $p=0.0003$. Group B vs Group C: Diff=-11.3000, 95%CI= [-16.1797 to -6.4203], $p=<0.00001$. Critical f=16.5164. Females were significantly more than males across all groups ($p<0.0001$). Group B had a significantly higher BMI compared to Group A ($p<0.00001$) and to group C ($p=0.0056$). There was no statistically significant difference between groups A and C.

EuroSCORE II was observed to be significantly higher in group B after ANOVA shows a level of significance of ($p<0.0001$). Group A vs Group B ($p<0.00001$). Group A vs Group C: ($p=0.0487$). Group B vs Group C: ($p<0.00001$).

There was no statistical significance among groups regarding the mean NYHA class. Patients are presented with one or multiple clinical symptoms. Patients in group C were presented with a significantly higher number of cases with atrial fibrillation $p<0.001$. (Table 2).

Most of the patients were diagnosed with mitral stenosis ($p=0.03$). patients of group B had a significantly higher rate of mitral regurge ($p<0.001$), while patients in group C had a prevalence of double mitral lesion ($p=0.02$). There was a statistically significant difference among the groups regarding the LVEF% (*p*=0.0005) and the left ventricular end diastolic dimensions (LVEDD) (*p*=0.0001). LVEDD preop revealed statistically significant differences between the groups. (Table 3).

Our data shows that Right ventricular end diastolic dimension (RVEDD) was significantly higher in Group C (*p*=0.0121). A significant relation was found between Group A vs Group C: *p*=0.0091, while Group A vs Group B and Group A vs Group C: failed to show statistically significant difference. (Table 4).

Regarding the Tricuspid annular plane systolic excursion (TAPSE), group B had a significantly higher TAPSE (F=3.302, *p*=0.042). ANOVA revealed statistically significant difference between Groups B and C (Diff=–2.5000, 95%CI=–4.8287 to –0.1713, *p*=0.0325). Group C had the significantly higher prevalence of cases with moderate and severe RV dysfunction (*p*=0.0, and <0.001 respectively). (Table 4).

Studying the right ventricular systolic pressure (RVSP) that corresponds to the pulmonary artery systolic pressure reveals no statistical significance among the groups (F=1.55, *p*=0.219). While Group C had significantly higher cases of severe pulmonary hypertension compared to the other groups (*p*= 0.01). Studying the TV, the data shows that group B had a significantly higher number of cases with severe TR (*p*<0.001). Also noted that the Tricuspid annular size was significantly larger in group C patients (*p*=0.013). (Table 4).

Regarding the operative data, Cross clamp and bypass times showed no statistically significant differences among the groups following ANOVA analysis. (Table 5).

Repair revisions and conversions: Two cases (8%) in the Devega group required repetition of the repair due to suboptimal result after saline test (*p*=0.018) while 1 case (4%) with pericardial strip annuloplasty repair was repeated due to moderate TR upon TEE. (Table 5).

One case (4%) in the Devega repair group required replacement due to failed repair and widely dilated annulus in one case and thickened valve leaflets in one case.

One case (4%) in group C who underwent a pericardial strip annuloplasty that had a mod TR upon saline test with a thickened structure of the valve, replacement was done using a porcine prosthesis. (Table 5).

Table (1): Baseline demographic and clinical data.

Demographic and clinical data	Group A De-Vega (n=25)	Group B Segmental (n=25)	Group C Others (n=25)	Overall Sample (n=75)	*p*-value
Age at surgery (years):					
Mean ± SD	42.38±6.52	50.72±4.35	39.42±9.72	46.86±7.3	<0.001*
Range	32-52	36-59	24-53	24-59	
Male/Female, n	7/18	12/13	8/17	27/48	<.0001*
Female gender, n (%)	18 (72)	13 (52)	17 (68)	48 (64)	
Weight (kg), mean ± SD	75.7 ± 13.2	90.47± 8.7	85.1 ± 12.2	86.2±11.52	<.0001*
Length (cm), mean ± SD	169.3 ± 9.8	170.7±5.6	172.2 ± 10.2	170.4 ± 9.6	N.S.
Body surface area, m^2	1.71-2.2	1.72-2.06	1.85-2.11	1.71-2.2	N.S.
BMI (kg/m^2), median	25.7	27.4	26.9	26.7	0.003
Range	23.4-28.7	24.5-29.6	25.7-31.6	23.4-31.6	
Hypertension, n (%)	2 (8)	4 (16)	2 (8)	7 (9.33)	N.S.
Diabetes, n (%)	1 (4)	3 (12)	1 (4)	9 (12)	N.S.
Hypercholesterolemia, n (%)	3 (12%)	2 (8)	0	5 (6.67)	N.S.
Coronary Artery disease, n (%)	0	1 (4)	0	1 (1.33)	N.S.
MV Infective endocarditis, n (%)	1 (4)	0	1 (4)	2 (2.67)	N.S.
Smoker, n (%)	4 (16)	5 (20)	8 (32)	17 (22.7)	N.S.
Ex-smoker, n (%)	1 (4)	3 (12)	2 (8)	5 (5.3)	
Never smoked, n (%)	20 (80)	17 (68)	15 (60)	53 (70.6)	
COPD, n (%)	5 (20)	7 (28)	9 (36)	21 (28)	N.S.
Status Post COVID pneumonia	2 (8)	3 (12)	1 (4)	6 (8)	N.S.
Renal failure, n (%)	2 (8)	4 (16)	3 (12)	9 (12)	N.S.
Renal Dialysis, n (%)	1 (4)	0	1 (4)	2 (2.67)	
Viral hepatitis C	7 (28)	5 (20)	2 (8)	14 (18.67)	0.04*
PVD, n (%)	0	1 (4)	0	1 (1.33)	N.S.
CVA, n (%)	1 (4)	0	1 (4)	2 (2.67)	N.S.
Beta-blockers, n (%)	19 (76)	17 (64)	13 (52)	49 (65.3)	N.S.
ACE inhibitor, n (%)	6 (24)	8 (32)	12 (48)	26 (48)	N.S.
Redo mitral surgery, n (%)	3 (12)	4 (16)	2 (8)	9 (12)	N.S.
Logistic EuroSCORE II %:					
Mean	7.4± 1.3	12.62± 2.1	8.61± 1.8	9.54±2.3	<0.001
Range	.56-37.4	2.22-49.3	1.85-61.19	.56-61.19	

Table (2): Preoperative patient symptomatology and clinical assessment.

Patient symptomatology and clinical assessment	Group A De-Vega (n=25)	Group B Segmental (n=25)	Group C Others (n=25)	Overall Sample (n=75)	*p*-value
*Clinical presentation n (%) *:*					
Dyspnea/congestive symp.	14 (56)	18 (72)	12 (48)	44 (58.67)	0.02
Palpitations	18 (72)	15 (60)	17 (68)	50 (92)	N.S.
Chest pain	4 (16)	3 (12)	5 (20)	12 (16)	0.06
Syncopal attacks	0	1 (4)	0	0	N.S.
NYHA class, mean ± SD:	2.4 ± 0.9	2.3±1.2	2.7 ± 1.1	2.5±1.1	N.S.
NYHA I, n (%)	2 (8)	1 (4)	1(4)	4 (5.3)	N.S
NYHA II, n (%)	11 (44)	9 (36)	12 (48)	32 (42.7)	
NYHA III, n (%)	8 (32)	12 (48)	10 (40)	30 (40)	
NYHA IV, n (%)	4 (16)	3 (12)	2 (8)	9 (12)	
Preoperative Cardiac Rhythm, n (%):					
Atrial fibrillation	10 (40)	8 (32)	15 (60)	33 (44)	<0.001
Complete heart block/paced	0	0	1 (4)	1 (1.33)	N.S.
Ventricular arrhythmia	0	1 (4)	0	1 (1.33)	N.S.
Post mitral interventions, n (%):	4 (16)	4 (16)	2 (8)	10 (13.33)	N.S.
Balloon mitral commissurotomy.	1 (4)	0	1 (4)	2 (2.67)	
Surgical mitral Commissurotomy.	2 (8)	1 (4)	0	3 (4)	
Mitral valve replacement	1 (4)	3 (12)	1 (4)	5 (6.67)	

*Data in this category are not mutually exclusive.

Table (3): Baseline echocardiographic data of the mitral valve and the left side of the heart.

Preoperative echo findings	Group A De-Vega (n=25)	Group B Segmental (n=25)	Group C Others (n=25)	Overall Sample (n=75)	*p*-value
MV pathology, n (%):					
Rheumatic	23 (92)	22 (88)	23 (92)	68 (90.66)	NS
Post IE	1 (4)	0	1 (4)	2 (2.67)	NS
Prosthetic MV dysfunction	1 (4)	3 (12)	1 (4)	5 (6.67)	
Mitral stenosis, n (%)	16 (64)	10 (40)	11 (56)	37 (49.3)	0.03
Mitral regurgitation, n (%):	4 (16)	8 (32)	2 (8)	14 (18.67)	<0.001
Moderate	1 (4)	0	0	1 (1.33)	
Severe	3 (12)	8 (32)	2 (8)	13 (17.33)	
Double mitral lesion, n (%):	5 (20)	7 (28)	12 (48)	24 (32)	0.02
LA dimension (cm)	6.8±1.32	6.3±3.14	6.9±0.88	6.7±2.57	1.139
LVEDD (cm)	4.9±0.6	5.41±0.72	5.76±0.62	5.57±0.67	0.0001
LVESD (cm)	3.21±0.6	3.44±0.51	3.87±0.62	3.21±0.42	NS
LVEF % (mean ± SD):	64±3.57	61.87±4.52	60.34±3.17	62.87±3.34	0.0005
≥60%, n (%)	16 (64)	12 (48)	10 (40)	38 (50.67)	
40-59%, n (%)	9 (36)	13 (52)	15 (60)	37 (49.33)	
20-39%, n (%)	0	0	0	0	

Table (4): Baseline echocardiographic assessment of the Tricuspid valve and the right side of the heart.

Preoperative echo findings	Group A De-Vega (n=25)	Group B Segmental (n=25)	Group C Others (n=25)	Overall Sample (n=75)	*p*-value
RVEDD (cm)	2.16±0.46	2.35±0.38	2.64±0.76	2.32±0.57	0.012*
TAPSE (mm):	18.6±3.56	19.9±0.68	17.4±4.73	18.21±2.74	0.042*
No dysfunction, n (%)	12 (48)	15 (60)	10 (40)	37 (49.33)	NS
Mild dysfunction, n (%)	9 (36)	6 (24)	4 (16)	19 (25.33)	NS
Moderate dysfunction, n%	4 (16)	3 (12)	7 (28)	14 (18.67)	0.03
Severe dysfunction, n (%)	0	1 (4)	4 (16)	5 (6.67)	<0.001
RVSP (PAP) systolic (mmHg):	49.2±12.5	46.3±14.7	53.76±17.6	48.43±15.2	NS
Normal / Mild (<30 mm Hg)	0	0	1 (4)	1 (1.33)	NS
Moderate (31-55 mm Hg)	22 (88)	17 (68)	13 (52)	52 (69.33)	NS
Severe (>55 mm Hg)	3 (12)	8 (32)	11 (44)	22 (29.33)	0.01
Grade of tricuspid regurge:					
Grade I (none / trace)	0	0	0	0	
Grade II (mild)	0	0	0	0	
Grade III (moderate)	6 (24)	4 (16)	7 (28)	17 (22.67)	NS
Grade IV (severe)	19 (76)	21 (84)	18 (72)	58 (77.33)	<0.001*
Preoperative TA size (mm)	37.4±4.5	35.3±4.2	38.9±3.9	36.4±4.5	0.013*
Tricuspid valve annular index (mm/m^2)	20.77±2.4	19.65±2.2	20.23±1.8	19.82±2.1	NS
Functional TR	25 (100)	25 (100)	25 (100)	75 (100)	NS

Table (5): Operative data of the studies patients (n=75).

Operative finding	Group A De-Vega (n=25)	Group B Segmental (n=25)	Group C Others (n=25)	Overall Sample (n=75)	*p*-value
Repair technique n (%)	Devega 25 (100)	Segmental 25 (100)	Bicuspidization 8 (32) Pericardial strip 8 (32) Ring annuloplasty 9 (36)		
Failure of repairs:	3 (12)	0	2 (8)	5 (6.67)	
Repetition for suboptimal repair	2 (8)	0	1 (4)	3 (4)	NS
Replacement with bio prosthesis	1 (4)	0	1 (4)	2 (2.67)	0.018
Operative timings:					
CBT (min), mean (SD)	95.24±24.31	93.14±19.47	93.14±19.47		NS.
CCT (min), mean (SD)	65.7±15.25	59.87±12.71	59.87±12.71		
Concomitant procedure:					
Mitral valve surgery:					
Procedure, n (%):					
Replacement	25 (100)	25(100)	25 (100)	75 (100)	NS
Implant, n (%):	16 (64)	10 (40)	11 (56)	37 (49.3)	
Mechanical valve	22 (88)	24 (96)	25 (100)	71 (94.67)	<0.001
Xenoprosthesis (biological)	3 (12)	1 (4)	0	4 (5.33)	
Mitral valve prosthesis size (mm) n (%):					
25 mm	4 (16)	0	1 (4)	5 (6.67)	<0.001
27 mm	17 (68)	12 (48)	18 (72)	47 (62.67)	
29 mm	3 (12)	9 (36)	6 (24)	18 (24)	
31 mm	1 (4)	4 (16)	0	5 (6.67)	
Explanted stuck prosthesis	1 (4)	3 (12)	3 (12)	5 (6.67)	
Urgency of surgery:					
Elective	15 (60)	17 (68)	18 (72)	50 (32.24)	<0.001
Urgent	9 (36)	5 (20)	6 (24)	20 (26.67)	
Emergency	1 (4)	3 (12)	1 (4)	5 (6.67)	
Salvage	0	0	0	0	

Thus, an early failure rate of 12% was recorded in cases of Devega annuloplasty, while pericardial strip annuloplasty had 8% failure, while no failures were recorded in the segmental annuloplasty and the tricuspid ring repairs in our group of patients.

Regarding the early postoperative complications, There was no statistical difference as regards the mechanical ventilation times in hours, while the length of ICU stay was significantly longer in group B patients after ANOVA analysis (d.f=2, F=4.54, *p*=0.014). The mean ICU stays in hours were 52.28±8.46, 58.38±7.45, and 56.74±6.14 in the 3 groups respectively. (Table 6).

The postoperative complications and major adverse cardiac events are present in Table (6). A total of 4 (5.3%) out of 9 (12%) required resternotomy for bleeding. Six cases (8%) were readmitted within 30 days due to uncontrolled INR that was significantly encountered in group B (*p*=0.018). Two cases were admitted for massive pericardial effusion due to uncontrolled INR. A total of 8 patients encountered rapid AF. One case with stuck mitral valve developed SVT. A total of 6 (8%) of cases encountered a second-degree heart block that resolved spontaneously within 24-48 hours. A total of 7 cases had prolonged mechanical ventilation. Three cases developed acute kidney injury of which one case had multiorgan.

Group C had 1 case of deep sternotomy wound infection. One case in group B presented with stuck mitral valve with a low cardiac output state that was complicated by multiorgan failure and mortality at 10 days post operatively. COVID pneumonia was the cause of death of 1 patient in Group A after 5 months and group C after 4 months.

Postoperative clinical evaluation revealed a significant improvement of the NYHA class among the operated patients. Group B has the most significant improvement of the NYHA class as compared to the other groups. All cases were assessed preoperatively, 2 weeks post op, 3 months and 6 months post operative. (Table 7).

Echocardiographic parameters of the TV grading show significant improvement following the repair in all groups with grading of TR decreasing upon follow-up as shown in Table (8).

Table (6): Operative and postoperative morbidity and mortality among the studied patients.

Complications n (%)	Group A De-Vega (n=25)	Group B Segmental (n=25)	Group C Others (n=25)	Overall Sample (n=75)	*p*-value
High drainage	4 (16)	2 (8)	3 (12)	9 (12)	NS
Re-sternotomy for bleeding	2 (8)	1 (4)	1 (4)	4 (5.3)	NS
Re-admission within 30 days:	2 (8)	3 (12)	1 (8)	6 (8)	NS
Uncontrolled INR	2 (8)	3 (8)	0	5 (6.67)	0.018
Massive pericardial effusion	1 (4)	1 (4)	0	2 (2.67)	NS
Mitral prosthesis dysfunction	1 (4)	0	1 (4)	2 (2.67)	NS
Prolonged ventilation	1 (4)	4 (16)	2 (8)	7 (9.3)	0.018
Respiratory complications	2 (8)	2 (8)	3 (12)	7 (9.3)	NS
Arrhythmias:	3 (12)	5 (20)	7 (9.3)	15 (20)	NS
Rapid AF	1 (4)	3 (12)	4 (16)	8 (10.67)	0.03
SVT	0	1 (4)	0	1 (1.33)	NS
Heart block	2 (8)	1 (4)	3 (12)	6 (8)	NS
Pacemaker:					
Temporary	2 (8)	1 (4)	3 (12)	6 (8)	0.041
Permanent	0	0	0	0	0.018
Renal failure	1 (4)	2 (8)	0	3 (3.27)	NS
Multi organ failure	0	1 (4)	0	1 (1.33)	NS
Stroke	0	1 (4)	0	1 (1.33)	NS
Sepsis	1 (4)	0	0	1 (1.33)	NS
DSWI	0	0	1 (4)	1 (1.33)	NS
TIA	0	0	0	0	NS
Low cardiac output	0	1 (4)	0	0	
Perioperative MI	0	0	0	0	
Operative death, n (%):					
Cardiac	0	1 (4)	0	1 (1.33)	NS
Non cardiac	0	0	0	0	
Late mortality:					
COVID pneumonia	1 (4)	0	1 (4)	2 (2.67)	0.135

Table (7): Distribution of the dyspnea NYHA class among the patients.

NYHA Dyspnea Classification n (%)	NYHA I	NYHA II	NYHA III	NYHA IV	p-value
	Group A (De-Vega) (n=25 – 1 morality at 5M)				
Preoperative	0	0	6 (24)	19 (76)	<0.0001
2W Post operative	1 (4)	19 (76)	3 (12)	2 (8)	<0.0001
3 months PO	19 (76)	5 (20)	1 (4)	0	<0.0001
6 months PO	22(91.67)	2 (8.3)	0	0	<0.0001
Died (COVID)	1 (4)				
	Group B (segmental) (n=25 – 1 mortality at 10D)				
Preoperative	0	0	4 (16)	21 (84)	<0.0001
2W Post operative	8 (33.33)	13 (54.17)	2 (8.33)	1 (4.17)	<0.0001
3 months PO	20 (83.33)	3 (12.5)	1 (4.17)	0	<0.0001
6 months PO	21 (87.5)	2 (8.33)	1 (4.17)	0	<0.0001
	Group C (Others) (n=25 – 1 mortality at 4M)				
Preoperative	0	0	7 (28)	18 (72)	<0.0001
2W Post operative	3 (12)	15 (60)	5 (20)	2 (8)	<0.0001
3 months PO	18 (72)	6 (24)	1 (4)	0	<0.0001
6 months PO	21 (87.5)	3 (12.5)	0	0	<0.0001

Table (8): Distribution of grades of TR in preoperative and post operative aspects.

Tricuspid valve echo findings	Grade I (None/Trace)	Grade II (Mild)	Grade III (Moderate)	Grade IV (Severe)	p-value
	Group A (De-Vega) (n=25 – 1 morality at 5M due to COVID pnemumonia)				
Preoperative	0	0	6 (24)	19 (76)	<0.0001
2W Post operative	20 (80)	2 (8)	3 (12)	0	<0.0001
3 months PO	22 (88)	2 (8)	1 (4)	0	<0.0001
6 months PO	20 (83.33)	3 (12.5)	1 (4.16)	0	<0.0001
	Group B (segmental) (n=25 – 1 mortality at 10D due to LCO, MOF)				
Preoperative	0	0	4 (16)	21 (84)	<0.0001
2W Post operative	20 (83.3)	2 (8.33)	2 (8.33)	0	<0.0001
3 months PO	21 (87.5)	3 (12.5)	0	0	<0.0001
6 months PO	22 (91.67)	2 (8)	0	0	<0.0001
	Group C (Others) (n=25 – 1 mortality at 4M due to COVID pneumonia)				
Preoperative	0	0	7 (28)	18 (72)	<0.0001
2W Post operative	22 (88)	2 (8)	1 (4)	0	<0.0001
3 months PO	23 (92)	2 (8)	0	0	<0.0001
6 months PO	22 (91.67)	2 (8.33)	0	0	<0.0001

There was a statistically significant improvement of the LV and RV function as well as reduction of left atrial and left ventricular dimension among the studied groups. The RVSP has a significant drop among the groups and duration of follow-up as depicted in Table (9).

Logistic regression analysis was used to identify the independent predictors for tricuspid repair failure. The only positive predictors of tricuspid valve failure were Tricuspid annular diameter >40mm in cases without ring annuloplasty (0.042), severe preoperative TR (p<0.001), and preoperative heart failure (p=0.037). Other parameters failed to show statistical significance probably due to the very low number of events.

Table (9): Echocardiographic assessment of the right and left ventricular functions in preoperative versus postoperative setting.

Preoperative echo findings	*Group A De-Vega* (n=25)	*Group B Segmental* (n=25)	*Group C Others* (n=25)	ANOVA	*p*-value
RVEDD (cm):					
Preop	*2.16±0.46*	*2.35±0.38*	*2.64±0.76*	*F=4.69*	0.012
2W post op	*2.72±0.34*	*2.83±0.63*	*3.02±0.23*	*F=3.055*	*0.053*
3M post op	*2.31±0.31*	*2.57±0.53*	*2.72±0.37*	*F=6.28*	*0.0031*
6M post op	*2.09 ± 1.25*	*2.26 ± 0.92*	*2.62 ± 0.68*	F=1.921	0.15
	p<0.0001	*p*=0.0117	*p=0.045*		
RVSP (PAP) systolic (mmHg):					
Preop	*49.2±12.5*	*46.3±14.7*	*53.76±17.6*	F=1.55	0.219
2W post op	*45.47±6.23*	*43.75±5.32*	*47.51±6.21*	F=2.51	0.081
3M post op	*44.97±5.4*	*40.37±5.68*	*36.75±5.37*	*F=14.1*	<0.0001
6M post op	*42.56±8.4*	*36.74±6.32*	*31.52±7.87*	*F=13.27*	<0.0001
	p=0.063	*p*=0.002	*p*<0.0001		
LVEDD cm:					
Preop	*4.9±0.6*	*5.41±0.72*	*5.76±0.62*	F=11.11	0.0001
2W post op	*4.6±0.64*	*4.92±0.97*	*5.27±0.38*	*F=5.634*	*0.0053*
3M post op	*4.37±0.47*	*4.57±3.74*	*4.94±0.38*	*F=0.437*	*0.647*
6M post op	*3.97± 0.67*	*4.22±5.47*	*4.57±3.75*	*F=0.153*	0.85
	p<0.0001	NS	NS		
LAD:					
Preop	*6.8±1.32*	*6.3±1.14*	*6.9±0.88*	*F=2.04*	*0.139*
2W post op	*6.07±0.78*	*5.7±0.78*	*5.9±0.34*	*F=1.93*	0.152
3M post op	*5.46±0.34*	*5.26±0.26*	*5.19±0.54*	*F=3.1*	0.05
6M post op	*5.25±0.43*	*5.12±0.54*	*5.07±0.65*	*F=0.69*	0.5
	p<0.0001	*p*<0.0001	*p*<0.0001		
LVEF %:					
Preop	*64.7 ± 3.57*	*61.87±4.52*	*60.34±3.17*	*F=8.49*	0.0005
2W post op	*62.24±2.17*	*59.34±3.14*	*58.21±4.15*	F=10.19	0.0001
3M post op	*60.64±3.54*	*58.63±2.97*	*58.74±3.14*	*F=3.07*	*0.053*
6M post op	*59.74±0.43*	*57.3 ± 4.7*	*58.3 ± 3.7*	*F=3.31*	*0.049*
	p<0.0001	*p*=0.0009	NS		

Discussion

In this prospective randomized controlled trial that included 75 patients, we performed a comparison of three arms for different techniques of tricuspid valve repair in adults in concomitance with mitral valve surgery with the majority encountered being secondary tricuspid regurgitation despite our intention to include all tricuspid valve pathologies with regurgitation. Our study question was which annuloplasty technique is better in terms of short-term outcomes. We tried to explore the different predictors of repair failure.

Regarding baseline demographic data, the low *mean age in our study is 46.86 years (IQR 24-59) and the female predominance (64%) of our patients.* Rheumatic fever, which is endemic in most developing countries including Egypt affecting predom*inantely females which was reflected on our study* groups. Our results regarding patient demographics came in accordance with results from multiple studies in this regard [4-6]. Other studies that disagreed *had a higher mean age of 60 years plus with male* predominance [7-9].

Regarding the preoperative clinical presentation and patients' functional status, our patients had 2.5 as a mean NYHA class. NYHA functional class II *(42.7%) and III (40%) with only (6.67%) being redo* cases. Most studies came in agreement with our results [7,9]. Other studies had higher rates of redo cases and larger number of patients with NYHA IV dyspnea class [10-12]. This variation of results can be attributed to the country where the patients had presented for treatment, adequacy of medical treatment and levels of medical care across the different centers.

Regarding the preoperative mitral valve and tricuspid valve pathologies, Rheumatic mitral valve *disease is the main pathology represents 90.7% of cases, while only 2.7% were diagnosed with post IE of the mitral valve and 6.7% had an emergency of* mitral prosthesis dysfunction. In this regard, results of multiple studies in literature were variable according to the predominant pathology at the country of the study being performed. Navia et al., [10] *included Only 20% of the cases that had rheumatic mitral pathologies, while the majority of 32% were* degenerative lesions. They also included multiple aortic and mitral pathologies of different etiologies.

*Regarding our preoperative findings of the tri-*cuspid valve and the right side of the heart. All the cases encountered were diagnosed with functional

TR. Most studies showed a variable percentage of RV dysfunction among patients where cases with severe RV dysfunction had better results with ring annuloplasty *[10,13-15]*.

Concerning the operative data, the cross clamp and bypass times were within average with no significant difference among the groups. We had 3 groups who underwent tricuspid repair using 6 different techniques. There was a vast variety and combinations of procedures across different studies. Navia et al., *[10]* divided tricuspid valve repair techniques into 8 groups .6 isolated to 1 level annular using (flexible ring [standard and 3-dimensional], rigid ring, Peri-Guard ring, and De Vega technique; commissural: Kay technique). Two involving 2 levels (edge-to-edge plus prosthetic annuloplasty, edge-to-edge plus Kay technique).

Regarding the ventilation time and ICU stay, in our study, the mean postoperative ICU stay was 55.32 hours (2.3 days) and the mean mechanical ventilation time was 6.62 hours with segmental group having the significantly longer ICU stay of 58.38 hours compared to the other groups. A total of 7 cases had prolonged mechanical ventilation. One case in group B presented with stuck mitral valve with a low cardiac output state that was complicated by multiorgan failure and mortality at 10 days postoperatively. The Lafçı et al., *[4]* study reported that postoperative need for positive inotropic support, duration of mechanical ventilation, and length of intensive care unit and hospital stay were significantly higher in the de Vega annuloplasty group.

Regarding perioperative morbidity and mortality, viewing our patient outcomes, A total of 4 (5.3%) out of 9 (12%) required re-sternotomy for bleeding but without statistical significance among the studied. Six cases (8%) were readmitted within 30 days due to uncontrolled INR that was significantly encountered in group B (***p***=0.018). Two cases were admitted for massive pericardial effusion due to uncontrolled INR that were aspirated under echocardiographic guidance.

Our study had a statistically significant increase in incidence of postoperative rapid AF and need for temporary pacing in group C compared to the other groups. A Total of 8 patients encountered rapid AF that was resolved using Amiodarone. One case with stuck mitral valve developed SVT that was treated using DC shock cardioversion. A total of 6 (8%) of cases encountered a second-degree heart block that was managed by temporary epicardial pacing and resolved spontaneously within 24-48 hours.

A total of 7 cases had prolonged mechanical ventilation. Three cases developed acute kidney injury, of which, one case had multiorgan failure required hemofiltration.

Group C had 1 case of deep sternotomy wound infection that was managed conservatively. One case in group B was presented with stuck mitral valve with a low cardiac output state that was complicated by multiorgan failure and mortality at 10 days post operatively. COVID pneumonia was the cause of death of 1 patient in Group A after 5 months and group C after 4 months. Multiple studies failed to find better survival among the different techniques *[4,16]*. Csanády et al., *[17]* mentioned a higher operative mortality in the De-Vega group.

Regarding the patient's postoperative functional status and ventricular function, All types of TV annuloplasty were associated with substantial improvement in NYHA functional class 6 months' post-operative compared to the preoperative NYHA class. It was observed that the segmental tricuspid annuloplasty group had the most significant improvement of the NYHA class IV to class I at 2 weeks post operative, while Devega and Kay groups had equal improvement from Class IV to class I at 6 months of follow-up yet without statistically significant difference. There was also statistically significant improvement of the LV and RV function as well as reduction of the left atrial and left ventricular dimensions among the studied groups. The RVSP had a significant drop among the groups upon follow-up. Fang et al., *[16]* on the contrary illustrated that early improved efficiency of TR after Cosgrove-Edwards annuloplasty is superior to Kay annuloplasty and DeVega annuloplasty.

Regarding the durability of the tricuspid repair techniques. The Devega annuloplasty in our study encountered 3 technical failures of Devega repair intraoperatively, for which 2 cases (8%) were revised and 1 case (4%) required replacement with bioprosthetic valve due to failed repair. Thus, an early intraoperative failure rate of 12% was recorded. Our study did not mention any short-term failures post operative and none of our patients required reoperation. The broken stitches and contracted or fallen apart leaflets were the main cause of failure of Devega repair in 10-40% of patients during mid and long-term follow-up. It works for low cost and being an effective alternative *[18,19]*. Khorsandi et al., *[18]* metanalysis stated that failure of Devaga repair is 20% and when repair is not augmented by the ring it will be predictor for reoperation.

Regarding the results of segmental repair, none of our cases encountered any technical failures or short-term recurrence of TR. Abual-Ela et al., *[14]* founded segmental repair is superior to Devaga repair with 85% free from TR at 6 months follow-up vs 75% free from Devaga group at 6 moths. 6.7% was the mortality rate which was caused by RV failure and LCO.

Regarding the results of Kay's repair (bicuspidization), none of our cases required perioperative revisions or replacement.

A large study by Hirji et al., *[20]* (324 Ring and 326 Suture-bicuspidization) mentioned a higher incidence of valve leakage, and reoperation in suture bicuspidization group at 1 year follow-up. Suture bicuspidization had 88.2% versus 96.6% in ring annuloplasty regarding freedom from TR recurrence at 1 year. While 30 days echo between the 2 groups shows significant difference regarding RV dysfunction was more in ring repair vs Devaga (10% versus 4%; p=0.03). The study shows the superiority of ring repair vs suture bicuspidization.

Autologous pericardial strip annuloplasty showed an intraoperative failure rate of 4% (1 case in our study) that required replacement with bio prosthesis. Nasso et al., *[21]* studied the findings of autologous pericardial strip (group P-TAP) in 109 patients versus prosthetic ring (group R-TAP) in 115 patients all with FTR. Freedom from death, all causes, were comparable among groups. There were no statistically significant differences between the two groups in TAPSE, LVESD, LVEF, and left atrial diameter. They concluded that the pericardial strip had non inferior results comparable to the ring.

Regarding results of the durability of tricuspid ring annuloplasty, we operated 9 cases (36% of group C) using tricuspid ring. There was no incidence of intraoperative failure of the repair. Gammie et al. *[7]* mentioned the likelihood of moderate or severe TR was 3% at 6 months postoperative. Benedetto et al., *[22]* mentioned thatOperative mortality was 4.5% in each group. At 1 year follow-up, there was no TR in 71% of the annuloplasty group. Moderate to severe tricuspid regurgitation (≥+3) was present in 0% of the annuloplasty group. They concluded thattricuspid valve annuloplasty in patients with dilated tricuspid annulus undergoing mitral valve surgery was linked to a reduced rate of TR progression, improved RV remodeling, and satisfactory functional outcomes.

This study had some shortcomings. The small sample size may decrease the power of conclusion and did not allow us to perform a proper multivariate analysis for the predictors of tricuspid valve failure or perform a subgroup analysis for group C. All the cases encountered were diagnosed with Functional TR despite our plan to include all tricuspid valve pathologies. The period of follow-up of the patients in our study was short compared to other studies. The study was conducted in times of COVID-19 pandemic where in person follow-ups were troublesome and respiratory complications were predominant, some patients had previous COVID pneumonia and received steroids which could have been confounding to the results.

Conclusions:

The techniques of tricuspid repair are comparable. There was a significant improvement in right and left ventricular dimensions, as well as the pulmonary artery pressures following surgery. There was a significant improvement in the clinical and functional status of the patient's following surgery. An early failure rate of Devega annuloplasty was higher than other techniques like pericardial strip annuloplasty. However, no failures were recorded in the segmental annuloplasty and the tricuspid ring repairs in our group of patients recording the least failure rate. There was no statistically significant difference as regards mortality among the patients who underwent the different techniques in our study.Most of failure of valve repair were related to a large tricuspid annular diameter >40mm, severe preoperative TR, and preoperative heart failure.A larger sample size and longer follow-up in a multicenter trial is required to establish mid- and long-term outcomes of different techniques.

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النتائج قصيرة الامدو طرق الإصلاح الجراحى لإرتجاع الصمام الثلاثى الشرفات بالقلب فى البالغين: دراسة اكلينيكية عشوائية مستقبلية

مع ظهور تقنيات اكثر تعقيدا وتطورا، باتت خيارات اصلاح الصمام الثلاثى تعطى نتائج افضل للمرضى.

تهدف هذه الدراسة المستقبلية العشوائية المضبوطة المعشاه ثلاثية التعمية لتقييم النتائج قريبة المدى لمختلف طرق اصلاح الصمام الثلاثى الشرفات مع جراحة استبدال الصمام الميترالى.

اجريت هذه الدراسة العشوائية المستقبلية على عدد خمسة وسبعين مريضاً يجرى لهم جراحة للصمام الثلاثى بقسم جراحة القلب والصدر، بكلية الطب، جامعة المنصورة، مصر وذلك فى الفترة من سبتمبر ٢٠١٧ وحتى يناير ٢٠٢١ .

الحالات التي تتضمنها الدراسة هى مريض يخضع للتدخل الجراحى لاصلاح الصمام الثلاثى بجانب اجراء جراحة للصمام الميترالى فى البالغين.

يستبعد جميع المرضى المصابون بعدوى بالصمام الثلاثى او النساء الحوامل او جراحة سابقة للصمام الثلاثى او الرافضون الانضمام للدراسة أو الحالات التى تم تشخيصها بألتهاب على الصمام الثلاثى يستلزم تغييره.

يحدد توزيع المرضى على المجموعات عشوائياًوتم تقسم الحالات إلى ثلاثة مجموعات:

– مجموعة (أ): اجراء اصلاح للصمام الثلاثى بطريقة دى فيغا (٢٥ مريض).

– مجموعة (ب): تم اجراء لها اجراء الثلاثى بطريقة الجزئية (٢٥ مريض).

– مجموعة (ج): تم لها اجراء الثلاثى بطرق اخري و تنقسم الى استخدام حلقة صناعية (٩ مرضى) او حلقة من الغشاء التامور (٨ مرضى) او تحويل الصمام الى ثنائى الشرفات (٨ مرضى).

كشفت الدراسة الحالية عن النتائج التالية:

١– تحسن كبير فى كفائة البطينين الايمن والايسر للقلب فى المجموعات خلال فترة ما بعد الجراحة.

٢– فرق ذو دلالة إحصائية فى انخفاض ضغط الشريان الرئوى.

٣– نسبة فشل المجموعة الاولى ٨٪ والثانية ٤٪ والثالثة ٨٪.

٤– احتياج ٤٪ من حالات التى أجريت لها طريقة ديفيجا الى استبدال الصمام نظار لفشل إصلاحه اثناء الجراحة.

٥– فشل اصلاح بالغشاء التامور بنسبة ٤٪ واحتياجها لاستبدال الصمام.

٦– لا توجد فروقات ذات دلالة إحصائية فى وقت الجراحة او فترة التنفس الصناعى او الوفيات بين المجموعات المختلفة.

٧– ثبت زيادة فترة الحجز بالعناية المركزة فى المجموعة ب بالمقارمنة بالمجموعات الأخرى و ذات دلالة احصائية.

٨– ثبت تحسن ذو دلالة إحصائية فى تحسن الحالة الاكلينيكية للمريض ومقياس نيو يورك للقلب.

٩– ثبت تحسن قياسات الموجات الصوتية للبطينين الأيمن والايسر و ضغط الشريان الرئوى بعد الجراحة.

١٠– ثبت ان مقياس الحلقى للصمام الثلاثى اكثر من ٤٠ مم والارتجاع الشديد بالصمام الثلاثى قبل الجراحة كان عامل ذو دلالة إحصائية فى زيادة نسب فشل الإصلاح.