

Evaluation of Outcomes of Tricuspid Valve Flexible Ring Annuloplasty with Left Sided Heart Valve Surgery

Kinnaresh Baria¹, Jignesh Kothari², Sanjay Patel³, Yogini Kandre⁴

Authors Affiliation:

¹Assistant Professor ²Professor,
Department of Cardio vascular and
Thoracic Surgery, ³Research Assistant
⁴Lab Technician, Department of
Research, U.N. Mehta Institute of
Cardiology and Research Center,
(Affiliated to B. J. Medical College),
New Civil Hospital Campus, Asarwa,
Ahmedabad,
Gujarat 380016, India.

Corresponding Author:

Kinnaresh Baria

Assistant Professor, Department
of Cardio vascular and Thoracic
Surgery, U.N. Mehta Institute of
Cardiology and Research Center,
(Affiliated to B. J. Medical College),
New Civil Hospital Campus, Asarwa,
Ahmedabad,
Gujarat 380016, India.
E-mail: drkinnaresh@gmail.com

Received on 27.06.2018

Accepted on 09.08.2018

Abstract

Introduction: The results regarding durability of tricuspid valve (TV) repair by flexible ring annuloplasty are controversial and the available literature is inconclusive. Identification of natural history of tricuspid regurgitation (TR) after flexible ring annuloplasty is necessary to improve results of TV repair. The purpose of this study was to assess the fate of tricuspid regurgitation after tricuspid valve flexible ring repair with left sided heart valve surgery. **Materials and Methods:** This retrospective observational study consisted of 142 patients with TR who had echocardiography preoperatively, early postoperatively (7 days), and at regular interval of six months for two years after TV flexible ring annuloplasty. Detailed echocardiographic measurements were performed, including TR severity, TV annular dimension, TV leaflet displacement, left ventricular (LV) function, and right ventricular (RV) function and pressures. **Results:** Mid-term follow up of tricuspid valve repair with flexible ring is promising. In addition, increased RV pressure was related to worse TR during late follow-up. **Conclusion:** The Flexible annuloplasty ring proved easy to implant, effectively corrected TR, and without progression of significant TR in mid-term follow up.

Keywords: Tricuspid Valve; Tricuspid Regurgitation; Tricuspid Annular Plane Systolic Excursion.

Introduction

Optimal management of tricuspid valve (TV) disease remains a challenge among cardiac surgeons, because patients are often asymptomatic. Organic TV disease often requires TV replacement surgery, but the procedure is rare and is associated with significant mortality and morbidity [1]. The most common TV disease etiology is tricuspid regurgitation (TR) secondary to left heart pathology, such as mitral valve disease and left heart failure [2]. Secondary (also known as "functional") TR can usually be corrected with TV repair, which is associated with lower perioperative risk than TV replacement. Without treatment, TR may worsen over time leading to severe symptoms, biventricular failure and death [3]. Several echocardiographic and angiographic studies have suggested important changes in the TV geometry

in patients with functional TR, including annular dilatation and tethering of the leaflets [4-6]. These TV deformations may restrict the motion of the leaflets and decrease coaptation.

Clinical and surgical management of functional TR has evolved from conservative approaches [7] (that is, no directed treatment and hope for spontaneous regression after correction of left-sided disease) to a more direct approach to the valve [8,9]. TV annuloplasty is now recommended for treatment of functional TR at the time of cardiac surgery; however, residual regurgitation is common [3,10-12]. Patients with symptomatic functional TR despite optimized medical therapy are candidates for TV repair [8,13]. TV repair is also indicated in patients with asymptomatic moderate or severe TR undergoing concomitant cardiac surgery, particularly if pulmonary hypertension or right ventricular dilation are present [8,13]. Functional

TR secondary to annular dilation may be repaired with or without an annuloplasty ring. Current literature on recommendation of either repair technique remains controversial, and relatively few studies have reported long-term results. The mechanisms responsible for recurrent or residual TR at mid-term follow-up after annuloplasty have not been determined.

The current study was therefore undertaken to assess the natural history of tricuspid regurgitation after tricuspid valve flexible ring repair with left sided heart valve surgery and its mid-term progression postoperatively.

The operative indications for addressing TR with left sided heart valve surgery were:

- Moderate to severe secondary or functional TR with
- Tricuspid annular dilatation or
- Severe TR diagnosed on intraoperative Trans Esophageal Echocardiography.

The patients were assessed immediate postoperatively with echocardiography. The patient's follow-up will be based on echocardiography evaluation as an outpatient basis after discharge from hospital, and evaluating right ventricular systolic pressure (RVSP), tricuspid annular plane systolic excursion (TAPSE), right ventricular fractional area change (RVFAC), right atrial dimensions and TR severity.

Aims and Objectives

Aim: Assessment of the tricuspid regurgitation after tricuspid valve flexible ring repair with left sided heart valve surgery and its progression postoperatively.

Design: Retrospective, Single-center, Multiple Surgeons, Observational Study

Setting: A Tertiary Referral Centre (UNMICRC).

Participants: Total number of patients who underwent tricuspid valve flexible ring repair with left sided heart valve surgery in the institute from 2013 to 2014 were included.

Materials and Methods

In the period, July 2013 through July 2014 we have used the flexible ring to perform tricuspid valve annuloplasty in 142 consecutive patients with significant TR and dilatation of the right-sided cardiac chambers due to left sided valve

disease. Right heart dilatation and tricuspid disease were assessed preoperatively by means of two-dimensional transthoracic echocardiography and confirmed at surgery by transesophageal echocardiography, inspection of the heart and visual exploration of the tricuspid valve following right atriotomy.

Prosthesis:

Duran Ancore ring is made of polyester containing a radiopaque barium impregnated silicon marker mounted on a buttress holder.

It was selected for repair as it's the only FDA approved tricuspid repair ring available at our institute during study period. All the rings were implanted in the same surgical manner.

The inclusion criteria for the study were:

- Patients having primary diagnosis of left sided heart valve disease with concomitant tricuspid regurgitation.
- Patients who underwent left sided valve replacement with tricuspid valve repair with flexible ring.

The exclusion criteria were:

- Patients with other associated lesions such as coronary artery disease, cardiomyopathies and congenital heart diseases.
- Patients in whom other procedures were performed such as CABG, septal myectomies, surgeries for congenital heart etc.
- Patients with history of infective endocarditis.
- Patients with RV endocardial pacing lead in situ.

The study was undertaken in a retrospective fashion going through the medical records of the included cases in the medical records department of U.N. Mehta Institute of Cardiology and Research Centre. All cases had their preoperative echocardiography done as an OPD procedure prior to admission for surgery for routine preoperative workup. Qualified cardiologists did the echocardiography.

Mitral valve disease, consisted in stenosis in forty-two (29.57%), incompetence in one hundred (70.42%), and patients having both aortic and mitral valve affected in twenty-eight (19.71%). The etiology was rheumatic in all the patients. Ten patients (7.04%) had undergone prior cardiac surgery from 4.4 to 30.2 years previously. Four patients (2.81%)

had coronary artery disease and were on medical management for the same. All patients were in New York Heart Association (NYHA) functional class III or IV. Permanent or paroxysmal atrial fibrillation was recorded in eighteen patients (12.0% of cases). Additional demographic and clinical descriptors are shown in Table 1.

Preoperatively, color-doppler echocardiography was performed in all patients.

Tricuspid regurgitation was ultrasonographically assessed using Doppler color-flow imaging and recorded as follows:

1. Absent (no tricuspid regurgitant jet);
2. Mild (Central jet area <5.0 cm², CW jet density and contour: soft and parabolic, Hepatic vein flow: systolic dominance);
3. Moderate (Central jet area 5–10 cm², Vena contracta width not defined but <0.70 cm, CW jet density and contour: dense, variable contour, Hepatic vein flow: systolic blunting);
4. Severe (severe annular dilation >40 mm or 21 mm/m²) Marked leaflet tethering

Central jet area >10.0 cm² Vena contracta width >0.7 cm CW jet density and contour: dense, triangular with early peak Hepatic vein flow: systolic reversal.

Using a clinical estimate of the right atrial pressure, the pulmonary artery systolic pressure was calculated summing up the right ventricle-to-right atrium systolic gradient (obtained from the simplified Bernoulli equation applied to the regurgitant jet). Echocardiographic left ventricular volumes and ejection fraction were calculated according to the modified Simpson method. The right ventricular shortening fraction was retrospectively measured by reviewing recorded echo-cardiographic examinations, and adopted for right ventricular systolic functional assessment.

Operative Technique

The three fundamental principles of tricuspid valve reconstruction are:

Table 1: Demographic details

Age (Years)	N (%)
13-18 (Adolescent)	9 (6.33%)
19-44 (Adult)	81 (57.04%)
45-64 (Middle Age)	48 (33.80%)
65-79 (Aged)	4 (2.80%)
> 80	None
Gender	
Male	66 (46.4%)
Female	76 (53.5%)
NYHA	
III	140 (98.6%)
IV	2 (1.4%)
Permanent AF	18 (12.67%)
TR Grade	
Moderate	27 (19.01%)
Severe	115 (80.98%)
Mixed Lesion TR+TS	1
LVEF	54.33%
LVEF <50%	32 (22.53%)
Comorbidities	
CAD	4 (2.81%)
DM	9 (6.33%)
COPD	12 (8.45%)
Chronic Renal Failure	7 (4.92%)
Cocombitant Procedure	
MVR	117 (82.39%)
DVR	25 (17.60%)

- Restore or preserve full leaflet mobility.
- Provide a large surface of leaflet coaptation.
- Remodel and stabilize the annulus.

Anaesthesia

A standard anaesthetic for cardiac procedures is utilized. A transesophageal echocardiography (TEE) probe is inserted and used to confirm cardiac pathology, and the adequacy of repair post bypass.

Operative setup

After systemic heparinization, standard aortic and bicaval cannulation is accomplished. We usually perform tricuspid procedures as a concomitant procedure at the end of a complex operation. If a patent foramen ovale is identified, tricuspid valve is repaired before declamping.

After full deairing, tapes are secured about the IVC and SVC to achieve right heart isolation. Should adhesions be significant, SVC isolation can be achieved with a caval clamp.

Approach and Intraoperative Valve Analysis

A horizontal atriotomy. Once the atrium has been exposed, it is carefully inspected to detect endocardial thickening, thrombus formation, or jet lesions. The interatrial septum is carefully inspected to detect a patent foramen ovale, which could be the cause of paradoxical emboli. The tricuspid valve is then examined to detect valvular lesions. The tricuspid annulus is measured, comparing its size with the surface area of valvular tissue in order to assess the presence and severity of annular dilatation.

Significant annular dilatation compared to the surface area of the leaflet tissue and organic lesions, irrespective of the size of the annulus, require reconstructive valve surgery.

A systematic analysis of the three leaflets using nerve hooks guide the techniques to be used.

A hand-held retractor is used. Occasionally, fine traction sutures are placed at the edges of the atriotomy to enhance exposure. A flexible weighted vent is placed in the LA through PFO to scavenge blood.

Attention is then directed toward the tricuspid valve. The valve is inspected and the pathology addressed. Regurgitation due to annular dilatation is best treated by annular remodelling. The size

of the prosthetic ring is chosen according to the surface area of the leaflet tissue.

Ring Implantation

Once the ring has been selected, a series of 2-0 polyester horizontal mattress sutures are placed at equidistant points around the tricuspid annulus.

The prosthetic ring is lowered into position, thus remodelling the annulus and ensuring adequate surface of coaptation while preserving full mobility of the leaflets. The normal geometry of the closure line is tested by using a bulb syringe to inject saline solution into the ventricular cavity (Figure 1). A regular line of closure indicates that a large surface of coaptation has been restored, which is confirmed by echocardiography.

The conduction system is preserved by typically not placing any sutures in the annulus adjacent to the septal leaflet past the medial aspect of the coronary sinus. The triangle of Koch, defined by the tendon of Todaro, septal leaflet of the tricuspid valve and coronary sinus, is thus not violated and the conduction system is preserved.

Rings were labelled 25 mm in fifteen patients (10.56%), 27 mm in thirty-five patients (24.65%), 29 mm in forty-four patients (30.98%) and 31 mm in the remaining forty-eight patients (33.8%).

All patients had a concomitant mitral procedure consisting in valve repair (=1), valve replacement (=141). In addition, aortic valve replacement was performed in twenty-eight patients. Mean cardiopulmonary bypass and aortic cross-clamp times were 133.07 min and 102.79 min, respectively.

Echocardiographic evaluations of the tricuspid repairs were carried out intraoperatively by the transesophageal approach, and by the transthoracic approach before hospital discharge, at two months from operation, and half-yearly thereafter for two years.

Specifically recorded were symptoms and; RA area, RV fractional area change, RVSP, TAPSE and LV EF on echocardiography evaluation.

Clinical follow-up was completed for all patients from 42.13 to 43.38 months, and averaged 42.75 months.

Deaths and complications were defined according to guidelines of The Society of Thoracic Surgeons and The American Association for Thoracic Surgery. Data were recorded in a prospective manner.

Statistical Analysis

Values are expressed as absolute number of cases with percentage, or mean ± S.D. Survival and freedom from TR were estimated with the actuarial survival method. Statistical analysis was performed using IBM SPSS statistics software.

Observation and Results

Patients who required TV repair were

Table 2: Age distribution

Age (Years)	N (%)
13-18 (Adolescent)	9 (6.33%)
19-44 (Adult)	81 (57.04%)
45-64 (Middle Age)	48 (33.80%)
65-79 (Aged)	4 (2.80%)
80	0

significantly younger (57.04% in adult age group) (Table 2) and more likely female (53.5%). Patients in NYHA functional class III and IV were 98.6% and 1.4 % respectively. Two patients i.e. 1.4% had TV repair on an emergency basis as compared to 98.59% who had it electively.

Preoperatively, TV annular diameter had mean of 44.56 mm with range of 40-67 mm.

Symptom Relief

The symptoms of right heart failure improved

significantly after surgery. Pulsatile liver and ascites were no longer seen after surgery.

Changes in Echocardiographic Parameters after TV Annuloplasty

Changes over time in LV ejection fraction, RV systolic pressure, TAPSE, RV fractional area change, and RA area after surgery were recorded (Figure 2). Repeated measures analysis of variance showed no significant differences in LV ejection fraction, TAPSE, RV fractional area change, and RA area at the 4 time points. In contrast, RV Systolic pressure significantly decreased immediately after surgical procedure, and were relatively stable thereafter.

Left Ventricular Ejection Fraction (%)

LV EF mostly remained unaltered in post-operative period.

Right Ventricular Systolic Pressure

TR velocity reliably permits estimation of RVSP with the addition of RA pressure, assuming no significant RVOT obstruction. It is recommended to use the RA pressure estimated from IVC and its collapsibility, rather than arbitrarily assigning a fixed RA pressure. In general, TR velocity > 2.8 to 2.9 m/s, corresponding to PASP of approximately 36 mm Hg, assuming an RA pressure of 3 to 5 mm Hg, indicates elevated RV systolic and PA pressure. PASP may increase, however, with age and in obesity. In addition, PASP is also related to stroke volume and systemic blood pressure.

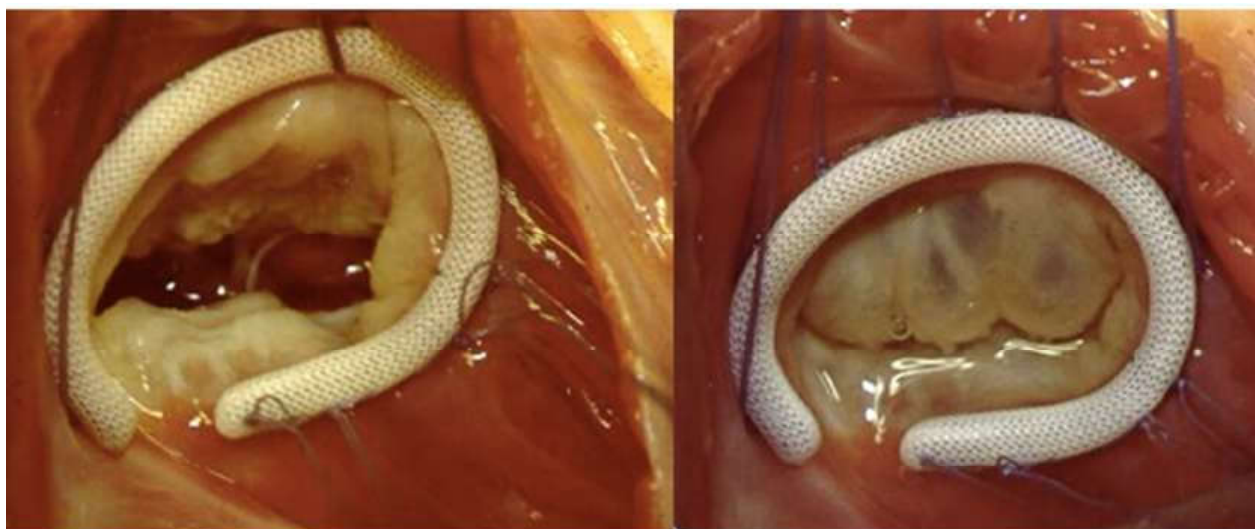


Fig. 1: Saline injection test

Elevated PASP may not always indicate increased pulmonary vascular resistance (PVR). In general, those who have elevated PASP should be carefully evaluated. It is important to take into consideration that the PASP are influenced by the systolic and diastolic function of the left heart. PA pressure should be reported along with systemic blood pressure or mean arterial pressure.

RVSP improved significantly in immediate post-operative period and remained stable thereafter.

RV Systolic Function

RV systolic function has been evaluated using several parameters, namely, TAPSE, RV FAC.

Tricuspid Annular Plane Systolic Excursion (TAPSE)

TAPSE is easily obtainable and is a measure of RV longitudinal function. TAPSE < 16 mm indicates RV systolic dysfunction. It is measured from the tricuspid lateral annulus. Although it measures longitudinal function, it has shown good correlation with techniques estimating RV global systolic function, such as radionuclide-derived RV EF, 2D RV FAC, and 2D RV EF.

TAPSE didn't deteriorate in post-operative period.

Right Ventricular Fractional Area Change (%)

RV FAC (as a percentage) provides an estimate of RV systolic function. Two-dimensional FAC < 35% indicates RV systolic dysfunction. It is important to make sure that the entire right ventricle is in the view, including the apex and the lateral wall in both systole and diastole. Care must be taken to exclude trabeculations while tracing the RV area.

RVFAC didn't Change Postoperatively.

RA Area

The apical 4-chamber view allows estimation of the RA dimensions. RA area > 18 cm², RA length (referred to as the major dimension) > 53 mm,

and RA diameter (otherwise known as the minor dimension) > 44 mm indicate at end-diastole RA enlargement.

RA area remained the same with end diastole RA enlargement.

Tricuspid Valve Competence

Preoperatively TR grades, Severe TR was recorded in 115 patients, while moderate TR in 27 patients.

Postoperatively TR grades were noted on echocardiography evaluation, Mild TR in 126 patients and 16 patients had Moderate TR, which remained stable in 2 years follow up.

Regurgitation significantly decreased even in patients with persistent left ventricular dysfunction after surgery. There were no significant correlations between post-operative TR grade and persisting of symptoms of right heart failure.

Functional Status

In survivors, NYHA class improved from 3.7 to 1.05.

Re Operation

Within an observation period of 2 years, none of the patients required a tricuspid valve re-operation after the initial operation.

Valve related Complications

None of the patient experienced thromboembolic event two years after initial operation.

Survival

Length of stay in the hospital and total postoperative hospital stay averaged 20 days (range 8–78, median 19) and 12 days (range 4–46, median 8), respectively. The 2-year actuarial survival (including in-hospital deaths) was 97.2% (Table 3, Figure 3). All 4 events were noted during follow up

Table 3: Case Processing Summary

Total N	N of Events	Censored	
		N	Percent
142	4	138	97.2%

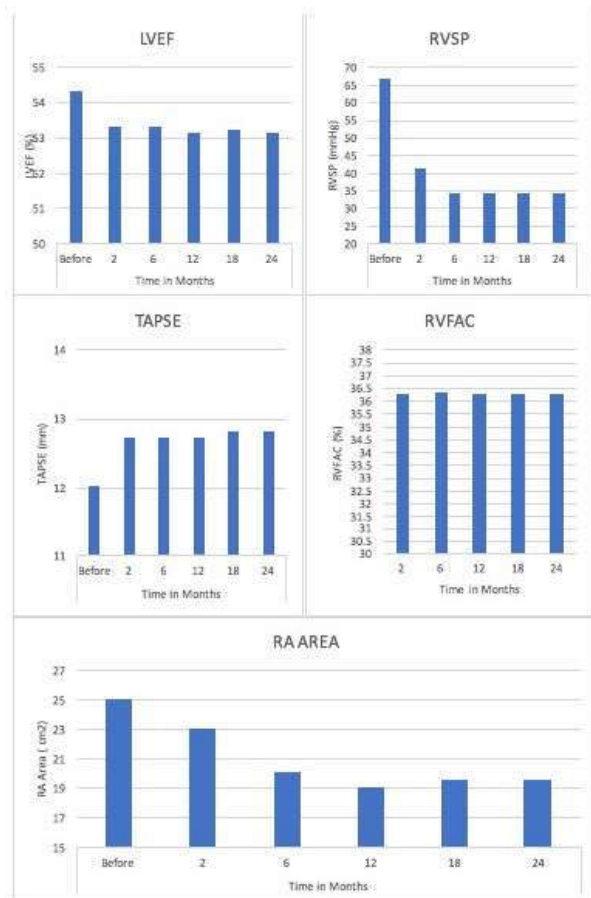


Fig. 2: Changes in LVEF, RVSP, TAPSE, RVFAC, RA area over time

and were not cardiac. No other complications were recorded during follow-up.

Discussion

Significant TR secondary to right ventricular dilatation and dysfunction associated with mitral valve disease is a risk factor for poor functional outcome and mortality after mitral surgery [14]. Satisfactory correction of left-sided valve disease does not assure, by itself, against the persistence or even worsening of TR, while predicting the fate of unrepaired TR remains a disputed question [3,12,14,15]. On the other hand, reoperations to correct residual or recurrent TR have been associated with high operative mortality and disappointing long-term results [14,16]. This all would make highly desirable that sensitive detection and liberal correction of TR be accomplished at the time of initial left sided heart valve surgery [2,3,15,16]. The significance of TR has been often overlooked in cardiac surgery [8], however the importance of this issue has been recently addressed in the updated guidelines of both the ACC/AHA and ESC valve disease [8,17]. In our study patients after TV annuloplasty showed a significant decrease in TR grade, and there were no instances of annuloplasty failure reported.

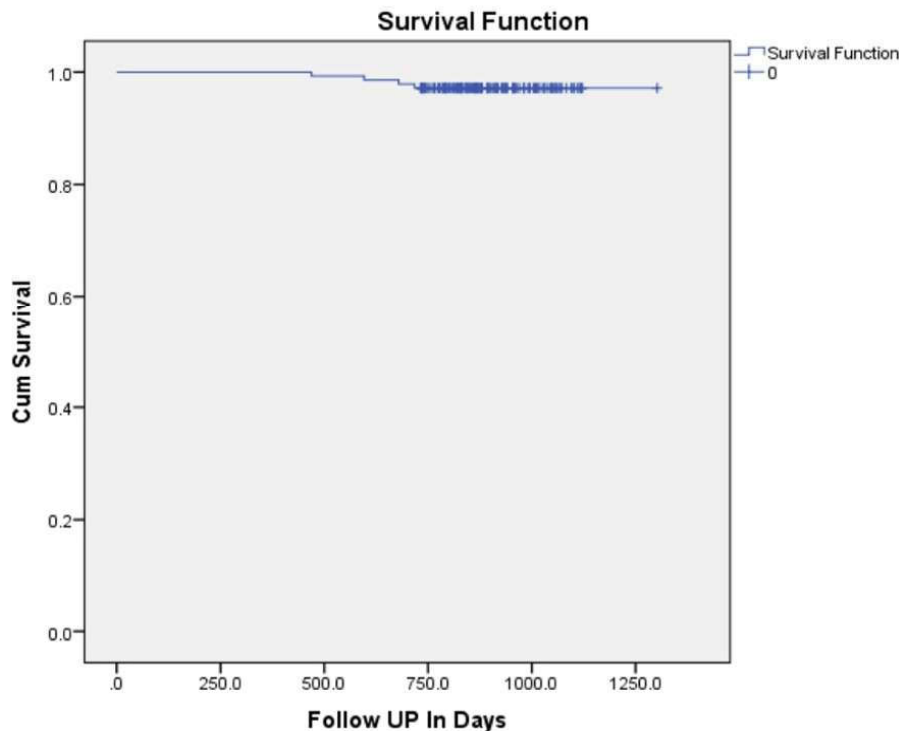


Fig. 3: Actuarial overall survival rate for patients evaluated by the Kaplan-Meier method.

Historically, it was thought that MV Repair / MVR would lead to a reduction in functional TR [7]. However, increasing evidence has shown that functional TR does not always disappear but can progress or even appear de novo if the tricuspid valve is left untreated at the time of left-sided surgery [18–20]. In addition, significant progression of TR in patients having moderate TR undergoing MV Repair / MVR will occur in up to 25% of cases at 1 year, up to 53% at 3 years, and more than 74% at long-term follow-up [21]. Therefore, the traditional view that functional TR or tricuspid annulus dilation diminishes with surgical correction of left-sided lesions is no longer accepted [22]. This is reflected by the endorsement of TV repair to be performed during left-sided cardiac surgery in case of tricuspid annulus dilation or functional TR by the Guidelines from the European Society of Cardiology, American Heart Association, and American College of Cardiology [8,17].

From the surgical point of view, several techniques are available to correct TR. The simple suture annuloplasty approach is easy and effective in the immediate, but recurrent TR and reoperation have been reported in 34% and 10% of the survivors, respectively, at midterm follow-up [23]. Several studies have indeed found the simple suture annuloplasty to be a risk factor for tricuspid repair failure [3,15]. Perhaps, suture annuloplasty is reliable when used for minor degrees of TR in the absence of right heart dilatation. On the other hand, prosthetic annuloplasty remodels the annulus, decreases tension on suture lines, increases leaflet coaptation, and prevents recurrent annular dilatation [14,24–27]. There are no reports in the literature, however, to demonstrate any differential effect of variable ring/band designs and their mechanical properties on both the right ventricular function and the tricuspid valve efficiency. By its very design a flexible band corrects the excess lengthening of the tricuspid annulus corresponding to the right ventricular free wall, i.e. along the anterior and posterior leaflets hinge, and theoretically allows annular and ventricular shape changes throughout the cardiac cycle. The septal annulus is ignored as it is not expected to lengthen significantly, which simplifies the procedures and prevents inadvertent injury to the conduction system [27]. Spherical remodeling of the overloaded right ventricle may cause the septum- parietal dimension to preferentially increase, similar to what happens to the left ventricle with cardiomyopathy. The very reasons why many surgeons do prefer rigid mitral rings in that setting could therefore

apply to tricuspid valve pathology as well.

Our study aimed to evaluate the fate of tricuspid regurgitation after application of a flexible prosthetic ring to repair tricuspid valve with left sided heart valve surgery. Patients studied had moderate or severe TR associated with mitral or aortic valve disease, though cases with moderate TR were similarly treated in the presence of significant dilatation of right heart chambers.

Significant postoperative improvement in symptoms of right heart failure and decrease of right ventricular systolic pressure confirmed better right ventricular performance and good tricuspid competence.

Limitation

We are well aware that the study population is small in this retrospective observational study. Long term evaluation in terms of randomized trials are required to determine the stability of tricuspid valve repair using this device.

Conclusion

Our results support an aggressive surgical approach to significant tricuspid regurgitation as defined above. Significant decrease of NYHA class and right ventricular systolic pressure confirmed good surgical treatment of the left-sided cardiac valves pathology. Tricuspid regurgitation significantly improved even in patients at higher risk for tricuspid repair failure or with persisting left ventricular dysfunction. No tricuspid repair failures came to notice.

In conclusion, the Flexible annuloplasty ring proved easy to implant, effectively corrected TR, and provided satisfactory mid-term clinical and echocardiographic results in our series.

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