Flexible band made of autologous pericardium for functional tricuspid regurgitation repair

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**ABSTRACT**

Introduction: Secondary (Functional) tricuspid regurgitation (TR) is a common problem in cardiac surgery that occurs secondary to left-sided valvular heart disease, more evident with mitral valve pathology, especially mitral stenosis. Right ventricular overload caused by pulmonary hypertension is the main leading factor causing right ventricular enlargement and tricuspid annular dilation. Many techniques were developed for repair of tricuspid incompetence. Some techniques failed to show good results and even the regurgitation may recur with progression of disease. We studied the early results of tricuspid annuloplasty procedure using flexible band made of autologous pericardium.

Methods: The study was conducted from September 2016 to July 2018. Thirty patients treated with tricuspid annuloplasty using flexible band made of autologous pericardium for functional TR. Concomitant procedures included mitral valve replacement in 24 patients and mitral-aortic valve replacement in 6 patients. Follow-ups both clinically to assess the functional status (NYHA class) and by echocardiography were used to judge on success of repair. During the study, another nine patients were treated with Devega repair due to surgeon preference. The results with this method were compared with a group collected from the records.

Results: Thirty patients were operated using a flexible band of pericardium and followed up for at least 1 year. There was no mortality, neither in hospital nor during follow-up period. The severity of TR and the functional status improved with time. Twenty-eight patients (93.3%) were in NYHA class I at 1-year postoperative follow-up. Freedom from recurrent TR was 96.7% at 1 year. In comparison to the traditionally used Devega repair, there were no statistical differences neither in postoperative TR nor in functional status.

Discussion: Tricuspid repair using flexible band of autologous pericardium is an option for functional TR. Further studies with a larger number of samples and a longer term of follow-up are necessary to confirm our findings.

1. Introduction

Tricuspid incompetence is a commonly encountered valvular problem in cardiac surgery. More than 80% of tricuspid regurgitation (TR) encountered in clinical practice is secondary or functional in nature [1].

The disturbed anatomy and so the function of tricuspid valve is mainly due to dilation of right ventricle and tricuspid annulus [2].

Secondary (functional) TR affects the quality of life regarding the functional status and use of anti-failure medications [3].

Repair is the first surgical choice for FTR due to the high-risk of postoperative complications after tricuspid valve replacement [4].

Suture annuloplasty technique is routinely used for tricuspid valve repair by bicuspidization or reducing the annular size semicircularly [5,6]. Although technically easy, it is associated with a relatively high incidence of recurrence [7].

In the current practice, there is a controversy for using either rigid or flexible rings for repair of the tricuspid valve [8].

The end point of this study is to evaluate the efficacy and durability of tricuspid annuloplasty using flexible band made of autologous pericardium for functional TR.

2. Patients and methods

This study was conducted from September 2016 to July 2018 in Alexandria main university hospital under protocol approved by research ethics committee of Faculty of Medicine Alexandria University numbered (020958).

Inclusion criterion was any patient scheduled for left-sided valvular replacement with concomitant TR which was moderate or more than moderate. Exclusion criteria were patients with organic TR, isolated TR, patients undergoing redo surgery, patients...
managed with mitral repair, and patients with hepatic insufficiency due to another cause not due to TR. All patients signed an informed consent.

Thirty patients with moderate, moderate-to-severe, or severe TR were enrolled in this study. All had associated left-sided valvular lesions (mitral stenosis in 20 patients, mitral regurgitation in 4, and double valve affection in 6). They were managed by mechanical valve replacement and tricuspid repair using flexible band of autologous pericardium.

Patients clinical data, functional status, and echocardiographic data were collected preoperatively, and follow-up was made 1 week postoperatively and at 3-month intervals for 1 year.

During the study, nine other patients were treated with Devega repair due to surgeon preference. They were taken as a base for a comparison group to this technique. This group completed 30 patients from the records with similar preoperative characteristics. A comparison was made regarding the postoperative TR and the functional status.

2.1. Operative technique

We started by harvesting and preparing an autologous pericardial patch (10 cm in length, 15–20 mm in width); this patch was immersed in 0.6% glutaraldehyde solution for 10 min and then washed in 0.9% saline solution three times each for 5 min. In all cases, mechanical valve replacement was used for left-sided valvular lesion. Antegrade crystalloid cardioplegia was used for all cases. Repair of tricuspid valve was done on a beating heart after deairing and declamping. The length of the band was determined after sizing the annulus using the Carpentier Edward sizer and accordingly we measured the rounded margin between the two notches of the selected sizer. To standardize the length of the band according to the accurate sizer, the distance between the two notches on each sizer is previously measured in centimeters. Table [1] showed matched length of band to the used sizer.

The patch of pericardium was rolled on itself to keep smooth surface outward. Then, it was strengthened by ethibond suture 2–0 rolled around (Figure 1). Now the length of the band can be applied to the annulus as incomplete ring avoiding suturing in the annulus opposite the septal leaflet.

An average of seven 2–0 ethibond sutures were placed on the annulus along the anterior and posterior leaflets starting from the posteroinferior aspect of the septal leaflet to the anterior septal commissure. There are 2–3 mm interval sutures in the autologous pericardial band and 5–6 mm interval sutures in the tricuspid annulus (Figure 2).

Devega repair was applied according to surgeon system, some using pligated ethibond 2–0 suture and some using pligated prolene 3–0 suture. Some surgeons used 2 finger width as a measure for the desired annular size and some using a mitral sizer of 29 as a desired annular size.

Saline test was used for intraoperative testing of repair by injecting normal saline into the right ventricle and inspecting the valve competence.

| Table 1. The length of the band according to the used sizer. |
|------------------|------------------|
| Sizer | Length (cm) |
| 26    | 5.1            |
| 28    | 5.4            |
| 30    | 5.7            |
| 32    | 6              |
| 34    | 6.2            |
| 36    | 6.5            |
| 38    | 6.7            |
| 40    | 7              |

Figure 1. Flexible band of autologous pericardium rolled on and reinforced with ethibond 2–0 measured according to the sizer.

Figure 2. The band sutured to tricuspid annulus along the anterior and posterior leaflets.
Transesophageal echocardiography was not available in all cases. However, it was used intraoperatively to assess the adequacy of repair when available.

3. Results

Sixty patients were included in this study. We operated 30 patients with moderate, moderate-to-severe, or severe functional TR using flexible band of autologous pericardium (band group). Another group of 30 patients with Devega repair was used as a control group from the records of the hospital (Devega group). All had associated left-sided valvular lesion. There were no statistical differences regarding the preoperative characteristics. Table 2 showed the preoperative characteristics.

There was no mortality, neither in hospital nor during follow-up period in both groups. Regarding morbidity, in band group, one patient had severe tamponading pericardial effusion 10 days postoperatively and it was related to overdosage of oral anticoagulant. Four patients suffered rapid atrial fibrillation during in-hospital stay and they were controlled with amiodarone and discharged controlled.

In Devega group, one patient suffered deep sternal wound infection which required vacuum therapy for 2 weeks followed by rewiring and closure of the wound. Six patients suffered rapid atrial fibrillation and were also controlled predischarge.

All patients had associated left-sided rheumatic valvular lesion. In band group, mitral valve stenosis was found in 20 patients (66.7%), mitral regurgitation in 4 patients (13.3%), and double valve affection (aorta and mitral) in 6 patients (20%). In Devega group, 21 (70%) patients had mitral stenosis, 5 (16.7%) patients had mitral regurgitation, and 4 (13.3%) patients had double valve affection.

During the follow-up period, the grade of TR was greatly improved. Recurrent TR was defined as postoperative moderate and above TR. At follow-up of 1 year, in band group, 27 patients (90%) had no or trivial TR. Only one patient (3.3%) had recurrent TR who had certain preoperative characteristics of low ejection fraction (38%), severe pulmonary hypertension, associated mitral regurgitation, and severely dilated both right ventricle and tricuspid annulus. Two patients (6.7%) had persistent mild TR which was well tolerated not requiring anti-failure treatment. In Devega group, at 1 year postoperative, 24 (80%) patients had no or trivial regurgitation, 3 (10%) patients had mild TR, 2 (6.7%) patients had moderate regurgitation, and 1 (3.3%) patient had severe regurgitation. Table 3 showed the postoperative follow-up of TR.

Regarding the functional status, at 1-year follow-up, 28 patients (93.3%) were in NYHA class I showing dramatic clinical improvement, while in Devega group, 27 (90%) patients were in NYHA class I. Table 4 showed the postoperative follow-up of and NYHA functional class.

4. Discussion

Insufficient tricuspid valve negatively impacts the functional status of patients postoperatively, and reoperations for isolated TR have high mortality rate [9]. The concept of regression or improvement of tricuspid valve regurgitation after removing the leading pathology cannot be defended, especially in patients with dilated annulus and more than moderate regurgitation [10].

Regarding recurrence of TR and survival, the evidence is supporting ring annuloplasty over conventional De Vega stitch [11]. Wang et al. [8] compared rigid and flexible prosthetic ring for tricuspid annuloplasty and results showed no statistical difference. Filsoufi et al. [12] recommended the use of Edwards MC3 remodeling ring with its 3D saddle shape. Pfannmüller et al. [13] studied both flexible band and rigid ring and found that the use of a rigid ring has a risk of subsequent ring dehiscence. In addition, Galiñanes et al. [14] reported four cases of extremely...
rare complication, i.e. fracture of the Carpentier rigid ring in the tricuspid position. McCarthy and Cosgrove recommended the use of Cosgrove band being malleable and not disturbing the free wall motion of right ventricle [15]. Chang et al. [16] used a pericardial strip for tricuspid annuloplasty with good results regarding long-term survival in comparison to suture annuloplasty (De Vega or Kay). We modified the technique used by Chang taking pericardial patch (10 cm x 2 cm) treated in gluteraldehyde 0.6% and rolled on itself keeping the smooth surface outward and reinforced with ethibond 2–0 rolled around. This gave the pericardium the strength of a band and at the same time the malleability and flexibility taking the shape of the annulus, not disturbing the free wall motion of the right ventricle and preserving the dynamic variability of the annulus during cardiac cycle. Moreover, the advantage of using pericardium (autologous tissue) is in repair and keeping only its smooth surface exposed to blood. Results showed favorable outcome.

In this study, we had only one patient with significant TR in the band group. This patient had mitral regurgitation pathology, low ejection fraction, severe pulmonary hypertension, severely dilated right ventricle and tricuspid annulus. Two patients had persistent mild TR which was controlled with medical treatment. Regarding functional status, all patients showed dramatic improvement and stayed in NYHA class I except for that patient with recurrent significant TR. The limitations of this study were being single-centered design, relatively short duration of follow-up, and small sample size which may produce potential bias. Therefore, the results obtained can, in no way, be considered conclusive and should be confirmed by further studies. We need to carry out more studies to compare it with rigid annuloplasty in the future. However, our results are encouraging, and long-term results would be very valuable.

5. Conclusion
Tricuspid annuloplasty using pericardial band of autologous pericardium for functional TR is an accepted option. However, further studies with a larger number of samples and a longer term of follow-up are necessary to confirm our findings.

Disclosure statement
No potential conflict of interest was reported by the authors.

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Table 3. Comparison between the two groups according to TR.

| TR       | 1 Week | 3 Months | 6 Months | 9 Months | 1 Year |
|----------|--------|----------|----------|----------|--------|
| BAND group |        |          |          |          |        |
| No       | 26 (86.7%) | 27 (90%) | 27 (90%) | 27 (90%) | 27 (90%) |
| Mild     | 4 (13.3%)  | 3 (10%)  | 2 (6.7%)  | 2 (6.7%)  | 2 (6.7%)  |
| Moderate | 0        | 0        | 1 (3.3%)  | 1 (3.3%)  | 0       |
| Moderate-severe | 0 | 0 | 0 | 0 | 1 (3.3%) |
| Severe   | 0        | 0        | 0         | 0         | 1 (3.3%) |
| Devega group |        |          |          |          |        |
| No       | 26 (86.7%) | 27 (90%) | 27 (90%) | 26 (86.7%) | 24 (80%) |
| Mild     | 4 (13.3%)  | 3 (10%)  | 2 (6.7%)  | 3 (10%)  | 3 (10%)  |
| Moderate | 0        | 0        | 1 (3.3%)  | 1 (3.3%)  | 2 (6.7%)  |
| Moderate-severe | 0 | 0 | 0 | 0 | 0 |
| Severe   | 0        | 0        | 0         | 0         | 0       |
| p-Value  | 1.000    | 1.000    | 1.000     | 0.896    | 0.498   |

Table 4. Comparison between the two groups according to F. status.

| F. status | 1 Week | 3 Months | 6 Months | 9 Months | 1 Year |
|-----------|--------|----------|----------|----------|--------|
| BAND group |        |          |          |          |        |
| I         | 0      | 2 (6.7%) | 27(90%)  | 28 (93.3%) | 28 (93.3%) |
| II        | 3 (10%)| 26 (86.7%) | 3 (10%)  | 2 (6.7%)  | 2 (6.7%)  |
| III       | 25 (83.3%) | 2 (6.7%) | 0        | 0        | 0       |
| IV        | 2 (6.7%) | 0        | 0        | 0        | 0       |
| Devega group |        |          |          |          |        |
| I         | 0      | 2 (6.7%) | 27(90%)  | 28 (93.3%) | 27 (90%)  |
| II        | 3 (10%)| 26 (86.7%) | 3 (10%)  | 2 (6.7%)  | 3 (10%)  |
| III       | 25 (83.3%) | 2 (6.7%) | 0        | 0        | 0       |
| IV        | 2 (6.7%) | 0        | 0        | 0        | 0       |
| p-Value   | 1.000  | 1.000    | 1.000    | 1.000    | 1.000   |
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