Late Outcome of Tricuspid Annuloplasty Using a Flexible Band/Ring for Functional Tricuspid Regurgitation

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**Background:** We assessed late outcome after tricuspid annuloplasty (TAP) using a flexible band or ring for functional tricuspid regurgitation (FTR).

**Methods and Results:** We reviewed 220 consecutive patients (mean age, 65.4±11.4 years) who underwent TAP for FTR during mitral valve surgery between January 2000 and December 2010. Indications for TAP included the following: (1) TR grade greater than mild; (2) history of right heart failure; (3) atrial fibrillation; and (4) systolic pulmonary artery pressure (SPAP) ≥50 mmHg. The mean follow-up period was 4.4±2.6 years. Overall hospital mortality was 5.5% (12/220). The 5- and 10-year survival rates were 90.2±2.1% and 82.4±5.6%, respectively. Freedom from recurrent TR at 8 years was 78.0±6.6%. Twenty patients had a greater than mild TR grade at final follow-up. Elevated SPAP was a predictor of recurrent TR (hazard ratio, 1.091; P=0.0003), which was associated with advanced age, atrial fibrillation, rheumatic etiology and preoperative TR grade. There was a significant difference in freedom from valve-related events between residual TR greater than mild and less than moderate (log-rank test, P=0.0464). Factors affecting residual TR were preoperative TR grade (OR, 7.368; P=0.0267) and mitral valve replacement (OR, 4.369; P=0.0402).

**Conclusions:** Late outcome of TAP in the present series was acceptable. Late outcome can be improved by performing TAP before deterioration of TR. (Circ J 2015; 79: 1299–1306)

**Key Words:** Functional tricuspid regurgitation; Tricuspid annuloplasty

Functional tricuspid regurgitation (FTR) mainly occurs because of tricuspid annular dilation and right ventricular enlargement and/or right ventricular dysfunction in mitral valve diseases. Functional tricuspid regurgitation causes further right ventricular dilatation, dysfunction, or more annular dilation, subsequently worsening FTR. Increasing severity of FTR is associated with poor survival in healthy men irrespective of left ventricular function or pulmonary hypertension. Despite improved understanding of FTR and its surgical management, reports of late survival associated with FTR are limited. Guenther et al showed that 10-year survival after tricuspid annuloplasty (TAP) was 46%, and Pfannmuller et al showed that 5-year survival was approximately 60%. Persistent FTR after mitral prosthetic replacement is reported to be a risk factor for postoperative congestive heart failure and late mortality. In redo series of mitral valve surgery, persistent FTR had a negative effect on late survival. FTR after TAP in redo valvular surgery also affected late outcome.

Evidence supports the superiority of TAP with an annuloplasty ring over suture annuloplasty. We have consistently performed TAP using a flexible ring or band for >10 years.

This study assessed late survival and freedom from recurrent or progressive FTR following TAP for FTR. Additionally, the effect of residual TR on late outcome was investigated.

**Methods**

This retrospective study was approved by the institutional review board. We retrospectively reviewed the medical records of 220 patients (mean age, 65.4±11.4 years; range, 16–83 years) who underwent TAP for FTR in the setting of mitral valve surgery at Kobe City Medical Center General Hospital between January 2000 and December 2010. Of 220 patients, 160 (72.7%) underwent mitral valve repair (MVP), and 60 (27.3%) underwent mitral valve replacement (MVR). Patient preoperative characteristics are listed in Table 1. With regard to mitral etiology, degenerative entities comprised 94% in patients who had MVP, and rheumatic disease accounted for 87% in those who had MVR.
who had MVR.

TR was graded using transthoracic echocardiography as 0 for no regurgitation, 1+ for mild regurgitation, 2+ for moderate regurgitation, 3+ for moderately severe regurgitation and 4+ for severe regurgitation. Late recurrent TR was defined as an increase in TR greater than 1 grade compared with the grade of FTR before discharge, and TR grade greater than mild at final follow-up.

The mean follow-up period was 4.4±2.6 years (range, 0.01–12.3 years). The rate of follow-up was 100% when present data were collected. The follow-up rate for transthoracic echocardiography was 87.9%.

Indications for TAP for FTR

Before September 2007, TAP was indicated for patients with FTR greater than mild or a physical history of right heart failure (eg, leg edema or jaundice). During follow-up after mitral valve surgery, atrial fibrillation and pulmonary hypertension were recognized as risk factors for the development of recurrent TR based on our previous experience. Therefore, as of September 2007, new surgical indications for TAP included one of the following conditions: (1) TR grade greater than mild; (2) history of right heart failure; (3) atrial fibrillation; and (4) systolic pulmonary artery pressure (SPAP) >50 mmHg. The number of patients before September 2007 was 67 (30.0%).

Surgical Procedure

After standard median sternotomy and bivacal/aortic cannulation, the superior and inferior venae cavae were tapped together. After obtaining cardiac arrest, mattress sutures with 2-0 braided suture (RB1) were placed on the tricuspid annulus from the anterior part of the anteroseptal commissure to the center of the septal annulus. Half corresponded to the posterior annulus and part of the posterior commissure to the posteroseptal commissure. Half of the band corresponded to the anterior annulus and the other half corresponded to the posterior annulus and part of the septal annulus.

In this study, patients who required an additional tricuspid procedure were not included.

Concomitant procedures, except for mitral valve surgery, included aortic valve replacement (n=32), maze procedure (n=30), coronary artery bypass grafting (n=19), closure of atrial septal defect (n=6), left atrial plication (n=3), and closure of ventricular septal defect (n=1).

Mean duration of cardiopulmonary bypass and cardiac arrest were 194.9±61.4 min and 144.1±47.2 min, respectively.

Statistical Analysis

Statistical analysis was done using StatView version 5.0 (SAS Institute, Cary, NC, USA). Categorical variables are expressed as the number of patients (%) and were compared between groups using chi-squared test. Continuous variables are expressed as mean±SD and were compared between groups using Student’s unpaired t-test. The Kaplan-Meier method was used to calculate long-term survival and freedom from postoperative complications.
Univariate analysis was performed with Fisher’s exact probability test or Student’s unpaired t-test.

Variables that were not significant on univariate analysis, but had P<0.2 were included in multivariate logistic regression analysis to determine the independent predictors of hospital morbidity and mortality. Risk factors for long-term survival were evaluated using Cox multivariate regression analysis.

**Results**

A total of in 11 patients (18.3%) who had MVR and 32 (20%) who had MVP were older the 75 years. More patients had a history of atrial fibrillation in the MVR group than in the MVP group (P<0.0001). New York Heart Association (NYHA) functional class greater than III was more frequent in the MVR group compared with the MVP group (P<0.0001).

Preoperative transthoracic echocardiographic data are given in Table 2. TR grade greater than mild was present in 124 patients (56.3%). Severe TR grade was observed in 55 patients (25.0%).

**Early Outcome**

Overall hospital mortality was 5.5% (12/220), and 30-day mortality was 2.7% (6/220). Cause of death was pneumonia (n=6), postoperative mediastinitis (n=3), gastrointestinal necrosis (n=2), low output syndrome (n=1) and hepatic failure (n=1). Postoperative comorbidities are listed in Table 3. Newly required pacemaker implantation was necessary in 9 patients (4.1%). Mediastinitis occurred in 6 patients (2.7%), and 2 of them died.

Predischarge transthoracic echocardiographic data are given in Table 2. The left atrial diameter became smaller and SPAP was decreased with a mean pressure of 35.4 mmHg. The severity of TR was 0.7, and greater than mild TR was present in 16 survivors (7.7%).

A total of 124 patients had TR greater than mild preoperatively, and 14 (3.2%) of them had residual TR greater than mild after TAP.

**Late Survival**

The 5- and 10-year survival rates were 90.2±2.1% and 82.4±5.6%, respectively (Figure 1). There were 10 late deaths, due to heart failure (n=4), pneumonia (n=3), rupture of the sinus of Valsalva (n=1), prosthetic valve endocarditis (n=1), and an unknown cause (n=1). Heart failure occurred in 4 patients within 3 years after discharge and their left ventricular ejection fraction was ≤40% at predischarge echocardiography.

Prosthetic valve endocarditis was present in a 62-year-old woman. Her initial surgery included TAP, MVP, and aortic valve replacement for active endocarditis. Recurrence of infection was strongly suspected, but she refused redo surgery.

**Recurrent TR and Analysis of Predictors**

Rate of freedom from recurrent TR at 5 and 8 years was 87.7±2.2% and 78.0±6.6%, respectively (Figure 2). Twenty patients had greater than mild TR at final follow-up. Of these 20 patients, 16 with a TR grade of moderate were asymptomatic. Among 4 patients with a severe TR grade, however, 2 developed edema that required an additional dose of diuretics and 2 complained of dyspnea on excursion. One patient needed readmission because of heart failure. The causes of severe FTR were tricuspid valve tethering in 1 patient, and tricuspid annular dilatation with persistent SPAP in 3 patients.

Elevated SPAP was identified as a predictor of recurrent TR (hazard ratio, 1.091; 95% CI: 1.041–1.144; P=0.0003). Furthermore, to identify the preoperative characteristics of recurrent TR, survivors were classified into 2 groups based on SPAP at final follow-up (Table 4). In the group with SPAP ≥50 mmHg, advanced age, higher frequency of atrial fibrillation, and rheumatic etiology were observed. With regard to echocardiographic data, there was a significantly greater number of patients with greater than mild TR in the elevated SPAP group.

With regard to electrocardiogram at late follow-up in 187 patients (follow up rate, 89.9%), 68 patients (36.4%) had atrial fibrillation.
fibrillation, and 100 patients (53.5%), sinus rhythm. Of these 100 patients, 48 had atrial fibrillation preoperatively.

**Effect of Residual TR on Late Outcome**
The effect of residual TR that was less than moderate or greater than mild after TAP on late survival, and on valve-related events, was analyzed. There was no significant difference in late survival between residual TR that was less than moderate and greater than mild (log-rank P=0.4400; Figure 3A). There was a significant difference, however, in freedom from valve-related events between the 2 groups (log-rank P=0.0464; Figure 3B). Risk factors of residual TR greater than mild following TAP were preoperative TR grade (OR, 7.368; 95% CI: 1.259–42.985; P=0.0267) and MVR (OR, 4.369; 95% CI: 1.068–17.868; P=0.0402). These 2 factors were consistent with those for recurrent TR, as described earlier.

**Effect of Preoperative TR Grade on Survival**
As preoperative TR grade worsened, late survival was likely to be poorer (log-rank P=0.0622; Figure 4). The survival rate at 6 years was 93.6±2.5% for less than moderate vs. 91.7±3.7% for moderate TR, vs. 82.8±5.2% for severe TR.

**Discussion**
The 5- and 10-year survival rates following mitral valve procedures associated with TAP were 90.2±2.1% and 82.4±5.6%, respectively, in the present series. Because moderate to severe FTR has a negative effect on late survival after surgery, the main objective of TAP for FTR is to improve late survival.
without considerable residual FTR. We determined the effect of residual TR after TAP on late outcome. Residual TR greater than mild had a negative effect on freedom from valve-related events (Figure 3B), but there was no significant difference in survival. At 8 years, survival with residual TR greater than mild appeared to be poorer than that for residual TR less than moderate (Figure 3A). This finding suggests that no residual TR after TAP leads to improvement of late outcome.

In this series, we focused on patients who underwent TAP and mitral procedures. Previously, we reported the importance of aggressive surgical intervention for FTR in the setting of MVP for degenerative mitral regurgitation. Although mitral procedures, including repair or valve replacement, affect survival and recurrent FTR, these annuloplasty procedures were applied in this series. Patients who required TAP in this series were a high-risk group and had advanced NYHA functional class. Hospital and 30-day mortality rates were 5.5% and 2.7%, respectively. These rates were relatively higher than those in the annual report of the Japanese Association for Thoracic Surgery. The report showed that hospital and 30-day mortality rates after TAP and MVP were 2.7% and 1.9%, respectively. Although the reason for this discrepancy in mortality rate is not known, prolonged duration of cardiopulmonary bypass and cardiac arrest might contribute to these outcomes in addition to high-risk classification.

Overall survival rate, however, was acceptable compared with other reports, taking into consideration mean patient age. The incidence of recurrent FTR is generally higher in suture annuloplasty compared with ring annuloplasty. With regard to ring annuloplasty for FTR, there is still controversy regarding selection of size and the type of prosthetic ring. The tricuspid annulus in healthy subjects has a non-planar configuration and changes its size and shape dynamically during the cardiac cycle. The ideal target size and shape in tricuspid ring annuloplasty is theoretically considered to be normal systolic size and shape unless there is right ventricular dysfunction. There were 2 reasons why a flexible ring or band was selected in TAP in this series: (1) early surgery and the maze procedure might restore physiological motion of the tricuspid annulus after ring annuloplasty; and (2) a flexible band/ring has a low incidence of dehiscence after ring annuloplasty.

Selection of prosthetic band size has traditionally been determined by measuring the distance of the septal leaflet or the surface area of the anterior leaflet. Actually, neither size is reliable for selecting ring size. Therefore, in the present study, selection of ring size was determined by body surface area to obtain a normal systolic size in individual patients, and plication was carefully measured as described by Carpentier et al.

Freedom from FTR greater than mild at 5 and 8 years was 87.7±4.2% and 78.0±26.6%, respectively. Twenty patients experienced recurrent TR greater than mild. The rate of recurrent TR at late follow-up was 9.6% (20/208). Of the 20 patients, 4 had severe recurrent TR. Gatti et al described outcomes of TAP using the Cosgrove-Edwards flexible ring with a mean follow-up of approximately 20 months. On final follow-up echocardiography, TR in survivors was controlled to within

### Table 4. Preoperative Patient Characteristics vs. Final SPAP

<table>
<thead>
<tr>
<th>Variables</th>
<th>SPAP &lt;50 mmHg (n=160)</th>
<th>SPAP ≥50 mmHg (n=23)</th>
<th>P-value</th>
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<tr>
<td>Age (years)</td>
<td>64.1±12.2</td>
<td>69.3±5.9</td>
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<tr>
<td>Hypertension</td>
<td>69 (43)</td>
<td>10 (43)</td>
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<td>Diabetes mellitus</td>
<td>23 (14)</td>
<td>7 (30)</td>
<td>0.4163</td>
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<tr>
<td>Hyperlipidemia</td>
<td>40 (25)</td>
<td>5 (22)</td>
<td>0.2896</td>
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<tr>
<td>COPD</td>
<td>5 (3)</td>
<td>1 (4)</td>
<td>0.4809</td>
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<tr>
<td>Congestive HF</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0.4953</td>
</tr>
<tr>
<td>PAD</td>
<td>7 (4)</td>
<td>2 (9)</td>
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</tr>
<tr>
<td>Stroke</td>
<td>18 (11)</td>
<td>4 (17)</td>
<td>0.4278</td>
</tr>
<tr>
<td>Creatinine ≥1.5 mg/dl</td>
<td>10 (6)</td>
<td>3 (13)</td>
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<td>Hemodialysis</td>
<td>4 (3)</td>
<td>1 (4)</td>
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</tr>
<tr>
<td>Liver cirrhosis</td>
<td>0 (0)</td>
<td>3 (13)</td>
<td>0.5136</td>
</tr>
<tr>
<td>CAD</td>
<td>18 (11)</td>
<td>3 (13)</td>
<td>0.4221</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>101 (63)</td>
<td>22 (96)</td>
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<td>NYHA III or IV</td>
<td>34 (21)</td>
<td>7 (30)</td>
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<tr>
<td>Non-elective</td>
<td>3 (2)</td>
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<tr>
<td>Infective endocarditis</td>
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<td>0 (0)</td>
<td>0.4759</td>
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<td>Etiology</td>
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<td>Degenerative</td>
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<tr>
<td>Rheumatic</td>
<td>38 (24)</td>
<td>10 (43)</td>
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<td>Echocardiographic data</td>
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<tr>
<td>LVEDD (mm)</td>
<td>52.8±8.3</td>
<td>48.7±7.7</td>
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<tr>
<td>LVESD (mm)</td>
<td>33.7±8.5</td>
<td>31.0±5.8</td>
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<td>LAD (mm)</td>
<td>51.3±10.7</td>
<td>57.8±11.5</td>
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<tr>
<td>LVEF (%)</td>
<td>62.6±9.5</td>
<td>64.5±7.2</td>
<td>0.5773</td>
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<td>SPAP (mmHg)</td>
<td>45.7±13.6</td>
<td>49.4±16.2</td>
<td>0.4743</td>
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<tr>
<td>TR grade</td>
<td>1.8±0.8</td>
<td>2.5±0.7</td>
<td>0.0765</td>
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<tr>
<td>TR ≥moderate</td>
<td>83 (52)</td>
<td>19 (83)</td>
<td>0.0055</td>
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Data given as n (%) or mean ± SD. Abbreviations as in Tables 1,2.
Elevated SPAP was associated with the following factors: advanced age, atrial fibrillation, rheumatic etiology in the mitral valve and severe preoperative TR. Of these 4 factors, rheumatic etiology and preoperative TR grade were mild. In another report, 10% of the survivors had moderate TR at final follow-up, which was similar to the present rate of recurrent TR.

We found that elevated SPAP at follow-up was a risk factor for recurrent TR. Elevated SPAP was associated with the following factors: advanced age, atrial fibrillation, rheumatic etiology in the mitral valve and severe preoperative TR. Of these 4 factors, rheumatic etiology and preoperative TR grade were
also associated with residual TR greater than mild after TAP. Although we cannot change mitral etiology, we can improve preoperative TR grade. Early intervention for TR can lead to prevention of residual TR greater than mild and recurrent TR, subsequently resulting in better late outcome.

Song et al analyzed factors associated with development of late TR after left-sided heart valve surgery without tricuspid valve intervention. The overall rate of late TR was 7.7% and rheumatic etiology was one of the negative factors for late TR. Similarly, we found that rheumatic etiology in the mitral valve was associated with recurrent TR. Patients with rheumatic valves tend to be operated on at an advanced stage of disease. In the present study, patients who underwent MVR for mainly rheumatic etiology had a higher frequency of atrial fibrillation and had an advanced stage of NYHA. We consider that these associations cause development of atrial fibrillation or elevated SPAP, subsequently resulting in recurrent TR in the setting of rheumatic etiology. Optimal referral to surgery should be considered before irreversible cardiac changes occur.

Yiu et al recommended tricuspid valve surgery before the development of symptoms because symptom-based surgery for TR has devastating outcomes. Huang et al described the outcome in TAP for FTR compared with suture and ring annuloplasty. They found that risk factors for recurrent TR included severity of preoperative TR, atrial fibrillation, and elevated SPAP, similar to the present study. Another study showed that left ventricular dysfunction, the presence of a permanent pacemaker, and suture annuloplasty were risk factors for recurrent TR. Atrial fibrillation has been reported to be strongly associated with recurrent TR. The utility of the maze procedure has been studied to treat atrial fibrillation, but there is controversy as to whether this is effective. In the present study, of 148 patients, 30% (20%) underwent the maze procedure. The grade of FTR in patients who have a chance to have cardiac rhythm restored by the maze procedure may be well controlled by combination of this with ring annuloplasty. Recurrent moderate to severe FTR develops in patients who are not good candidates for the maze procedure. With regard to elevated SPAP as a risk factor for recurrent TR, there were 2 patients with late severe TR and persistent elevated SPAP postoperatively. The present study demonstrated that preoperative SPAP did not affect late recurrent TR.

McCarthy et al described left ventricular dysfunction as a risk factor for recurrent TR. In the present study, left ventricular function was normal in patients with recurrent TR and was not a risk factor. There are several tricuspid procedures including suture annuloplasty and ring annuloplasty. As we previously reported, tricuspid leaflet augmentation using glutaraldehyde-treated autologous pericardium is an alternative technique for recurrent severe FTR associated with tricuspid tethering.

Tricuspid valve replacement (TVR) is another alternative for managing severe FTR. We have carried out only a few TVR, including redo surgery in the past 10 years, because outcome in TVR is worse than in TAP. We have performed TAP as much as possible. A recent report noted 5- and 10-year survival rates after TVR with a bioprosthesis of 63.6±8.9% and 56.5±10.3%, respectively. Freedom from reoperation at 10 years was 100%. In specific cases, such as stenotic valve disease associated with rheumatic change, TVR may be indicated. We found that rheumatic etiology was a factor for late recurrent TR. Therefore, TVR for patients with rheumatic diseased valves is appropriate. In the present study, 1 patient who underwent TAP with anterior leaflet augmentation had severe late recurrent TR because of leaflet tethering caused by right ventricular dysfunction. TVR should be considered as an alternative procedure to TAP because TAP alone cannot prevent massive residual TR.

The present study, which was retrospective in nature, has 2 main important limitations. The first limitation is the large heterogeneous patient group, because the present study included all patients who underwent concomitant TAP for FTR in the setting of MVP or MVR. We introduced strict indications for TAP and performed TAP for 172 patients (78.2%) after 2007. These conditions might have affected late survival or freedom from recurrent TR.

The second limitation is the lack of echocardiography data, such as right ventricular function, diameter and tricuspid valve tethering area or height, which are important variables for predicting the outcome of TAP. This is because it was difficult to measure these parameters. The third limitation is that we do not have data supporting the flexibility of implanted bands after TAP. The idea of using a flexible band/ring was based on mitral annular analysis after implantation of a flexible band. In the future, we will investigate tricuspid annular motion on imaging.

Regardless of these limitations, we included a relatively large number of patients (n=220) who underwent TAP using a flexible band, and the patient follow-up rate was 100%. Additionally, an optimal follow-up rate of echocardiography was achieved (87.9%).

Conclusions

Late outcome of TAP using a flexible ring or band based on the current strategy is acceptable. Optimal timing for surgery, especially before TR progression, should be taken into account to prevent residual TR greater than moderate, and recurrent TR.

Disclosures

Conflict of Interest: The authors declare no conflict of interest.

References


