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Clinical Research

Optimal Tricuspid Annular Size for Tricuspid Annuloplasty in Patients with Less-Than-Moderate Functional Tricuspid Regurgitation

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Background: We evaluated the association between tricuspid annular dilatation and the development of moderate or severe tricuspid regurgitation (TR). Additionally, we determined the optimal tricuspid annular dilatation threshold to use as an indicator for tricuspid annuloplasty in patients with less-than-moderate functional TR (FTR).
Methods: Between August 2007 and December 2014, 227 patients with less-than-moderate TR underwent mitral valve surgery without a tricuspid valve (TV) procedure. The TV annular diameter was measured via transthoracic echocardiography. The TV annular index (TVAI) was calculated as the TV annular diameter divided by the body surface area. The mean duration of echocardiographic follow-up was 42.0 months (interquartile range, 9.3–66.6 months).
Results: Eight patients (3.5%) developed moderate or severe TR. The rate of freedom from development of moderate or severe TR at 5 years was 96.2%. TV annular diameter, left atrial diameter, preoperative atrial fibrillation, and TVAI were found to be associated with the development of moderate or severe TR in the univariate analysis. A cut-off TVAI value of 19.8 mm/m^2 was found to predict the development of moderate or severe TR, and a significant difference was observed in the development of TR of this severity based on this cut-off ($p<0.001$).
Conclusion: The progression of TR was not infrequent in patients with untreated less-than-moderate FTR. An aggressive treatment approach can be helpful to prevent the progression of FTR for patients with risk factors, especially TVAI greater than 19.8 mm/m^2.

Keywords: Valve disease, Tricuspid valve, Tricuspid valve surgery, Tricuspid valve insufficiency

Introduction

Concomitant tricuspid valve (TV) surgery is recommended for patients with moderate or severe functional tricuspid regurgitation (FTR) undergoing left-sided valve surgery. This recommendation is made because untreated moderate or severe FTR is associated with tricuspid regurgitation (TR) recurrence and a relatively low survival rate [1-7]. However, whether concomitant TV surgery is beneficial in patients with less-than-moderate FTR is still a subject of debate. As the progression of untreated less-than-moderate FTR and the advantages of prophylactic tricuspid annuloplasty (TAP) have been reported in some recent studies, aggressive TAP has gained more interest [8-10].

The current guidelines recommend performing concomitant TV surgery in cases of less-than-moderate TR with tricuspid annular dilatation. In the guidelines, the criteria for annular dilatation are a TV annular size of >40 mm or 21 mm/m^2 [11,12]. To the best of our knowledge, although TV annular size has been used as the indicator for performing concomitant TV surgery, no report has analyzed the association between TV annular size and clinical outcomes in patients with less-than-moderate FTR. Therefore, we evaluated the association between TV annular dilatation and the development of moderate or severe TR. Additionally, we calculated the optimal TV annular diameter

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threshold to use in predicting the development of moderate or severe TR in patients with untreated less-than-moderate FTR.

Methods

Ethics statement

The institutional review board of Seoul National University Hospital Biomedical Research Institute reviewed the protocol for this study, which was approved as a minimal-risk retrospective study (approval no., H-1811-014-982) that did not require the informed consent of the patients who participated.

Study population

Between August 2007 and December 2014, 249 patients underwent mitral valve surgery due to rheumatic or degenerative disease without a TV procedure. Eight patients without FTR, 7 patients without postoperative echocardiography, 6 patients with moderate or severe FTR, and 1 patient with primary TR were excluded from the study. A total of 227 patients were enrolled.

Echocardiographic evaluation

All patients underwent preoperative transthoracic echocardiography (TTE), and the severity of TR was graded as none, trivial, mild, moderate, or severe [13]. FTR was defined as central TR without any structural TV problem observed on the preoperative TTE findings. The TV annular diameter was measured in the transthoracic apical 4-chamber view in late diastole, at the time of maximal tricuspid opening [14]. The TV annular index (TVAI) was calculated as the tricuspid annular diameter divided by the body surface area. During follow-up, routine echocardiographic evaluations were performed at the discretion of the operating surgeons, and the last follow-up echocardiographic evaluation was performed at a mean of 42.0 months (interquartile range, 9.3 to 66.6 months) after surgery. We did not consider an event to constitute TR recurrence when it improved naturally without the aid of an additional procedure.

Surgical procedures

All operations were performed under aortic and bicaval cannulation, moderate hypothermia, and cold cardioplegic arrest through a median sternotomy. The operating surgeon made the decision of whether to perform mitral valve repair or mitral valve replacement; however, repair has generally been the preferred method at Seoul National University Hospital. All patients who underwent mitral repair were weaned from cardiopulmonary bypass after the surgeons used intraoperative transesophageal echocardiography to confirm that no or less-than-mild regurgitation or stenosis was present.

Mitral valve replacement was performed using everted mattress sutures buttress-reinforced with polytetrafluoroethylene as a pledget or a tubule, and a subvalvular apparatus-sparing technique was utilized whenever possible. Arrhythmia surgery (a modified Cox maze IV procedure or left-sided maze procedure) was usually performed using a cryoablator or bipolar radiofrequency ablator before left-sided valve surgery.

Evaluation of clinical outcomes

Operative mortality was defined as any death within 30 days after surgery or during the same hospital admission as surgery. Patients underwent regular postoperative follow-up in the outpatient clinic at 3- to 4-month intervals. Clinical follow-up ended on July 31, 2018. If patients did not visit the clinic at the scheduled time, they were contacted by telephone to determine their condition. Follow-up was completed in 220 patients (96.1%), and the mean follow-up duration was 76.1 months (interquartile range, 50.7–102.4 months). The following were considered major adverse valve-related events (MAVEs): (1) cardiac death, (2) TV reoperation, (3) the development of moderate or severe TR, (4) congestive heart failure requiring admission, and (5) major bleeding or thrombosis.

Statistical analysis

Statistical analyses were performed using IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA). Data were expressed as means±standard deviations, as medians with ranges, or as proportions. Survival rates were estimated using the Kaplan-Meier method, while risk factors for time-related events were analyzed using the Cox proportional hazards model. For risk factors in the univariate analysis, $p<0.05$ was considered to indicate statistical significance. The restricted cubic spline function was performed for risk factors corresponding to continuous variables deemed to have statistical significance in the univariate analysis to confirm the existence of threshold values for the development of

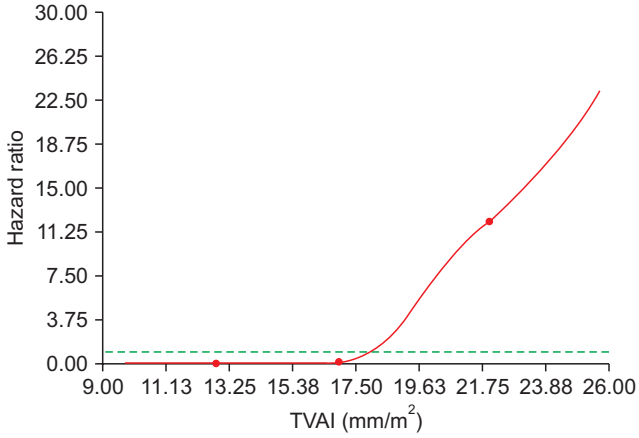

Fig. 1. Hazard ratio for the development of moderate or severe tricuspid regurgitation according to the TVAI (cut-off value, dashed line). TVAI, tricuspid valve annular index.

moderate or severe TR. The graphical relationship estimated using the restricted cubic spline function showed that a cut-off value for TVAI may exist, as the risk of development of moderate or severe TR did not change in patients in the bottom 50% with regard to TVAI, while that risk increased with increasing TVAI values in patients in the top 50% (Fig. 1). Other risk factors displayed linear associations with TR progression, meaning that no threshold values for those variables were identified. The minimal p-value approach was used to estimate a threshold TVAI value that predicted the development of moderate or severe TR [15]. We also explored whether the relationship between the TVAI and the development of moderate or severe TR differed according to other risk factors. The interaction term between the TVAI and the presence of other risk factors was statistically insignificant (p=0.872). A p-value <0.05 was considered to indicate statistical significance.

Results

Preoperative characteristics and operative data

The preoperative characteristics of the patients in the present study are summarized in Table 1. Regarding preoperative TR grade, 153 patients (67.4%) had trivial and 74 patients (32.6%) had mild TR. Eighty-three patients (36.2%) had preoperative atrial fibrillation, and 88 patients (38.4%) had rheumatic valve disease. The mean preoperative TV annular diameter and TVAI were 28.1±4.3 mm and 17.2±2.9 mm/m^2, respectively. The mean preoperative pulmonary arterial systolic pressure was 45.4±14.9 mm Hg. The concomitant procedures included aortic valve surgery (n=61), arrhythmia surgery (n=71), and coronary artery bypass grafting (n=17) (Table 2). The mean cardiopulmonary bypass and aortic cross-clamp times were 204±69 minutes and 132±52 minutes, respectively.

Table 1. Preoperative characteristics and risk factors of the participants (N=227)

Characteristic	Value
Age (y)	57.8±12.3
Male	116 (51.1)
New York Heart Association functional class ≥3	73 (31.9)
Tricuspid regurgitation grade	
Trivial	153 (67.4)
Mild	74 (32.6)
Risk factors	
Smoking	46 (20.1)
Overweight (body mass index >25 kg/m^2)	61 (26.6)
Diabetes mellitus	43 (18.8)
Hypertension	70 (30.6)
History of stroke	15 (6.6)
Chronic renal failure	84 (36.7)
Atrial fibrillation	83 (36.2)
Previous cardiac surgery	3 (1.3)
Preoperative echocardiography	
Left ventricular ejection fraction (%)	58.3±8.0
Pulmonary artery systolic pressure (mm Hg)	45.4±14.9
Left atrial size (mm)	55.7±8.7
Tricuspid valve annular diameter (mm)	28.1±4.3
Tricuspid valve annular index (mm/m^2)	17.2±2.9

Values are presented as mean±standard deviation or number (%).

Table 2. Operative data of the participants (N=227)

Variable	Value
Mitral valve surgery	
Replacement	100 (44.1)
Repair	127 (56.0)
Residual mitral regurgitation >mild at discharge (repair group, n=127)	8 (6.3)
Concomitant surgery	
Aortic valve surgery	
Replacement	58 (25.4)
Repair	3 (1.3)
Arrhythmia surgery	71 (31.3)
Aorta surgery	16 (7.0)
Coronary artery bypass graft	17 (7.4)
Others	9 (3.9)
Mitral valve etiology	
Rheumatic	88 (38.8)
Degenerative	139 (61.2)
Cardiopulmonary bypass time (min)	204±69
Aortic cross-clamping time (min)	132±52

Values are presented as number (%) or mean±standard deviation.

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Early clinical outcomes

The operative mortality rate was 1.7% (4 of 227 patients). The causes of death were acute respiratory distress syndrome (n=2), prosthetic valve endocarditis (n=1), and sepsis (n=1). Postoperative morbidities included new-onset atrial fibrillation (n=36), low cardiac output syndrome (n=10), respiratory complications (n=10), and bleeding requiring reoperation (n=8) (Table 3).

Eighty-three (36.6%) of the 227 patients had preoperative atrial fibrillation. Among them, 71 patients (85.5%) underwent surgical ablation. Forty-two (59.2%) of the patients who underwent surgical ablation were discharged with normal sinus rhythm, and only 12 of the 71 patients (17.0%) still exhibited atrial fibrillation at the last follow-up electrocardiogram. The mean follow-up duration was 58.9 months (interquartile range, 41.7–89.5 months). Early aggravation of moderate TR occurred in 6 patients at the time of postoperative echocardiography, and 5 patients improved spontaneously without any additional TV procedure.

Table 3. Early clinical results (N=227)

Variable	No. (%)
Operative mortality	4 (1.7)
Postoperative complications	55 (24.2)
Atrial fibrillation (new onset)	36 (15.8)
Acute kidney injury	4 (1.8)
Low cardiac output syndrome	10 (4.4)
Bleeding requiring reoperation	8 (3.5)
Respiratory complications	10 (4.4)
Stroke	2 (0.9)
Mediastinitis	0

Long-term clinical outcomes

Late death occurred in 11 patients, and the overall survival rates at 5 and 10 years were 94.0% and 91.1%, respectively. MAVEs occurred in 23 patients; these included the development of moderate or severe TR (n=8), major bleeding or thrombosis (n=8), cardiac death (n=5), TV reoperation (n=1) and congestive heart failure requiring admission (n=1). The rates of freedom from MAVEs at 5 and 10 years were 91.4% and 85.9%, respectively.

Eight patients had developed moderate or severe TR (moderate, 6; severe, 2) by 42.7 months after surgery. The rate of freedom from moderate or severe TR at 5 years after surgery was 96.2% (Fig. 2A). Among the 8 patients who developed moderate or severe TR, death occurred in 3 patients, congestive heart failure requiring admission in 2 patients, and significant bleeding in 3 patients.

In the univariate analysis, TV annular diameter, TVAI, preoperative atrial fibrillation, and left atrial size were found to be statistically significant risk factors for the development of moderate or severe TR (Table 4). Rheumatic valve disease and mitral valve replacement were not found to be associated with the development of moderate or severe TR (p=0.178 and p=0.828, respectively). A TVAI of 19.8 mm/m^2 was determined to be the cut-off value for predicting the development of moderate or severe TR using the minimal p-value approach. This cut-off value of 19.8 mm/m^2 is lower than the currently-recommended cut-off

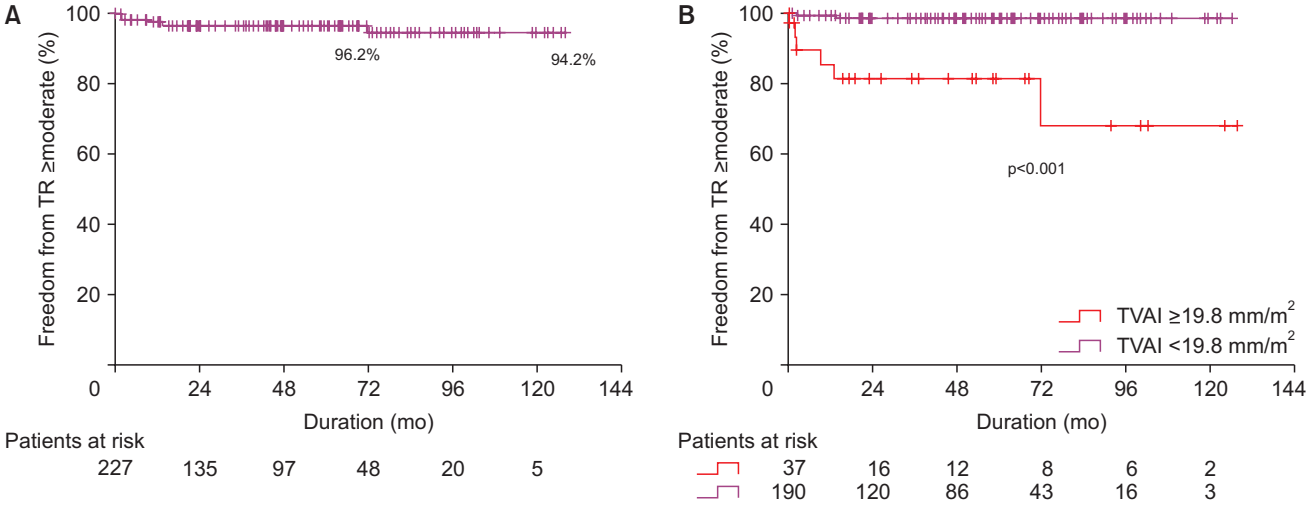

Fig. 2. (A) Kaplan-Meier curve for freedom from moderate or severe TR in the entire study population. (B) Risk of development of moderate or severe TR by TVAI. TR, tricuspid regurgitation; TVAI, tricuspid valve annular index.

Table 4. Univariate analysis for the potential risk factors of development of moderate or severe TR during follow-up

Variable	Hazard ratio (95% confidence interval)	p-value
Age	1.056 (0.989–1.127)	0.104
Female sex	0.135 (0.017–1.094)	0.061
Smoking	0.034 (0.000–43.278)	0.353
Hypertension	1.408 (0.336–5.903)	0.639
Coronary artery disease	1.665 (0.205–13.555)	0.634
Liver disease	5.799 (0.695–48.373)	0.104
Dialysis	0.049 (0.000–3.178×10^{11})	0.841
Chronic obstructive pulmonary disease	0.049 (0.000–7.987×10^{38})	0.949
Stroke	2.525 (0.310–20.585)	0.387
Rheumatic etiology	0.373 (0.089–1.564)	0.178
Mitral valve replacement	0.858 (0.214–3.438)	0.828
TV annular diameter (mm)	1.256 (1.084–1.455)	0.002
Preoperative TR grade	3.224 (0.923–11.261)	0.067
TV annular index (mm/m^2)	1.572 (1.253–1.971)	<0.001
Left atrial diameter (mm)	1.082 (1.007–1.163)	0.031
Preoperative atrial fibrillation	14.245 (1.741–116.578)	0.013
Preoperative pulmonary artery systolic pressure (mm Hg)	1.004 (0.959–1.052)	0.854

TR, tricuspid regurgitation; TV, tricuspid valve.

of 21 mm/m^2. A significant difference was observed in the frequency of progression to moderate or severe TR according to the cut-off value of 19.8 mm/m^2 (p<0.001) (Fig. 2B). Using the restrictive cubic spline function, we also explored the possibility of cut-off values for TV annular diameter and left atrial size. However, both parameters were linearly associated with TR progression, so it was impossible to calculate cut-off values for those variables.

Discussion

This study yielded 3 main findings. First, although the follow-up duration was short, the progression of TR was not infrequent in patients with untreated less-than-moderate FTR. Second, TV annular diameter, left atrial diameter, preoperative atrial fibrillation, and TVAI were found to be associated with the development of moderate or severe TR. Third, a TVAI of 19.8 mm/m^2, which is lower than the value in the current guidelines, was determined to be the cut-off value for predicting the development of moderate or severe TR.

Untreated moderate or severe FTR is known to be a risk factor for the aggravation of TR after left-sided valve surgery [1,16]. However, data are lacking regarding the results of untreated less-than-moderate FTR. The present study showed that the progression of TR was not infrequent in patients with untreated less-than-moderate FTR, even though left-sided valve lesions were corrected appropriately. Kusajima et al. [16] similarly showed that more than half of cases of untreated mild FTR became aggravated to moderate or severe TR over 10 years of follow-up. In the present study, the rate of freedom from the development of moderate or severe TR at 5 years was 96.2%. Considering the relatively poor clinical outcomes in patients who developed moderate or severe TR in this study, more suitable surgical indications of TV surgery for less-than-moderate FTR are required to prevent the aggravation of TR.

According to the current guidelines, the 2 preoperative criteria to assess annular dilatation [11,12] are TV annular diameter and TVAI. A TV annular diameter of 40 mm on transthoracic echocardiography has been suggested as a criterion for TV annular dilatation. However, considering that the normal TV annular size differs from person to person, simple TV annular diameter has limited utility in assessing TV annular dilatation. In this study, TV annular diameter and TVAI were found to be significantly associated with the development of moderate or severe TR in the univariate analysis. Therefore, the body surface area should also be considered when evaluating TV annular dilatation.

The current guidelines also suggest a TVAI of 21 mm/m^2 as a criterion for TV annular dilatation. However, this threshold was not determined by calculating the cut-off value for predicting adverse clinical outcomes such as overall death or aggravation of TR [17]. In this study, we calculated the cut-off value for predicting the aggravation of TR using the minimal p-value approach. The determined cut-off value of 19.8 mm/m^2 is lower than the value of 21 mm/m^2 that is recommended by the current guidelines as an indication for TV surgery. This result indicates that broadening the indication of TAP and taking an aggressive approach for FTR treatment can be helpful in preventing the aggravation of TR in patients with preoperative atrial fibrillation or large TVAI.

In this study, we evaluated the incidence of progression to moderate or severe TR. According to the current guidelines, moderate TR is not a class I indication for surgical repair. However, some studies have verified the clinical significance of moderate TR. Nath et al. [6] showed that moderate or severe TR, when compared with mild or less severe TR, was associated with increased long-term mortality; as such, the former was associated with a worse prognosis. Some reports have also shown that moderate TR is a risk factor for TR progression [2,3,5]. Therefore, we

evaluated the incidence and risk factors for the development of moderate or severe TR.

Concerns exist that concomitant TV repair could increase the surgical risk because concomitant TAP increases aortic cross-clamping time and the risk of postoperative complete atrioventricular block [18]. However, some reports have demonstrated the safety of prophylactic TAP. In our previous study, although concomitant TV surgery increased the aortic cross-clamping time by an average of 30 minutes, significant differences were noticed in mortality rate, hospital stay, and postoperative complications between the patients who underwent MV replacement with TAP and those who had surgery without TAP [8]. Badhwar et al. [19] compared the clinical outcomes of a total of 88,473 patients who underwent MV replacement or repair according to whether they underwent concomitant TV repair. In their study, concomitant TV repair was associated with an increase in morbidity, but not with an increase in risk-adjusted mortality [19]. Lee et al. [10] evaluated the clinical outcomes of 293 patients with less-than-moderate TR who underwent MV replacement with or without TAP. Overall survival and freedom from cardiac-related mortality were not significantly different between the TAP group and the no-TAP group, but the rate of freedom from recurrence of moderate or higher TR was significantly higher in the TAP group [10]. Considering these results, concomitant TV surgery can be worthwhile for patients at high risk of TR progression.

Preoperative atrial fibrillation is a well-known risk factor for the development of moderate or severe TR [1,3]. This study reconfirms this finding. Among the 8 patients who developed moderate or severe TR in the present study, 7 patients had preoperative atrial fibrillation, and all patients underwent concomitant surgery for arrhythmia. Although 3 of the 7 patients with preoperative atrial fibrillation converted to a normal sinus rhythm, they experienced TR aggravation during follow-up. A possible hypothesis is that a preexisting pathologic change in the heart in a patient with preoperative fibrillation could cause the aggravation of TR, irrespective of sinus conversion. This finding implies that more aggressive TV surgery should be performed to prevent the aggravation of TR in patients with combined atrial fibrillation.

The present study has several noteworthy limitations. First, it was a retrospective observational study conducted at a single institution. Therefore, the number of enrolled patients was not as large as would have been ideal to draw definitive conclusions for risk factor analysis and calculate a cut-off value. Second, the follow-up duration was short; we were unable to enroll patients who underwent surgery before 2007 because we could not measure their TV annular diameter. Third, although the patients who developed moderate or severe TR showed worse clinical outcomes than the patients who did not, we failed to show significant relationships between TVAI and MAVEs or overall death. This lack of a significant difference may have been affected by the short follow-up duration and the small study population. Lastly, the progression of TR to moderate or severe only occurred in 8 patients, so a multivariable model could not be used due to overfitting.

In conclusion, although the follow-up duration was short, the progression of TR was not infrequent in patients with untreated less-than-moderate FTR. TV annular diameter, left atrial diameter, preoperative atrial fibrillation, and TVAI were found to be associated with the development of moderate or severe TR, and a TVAI of 19.8 mm/m^2, which is lower than the current guideline, was determined to be the cut-off value for predicting the development of moderate or severe TR. Therefore, an aggressive treatment approach for FTR would be helpful to prevent the progression of less-than-moderate FTR in patients with preoperative atrial fibrillation or TVAI greater than 19.8 mm/m^2.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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