

# The better substitute for tricuspid valve replacement in patients with severe isolated tricuspid regurgitation

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## ABSTRACT

**Objective:** The ideal alternative for tricuspid valve replacement (TVR) in patients with severe isolated tricuspid regurgitation remains unclear. The aim of the present study was to retrospectively investigate the outcomes of using bioprosthetic and mechanical valves at the tricuspid position.

**Methods:** A total of 98 consecutive patients without left-side cardiac disease or history of heart surgery who underwent first-time TVR between January 2010 and March 2017 at the West China Hospital, China were included in the study. Patient data, including all-cause death and need for tricuspid valve reoperation as the main end points, were retrospectively evaluated.

**Results:** A total of 76 patients were enrolled into the study. The mean follow-up period was  $43.3 \pm 21.9$  (10–87) months. The mean age of the patients was  $45.7 \pm 13.4$  years. The study comprised 32.9% of male patients. During the follow-up period, 4, 3, 12, and 3 cases of death, reoperation, prosthesis dysfunctions, and prosthesis-related thrombosis were noted, respectively. Biological and mechanical valves were used in 56.6% and 43.4% of the patients, respectively. However, there was no significant difference between mechanical and biological valves with respect to echocardiographic date and survival, reoperation, prosthetic valve dysfunction, and thromboembolism rate.

**Conclusion:** TVR is not a very high-risk procedure in patients with isolated tricuspid regurgitation, and the decision for prosthesis implantation in TVR should be made on an individual basis according to suitable clinical judgment. (*Anatol J Cardiol* 2019; 22: 00-00)

**Keywords:** tricuspid valve replacement, mechanical valve, biological valve

## Introduction

Primary tricuspid valve regurgitation is rarely observed in adults and is known to result from congenital heart disease, rheumatic heart disease, myxomatous valve disease, infective endocarditis, carcinoid syndrome, and/or infiltrative valvulopathy (1). Tricuspid valve repair is the first option for patients with primary or secondary tricuspid regurgitation. However, valve replacement, instead of repair, may be better for those with severe structural valve dysfunction.

In patients with isolated tricuspid valve regurgitation, tricuspid valve replacement (TVR) has been associated with a considerable reported risk of mortality and a high incidence of prosthesis-related complications, which could lead to a high number of reoperations (2). With regard to prosthesis, the choice between mechanical and bioprosthetic valves remains controversial. Furthermore, only a few studies have assessed the clinical out-

comes of patients with primary tricuspid valve regurgitation after isolated TVR.

The aim of the present study was to evaluate the long-term outcomes in patients undergoing first-time TVR with a mechanical or bioprosthetic valve for severe isolated tricuspid valve regurgitation.

## Methods

### Patients

A total of 98 patients with primary tricuspid valve regurgitation underwent first-time TVR at the West China Hospital in China between January 2010 and March 2017. The prosthesis used was determined by the attending physician after considering age, symptoms, other comorbidities, and particularly the will of the patients. The present study was

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approved by the Institutional Ethics Committee Board of the West China Hospital. At the end of the study, 76 consecutive patients completed the follow-up.

### Operative techniques

Cardiopulmonary bypass was established through median sternotomy. The sternotomy approach involved conventional ascending aorta and bicaval cannulation. Tricuspid valve surgery was performed under cardioplegic arrest conditions. The septal leaflet and subvalvular structure were preserved in cases of TVR with mechanical valve, whereas the leaflets and subvalvular structures were preserved in cases of TVR with a bioprosthesis. Transesophageal echocardiography was performed prior to weaning from the cardiopulmonary bypass.

### Follow-up

Follow-up data were obtained until the end of June 2018 via visit or telephone interviews at 3- to 6-month intervals. The mean duration of follow-up was 43.3±21.9 (10–87) months. The main end point was defined as all-cause death and the need for tricuspid valve reoperation. All deaths were considered to have been of cardiac origin unless a non-cardiac origin had been established clinically or determined at autopsy.

### Statistical analysis

All data were analyzed using the SPSS version 17.0 statistical analysis software (SPSS Inc., Chicago, IL, USA). Data are expressed as mean±standard deviation, unless specified otherwise. Student's t-test was used to analyze data. Categorical variables are presented as frequencies and percentages (%). Fisher's exact test was used to compare categorical variables. Kaplan–Meier curves were used to delineate the survival or prosthesis-related complication rate. A p value of <0.05 was considered significant.

## Results

### Baseline characteristics

A total of 76 patients were enrolled into the present study. The study included 25 male patients. The mean age at surgery of the patients was 45.7±13.4 years. Of the 76 patients, 7 (9.2%) had hypertension, and 30 (39.5%) had atrial fibrillation. According to the New York Heart Association (NYHA) classification, 19 (25%) patients were classified as NYHA III or IV grade. With regard to etiology, 25 (33.9%) patients had congenital heart disease (Ebstein anomaly) and 5 (6.6%) patients had endocarditis, whereas others had isolated annular dilatation with either leaflet prolapse or tethering. Of the 76 patients who underwent TVR, 43 bioprosthetic valves (bovine valves in 23 and porcine valves in 20) and 33 mechanical valves were implanted. The concomitant procedures included atrial septal defect closure, ventricular septal defect closure, and surgical ablation for atrial fibrillation.

The baseline demographic and echocardiographic profiles are summarized in Table 1.

### Early surgical outcomes

Two patients exhibited postoperative refractory right ventricular (RV) dysfunction. One patient with bioprosthetic TVR who underwent extracorporeal membrane oxygenation recovered, whereas another patient with mechanical TVR died. A superior vena cava thrombosis was noted on postoperative day 5 in a patient who had undergone mechanical TVR. With regard to perioperative complications, the most common included re-exploration for bleeding, low cardiac output syndrome, acute renal failure, wound infection, and pulmonary infection. However, there were no significant differences with respect to early

**Table 1. Preoperative and intraoperative data**

	Bioprosthetic valve (n=43)	Mechanical valve (n=33)	P value
Age, year	47.7±14.7	43.2±11.2	0.065
Male gender, n (%)	15 (34.9%)	10 (30.3%)	0.674
Hypertension, n (%)	3 (7.0%)	4 (12.1%)	0.442
Atrial fibrillation, n (%)	19 (44.2%)	11 (33.3%)	0.337
NYHA functional class, n (%)			
I	5 (11.6%)	7 (21.2%)	0.256
II	27 (62.8%)	18 (54.5%)	0.468
III	8 (18.6%)	6 (18.2%)	0.962
IV	3 (7.0%)	2 (6.1%)	0.873
Echocardiographic data			
LVEDD, mm	41.9±7.1	40.1±6.4	0.814
RVEDD, mm	34.4±7.4	34.4±8.9	0.494
TAPSE	18.6±4.9	19.1±4.8	0.838
EF, %	60.5±8.5	63.6±6.2	0.109
Associated procedures, n (%)			
ASD	3 (7.0%)	5 (15.2%)	0.250
VSD	2 (4.7%)	2 (6.1%)	0.785
MAZE	7 (16.3%)	1 (3.0%)	0.062
Prosthesis sizes, n (%)			
25	0	1 (3%)	0.251
27	1 (2.3%)	1 (3%)	0.849
29	16 (37.2%)	4 (12.1%)	0.014*
31	26 (60.5%)	19 (57.6%)	0.799
33	0	8 (24.2%)	0.001*

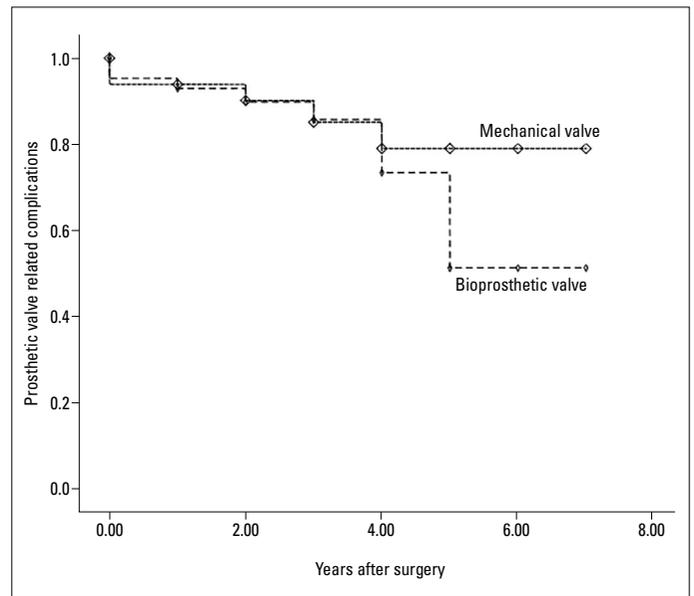
\*P<0.05.

LVEDD - left ventricular end diastolic dimension; RVEDD - right ventricular end diastolic dimension; TAPSE - tricuspid annular plane systolic excursion; EF - ejection fraction; ASD - atrial septal defect; VSD - ventricular septal defect

postoperative complications between the bioprosthetic and mechanical TVR groups (Table 2).

**Long-term outcomes**

A total of 14 patients presented with prosthesis-related complications. Among these patients, 8 (18.6%) with bioprosthetic TVR exhibited either moderate-to-severe regurgitation or decreased effective orifice area (EOA). In addition, prosthesis-related thrombosis was noted in 2 (4.7%) patients with bioprosthetic TVR within 6 months after surgery; of these patients, 9 refused to undergo redo surgery. In patients with mechanical TVR, 4 (12.1%) exhibited impaired prosthetic motion and decreased EOA, whereas only 1 patient required redo surgery. The final follow-up echocardiographic parameters are summarized in Table 3. Figure 1 shows the data on freedom from prosthesis-related complications, including prosthesis dysfunction and thrombosis. There was no significant difference with respect to prosthesis-related complications between the groups, although the frequency of bioprosthetic valve dysfunction significantly increased at year 5 (log rank  $p=0.276$ ).



**Figure 1.** The freedom from prosthesis-related complications after TVR with bioprosthetic and mechanical valves

**Table 2. Early postoperative outcomes in patients with bioprosthetic and mechanical valves**

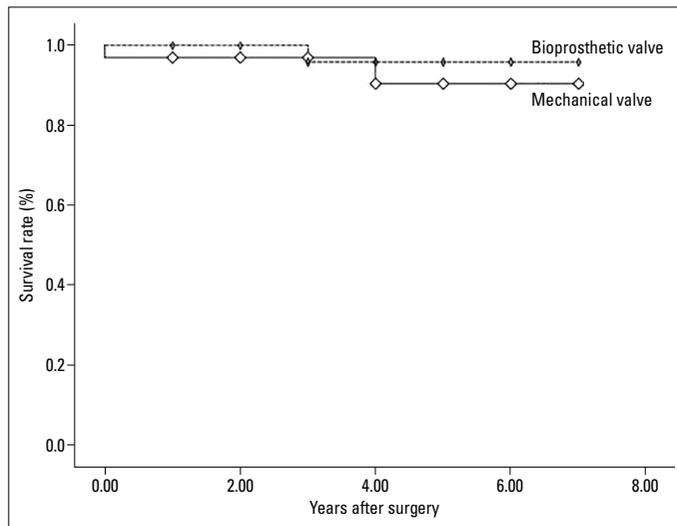
	Bioprosthetic valve (n=43)	Mechanical valve (n=33)	P value
Early or in-hospital mortality, n (%)	0	1 (3.0%)	0.251
No. of patients with major complications, n (%)			
Reexploration for bleeding	0	1 (3.0%)	0.251
Low cardiac output syndrome	5 (11.6%)	1 (3.0%)	0.168
Acute renal failure	2 (4.7%)	0	0.209
Wound infection	1 (2.3%)	3 (9.1%)	0.190
Pulmonary infection	8 (18.6%)	5 (15.2%)	0.692
ECMO	1 (2.3%)	0	0.378
Valve thrombosis in prostheses, n (%)	0	1 (3.0%)	0.251

ECMO - extracorporeal membrane oxygenation

**Table 3. Comparison of long-term follow-up outcomes between bioprosthetic and mechanical valves**

	Bioprosthetic valve (n=43)	Mechanical valve (n=33)	P value
Prosthesis dysfunction, n (%)	8 (18.6%)	4 (12.1%)	0.312
Valve thrombosis in prostheses, n (%)	2 (4.7%)	0	0.209
Echocardiographic data			
LVEDD, mm	45.8±4.6	44.6±5.6	0.306
RVEDD, mm	26.6±5.4	27.8±8.8	0.070
EF, %	62.2±8.5	62.9±7.3	0.713
Velocity (m/s)	1.43±0.33	1.39±0.42	0.169
Mortality, n (%)	2 (4.7%)	1 (3.0%)	0.719
Redo surgery, n (%)	1 (2.3%)	1 (3.0%)	0.849

LVEDD - left ventricular end diastolic dimension; RVEDD - right ventricular end diastolic dimension; EF - ejection fraction



**Figure 2.** The survival rate after TVR with bioprosthetic and mechanical valves

During the mean follow-up period of  $43.3 \pm 21.9$  (10–87) months, three late deaths were noted, including two patients with bioprosthetic TVR and one patient with mechanical TVR. The overall survival rate was 94.7%. Figure 2 shows the overall survival rates according to surgical type, and there was no significant difference in the survival rate between the two groups (log rank  $p=0.478$ ).

## Discussion

Although the tricuspid valve repair is considered as a first-line treatment for tricuspid regurgitation, valves with severe leaflet tethering and morphological abnormality may be suitable for replacement rather than repair. Kim et al. (3) investigated the outcomes after the surgical correction of severe isolated tricuspid regurgitation and suggested that patients with a higher risk of postoperative tricuspid regurgitation after repair may benefit from TVR.

Only a few studies have investigated the clinical outcomes after isolated TVR because of the relative scarcity of patients with isolated tricuspid valve regurgitation in the clinical setting. There may be two major reasons for the lack of sufficient numbers of patients. One reason may be the good tolerance of patients with isolated tricuspid regurgitation, which might not be detected for a long period, particularly among patients in developing countries. The other reason is the reported high mortality rates (10%–40%) (4-6), which leads both surgeons and patients to prefer conservative treatment. However, the results in the present study indicated that the mortality rate was only 5.3%, which was consistent with the findings of a long-term follow-up study by Brown et al. (7). This favorable result may be attributed to the fact that patients who had undergone left-sided heart valve surgery were excluded from our study. In addition, the long-term survival after TVR is reportedly affected by preop-

erative parameters, such as symptoms and RV function (3). In the present study, most of the patients were categorized as NYHA functional classes II and I. Therefore, TVR may not be as high-risk procedure as traditionally believed.

The ideal alternative for TVR in patients with severe tricuspid valve regurgitation remains unclear. Previous studies found that there was no significant difference between mechanical and biological valves with respect to survival, reoperation, or prosthetic valve failure rate (8-10). With regard to prosthesis size, the most common are 29 and 31 for either biological or mechanical valve. The difference in size may be because bioprosthesis is designed with bigger body size.

Despite the findings of previous studies being consistent with our study, there is no gold standard for prosthetic TVR. Therefore, prosthesis cost is the major determinant for patients in cases where surgeons cannot offer suggestions on the choice of prosthesis, particularly in developing countries, such as China. In the present study, the financial burden was the main reason for the lower rates of the concomitant surgical ablation and the reoperation for prosthesis dysfunction.

The choice between using biological or mechanical prosthesis in the tricuspid position should be made on an individual basis according to clinical judgment (11). The advantage of the bioprosthesis is that it does not require long life anticoagulation therapy and is associated with a low risk of hemorrhage with increasing age (12). Bioprosthesis was preferred in these patients, given the need for higher quality of life and presence of contraindications for anticoagulation, such as pregnancy and older age. The average time for structural valve deterioration (SVD) was reported to be 7 years, and the 10-year freedom rate from SVD was only 58% (13, 14). In the present study, the frequency of SVD significantly increased at year 5 after surgery. Although SVD of the bioprosthesis is a significant problem, transcatheter tricuspid valve interventions are emerging as an alternative for those deemed to be at high risk for conventional surgery and those requiring redo surgery after TVR with bioprosthesis (13). Younger age at implantation and smaller size of the implanted prosthesis are major determinants of early SVD (15). Owing to the desirable hemodynamic properties, low gradients, low disturbances in flow, and long durability, the mechanical valves are preferred in younger age groups and in patients simultaneously receiving another mechanical valve. In the present study, the 43.3-month rate of freedom from bioprosthesis dysfunction was 81.6%, whereas the rate of freedom from mechanical prosthesis-related thromboembolism was 97%. However, it is crucial to continue anticoagulation drug within the first 6 months in patients with either biological or mechanical prosthesis TVR.

## Study limitations

The present study has several limitations. First, the study was retrospective in nature, and the sample size was small. Furthermore, the fact that the choice of the prosthesis type was determined by the attending physician may have resulted in bias.

Second, patients who had previously undergone left-side heart valve surgery were excluded from the present study. Finally, the choice between bovine or porcine biological prosthesis was not studied.

## Conclusion

TVR may not be such a high-risk procedure in patients with isolated tricuspid regurgitation. Although there was no significant difference between mechanical and biological valves with respect to survival, reoperation, prosthetic valve dysfunction, and thromboembolism, the decision regarding prosthesis implantation in TVR should be made on an individual basis according to suitable clinical judgment.

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