







## Research Article

# Evaluation of Risk Factors and Outcomes of Isolated Tricuspid Valve Replacement with a Conventional Surgical Approach: A Retrospective Cohort Study

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**Introduction.** Tricuspid valve (TV) disease is substantially less common than mitral or aortic valve disease, and it is commonly missed due to the tolerability of stenosis or regurgitation. Adults seldom have primary tricuspid valve regurgitation, which is linked to rheumatic heart disease, infectious endocarditis, myxomatous valve disease, congenital heart disease, carcinoid syndrome, and/or infiltrative valvopathy. **Materials and Methods.** The authors examined the Valve Surgery Data Bank retrospectively to identify all patients who underwent TV replacement without concomitant surgeries between 2004 and 2014. In addition, the exclusion criteria suggested that all instances involving solitary valve repair were eliminated. Through visits or phone interviews, long-term follow-up was collected through the end of June 2022 in order to gather information on postoperative occurrences among the patients. The average follow-up time was  $10.7 \pm 2.1$  (5–15) years. **Results.** The overall survival rate was 90.9%. Survival rate was not significantly different between bioprostheses and mechanical ones (log rank  $p = 0.05$ ). The incidence of endocarditis and valvar thrombosis in short-term was higher in the mechanical group than in the biological group, but the frequency of valve malfunction and redo surgery was higher in the replacement group. We found a higher incidence of valvular thrombosis, GI bleeding, and myocardial infarction rate in mechanical valve complications compared to the bioprosthetic group regarding late complications.

## 1. Introduction

Tricuspid valve (TV) disease is considerably less prevalent than mitral or aortic valve disease, and it is frequently overlooked since stenosis or regurgitation can be well tolerated [1]. Primary tricuspid valve regurgitation is uncommon in adults and is associated with rheumatic heart disease, infective endocarditis, myxomatous valve disease, congenital heart disease, carcinoid syndrome, and/or infiltrative valvulopathy [2]. Secondary causes in patients with normal leaflets are usually due to left heart pathology like

pulmonary hypertension, left-side heart failure, and progressive biventricular dysfunction.

The use of mechanical vs. bioprosthetic tricuspid valve replacement (TVR) has been the topic of ongoing discussion. Studies have showed conflicting results advocating either the use of biological or mechanical prostheses. Lower right ventricular pressures and flows increase the risk of thromboembolic complications following mechanical valve implantation [3, 4]. On the other hand, Bioprostheses are more prone to tissue degeneration and destruction, and their low durability precludes their universal recommendation,

especially in destructive processes such as the carcinoid syndrome.

Therefore, this study aimed to assess the clinical outcome of patients who received TVR, with a particular focus on long-term survival and valve-associated complications.

## 2. Materials and Methods

In June 2022, we retrospectively queried the Tehran Heart Center Valve Surgery Data Bank to determine all the patients who had TV replacement. Between 2004 and 2014, a total of 1591 tricuspid repairs and 401 TVR were carried out. The exclusion criteria indicated that all those cases that underwent concomitant operations were excluded. The research ethics committee of Tehran University of Medical Sciences reviewed and approved the protocol of the study (No: IR.TUMS.THC.REC.1400.067).

In accordance with the protocol of the Tehran Heart Center Surgery Data Bank, general practitioners and research nurses questioned and examined patients to collect information regarding their symptoms, main risk factors for cardiovascular disease, and baseline features. The decision to perform surgery was made at the discretion of the attending surgeon, taking into consideration the anatomic factors and patient's age, symptoms, and other comorbidities. The final choice of bioprosthetic versus mechanical valve was a shared decision between the patient and the physician.

During hospitalization and for 90 days after surgery, the patients were followed and interviewed to document any early in-hospital mortality and readmission. After analyzing the database for all the patients, the data on echocardiographic indices before surgery, demographics, past medical history, and any morbidities were gathered.

In addition, long-term follow-up were obtained until the end of June 2022 via visit or telephone interviews to collect data of postoperative events among the patients. The mean duration of follow-up was  $10.7 \pm 2.1$  (5–15) years. All deaths were considered to have been of cardiac origin unless a noncardiac origin had been established clinically or determined at autopsy.

**2.1. Statistical Analysis.** Continuous variables were presented as mean  $\pm$  standard deviation. Categorical variables are presented as numbers (percentages). Fisher's exact and chi-square tests were used to compare treatment outcomes between the groups. Student *T*-tests and ANOVA tests were also used to analyze the significance of the differences between means and variances. The level of *P* value for statistical significance was set as less than 0.05. Data analysis was performed using SPSS software (IBM Corp., Armonk, New York, United States) (version 26).

## 3. Results

Out of seventy patients who underwent TVR, 40 bioprosthetic valves (60.6%) and 26 mechanical valves (39.4%) were implanted. For 12 patients (18.2%), this was a second-time tricuspid valve operation and for 4 patients this was the third-time (6.0%). The study included 44 female patients

(66.7%). The main etiology for operation was rheumatic in 11 patients (16.7%), endocarditis in 6 patients (9.0%), and congenital heart disease (Ebsteins anomaly) in 5 patients (7.6%); other patients had isolated annular dilatation with either leaflet prolapse or tethering.

The mean age at surgery for bioprosthetic TVR ( $53.21 \pm 13.0$ ) was higher than the mean age at surgery for mechanical TVR ( $46.58 \pm 14.23$ ), but this difference was not statistically significant ( $p = 0.06$ ). There were no significant differences between the two groups regarding risk factors and comorbidities except for higher rates of TR regurgitation in patients who underwent mechanical valve implantation (80.7 vs. 40.0%,  $p < 0.001$ ).

In terms of ICU admission duration and overall admission duration, there were no statistically significant differences between the two groups; the *p* values for ICU admission duration and overall admission duration were 0.10 and 0.09, respectively. The baseline demographics of patients are summarized in Table 1.

The early mortality rate was 4.5% in this cohort, one patient with biological prosthesis and two patients with mechanical TVR. During the mean follow-up period of  $10.7 \pm 2.1$  (5–15) years, three late cardiac deaths were noted, including two patients with bioprosthetic TVR and one patient with mechanical valve. Moreover, during this period, 7 noncardiac deaths occurred (4 unknown, 2 malignancies, and one injury). The overall survival rate was 90.9%. Survival rate was not significantly different between bioprostheses and mechanical ones (log rank  $p = 0.05$ ) (Figure 1).

In addition, we evaluated the complications associated with both short- and long-term valve implantations. According to our definition, any difficulty occurring within three months is regarded to be short-term, but any complication occurring after three months is considered to be long-term (Table 2).

Six patients (9.1%) underwent reoperation for prosthetic valve failure (five bioprosthetic and two mechanical). Two patients required repeat TVR due to prosthetic valve thrombosis in the mechanical valve group. Five patients had their TV shifted from bioprosthetic to mechanical due to failure or degeneration of the valve.

As it is shown, the incidence of endocarditis and valvar thrombosis in short-term was higher in the mechanical group than in the biological group ( $p$  value = 0.56 and 0.15, respectively), but the frequency of valve malfunction and redo surgery was higher in the bioprosthetic replacement group ( $p$  value = 0.46). We found a higher incidence of valvular thrombosis, GI bleeding, and myocardial infarction rate in mechanical valve complications compared to the bioprosthetic group regarding late complications ( $p$  value = 0.15, >0.99, and >0.99, respectively).

## 4. Discussion

Tricuspid valve operations account for less than 10% of all cardiac procedures [5]. Moreover, tricuspid annuloplasty with a suture plication or the insertion of a prosthetic ring yields favorable outcomes for the majority of patients [6]. However, between 5% and 15% of patients with tricuspid

TABLE 1: Comparison of patient characteristics, risk factors, and outcomes between patients undergoing tricuspid valve replacement by bioprosthetic and mechanical valves.

	Bioprosthetic ( $n = 40$ )	Mechanical ( $n = 26$ )	$p$ value*
Age	53.21 $\pm$ 13.02	46.58 $\pm$ 14.23	0.06
Gender (female)	72.5%	57.7%	0.28
<i>Risk factors</i>			
Hypertension	30.0%	30.8%	>0.99
Dyslipidemia	17.5%	11.5%	0.17
Diabetes	15.0%	7.7%	0.46
Smoking	15.0%	11.5%	>0.99
Opium use	7.5%	3.8%	>0.99
Previous myocardial infarction	10.0%	3.8%	0.64
Familial history of cardiac diseases	15.0%	11.5%	>0.99
CVA or TIA	5.0%	0.0%	0.51
Previous CABG	5.0%	3.8%	>0.99
Previous PCI	0.0%	3.8%	>0.99
Previous atrial fibrillation	22.5%	15.4%	0.54
Heart failure	5.0%	3.8%	>0.99
Renal insufficiency	2.5%	0.0%	>0.99
Tricuspid valve stenosis	12.5%	23.1%	0.32
Tricuspid valve regurgitation	40.0%	80.7%	0.002
ICU admission duration	10.67 $\pm$ 13.0	6.41 $\pm$ 2.65	0.10
Hospital admission duration	28.15 $\pm$ 12.6	23.21 $\pm$ 10.2	0.09
<i>NYHA functional class</i>			
II	27.5%	19.2%	
III	45.0%	57.7%	0.58
IV	27.5%	23.1%	
Ejection fraction, mean (SD)	45.60 $\pm$ 9.87	46.51 $\pm$ 8.91	0.09
PAP, mean (SD)	47.81 $\pm$ 8.42	46.10 $\pm$ 9.2	0.44

\*  $P$  values report the significance of differences between the two groups; Fisher's exact test was used for the analysis;  $P$  values <0.05 were considered significant.

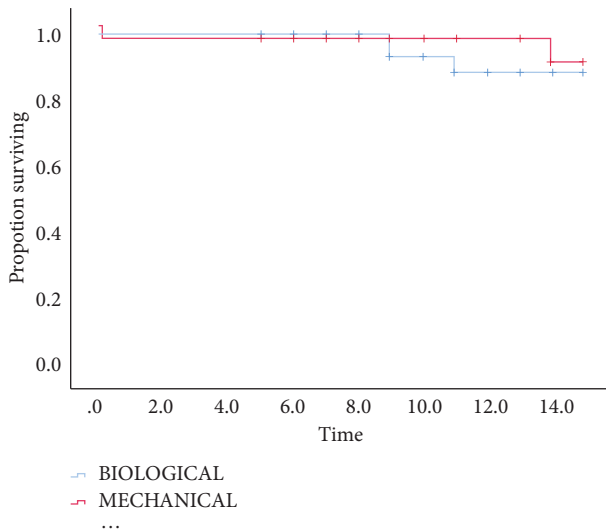


FIGURE 1: Comparison of follow-up mortality and survival rates between patients undergoing tricuspid valve replacement by bioprosthetic and mechanical valves. The reported time frame is in years.

valve disease require TVR for reasons like organic abnormalities (e.g., rheumatic valve disease and tricuspid valve endocarditis), failure of tricuspid valve repair, and a desire to prevent a future reoperation [7].

The selection of a suitable valve for TVR in patients remains controversial. According to proponents of the

mechanical TVR, bioprosthetic TVRs are connected with long-term structural valve degradation [5, 8]. Opponents support bioprosthetic valves owing to a high incidence of valve-related complications after mechanical TVRs, including valve thrombosis and bleeding events related to anticoagulation therapy, limited life expectancy regardless of the type of TVR at long-term follow-up, and expected long-term durability of bioprostheses at the tricuspid position because of low pressures and, thus, low stress in the right-side heart chambers. Moreover, the authors support the use of bioprostheses, because of limited life expectancy, which is unrelated to the type of tricuspid prosthesis during long-term follow-up [9].

Early mortality rates after TVR have been reported between 10% and 25% [3, 7, 10]. In the current study, the early mortality rate was 4.5%. This was better than mortality rates from previous studies. Various factors contribute to the better hospital mortality rate. Age has been recognized as a key predictor of hospital mortality; hence, a younger patient population is a significant issue [11]. The average age of our patients was 48 years, while other studies were commonly more than 50 or even 60 years. Moreover, advances in perioperative management, myocardial protection methods, and postoperative intensive care may have had a positive impact on recent improved rates [12].

Our data revealed that hospital stays were lengthy for both biological and mechanical TVR (28.15  $\pm$  12.6 and 23.21  $\pm$  10.2, respectively). In a study by Alqahtani et al. [13], surgical outcomes in 45,477 patients, out of whom 15% had

TABLE 2: Comparison of follow-up mortality and survival rates and respective complications. Risk factors and outcomes between patients undergoing tricuspid valve replacement by bioprosthetic and mechanical valves.

Variables	Valve type		<i>p</i> value*	
	Bioprosthetic ( <i>n</i> = 40)	Mechanical ( <i>n</i> = 26)		
Survival	Early survival	95.0%	96.1%	0.05
	10-year survival rate	90.0%	92.3%	
Cause of death	Cardiac	2	1	>0.99
	Noncardiac	5	2	
Short-term complications	Hemorrhage	2.5%	0.0%	>0.99
	Cardiac tamponade	2.5%	0.0%	>0.99
	Pneumonia	0.0%	3.8%	>0.99
	Surgical site infection	2.5%	3.8%	>0.99
	Valvular thrombosis	0.0%	7.7%	0.15
	Endocarditis	2.5%	7.7%	0.56
	CVA	2.5%	0.0%	>0.99
Long-term complications	Atrial fibrillation	20.0%	15.4%	0.73
	GI bleeding	2.5%	3.8%	>0.99
	Valvular thrombosis	0.0	7.7%	0.15
	MI	2.5%	3.8%	>0.99
Reoperation rate	CVA	2.5%	0.0	>0.99
		6	2	0.46

\* *P* values report the significance of differences between the two groups; Fisher's exact test was used for the analysis; *P* values <0.05 were considered significant.

isolated tricuspid surgery, were evaluated and they found longer hospitalization duration in patients underwent TV surgery, compared with other types of valve surgeries.

Valve thrombosis is considered the Achilles' heel of mechanical prosthesis in the tricuspid position and is a well-documented complication by literature [14–16]. A meta-analysis reported rates of 1.28% patient/year (range from 0.1 to 4.6% patient/year) [17]. Our results revealed higher rates of valvar thrombosis in the mechanical TVR group in both early stage and during fifteen years' follow-up.

**4.1. Limitations.** Our study is limited by its retrospective nature with all of the inherent limitations of such investigations. However, the current study is the only series to date comparing mechanical and biological TV replacement in Iran. The small sample size of our study did not allow us to statistically determine risk factors which contributed to early and late mortality. Finally, the choice between bovine or porcine biological prosthesis was not studied.

In addition, our follow-up was nearly complete. Therefore, we feel our results are important for cardiac surgeons to consider when making the difficult decision of whether to repair or replace a TV with structural leaflet pathology.

## Data Availability

Data is available on request due to privacy/ethical restrictions.

## Ethical Approval

This study was ethically approved by the Ethical Committee of the Tehran University of Medical Sciences (No: IR.TUMS.THC.REC.1400.067).

## Consent

All patients signed informed consent forms.

## Conflicts of Interest

The authors declare that there are no conflicts of interest.

## Authors' Contributions

E.S conducted data gathering, statistical analysis, and drafted and revised the manuscript. A.H conducted data gathering, performed statistical analysis, drafted and revised the manuscript. A.A helped with the formation and revision of the manuscript. A.T helped in drafting and revising the manuscript. H.A helped in drafting and preparation of tables. K.A helped in drafting and preparation of tables. N.M helped in drafting and revising the manuscript. S.D conceived the idea, helped in data gathering, and revision of the manuscript.

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