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Review

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National Estimates for the Percentage of All Readmissions With Demographic Features, Morbidity, Overall and Gender-Specific Mortality of Transcutaneous Versus Open Surgical Tricuspid Valve Replacement/Repair

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Abstract

Background: The aim of the study was to determine national estimates for the percentage of all readmissions with demographic features, length of stay (LOS), cost analysis, comorbidities, complications, overall and gender-specific mortality and complications of transcutaneous tricuspid valve replacement/repair (TTVR) vs. open surgical tricuspid valve replacement/repair (open TVR).

Methods: Data were extrapolated from the Nationwide Readmissions Database (NRD) 2015-19. Of the 75,266,750 (unweighted) cases recorded in the 2015 - 2019 dataset, 429 had one or more of the percutaneous approach codes as per the ICD-10 dataset, and 10,077 had one or more of the open approach codes.

Results: Overall, the number of cases performed each year through open TVR was higher than TTVR, but there was an increased trend towards the TTVR every passing year. TTVR was performed more in females and advanced age groups than open TVR. The LOS and cost were lower in the TTVR group than in open TVR. Patients undergoing TTVR had more underlying comorbidities like congestive heart failure, hypertension, and uncomplicated diabetes mellitus. Overall mortality was 3.49% in TTVR vs. 6.09% in open TVR. The gender-specific analysis demonstrated higher female mortality in the open TVR compared to TTVR (5.45% vs. 3.03%). Male mortality was statistically insignificant between the two groups (6.8% vs. 4.3%, P-value = 0.15). Patients with TTVR had lower rates of complications than open TVR, except for arrhythmias, which were higher in TTVR. Patients undergoing open TVR required more intracardiac support, such as intra-aortic balloon pump (IABP) and Impella, than TTVR.

Conclusion: TTVR is an emerging alternative to open TVR in patients with tricuspid valve diseases, especially tricuspid regurgitation. Despite having more underlying comorbidities, the TTVR group had lower in-hospital mortality, hospital cost, LOS, and fewer complications than open TVR.

Keywords: Tricuspid regurgitation; Tricuspid valve replacement/repair; Surgery; Tricuspid valve diseases; Transcatheter

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Introduction

Recent data demonstrate that tricuspid valve (TV) pathology, especially tricuspid regurgitation (TR), is associated with poor long-term survival if left untreated [1]. Intervention in diseased TV, whether open or transcatheter, has improved these patients' quality of life and severity of the valvular disease [2]. Tricuspid stenosis (TS) is uncommon and accounts only for 2.4% of TV diseases [3, 4], but TR is very common, and it affects > 1.6 million people in the United States and > 70 million people worldwide [5]. The causes of primary TR include rheumatic heart disease, direct valvular injury during procedures, infective endocarditis (IE), and connective tissue disorders [6]. Secondary TR is often functional from right ventricular (RV)

Table 1. ICD-10 Procedure Codes Used for Identifying TTVR and TVR Procedures

ICD-10 code	Description
02QJ	Replacement of tricuspid valve
02QJ0	Replacement of tricuspid valve with synthetic substitute, open approach
02QJ0ZG	Replacement of tricuspid valve with synthetic substitute, open approach, guidewire
02QJ0ZZ	Replacement of tricuspid valve with synthetic substitute, open approach, no device
02QJ3Z	Replacement of tricuspid valve with synthetic substitute, percutaneous endoscopic approach
02QJ3ZG	Replacement of tricuspid valve with synthetic substitute, percutaneous endoscopic approach, guidewire
02QJ3ZZ	Replacement of tricuspid valve with synthetic substitute, percutaneous endoscopic approach, no device
022QJ4	Replacement of tricuspid valve with synthetic substitute, percutaneous approach
02QJ4ZG	Replacement of tricuspid valve with synthetic substitute, percutaneous approach, guidewire
02QJ4ZZ	Replacement of tricuspid valve with synthetic substitute, percutaneous approach, no device

TTVR: transcutaneous tricuspid valve replacement/repair; TVR: tricuspid valve replacement/repair.

dilatation secondary to left-sided heart diseases or diseases of the pulmonary system with normal TV leaflet anatomy [7]. TS is rare and usually is due to congenital or acquired diseases affecting less than 1% of the general population in the developed world due to a decrease in the prevalence of rheumatic heart diseases [8]. Data from the European Society of Cardiology demonstrate that surgical intervention is recommended for severe symptomatic TR and severe symptomatic TS alone or at the time of surgery for left-sided valvular heart diseases [9]. Due to the high surgical mortality associated with these valvular interventions, medical management was preferred in the past over surgery in the vast majority of these patients [10]. However, there has been a recent increase in transcutaneous tricuspid valve replacements/repairs (TTVRs) for severe symptomatic TV diseases, especially in patients at higher risk with isolated TV disease [11, 12]. These interventions showed improved functional status and reduced severity of valvular disease and mortality [13, 14]. Although we have seen significant advances in transcatheter treatments for mitral and aortic valves, transcatheter interventions for TVs are still in the developmental phase [15]. There are also limited data on head-to-head comparison of TTVRs vs. open surgical tricuspid valve replacements/repairs (open TVRs). Therefore, we sought to use the Nationwide Readmissions Database (NRD) dataset to identify, for the first time ever, the demographic features, including morbidity and mortality analysis of transcatheter vs. open surgical TV interventions.

Materials and Methods

We utilized the Healthcare Cost and Utilization Project (HCUP) NRD from 2015 to 2019 for this research. The NRD is a publicly available dataset sponsored by the Agency for Healthcare Research and Quality (AHRQ). It encompasses data from a vast array of hospitals across 28 states, providing a rich source of information on healthcare utilization, costs, and outcomes. The NRD captures approximately 35 million annual weighted discharges, offering a robust sample size for analysis. Each patient within the NRD is assigned a unique identifier to facilitate tracking of readmissions within a calendar year, ensuring longitudinal data integrity. It is important to note that the NRD maintains a deidentified nature, thereby safeguarding patient privacy. Due to the anonymized nature of the dataset, our study did not require Institutional Review Board (IRB) approval or informed consent. By leveraging the HCUP NRD, our research benefits from its breadth and depth of healthcare data, enabling us to conduct comprehensive analyses and draw meaningful conclusions regarding healthcare trends and outcomes.

Because the NRD dataset is not a simple random sample, we applied a weighting scheme to ensure accurate representation. We used SAS PROC SURVEYMEANS with the following specifications: WEIGHT discwt (weight to discharges in the American Hospital Association universe), CLUSTER hosp_nrd (NRD hospital identifier), and STRATA nrd_stratum (NRD stratum used for weighting). For each variable of interest, we calculated the weighted mean or percentage and the weighted standard error (SE) within each subgroup, categorized as cases with the percutaneous approach, cases with the open approach, or cases with neither.

Our study included patients who underwent TTVR or open TVR procedures as captured by the NRD. In this study, the term "gender" refers to the social and cultural roles, behaviors, activities, and attributes that a given society considers appropriate for men and women. It is important to note that the NRD classifies gender based on the information recorded at the time of hospital admission, which typically aligns with the binary categories of male and female. We acknowledge that this classification does not capture the full spectrum of gender identities, but it reflects the data available within the NRD.

To compare the percutaneous approach to the open approach, we used the HCUPnet data tools and the z-test calculator (accessed on January 25, 2023) to generate P-values for the variables of interest. Procedures were identified using specific ICD-10 codes. Out of 75,266,750 (unweighted) cases recorded in the 2015 - 2019 dataset, 429 cases had one or more percutaneous approach codes, and 10,077 cases had one or more open approach codes as per the ICD-10 dataset. Table 1 lists the ICD-10 procedure codes used for this identification process.

Table 2. Baseline Characteristics of Patients in TTVR vs. Open TVR

Variables	Percutaneous approach	Open approach	P-value
Mean age (years)	57.8 (1.2458)	40.8 (1.2752)	< 0.001
Female gender (%)	66.04 (2.4172)	55.20 (0.6283)	< 0.001
Comorbidities (%)			
CHF	75.43 (2.3292)	53.48 (1.1088)	< 0.001
DM - uncomplicated	8.74 (1.5020)	5.41 (0.2946)	0.029
DM - complicated	0 (0)	0.83 (0.0266)	0.002
COPD	19.9 (1.9635)	16.6 (0.6808)	0.1089
HTN	61.16 (2.8370)	45.53 (1.1936)	< 0.001
HTN - complicated	11.03 (1.5900)	17.38 (0.5095)	< 0.001
HTN - uncomplicated	50.5 (3.0331)	28.9 (1.0479)	< 0.001
OSA	16.1 (1.9607)	7.96 (0.3721)	< 0.001

Standard error in parenthesis. CHF: congestive heart failure; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; HTN: hypertension; Open TVR: open surgical tricuspid valve replacement/repair; OSA: obstructive sleep apnea; TTVR: transcutaneous tricuspid valve replacement/repair.

Each code corresponds to different approaches and devices used in the procedures, ensuring comprehensive capture of all relevant cases.

Results

Baseline characteristics of patients

Data on demographics and baseline comorbidities demonstrated significant differences between the two groups, as shown in Table 2. Patients undergoing open TVR were relatively younger as compared to the TTVR group (mean age 40.8 vs. 57.8 years, P-value < 0.001), but there were more females in the TTVR group (66.04% vs. 55.20%, P-value < 0.001). Data also revealed that patients in the TTVR group were significantly sicker with more comorbidities, as shown below. The percentage of congestive heart failure (CHF), uncomplicated hypertension (HTN), obstructive sleep apnea (OSA), and uncomplicated diabetes mellitus (DM), respectively, was 75.43%, 61.16%, 16.1%, and 8.74% in the TTVR group as compared to 53.48%, 45.53%, 7.96% and 5.41% in the open TVR group (Table 2). In contrast, complicated DM and complicated HTN were higher in the open TVR group (0.83% and 17.38% vs. 0% and 11.03%). Patients in the TTVR group also had a trend toward a higher prevalence of chronic obstructive pulmonary disease (COPD), but the data were not statistically significant (19.9 vs. 16.6, P-value = 0.1089).

National estimates for percentage of all readmissions

Of the 75,266,750 cases, 429 underwent TTVR, and 10,077 underwent open TVR. Although overall, the number of cases performed each year through open TVR was higher than TTVR, there was an increased trend towards the TTVR with every passing year (except for a slight decrease in 2016), as shown in Table 3.

In-hospital outcomes

Our patient population's overall mortality was 3.49% among the TTVR group vs. 6.09% in open TVR. The gender-specific analysis demonstrated higher female mortality in the open TVR compared to the TTVR group (5.45% vs. 3.03%, P-value = 0.023). There was, however, no statistical difference in mortality among males (6.8% vs. 4.3%, P-value = 0.15) (Table 4). The overall length of inpatient stay (LOS) was also more than double in open TVR as compared to the TTVR group (23.07 vs. 9.8 days, P-value < 0.001) (Table 4). Cost analysis among the cases from 2019 (n = 2,471 open TVR, n = 150 TTVR) demonstrated significantly higher mean costs in the open group vs. TTVR (mean 509,107$ vs. 308,394$), respectively (Table 4).

Complications

Overall, patients in the open TVR group had more complications than those in the TTVR group. The incidence of cardio-

Table 3. National Estimate for Percentage of All Readmissions for TTVR vs. Open TVR

Year	Percutaneous approach	Open approach
2015	0.0003197 ($10^{-3.4}$)	0.0147 ($10^{-1.83}$)
2016	0.0002789 ($10^{-3.5}$)	0.0144 ($10^{-1.84}$)
2017	0.0004506 ($10^{-3.3}$)	0.0148 ($10^{-1.82}$)
2018	0.0005399 ($10^{-3.2}$)	0.0143 ($10^{-1.84}$)
2019	0.0007247 ($10^{-3.1}$)	0.0147 ($10^{-1.83}$)

Open TVR: open surgical tricuspid valve replacement/repair; TTVR: transcutaneous tricuspid valve replacement/repair.

Table 4. In-Hospital Outcomes of TTVR vs. Open TVR

Variables	Percutaneous approach	Open approach	P-value
Mean LOS (days)	9.85 (0.7845)	23 (0.4566)	< 0.001
Overall mortality (%)	3.49 (0.8874)	6.09 (0.3066)	0.0057
Female mortality	3.03 (1.0185)	5.45 (0.3812)	0.023
Male mortality	4.39 (1.6394)	6.82 (0.4528)	0.1534
Cost (dollars)	308,394	509,107	

Standard error in parenthesis. LOS: length of stay; Open TVR: open surgical tricuspid valve replacement/repair; TTVR: transcutaneous tricuspid valve replacement/repair.

pulmonary arrest was 2.79% in open TVR vs. 1.05% in the TTVR group. There was also an increased incidence of acute respiratory distress syndrome (ARDS) in the open TVR group (0.72% vs. 0%, P-value < 0.001). Interestingly, no ARDS cases were reported in the TTVR group, as shown in Table 5. Extracorporeal membrane oxygenation (ECMO) requirements, however, were almost similar in both groups (0.75% vs. 0.70% in open TVR vs. TTVR, P-value = 0.907). Regarding major bleeds and blood loss anemia, data showed almost equal incidence in both groups (4.48% vs. 4.2% and 1.3% vs. 1.01% in open TVR vs. TTVR, P-value = 0.83 and 0.56, respectively).

A higher percentage of patients in the open TVR group required permanent pacemaker (PPM) placement than TTVR (12.7% vs. 4.13%, P-value < 0.001). Similarly, there was an increased incidence of pericardial effusion and cardiac tamponade in the open TVR population compared to the TTVR population (8.35% vs. 1.2% and 1.2% vs. 0.2%, P-value < 0.001). Patients in the open TVR group also required more mechanical support than the TTVR group (intra-aortic balloon pump (IABP): 4.7% vs. 1.6%, P-value < 0.001, left ventricular assist device (LVAD): 1.8% vs. 0.46%, P-value < 0.001). Data on the requirement for Impella support were non-significant between the two groups, but an increased trend was noted in the open group (0.5% vs. 0.2%, P-value = 0.119) as shown in Table 5. Patients in open TVR also had more IE and a higher incidence of stroke as compared to the TTVR group (25% vs. 3.6% and 1.4% vs. 0.57%, P-value < 0.001 and 0.037, respectively). However, patients in the TTVR group were found to have more post-operative arrhythmias than in the open group (76.27% vs. 62.2%, P-value < 0.001). The incidence of para-valvular leak was also higher (2.36%) in the TTVR group compared to 0.56% in open TVR (P-value = 0.035).

Discussion

Our analysis revealed several key findings regarding the use of TTVR compared to open surgery. Although the number of

Table 5. Complications of TTVR vs. Open TVR

Variables	Percutaneous approach	Open approach	P-value
Major bleed	4.2632 (1.0269)	4.4781 (0.2580)	0.839
Cardiac arrest	1.0505 (0.4580)	2.7872 (0.1913)	< 0.001
ARDS	0 (0)	0.7294 (0.0939)	< 0.001
Cardiac tamponade	0.2127 (0.2113)	1.9164 (0.1504)	< 0.001
Pleural effusion	1.1908 (0.5212)	8.3524 (0.3403)	< 0.001
Arrhythmias	76.2786 (2.3614)	62.2894 (1.1188)	< 0.001
IABP	1.6158 (0.7511)	4.7343 (0.3247)	< 0.001
Impella	0.1907 (0.1912)	0.5093 (0.0723)	0.119
ECMO	0.7012 (0.4101)	0.7506 (0.1093)	0.907
Permanent pacemaker	4.1286 (0.9556)	12.7029 (0.5321)	< 0.001
Stroke	0.5738 (0.4165)	1.4839 (0.1282)	0.037
LVAD	0.4611 (0.3281)	1.8043 (0.2020)	< 0.001
Blood loss anemia	1.0130 (0.4428)	1.2706 (0.1410)	0.568
Infective endocarditis	3.57 (1.0050)	25	< 0.001
Paravalvular leak	2.36 (0.8487)	0.56 (0.0798)	0.035

Data are presented as the weighted percentage with standard error in parenthesis. ARDS: acute respiratory distress syndrome; ECMO: extracorporeal membrane oxygenation; IABP: intra-aortic balloon pump; LVAD: left ventricular assist device; Open TVR: open surgical tricuspid valve replacement/repair; TTVR: transcutaneous tricuspid valve replacement/repair.

TTVR procedures was significantly lower, there was an increasing trend towards this minimally invasive approach over the years, except for a slight decrease in 2016. Patients undergoing TTVR were generally older and sicker, which likely influenced the preference for this approach due to the higher risk of complications associated with conventional surgery. Notably, TTVR was predominantly performed in patients with isolated TR (11.17% vs. 2.9%, P-value < 0.001), in contrast to open surgery, which often involved younger patients with congenital heart disease and associated structural or valvular abnormalities. TR in older patients is typically secondary to annular dilation, possibly accompanied by other cardiac conditions [16, 17]. To our knowledge, this is the most extensive and first-ever study comparing in-hospital outcomes and national readmission rates of TTVR versus open TVR in the American population. Our findings indicate a significant trend towards TTVR from 2015 to 2019, with this approach being associated with lower overall and female mortality rates compared to open TVR. The TTVR approach was also more cost-effective, resulting in shorter hospital stays, reduced hospitalization costs, and lower complication rates. These results highlight the potential advantages of TTVR, particularly for older patients with secondary TR due to annular dilation.

The two common pathologies of the TV are TR and TS. TR is a more common pathology than TS. The prevalence of TR increases with age, and it is also more prevalent in females [18]. Its management depends on the disease's severity and etiology (primary vs. secondary). Mild to moderate TR can be managed medically, while severe TR is managed with either surgical or transcatheter intervention. The American College of Cardiology/American Heart Association Joint Committee on Clinical Practice guidelines favor surgical repair over valve replacement if possible [19]. The choice of a specific surgical technique depends on the stage of TR. Ring annuloplasty with prosthetic rings is usually performed at the mitral or aortic valve surgery in patients with mild to moderate TR with tricuspid annulus (TA) dilation and no significant tethering (coaptation height < 8 mm) [20]. However, rigid undersize prosthetic rings may be used in patients with severe TA dilation (> 45 mm) without significant leaflet tethering [21]. However, if valve replacement is indicated, bioprosthetic valves are preferred over mechanical valves due to the low risk of thromboembolism. Controversy exists in the literature regarding the appropriate timing of intervention for severe TR, which is crucial to avoid irreversible damage to the RV and worsening heart failure [22]. In the past, severe TR was usually medically managed with preload reduction, including diuretics, due to the high mortality associated with surgical intervention. There has been, however, an increasing trend towards surgical repair of symptomatic severe TR, especially during surgical intervention for left-sided valvular heart diseases [23]. Studies have reported a poor prognosis in these patients if TR is left untreated during intervention for left-sided valvular heart diseases [24]. The European Society of Cardiology's Valvular Heart Disease guidelines recommend TVR as a class 1C recommendation for symptomatic severe TS (especially during left-sided valve surgery), severe primary TR undergoing left-sided valve intervention, isolated severe primary TR without severe RV dysfunction and as a class 1B recommendation for severe secondary TR undergoing left-sided valve surgery [25]. Recent studies have shown that TTVR can be used as an alternative option in select patients deemed surgically poor candidates [7]. A study performed on TTVR interventions by Taramasso et al showed that TTVR has low overall mortality and good functional outcomes with reasonable success rates in patients with severe TR [26]. Another study by Taramasso et al showed that the all-cause mortality and 1-year rehospitalization were lower with TTVR compared to medical management in patients with symptomatic severe TR [27]. Our analysis also demonstrated similar findings with lower mortality and morbidity outcomes with the TTVR.

We found that TTVR performed more frequently in females and older populations than open TVR because of the higher prevalence of TR and surgical inoperability in those groups [18]. There was also a higher prevalence of comorbidities in patients in the TTVR group compared to the open TVR group. The most common comorbidities were CHF, DM, and HTN. Especially patients with left ventricular ejection fraction (LVEF) < 40%, RV dysfunction, and or pulmonary HTN carry higher surgical risk and thus may benefit more from TTVR [28]. It also explains the higher prevalence of heart failure in patients undergoing TTVR in our study.

Prior studies have shown significant morbidity and mortality with surgical interventions for TV diseases. Some retrospective studies have reported an in-hospital mortality of 10.9% and 8.1% with surgical isolated TV replacement and repair, respectively [29]. This can be as high as ≥ 20-30% in patients with pre-operative RV dysfunction. Another study showed an in-hospital mortality of 8% in patients undergoing TV annuloplasty, while the mortality was 37% in cases of reoperation (due to failure) [30]. The main prognostic factors contributing to mortality post-surgery were the presence of pre-operative RV dysfunction, pre-operative organ dysfunction (for example, renal or liver dysfunction), underlying comorbidities, and reduced left ventricular function [31]. Late presentation for TV surgery itself was a risk factor for higher mortality [32]. Our study showed an overall mortality of 3.49% in TTVR vs. 6.09% in open TVR. Previous studies performed on TTVR have reported varying degrees of mortality. One study reported in-hospital mortality of 10% [33], while another reported around 13% [34]. The mortality in transcatheter interventions depends on whether replacement or repair was done. A study has shown almost no mortality with the repair. The mortality with valve replacement was 5.7% and 12.5% with LUX and NAVIGATE valve systems, respectively [35]. Our study showed low mortality with TTVR despite more underlying comorbidities in that group.

The study by Zack et al showed that higher hospitalization cost directly correlates with the LOS, utilization of pacemakers, and in-hospital mortality [10]. In our study, the cost was higher for patients with open TVR than for patients with TTVR, which can be explained by the higher LOS, mortality, and incidence of PPM placement in the open group. Similarly, the LOS depends on the approach for TV interventions and pre-operative RV function. Studies have shown an increased LOS in patients with RV dysfunction at the time of intervention [36]. A study performed by Fu et al showed higher rates of cardiopulmonary bypass time, longer intensive care unit stay, and longer ventilation time for patients with TV replacement compared to repair [37], which can also contribute to the longer LOS. Our analysis showed that the LOS in an open TVR was almost double that of TTVR (23.07 vs. 9.8). A study by Bugan et al found that the average LOS was 10.7 days in patients with TTVR, similar to our study [14]. To summarize, the main findings of our study indicate that TTVR demonstrates favourable outcomes compared to open TVR in patients with TR. This aligns with the studies published by other authors. Wang et al [38] found that TTVR was associated with lower inpatient mortality, cardiovascular complications, hemodynamic complications, infectious complications, renal complications, and need for blood transfusion compared to open TVR. Similarly, Mohamed et al [39] observed a decrease in inpatient mortality and clinical events with TTVR compared to surgical interventions. These consistent findings support the potential superiority of TTVR over surgical approaches for TV disease management.

Data show that during cardiac surgery, around 0.2% to 6% of patients can develop post-cardiotomy cardiogenic shock, which is characterized by tissue hypo-perfusion and end-organ damage despite adequate preload [40]. It is usually treated with vasopressors, ionotropic support, or, in some cases, mechanical support such as an IABP. Around 0.5-1% of these patients can also develop refractory post-cardiotomy cardiogenic shock that is not responsive to these measures, in which case accelerated support such as ECMO is needed [41, 42]. Patients with pre-operative RV dysfunction are at higher risk of requiring intracardiac support, such as IABP and Impella, due to low cardiac output associated with RV dysfunction [43]. In our study, patients who underwent open TVR were more likely to require an IABP and Impella (although statistically insignificant) than TTVR. ECMO support was almost similar in both groups and statistically insignificant. Different studies have shown poor prognosis and higher short and long-term mortality in patients who required IABP or ECMO support after TAVR [44], but there are limited such data on TTVR.

We also found a higher utilization of PPMs in patients with open TVR than in patients with TTVR. Several factors implicated in the requirement of a pacemaker during TV surgery include intra-operative hypothermia, duration of cardiopulmonary bypass, and proximity of the TA to the atrioventricular (AV) node [45]. The main reason for PPM placement is a complete heart block resulting from compression of the AV node by valve frame or ventricular anchors due to its proximity to the septal leaflet of the TV [46]. Other predictors of PPM placement are IE leading to AV block and baseline heart rhythm disturbance [47]. Previous studies have reported similar findings regarding the PPM requirement after valvular heart surgery. Two different studies on clinical outcomes of TV surgery showed that 21% and 28% of patients required PPMs [48, 49]. Our study showed that 12% of the patients required PPMs after the open TVR. A study on 3,420 patients has reported that 14.1% of patients underwent PPM implantation after transcatheter aortic valve replacement (TAVR) [50]. Other studies have reported a 9-26% prevalence of PPM placement after TAVR [51-53]. However, there are limited data on the need for PPMs after TTVR.

Pericardial effusion is a common complication after open cardiac surgery and can occur in up to 80% of patients [54]. The exact mechanism for developing pericardial effusion is unknown, but the mechanical process of surgery and the inflammatory cytokines are thought to play an important role [55]. Anticoagulation also increases the risk of significant pericardial effusion and the development of cardiac tamponade [56-58]. Our study found that patients with open TVR have a higher incidence of pericardial effusions and cardiac tamponade than TTVR. This is understandable as open surgery by nature is more invasive and results in significant disruption of the intra-cardiac environment and homeostasis as compared to the transcatheter approach. A retrospective observational cohort study on 1,460 patients showed that 16% of patients undergoing heart valve surgery developed significant pericardial effusion requiring drainage [59]. A study on isolated TV surgery reported that 8% of patients developed cardiac tamponade after the surgery [60]. There are, however, limited data available on the incidence of tamponade with TTVRs.

Patients with intra-cardiac valve replacement also have a significant risk of IE. This is usually due to resulting foreign material in the valve, subsequent paravalvular leaks, and damage to the native calcified valves from valve insertion and subclinical thrombosis [61, 62]. Some 10-30% of all IE cases are caused by surgical prosthetic valve endocarditis. Numerous studies have shown a 5-50% in-hospital mortality from IE post-valvular surgery [63, 64]. Our analysis also showed a higher incidence of IE in patients with open TVR than in the TTVR group. However, there are limited data in the literature on the incidence of IE from transcatheter tricuspid interventions. A recent review article on TAVRs, the best studied among transcatheter interventions, showed no difference in the incidence of prosthetic valve endocarditis between surgical and TAVR [65]. Another study from an extensive multicenter registry showed the 1-year incidence of IE post-TAVR to be 0.50% [66]. Further studies, however, are needed in our case to elucidate any differences in IE between the transcatheter and open groups, if any.

Stroke is a rare but serious complication after interventions for valvular heart diseases, which increases morbidity and mortality in these patients. Due to the emerging nature of procedures, there are limited data on the risk of stroke with right-sided transcatheter valvular interventions. The available data on TTVRs have shown the incidence of stroke to be close to 1%, but the number of patients included in those studies was low [26, 67]. Data from interventions for left-sided valvular heart diseases showed a relatively higher incidence of stroke. This could be due to a higher prevalence of atrial fibrillation in left-sided valvular heart diseases or a higher risk of atrial fibrillation from those interventions [68]. A multicentric German TAVI registry study showed the incidence of cerebrovascular events to be 3.2%, with significantly higher in-hospital and 1-year mortality in patients developing cerebrovascular events [69]. The risk of stroke has been reported to be higher with surgical as compared to transcutaneous approaches in those patients [51, 70]. Our study showed a higher incidence of stroke from open TVR than TTVR. However, more studies will be needed to accurately predict the risk of stroke in TV interventions.

Conclusion

TTVR is an emerging alternative to open TVR in patients with TV diseases, especially high-risk populations with severe TR, to improve the quality of life. Our study's analysis of a large pool of NRD data has shown promising trends towards lower morbidity and mortality and lower overall healthcare cost burden with TTVR compared to open TVR.

Limitations

The administrative data and retrospective observational study design have their inherent limitations. As hospitalizations and not individual patients are represented in the data, there is a potential for overestimating the number of patients. The number of patients with TTVR in our study cohort was much smaller than open TVR, potentially affecting the significance of certain comparisons due to low power. However, the considerable sample size obtained from these large databases attenuates most of the limitations.

Additionally, since the NRD captures hospitalization data at the national level but does not provide individual patient histories or longitudinal procedural information, therefore, while we can identify patients who underwent either TTVR or open TVR during their hospitalization, we do not have access to their complete medical histories, including prior procedures or subsequent interventions. As a result, we are unable to ascertain whether patients with TTVR or TVR in our dataset had previously undergone a similar procedure or subsequently received one. This lack of longitudinal patient data is a recognized constraint of administrative databases like the NRD. While we acknowledge the importance of understanding the sequence of interventions for a comprehensive analysis, such information falls beyond the scope of the available dataset. Despite this limitation, our study aims to provide valuable insights into the comparative outcomes of TTVR and TVR based on the available hospitalization data, contributing to the broader understanding of TV interventions.

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Conflict of Interest

None to declare.

Author Contributions

Muhammad Shayan Khan: conceptualization, methodology, data curation, writing - original draft preparation. Abdul Baqi: data analysis, writing - review and editing. Ghulam Mujtaba Ghumman: data analysis, visualization, investigation. Waqas Ullah: methodology, software, formal analysis. Jay Shah: writing - review and editing, supervision. Yasar Sattar: writing - review and editing, resources. Tanveer Mir: conceptualization, methodology, project administration. Zain Sheikh: conceptualization, validation, writing - review and editing. Ayesha Tahir: data curation, writing - original draft preparation. Fnu Salman: investigation, writing - review and editing. Moaaz Baghal: visualization, supervision, validation. Kritika Luthra: conceptualization, methodology, software. Vinod Khatrig: methodology, data curation, writing - original draft preparation. Zainulabedin Waqar: writing - review and editing, visualization. Malik Waleed Zeb Khan: conceptualization, writing - review and editing. Mohammed Taleb: writing - review and editing, resources. Syed Sohail Ali: methodology, writing - review and editing.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

ARDS: acute respiratory distress syndrome; CHF: congestive heart failure; DM: diabetes mellitus; HCUP: Healthcare Cost and Utilization Project; HTN: hypertension; IABP: intra-aortic balloon pump; LOS: length of stay; LVAD: left ventricular assist device; Open TVR: open surgical tricuspid valve replacement/repair; OSA: obstructive sleep apnea; TV: tricuspid valve; TR: tricuspid regurgitation; TS: tricuspid stenosis; TTVR: transcutaneous tricuspid valve replacement/repair

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