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# Transcatheter edge-to-edge repair of the tricuspid valve: The US experience

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## Abstract

**Objectives:** To examine the trends in utilization and outcomes of tricuspid valve (TV) transcatheter edge-to-edge repair (TEER).

**Background:** Surgery for isolated tricuspid regurgitation is associated with high morbidity and mortality and is rarely performed. TV TEER is an attractive alternative.

**Methods:** The Nationwide Readmissions Database was queried using the International Classification of Diseases, 10th Revision, procedure code for TV TEER for years 2016–2019. The main outcomes were trends in utilization and in-hospital all-cause mortality.

**Results:** We identified 918 hospitalizations for TV TEER. There was an uptrend in its utilization from 13 cases in the first quarter of 2016 to 122 cases in the last quarter of 2019 ( $p$  trend < 0.001). Concomitant mitral valve (MV) TEER was performed in 42.1% of admissions. The overall in-hospital mortality was 2.1%. Surgical TV replacement was needed in 1.1% of admissions; none of them died during the index hospitalization. Unplanned rehospitalizations were common at 30 days (15.7%); 38.2% of those were due to heart failure. There was no difference in in-hospital mortality between isolated TV TEER and combined MV and TV TEER (1.7% vs. 2.6%,  $p = 0.359$ ). However, admissions receiving combined procedure had lower length of stay and urgent readmission rate.

**Conclusion:** The current study showed that there was an increase in the utilization of TV TEER over 2016–2019 in the United States. TV TEER was associated with low rates of in-hospital mortality; however, the rate of urgent readmission remains high, mainly due to heart failure.

## KEYWORDS

MitraClip, Nationwide Readmission Database, tricuspid regurgitation

## 1 | INTRODUCTION

Significant tricuspid regurgitation (TR) is a common valvular heart disease with an estimated prevalence ranging from 0.55% to 6%<sup>1-4</sup> and is associated with poor long-term outcomes.<sup>5</sup> Most cases are functional, secondary to tricuspid annular dilatation and/or leaflet tethering in the setting of right ventricular (RV) volume or pressure overload.<sup>5</sup> Untreated patients develop right-sided heart failure with peripheral edema and liver congestion.<sup>6</sup> Medical management involves diuretic therapy to relieve the symptoms of right-sided heart failure and in those with secondary TR, therapies directed toward the primary cause can be helpful (e.g., guideline-directed medical therapy for heart failure or control of atrial fibrillation).<sup>5,7</sup> Unfortunately, surgery for isolated TR is seldom performed as it is associated with high morbidity and mortality (8–20%).<sup>5,8-10</sup> The benefit of the tricuspid valve (TV) surgery—either isolated or during left-sided valve surgery—on prognosis is not clear.<sup>11</sup> Additionally, reoperation for severe TR after left-sided valve surgery is associated with high perioperative mortality reaching up to 25%.<sup>5</sup>

In recent years, the interest in transcatheter therapy for severe symptomatic TR has grown exponentially.<sup>5,7,8,12,13</sup> Different interventional devices and techniques are under investigation, including the PASCAL transcatheter valve repair system (Edwards Lifesciences)<sup>14</sup> and the MitraClip system (Abbott Vascular).<sup>7</sup> The off-label transcatheter edge-to-edge repair (TEER) using the MitraClip system in the tricuspid position has been the most commonly used transcatheter procedure.<sup>10,12,13</sup> Most recently, the MitraClip system has been redesigned for dedicated use in TR<sup>12</sup> and it is currently under investigation in the TRILUMINATE trial (Clinical Trial to Evaluate Cardiovascular Outcomes In Patients Treated With the Tricuspid Valve Repair System).<sup>15</sup> We aimed to examine the national trends in utilization, mortality, and outcomes of TV TEER in recent years as reported in the Nationwide Readmissions Database (NRD).

## 2 | MATERIALS AND METHODS

### 2.1 | Data source

The NRD, Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality was utilized to extract the study cohort. The NRD contains discharge data from 28 geographically dispersed States, accounting for 60% of the total US resident population and 58.2% of all US hospitalizations. The study cohort, procedures, and outcomes were identified using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD 10-CM) and procedure (ICD 10-PCS) codes. The codes used are summarized in Table S1.

The NRD database was queried using the ICD 10-PCS code for TV TEER (O2UJ3JZ) for the years 2016–2019. Those who underwent concomitant mitral valve (MV) TEER were identified using

the ICD 10-PCS code O2UG3JZ. Patient and hospital-level variables provided by HCUP NRD were used to identify demographics and baseline characteristics. The Elixhauser method was used to assess comorbidities.<sup>16</sup> The rest of the comorbidities were identified using appropriate ICD 10-CM codes (Table S1). The NRD is a publicly available database with deidentified hospitalization records; therefore, institutional review board approval was not required.

### 2.2 | Outcomes

The trends in utilization of TV TEER across the 4 years by quarters were examined. The main outcome of interest was all-cause in-hospital mortality. Other clinical outcomes included the rates of surgical TV replacement, permanent pacemaker (PPM) implantation, cardiogenic shock, cardiac tamponade, complete atrioventricular (AV) block, and major bleeding events. Major bleeding was defined as intracranial hemorrhage, respiratory hemorrhage, gastrointestinal hemorrhage, retroperitoneal hemorrhage, post-procedural bleeding, hemothorax, hemopericardium or the need for blood transfusion using the appropriate ICD-10 codes as shown in Table S1.

The outcomes in admissions receiving isolated TV TEER and in those receiving concomitant MV TEER were examined. Additionally, the outcomes of interest were compared based on the annual hospital procedural volume and the presence or absence of PPM or implantable cardioverter-defibrillator (ICD).

The 30-day readmission rates in the overall cohort after the exclusion of those admitted in December (30-day readmissions for hospitalizations in December could not be obtained since the NRD does not cross the calendar year) and those who died in the index admission were examined. The percentage of urgent heart failure readmissions among all urgent readmissions was identified through the ICD-10 codes of the first three recorded readmission diagnoses. Finally, the 30-day readmission rates in admissions undergoing combined TV and MV TEER and those undergoing isolated TV TEER were compared.

### 2.3 | Statistical analysis

All analyses were conducted using the appropriate weighting, stratifying, and clustering samples following HCUP regulations.<sup>17,18</sup> Categorical variables are displayed as numbers and percentages and compared with Pearson's  $\chi^2$  or Fisher's exact tests as appropriate. Continuous variables are summarized as medians and interquartile range (IQR) (25th and 75th percentiles) and compared with the Mann-Whitney *U* test. All *p* values are two-sided with a significance threshold <0.05. Trend analysis was performed using the Poisson regression method. Statistical analysis was performed using STATA Software for Windows (version 17.0; StataCorp LLC) and IBM SPSS Statistics for Windows (version 27.0; IBM Corp).

### 3 | RESULTS

#### 3.1 | Characteristics and outcomes of admissions undergoing TV TEER

A total of 918 weighted hospitalizations undergoing TV TEER were identified during the study period. There was an uptrend in the utilization from 13 cases in the first quarter of 2016 to 122 cases in the last quarter of 2019 ( $p$  trend < 0.001) (Figure 1). The median hospital annual procedural volume was 9 (IQR: 4–23) procedures/year. The baseline demographics, comorbidities, and hospital characteristics are shown in Table 1 and the outcomes and complications are shown in Table 2. The median age was 78 (IQR: 70–85) years and 57.7% of patients were females. Congestive heart failure (91%), systemic hypertension (83.8%), and atrial fibrillation (80%) were the most common comorbidities. Most of the procedures were performed in teaching (93.2%) or large hospitals (84.9%).

The overall all-cause in-hospital mortality was 2.1%. Surgical TV replacement was needed in 1.1% of hospitalizations; none of them died during the index hospitalization. Cardiogenic shock occurred in 7.7%, tamponade in 0.9%, and complete AV block in 2.7% of admissions. PPM implantation was performed in 1.7% admissions. The overall bleeding complications were low and none of the admissions had intracranial hemorrhage. The median length of stay (LOS) was 4 days (IQR: 1–9). The urgent 30-day readmission rate was 15.7%; 38.2% of these were due to heart failure. Hospitals with a high procedural volume ( $\geq 23$  procedures/year, i.e., 75th percentile) were associated with a trend toward lower all-cause in-hospital mortality without reaching statistical significance (0.5% vs. 2.6%,  $p = 0.06$ ). Additionally, none of the admissions in high-volume hospitals required surgical TV replacement (Table 3).

In patients with a history of PPM or ICD implantation (19.8%,  $n = 182$ ), all-cause in-hospital mortality (3.8% vs. 1.6%,  $p = 0.077$ ), need for surgical TV replacement (2.2% vs. 0.8%  $p = 0.116$ ), and bleeding complications were similar to those patients without such history as shown in Table S2.

#### 3.2 | Characteristics and outcomes of admissions undergoing combined TV and MV TEER

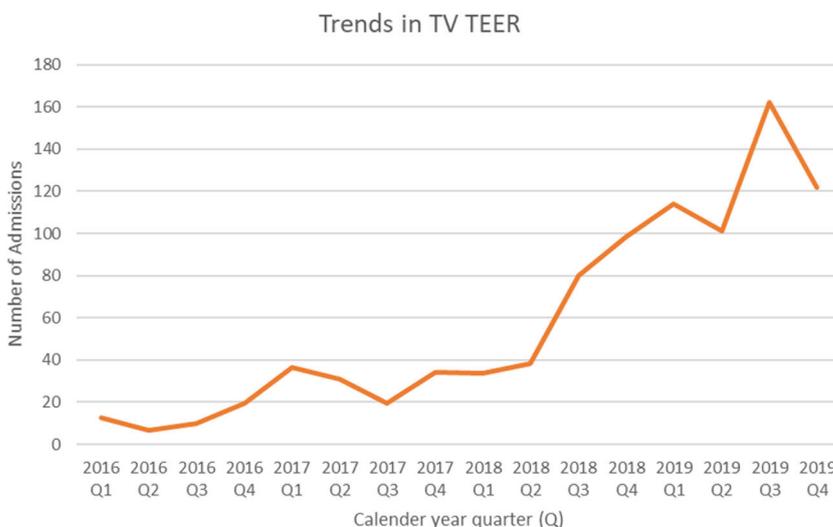
Combined TV and MV TEER was performed in 387 (42.1%) admissions. The baseline demographics, comorbidities, and hospital characteristics are shown in Table 1. Admissions undergoing the combined procedure were older (81 [IQR: 73–86] vs. 76 [IQR: 68–83] years,  $p < 0.001$ ) and had higher prevalence of pulmonary hypertension (45% vs. 34.5%,  $p = 0.002$ ). History of the prosthetic valve was less common compared with admissions undergoing isolated TV TEER (7.2% vs. 19.8%,  $p < 0.001$ ).

Compared with those undergoing isolated TV TEER, admissions undergoing combined TV and MV TEER had similar rates of all-cause in-hospital mortality (2.6% vs. 1.7%,  $p = 0.36$ ), cardiac tamponade (0.3% vs. 1.3%,  $p = 0.15$ ), and cardiogenic shock (5.7% vs. 9.2%,  $p = 0.06$ ) (Table 2). Bleeding complications were similar between both groups. However, complete AV block (1.3% vs. 3.8%,  $p = 0.02$ ), PPM implantation (0.3% vs. 2.8%,  $p = 0.003$ ), and surgical TV replacement (0% vs. 1.9%,  $p = 0.007$ ) were less common in the combined procedure. Additionally, the LOS was shorter, and the rate of urgent readmissions was lower in admissions undergoing the combined procedure.

### 4 | DISCUSSION

In this analysis of the trends and outcomes of TV TEER using the NRD for years 2016–2019, we found that: (1) The number of admissions undergoing TV TEER increased over the study period, from 13 in the first quarter of 2016 to 122 in the last quarter of 2019. (2) The overall rate of all-cause in-hospital mortality in admissions undergoing TV TEER was 2.1%. TV surgery was needed in 1.1% of admissions; none of them died during the index hospitalization. (3) 42.1% of admissions underwent concomitant MV TEER and were associated with a similar rate of all-cause in-hospital mortality and bleeding complications. (4) The urgent 30-day

**FIGURE 1** National trends in transcatheter edge-to-edge repair of the tricuspid valve. TEER, transcatheter edge-to-edge repair, TV, tricuspid valve [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**TABLE 1** Baseline patients' and hospitals' characteristics of admissions undergoing TV TEER

	Overall (n = 918)	Isolated TV TEER (n = 531)	Combined TV and MV TEER (n = 387)	p value
Age, median (IQR), mean $\pm$ SD	78 (70–85), 75.4 (12.4)	76 (68–83), 73.6 (13.3)	81 (73–86), 77.9 (10.5)	<0.001
Female, n (%)	530 (57.7)	324 (61)	206 (53.2)	0.021
Comorbidities				
Heart failure, n (%)	836 (91)	482 (90.8)	354 (91.2)	0.907
Hypertension, n (%)	770 (83.8)	440 (82.9)	330 (85.1)	0.415
Atrial fibrillation/flutter, n (%)	734 (80)	416 (78.3)	318 (82.2)	0.157
History of smoking, n (%)	266 (29)	159 (29.9)	107 (27.6)	0.462
Anemia, n (%)	280 (30.5)	172 (32.4)	108 (27.9)	0.147
Diabetes mellitus, n (%)	234 (25.5)	155 (29.2)	79 (20.4)	0.003
Chronic pulmonary disease, n (%)	206 (22.4)	118 (22.2)	88 (22.7)	0.873
Pulmonary hypertension, n (%)	357 (38.9)	183 (34.5)	174 (45)	0.002
Prior CABG, n (%)	171 (18.6)	98 (18.4)	73 (18.9)	0.864
Coagulopathy, n (%)	168 (18.3)	104 (19.5)	64 (16.5)	0.262
History of permanent pacemaker or ICD, n (%)	182 (19.8)	109 (20.5)	73 (18.9)	0.558
Prior stroke, n (%)	95 (10.3)	56 (10.5)	39 (10.1)	0.913
Prior MI, n (%)	98 (10.7)	50 (9.4)	48 (12.4)	0.160
Severe renal disease, n (%)	155 (16.9)	103 (19.4)	52 (13.4)	0.020
Morbid obesity, n (%)	46 (5)	30 (5.6)	16 (4.1)	0.359
Sever liver disease, n (%)	31 (3.4)	22 (4.1)	9 (2.3)	0.143
Prior PCI, n (%)	17 (1.8)	9 (1.7)	8 (2.1)	0.805
Carcinoid syndrome, n (%)	0 (0)	0 (0)	0 (0)	
Carotid disease, n (%)	16 (1.7)	7 (1.3)	9 (2.3)	0.309
Infective endocarditis, n (%)				
History of valve prosthesis, n (%)	133 (14.5)	105 (19.8)	28 (7.2)	<0.001
Hospital and payer				
Large-sized hospital, n (%)	781 (84.9)	469 (88.2)	312 (80.4)	0.001
Teaching hospital, n (%)	856 (93.2)	515 (97)	341 (88.1)	<0.001
Medicare, n (%)	779 (84.9)	451 (84.9)	328 (84.8)	1

Abbreviations: CABG, coronary artery bypass surgery; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; MI, myocardial infarction; MV, mitral valve; PCI, percutaneous coronary intervention; TEER, transcatheter edge-to-edge repair; TV, tricuspid valve.

readmission rate was 15.7%; 38.2% of these were due to heart failure.

The utilization of TV TEER in the United States showed impressive growth over the study years, and it was associated with low in-hospital mortality and complications. Data from previous studies showed an in-hospital mortality rate ranging from 2.5% to 5%.<sup>7,10</sup> In the current real-world more recent analysis, we found even lower in-hospital mortality of 2.1% which can be partially explained by the amount of experience in

steering the MitraClip system for mitral regurgitation (MR) especially in patients with complex or unusual anatomy.<sup>7</sup> However, the urgent 30-day readmission rates were high reflecting the magnitude of comorbidities especially heart failure and may point to the fact that the majority of these patients receive such therapy at an advanced stage of their disease. Although the optimal timing of TV intervention remains controversial, an early approach, before significant RV dilation and systolic dysfunction occur, should be further studied.

**TABLE 2** Outcomes of TV TEER

	Overall (n = 918)	Isolated TV TEER (n = 531)	Combined TV and MV TEER (n = 387)	p value
In-hospital mortality, n (%)	19 (2.1)	9 (1.7)	10 (2.6)	0.359
Discharge to a facility, n (%)	122 (13.3)	77 (14.5)	45 (11.6)	0.238
Urgent readmission, n (%) <sup>a</sup>	128/817 (15.7)	90/475 (18.9)	38/342 (11.1)	0.002
<b>Cardiac complications</b>				
Need for surgical TV replacement, n (%)	10 (1.1)	10 (1.9)	0 (0)	0.007
Need for PPM implantation, n (%)	16 (1.7)	15 (2.8)	1 (0.3)	0.003
Complete AV block, n (%)	25 (2.7)	20 (3.8)	5 (1.3)	0.024
Cardiogenic shock, n (%)	71 (7.7)	49 (9.2)	22 (5.7)	0.060
Tamponade, n (%)	8 (0.9)	7 (1.3)	1 (0.3)	0.148
<b>Neurological complications</b>				
Ischemic stroke, n (%)	6 (0.7)	4 (0.8)	2 (0.5)	1
Hemorrhagic stroke, n (%)	0 (0)	0 (0)	0 (0)	
<b>Bleeding complications</b>				
Intracranial hemorrhage, n (%)	0 (0)	0 (0)	0 (0)	
Postprocedural bleeding, n (%)	15 (1.6)	11 (2.1)	4 (1)	0.295
Respiratory hemorrhage, n (%)	20 (2.2)	12 (2.3)	8 (2.1)	1
Gastrointestinal bleeding, n (%)	25 (2.7)	14 (2.6)	11 (2.8)	0.841
Retroperitoneal bleeding, n (%)	3 (0.3)	3 (0.6)	0 (0)	0.268
Hemothorax, n (%)	2 (0.2)	2 (0.4)	0 (0)	0.512
Hemopericardium, n (%)	0 (0)	0 (0)	0 (0)	
Blood transfusion, n (%)	69 (7.5)	46 (8.6)	23 (5.9)	0.130
<b>Circulatory and ventilatory support</b>				
Impella, n (%)	3 (0.3)	2 (0.4)	1 (0.3)	1
Intra-aortic balloon pump, n (%)	10 (1.1)	7 (1.3)	3 (0.8)	0.532
ECMO, n (%)	0 (0)	0 (0)	0 (0)	
Vasopressors, n (%)	17 (1.8)	10 (1.9)	7 (1.8)	1
Mechanical ventilation, n (%)	54 (5.5)	32 (6)	19 (4.9)	0.560
LOS (median, IQR) (days)	4 (1–9)	5 (2–10)	3 (1–7)	<0.001
Cost (median, IQR) (US dollars)	50,736 (36,464–77,285)	46,518 (35,053–68,259)	58,049 (40,026–81,242)	<0.001

Abbreviations: AV, atrioventricular; ECMO, extracorporeal membrane oxygenation; IQR, interquartile range; LOS, length of stay; MV, mitral valve; PPM, permanent pacemaker; TEER, transcatheter edge-to-edge repair; TV, tricuspid valve.

<sup>a</sup>After the exclusion of those admitted in December and those who died in the index admission.

As with most interventional procedures, the learning curve and operator experience play an important role in procedural success and clinical outcomes. The current analysis showed that annual procedural volume  $\geq 23$  procedures/year was associated with a trend toward lower mortality. Additionally, none of the admissions in high-volume hospitals required surgical TV replacement. In the TriValve (Transcatheter Tricuspid Valve Therapies) registry, the procedural success in the first two patients treated at each site was 46.4% compared with 81% in the subsequent patients.<sup>10</sup>

The presence of a pacemaker or ICD lead can be challenging but it is not an absolute contraindication for TV TEER.<sup>6</sup> One-third of the patients from large registries<sup>7,10</sup> had PPM or ICD lead. In the current analysis, ~20% of admissions had a history of ICD or PPM, and they were associated with similar in-hospital mortality and other complications compared with those without such history. Careful patient selection using transthoracic and transesophageal echocardiography is needed for determining patients' eligibility for the procedure.<sup>6</sup> The utilization of intracardiac echocardiogram offers an alternative

**TABLE 3** Outcomes of TV TEER based on hospital volumes

	Hospitals performing $\geq 23$ procedures/year ( $n = 220$ )	Hospitals performing $< 23$ procedures/year ( $n = 698$ )	<i>p</i> value
In-hospital mortality, <i>n</i> (%)	1 (0.5)	18 (2.6)	0.058
<b>Cardiac complications</b>			
Need for surgical TV replacement, <i>n</i> (%)	0 (0)	10 (1.4)	0.129
Need for PPM implantation, <i>n</i> (%)	2 (0.9)	15 (2.1)	0.388
Complete AV block, <i>n</i> (%)	2 (0.9)	22 (3.2)	0.088
Cardiogenic shock, <i>n</i> (%)	17 (7.7)	53 (7.6)	1
Tamponade, <i>n</i> (%)	0 (0)	8 (1.1)	0.210
<b>Neurological complications</b>			
Ischemic stroke, <i>n</i> (%)	0 (0)	5 (0.7)	0.345
<b>Bleeding complications</b>			
Postprocedural bleeding, <i>n</i> (%)	2 (0.9)	13 (1.9)	0.542
Respiratory hemorrhage, <i>n</i> (%)	6 (2.7)	14 (2)	0.596
Retroperitoneal bleeding, <i>n</i> (%)	0 (0)	3 (0.4)	1
Gastrointestinal bleeding, <i>n</i> (%)	8 (3.6)	17 (2.4)	0.346
Hemothorax, <i>n</i> (%)	0 (0)	2 (0.3)	1
Blood transfusion, <i>n</i> (%)	17 (7.7)	52 (7.4)	0.884
<b>Circulatory and ventilatory support</b>			
Impella, <i>n</i> (%)	0 (0)	3 (0.4)	1
Intra-aortic balloon pump, <i>n</i> (%)	0 (0)	10 (1.4)	0.129
Vasopressors, <i>n</i> (%)	0 (0)	17 (2.4)	0.018
Mechanical ventilation, <i>n</i> (%)	13 (5.9)	38 (5.5)	0.866
LOS (median, IQR) (days)	4 (2–9)	4 (1–9)	0.624
Cost (median, IQR) (US dollars)	50,597 (38,057–66,417)	50,944 (36,022–79,911)	0.519

Abbreviations: AV, atrioventricular; ECMO, extracorporeal membrane oxygenation; IQR, interquartile range; LOS, length of stay; MV, mitral valve; PPM, permanent pacemaker; TEER, transcatheter edge-to-edge repair; TV, tricuspid valve.

imaging technique to help leaflet grasping, but this is still an emerging technique.<sup>19,20</sup>

Current data suggest that TV TEER is a safe procedure.<sup>7,10,21–23</sup> Combining the safety data from the two largest studies to date<sup>7,10</sup> comprising 313 patients, conversion to open-heart surgery was needed only in 1 patient (0.3%), stroke occurred in 2 patients (0.6%), bleeding in 18 patients (5.7%), pericardial effusion or tamponade in 1 patient (0.3%). However, in our analysis, the rates of adverse outcomes were somewhat higher. Notably, surgical TV replacement was needed in six (1.1%) cases, cardiac tamponade occurred in 0.9% and complete AV block occurred in 2.7% of admissions. Higher adverse outcomes in our analysis can be partially explained by the burden of comorbidities in our study population especially heart failure (91%), atrial fibrillation (80%), and pulmonary hypertension (~39%). As stated earlier, the optimal timing of TV TEER and operator experience plays an important role in clinical outcomes. Although

higher complications rates did not result in higher in-hospital mortality, significant comorbidities would worsen the quality of life of these patients who might be already suffering in the terminal stage of their disease.

One of the advantages of the TV TEER is the ability to treat concomitant MR during the same procedure using the same vascular access.<sup>12</sup> It is estimated that about 20% of patients undergoing MV TEER have also significant TR<sup>12</sup> and that in two-thirds of the cases it persists even after improvement in MR.<sup>24</sup> Residual significant TR after MV TEER is associated with worse outcomes.<sup>6</sup> Despite possible improvement in the degree of functional TR following MV TEER,<sup>25,26</sup> the long-term durability of this improvement is unclear.<sup>8</sup> In the current analysis, ~42% of admissions underwent concomitant MV TEER which is similar to what is reported in previous studies.<sup>7,10</sup> We found that admissions undergoing both procedures were not associated with increased risk of in-hospital mortality or worse

outcomes. In fact, those patients had lower LOS, lower urgent readmission rates, and less need for TV replacement or PPM implantation. Data from observational studies suggested that combined TV and MV TEER was associated with higher 1-year survival<sup>27</sup> and fewer hospitalization or heart failure at 18 months.<sup>28</sup> Further randomized controlled trials are warranted to confirm such findings.

The MitraClip system has been modified for dedicated use in the TV as the TriClip system (Abbott) and it was evaluated in the TRILUMINATE multicenter trial<sup>24</sup> which showed a 40% reduction in hospitalizations. Overall all-cause mortality at 1 year was 7.1%, while 11.9% had major bleeding. Currently, the TRILUMINATE Pivotal Trial (NCT03904147) is randomizing patients with severe TR into optimal medical therapy plus TriClip system versus optimal medical therapy alone. It will give a better understanding of the role of TV clipping for the management of severe TR.

## 5 | LIMITATIONS

Our study has several limitations that bear mention. First, our study is a retrospective observational study with its inherent limitation of selection bias. Second, given the administrative database structure of NRD, the study is subject to coding errors and data quality at the site of collection, without the ability to adjudicate accuracy. Third, the temporal relationship of certain outcomes cannot be reliably established. Fourth, long-term outcomes, including long-term major adverse events, bleeding, or stroke, could not be assessed. Fifth, although TEER for treatment of severe TR is approved in Europe, its use in the United States is off-label and not covered by payers. Therefore, patients being offered treatment may represent a select group of very symptomatic patients with no options where TR is associated with definite RV failure tipping into cardiogenic shock, which might explain the high rate of cardiogenic shock and other adverse outcomes in our patients. Finally, echocardiographic and clinical data before and after the procedure are lacking. The procedural data, including the number and type of clips, are unavailable. We do not have information regarding residual TR grades, an important factor when considering recurrent heart failure readmissions.

## 6 | CONCLUSIONS

In this nationwide observational study, the number of admissions undergoing TV TEER has significantly increased over 2016–2019 with low rates of in-hospital complications. However, the rate of urgent readmission remains high, mainly due to heart failure. The ongoing TRILUMINATE Pivotal Trial and future trials will give a better understanding of the role of TV clipping for the management of severe TR.

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## CONFLICT OF INTERESTS

Azeem Latib reports the following disclosures: Consultant (honoraria)—Edwards Lifesciences, Abbott Vascular; Boston Scientific, Medtronic, Philips, WL Gore; Scientific Advisory Boards (equity)—Supira, NuevoSono, NeoChord, CorFlow, VVital, and Institutional Funding to Montefiore Medical Center from—Edwards Lifesciences, Medtronic, Abbott Vascular, Boston Scientific. All other authors have nothing to disclose.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are derived from National Readmissions Database which is available on the HCUP website at [https://www.hcup-us.ahrq.gov/tech\\_assist/centdist.jsp](https://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp)

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#### SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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