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Comparison of Transcatheter Versus Surgical Tricuspid Repair Among Patients With Tricuspid Regurgitation: Two-Year Results

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BACKGROUND: Evidence is limited as to whether outcomes differ between patients with tricuspid regurgitation (TR) treated with tricuspid transcatheter edge-to-edge repair (T-TEER) versus surgical tricuspid valve repair. We aimed to compare outcomes between these 2 approaches.

METHODS: We analyzed the data on Medicare fee-for-service beneficiaries aged 65 to 99 years with TR who underwent T-TEER or isolated surgical repair between July 2016 and December 2020. The primary outcome was 2-year all-cause mortality. Other outcomes included in-hospital mortality and permanent pacemaker implantation as well as 2-year heart failure hospitalization and tricuspid valve reintervention. A propensity score matching weight analysis was used to adjust for potential confounders.

RESULTS: A total of 1143 patients were included (409 T-TEER versus 734 surgery). The proportion of T-TEER cases increased from 2% in the third quarter of 2016 to 67% in the last quarter of 2020 among all isolated TR procedures. After adjustment for potential confounders, we found no evidence that 2-year all-cause mortality differs between patients treated with T-TEER versus surgical repair (adjusted hazard ratio, 0.84 [95% CI, 0.63–1.13]). Patients treated with T-TEER experienced lower in-hospital mortality (2.5% versus 12.5%, $P<0.001$) and permanent pacemaker implantation rates (0.0% versus 12.7%, $P<0.001$) than those treated by surgical repair. At 2 years, we found no differences in heart failure hospitalizations, but tricuspid valve reinterventions were more frequent in the T-TEER group (subdistribution hazard ratio, 8.03 [95% CI, 2.87–22.48]).

CONCLUSIONS: Among Medicare beneficiaries with TR, the 2-year mortality rate was comparable between T-TEER and surgical repair. T-TEER showed advantages in perioperative outcomes, including lower in-hospital mortality and pacemaker implantation rates, whereas tricuspid valve reinterventions were more frequent in the T-TEER group. Further studies are necessary to refine indications, patient selections, and optimal timing for intervention with either treatment strategy.

GRAPHIC ABSTRACT: A [graphic abstract](#) is available for this article.

Key Words: catheters ■ heart failure ■ Medicare ■ mortality ■ tricuspid valve

See Editorial by Lane and Eleid

Tricuspid regurgitation (TR) is a prevalent condition affecting up to 2 million people in the United States, yet it remains often undertreated.¹ Recent studies

have highlighted untreated TR as an independent predictor of mortality, drawing attention to its treatment options.² Current American and European guidelines

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WHAT IS KNOWN

- Isolated surgical repair has been the treatment of choice for tricuspid regurgitation, but it carries high risks of mortality and morbidity.
- Transcatheter interventions have emerged as a less invasive alternative to surgery.

WHAT THE STUDY ADDS

- In older patients with tricuspid regurgitation, we found no evidence that mortality and heart failure hospitalization differed 2 years after transcatheter and surgical tricuspid valve repair.
- Despite a higher burden of comorbidities, the transcatheter group experienced fewer in-hospital complications, including lower rates of death and permanent pacemaker implantation, but a higher rate of tricuspid reinterventions at 2 years.

Nonstandard Abbreviations and Acronyms

aHR	adjusted hazard ratio
CIED	cardiac implantable electronic device
ICD-10-CM	<i>International Classification of Diseases-Tenth Revision, Clinical Modification</i>
MW	matching weight
sdHR	subdistribution HR
TR	tricuspid regurgitation
T-TEER	tricuspid transcatheter edge-to-edge repair

endorse isolated tricuspid surgery as class IIa and I recommendations, respectively.^{3,4} However, isolated tricuspid surgery is often associated with suboptimal outcomes, particularly when compared with isolated aortic and mitral surgery.^{5,6} These challenges are compounded by the associated morbidities, including heart, liver, and kidney failures, with many patients presenting in late stages.⁵ Because of such factors, operative mortality of isolated tricuspid operations has been reported to be ≈5% to 10%.^{5,6} Consequently, the benefits of surgery over medical therapy remain controversial, resulting in limited adoption of surgery for TR treatment.⁷

Transcatheter edge-to-edge repair (TEER), widely adopted for severe mitral regurgitation, has been extended to the treatment of TR. Registry studies have demonstrated the feasibility and safety of tricuspid TEER (T-TEER).⁸⁻¹³ The TRILUMINATE Pivotal Trial (Trial to Evaluate Cardiovascular Outcomes in Patients Treated With the Tricuspid Valve Repair System) recently demonstrated a favorable composite end point with T-TEER compared with medical therapy.¹⁴ However, this was primarily driven by improvements in quality of life, without benefits for survival and reintervention rates.¹⁴ Currently,

indications of T-TEER remain unclear for severe TR patients.^{3,4} Furthermore, comparative data on surgical repair and T-TEER is scarce, with the current literature limited by the lack of adjustment for confounders^{15,16} and mid-term outcomes.^{16,17}

To address these critical knowledge gaps, we conducted a retrospective observational study using the Medicare claims database to evaluate outcomes of T-TEER and isolated surgical tricuspid valve repair.

METHODS

The study followed the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.¹⁸ The institutional review board at the University of California Los Angeles reviewed the study protocol and granted an exemption with a waiver for patient consent due to the nature of the secondary analysis of existing databases. The data that support the findings of this study are available from the corresponding author on reasonable request.

Data Source

We used the 100% Medicare fee-for-service Inpatient Claims and Master Beneficiary Summary Files from 2016 to 2020 as provided by the Centers for Medicare and Medicaid Services to identify the patient population. Demographic details of patients, including age, sex, and race and ethnicity were extracted using the Master Beneficiary Summary File. We extracted the preoperative comorbidities using the 27 Chronic Conditions Warehouse Chronic Conditions and Other Chronic Conditions segments from the Master Beneficiary Summary File, from the year of the index procedure.¹⁹ Identifications of other conditions and performed procedures were determined if the corresponding *International Classification of Diseases-Tenth Revision, Clinical Modification (ICD-10-CM)* and Procedure Coding System codes were present in any position among 25 diagnostic and procedural codes (Table S1).

Patients

We identified patients aged between 65 and 99 years with TR undergoing either T-TEER or isolated surgical tricuspid repair in the United States between July 2016 and December 2020. Because the claims-based frailty score calculation required 6 months of preprocedural data,²⁰ patients from January to June 2016 were excluded. We defined isolated tricuspid procedures (T-TEER or surgical repair) when other concomitant cardiac procedures were not performed on the same day as the index procedures. Patients were excluded if they had a diagnosis of infective endocarditis, tricuspid stenosis, history of heart transplants, congenital cardiac disease, myxoma, pericardial malignancy, or carcinoid syndrome, as patients with these conditions may be a distinct population.^{21,22} We also excluded patients with a history of prior tricuspid valve replacement. Patients were also excluded if they were not discharged by the end of the study period or enrolled in the Medicare Advantage plan at the time of the procedure to ensure the consistency of the follow-up.

Patients were subcategorized into primary (degenerative) or secondary (functional) TR. Those with a history of heart failure, left-sided valve disease, dilated cardiomyopathy, atrial

fibrillation, atrial flutter, and pulmonary hypertension, but without isolated rheumatic tricuspid valve conditions, were classified as secondary TR patients.²³

Outcomes

Our primary outcome was mid-term (up to 2 years) all-cause mortality from the index procedure. The mortality data and corresponding death dates were obtained from the Master Beneficiary Summary File and verified by the Centers for Medicare and Medicaid Services. Secondary outcomes included 2-year heart failure hospitalization, ischemic stroke, permanent pacemaker implantation, tricuspid valve reintervention, and reintervention with T-TEER. Secondary outcomes also included various in-hospital outcomes, including death, ischemic stroke, intracranial hemorrhage, acute kidney injury, cardiogenic shock, permanent pacemaker implantation in patients without baseline cardiac implantable electronic devices (CIEDs), respiratory complications, postoperative hemorrhage, transfusion, pericardial effusion/tamponade, heart failure, and length of stay in hospital. For in-hospital outcomes, the present-on-admission flag was used to distinguish the events from historical diagnoses. We defined occurrences of secondary outcomes by the corresponding *ICD-10-CM* codes in the admitting diagnosis or principal diagnosis upon readmission after the index procedures.²⁴ Tricuspid valve reintervention was defined if either surgical tricuspid repair or replacement, or transcatheter tricuspid repair, regardless of concomitant procedures, occurred at any point after the day of the index procedure.

Patients were followed from the day of the index procedure until disenrollment from Medicare fee-for-service, the event of an outcome occurrence during follow-up, the termination of the study duration (December 31, 2020), or 2 years after the index procedure, whichever occurred first.

Statistical Analysis

Baseline characteristics of 2 patient groups were compared. Continuous variables were reported as median (interquartile range). Categorical variables were expressed as proportions. Comparison of baseline characteristics between groups was performed by calculating standardized mean difference with a value <0.10 considered nonsignificant. In addition, the temporal trend in the quarterly case volumes was evaluated using a linear regression model for each procedure.

We performed a propensity score matching weight (MW) analysis to compare the outcomes of patients treated with T-TEER versus surgical repair while accounting for measured confounders.²⁵ We calculated the propensity score using a multivariable logistic regression model. We included the following covariates: age, sex, race and ethnicity, Medicaid dual-eligible status, the 27 Chronic Condition comorbidities in the Chronic Conditions Warehouse, liver disease, peripheral vascular disease, obesity, cause (primary/secondary), rheumatic tricuspid heart disease, the presence of CIEDs, right heart failure, pulmonary hypertension, procedure setting (elective, urgent, emergent), prior history of cardiac operations, Charlson Comorbidity Index, and frailty score.

The frailty score was calculated using a previously published method based on administrative claims data without physical performance measures.^{20,26} The ICD-10 codes for the calculation of frailty were extracted from previous studies demonstrating its validity (Table S2).^{20,26,27}

Comparative mid-term outcomes were presented using Kaplan-Meier survival curves for all-cause mortality and cumulative incidence curves for other secondary end points, after propensity score MW analysis. For all-cause mortality, the Cox proportional hazards regression model was applied to the analysis to calculate the adjusted hazard ratio (aHR) and corresponding 95% CIs. For the secondary end points, death was considered as a competing risk to construct cumulative incidence curves. A competing risk regression analysis using the Fine-Gray subdistribution hazard model was performed to provide the subdistribution HR (sdHR) with 95% CI.²⁸ In-hospital outcomes were compared using either the Pearson χ^2 or Fisher exact test, depending on whether the expected count was ≥ 5 .

To analyze the association between institutional procedural volume and outcomes, we counted the procedural volume of each procedure (T-TEER or surgical repair) at each institution. To assess the volume-outcome relationship between procedural volume and 2-year mortality for T-TEER and surgical repair, we used restricted cubic splines. For both procedures, the aHR was plotted on the *y* axis against the institutional procedural volume on the *x* axis, with the aHR set to 1.0 at a procedural volume of 5 during the study duration. The model adjusted for the same covariates used in the propensity score calculation.

Sensitivity Analyses

We performed several sensitivity analyses. First, we restricted the cohort to patients with preprocedural CIEDs because the patients with device leads may be a distinct population from those without. Second, we reanalyzed the data, restricting the patients to those aged ≥ 75 years. Third, we reanalyzed the data, restricting the cohort to elective cases. Fourth, because the hospitals' ability to perform certain procedures may affect the outcomes as well as treatment selection, we included hospital fixed-effect in the propensity score calculation to effectively compare outcomes of patients treated with T-TEER versus surgical repair at the same hospital while restricting the hospitals to those that performed both isolated T-TEER and surgical repair during the study period.²⁹ For each sensitivity analysis above, we separately calculated the propensity scores and the MWs for each group. Fifth, to account for potential unmeasured confounding, we performed an instrumental variable analysis.³⁰ We chose the cross-sectional institutional preference as the instrument, assuming that patients treated at hospitals with higher probabilities of using T-TEER in the previous year would more likely be treated with T-TEER, even when patient characteristics were similar. We obtained the proportions of T-TEER use among all isolated surgical and transcatheter tricuspid repair for TR from 1 year before each index procedure at a given institution and treated the percentage as the instrument (therefore, patients who underwent tricuspid valve repair before July 1, 2017, were excluded). Subsequently, we applied a 2-stage residual inclusion approach using the *ivtools* package.²⁵ In the first stage, we assessed the relevance of the instrument to the treatment selection by F statistics (cutoff ≥ 10) by comparing the fit of multivariable logistics regression models with and without the instrument.³¹ In the second stage, we used a multivariable Cox regression model incorporating the residuals from the first-stage model.²⁵ Sixth, we evaluated the association between tricuspid repair and the incidence of pneumonia as a falsification end point, assuming that the incidence of pneumonia is unlikely affected by the assignment of the index

procedure in the mid-term.^{32,33} Seventh, despite all sensitivity analysis, it is still possible that 2-year mortality differs between patients treated with T-TEER versus surgical repair, but the true difference was masked by unmeasured confounders. To quantify this potential, we calculated *E* value, which showed how strongly the unmeasured confounders would need to be associated with both exposures and outcomes to obtain a null relationship.³⁴

Statistical significance was determined by using 2-tailed tests with $P < 0.05$ considered significant. Data acquisition was performed with SAS 9.4 (SAS Institute Inc, Cary, NC), and statistical analyses were performed with R 4.2.2 (R Foundation for Statistical Computing, Vienna, Austria) programming language.

RESULTS

Study Cohort

We included 1143 patients meeting our selection criteria in our analysis, of which 409 and 734 patients were treated with T-TEER and surgery, respectively (Figure S1). The median follow-up period was 13.3 months (interquartile range, 3.5–24 months). Patients receiving T-TEER were older and more likely to have a history of comorbidities, rheumatic heart disease, and preoperative CIEDs (Table 1). Patients receiving surgical repair were more likely to have a history of previous cardiac surgery. The Charlson Comorbidity Index score and frailty score were significantly higher in the T-TEER cohort. The quarterly volume of both procedures during the study period is summarized in Figure S2. The proportion of T-TEER cases increased from 2% in the third quarter of 2016 to 67% in the last quarter of 2020.

Mid-Term Outcomes

In the MW analysis, the T-TEER group was associated with a comparable 2-year mortality to the surgical group (aHR, 0.84 [95% CI, 0.63–1.13]; $P=0.25$; Figure 1). The rates of heart failure hospitalization and stroke were comparable between both procedures (Figure 2). The rate of permanent pacemaker implantation was lower in the T-TEER group (sdHR, 0.14 [95% CI, 0.06–0.30]; $P < 0.001$; Figure 3A). The tricuspid valve reintervention rates were higher in the T-TEER group (sdHR, 8.03 [95% CI, 2.87–22.48]; $P < 0.001$; Figure 3B). A total of 35 patients required tricuspid reinterventions, with 16 patients undergoing T-TEER as reintervention (1 patient after surgery, 15 patients after T-TEER; Figure 3C).

In-Hospital Outcomes

In the adjusted cohorts, the T-TEER group was associated with significantly lower rates of in-hospital deaths (Table 2). Similarly, the T-TEER group was demonstrated to have lower in-hospital rates of acute kidney injury,

permanent pacemaker implantation, respiratory complications, transfusions, pericardial effusion/tamponade, and heart failure. The length of hospital stay was also significantly shorter in the T-TEER group, with a higher proportion of patients being discharged to home.

Institutional Procedure Volume and Outcomes

Between July 2016 and December 2020, 312 institutions performed either T-TEER or surgical repair of TR throughout the study period. 57 institutions performed both procedures, while 25 and 230 institutions performed only T-TEER and surgical repair, respectively.

In our analysis of volume-outcome association, independently performed for T-TEER and surgical repair, the adjusted restricted cubic spline curve demonstrated significant associations between increasing procedural volume and a decreased 2-year mortality for both procedures (Figure S3).

Sensitivity Analyses

The results were qualitatively similar to the principal analysis when we reanalyzed the data after restricting the cohort to patients with preprocedural CIEDs, to patients aged ≥ 75 years, to patients undergoing elective procedures, and to patients treated at hospitals capable of both T-TEER and surgical repair (Tables S3 and S4; Figure S4). Our instrumental variable analysis showed the F statistic of 154.6, indicating that the previous institutional practice pattern was a strong predictor of the use of T-TEER. We found a similar association for 2-year mortality to the principal analysis (T-TEER versus surgical repair; aHR, 0.61 [95% CI, 0.33–1.11]).

In the analysis of the falsification end point, we found no evidence that the incidences of pneumonia differed between the 2 groups at 2 years by the MW analysis (sdHR, 0.88 [95% CI, 0.41–1.87]).

According to our hypothetical simulations, where the true causal effects would have been explained away due to potential unmeasured confounders, the confounders would need to be associated with both being treated with T-TEER or surgical repair and 2-year mortality with > 1.8 -fold, which might be possible given the unavailability of certain types of data (eg, blood test and echocardiography; Table S5).

DISCUSSION

Our analysis comparing T-TEER and surgical repair for TR using a nationally representative database yielded several significant findings. First, we observed a significant increase in T-TEER utilization, with a concurrent decrease in surgical repair volume from 2016 to 2020. Second, T-TEER and surgical repair showed comparable 2-year mortality and heart failure hospitalizations after

Table 1. Baseline Characteristics

	Crude cohort			Matching weight analysis		
	T-TEER	Surgery	SMD	T-TEER	Surgery	SMD
Patients	409	734		409	734	
Age, y	81.0 [76.0, 85.0]	74.0 [69.0, 78.0]	0.943	77.0 [73.0, 82.0]	78.0 [74.0, 81.0]	0.012
Female	242 (59.2%)	422 (57.5%)	0.034	58.3%	57.2%	0.022
Race			0.207			0.14
White	353 (86.3%)	617 (84.1%)		86.0%	86.7%	
Black	18 (4.4%)	50 (6.8%)		5.6%	5.1%	
Asian	19 (4.6%)	17 (2.3%)		4.3%	2.7%	
Hispanic	≤10	30 (4.1%)		1.7%	3.3%	
Hypertension	390 (95.4%)	659 (89.8%)	0.214	94.2%	94.6%	0.016
Hyperlipidemia	333 (81.4%)	553 (75.3%)	0.148	79.4%	79.8%	0.01
Diabetes	136 (33.3%)	254 (34.6%)	0.029	35.4%	35.5%	0.002
Prior myocardial infarction	≤10	35 (4.8%)	0.249	1.0%	0.9%	0.013
Ischemic heart disease	340 (83.1%)	627 (85.4%)	0.063	84.4%	84.6%	0.006
Congestive heart failure	399 (97.6%)	633 (86.2%)	0.424	95.9%	95.8%	0.003
Atrial fibrillation	353 (86.3%)	510 (69.5%)	0.414	81.1%	81.6%	0.014
Chronic kidney disease	282 (68.9%)	381 (51.9%)	0.354	62.9%	62.3%	0.014
Prior stroke/TIA	31 (7.6%)	45 (6.1%)	0.057	7.1%	7.4%	0.013
COPD	126 (30.8%)	183 (24.9%)	0.131	30.3%	29.0%	0.029
Asthma	47 (11.5%)	74 (10.1%)	0.045	10.2%	10.5%	0.01
Liver disease	127 (31.1%)	122 (16.6%)	0.344	25.9%	26.2%	0.007
Anemia	307 (75.1%)	507 (69.1%)	0.134	74.2%	73.9%	0.008
Peripheral vascular disease	163 (39.9%)	186 (25.3%)	0.313	32.3%	32.4%	0.003
Dementia	63 (15.4%)	59 (8.0%)	0.23	10.8%	11.4%	0.02
Depression	103 (25.2%)	156 (21.3%)	0.093	24.5%	23.6%	0.022
Cancer	61 (14.9%)	88 (12.0%)	0.086	12.5%	13.8%	0.04
Arthritis	201 (49.1%)	307 (41.8%)	0.147	46.0%	46.3%	0.006
Obesity	104 (25.4%)	212 (28.9%)	0.078	28.9%	27.8%	0.025
Procedural setting			0.409			0.045
Elective	307 (75.1%)	463 (63.1%)		74.8%	76.7%	
Emergency	29 (7.1%)	152 (20.7%)		7.5%	7.0%	
Urgent	72 (17.6%)	119 (16.2%)		17.7%	16.3%	
Secondary TR	248 (60.6%)	526 (71.7%)	0.235	64.9%	65.0%	0.004
Rheumatic disease	161 (39.4%)	192 (26.2%)	0.284	34.9%	34.9%	0.001
Pacemaker/ICD leads	92 (22.5%)	99 (13.5%)	0.236	18.4%	18.2%	0.006
Right heart failure	46 (11.2%)	60 (8.2%)	0.104	11.2%	10.9%	0.009
Pulmonary hypertension	19 (4.6%)	95 (12.9%)	0.296	5.8%	5.8%	0.003
Prior cardiac surgery	30 (7.3%)	248 (33.8%)	0.693	11.3%	10.7%	0.019
Charlson score	7.0 [5.0, 8.0]	5.0 [4.0, 7.0]	0.413	6.0 [5.0, 8.0]	6.0 [5.0, 8.0]	0.053
Frailty score	0.25 [0.17, 0.36]	0.15 [0.09, 0.22]	0.899	0.21 [0.14, 0.27]	0.20 [0.14, 0.28]	0.004

Baseline characteristics of patients undergoing T-TEER and surgical repair before and after propensity score matching weight analysis. Values are median [Q1, Q3] or n (%) and % in the weighted cohort. Cells with ≤10 patients are suppressed to protect the privacy of beneficiaries in accordance with the Centers for Medicare and Medicaid Services guidance. COPD indicates chronic obstructive pulmonary disease; ICD, implantable cardioverter defibrillator; SMD, standard mean difference; TIA, transient ischemic attack; TR, tricuspid regurgitation; and T-TEER, tricuspid transcatheter edge-to-edge repair.

adjustment. Third, T-TEER was consistently associated with more favorable in-hospital outcomes, including a markedly lower mortality and permanent pacemaker implantation rate.

There is an ongoing paradigm shift in the management of severe TR. Various transcatheter approaches, including T-TEER, annuloplasty, and replacement, have been introduced, with T-TEER being studied the most

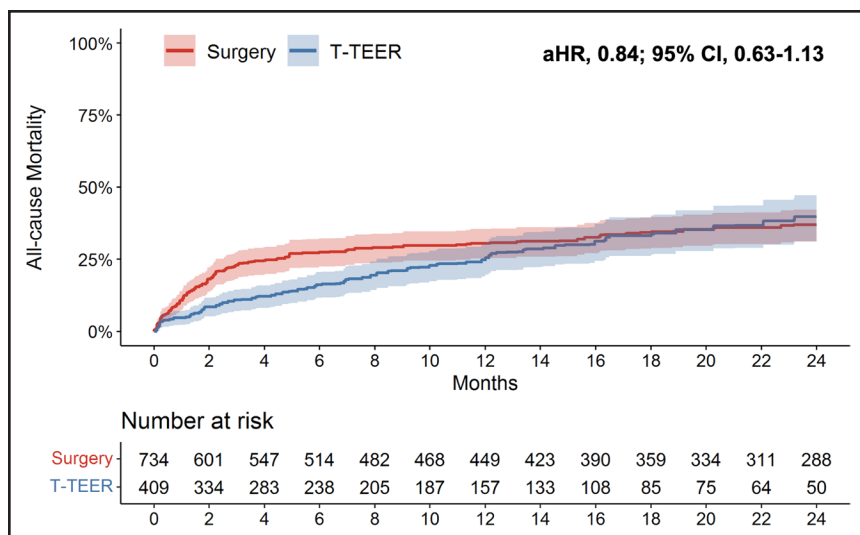


Figure 1. Two-year all-cause mortality after propensity score matching weight analysis.

Kaplan-Meier analysis of all-cause mortality. Solid lines represent the estimates, and the surrounding bands represent the 95% CIs. aHR indicates adjusted hazard ratio; and T-TEER, tricuspid transcatheter edge-to-edge repair.

extensively.^{8,9,14,35} For T-TEER, 3 devices were possibly used during the study period; the TriClip system (Abbott Structural Heart, Santa Clara, CA), the MitraClip system (Abbott), and the PASCAL device (Edwards Lifesciences LLC, Irvine, CA). Although the MitraClip and PASCAL devices were originally designed for the treatment of mitral regurgitation, the TriClip is a modified version of MitraClip specifically designed for TR treatment, which received Food and Drug Administration approval in 2024. In our study, the majority of T-TEER cases likely involved off-label MitraClip, with smaller portions of TriClip and PASCAL devices.^{36,37} However, the comparative performance of T-TEER against surgical repair remains underexplored.^{15-17,38} The guidelines lack consensus on the role of T-TEER in TR management; the European guidelines classify it as a class IIb recommendation, whereas it is not stated in the American guidelines.^{3,4}

Propensity score MW analysis showed in-hospital outcomes consistently favoring T-TEER over surgery, aligning with previous reports.¹⁷ A trend of higher early

risk in the surgical arm with converging survival curves in the mid-term was also observed in the analysis of TRIGISTRY.^{15,38} Surgical tricuspid repair often allows definitive repair of TR whereas ~50% of T-TEER cases have moderate or residual postprocedural TR, potentially contributing to the outcome convergence by the 2-year mark. Although our analysis adjusted for confounders, unmeasured confounders likely influenced mid-term results, given substantial baseline differences between the groups. Overall, we demonstrated T-TEER as a safe alternative to surgery in high-risk population, offering perioperative advantages despite the higher comorbidity burden.

Notably, the rates of permanent pacemaker implantations were significantly lower in the T-TEER group compared with the surgical arm at mid-term. Tricuspid surgical repair carries a high risk of conduction system injury because of the atrioventricular node's proximity to the septal leaflet of the valve.³⁹ Avoiding CIEDs after tricuspid intervention is crucial because transvalvular leads

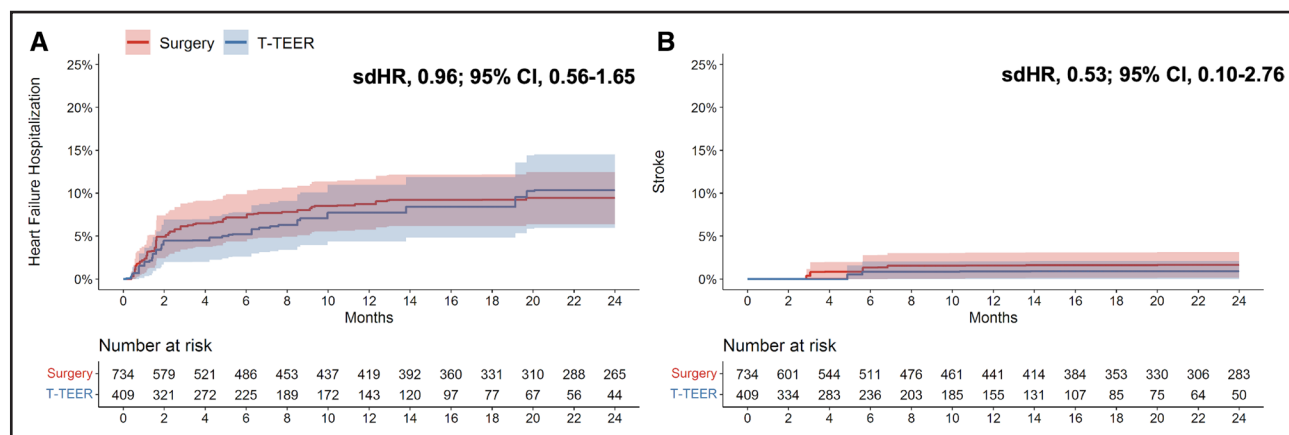


Figure 2. Two-year outcomes regarding heart failure hospitalization and stroke after propensity score matching weight analysis.

Analysis of (A) heart failure hospitalization and (B) stroke. Solid lines represent the estimates, and the surrounding bands represent the 95% CIs. sdHR indicates subdistribution hazard ratio; and T-TEER, tricuspid transcatheter edge-to-edge repair.

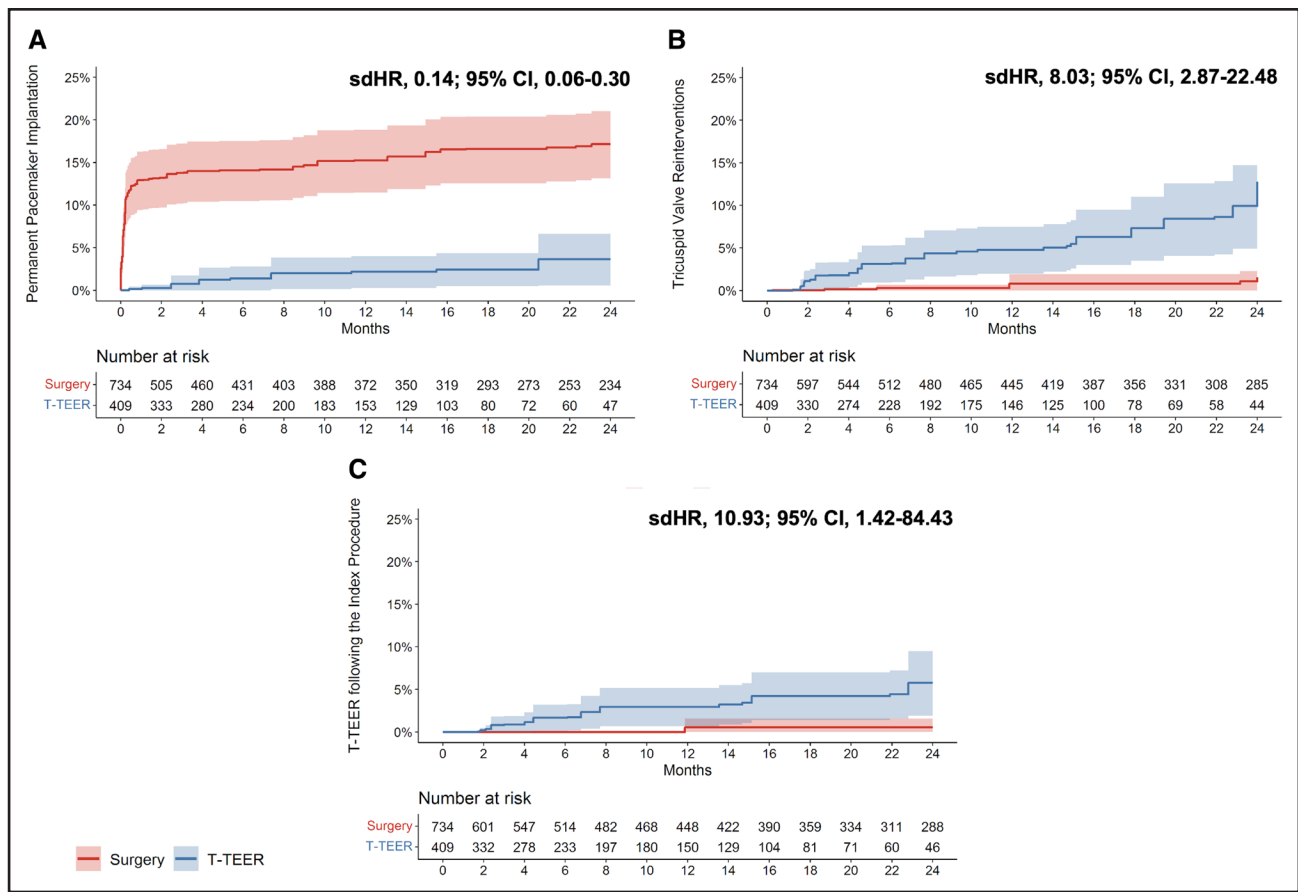


Figure 3. Two-year outcomes regarding pacemaker implantations and tricuspid valve reinterventions after propensity score matching weight analysis.

Analysis of (A) permanent pacemaker implantations, (B) tricuspid valve reinterventions, and (C) tricuspid valve reinterventions specific to tricuspid transcatheter edge-to-edge repair (T-TEER). Solid lines represent the estimates, and the surrounding bands represent the 95% CIs. sdHR indicates subdistribution hazard ratio.

have been linked to heart failure.⁴⁰ The potential use of leadless pacemakers in patients undergoing tricuspid interventions is warranted in this regard.⁴¹

Interestingly, our analysis of the volume-outcome relationship for T-TEER and surgical repair revealed that 2-year mortality was significantly associated with procedural volume for both procedures. These data underscore the importance of performing isolated tricuspid procedures at experienced centers for optimal outcomes.⁴² It is recommended to refer patients with severe symptomatic TR early to highly experienced centers with a comprehensive heart team for both T-TEER and surgical repairs.⁴² Our analysis provides insights to facilitate informed discussions with TR patients and their families regarding the choice between T-TEER and surgical options, emphasizing the need to consider both the expertise of the treating center and the individualized approach to meet the patients' preferences.

Limitations

Our study has limitations. First, because of its retrospective design, we cannot eliminate the effect of

confounders. Although our main analysis used MW analysis with propensity scores to account for measured confounders, unmeasured confounders may still exist. However, sensitivity analyses using an instrumental variable method and a falsification end point suggest our findings are robust. Second, the claims database lacked data on the laboratory values, imaging studies (echocardiographic data including the severity of TR at baseline and residual TR, computed tomography data, etc.), and quality of life metrics. Furthermore, we could not identify specific repair techniques or the number of clips used in T-TEER cases. Third, we lacked frailty assessment or risk scores, such as the TRI-SCORE and the Society of Thoracic Surgeons scores, although we calculated the claim-based frailty score and the Charlson Comorbidity Index score. Fourth, mid-term outcomes including heart failure hospitalization and stroke were detected based on the presence of corresponding ICD-10-CM codes in the admitting or principal diagnosis upon another hospitalization after the index procedure, which may underestimate these outcomes.⁴³ Fifth, no causes of death were defined based on our analyses due to the nature of the database. Sixth, the study cohort comprised only Medicare

Table 2. In-Hospital Outcomes

	Crude cohort			Matching weight analysis		
	T-TEER	Surgery	P value	T-TEER	Surgery	P value
Patients	409	734		409	734	
In-hospital death	≤10	79 (10.8%)	<0.001	2.5%	12.5%	<0.001
Ischemic stroke	≤10	18 (2.5%)	0.003	0.4%	1.5%	0.204
Intracerebral hemorrhage	≤10	≤10	0.167	0.0%	0.9%	0.083
Acute kidney injury	48 (11.7%)	225 (30.7%)	<0.001	11.9%	33.8%	<0.001
Cardiogenic shock	14 (3.4%)	117 (15.9%)	<0.001	4.0%	17.1%	<0.001
Permanent pacemaker	≤10	93 (14.6%)	<0.001	0.0%	12.7%	<0.001
Respiratory complications	≤10	79 (10.8%)	<0.001	1.9%	11.4%	<0.001
Postoperative hemorrhage	≤10	26 (3.5%)	0.016	0.8%	2.0%	0.138
Transfusions	23 (5.6%)	156 (21.3%)	<0.001	4.7%	21.9%	<0.001
Pericardial effusion/tamponade	≤10	36 (4.9%)	0.005	1.5%	4.2%	0.035
Heart failure	11 (2.7%)	69 (9.4%)	<0.001	3.8%	10.0%	0.004
Length of stay, d	2.0 [1.0, 7.0]	12.0 [7.0, 21.0]	<0.001	2.0 [1.0, 7.0]	11.0 [6.0, 20.0]	<0.001
Discharge location			<0.001			<0.001
Home	350 (85.6%)	385 (52.5%)		88.4%	48.4%	
Hospice	≤10	≤10		0.7%	0.2%	
Long-term care	≤10	54 (7.4%)		0.9%	7.4%	
Skilled nursing facility	11 (2.7%)	86 (11.7%)		2.7%	13.6%	

In-hospital outcomes of patients undergoing T-TEER and surgical repair before and after propensity score matching weight analysis. Values are median [Q1, Q3] or n (%) and % in the weighted cohort. Cells with ≤10 patients are suppressed to protect the privacy of beneficiaries in accordance with the Centers for Medicare and Medicaid Services guidance. T-TEER indicates tricuspid transcatheter edge-to-edge repair.

fee-for-service beneficiaries aged 65 years or older. Our findings may not be generalizable to younger patients, Medicare Advantage populations, and patients treated outside the United States. Seventh, with fewer than 20% of institutions performing both surgical tricuspid repair and T-TEER, the generalizability of our comparative findings may be limited. Nevertheless, sensitivity analyses restricted to these centers yielded outcomes consistent with the main analysis. Eighth, despite its less invasive nature, T-TEER may not be the preferred repair strategy for every operator, particularly for those with experience. Ninth, it is possible that a portion of the devices in the T-TEER group were used off-label. Although we have based the coding of T-TEER on information available from the Medicare Electronic Application Request Information System and aligned it with prior studies, the off-label status necessitates careful interpretation of our findings.^{44,45} Lastly, although the Heart Team approach is important for individualized care, we could not capture its role and influence on outcomes in our claims data.

Conclusions

Among Medicare beneficiaries, 2-year mortality and heart failure hospitalization rates were comparable between the 2 groups. Notably, T-TEER showed advantages in perioperative outcomes, including in-hospital mortality and pacemaker implantation rates while tricuspid valve

reinterventions were more frequent in the T-TEER group. Further studies are necessary to refine indications, patient selections, and optimal timing for intervention with either strategy.

ARTICLE INFORMATION

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Disclosures

Dr Latib has been a consultant and serves on the Advisory Board of Medtronic, Abbott, Boston Scientific, Edwards Lifesciences, V-Dyne, NeoChord, Nyra Medical, Tioga, Shifamed, and Philips. Dr Kaneko has received consulting fees from Edwards Lifesciences, Medtronic, 4C Medical, CardioMech, and Cook Medical; and has been a speaker for Abbott and Baylis. Dr Zajarias has received consulting fees from Edwards Lifesciences. Dr Elmariyah has received consulting fees from Edwards Lifesciences and Medtronic. Dr Takayama has received consulting fees from Artivion and Edwards Lifesciences. Dr Tsugawa serves on the board of directors of M3, Inc. Study sponsors were not involved in study design, data interpretation, writing, or the decision to submit the manuscript for publication. The other authors report no conflicts.

Supplemental Material

Tables S1–S5
Figures S1–S4

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