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ORIGINAL RESEARCH

Comparison of Outcomes of Leadless Versus Transvenous Pacemakers Following Tricuspid Valve Surgery

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BACKGROUND: Transvenous pacemaker implantation after tricuspid valve surgery may cause adverse outcomes due to lead–valve interactions. Although leadless pacemakers may mitigate these risks, empirical data remain limited.

METHODS: We compared outcomes of leadless versus transvenous pacemakers following tricuspid surgery using a target trial emulation framework. We analyzed Medicare beneficiaries aged ≥65 years who underwent tricuspid valve surgery and received a pacemaker during the index admission between 2017 and 2021, using propensity score matching weight analysis to control for confounders. Primary outcomes were in-hospital death and 2-year heart failure hospitalization. Secondary outcomes included 2-year death.

RESULTS: We included 185 and 1336 patients in the leadless and transvenous groups, respectively. Use of leadless pacemakers increased from 6.3% in 2017 to 17.5% in 2021. Leadless pacemaker recipients more often underwent tricuspid valve replacement (29.2% versus 8.5%) while concomitant mitral surgery was less common (69.2% versus 86.8%). After adjustment, we found no evidence that in-hospital death (adjusted odds ratio, 1.82 [95% CI, 0.65–5.13] for leadless) and 2-year heart failure hospitalizations (subdistribution hazard ratio [HR], 0.88 [95% CI, 0.60–1.30] for leadless) differed between the 2 groups. We also found no evidence that 2-year death (adjusted HR, 1.04 [95% CI, 0.69–1.57] for leadless) differed between groups.

CONCLUSIONS: No statistically significant differences were detected between leadless versus transvenous pacemaker implantations after tricuspid valve surgery. However, CIs were wide, and a clinically meaningful difference in either direction cannot be excluded. The study may therefore be underpowered, and the absence of echocardiographic data limits assessment of tricuspid regurgitation, warranting prospective studies.

Key Words: leadless pacemaker ■ pacemaker ■ tricuspid valve surgery

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Tricuspid regurgitation (TR) is increasingly recognized as a condition with substantial morbidity and mortality risk, with untreated patients experiencing mortality rates approaching 35%.[1,2] Surgical management has therefore grown in volume, both concomitant and isolated tricuspid procedures.[1–3] However, postoperative atrioventricular block remains a significant concern. Despite preventive efforts,[4,5] up to 14% of patients require permanent pacemaker implantations,[6,7] particularly after valve replacement.[3,7,8]

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CLINICAL PERSPECTIVE

What Is New?

- This is the first study to directly compare leadless and transvenous pacemakers after tricuspid valve surgery.
- Leadless and transvenous pacemakers were associated with comparable outcomes after tricuspid valve surgery, including 2-year heart failure readmissions and death, as well as in-hospital complications.

What Are the Clinical Implications?

- Despite the use of target trial emulation and multiple analytical approaches, including propensity score matching weight analysis, the modest sample size and limited follow-up duration constrain interpretation; adequately powered randomized clinical trials are needed to define the clinical impact of leadless pacemakers in patients undergoing tricuspid valve surgery.

Nonstandard Abbreviations and Acronyms

TR	tricuspid regurgitation

Transvenous pacemakers, though most commonly used, carry drawbacks in this setting. Transvalvular leads can interfere with repaired or replaced valves and exacerbate TR,[9–13] contributing to worse outcomes including increased heart failure hospitalizations.[9] Alternatives including epicardial or coronary sinus pacing have their own limitations.[14–16] Leadless pacemakers, which avoid both transvalvular leads and pockets, have emerged as an attractive option and are supported by recent American and European position papers.[17,18] However, current evidence is restricted to small case series,[19,20] and their comparative safety and effectiveness after tricuspid surgery, as well as the ability to draw causal inferences, remain uncertain and warrant further investigation.

Therefore, using the US national data on Medicare beneficiaries, we implemented a target trial emulation framework to assess the comparative effectiveness and safety of leadless versus transvenous pacemakers following tricuspid surgery.[21]

METHODS

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. Medicare claims data are available from https://resdac.org. Statistical codes are available from the corresponding author upon reasonable request. The study protocol was not registered.

Target Trial Emulation

Target trial emulation is a methodological framework designed to imitate a hypothetical clinical trial, thereby overcoming inherent biases associated with retrospective studies, including selection bias and immortal time bias.[22] In this study, we sought to emulate a clinical trial that would randomize the patients meeting the following criteria to the leadless and transvenous arm: (1) patients aged ≥65 years, (2) patients who underwent tricuspid surgery during the same index hospitalization, and (3) patients receiving pacemaker implantation after tricuspid surgery. Our study aimed to follow up patients from the date of the pacemaker implantation procedure to a maximum of 2 years to compare the safety and effectiveness of the 2 types of pacemakers (Table S1). The causal contrast of interest was the intention-to-treat effect, defined by a total effect of treatment assignment, regardless of subsequent treatment changes or crossover. This study was performed in accordance to the Transparent Reporting of Observational Studies Emulating a Target Trial guideline.[23]

Data Source

We used the Inpatient Claims and Master Beneficiary Summary Files on the 100% sample of the Medicare fee-for-service beneficiaries from 2017 to 2021, provided by the Centers for Medicare and Medicaid Services. January 2017 was chosen because this was when Micra VR (Medtronic Inc) gained national coverage by the Centers for Medicare and Medicaid Services.[24] Demographic details of individual patients, including age, sex, and race and ethnicity, were extracted using the Master Beneficiary Summary File. We extracted the preprocedural comorbidities using the 27 chronic conditions from the Chronic Conditions Warehouse from the Master Beneficiary Summary File. Identifications of other conditions and performed procedures were determined if the corresponding *International Classification of Diseases*, *Tenth Revision*, *Clinical Modification* (*ICD-10-CM*) and *Tenth Revision*, *Procedure Coding System* (*ICD-10-PCS*) codes were present in any position among 25 diagnostic and procedural codes (Table S2).

Patients

We included patients aged ≥65 years who underwent tricuspid surgery with subsequent leadless or

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transvenous pacemaker implantation during the same hospitalization between January 2017 and December 2021. Exclusion criteria were prior heart transplantation,[25] enrollment in Medicare Advantage, or failure to be discharged before the end of the study period. We excluded patients who received cardiac resynchronization therapy devices or defibrillators due to potential confounding by indication.[17] We also excluded patients who received a mechanical tricuspid valve, as implantation of transvenous pacemakers in this population is contraindicated.[16] We excluded patients with missing covariate information at time zero.

Outcomes

Our primary outcomes were in-hospital all-cause death and midterm (up to 2 years) heart failure hospitalization. Secondary outcomes included 2-year all-cause death, infective endocarditis, device-related complications, and tricuspid valve reintervention. Secondary outcomes also included various in-hospital outcomes, including overall complications, comprising cardiac effusion/perforation/tamponade, embolism and thrombosis, puncture site complications, device-related complications, and other complications (Table S2).[24,26] Individual components of these outcomes were also assessed separately. Additionally, the length of stay was assessed.

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. We identified in-hospital outcomes on the basis of *ICD-10-CM* codes recorded in any of the 25 diagnosis fields and distinguished new events from preexisting conditions using the present-on-admission flag. We identified midterm incidence of heart failure hospitalization and infective endocarditis by using the Inpatient Claims File on the basis of the presence of corresponding *ICD-10-CM* codes in the admitting, principal, first, and secondary diagnoses upon rehospitalization after the procedure, to ensure that it constituted the primary reason for hospitalization rather than historical diagnoses. We identified midterm occurrences of device-related complications using the Inpatient and Outpatient Claims File on the basis of the presence of corresponding *ICD-10-CM* codes in any position among the 25 diagnosis codes. Tricuspid valve reintervention was defined as either surgical tricuspid repair or replacement, tricuspid transcatheter edge-to-edge repair, or transcatheter tricuspid valve replacement that occurred at any point after the day of pacemaker insertion.

Patients were followed from the day of the pacemaker implantation until disenrollment from Medicare fee-for-service, the occurrence of the outcome of interest during follow-up, the end of the study period (December 31, 2021), or 2 years after the pacemaker implantation, whichever occurred first.

Statistical Analysis

Baseline characteristics of the 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 the standardized mean difference, with a value of <0.10 considered to indicate a well-balanced covariate distribution.[27]

We performed a propensity score matching weight analysis to compare the outcomes of patients treated with leadless versus transvenous pacemaker implantation while accounting for measured confounders.[28] We computed the propensity score using a multivariable logistic regression model. We included the following covariates: age, sex, race and ethnicity, Medicaid dual-eligibility status, the 27 Chronic Condition comorbidities in the Chronic Conditions Warehouse, TR, infective endocarditis at baseline, liver disease, peripheral vascular disease, obesity, tricuspid replacement procedure, concomitant mitral and aortic valve procedures, concomitant coronary artery bypass grafting, conduction disturbances, and days between index tricuspid valve surgery and pacemaker insertion.

Comparative midterm outcomes were presented with cumulative incidence curves after adjustment using the propensity score matching weight analysis. A Cox proportional hazards regression model was applied to calculate the adjusted hazard ratio (aHR) and corresponding 95% CIs. For the secondary midterm end points, death was considered as a competing risk to construct cumulative incidence function curves. A competing risk regression analysis using the Fine–Gray subdistribution hazard model was performed to provide the subdistribution hazard ratio (sdHR) with 95% CI.[29] For in-hospital binary outcomes, we used a weighted logistic regression with a logit link to estimate relative effects, presented as adjusted odds ratios with corresponding 95% CIs. For continuous variables, weighted linear regression with a Gaussian distribution and identity link was used to assess the adjusted mean difference with the corresponding 95% CIs.[30]

Sensitivity Analysis

We performed several sensitivity analyses. First, we performed a sensitivity analysis restricting the sample to patients receiving tricuspid repair and those undergoing replacement, as these groups represent different characteristics.[3,8] We also evaluated the association between the modes of pacemakers and incidence of pneumonia as a falsification end point, assuming that the incidence of pneumonia is unlikely to be affected by

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the assignment of the index procedure in the midterm. Furthermore, we performed a propensity score matching analysis using nearest-neighbor matching with a caliper of 0.2 SDs of the logit of the propensity score. For each of the sensitivity analyses, a propensity score was separately calculated and weighted. No formal adjustments for multiple testing were performed.

Statistical significance was determined by using 2-tailed tests, with *P* values <0.05 considered significant.

Data preparation was performed with SAS 9.4 (SAS Institute, Inc., Cary, NC), and analyses were performed with R version 4.2.2 (R Foundation for Statistical Computing, Vienna, Austria).

Patient and Public Involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination plans of this research.

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RESULTS

Patient Population

We included 1521 older adults who met the eligibility criteria (Figure S1) including 185 and 1336 patients who received leadless or transvenous pacemaker implantations after tricuspid valve surgeries during the index hospitalization. During the study period, 461 institutions implanted pacemakers following tricuspid valve surgeries, including 82 institutions that performed both leadless and transvenous pacemaker implantations. Sixteen and 363 institutions performed only leadless and transvenous pacemaker implantations, respectively (Figure S2). The median follow-up was 23.1 (interquartile range, 9–24) months.

The characteristics of both patient groups are summarized in Table 1. The median age was 75 years in both groups. Both groups received pacemaker implantation at a median of 6.0 days postoperatively. The proportion of leadless pacemaker implantations increased from 6.3% in 2017 to 17.5% in 2021. A greater proportion of the leadless pacemaker group underwent tricuspid valve replacement (29.2% versus 8.5%), while concomitant mitral valve surgery was less common (69.2% versus 86.8%). After propensity score matching weight analysis, the baseline characteristics were well balanced between the 2 groups (concordance statistics of propensity score=0.77).

Main Outcomes

After weighting, we found no evidence that in-hospital outcomes differed between the 2 groups, with death occurring in 3.8% of the leadless group versus 2.1% of the transvenous group (adjusted odds ratio, 1.82 [95% CI, 0.65–5.13] for leadless). The in-hospital outcomes are summarized in Table 2. After adjustment, overall complication rates were 21.0% versus 17.8%. We found no evidence that overall complications (adjusted odds ratio, 1.22 [95% CI, 0.79–1.90] for leadless), as well as specific complications, including cardiac effusions, embolic or thrombotic complications, puncture site complications, and lead-associated complications, differed between groups. The median length of stay was 12 and 13 days in both groups.

After weighting, the cumulative incidence of heart failure hospitalization was 20.6% (95% CI, 13.8–26.9) in the leadless group and 23.4% (95% CI, 19.6%–27.1%) in the transvenous group. We found no evidence that midterm heart failure hospitalization differed between the 2 groups (sdHR, 0.88 [95% CI, 0.60–1.30] for leadless; Figure 1). The midterm absolute risk of death was 21.1% (95% CI, 14.4–27.8) in the leadless group and 20.6% (95% CI, 16.7–24.5) in the transvenous group. We found no evidence that midterm death differed between the 2 groups (adjusted HR, 1.04 [95% CI, 0.69–1.57] for leadless; Figure 2A). We also found no evidence that midterm outcomes, including infective endocarditis rates (sdHR, 0.97 [95% CI, 0.30–3.15] for leadless; Figure 2B), and device complication rates (sdHR, 1.05 [95% CI, 0.51–2.17] for leadless; Figure 2C) differed between the 2 groups. Tricuspid valve reinterventions were rare (≤10 events in each group).

Secondary Analyses

Sensitivity analysis restricted separately to patients receiving tricuspid repair and replacement also demonstrated consistent findings (Table 3, Tables S3 and S4). In the analysis of the falsification end point, we found no evidence that the incidence of pneumonia differed between the 2 groups (sdHR, 0.63 [95% CI, 0.23–1.69] for leadless), although numerically lower in the leadless group. In our sensitivity analysis using propensity score matching, we also found no differences in midterm death (adjusted HR, 0.94, [95% CI, 0.58–1.50] for leadless).

DISCUSSION

Using nationally representative data on older adults in the United States, we compared the outcomes of leadless and transvenous pacemakers following tricuspid valve surgery. First, we found no statistically significant difference in in-hospital death and midterm heart failure hospitalization rates between the 2 groups. Second, we also found no statistically significant difference in other secondary outcomes between the 2 groups. These findings remained consistent with our sensitivity analyses. While point estimates were near the null for all outcomes, the CIs were wide, with upper

Table 1. Baseline Characteristics

Patient demographics	Crude cohort			Weighted cohort, %		
	Leadless	Transvenous	SMD	Leadless	Transvenous	SMD
Number of patients	185	1336		185	1336	
Age, y	75.0 (70.0–80.0)	75.0 (70.0–79.0)	0.142	75.0 (70.0–80.0)	76.0 (72.0–80.0)	0.008
Male sex	92 (49.7)	529 (39.6)	0.205	48.9	50.0	0.021
Race and ethnicity			0.103			0.012
Black	≤10	72 (5.4)		4.0	3.8	
White	158 (85.4)	1149 (86.0)		85.3	85.8	
Others	20 (10.8)	115 (8.6)		10.7	10.4	
Hypertension	164 (88.6)	1193 (89.3)	0.021	88.8	88.9	0.002
Hyperlipidemia	148 (80.0)	1014 (75.9)	0.099	80.2	81.3	0.027
Diabetes	68 (36.8)	384 (28.7)	0.171	36.1	37.1	0.019
Prior myocardial infarction	≤10	32 (2.4)	0.080	3.9	4.0	0.008
Ischemic heart disease	160 (86.5)	1107 (82.9)	0.101	86.2	86.0	0.007
Congestive heart failure	156 (84.3)	1091 (81.7)	0.071	83.7	83.4	0.007
Atrial fibrillation	163 (88.1)	973 (72.8)	0.393	87.6	86.9	0.019
Chronic kidney disease	111 (60.0)	669 (50.1)	0.201	59.2	59.9	0.014
Prior stroke/transient ischemic attack	19 (10.3)	109 (8.2)	0.073	10.6	10.7	0.004
Chronic obstructive pulmonary disease	47 (25.4)	319 (23.9)	0.035	25.4	26.3	0.021
Asthma	18 (9.7)	134 (10.0)	0.010	10.2	10.9	0.023
Liver disease	32 (17.3)	113 (8.5)	0.266	15.9	15.4	0.014
Anemia	145 (78.4)	991 (74.2)	0.099	78.2	78.0	0.003
Peripheral vascular disease	45 (24.3)	293 (21.9)	0.057	23.1	22.9	0.003
Dementia	14 (7.6)	81 (6.1)	0.060	7.1	6.3	0.031
Depression	34 (18.4)	288 (21.6)	0.080	18.2	18.4	0.004
Cancer	22 (11.9)	194 (14.5)	0.078	11.3	10.6	0.023
Arthritis	73 (39.5)	553 (41.4)	0.039	39.1	38.1	0.021
Obesity	48 (25.9)	387 (29.0)	0.068	26.5	25.6	0.019
Tricuspid regurgitation	163 (88.1)	1223 (91.5)	0.114	88.0	87.9	0.004
Infective endocarditis	19 (10.3)	49 (3.7)	0.262	10.4	10.8	0.012
Indication			0.378			0.036
Complete heart block	106 (57.3)	845 (63.2)		58.7	60.0	
Other heart block at risk	≤10	37 (2.8)		4.2	4.4	
Persistent atrial fibrillation with bradycardia	≤10	≤10		0.7	0.5	
Sinus node dysfunction	27 (14.6)	303 (22.7)		15.3	14.7	
Unknown	42 (22.7)	147 (11.0)		21.1	20.4	
Operative characteristics						
Tricuspid valve replacement	54 (29.2)	113 (8.5)	0.550	26.8	27.1	0.008
Concomitant surgery						
Mitral surgery	128 (69.2)	1159 (86.8)	0.434	71.7	71.2	0.011
Aortic surgery	48 (25.9)	272 (20.4)	0.133	26.3	26.5	0.004
Coronary artery bypass grafting	28 (15.1)	253 (18.9)	0.101	15.8	15.0	0.024
Others						
Days from surgery to pacemaker	6.0 (3.0–9.0)	6.0 (4.0–7.0)	0.115	6.0 (3.0–9.0)	6.0 (4.0–8.0)	0.038
Medicaid dual	19 (10.3)	137 (10.3)	0.001	10.3	10.2	0.004

Values are shown as median (interquartile range) or n (%). SMD indicates standard mean difference.

bounds that include clinically important effect sizes. These findings should therefore be interpreted as inconclusive rather than as evidence of equivalence.

Leadless pacemakers are theoretically advantageous in patients with prior tricuspid valve surgery,[15,16] given the avoidance of transvalvular leads and associated risks

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Table 2. In-Hospital Outcomes

Patient demographics	Crude cohort		Weighted cohort, %		
	Leadless	Transvenous	Leadless	Transvenous	Effect estimate*
Number of patients	185	1336	185	1336	
Death	≤10	18 (1.3)	3.8	2.1	1.82 (0.65 to 5.13)
Overall	38 (20.5)	176 (13.2)	21.0	17.8	1.22 (0.79 to 1.90)
Cardiac effusion/perforation/tamponade	14 (7.6)	61 (4.6)	7.9	6.5	1.24 (0.63 to 2.43)
Embolism and thrombosis	≤10	18 (1.3)	1.1	2.7	0.41 (0.09 to 1.97)
Deep venous thrombosis	≤10	12 (0.9)	1.1	1.8	0.63 (0.12 to 3.22)
Device-related complications	≤10	20 (1.5)	2.8	2.0	1.39 (0.44 to 4.36)
Other complications	25 (13.5)	98 (7.3)	13.6	9.1	1.57 (0.92 to 2.69)
Vascular complication	≤10	29 (2.2)	1.7	2.8	0.60 (0.17 to 2.14)
Hemothorax	12 (6.5)	32 (2.4)	6.3	4.0	1.62 (0.72 to 3.65)
Pneumothorax	≤10	27 (2.0)	3.4	1.9	1.83 (0.68 to 4.94)
Length of stay	13.0 (9.0 to 22.0)	11.0 (8.0 to 16.0)	12.1 (9.0 to 20.1)	13.0 (8.0 to 20.0)	1.79 (−0.94 to 4.52)
Discharge location					
Home	114 (61.6)	769 (57.6)	62.0	54.8	
Long-term care	12 (6.5)	34 (2.5)	6.2	4.2	
Skilled nursing facility	50 (27.0)	506 (37.9)	26.9	38.1	

Values are shown as median (interquartile range) or n (%).
*Values are estimate (95% CI).

such as lead-induced TR and pocket complications.[17,18] Prior studies in general populations have demonstrated favorable procedural safety and reduced lead-related complications with leadless devices.[31–33] In our cohort, these theoretical benefits did not translate into measurable improvements in in-hospital and midterm outcomes. Meanwhile, concerns about leadless pacemaker implantation include the introduction of a large-bore delivery sheath across a repaired valve. While limited by the nature of claims data, we found no evidence that heart failure readmissions or device-related complications differ between groups, with minimal tricuspid reinterventions.

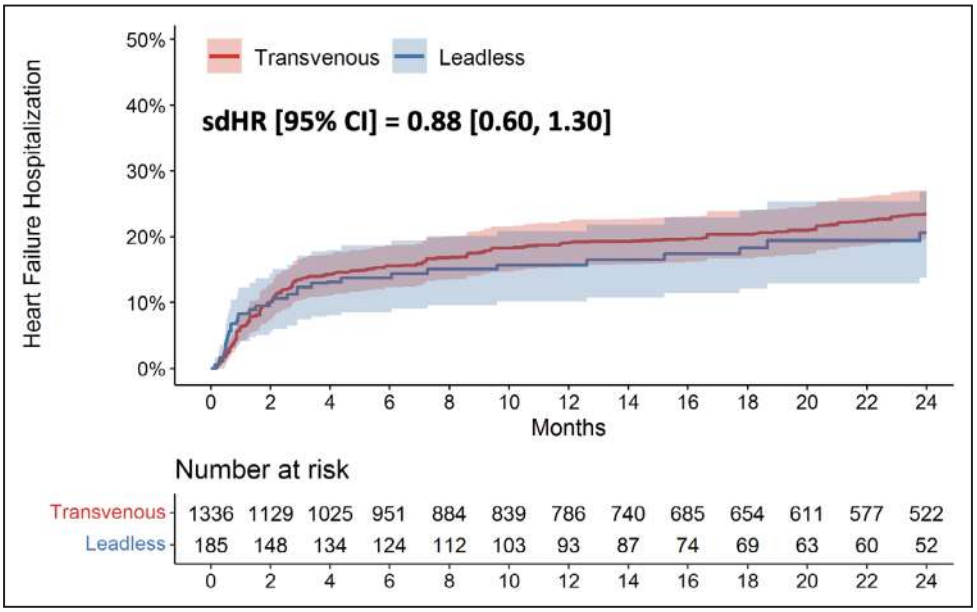

Figure 1. Two-year heart failure hospitalization following propensity score matching weight analysis.
A comparison of the cumulative incidence of heart failure hospitalization. Solid lines represent the estimates, and the surrounding bands represent the 95% CIs. The numbers at risk reflect the weighted population. sdHR indicates subdistribution hazard ratio.

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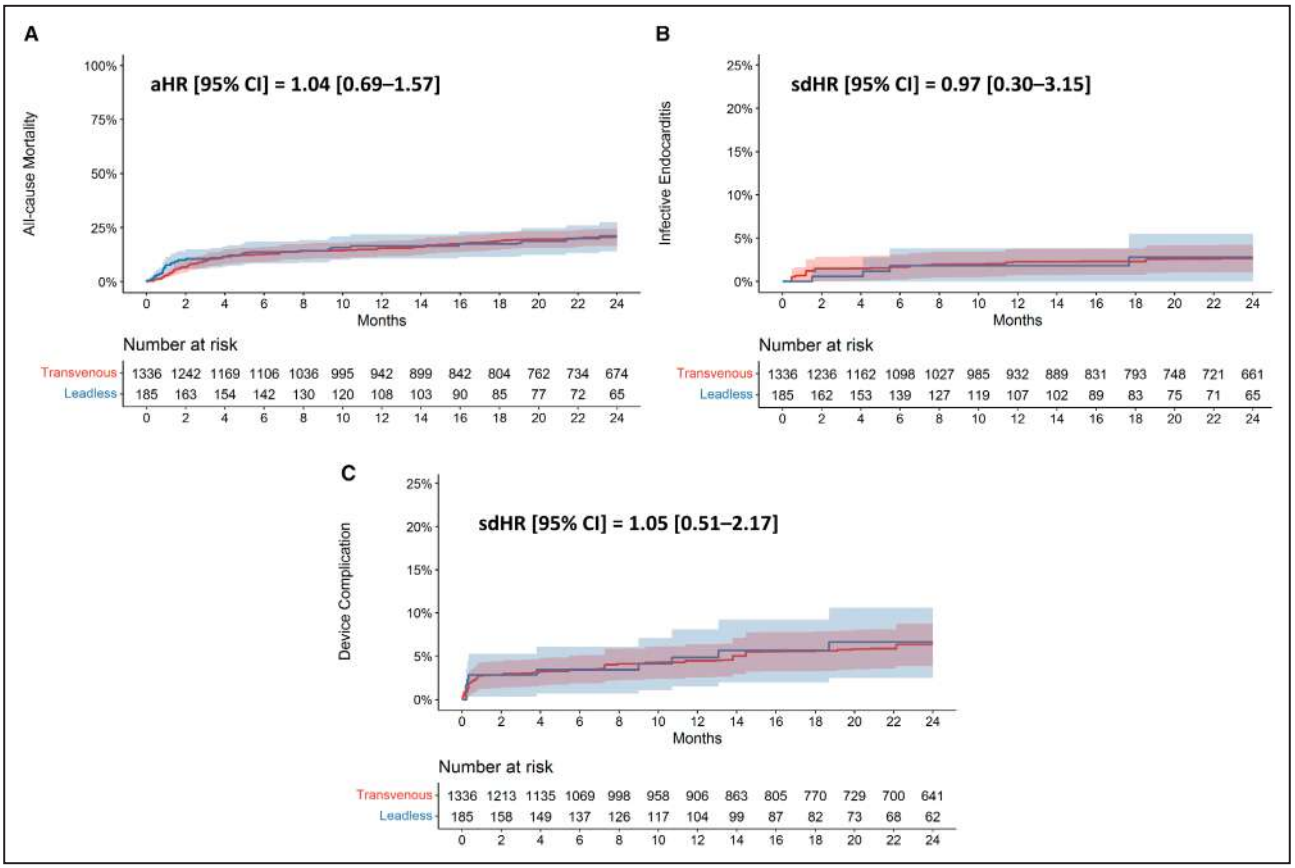

Figure 2. Two-year outcomes for all-cause death, infective endocarditis, and device complications following propensity score matching weight analysis.
Analysis of (**A**) all-cause death, (**B**) infective endocarditis, and (**C**) device complications. Solid lines represent the estimates, and the surrounding bands represent the 95% CIs. The numbers at risk reflect the weighted population. aHR indicates adjusted hazard ratio; and sdHR, subdistribution hazard ratio.

However, the absence of echocardiographic data precludes assessment of TR and mechanistic effects on valve function. Future studies with granular imaging data may add further insight.

Interestingly, we found no evidence that midterm outcomes differ between the 2 pacemaker groups, including heart failure hospitalization and death. This contrasts with prior studies in the general population that have demonstrated midterm benefits with leadless pacemakers.[26,34] These results may reflect limited statistical power and follow-up duration, particularly relative to prior studies in the general population with >16 000 patients and 3-year follow-up,[32] which may preclude detection of clinically meaningful differences. Alternatively, the absence of midterm benefit may reflect the higher risk profile of our leadless pacemaker cohort, which included more isolated tricuspid surgery cases and a higher proportion of replacement cases. Furthermore, the lack of observed advantages with the leadless devices may be attributed to potential TR progression and pacing-induced ventricular desynchrony. Although septal implantation reduces perforation risk and provides more physiologic pacing compared with apical placement, a study in the general population reported TR progression at 1 year with septal implantation.[35,36] The proximity of the device to the tricuspid annulus predicts worsening TR severity through direct device interaction with the leaflet apparatus.[37] However, such worsening TR has not been observed in case series for leadless pacemaker implantations

Table 3. Midterm Clinical Outcomes in Sensitivity Analyses

Outcomes, HR (95% CI)	Heart failure hospitalization	All-cause death	Infective endocarditis	Device-related complications
Valve repair	0.97 (0.62–1.51)	1.09 (0.67–1.76)	1.72 (0.48–6.13)	0.95 (0.38–2.37)
Valve replacement	0.63 (0.28–1.43)	1.94 (0.79–4.79)	1.16 (0.09–14.31)	1.57 (0.34–7.22)

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following prior tricuspid surgery.[19,20,38] Unfortunately, our claims-based data lack the echocardiographic data to confirm this mechanism.

In our study, we found no evidence that periprocedural outcomes differ between the 2 groups, consistent with prior reports demonstrating comparable overall complication rates in the general population.[26,34] Leadless devices eliminate lead- and pocket-related complications but introduce distinct risks of myocardial perforation or vascular injury due to the large-bore access.[26,34] However, these device-specific risks may be outweighed by the elevated pre- and perioperative risks associated with tricuspid surgery in the older cohort, potentially masking device-related differences.[8] The absence of between-group differences may reflect limited statistical power and limited follow-up.

Some studies have raised concern that large-bore delivery systems of leadless devices may cause tricuspid valve injury and worsening TR. Careful implantation under echocardiographic guidance can help mitigate this risk,[19] and our study demonstrated comparable in-hospital outcomes, including puncture site complications, with no major periprocedural drawbacks. Overall, progression of heart failure and TR may result from acute implant-related injury, chronic device interference with the tricuspid valve apparatus, or pacing-based dyssynchrony.[36] Notably, studies with shorter echocardiographic follow-up reported the lowest rates of TR progression, supporting a predominantly chronic rather than acute mechanism.[36]

While this study did not demonstrate the superiority of leadless devices, the findings suggest their safety as an alternative in this high-risk population. These devices may be particularly beneficial for specific subgroups with unique challenges with transvenous devices, such as those with limited vascular access,[39] a history of severe infections, or comorbidities like liver failure or end-stage renal disease. Given the high comorbidity burden among patients undergoing tricuspid surgery, these potential advantages of leadless devices and our study results may inform clinical decision making.

Comparison of leadless pacemaker device types, Micra and AVEIR, is warranted. Due to its larger profile, AVEIR devices may be less favorable than Micra devices for the post–tricuspid surgery patient cohort.[39] Furthermore, new device types have been introduced, which include atrioventricular synchronous Micra devices (Micra AV), as well as dual-chamber leadless (AVEIR DR). Taken together, these devices offer all pacing modes, in addition to VVI pacing, which would improve the prognosis of this population. Further studies comparing device types and alternative pacing modes, including epicardial or coronary sinus pacing, are warranted.[14]

Limitations

Our study has limitations. First, we cannot exclude the possibility of unmeasured confounders due to the lack of randomization, even though we used a target trial emulation framework and used matching weight analysis with propensity scores. We also included sensitivity analyses and additional methods, including propensity score matching and falsification end points, to demonstrate the robustness of our findings. Second, we identified the diagnoses, procedures, and outcomes on the basis of *ICD-10-CM* and *ICD-10-PCS* codes, and the data extraction may be subject to misclassification bias. We also lacked granular data, including laboratory values, imaging studies (echocardiographic data, including severity of TR at baseline and postprocedurally), types of operations performed, and device types, as well as risk scores such as the TRI-SCORE, the Society of Thoracic Surgeons scores, and the frailty assessment. Furthermore, outcomes were not adjudicated, and midterm outcomes, including heart failure hospitalization and infective endocarditis, were captured on the basis of the presence of the *ICD-10-CM* codes upon readmission, which may underestimate these outcomes.[40] However, the short-term outcomes and the *ICD-10-CM* codes used to identify them were adapted from codes validated in prior studies to have high agreement with physician-adjudicated data collection.[24,41] Third, our data may lack statistical power, with only 185 patients in the leadless group, and therefore cannot exclude clinically meaningful differences between groups. As a result, the CIs are wide and do not exclude clinically meaningful differences; therefore, the absence of a statistically significant difference should not be interpreted as evidence of equivalence. Instead, the findings should be considered inconclusive, and a type II error cannot be excluded. Notably, our study reports the largest cohort of patients receiving leadless pacemakers following tricuspid surgery, 4 times as many patients compared with the biggest prior report.[19] We also included the comparative arm with transvenous pacemakers, which has not been reported previously. Fourth, the follow-up duration must be considered. Our study included 2 years of follow-up, which may be insufficient to detect clinically meaningful differences. Fifth, our findings may not apply to the younger generation. Prior Medicare analyses of patients undergoing tricuspid surgery reported higher age and event rates compared with other national registry studies.[8] Sixth, no causes of death were defined on the basis of our analyses. Finally, after February 5, 2020, when Micra AV devices became nationally covered by the Centers for Medicare and Medicaid Services, we could not distinguish between Micra VR and Micra AV devices using *ICD-10* codes. Given differences in pacing characteristics and potential clinical outcomes, these findings should be interpreted with

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caution, and further studies accounting for device type are needed.

CONCLUSIONS

To our knowledge, this is the first comparative study to investigate the safety and effectiveness of leadless pacemakers following tricuspid valve surgery. Despite the theoretical potential for leadless pacemakers to lower risks of adverse outcomes, no statistically significant differences were detected between leadless versus transvenous pacemakers. However, the study may be underpowered to detect clinically meaningful differences, as reflected by wide CIs that do not exclude clinically meaningful differences. Furthermore, given the limitations of claims data, we could not assess valve structure or TR progression. Prospective studies with standardized echocardiographic follow-up are needed to define the impact of pacing strategy on tricuspid valve function and clinical outcomes.

ARTICLE INFORMATION

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Dr Kaneko is a speaker for Medtronic and Edwards Lifesciences and a consultant for Baylis Medical and 4C Medical. Dr Fukuhara is a consultant for Terumo Aortic, Medtronic, Edwards Lifesciences, and Artivion. Dr Ailawadi is a consultant for Medtronic, Abbott, Johnson & Johnson MedTech, Philips, Arthrex, Anteris Technologies Ltd, and W.L. Gore & Associates Inc. Dr Tsugawa receives funding from the National Institute of Health (Award No. R01AG068633, R01AG082991, and R01MD013913) and GRoW @ Annenberg for other work not related to this study, and serves on the board of directors of M3, Inc. The remaining authors have no disclosures to report.

Supplemental Material

Tables S1–S4
Figures S1–S2
STROBE Checklist

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