Pacemaker implantation following tricuspid valve annuloplasty

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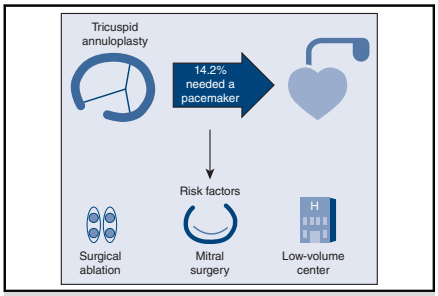
ABSTRACT

Objective: Tricuspid annuloplasty is associated with increased risk of atrioventricular block and subsequent implantation of a permanent pacemaker. However, the exact incidence of permanent pacemaker, associated risk factors, and outcomes in this frame remain debated. The aim of the study was to report permanent pacemaker incidence, risk factors, and outcomes after tricuspid annuloplasty from nationwide databases.

Methods: By using data from multiple Swedish mandatory national registries, all patients (n = 1502) who underwent tricuspid annuloplasty in Sweden from 2006 to 2020 were identified. Patients who needed permanent pacemaker within 30 days from surgery were compared with those who did not. The cumulative incidence of permanent pacemaker implantation was estimated. A multivariable logistic regression model was fit to identify risk factors of 30-day permanent pacemaker implantation. The association between permanent pacemaker implantation and long-term survival was evaluated with multivariable Cox regression.

Results: The 30-day permanent pacemaker rate was 14.2% (214/1502). Patients with permanent pacemakers were older (69.8 ± 10.3 years vs 67.5 ± 12.4 years, $P = .012$). Independent risk factors of permanent pacemaker implantation were concomitant mitral valve surgery (odds ratio, 2.07; 95% CI, 1.34-3.27), ablation surgery (odds ratio, 1.59; 95% CI, 1.12-2.23), and surgery performed in a low-volume center (odds ratio, 1.85; 95% CI, 1.17-2.83). Permanent pacemaker implantation was not associated with increased long-term mortality risk (adjusted hazard ratio, 0.74; 95% CI, 0.53-1.03).

Conclusions: This nationwide study demonstrated a high risk of permanent pacemaker implantation within 30 days of tricuspid annuloplasty. However, patients who needed a permanent pacemaker did not have worse long-term survival, and the cumulative incidence of heart failure and major adverse cardiovascular events was similar to patients who did not receive a permanent pacemaker. (JTCVS Open 2023;16:276-89)



Pacemaker implantation after TA in Sweden 2006 to 2020.

CENTRAL MESSAGE

The 30-day pacemaker implantation rate after TA is 14%. Risk factors were mitral surgery, ablation, and operation in a low-volume center.

PERSPECTIVE

The 30-day pacemaker implantation rate after TA varies from 3% to 15%. In a recent randomized trial of concomitant mitral and tricuspid operations, the incidence was higher than expected. The implantation rate in this nationwide study was 14%. Mitral valve surgery, surgical ablation, and a low surgical center volume were associated with PPM implantation.

See Discussion on page 290.

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Abbreviations and Acronyms

aHR = adjusted hazard ratio
AVB = atrioventricular block
MACE = major adverse cardiovascular events
OR = odds ratio
PPM = permanent pacemaker
TA = tricuspid annuloplasty
TR = tricuspid regurgitation

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The most common mechanism of tricuspid regurgitation (TR) is annular dilatation secondary to mitral or aortic valve diseases. Functional TR is best addressed with tricuspid annuloplasty (TA). According to clinical guidelines, which are largely based on observational studies, TA should be used liberally in patients undergoing left-sided surgery and who have severe TR.[1,2] In addition, a recent prospective randomized trial showed that performing concomitant tricuspid valve repair for moderate TR or severely enlarged annuli at the time of mitral valve surgery reduces progression of TR.[3] One of the major concerns in performing TA is the proximity of the tricuspid valve to the atrioventricular node and the bundle of His, which makes the risk of postoperative bradyarrhythmia requiring permanent pacing particularly high.[4] The rate of permanent pacemaker (PPM) implantation after TA varies considerably in observational studies, ranging from 2.5% to 15.0%.[5-7] In the trial by Gammie and colleagues,[3] patients who underwent TA had a 30-day PPM implantation rate of 14.1%, and at 2-year follow-up, the total rate was 16.0%.[8]

The incidence of PPM and associated risk factors are not fully understood, and this has not been investigated in contemporary multicenter studies. Furthermore, the long-term associations between PPM implantation after TA and long-term survival, incidence of heart failure, and major adverse cardiovascular events (MACE) have not previously been reported.

The aim of the study was to report PPM incidence, identify independent risk factors, and determine outcomes after TA using nationwide data from multiple mandatory Swedish registries.

MATERIALS AND METHODS

Study Population

All patients in Sweden who underwent tricuspid valve annuloplasty between January 2006 and December 2020, and who did not have a pacemaker at the time of surgery were initially included. Exclusion criteria were (1) placement of an implantable cardioverter defibrillator and (2) placement of a PPM the same day as tricuspid valve surgery. We excluded patients who had a PPM on the day of surgery because these PPM implantations are usually scheduled before the tricuspid valve surgery. Seven patients were lost to follow-up due to emigration during the study period. These patients contributed with follow-up time until the day of their emigration, at which time they were censored. A flowchart of the included and excluded patients is presented in Figure 1. The study was approved by the Swedish Ethical Review Authority with the Approval Number 2021-00122, approved March 31, 2021.

Data Sources

The study population was collected from the Swedish Cardiac Surgery Registry, which is a part of the SWEDEHEART Registry.[9,10] The registry holds information on all cardiac operations in Sweden since 1992 and had full coverage throughout the study period. In the registry, details of the performed surgery, preoperative patient data, and comorbid conditions are entered at the time of surgery. Everyone who lives in Sweden receives a personal identification number at the time of birth or immigration. This unique identifier was used to link the data from the Swedish Cardiac Surgery Registry with the National Patient Registry and the Cause of Death Registry. Both registries have nationwide coverage and reported excellent validity.[11,12] The National Patient Registry contains data regarding the primary and any secondary diagnoses that are associated with every hospitalization in the country. The financial reimbursement to the departments is based on that these diagnosis codes are entered into the registries. Therefore, the accuracy of the registries tends to be satisfactory.[12] The Registries used the International Classification of Diseases, 10th Revision during the study period. A list of International Classification of Diseases, 10th Revision codes used in the study is included Table E1. The data were thereafter linked to the Swedish ICD and Pacemaker Registry, which has been operational since 1989. The Swedish ICD and Pacemaker Registry (http://www.pacemakerregistret.se) records data on all pacemaker procedures in Sweden, and data are entered at the time of the procedure. It contains data on the type of electronic device implanted and the reason for device implantation. All centers in Sweden that offer cardiac electronic device implantation contribute to the Registry.

Statistical Analysis

There were several outcomes estimated in the study. The first was PPM implantation within 30 days from the index procedure. Additional outcomes were the risk of mortality, heart failure, or MACE: a composite of all-cause mortality, myocardial infarction, or stroke, in patients who had a pacemaker placed after TA. Baseline data were stratified by pacemaker implantation within 30 days. Normally distributed continuous variables were presented as means with SD. Categorical variables are presented as numbers and frequency (percentage). Several variables had missing data, body mass index (n = 1 [0.07%]), left ventricular ejection fraction (n = 8, [0.5%]) surgical center volume (n = 530, 35.3%), tricuspid ring size (n = 421), and type of ring model (n = 254). Missing data were handled using multiple imputation using logistic regression or polytomous regression, as appropriate depending on the type of variable. The cumulative incidence of PPM implantation was estimated with the Kaplan–Meier function for the first 30 days. Long-term cumulative incidence was plotted with a cumulative incidence function where competing risk of death was taken into account. To identify risk factors associated with PPM implantation within 30 days after TA, a logistic regression analysis was performed. The analysis was extensively adjusted, with adjustments decided on before analysis based on previous studies. The logistic regression analysis was adjusted for the following risk factors: age, sex, prior myocardial infarction, heart failure, low ejection fraction, atrial fibrillation, diabetes, concomitant coronary surgery, concomitant aortic valve surgery, concomitant mitral valve surgery, concomitant arrhythmia surgery, type of annuloplasty performed (use of ring or suture annuloplasty), if a ring was used, the

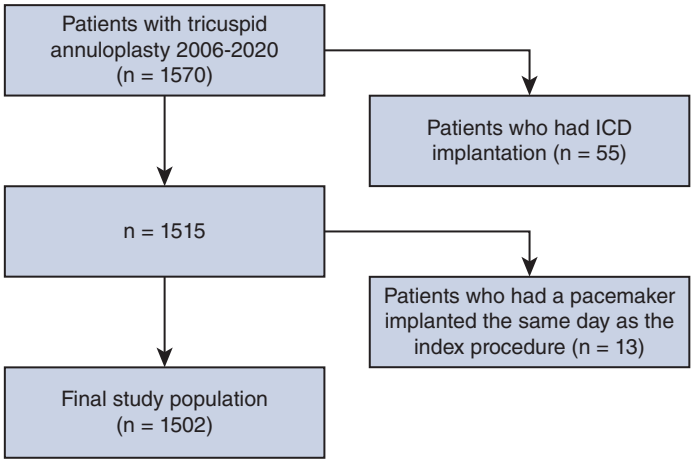

FIGURE 1. Study flow chart. *ICD*, Implantable cardioverter defibrillator.

size of the tricuspid ring used at the time of surgery, and operational volume of the hospital. Surgical case volume was dichotomized with hospitals with an annual volume less than 10 procedures considered as low-volume centers and hospitals with an annual volume of more than 10 procedures considered as high-volume centers. TA size was dichotomized into large rings (≥31 mm) and smaller rings (≤30 mm). Sensitivity analyses were performed with TA size as a continuous variable and another model where low-volume center was excluded from the analysis. A multivariable logistic regression was performed to identify risk factors of late (>30 days) PPM implantation.

Long-term survival in the 2 groups was estimated with the Kaplan–Meier function. Cox proportional hazards models were used to calculate adjusted hazard ratios (aHRs) with 95% CI associated with pacemaker implantation for MACE, heart failure, and mortality. Because these analyses were used to evaluate the association between pacemaker implantation within 30 days and long-term outcomes, all patients had to survive 30 days to be included. A sensitivity analysis evaluating long-term mortality, after 1 year of follow-up, and using the Kaplan–Meier was included. Patients had to survive the first year after surgery to be included in this analysis. The proportional hazards assumption was tested with the use of scaled Schoenfeld residuals. The model did not meet the assumption for MACE and all-cause mortality. Therefore, robust standard errors were used to account for the invalid hazards proportionality. The model was adjusted for the same variables as the logistics regression analysis. Sensitivity analyses were performed on the same Cox regression models. PPM implantation within 30 days was replaced with PPM implantation occurring between 30 days and 1 year after surgery. Using the Kaplan–Meier function, we also compared long-term survival in patients who received a pacemaker within the first year from surgery with those who did not receive a pacemaker within the first year from surgery.

All tests were 2-tailed, and all analyses were performed using R version 4.03 (R Foundation for Statistical Computing).

Ethical Considerations

The study was approved by the Swedish Ethical Review Authority (Registration Number 2021-00122). The need for individual patient consent in this retrospective, population-based study was waived by the committee. The linkage of the databases was carried out by the Swedish National Board of Health and Welfare (Socialstyrelsen), and the final

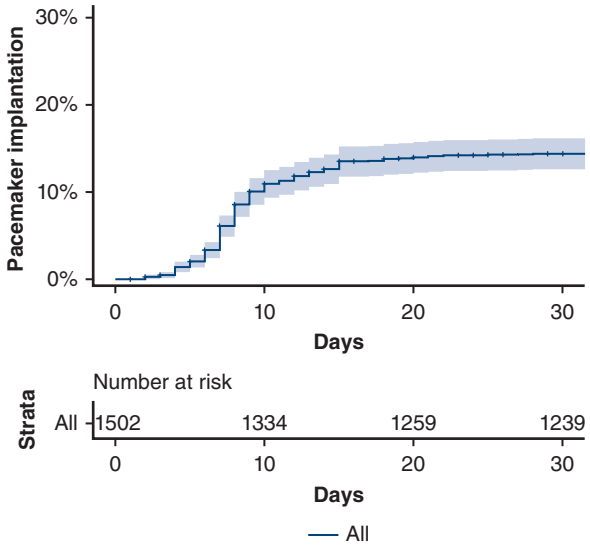

FIGURE 2. Kaplan–Meier curve showing the estimated rate of PPM implantation in the first 30 days after tricuspid valve repair (*blue line*, percentage; shaded area, 95% CI).

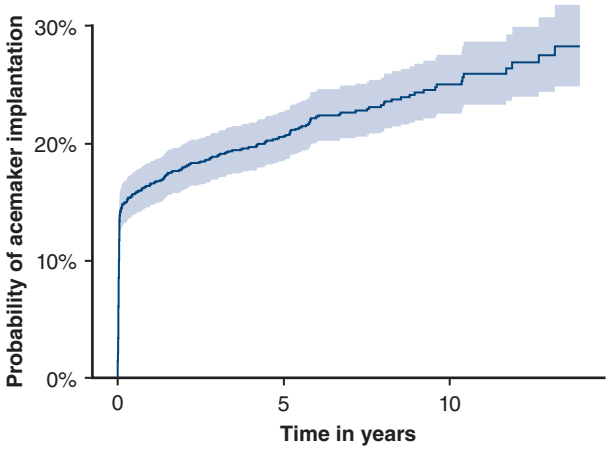

FIGURE 3. Cumulative incidence function curve showing the estimated long-term rate of PPM implantation after tricuspid valve repair (*blue line*, percentage; shaded area, 95% CI).

TABLE 1. Baseline characteristics of patients who did and did not have a pacemaker implanted within 30 days of tricuspid annuloplasty

	All patients (n = 1502)	Patients without pacemaker implanted (n = 1288)	Patients with pacemaker implanted (n = 214)	*P* value
Age (SD), y	67.8 (12.2)	67.5 (12.4)	69.8 (10.3)	.012*
Sex (male)	974 (64.8%)	831 (64.5%)	143 (66.8%)	.51
BMI				.068
Underweight	120 (8.0%)	105 (8.2%)	15 (7.0%)	
Normal	665 (44.3%)	554 (43.0%)	111 (51.9%)	
Overweight	519 (34.6%)	453 (35.2%)	66 (30.8%)	
Obese	198 (13.2%)	176 (13.7%)	22 (10.3%)	
Diabetes	143 (9.5%)	119 (9.2%)	24 (11.2%)	.36
Atrial fibrillation				
Preoperative	951 (63.3%)	805 (62.5%)	146 (68.2%)	.11
New-onset postoperative	227 (15.1%)	192 (14.9%)	35 (16.4%)	.58
All AF	1178 (78.4%)	997 (77.4%)	181 (84.6%)	.018*
Heart failure	883 (58.8%)	776 (59.5%)	117 (54.7%)	.19
Previous MI	132 (8.8%)	115 (8.9%)	17 (7.9%)	.64
Previous stroke	130 (8.7%)	115 (8.9%)	15 (7.0%)	.36
Perioperative endocarditis	72 (4.8%)	64 (5.0%)	8 (3.7%)	.44
LVEF (<50%)	672 (44.7%)	578 (44.9%)	94 (43.9%)	.97
Coronary surgery	263 (17.5%)	231 (17.9%)	32 (15.0%)	.29
Mitral surgery	1127 (75.0%)	944 (73.3%)	183 (85.5%)	<.001*
Mitral valve repair	769 (51.2%)	659 (51.2%)	110 (51.4%)	.95
Mitral valve replacement	358 (23.8%)	285 (22.1%)	73 (34.1%)	<.001*
Aortic valve surgery	239 (15.9%)	211 (16.4%)	28 (13.1%)	.22
Ablation surgery	374 (24.9%)	300 (23.3%)	74 (34.6%)	<.001*
Isolated TA	152 (10.1%)	145 (11.3%)	7 (3.3%)	<.001*
Tricuspid ring size	32.4 (2.7)	32.4 (2.6)	32.9 (3.4)	.034*
High-volume center	1163 (77.4%)	988 (76.7%)	175 (81.8%)	.99

BMI, Body mass index; *AF*, atrial fibrillation; *MI*, myocardial infarction; *LVEF*, left ventricular ejection fraction; *TA*, tricuspid annuloplasty. *Statistically significant.

dataset was given to the authors without personal identification numbers. The study was performed in accordance with the 1975 Declaration of Helsinki. The article was composed in agreement with the suggestions in the Strengthening the Reporting of Observational Studies in Epidemiology statement.[13]

RESULTS

Early Incidence and Cumulative Incidence of Permanent Pacemaker Implantation

Of 1502 patients who underwent TA, 214 (14.2%) received a PPM within the first 30 postoperative days. The rate of PPM implantation was highest between 4 and 16 days after the surgery (Figure 2). Thirty-day mortality in the PPM group was 1.9% (n = 4) compared with 3.8% (n = 49) in the no-PPM group (*P* = .22).

The cumulative incidence of PPM implantation with the Kaplan–Meier method is shown in Figure E1. The estimated cumulative long-term PPM rate, where competing risk of death was taken into account, is shown in Figure 3. The 1-year PPM rate was 16.9% (95% CI, 14.9-18.7), the 2-year PPM rate was 17.9% (95% CI, 16.0-19.9), and the 5-year rate was 20.5% (95% CI, 18.5-22.7). The 30-day PPM rate per year during the study period is shown in Figure E2. There was no significant association between year of surgery and the 30-day PPM rate. During the study period, a total of 7539 mitral valve surgeries (repair or replacement) were performed in Sweden on patients without previously implanted pacemakers and without TA. The proportion of patients undergoing mitral valve surgery who had concomitant TA was 13.0% (1127/8666). The incidence of PPM implantation after mitral valve surgery without concomitant TA was 6.2%.

Indications for Permanent Pacemaker Implantation

Overall, the most common indication for PPM was atrioventricular block (AVB) (70.1%, n = 150/214), whereas the rest had sinus node dysfunction. The proportion of patients with AVB as the indication was 75.8% (n = 69/91) in patients who underwent concomitant

TABLE 2. Associations between preoperative and perioperative factors and permanent pacemaker implantation within 30 days after surgery (multivariable logistic regression analysis)

Factor	RR	*P* value
Age (per year)	1.01 (1.00-1.03)	.09
Sex (male)	1.10 (0.81-1.52)	.56
Myocardial infarction	1.10 (0.61-1.88)	.75
Heart failure	0.79 (0.58-1.09)	.15
LVEF <50%	1.05 (0.76-1.43)	.77
Atrial fibrillation	1.18 (0.76-1.87)	.48
Diabetes mellitus	1.35 (0.81-2.16)	.23
Coronary surgery	0.81 (0.52-1.23)	.33
Mitral surgery	2.07 (1.34-3.27)	.001*
Aortic valve surgery	1.06 (0.65-1.67)	.81
Ablation surgery	1.59 (1.12-2.23)	.008*
Suture annuloplasty	1.30 (0.90-1.85)	.15
Tricuspid ring size >30 mm (only in patients with ring)	1.67 (1.00-2.91)	.058
Low-volume center	1.85 (1.17-2.83)	.007*
Age (per year)	1.01 (1.00-1.03)	.09

RR, Relative risk; *LVEF*, left ventricular ejection fraction. *Statistically significant.

mitral valve surgery compared with 40.5% (n = 30/74) in patients who underwent concomitant ablation surgery ($P < .001$).

Unadjusted Comparison of Patients With and Without Permanent Pacemaker Implantation Within 30 Days

Baseline characteristics of both groups are shown in Table 1. The PPM group was older (mean age, 69.8 years [SD, 10.3] vs 67.5 years [SD, 12.4], $P = .012$). The sex distribution was similar in both groups. Patients in the PPM group were more likely to have had atrial fibrillation, to have had concomitant ablation surgery, and to have undergone concomitant mitral valve surgery compared with patients in the no-PPM group. Mitral valve replacement was more common in the PPM group compared with the no-PPM group, whereas the proportion of mitral valve repair was similar in both groups. Compared with the no-PPM group, the PPM group received, on average, larger annuloplasty rings. Isolated TA was more common in the no-PPM group compared with the PPM group. The types of annuloplasty rings used during the study period are shown in Table E2. The PPM rate in patients who underwent tricuspid suture annuloplasty compared with those who had a ring annuloplasty is shown in Figure E3.

Factors Associated With Permanent Pacemaker Implantation

In multivariable analysis, mitral valve surgery, ablation surgery, and undergoing operation in a low-volume center were independent risk factors of PPM implantation within 30 days (Table 2). By fitting a risk model with the risk factors of concomitant mitral valve surgery, concomitant ablation surgery, and low-volume center, a patient with any of the 3 risk factors would have an odds ratio (OR) of 2.43 (95% CI, 1.22-5.39) to receive a PPM, a patient with 2 risk factors would have an OR of 3.08 (95% CI, 1.54-6.88), and a patient with all 3 risk factors would have an OR of 4.41 (95% CI, 2.04-10.44). Two sensitivity analyses were performed: (1) a model with tricuspid ring size as a continuous variable and (2) a model with low center volume excluded (Tables E3 and E4). Risk factors of late PPM implantation (ie, >30 days after surgery) are shown in Table E5.

Associations Between Permanent Pacemaker Implantation Within 30 Days and Long-Term Outcome

The cumulative survivals in the PPM and the no-PPM groups are shown in Figure 4. Long-term survival was significantly better in the PPM group compared with the no-PPM group. Figure 5 shows the aHRs of MACE, heart failure, and death associated with PPM implantation within 30 days from tricuspid valve annuloplasty. PPM was not associated with MACE or heart failure. The aHR for death from PPM implantation was 0.73 (95% CI, 0.53-0.101) ($P = .059$). Figure 6 shows the Graphical Abstract of the study.

Sensitivity Analyses on Permanent Pacemaker Implantation and Long-Term Outcome

In unadjusted analysis, we found no significant difference in survival between all patients who received a pacemaker within 1 year from surgery and patients who did not receive a pacemaker within 1 year from surgery (Figure E4). We performed sensitivity analyses to see whether the hazard ratios from PPM implantation between 30 days and 1 year after surgery were any different than PPM implantation within 30 days of surgery. In these analyses, PPM implantation was associated with an aHR of 1.49 (95% CI, 0.89-2.48, $P = .13$) for all-cause mortality, 0.95 (95% CI, 0.42-2.18, $P = .92$) for heart failure, and 1.42 (95% CI, 0.88-2.23, $P = .15$) for MACE.

DISCUSSION

This nationwide study, with complete long-term follow-up, shows that there was a significant risk of PPM need after TA, with a PPM implanted in more than 14% of the patients during the first 30 days after surgery. In the recent Cardiothoracic Surgical Trials Network study by Gammie and colleagues,[3] patients who underwent concomitant TA for moderate TR or dilated tricuspid annulus during surgery for degenerative mitral regurgitation had a similar risk of PPM implantation as patients in the current study. Observational studies have reported

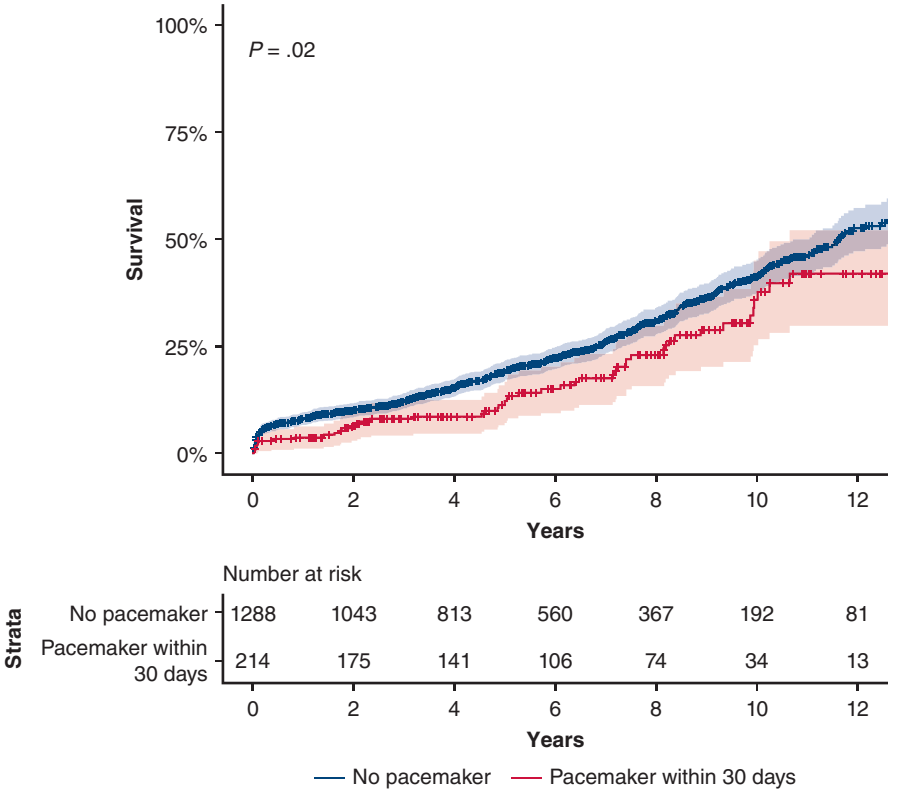

FIGURE 4. Kaplan–Meier curves showing the cumulative survival in patients who underwent tricuspid valve repair comparing those who got a PPM within 30 days (*red line*, percentage; shaded area, 95% CI) with those who did not get a PPM within 30 days after surgery (*blue line*, percentage; shaded area, 95% CI).

pacemaker rates between 2.4% and 15%.[5-7,14] Thus, the current data showed a rate at the higher end of this spectrum. Although these previous studies are valuable for comparison with the current study, it is important to note that the cohorts presented in these studies differ from the current cohort: an all-comers cohort in whom concomitant mitral valve surgery was performed in 75% only. In addition, the current study included patients who underwent suture TA (DeVega annuloplasty).

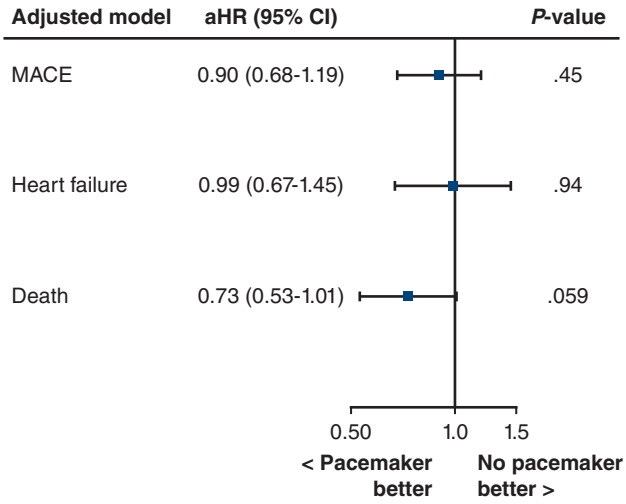

FIGURE 5. Forest plot showing the aHRs of MACE, heart failure, and death from PPM implantation after tricuspid valve repair. Adjusted for age, sex, aortic surgery, coronary surgery, mitral surgery, myocardial infarction, arrhythmia surgery, heart failure, low ejection fraction (<50%), atrial fibrillation, and diabetes mellitus. *aHR*, Adjusted hazard ratio; *MACE*, major adverse cardiovascular events.

Pacemaker implantation is associated with several short- and long-term complications such as thrombosis, infection, pacemaker-induced TR, and pacing-induced ventricular dysfunction.[4] An area of uncertainty in previous studies on PPM after TA has been the effect, if any, on long-term outcomes. In the present study, we could not determine the long-term risk of thrombosis, infective endocarditis, or grade of TR at follow-up. However, in unadjusted analysis, we were able to demonstrate that PPM implantation within 30 days after TA was associated with better long-term survival compared with no PPM implantation. In the adjusted Cox regression analysis, PPM was associated with a similar benefit (effect size) as seen in the unadjusted analysis, although with no statistical significance. Furthermore, we found that PPM implantation within 30 days was not associated with increased hazard of readmission for heart failure or MACE.

These results are in contrast to previously published findings, where right ventricular apex pacing has been shown to be associated with both heart failure and worse

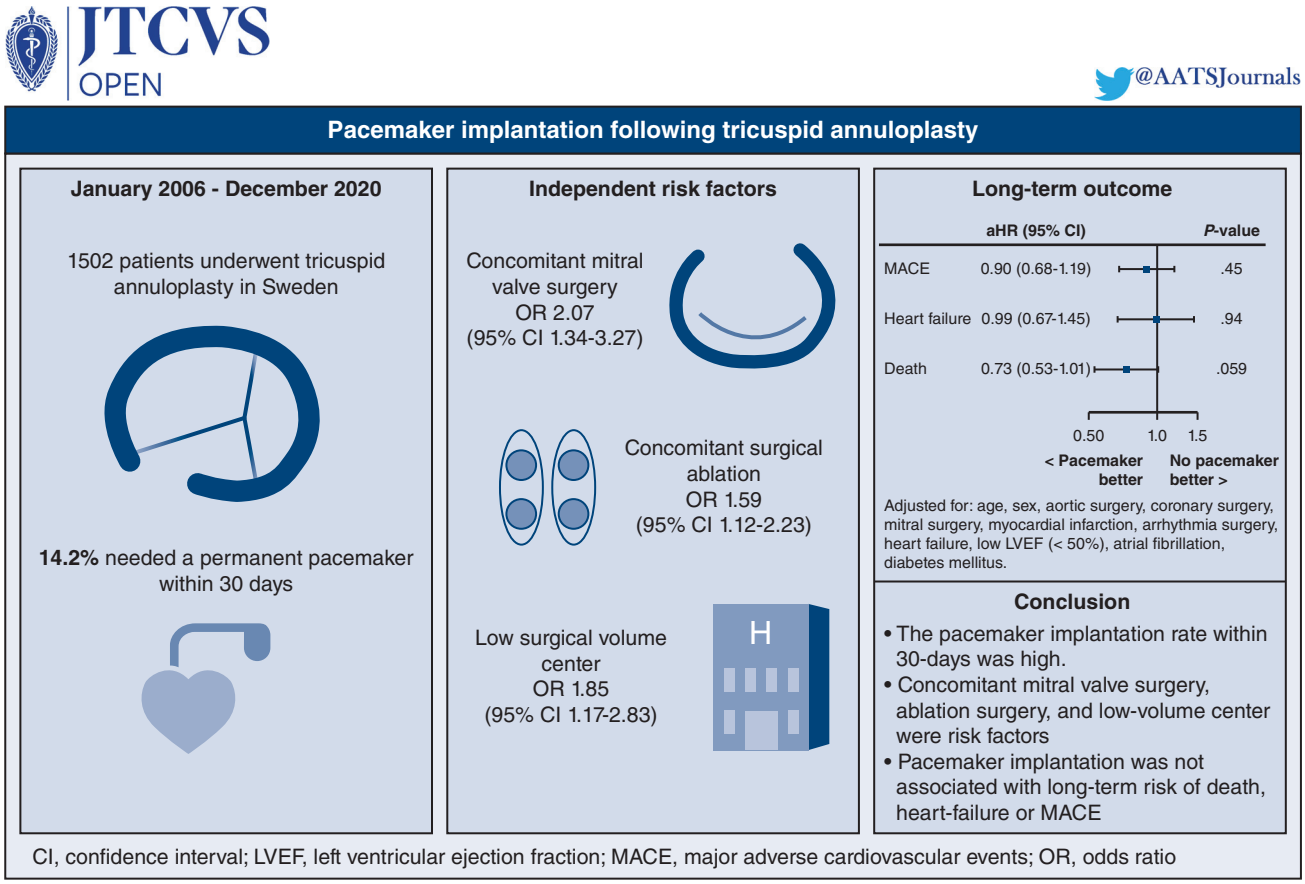

FIGURE 6. Pacemaker implantation following tricuspid annuloplasty: Graphical abstract. *OR*, Odds ratio; *aHR*, adjusted hazard ratio; *MACE*, major adverse cardiovascular events; *LVEF*, left ventricular ejection fraction.

survival.[15-19] Therefore, we compared the long-term survival of patients who received a pacemaker within the first year from surgery with those who did not and found the estimated survival in these 2 groups to be the same. Furthermore, we performed sensitivity analyses on the hazards of receiving a PPM between 30 days and 1 year after surgery. The model for all-cause mortality showed an aHR of 1.49 instead of the aHR of 0.73 seen in the original model. Although both models were not significant, the sensitivity analysis shows that the patients who received a PPM within 1 year of surgery but after the initial 30 days may have had a higher hazard from PPM implantation than those who received a pacemaker within 30 days. A possible explanation for these findings may be that patients who received a PPM within 30 days may have been healthier in some capacity and had a less complicated postoperative phase. In other words, there may be an inextricably attached confounding factor driving the outcome.

Our study demonstrated that undergoing operation at a surgical center where fewer than 10 TAs per year are performed was a significant risk factor of PPM implantation. Technical factors are likely to play a significant role in the development of conduction abnormalities after TA. Given the previously well-established relationship between right ventricular apical pacing and worse outcomes, it is important that all surgeons performing TA be familiar with the anatomy of the tricuspid valve and that those who have little experience in performing TA learn from experienced colleagues how to minimize the risk of conduction abnormalities.

An important finding of this study was that the indication for pacemaker was primarily AVB. However, a significant proportion of the patients had sinus node disease as the main indication, especially in the subgroup of patients who had concomitant ablation surgery. Ailawadi and colleagues[8] reported that 76% of patients in the Cardiothoracic Surgery Trials Network trial had AVB, which is the same proportion as in patients who underwent concomitant mitral surgery in the current cohort. The findings that a majority of patients who underwent concomitant ablation surgery had sick sinus syndrome suggest that many of these patients needed a pacemaker not because of the TA itself, but because of a sinus node dysfunction caused by or unmasked by the ablation surgery.

The rate of PPM implantation was high early in the postoperative period, and a significant proportion of patients

received a PPM within 7 days from surgery. Some of the PPMs may have been implanted prematurely. However, the findings are similar to what was reported by Ailawadi and colleagues,[8] where the majority of pacemakers were implanted within 10 days of surgery. The current dataset did not contain data from pacemaker interrogations; therefore, we could not determine the proportion of patients who had restoration of sinus rhythm after PPM implantation.

The current study shows that the cumulative incidence of PPM continues to increase at late follow-up, which prompts the question whether the risk factors of late PPM implantation differ from risk factors for early PPM implantation. We found that age, female sex, and surgical ablation were predictors of late implantation. Therefore, surgical ablation was an indicator of both early and late implantation.

Strengths and Limitations

This study included all patients who underwent tricuspid valve repair in Sweden during a 15-year period. The study reflects real-world practice using high-quality data from national registries. Patients with previously implanted pacemakers were excluded from the study, but the study had limited access to preoperative data regarding preexisting conduction abnormalities. Data on tricuspid annular size and the type of TA ring were not available. Data on other surgical details such as aortic crossclamp time had too many missing values to be used for statistical analysis. Data on lesion sets used in surgical ablation procedures were not available.

CONCLUSIONS

The current study showed that tricuspid valve repair with annuloplasty was associated with a high requirement of PPM implantation. The main risk factors for PPM were concomitant ablation surgery, concomitant mitral valve surgery, and operation in a low-volume center. Early PPM implantation did not translate into higher long-term risk for heart failure, MACE, or mortality.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://www.aats.org/resources/pacemaker-implantation-following-tricuspid-valve-repair-a-swedeheart-study.

Conflict of Interest Statement

A.T.: receives consulting fees for being a member of the Medtronic European Advisory Board. A.A.: receives consulting fees from JOMDD. A.G.: receives consulting fees for being a member of the Medtronic Strategic Surgical Advisory Board and from Edwards Lifesciences. M.K.: a physician proctor and a member of the medical advisory board for JOMDD, a physician proctor for Peter Duschek, a medical consultant for EVOTEC and Moderna, and has received speakers' honoraria from Medtronic and Terumo. D.M.: works as a proctor and has received lecturing honoraria from Medtronic, Abbott and Boston Scientific and is a member of advisory boards for Medtronic and Abbott for pacemaker and implantable cardioverter defibrillator development, unrelated to the present study. A.J.: received consulting fees from AstraZeneca, Werfen, and LFB Biotechnologies unrelated to the present study. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: pacemaker implantation, tricuspid annuloplasty, tricuspid valve repair

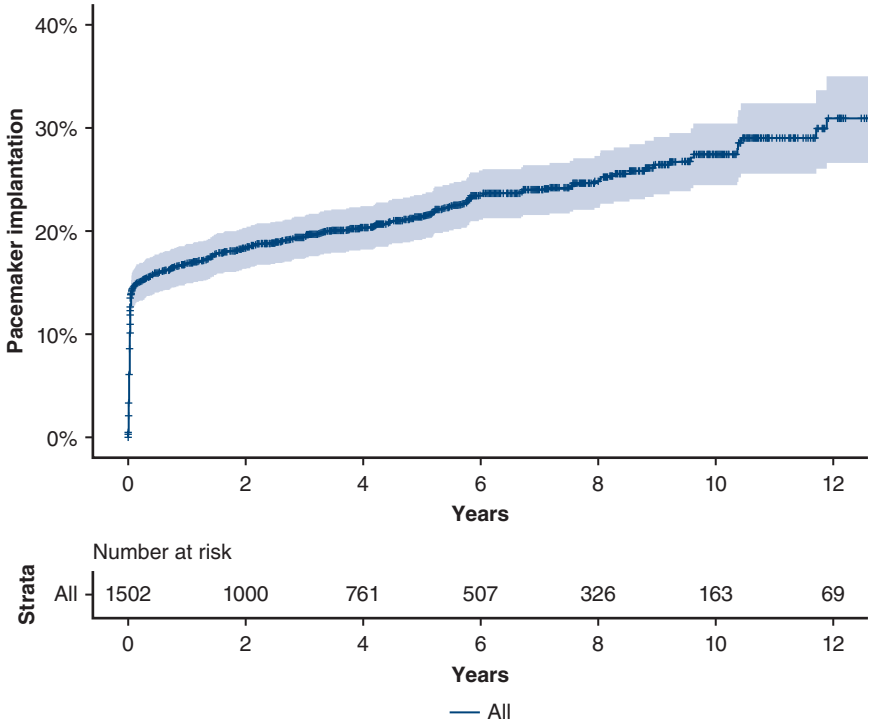

FIGURE E1. Kaplan–Meier curve showing the long-term cumulative rate of PPM implantation (*blue line*, percentage; shaded area, 95% CI).

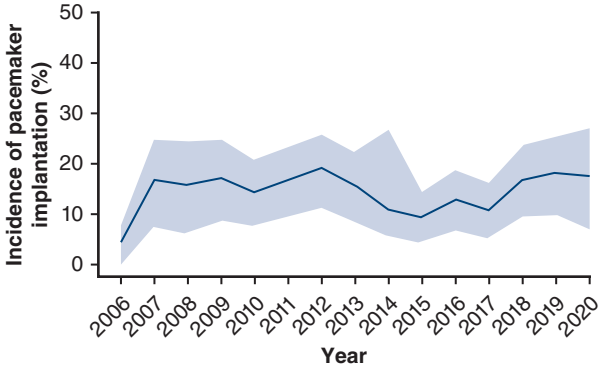

FIGURE E2. Incidence of pacemaker implantation within 30 days after surgery, by year of surgery (*blue line*, percentage; shaded area, 95% CI).

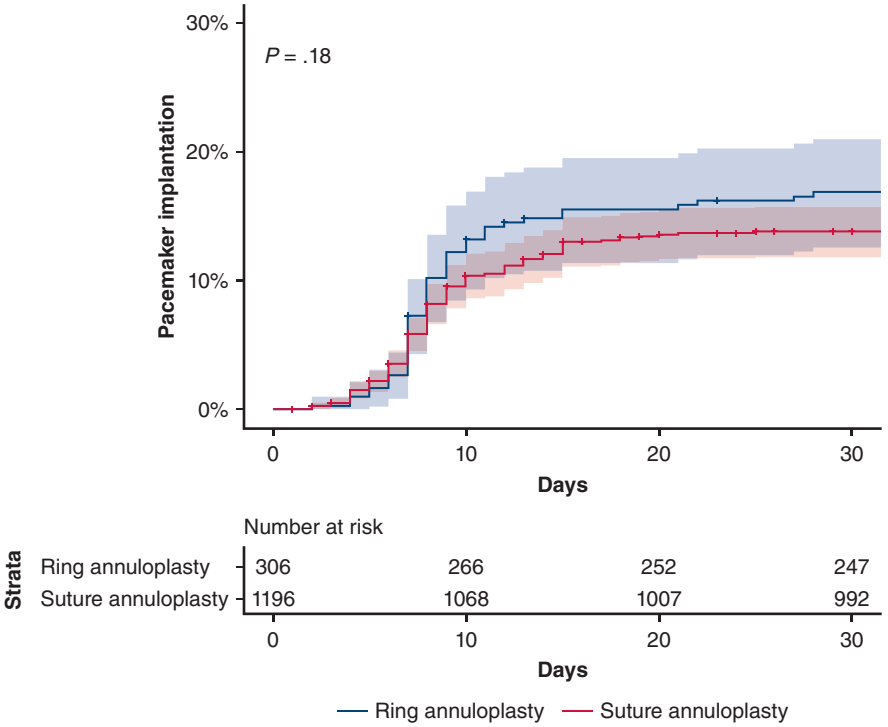

FIGURE E3. Kaplan–Meier curve showing the estimated rate of PPM implantation in the first 30 days after tricuspid valve repair in patients who had TA with an annuloplasty ring compared with those who had TA with a suture (De Vega annuloplasty). *Blue line*, percentage; shaded area, 95% CI.

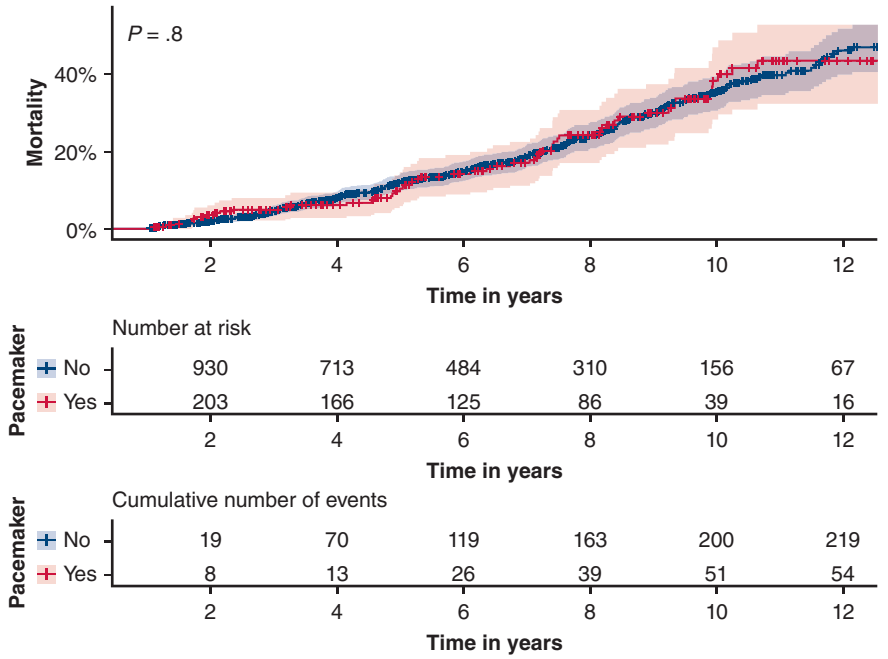

FIGURE E4. Kaplan–Meier curve showing the long-term survival in patients who received a PPM within 1 year from surgery compared with those who did not receive a pacemaker within the first year from surgery (*red line*, percentage; shaded area, 95% CI).

TABLE E1. International Classification of Diseases, 10th Revision codes used to identify different diagnoses in the study

Disease	ICD-10 codes (used from 1997)
Myocardial infarction	I21.0-I21.4
Diabetes	E10-E14
Hypertension	I10.0-I15.9
Heart failure	I50, I42-143.8, I11.0, I13.0, I13.2, I25.5
Atrial fibrillation	I48
Stroke	I61.0-I64
Chronic respiratory disease	J40-J47
Renal failure	N17-N19
Hyperlipidemia	E78
Peripheral artery disease	I70, I73.9, I74, I77
Left ventricular ejection fraction	Collected from SWEDEHEART

ICD-10, International Classification of Diseases, 10th Revision.

TABLE E2. Type of annuloplasty rings and their rigidity

Ring	No. of patients	Rigidity
No ring	306	Not applicable
Edwards Classic Tricuspid 4525ST	25	Flexible
Edwards Classic Tricuspid 4500T	25	Flexible
Edwards MCE Tricuspid Ring 4900T	10	Flexible
Medtronic Duran AnCore Ring 620RG	6	Rigid
Medtronic Simplici-T 670100	1	Flexible
Edwards Physio II Carpentier-Edwards 5200	4	Semi-rigid
Medtronic Contour 690R	97	Rigid
Edwards Physio Tricuspid Annuloplasty ring 6200	555	Semi-rigid
Missing	473	Not applicable

TABLE E3. Associations between preoperative and perioperative factors and permanent pacemaker implantation within 30 days after surgery (multivariable logistic regression analysis): Alternative model with tricuspid ring size as a continuous variable

Predictors	OR (95% CI)	*P* value
Age (per year)	1.01 (1.00-1.03)	.09
Sex (male)	1.00 (0.72-1.39)	.99
Myocardial infarction	1.11 (0.61-1.90)	.72
Heart failure	0.79 (0.61-1.07)	.13
LVEF <50%	1.04 (0.76-1.43)	.77
Atrial fibrillation	1.20 (0.77-1.91)	.42
Diabetes mellitus	1.35 (0.81-2.18)	.23
Coronary surgery	0.84 (0.54-1.28)	.43
Mitral surgery	2.05 (1.33-3.24)	.001*
Aortic valve surgery	1.10 (0.68-1.73)	.69
Ablation surgery	1.56 (1.11-2.19)	.001*
Tricuspid ring size per mm (only in patients with ring)	1.06 (0.99-1.14)	.12
Low-volume center	1.80 (1.15-2.76)	.008*

OR, Odds ratio; *LVEF*, left ventricular ejection fraction. *Statistically significant.

TABLE E4. Associations between preoperative and perioperative factors and permanent pacemaker implantation within 30 days after surgery (multivariable logistic regression analysis): Alternative model with surgical center volume excluded from the analysis

Predictors	OR (95% CI)	*P* value
Age (per year)	1.01 (1.00-1.03)	.062
Sex (male)	1.00 (0.72-1.40)	.99
Myocardial infarction	1.06 (0.59-1.03)	.39
Heart failure	0.76 (0.55-1.03)	.077
LVEF <50%	1.01 (0.74-1.38)	.95
Atrial fibrillation	1.16 (0.74-1.83)	.53
Diabetes mellitus	1.43 (0.87-2.29)	.14
Coronary surgery	0.83 (0.53-1.26)	.39
Mitral surgery	2.01 (1.31-3.17)	.002*
Aortic valve surgery	1.06 (0.66-1.67)	.80
Ablation surgery	1.55 (1.10-2.17)	.012*
Large TA ring	1.16 (0.85-1.60)	.35

OR, Odds ratio; *LVEF*, left ventricular ejection fraction; *TA*, tricuspid annuloplasty. *Statistically significant.

TABLE E5. Associations between preoperative and perioperative factors and permanent pacemaker implantation more than 30 days after surgery (multivariable regression analysis)

Predictors	OR (95% CI)	*P* value
Age (per year)	1.03 (1.01-1.05)	.010*
Sex (male)	0.61 (0.41-0.90)	.012*
Myocardial infarction	1.43 (0.74-2.63)	.27
Heart failure	1.07 (0.72-1.63)	.73
LVEF <50%	1.42 (0.96-2.13)	.083
Atrial fibrillation	1.05 (0.60-1.93)	.87
Diabetes mellitus	0.67 (0.30-1.32)	.29
Coronary surgery	0.88 (0.50-1.49)	.65
Mitral surgery	0.75 (0.47-1.21)	.23
Aortic valve surgery	1.09 (0.62-1.85)	.75
Ablation surgery	1.68 (1.08-2.59)	.019
Ring annuloplasty	1.03 (0.64-1.63)	.88
Low-volume center	1.04 (0.53-1.88)	.90

OR, Odds ratio; *LVEF*, left ventricular ejection fraction. *Statistically significant.