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ORIGINAL STUDY

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Incidence, predictors and clinical impact of permanent pacemaker insertion in women following transcatheter aortic valve implantation: Insights from a prospective multinational registry

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Abbreviations: $_{adj}$HR, adjusted hazard ratio; AV, atrioventricular; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; PPI, permanent pacemaker insertion; RBBB, right bundle branch block; TAVR, transcatheter aortic valve replacement; VARC-2, valve academic research consortium; WIN-TAVI, Women's International Transcatheter Aortic Valve implantation.

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Abstract

Objectives: To describe the incidence, predictors, and clinical impact of permanent pacemaker insertion (PPI) following transcatheter aortic valve replacement (TAVR) in women.

Background: Data on pacemaker insertion complicating TAVR in women are scarce.

Methods: The Women's International Transcatheter Aortic Valve implantation (WIN-TAVI) is a prospective registry evaluating the safety and efficacy of TAVR in women. We included patients without preprocedural pacemakers and divided them into two groups: (1) PPI and (2) no-PPI. We identified PPI predictors using logistic regression and studied its clinical impact on the Valve Academic Research Consortium (VARC)-2 efficacy and safety endpoints.

Results: Out of 1019 patients, 922 were included in the analysis. Post-TAVR PPI occurred in 132 (14.3%) patients. Clinical and procedural characteristics were similar in both groups. Pre-existing right bundle branch block (RBBB) was associated with a high risk of post-TAVR PPI (OR 3.62, 95% CI 1.85–7.06, $p < 0.001$), while implantation of balloon-expandable prosthesis was associated with a lower risk (OR 0.47, 95% CI 0.30–0.74, $p < 0.001$). Post-TAVR PPI prolonged in-hospital stay by a median of 2 days (11 [9–16] days in PPI vs. 9 [7–14] days in no-PPI, $p = 0.005$), yet risks of VARC-2 efficacy and safety endpoints at 1 year were similar in both groups ($_{adj}$HR 0.95, 95% CI 0.60–1.52, $p = 0.84$ and $_{adj}$HR 1.22, 95% CI 0.83–1.79, $p = 0.31$, respectively).

Conclusion: Pacemaker implantation following TAVR is frequent among women and is associated with pre-existing RBBB and valve type. PPI prolongs hospital stay, albeit without any significant impact on 1-year outcomes.

KEYWORDS
gender, pacemaker, TAVI, TAVR

1 | INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is a well-established therapy for patients with severe aortic stenosis and deemed high-risk for surgical aortic valve replacement (SAVR).[1,2] Technological developments in transcatheter heart valve systems and higher expertise of the heart teams have expanded TAVR indications to lower-risk populations.[3,4] However, despite significant reductions in periprocedural complications and death, the incidence of conduction disturbances requiring permanent pacemaker implantation (PPI) has not changed over time and remains a frequent complication of old and new generation devices.[5,6] Various factors impact PPI's need following TAVR, including anatomic, clinical, and procedure-related features as shown in prior studies.[7,8]

Men and women undergoing TAVR have strikingly distinct aortic root anatomy (i.e., women have smaller ascending aortic diameters, smaller sinuses, lower coronary heights, and smaller annulus compared with men) and baseline clinical characteristics.[9–12] The high degree of heterogeneity between the two sexes is reflected by a wide range of PPI rates across different cohorts. In a systematic review of 40 studies, including 17,139 TAVR recipients, women were more frequently found in studies reporting a high incidence of post-TAVR PPI (26.4%–36.1%), whereas men dominated those reporting low incidence of PPI (0%–12.1%).[6] Therefore, sex-based comparisons of patients undergoing TAVR appear inadequate, especially when evaluating PPI incidence and predictors. Aiming at better understanding the safety and performance of contemporary TAVR in women with aortic stenosis, the Women's International Transcatheter Aortic Valve implantation (WIN-TAVI) registry was formed

as a multinational prospective study dedicated to female patients undergoing TAVR for aortic stenosis. Therefore, we sought to investigate the incidence, predictors, and clinical impact of PPI in the WIN-TAVI registry.

2 | MATERIALS AND METHODS

2.1 | Study design

The WIN-TAVI registry has been previously described.[13–16] Briefly, this prospective registry included women undergoing TAVR with a commercially available device for symptomatic aortic stenosis in 19 high-volume centers in Europe and the United States between January 2013 and December 2015. All patients were deemed suitable for TAVR by the local heart team and provided informed consent to their data's anonymous processing. Procedural decisions regarding TAVR access site, valve type, aortic pre-and post-dilation, and post-TAVR antithrombotic therapy were at the discretion of the treating physicians. Similarly, post-TAVR indications for PPI were based on local practices and international guidelines.[17] All sites had institutional approval from the local ethics committee, and the study was conducted according to the principles of the Declaration of Helsinki, International Organization for Standardization Guidelines, and Good Clinical Practice guidelines.

2.2 | Data management

Information on pre-operative medical history, as per local standard of care, were collected. The Icahn School of Medicine at Mount Sinai (New York, United States) acted as the clinical and data coordinating center responsible of data entry and monitoring, database management, and statistical analysis. All data, including-in-hospital complication and follow-up, were site-reported. An independent Clinical Event Committee adjudicated all events.

2.3 | Study population and endpoints

Patients with a prior pacemaker or implantable cardiac defibrillator were excluded from the present analysis. The primary outcomes of interest were the one-year rates of the valve academic research consortium criteria 2 (VARC-2) efficacy and safety endpoints.[18] The VARC-2 efficacy endpoint was defined as a composite of all-cause mortality, stroke, myocardial infarction (MI), and hospitalization for valve-related symptoms or worsening congestive heart failure. The VARC-2 safety endpoint was defined as the composite of all-cause mortality, stroke, major vascular complication, life-threatening bleeding, stages 2 or 3 acute kidney injury, coronary artery obstruction requiring intervention, or repeat procedure for valve-related dysfunction. Follow-up was conducted by phone contact or clinic visit at 1, 6, and 12 months after TAVR.

2.4 | Statistical approach

Categorical data are presented as frequencies and percentages and compared using the chi-square or Fischer's exact test. Continuous variables are presented as mean ± standard deviation or median and interquartile range and compared using the Student's *t*-test or Wilcoxon signed-rank test whenever appropriate. The association between relevant baseline characteristics and post-TAVR PPI was assessed using a logistic regression model and expressed as odds ratios (OR). The covariates included in the model included: age (per one-year increase), use of non-balloon expandable prosthesis, pre-existing right bundle branch block (RBBB), pre-existing left bundle branch block (LBBB), left anterior fascicular block, pre-existing first or second-degree atrioventricular (AV) block, device diameter ≥ 26 mm (based on initial results from the WIN-TAVI registry showing worse outcomes with device diameter ≥ 26 mm) and balloon post-dilation.[15,19] Time-to-event analyses were performed using the Kaplan–Meier method, and outcomes were compared using the log-rank test. The association between PPI and clinical outcomes at 1 year was studied using multivariable Cox regression with adjustment for clinically relevant recorded baseline characteristics: age, logistic EuroSCORE I, diabetes, atrial fibrillation, and peripheral artery disease. All analyses were performed using Stata version 14.0 (StataCorp, Texas), and p values <0.05 were considered significant.

3 | RESULTS

3.1 | Incidence and predictors of post-TAVR PPI

Out of 1019 patients in the WIN-TAVI registry, 922 (90.5%) were included in this study after the exclusion of 97 (9.5%) patients with a prior pacemaker or cardiac defibrillator. Overall, the mean age was 82.4 ± 0.2 years, and mean EuroSCORE I was 17.6 ± 0.4. Post-TAVR PPI occurred in 132 (14.3%) patients, including 120 (11.8%) patients within the first 30 days following TAVR. Baseline clinical and procedural characteristics are detailed in Tables 1 and 2, respectively, with no significant differences between the two groups except for prosthetic valve type and baseline conduction abnormalities. Around 72% of PPI patients had a non-balloon expandable valve implanted during the procedure compared with 54% of those in the no-PPI group ($p < 0.001$). Among patients who received a self-expandable valve (Medtronic Evolut R or CoreValve), 31.2% had a post-TAVR pacemaker implanted while only 18.8% of patients with balloon-expandable valves (Edwards SAPIEN XT or SAPIEN 3) needed a pacemaker (Figure 1). Remarkably, 27.8% of patients with mechanically-expandable valves (Lotus) underwent pacemaker insertion. In addition, RBBB at baseline was the most common conduction defect in patients who underwent PPI, and its prevalence was higher (12.4%) than that in the opposite group (4.1%) ($p < 0.001$). Indeed, 34% of patients with baseline RBBB needed a pacemaker following aortic valve implantation, compared with 22% of patients with AV-block and 8.8% of those with baseline left bundle branch block (LBBB)

TABLE 1 Baseline clinical characteristics

	Post-TAVR permanent pacemaker pnsertion		
	No *n* = 790 (85.7%)	Yes *n* = 132 (14.3%)	p-value
Age (years)	82.3 ± 0.2	83.1 ± 0.5	0.91
Caucasian ethnicity	754 (98.7%)	128 (97.7%)	0.75
Body mass index (kg/m^2)	26.0 ± 0.2	25.9 ± 0.5	0.38
EuroSCORE I	17.8 ± 0.4	16.3 ± 0.8	0.08
Diabetes	203 (25.9%)	36 (27.3%)	0.73
Hypertension	639 (82.0%)	99 (75.6%)	0.08
Peripheral artery disease	65 (8.4%)	14 (10.7%)	0.40
Chronic kidney disease	236 (30.7%)	33 (25.4%)	0.23
Prior stroke	55 (7.0%)	13 (9.9%)	0.25
Prior PCI	180 (22.8%)	29 (22.0%)	0.83
Prior CABG	47 (6.0%)	10 (7.6%)	0.48
LVEF (%)	55.7 ± 0.4	57.6 ± 0.9	0.97
Atrial fibrillation	151 (19.1%)	31 (23.5%)	0.24
Pre-existing conduction defect[a]			<0.001
Right bundle branch block	31 (4.1%)	16 (12.4%)	
Left bundle branch block	83 (10.9%)	8 (6.2%)	
Left anterior fascicular block	19 (2.5%)	2 (1.6%)	
First degree atrioventricular block	39 (5.1%)	11 (8.5%)	

Note: Numbers are shown as *n* (%) or mean ± standard deviation.
Abbreviations: CABG, coronary artery bypass surgery; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; TAVR, transcatheter aortic valve replacement.
[a]Data are available for 890 patients.

(Figure 2). After adjustment, pre-existing RBBB remained significantly associated with an increased risk of post-TAVR PPI (OR 3.62, 95% CI 1.85–7.06, p < 0.001), while the use of a balloon-expandable device was associated with a lower risk as compared with self-expanding prosthesis (OR 0.47, 95% CI 0.30–0.74, p < 0.001) (Figure 3). Other factors, such as pre-existing LBBB and older age, did not significantly impact post-TAVR PPI.

3.2 | Clinical impact of post-TAVR PPI

Patients who underwent pacemaker implantation had a longer in-hospital stay (11 days [interquartile range 9–16 days]) compared with those who did not (9 days [interquartile range 7–14 days]) (p = 0.005). One-year clinical outcomes are reported as Kaplan–Meier estimates in Table 3. At a one-year follow-up, the VARC-2 efficacy endpoint occurred in 17.6% of patients who underwent PPI compared with 16.1% in patients without PPI (p = 0.67). Rates of the VARC-2 safety endpoint were numerically higher in patients who underwent PPI (26.5% vs. 20.3%, p = 0.07). In addition, post-TAVR PPI did not impact one-year mortality (13.0% in PPI vs. 10.8% in no-PPI, p = 0.48) (Figure 4). Table 4 shows unadjusted and adjusted hazard ratios (HR) for patients with PPI vs. those without regard to clinical endpoints. There was no significant adjusted association between PPI and the occurrence of the VARC-2 efficacy endpoint ($_{adj}$HR 0.95, 95% CI 0.60–1.52, p = 0.84) and safety endpoint ($_{adj}$HR 1.22, 95% CI 0.83–1.79, p = 0.31) at 1 year (Table 4).

4 | DISCUSSION

Post-procedural pacemaker implantation occurred in 14.3% of female patients enrolled in the WIN-TAVI registry. A self-expanding or mechanically expanding valve was implanted in most of these patients. Pre-existing RBBB increased the likelihood of post-TAVR PPI by almost fourfold, while the use of balloon-expandable devices was associated with a lower risk compared with other valve types. As for the clinical impact, post-TAVR PPI prolonged hospital stays by a median of 2 days but did not increase the risk of adverse clinical outcomes at 1 year.

The incidence of PPI in the current analysis (14.3%) falls within the full interval of PPI rates (2.3%–39.9%) reported in prior studies.[20–24] The majority of study participants who underwent pacemaker implantation (120 out of 132) did so within the first 30 days after TAVR. Around 8.5%–25.9% of all patients, men and women, undergoing TAVR require PPI within 30 days after the procedure compared with only 7% of patients who undergo surgical

TABLE 2 Baseline procedural characteristics

	Post-TAVR permanent pacemaker insertion		
	No $n = 790$ (85.7%)	Yes $n = 132$ (14.3%)	p-value
Femoral vascular approach	710 (89.6%)	121 (91.7%)	0.48
Access technique			0.67
Percutaneous	687 (87.0%)	113 (85.6%)	
Surgical cut down	103 (13.0%)	19 (14.4%)	
Sheath size ≤ 18 French	585 (74.4%)	103 (78.0%)	0.38
Balloon aortic valvuloplasty	558 (71.2%)	84 (63.6%)	0.08
Rapid pacing during deployment[a]	535 (77.0%)	79 (68.7%)	0.06
Valve generation[b]			0.13
Old	425 (56.4%)	82 (63.6%)	
New	329 (43.6%)	47 (12.5%)	
Valve model[b]			<0.001
Balloon-Expandable			
Edwards SAPIEN 3	189 (25.1%)	20 (15.5%)	
Edwards SAPIEN XT	157 (20.8%)	16 (12.4%)	
Non-Balloon expandable			
Medtronic Corevalve	268 (35.5%)	66 (51.2%)	
Medtronic Evolut R	62 (8.2%)	8 (6.2%)	
Direct flow	25 (3.3%)	4 (3.1%)	
Portico	8 (1.1%)	0 (0.0%)	
Lotus	39 (5.2%)	15 (11.6%)	
Symetris ACURATE neo	6 (0.8%)	0 (0.0%)	
Device diameter ≤ 26 mm	650 (82.7%)	98 (74.2%)	0.02
Balloon post-dilation	109 (14.0%)	23 (17.4%)	0.31
Periprocedural event			
Blood product transfusion	50 (6.7%)	6.9 (6.9%)	0.90
Post-TAVR grade 2 or 3 aortic regurgitation	53 (6.7%)	7 (5.3%)	0.55
Antithrombotic regimen at discharge ($n = 822$)			
Dual antiplatelet therapy	372 (53.5%)	53 (42.1%)	0.018
Oral anticoagulation	168 (24.1%)	48 (38.1%)	0.001
Triple therapy	25 (3.6%)	7 (5.6%)	0.3

Note: Numbers are shown as *n* (%).

Abbreviation: TAVR, transcatheter aortic valve replacement.

[a]Data are available in 810 patients.

[b]Data re available in 883 patients - old-generation devices comprised Edwards SAPIEN XT (Edwards Lifesciences, Irvine, California) and Medtronic CoreValve (Medtronic Inc., Minneapolis, Minnesota), all other prostheses types are considered new-generation devices.

valve replacement.[25–27] However, data specific to women is limited.[28] Due to the extension of TAVR indications towards lower-risk patients and substantial improvement in prosthetic valve design and delivery techniques, a gradual decline in post-TAVR PPI incidence is observed. Indeed, a report from the German TAVI registry showed that the incidence of post-TAVR PPI decreased from 12.6% in 2015 to 11.4% in 2016 ($p = 0.002$).[20] In contrast, the incidence has increased in other national registries such as the Society of Thoracic Surgeons/American Heart Association transcatheter valve therapy (STS/ACC TVT) and the FRANCE-TAVI registries.[21,29] The increase has been mainly attributed to a surge in self-expandable CoreValve use following its worldwide approval in 2014. Self-expandable devices have been commonly associated with higher rates of post-TAVR PPI as compared with balloon-expandable prosthetic valves.[23,29–31] In particular, Medtronic CoreValve use was linked in several studies to an increased risk of conduction abnormalities requiring a permanent pacemaker.[25,32] Indeed, more than half of patients who needed a pacemaker in our studied cohort had a CoreValve implanted during the procedure. The newer generation self-expandable valve, Evolut R, was associated with a lower incidence of PPI than CoreValve due to less ventricular implantation depth at the non-coronary cusp.[33,34] In a recent study, Giannini et al.

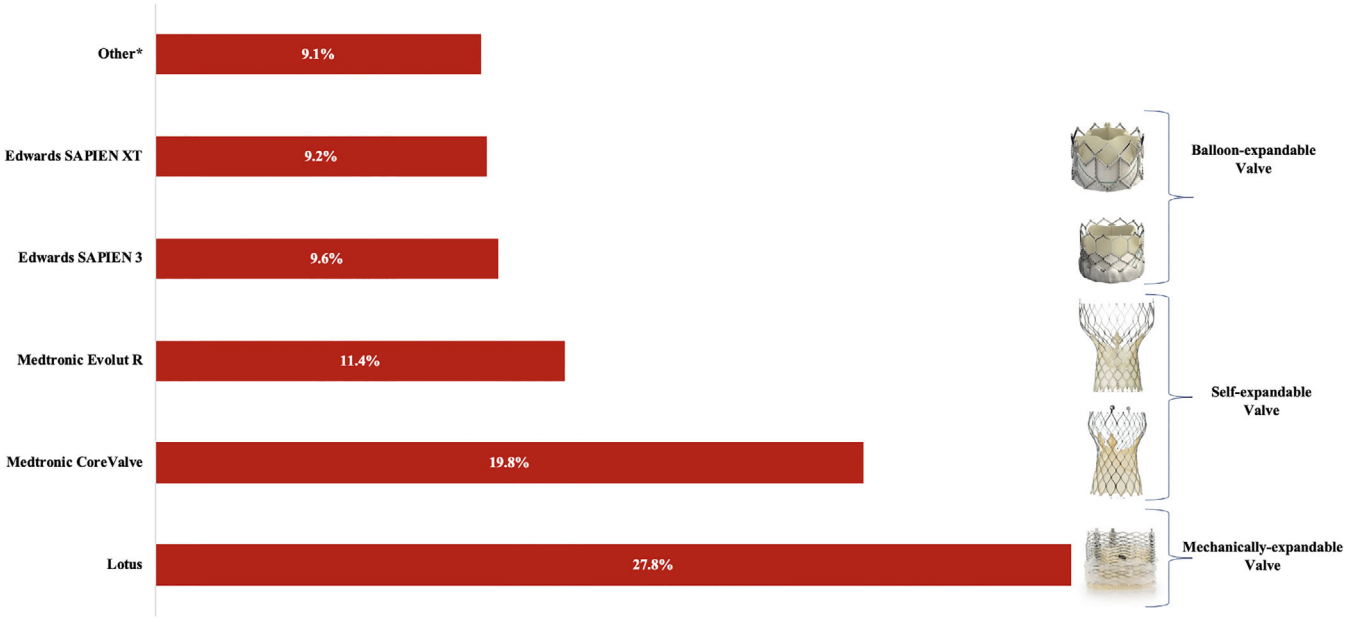

FIGURE 1 Need for pacemaker insertion with respect to valve prosthesis type ($n = 883$). *Grouped under one category due to low prevalence (includes Symetris Acurate Neo, Portico, and Direct flow valves)

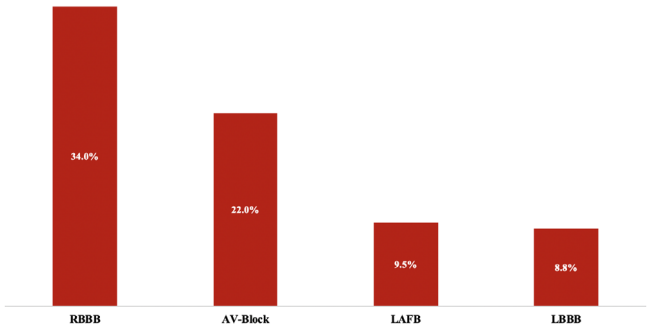

FIGURE 2 Need for pacemaker insertion with respect to pre-existing conduction defect ($n = 890$). AV-block, atrioventricular block; LAFB, left anterior fascicular block; LBBB, left bundle branch block; PPI, permanent pacemaker implantation; RBBB, right bundle branch block

revealed no significant difference in the need for pacemaker insertion between new generation self-expandable and balloon-expandable valves (10.1% vs. 8.0%, $p = 0.56$).[35] Nevertheless, our logistic regression model showed that the use of balloon-expandable devices decreased the odds of requiring a pacemaker following TAVR.

In addition to prosthetic valve choice, several factors contribute to the new onset of conductive disturbances after TAVR. One of these factors is the close anatomical relationship between the AV conduction pathway and the aortic valve; therefore, any manipulation of the valve can disrupt this pathway resulting in complete AV-block and need for a permanent pacemaker.[36] Moreover, the procedure itself can injure the AV node, and the left bundle of His.[37] Pre-procedural defects also can contribute to the development of conductive disturbances following TAVR. Our analysis showed that baseline RBBB is a strong predictor of post-TAVR PPI. Indeed, RBBB was the strongest electrocardiographic predisposing factor ($p < 0.001$) for post-TAVR PPI in the Placement of Aortic Transcatheter Valves (PARTNER) randomized trial, which included 1973 high-risk patients undergoing TAVR.[38] Moreover, a meta-analysis including 11,210 TAVR patients showed a three-fold increase in the risk of post-TAVR PPI in individuals with baseline RBBB (Relative risk 2.89; $p < 0.01$).[8] In fact, any injury to the left branch due to mechanical stress exerted by the prosthetic valve will undoubtedly lead to a complete AV-block in patients with pre-existent RBBB.[39] However, the pre-existent LBBB did not carry an additional risk for post-TAVR PPI, which is in accordance with previously published reports.[40] Instead, LBBB is commonly reported as a complication of TAVR occurring in up to 40% of patients.[41]

PPI's clinical impact is vast and includes additional procedures that carry its risks, prolonged hospital stay, loss of AV synchrony, and hemodynamic changes that contribute to the onset of atrial fibrillation and subsequent cerebrovascular events.[42] In our analysis, patients who needed post-TAVR PPI had a more extended hospital stay but a similar risk of adverse clinical outcomes at 1 year as those who did not. However, longer-term data are required. Over the past years, there has been much controversy surrounding the long-term impact of post-TAVR PPI on survival. A recent meta-analysis, including data from 17 studies, showed no association between long-term clinical outcomes and PPI status.[43] However, most of these studies had follow-up periods shorter than 2 years, which is considered insufficient for the observation of events directly related to chronic ventricular pacing.[44,45] On the other hand, an analysis from a US national registry showed an increase in mortality risk (HR 1.31; 95% CI

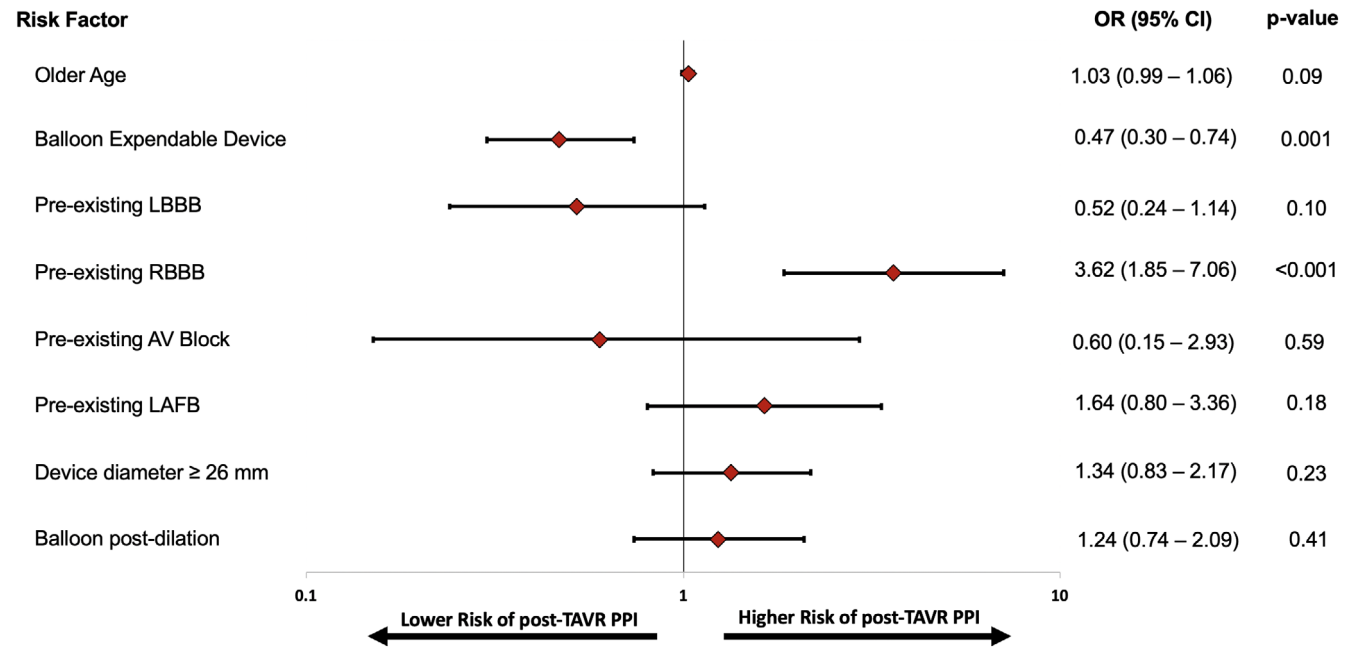

FIGURE 3 Predisposing risk factors for post-TAVR permanent pacemaker insertion. AV, atrioventricular; CI, confidence interval; LAFB, left anterior fascicular block; LBBB, left bundle branch block; OR, odds ratio; PPI, permanent pacemaker implantation; RBBB, right bundle branch block; TAVR, transcatheter aortic valve replacement

TABLE 3 One-year clinical outcomes presented as Kaplan–Meir estimates

	Post-TAVR permanent pacemaker insertion		
	No *n* = 790 (85.7%)	Yes *n* = 132 (14.3%)	p-value
VARC-2 efficacy endpoint[a]	127 (16.1%)	23 (17.6%)	0.67
VARC-2 safety endpoint[b]	160 (20.3%)	35 (26.5%)	0.07
Death, MI, stroke or bleeding	133 (16.9%)	23 (17.6%)	0.83
Death, MI or stroke	116 (14.7%)	19 (14.6%)	0.97
All-cause death	102 (13.0%)	14 (10.8%)	0.48
Cardiovascular death	86 (11.0%)	12 (9.3%)	0.55
Major vascular complications	61 (7.7%)	13 (9.9%)	0.41

Note: All values are shown as n (Kaplan–Meier estimate %).
Abbreviations: MI, myocardial infarction; VARC-2, valve academic research consortium; TAVR, transcatheter aortic valve replacement.
[a]Composite of mortality, stroke, myocardial infarction, hospitalization for valve-related symptoms or heart failure or valve-related dysfunction;
[b]Composite of mortality, stroke, major vascular complication, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction, or repeat procedure for valve-related dysfunction.

1.09–1.58, p = 0.003) at 1 year in patients who undergo post-TAVR PPI.[7] However, reported deaths were not secondary to cardiovascular etiologies hinting to potential confounders in the studied cohort. Therefore, amid these conflicting results, future research focusing on the long-term clinical impact of pacemaker implantation following TAVR is much needed.

Although prior TAVR studies have reported data from both men and women, the full range of PPI rates across these studies revealed the heterogeneity of the studied populations, which limited the generalizability of the results and its clinical implications on both sexes. The present analysis brings sex-specific real-word evidence on the incidence and predictors of post-TAVR PPI in women undergoing TAVR. Therefore, this study aims to provide insights on post-TAVR PPI in women rather than to explore sex-related differences in outcomes. The main findings of this study suggest that post-TAVR PPI incidence in women undergoing TAVR is lower or at least similar to the general population. Moreover, a thorough pre-procedural screening for baseline conduction abnormalities (i.e., RBBB) and adequate device choice (i.e., balloon-expandable valves) is needed to lower the risk of PPI in women undergoing TAVR. Overall, predictors of post-TAVR PPI in women are more or less similar to those reported in previous studies including both sexes.

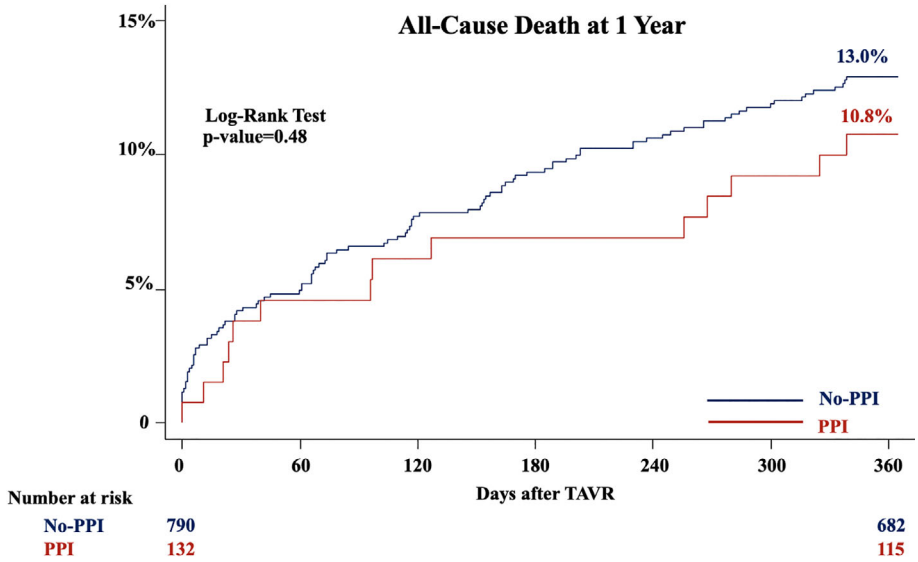

FIGURE 4 Cumulative incidence of 1-year all-cause death in women undergoing TAVR, according to post-TAVR pacemaker status. Outcomes are presented using time-to-event Kaplan–Meier curves. PPI, permanent pacemaker insertion; TAVR, transcatheter aortic valve replacement

TABLE 4 Unadjusted and adjusted hazard ratios for clinical outcomes at 1 year

	Unadjusted HR (95% CI)	p-value	Adjusted HR (95% CI)	p-value
VARC-2 efficacy[a] endpoint	1.04 (0.67–1.63)	0.85	0.95 (0.60–1.52)	0.84
VARC-2 safety[b] endpoint	1.29 (0.90–1.86)	0.16	1.22 (0.83–1.79)	0.31
Death, MI, stroke or bleeding	1.00 (0.64–1.56)	0.33	0.96 (0.69–1.52)	0.85
Death, MI or stroke	0.94 (0.58–1.53)	0.99	0.86 (0.51–1.44)	0.56
All-cause death	0.79 (0.45–1.38)	0.40	0.68 (0.37–1.24)	0.21
Cardiovascular death	0.80 (0.44–1.46)	0.47	0.67 (0.35–1.31)	0.24
Major vascular complications	1.12 (0.61–2.05)	0.71	1.06 (0.56–1.99)	0.85

Abbreviations: CI, confidence interval; HR, hazard ratio; MI, myocardial infarction; VARC-2, Valve Academic Research Consortium.
[a]Composite of mortality, stroke, myocardial infarction, hospitalization for valve-related symptoms or heart failure or valve-related dysfunction;
[b]Composite of mortality, stroke, major vascular complication, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction, or repeat procedure for valve-related dysfunction.

We acknowledge the existence of several limitations that could have impacted our results. First, the WIN-TAVI registry is by design limited to female patients undergoing TAVR; hence, no conclusion regarding sex differences can be drawn from the present analysis. Second, several variables that have been shown to be strongly associated with post-TAVR PPI were not collected in this registry, including depth of prosthesis implantation, left ventricular outflow tract and mitral annulus, and size of the prosthesis relative to the aortic annulus. Third, the registry lacked an assessment of left ventricular ejection fraction (LVEF) at follow-up; thus, the impact of post-TAVR PPI on LVEF was not determined. Fourth, the specific indication for pacemaker implantation was left at the discretion of each physician according to guidelines and local practices. In addition, due to funding limitations, we did not collect data on pacemaker type, pacemaker dependency over time, need for biventricular pacing in patients who developed LBBB, and outcomes at 2-year follow-up (as initially stated in the WIN-TAVI study design). Finally, data collection in the WIN-TAVI registry occurred only from 2013 till 2015; therefore, advances in the field that occurred over the past 5 years must be considered while interpreting the results.

5 | CONCLUSIONS

In this study of female patients undergoing TAVR, PPI frequently occurred within the first 30 days following the procedure. Pre-existing RBBB was a strong predictor of post-TAVR PPI, whereas balloon-expandable devices were associated with a lower risk of PPI than self-expanding valves. Although post-TAVR PPI prolonged in-hospital stay, it did not significantly impact adverse clinical outcomes at 1 year. Further exploration of the clinical impact of PPI beyond 1 year is needed.

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CONFLICT OF INTEREST

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DATA AVAILABILITY STATEMENT

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

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