

Predicting permanent pacemaker implantation following transcatheter aortic valve replacement: A contemporary meta-analysis of 981,168 patients



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BACKGROUND Heart block requiring permanent pacemaker (PPM) implantation is a relatively frequent complication of transcatheter aortic valve replacement (TAVR).

OBJECTIVE The purpose of this study was to perform a contemporary meta-analysis to provide an updated assessment of clinically useful predictors of PPM implantation post-TAVR.

METHODS Medline and EMBASE searches were performed to include all studies reporting PPM post-TAVR between 2015 and 2020. Pertinent data were extracted from the studies for further analysis. Rev-Man was used to create forest plots and calculate risk ratios (RRs).

RESULTS We evaluated 41 variables from 239 studies with a total of 981,168 patients. From this cohort, 17.4% received a PPM following TAVR. Strong predictors for PPM implant were right bundle branch block (RBBB) (RR 3.12; $P < .001$) and bifascicular block (RR 2.40; $P = .002$). Intermediate factors were chronic kidney disease (CKD) (RR 1.53; $P < .0001$) and first-degree atrioventricular block (FDAVB) (RR 1.44; $P < .001$). Weak factors (RR 1–1.50; $P < .05$) were male gender, age ≥ 80 years, body mass index ≥ 25 , diabetes

mellitus (DM), atrial fibrillation (AF), and left anterior fascicular block (LAFB). These factors along with increased left ventricular outflow tract (LVOT) area ($>435 \text{ mm}^2$) and/or aortic annulus diameter ($>24.4 \text{ mm}$) were incorporated to propose a new scoring system to stratify patients into high- and low-risk groups.

CONCLUSION Male gender, age ≥ 80 years, FDAVB, RBBB, AF, DM, CKD, Medtronic CoreValve, transfemoral TAVR, increased LVOT, and aortic annulus diameter were significant predictors of post-TAVR PPM implantation. Preprocedural assessment should consider these factors to guide clinical decision-making before TAVR. Validation of our scoring system is warranted.

KEYWORDS Atrioventricular block; Bundle branch block; Conduction disturbance; Pacemaker; Transcatheter aortic valve replacement

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Introduction

Aortic stenosis is the most common degenerative valvular disease and is particularly prevalent among elderly patients. Transcatheter aortic valve replacement (TAVR) has emerged as a viable alternative to surgical aortic valve replacement in selected patients.^{1,2} Despite the continuous improvement in TAVR technology and procedural techniques, postprocedural conduction disturbances remain frequent. The reported rate of conduction disturbances requiring permanent pacemaker (PPM) varies widely between 5% and 33%.^{3–8}

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Because of the financial and clinical implications of a PPM, numerous studies have attempted to discern modifiable predictors of PPM after TAVR. This study aims to perform an updated systematic review and a meta-analysis of the predictors of PPM after TAVR given the improved technology and techniques and the plethora of recently published studies.

Materials and methods

This review was completed following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards for systemic review and meta-analysis quality reporting (<http://www.prisma-statement.org>). Given the nature

KEY FINDINGS

- Male patients ≥ 80 years old with 1 of the following comorbidities—obesity, diabetes mellitus (DM), or chronic kidney disease (CKD)—are deemed at high risk for post-transcatheter aortic valve replacement (post-TAVR) permanent pacemaker (PPM) implantation. Moreover, the presence of preprocedural conduction abnormalities including first-degree atrioventricular block (FDAVB), bifascicular block (BB), left anterior fascicular block (LAFB), right bundle branch block (RBBB), atrial fibrillation (AF), and increased QRS duration significantly aggravated the risk of post-TAVR PPM implantation.
- Implantation of a Medtronic CoreValve was associated with a 2.4-fold and 1.1-fold increased risk of PPM implantation compared with the Edwards Sapien valve and Evolut R valve, respectively. With regard to the vascular approach, patients who underwent TAVR via transfemoral access showed a 1.5-fold higher risk of developing conduction disturbances requiring PPM implantation in contrast to the transapical approach.
- Increased left ventricular outflow tract area, aortic annulus diameter, and implantation depth are associated with higher rates of PPM implantation after TAVR.
- Preprocedural assessment should consider these factors to determine which patients are at high risk for receiving a pacemaker after TAVR, because timely identification of high-risk patients potentially can prevent the development of atrioventricular block and its associated devastating complications, such as syncope and sudden cardiac death.
- We proposed a new risk scoring system by classifying the pre-TAVR predictors that seemed to be significant in our analysis into strong risk factors—RBBB and BB; intermediate risk factors—FDAVB and CKD; and weak risk factors—male gender, age ≥ 80 years, body mass index ≥ 25 , DM, AF, and LAFB.

of the study, it was exempt from institutional review board review.

Search strategy and information sources

In June 2020, a professional librarian performed a broad, comprehensive, computerized literature search of PubMed and EMBASE for the following keywords: (pacemaker, OR artificial) AND (LBBB OR left bundle branch block OR RBBB OR right bundle branch block OR AVB OR atrioventricular block OR bundle-branch block OR atrioventricular Block) AND (transcatheter aortic valve replacement OR TAVR OR TAVI OR transcatheter aortic valve implantation OR transcatheter aortic valve replacement). For our purposes, we focused only on published data reported from January 2015 to June 2020.

Eligibility criteria

We considered eligible any original design study that assessed the incidence of cardiac rhythm disturbances requiring PPM implantation following TAVR. We included studies in which the risk ratios (RRs) for the incidence of PPM implantation regarding the predictors of interest are calculable using the published data. Our exclusion criteria included basic science/animal studies, conference abstracts, case reports, non-original research (eg, editorials, commentaries), studies that stated outcomes only for patients with valve-in-valve interventions, patients with prior PPM implantation unrelated to TAVR, and pregnant/pediatric populations. If different studies enrolled overlapping study populations (according to participating institutions and study period), the study with the most recent results was deemed eligible for our analysis; however, if different predictors were studied in reports of overlapping populations, each predictor was included and analyzed separately.

Study selection

Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) was used to select studies by 2 trained reviewers (AA, AY). Any conflicts were resolved by consensus and arbitration by a third investigator (AJD). The screening process was performed in 2 separate stages: (1) title and abstract screening for preliminary relevance; and (2) full-text screening for potentially relevant studies for final eligibility. Authors were contacted as needed for further information if possible. Studies with incomplete information after author contact were excluded. A kappa statistic was calculated to assess the agreement.⁹

Data abstraction

The following study- and patient-related information was extracted from the main report and accompanying [Supplemental Material](#): study design, country of origin, recruitment period, number of participants, number of PPM implantations after TAVR, age, gender, and length of follow-up. Two investigators (AA, AY or HA, or IH) independently participated in the data extraction, and any discordances were resolved by consensus and arbitration by a third investigator (AJD). Moreover, according to previously published reviews, we extracted information about all the baseline variables mentioned in >3 studies and plausibly could be correlated with predicting PPM implantation following TAVR.^{10,11} [Figure 1](#) shows all the variables that were assessed to predict PPM implantation after TAVR in our analysis.

Synthesis of results and statistical analysis

Categorical variables are expressed as number of cases (n) and percentage (%). Continuous variables are given as mean \pm SD. We calculated the crude RRs with 95% confidence intervals (CIs) for each predictor from individual studies and then analyzed them by fixed effect or random effect model, based on whether the absence of significant

heterogeneity was present. If the lack of heterogeneity was significant, the fixed effect model (Mantel-Haenszel test) was performed; if not, the random effect model (DerSimonian-Laird method) was used. $P < .05$ was considered significant. Statistical heterogeneity was assessed using the Cochran Q test and quantified using the I^2 statistical index, which ranges between 0% and 100%, with values of 25% typically suggesting low, 50% moderate, and 75% significant heterogeneity.¹ Statistical analyses were performed using Review Manager statistical software (RevMan 5.3; The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).¹²

Results

Inclusion of studies

A total of 6434 studies initially were imported for the screening process, of which 143 duplicates were removed; thus, 6291 were screened in the title and abstract levels. We excluded 4964 irrelevant studies, and 1327 were retrieved in full-text review and examined for eligibility. Finally, we identified 239 studies that fulfilled our prespecified inclusion criteria to be considered in our analysis. The kappa statistic for initial screening for inclusion was 0.73, indicating substantial agreement. The selection process is demonstrated in PRISMA-style flow diagram in [Figure 2](#).

Study and participant characteristics

The main features and patient demographics of all included studies are summarized in [Supplemental Table 1](#).

Of the 981,168 patients assessed in 239 studies, 170,446 (17.4%) received a PPM following TAVR. Mean age ranged between 53 and 92.7 years, and 461,385 patients (47.1%) were male. Follow-up duration ranged from 1 month to 5 years for individual studies. Pre-TAVR risk was evaluated by the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) or the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score in 208 of 239 studies (87%). Baseline comorbidities such as hypertension, diabetes mellitus (DM), and dyslipidemia were reported in 54.9% of patients in 185 studies, 20.9% in 214 studies, and 51.9% in 91 studies. Baseline electrocardiographic (ECG) data on rhythm and conductance disturbances were recorded in 23.8% of patients in 168 studies for atrial fibrillation (AF)/flutter, 14.7% of patients in 40 studies for atrioventricular block (AVB), 9.4% of patients in 47 studies for left bundle branch block (LBBB), and 18.4% of patients in 52 studies for right bundle branch block (RBBB).

Data synthesis

Forty-one variables from 239 studies of 981,168 patients were evaluated to determine the clinically valuable predictors of PPM implantation after TAVR. The number of patients who required PPM implantation after TAVR for each predictor of interest as given in each study is summarized in forest plots in [Supplemental Figures 1 to 47](#).

Demographics and comorbidities

The summary estimates indicated increased risk of PPM implantation after TAVR in men compared with women (RR 1.16; $P < .001$; I^2 56%), age ≥ 80 years (RR 1.07; $P = .002$; I^2 32%), and patients with body mass index (BMI) ≥ 25 (RR 1.08; $P = .05$; I^2 11%). Furthermore, comorbidities such as DM (RR 1.06; $P < .001$; I^2 23%) and chronic kidney disease (CKD) (RR 1.53; $P < .001$; I^2 70%) significantly elevated the risk of PPM implantation following TAVR ([Figure 3](#) and [Table 1](#)).

Electrophysiological factors

Baseline ECG changes including first-degree atrioventricular block (FDAVB) (RR 1.44; $P < .000001$; I^2 0%), bifascicular block (BB) (RR 2.40; $P = .002$; I^2 64%), left anterior fascicular block (LAFB) (RR 1.26; $P = .02$; I^2 0%), RBBB (RR 3.12; $P < .001$; I^2 67%), AF (RR 1.10; $P = .02$, I^2 64%), and increased QRS duration (mean difference [MD] 10.43; $P < .001$; I^2 47%) were significantly associated with PPM.

Type of valve

Implantation of the Medtronic CoreValve (MCV; Medtronic, Minneapolis, MN) was associated with a 2.4-fold and 1.1-fold increased risk of PPM implantation compared with the Edwards Sapien valve (ESV; Edwards Lifesciences, Irvine, CA) (RR 2.42; $P < .00001$; I^2 97%) and the Medtronic Evolut R valve (RR 1.13; $P = .03$; I^2 38%), respectively. In contrast, the risk of PPM was lower for MCV compared to Lotus valve (Boston Scientific, Marlborough, MA) implantation (RR 0.53; $P < .001$; I^2 6%).

Delivery approach

With regard to the vascular approach, patients who underwent TAVR via transfemoral access showed a higher risk of developing conduction disturbances requiring PPM implantation in contrast to transapical access (RR 1.54; $P < .001$; I^2 81%).

Implantation depth, left ventricular outflow tract, and aortic annulus

The increases in valve implantation depth (MD 0.95 mm; $P < .00001$; I^2 38%) with composite mean of 7.05 (95% CI 6.37–7.34) for the PPM group and 6.05 (95% CI 5.49–6.62) for the non-PPM group; left ventricular outflow tract (LVOT) area (MD 14.10 mm²; $P < .01$; I^2 45%) with composite mean of 435.79 (95% CI 377.34–494.25) for the PPM group and 418.28 (95% CI 348.15–488.40) for the non-PPM group; and aortic annulus diameter (MD 0.38 mm; $P < .01$; I^2 64%) with composite mean of 24.39 (95% CI 23.60–25.18) for the PPM group and 23.74 (95% CI 23.05–24.44) for the non-PPM group led to a significant rise in the risk of post-TAVR PPM implantation.

All extracted variables included in our analysis for predicting PPM implantation after TAVR.

General factors	Electrocardiographic factors:	Patient Comorbidities	Cardiovascular disorders	Cardiovascular measurements	TAVR-related factors	Medications	Procedures
1-Age 2-Gender 3- BMI 4- GFR	1- First-degree AV block 2- Second-degree AV block 3- Bifascicular block 4- LAFB 5- RBBB 6- LBBB 7- AF 8- QRS duration	1-HTN 2-DM 3-Dyslipidemia 4-CKD 5-COPD 6-Anemia 7-Pulmonary Hypertension 8-PVD 9-Stroke/Transient ischemic attack 10-Cancer	1-CAD 2-MI 3-CHF 4-AR 5-MR	1- NYHA 2- EF 3- LVOT measurement 4- Aortic annulus measurement	1-Access site 2-Type of valve prosthesis (MCV, ESV, Evolut R, Lotus) 3-Implantation depth	1-ACEI/ARB 2-Amiodarone 3-Beta blocker 4-Calcium channel blocker 5-Digoxin	1-PCI 2-CABG

ACEI: Angiotensin converting enzyme inhibitor, AF: Atrial Fibrillation, AR: Aortic regurgitation, ARB: Angiotensin receptor block, AV: Atrioventricular block, BMI: Body mass index, CABG: Coronary artery bypass graft surgery, CAD: Coronary artery disease, CHF: Congestive heart failure, CKD: Chronic kidney disease, COPD: Chronic Obstructive Pulmonary disease, DM: Diabetes Mellitus, EF: Ejection fraction, ESV: Edwards Sapien valve, GFR: Glomerular filtration rate, HTN: Hypertension, LAFB: Left anterior fascicular block, LBBB: Left bundle branch block, LVOT: Left ventricular outflow tract, MCV: Medtronic CoreValve Revalving System, MI: Myocardial infarction, MR: Mitral regurgitation, NYHA: New York heart association, PCI: Percutaneous coronary intervention, PVD: Peripheral vascular disease, RBBB: Right bundle branch block.

Figure 1 All extracted variables included in our analysis for predicting permanent pacemaker (PPM) implantation after transcatheter aortic valve replacement (TAVR).

Proposed risk scoring system for predicting post-TAVR PPM implantation

We proposed a new risk scoring system using the pre-TAVR predictors that seemed to be significant in our analysis (Figure 4). We classified them based on odds ratio into strong risk factors—RBBB and BB; intermediate risk factors—FDAVB and CKD; and weak risk factors—male gender, age ≥ 80 years, BMI ≥ 25 , DM, AF, and LAFB. These risk factors along with increased LVOT area ($> 435 \text{ mm}^2$) and/or aortic annulus diameter ($> 24.4 \text{ mm}$) were applied to stratify patients into 2 categories: high- and low-risk patient groups. The high-risk group was defined as the presence of ≥ 1 strong risk factors, or 2 intermediate risk factors, or 1 intermediate risk factor with increased LVOT area $> 435 \text{ mm}^2$ or aortic annulus diameter $> 24.4 \text{ mm}$, or 1 intermediate risk factor with ≥ 2 weak risk factors, or ≥ 3 weak risk factors, or 2 weak risk factors with increased LVOT area $> 435 \text{ mm}^2$ and/or aortic annulus diameter $> 24.4 \text{ mm}$. The low-risk group was described as the presence of 1 intermediate risk factor only, or 1 intermediate risk factor with 1 weak risk factor, or 2 weak risk factors without increased LVOT area $> 435 \text{ mm}^2$ and aortic annulus diameter $> 24.4 \text{ mm}$, or 1 weak risk factor regardless of LVOT area and aortic annulus diameter.

Discussion

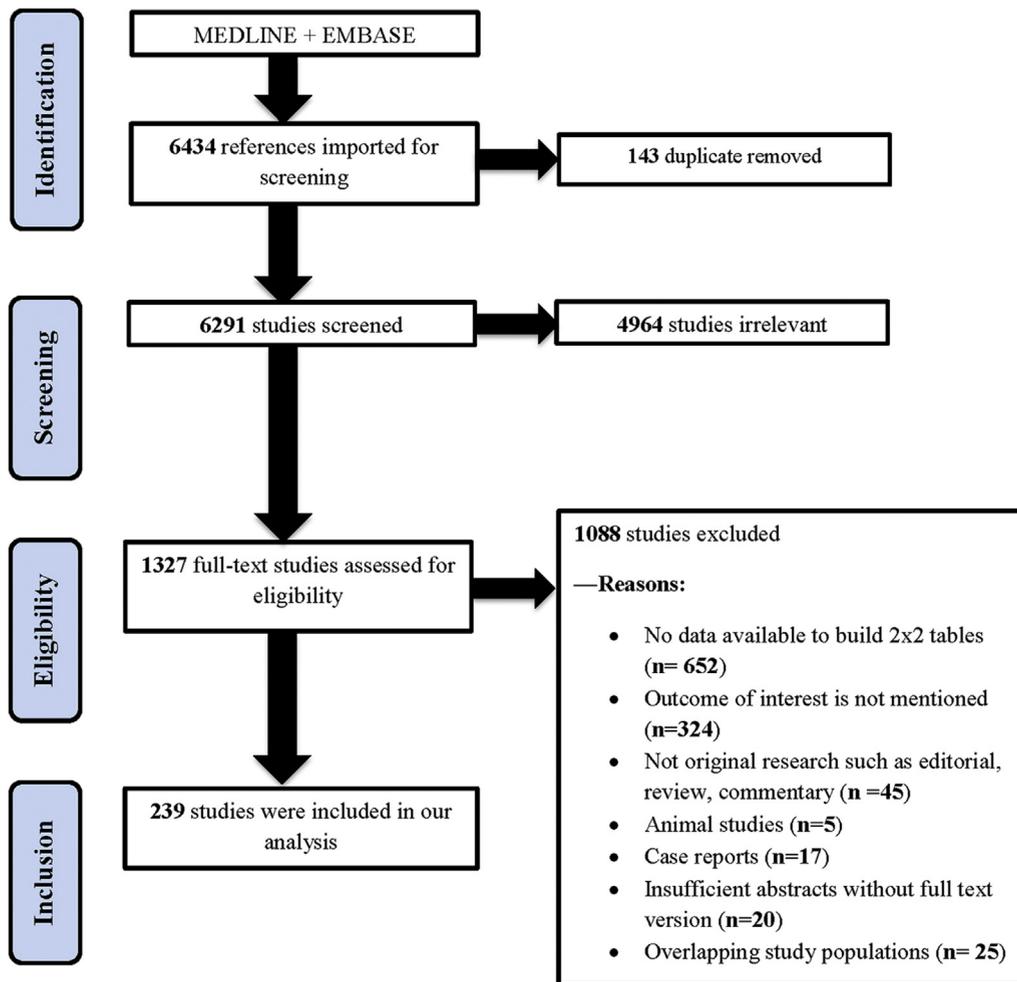
The current study is the largest updated contemporary meta-analysis to investigate the preprocedural predictors of permanent pacing after TAVR in patients with severe aortic stenosis. Our findings in 981,168 patients among 239 studies revealed that male gender, age ≥ 80 years, preprocedural evidence of conduction abnormalities (including FDAVB, LAFB, BB, RBBB, and wide QRS), AF, and specific comorbidities (BMI ≥ 25 , DM, CKD) are associated with an increased risk of PPM after TAVR. Moreover, vascular access and valve type were strongly associated with a higher risk of PPM implantation. MCV is associated with a 2.4- and

1.13-fold increased risk of PPM implantation compared to the ESV and Evolut R valve, respectively, but lower risk of PPM than Lotus valve implantation. Furthermore, patients who underwent TAVR via transfemoral access have 1.5 times the risk of experiencing PPM implantation compared to the transapical approach. The increases in valve implantation depth, LVOT area, and aortic annulus diameter led to a significant rise in the risk of post-TAVR PPM implantation.

With the increasing use of TAVR, a proactive approach must be established to mitigate the risk of PPM implantation.¹³ The incidence rate of post-TAVR PPM implantation was reported in a meta-analysis that evaluated 11,210 patients in 41 studies.¹¹ Overall, 917 (17%) received a PPM implantation, a rate comparable to that observed in our analysis. Among various conduction disorders, new-onset LBBB is the most commonly observed conduction disturbance after TAVR, with most events occurring within 24 hours of the procedure (85%–94%).^{14,15} Such a common complication is not unexpected, given that the AV node and the left bundle branch are in close anatomic proximity to the aortic valve, and the location of the bundle of His is in the membranous septum, which is highly susceptible to direct injury during and after valve deployment.^{16–18}

As a part of pre-TAVR assessment, it is essential to be cognizant of patient-related factors and comorbidities for the risk of PPM implantation following TAVR. Male patients ≥ 80 years old with obesity, DM, or CKD are deemed at high risk for post-TAVR PPM implantation.

Tissue inflammation, edema, compression, ischemia due to manipulation in the aortic valve annulus, and LVOT have been speculated to contribute to new-onset LBBB.^{19,20} Pre-existing conduction tissue disease also plays an essential role in conduction abnormalities following TAVR. Several reports highlight that baseline RBBB is a prime predictor for post-TAVR PPM implantation.^{21–23} In an analysis of 1973 patients who underwent TAVR in the randomized PARTNER (Placement of Aortic Transcatheter Valves) trial, pre-existing RBBB and LAFB were the



PRISMA flow diagram illustrating the results in each step of the systematic search and selection process to identify final studies with available data to calculate crude risk ratios for the predictors of interest

Figure 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)-style flow diagram of the study selection process.

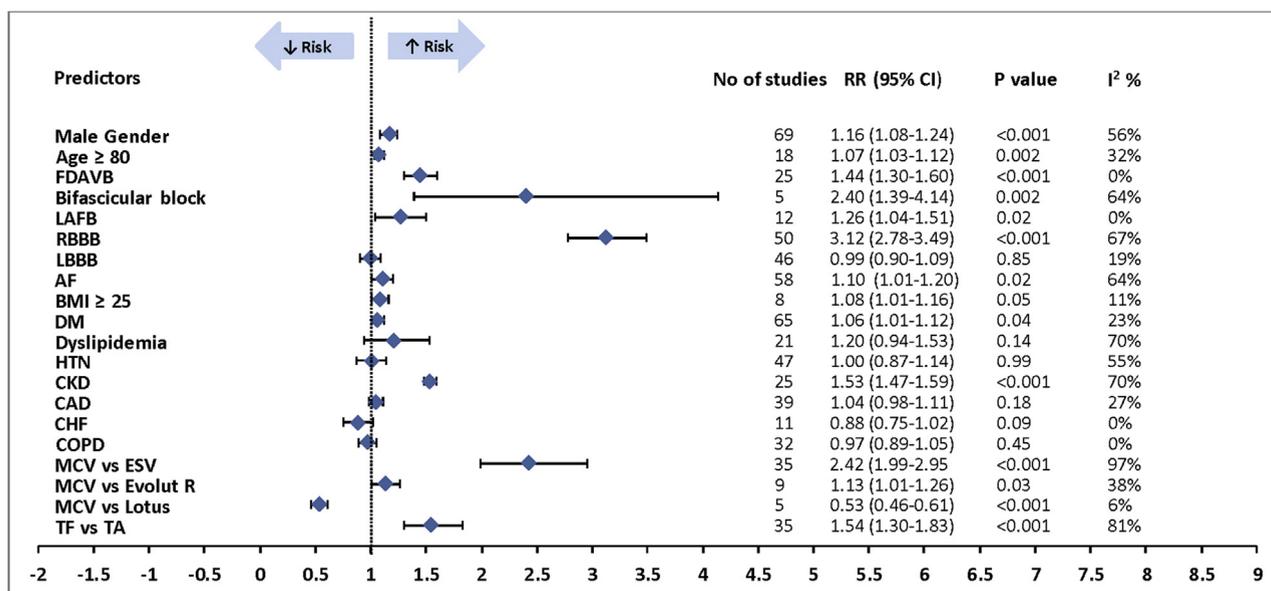
strongest ECG predictors of post-TAVR PPM implantation.²³ A previous meta-analysis that included 11,210 TAVR patients showed an increased risk of PPM patients with baseline FDAVB, LAFB, and RBBB.¹¹ Our meta-analysis runs in parallel with published findings showing that patients with RBBB, FDAVB, LAFB, BB, or wide QRS duration at baseline were at higher risk for PPM implantation after TAVR.^{11,21–23} In addition, AF has been independently associated with the need for PPM in patients undergoing TAVR.²⁴

The incidence of new-onset LBBB varies according to the type of valve implanted and ranges from 8% to 30% after ESV implantation and from 25% to 85% after MCV implantation.¹⁹ The increased risk of LBBB with MCV compared to ESV has been attributed to the MCV's length of skirt, self-expanding nature, and ability to deform into a more traditional LVOT ellipsoid shape providing asymmetric radial forces that could result in inflammation and ischemia in the LVOT and septal areas adjacent to the conduction system. As such, given the fundamental size and implantation type differences of the self-expanding MCV vs

balloon-expandable ESV systems, MCV use is an independent predictor of new-onset LBBB as well as PPM implantation following TAVR.^{8,15}

Despite cumulative experiences and vigorous efforts to redesign the transcatheter prosthesis and sheath, more conduction abnormalities still occur with transfemoral TAVR than transapical TA or transaortic TAo TAVR. Consistently, a higher incidence of PPM implantation may reflect the inherent limitations of the transfemoral approach. The conduction tissue injury is assumed to be due to the mechanical pressure from metal struts.²⁵ Some investigators also have suggested that the higher rate of PPM implantation in transfemoral TAVR patients may be related to position difficulty and repeated attempts during angiographic deployment.²⁵

The need for PPM implantation after TAVR was also associated with increased valve implantation depth, LVOT area, and aortic annulus diameter. A larger LVOT area and aortic annulus diameter could be related to higher pressure for valve inflation, leading to further traumatic compression force of the device on the conduction system tissue. It also could reflect overstretching of the LVOT and aortic annulus,



RR > 1 indicates increased risk of post-TAVR PPM while RR < 1 denotes decreased risk of post-TAVR PPM. AF: Atrial Fibrillation, AV: Atrioventricular block, BMI: Body mass index, CI: Confidence interval, CKD: Chronic kidney disease, DM: Diabetes Mellitus, ESV: Edwards Sapien valve, LAFB: Left anterior fascicular block, LBBB: Left bundle branch block, MCV: Medtronic CoreValve Revalving System, RBBB: Right bundle branch block, RR: Risk ratio, TF: Transfemoral, TA: Transapical

Figure 3 Forest plot of summary crude risk ratios (RRs) of clinically useful predictors of pacemaker implantation (PPM) implantation after transcatheter aortic valve replacement (TAVR). FDAVB = first-degree atrioventricular block; other abbreviations as in Figure 1.

resulting in more pressure on the surrounding conduction system.^{26–29}

It is clinically imperative to identify patients at higher risk for post-TAVR PPM implantation prior to a TAVR procedure,

because timely identification of high-risk patients potentially can prevent the development of atrioventricular block and its associated devastating complications such as syncope and sudden cardiac death. Also, increased PPM implantation is

Table 1 Number of reporting studies, number of patients who required PPM implantation, and RR per each clinically useful predictor of PPM implantation after TAVR

Categorical predictors	No. of studies	Predictor present		Predictor absent		RR	95% CI	P value	I ² for heterogeneity (%)
		PPM	Total	PPM	Total				
Male gender	69	5201	35,654	5063	37,481	1.16	1.08–1.24	<.00001	56
Age ≥80 y	18	11,775	46,627	28,647	12,7659	1.07	1.03–1.12	.002	32
First-degree AV block	25	325	1475	1418	8373	1.44	1.30–1.60	<.00001	0
Bifascicular block	5	29	52	134	801	2.40	1.39–4.14	.002	64
LAFB	12	87	300	586	3200	1.26	1.04–1.51	.02	0
RBBB	50	953	2154	2623	17,799	3.12	2.78–3.49	<.00001	67
AF	58	9674	43,025	13,822	79,874	1.10	1.01–1.20	.02	64
BMI ≥25	8	937	10882	1930	24573	1.08	1–1.16	.05	11
DM	65	3524	32,160	6582	58,701	1.06	1–1.12	.04	23
CKD	25	4270	35,919	11,048	128,568	1.53	1.47–1.59	<.00001	70
MCV vs ESV	35	12,110	44,258	12,268	73,210	2.42	1.99–2.95	<.00001	97
MCV vs Evolut R valve	9	1985	12,114	1175	8062	1.13	1.01–1.26	.03	38
MCV vs Lotus valve	5	229	1079	600	1735	0.53	0.46–0.61	<.00001	6
TF vs TA	35	8223	56,008	1895	22,920	1.54	1.30–1.83	<.00001	81

Continuous predictors	No. of studies	PPM group	Non-PPM group	Mean difference (PPM – non-PPM)	95% CI	P value	I ² for heterogeneity (%)
Implantation depth	11	626	1998	0.95	0.52–1.38	<.00001	67
LVOT area	6	672	1026	14.10	2.75–25.45	.01	45
Aortic annular diameter	13	753	2721	0.38	0.09–0.68	.01	64

AF = atrial fibrillation; AV = atrioventricular; BMI = body mass index; CI = confidence interval; CKD = chronic kidney disease; DM = diabetes mellitus; ESV = Edwards Sapien valve; LAFB = left anterior fascicular block; LVOT = left ventricular outflow tract; MCV = Medtronic CoreValve; PPM = permanent pacemaker; RBBB = right bundle branch block; RR = risk ratio; TA = transapical; TAVR = transcatheter aortic valve replacement; TF = transfemoral.

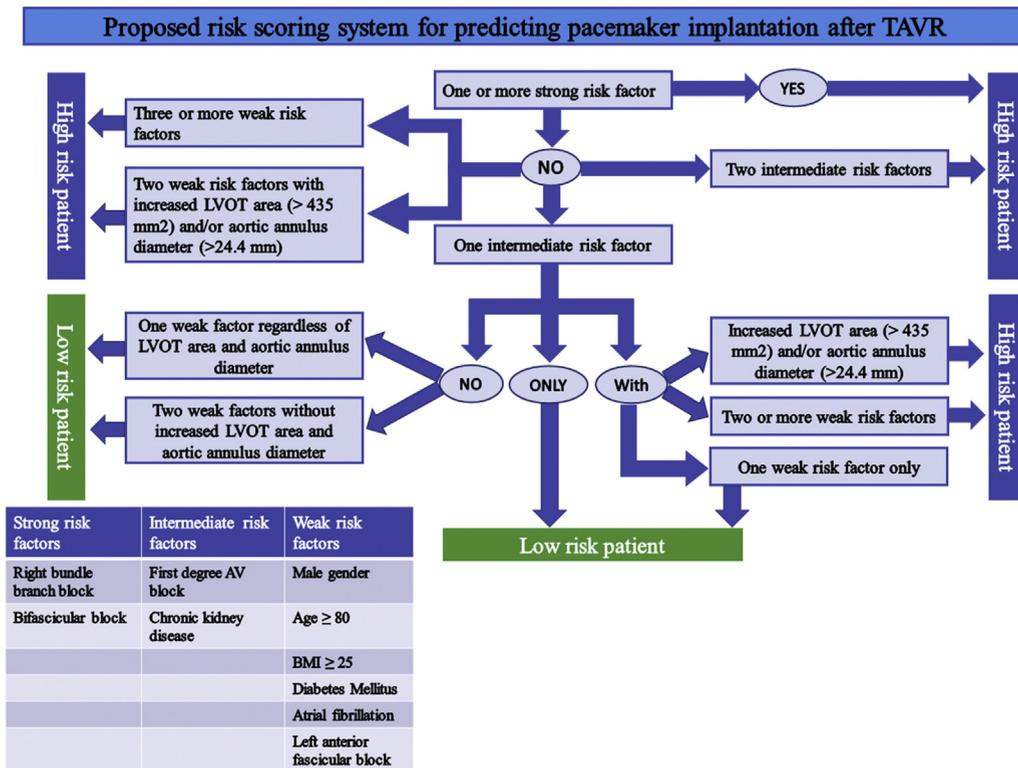


Figure 4 Proposed risk scoring system for predicting pacemaker implantation after transcatheter aortic valve replacement (TAVR). BMI = body mass index; LVOT = left ventricular outflow tract.

associated with significantly higher hospitalization and mortality rates, which place a high financial burden on health care budgets.³⁰ Therefore, analyzing PPM predictors in this context and establishing a risk score system can provide an opportunity to mitigate these risks and to favorably decrease the harm-to-benefit ratio. We included in this study a newly proposed risk scoring system that could help in identifying patients at higher risk for post-TAVR PPM implantation. To use this system, we need to include careful pre-TAVR assessment of demographics, comorbidities, ECG abnormalities, and measurements of LVOT, aortic annulus, and membranous septum on pre-TAVR computed tomography for patient risk stratification. For high-risk patients identified by our proposed scoring system, it is important to counsel the patients that the risk of need for PPM implantation is higher because of existing risk factors; to screen patient for signs and symptoms of conduction disturbances; to schedule TAVR for a time when physicians trained in PPM procedure are available within 24 hours; to consider selecting the valve (ESV instead of MCV) and the delivery access (transapical instead of transfemoral approach) associated with less risk of heart block based on the implanting team’s experience; and to consider implantation of a secure pacing lead before TAVR via an internal jugular venous approach at the discretion of the treatment team. Postprocedural monitoring on a telemetry unit, with a temporary pacemaker attached and programmed to provide backup pacing if required, is essential in high-risk patients, with consideration of electrophysiological study and PPM for new, progressive,

or pre-existing conduction disturbances that change postoperatively.

Study limitations

First, even though we investigated a considerable number of clinically significant variables, some variables could have been missed in our analysis. Second, heterogeneity among different studies for multiple variables was found. Third, the long-term clinical efficacy of PPM implantation could not be addressed because long-term follow-up data were not reported in the majority of the studies. Fourth, PPM implantation after TAVR does not represent a surrogate marker of AV conduction disturbances but may be influenced by several logistic and economic factors that were not discussed in our analysis. Fifth, further studies are warranted to validate the clinical predictive performance of our newly proposed risk scoring system in identifying patients at higher risk for post-TAVR PPM implantation. Finally, we only used crude RRs, so adjusted estimates for most of the predictors were not available. Therefore, we could not rule out the impact of measured and unmeasured confounders and define the independent role of individual predictors after appropriate adjustment.

Conclusion

The presence of preprocedural conduction abnormalities (including FDAVB, LAFB, BB, RBBB, and wide QRS) significantly aggravated the risk of post-TAVR PPM. Furthermore, increased LVOT area, aortic annulus diameter,

and implantation depth were associated with higher rates of PPM implantation after TAVR.

Male patients ≥ 80 years old with 1 of the following comorbidities—obesity, DM, or CKD—are deemed at high risk for post-TAVR PPM implantation. Preprocedural assessment should consider these factors in determining patients at high risk for receiving a pacemaker after TAVR.

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Ethics Statement: This review was completed following PRISMA standards for systemic review and meta-analysis quality reporting. Given the nature of the study, it was exempt from institutional review board review.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hroo.2022.05.001>.

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