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Research article

Predicting pacemaker dependency after transcatheter aortic valve replacement: Analysis of ECG, clinical, and CT-imaging parameters

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ABSTRACT

Objectives: Conduction disturbances necessitating permanent pacemaker (PPM) implantation following transcatheter aortic valve replacement (TAVR) have been observed. However, limited data exist on ECG, clinical, and CT-imaging factors predicting PPM dependency after TAVR. This study aimed to identify predictors of pacemaker dependency in selected patients who required PPM implantation after TAVR with SAPIEN 3 prostheses.

Materials and Methods: This study included consecutive patients who underwent transfemoral TAVR with SAPIEN 3 prostheses at our institution between May 2012 and December 2019. Exclusion criteria were incomplete or non-diagnostic data, valve-in-valve procedures, TAVR in mitral position, previous surgical repair, and pre-implanted PPM. The primary endpoint was PPM dependency, defined as ventricular pacing percentage ≥ 1 % at the first outpatient follow-up after PPM implantation post-TAVR. Regression analysis was performed to compare a limited prediction model for PPM dependency using only selected variables to a full model with all available variables.

Results: Out of 2105 patients who received TAVR, 350 (16.6 %) required pacemaker implantation post-TAVR. After exclusions, 301 patients remained, with 168 (55.8 %) PPM-dependent and 133 (44.2 %) non-dependent patients. Multivariate analysis identified prosthesis oversizing (OR: 1.09, $p < 0.001$), calcification below the left coronary cusp (LCC) (OR: 1.02, $p < 0.001$), and right bundle branch block (RBBB) prior to TAVR (OR: 2.20, $p = 0.025$) as significant predictors. A limited regression model predicted PPM dependency with an AUC of 0.752, significantly outperforming the full model (AUC: 0.660, $p = 0.037$).

Conclusion: RBBB prior to TAVR was the strongest predictor of PPM dependency post-TAVR, followed by prosthesis oversizing and calcification below the LCC. A limited prediction model with these variables demonstrated moderate predictive accuracy.

1. Introduction

Severe aortic stenosis is the most common valvular disease in the aging population of the developed world [1]. Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure that has been established as safe and effective for patients across high, intermediate, and low surgical risk categories [2]. Compared to surgical aortic valve replacement (SAVR), TAVR is associated with shorter hospital stays and lower complication rates, contributing to a steady increase in TAVR procedures [3,4].

Technological advancements, such as improved valve design and downsized vascular access sheaths, have optimized valve delivery and

Abbreviations: AIC, Akaike information criterion; AOA, aortic annulus; AUC, area under the curve; AVB, atrioventricular block; CT, computed tomography; COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; LAHB, left anterior hemiblock; LBBB, left bundle branch block; LCC, left coronary cusp; NCC, non-coronary cusp; PPM, permanent pacemaker; RBBB, right bundle branch block; RCC, right coronary cusp; ROC, receiver operator characteristic; TAVR, transcatheter aortic valve replacement; VIR, variance inflation factor.

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reduced procedure-related complications [4]. New-generation balloon- and self-expandable valve prostheses demonstrate equivalent effectiveness and complication rates [5]. However, the most frequent complication with these newer devices remains new-onset conduction disturbances requiring permanent pacemaker (PPM) implantation [5–7], largely due to mechanical injury to the conduction system near the prosthesis implantation site [4,5,8].

Atrioventricular block, with or without left bundle branch block (LBBB), are the most common disturbances leading to PPM implantation, occurring in 4–24 % of patients with the SAPIEN 3 aortic prosthesis [6,9]. PPM implantation post-TAVR has been associated with adverse cardiovascular outcomes, including increased heart failure hospitalizations and higher cardiovascular mortality [6,10]. Patients undergoing TAVR routinely receive pre-procedural CT imaging for anatomical assessment and procedural planning [11,12]. Anatomical information from CT, along with various clinical and procedural factors, has been identified as a critical predictor of PPM implantation after TAVR [13–16]. It remains unclear whether patients who undergo pacemaker implantation for post-TAVR conduction abnormalities are consistently or intermittently pacemaker-dependent. Follow-up studies indicate that approximately 30–50 % of patients undergoing pacemaker implantation after TAVR exhibit pacemaker dependency during subsequent evaluations [8,17–19].

Reliable prediction models for PPM dependency post-TAVR remain lacking. Many studies examining this question either have a limited number of patients, or use different valve models throughout their cohorts rendering an interpolation of the results difficult. This study aims to identify ECG, clinical, and CT imaging parameters associated with pacemaker dependency among patients who underwent PPM implantation following TAVR with the Edwards SAPIEN 3 prosthesis.

2. Materials and Methods

The study complied with the Declaration of Helsinki and received approval from the institutional ethics committee board. The need for informed consent was waived.

2.1. Population

This retrospective, single-center subanalysis was based on a previously published cohort of 2,105 patients who underwent transfemoral TAVR between May 2012 and December 2019 [20]. The present study specifically examines a high-risk subgroup of patients who developed new conduction disturbances post-TAVR requiring PPM implantation. From this population, we included only those with complete in-house preprocedural CT imaging and available follow-up pacemaker interrogation. Patients with valve-in-valve procedures, prior surgical repair, mitral valve TAVR, non-diagnostic CT scans, pre-existing PPM, or non-SAPIEN 3 prostheses were excluded. Consequently, all analyses and predictive modeling were restricted to TAVR patients who underwent postprocedural PPM implantation.

2.2. Definition of pacemaker dependency

The primary endpoint of this study was pacemaker dependency. All patients who required PPM implantation within 3 months after TAVR were recorded, as this follow-up period was chosen to adequately capture all TAVR-associated conduction disturbances. These patients were subsequently analyzed for pacemaker dependency, defined in accordance with previous literature as a ventricular pacing percentage of $\geq$ 1 % at the first outpatient follow-up [21,22], scheduled 3 months post-PPM implantation. This low threshold was chosen to capture both intermittent and continuous dependency, reflecting any persistent conduction abnormality requiring pacing support. Patients identified as pacemaker-dependent were then compared to non-dependent patients in terms of ECG, clinical, and CT-imaging characteristics.

2.3. Pre-procedural CT-imaging

All patients underwent in-house preprocedural CT imaging planning. Scans were conducted using one of three dual-source CT scanners: *SOMATOM Flash* and *SOMATOM Drive* with 256 slices with a temporal resolution of 75 ms, *SOMATOM Force* (Siemens, Forchheim, Germany) with 384 slices and a temporal resolution of 66 ms. Tube voltage and current were adjusted according to patient characteristics using *CARE Dose 4D* and *CARE kV* (Siemens, Forchheim, Germany). Collimation was set at 2 x 128 x 0.6 mm for *SOMATOM Flash* and *SOMATOM Drive*, and 2 x 192 x 0.6 mm for *SOMATOM Force*. The imaging protocol included a non-contrast scan of the heart to quantify calcifications, followed by a high-pitch contrast-enhanced scan in the end-systolic phase (30–40 % RR-interval), from the skull base to the femoral arteries. Patients received 70–140 cc of iomeprol-400 (*Iomeron,* Bracco Imaging SpA, Milan, Italy) at a rate of 3–7 cc/s, followed by a 30 cc saline chaser.

2.4. Imaging measurements

CT imaging measurements were performed in accordance with a previously published protocol [20]. All measurements were conducted using dedicated post-processing software (CVI 42, version 5.12; Circle Cardiovascular Imaging Inc., Calgary, Canada), following established guidelines [23]. Two experienced readers (initials blinded for review) evaluated the images in consensus. The aortic valve plane was reconstructed using the contrast-enhanced CT scan.

Measurements were recorded in the transverse double oblique view and included the aortic left ventricular outflow tract and aortic root, utilizing multiplanar reformatted images. Various parameters were assessed: area and perimeter as well as minimum and maximum diameters of the aortic annulus (AOA), distances from the annulus to the lowest points of the left and right coronary ostia, sinotubular junction height, sinus of Valsalva diameter, and angle of left ventricle to aortic root were measured. Calcium scoring covered the left ventricular outflow tract and aortic root, with detailed evaluations of calcifications below the annulus plane and of each coronary cusp. The nominal areas of the 23, 26 and 29 mm SAPIEN 3 prostheses, as provided by the manufacturer, were 407.2, 519.2, and 649.2 mm^2, respectively. Prosthesis oversizing was calculated using the formula: ((SAPIEN 3 nominal valve area/area of AOA $-$ 1) $\times$ 100), and eccentricity index was calculated as: 1 $-$ (minimum diameter of AOA/maximum diameter of AOA) [24,25].

2.5. Statistical analysis

Categorical variables were reported as counts with percentages, and ordinal and continuous variables were presented as medians with interquartile ranges. The Shapiro-Wilk test indicated non-normal distribution of numeric variables; therefore, Mann-Whitney U/Wilcoxon rank tests were used for their comparison between pacemaker-dependent and non-dependent patients. Categorical variables were analyzed using χ^2-tests.

Before logistic regression, multicollinearity was checked using a stringent Variance Inflation Factor (VIF) threshold of 3 [26], excluding variables exceeding this or involved in interactions. Univariate logistic regression explored associations with pacemaker dependency, followed by a multivariate prediction model, optimized via backward selection using the Akaike Information Criterion (AIC) [27].

The dataset was split into training (70 %) and testing (30 %) sets. Two logistic models were fitted: a full model with all predictors and an optimized limited model. Internal validation was done with 1000 bootstrap iterations, estimating Area Under the Receiver Operating Characteristic Curve (AUC) and 95 % confidence intervals (CIs). External validation involved testing set evaluation, generating Receiver Operating Characteristic (ROC) curves, and comparing model performance via DeLong's test. Model performance was assessed by AUC, sensitivity, specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV). Results were summarized in an odds ratio (OR) table, with multivariate outcomes visualized by a Forest plot. All analyses used R software (version 4.4.0, R Foundation, Vienna, Austria).

3. Results

3.1. Patient population

This study initially screened 2105 patients who underwent TAVR at our institution between May 2012 and December 2019. Of these, 1755 patients (83.4 %) did not require, while the remaining 350 patients (16.6 %) required pacemaker implantation following TAVR. Exclusions were applied to 49 patients: 28 patients did not receive SAPIEN 3 prostheses, 17 patients had incomplete data, 3 patients underwent a valve-in-valve prosthesis procedure, and 1 patient had TAVR performed in the mitral position. The final study population comprised 301 patients. Within this cohort, 168 patients (55.8 %) were, while 133 patients (44.2 %) were not PPM-dependent. The flowchart illustrating the study population selection is presented in Fig. 1.

3.2. Patient characteristics

The median age of the overall cohort was 81 years (IQR: 77–85), with no significant age difference between the non-PPM-dependent group (82 years, IQR: 76–84) and the PPM-dependent group (80 years, IQR: 77–86) ($p = 0.816$). The proportion of female patients was 32.2 %, with slightly more females in the non-PPM-dependent group (36.8 %) compared to the PPM-dependent group (28.6 %) ($p = 0.127$). The median duration from TAVR to PPM implantation was significantly shorter in the PPM-dependent group (5 days, IQR: 3–7) compared to the non-PPM-dependent group (6 days, IQR: 4–8) ($p = 0.045$).

As patients were stratified for pacemaker dependency, right ventricular pacing percentage was notably higher in the PPM-dependent group (79 %, IQR: 10–99) compared to the non-PPM-dependent group, which had no right ventricular pacing ($p < 0.001$). There was no significant difference for atrial pacing percentage between the two groups. There was no significant difference in prosthesis diameter between the groups, with 44.6 % of PPM-dependent patients and 32.3 % of non-dependent patients receiving a 29 mm prosthesis ($p = 0.051$). Anatomical measurements, including the maximum and minimum diameters of the AOA, area and perimeter of the AOA, and eccentricity index, were similar between the two groups. Prosthesis oversizing was significantly greater in the PPM-dependent group (10.5 %, IQR: 3.7–14.9) compared to the non-PPM-dependent group (2.9 %, IQR: 0.8–7.2) ($p < 0.001$). There was no significant difference in calcification of the LCC between the groups, with median values of 255 mm^3 (IQR: 124–448) in the PPM-dependent group and 210 mm^3 (IQR: 110–374) in the non-PPM-dependent group ($p = 0.105$). Notably, calcification below the LCC was significantly higher in the PPM-dependent group (5 mm^3, IQR: 0–75) compared to the non-PPM-dependent group (0 mm^3, IQR: 0–4) ($p < 0.001$).

The prevalence of atrial fibrillation prior to TAVR was 44.2 %, with no significant difference between the groups ($p = 0.379$). Right bundle branch block (RBBB) prior to TAVR was significantly more common in the PPM-dependent group (33.3 %) compared to the non-PPM-dependent group (18.0 %) ($p = 0.003$). Other pre-existing conduction disturbances such as LBBB, left anterior hemiblock (LAHB), atrioventricular block (AVB) and bifascicular block showed no significant differences between the groups. Boxplots visualizing significant differences

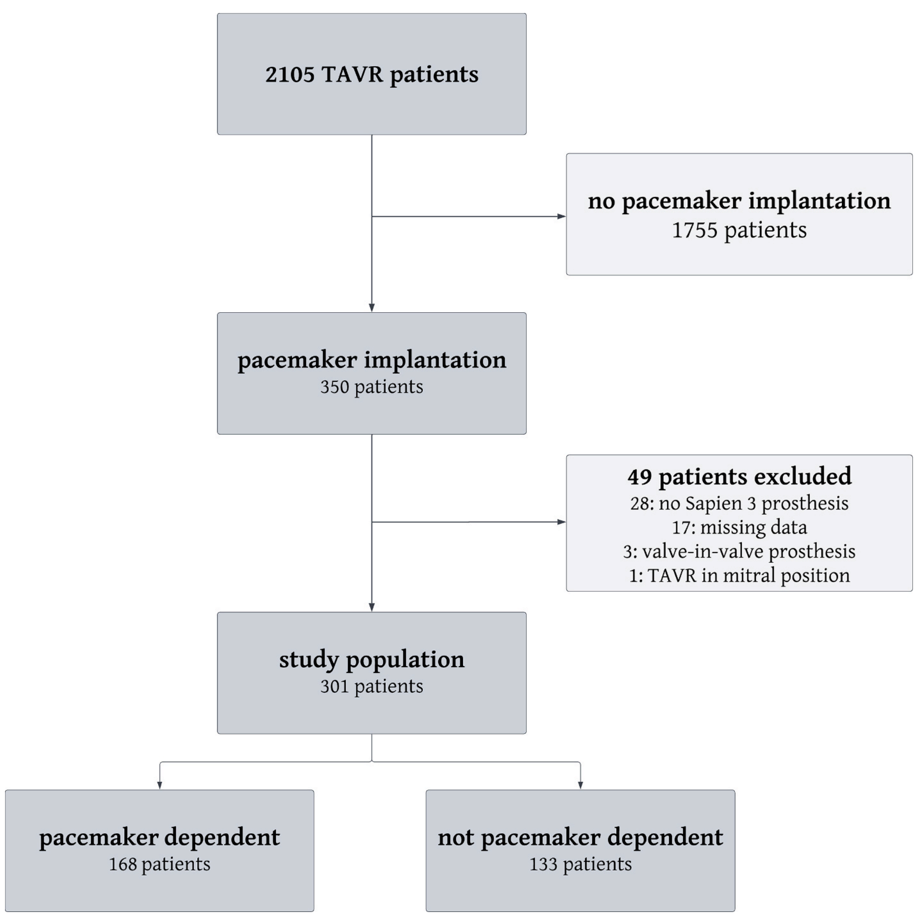

Fig. 1. Flow-chart of enrolled patients after transcatheter aortic valve reconstruction (TAVR) to final study population.

between the groups are shown in Fig. 2.

Comorbid conditions including mitral insufficiency, COPD, chronic renal dysfunction, arterial hypertension, diabetes mellitus, smoking history, and obesity were similarly distributed between the two groups, with no significant differences observed. Detailed results of patient analysis are given in Table 1.

3.3. Regression analysis

The variables included in the regression analysis were selected based on their VIF to minimize multicollinearity. Prosthesis diameter, as well as the maximum and minimum diameters and the area of the AOA, were excluded due to their high VIF of 3.85, 8.90, 9.72, and 13.10, respectively, which indicated potential multicollinearity and suspected interaction effects. After the selection process, all included variables had VIFs significantly below the threshold of multicollinearity, with prosthesis oversizing, maximum perimeter of the AOA, and eccentricity index of the AOA showing substantial reductions in VIF values (1.12, 1.38, and 1.20, respectively). The variable selection process is demonstrated in the Supplemental Table.

The univariate logistic regression analysis identified several factors associated with PPM dependency following TAVR. Prosthesis oversizing had a significant association with PPM dependency, with an odds ratio (OR) of 1.05 (95 % CI: 1.02–1.08, $p < 0.001$). Calcification below the LCC also showed a significant association (OR: 1.02, 95 % CI: 1.01–1.03, $p < 0.001$). RBBB prior to TAVR was another significant factor (OR: 2.27, 95 % CI: 1.33–3.97, $p = 0.003$). Age, sex, duration from TAVR to PPM implantation, maximum perimeter of the AOA, eccentricity index of the AOA, sinotubular junction height, diameter of the sinus of Valsalva, and other anatomical measurements and comorbid conditions did not show significant associations in the univariate analysis.

After building a limited prediction model using backwards selection with AIC, following variables remained in the model: sex, prosthesis oversizing, calcification below the LCC, RBBB prior to TAVR and the angle of the left ventricle to the aortic root. In the subsequent multivariate logistic regression analysis, prosthesis oversizing remained a significant predictor of PPM dependency (OR: 1.09, 95 % CI: 1.05–1.14, $p < 0.001$). Calcification below the LCC also remained significant (OR: 1.02, 95 % CI: 1.02–1.04, $p < 0.001$). RBBB prior to TAVR continued to be a significant factor with an adjusted OR of 2.20 (95 % CI: 1.12–4.44, $p = 0.025$). The angle of the left ventricle to the aortic root and sex did not reach statistical significance in the multivariate analysis. Detailed results of regression analysis are given in Table 2. Representative CT angiography examples illustrating the absence and presence of calcification below LCC are shown in Fig. 3.

3.4. Model comparison

The full model achieved an AUC of 0.660 (95 % CI: 0.546–0.775), indicating moderate discrimination ability. It demonstrated a sensitivity of 38.6 %, specificity of 93.2 %, PPV of 85.0 %, and NPV of 60.3 %. In contrast, the limited model showed a significantly higher AUC of 0.752 (95 % CI: 0.651–0.853) ($p = 0.037$), suggesting better overall performance. It exhibited a markedly higher sensitivity of 93.2 % but a lower specificity of 47.7 %, with a PPV of 64.1 % and an NPV of 87.5 %. The performance of the full and limited model are depicted in an ROC-plot in Fig. 4.

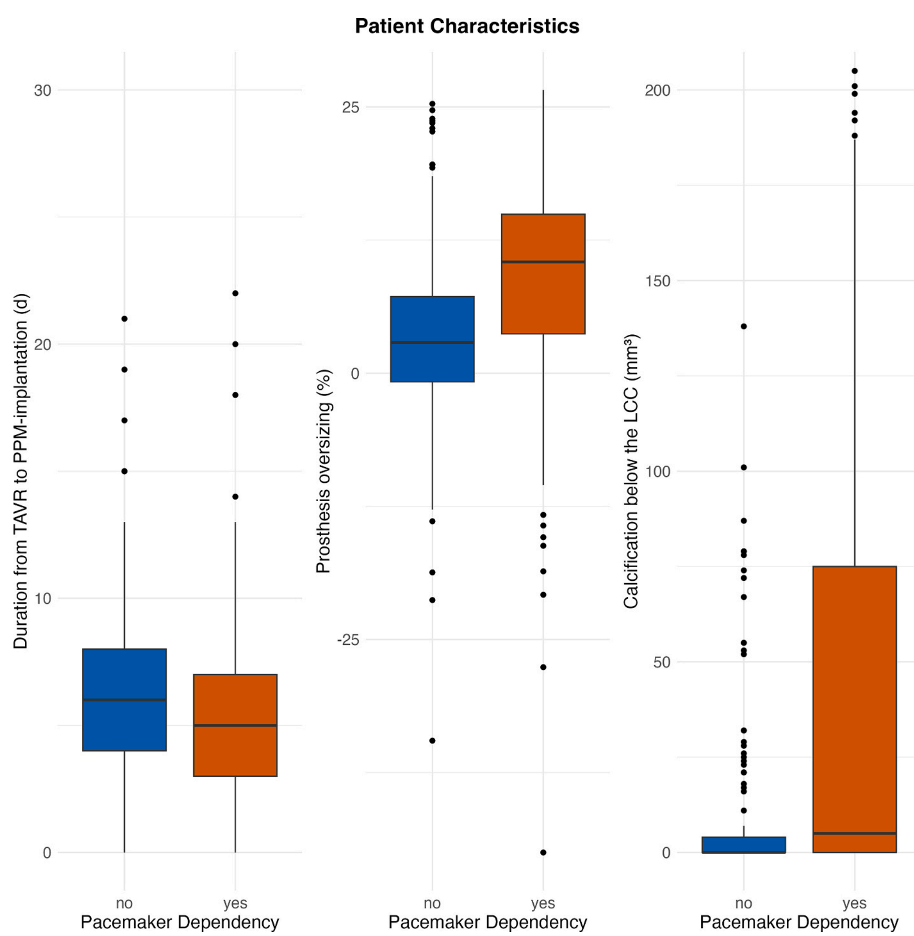

Fig. 2. Boxplots depicting significant differences in subgroup analyses stratified by permanent pacemaker dependency after transcatheter aortic valve reconstruction (TAVR). LCC = left coronary cusp, PPM = permanent pacemaker.

Table 1
Patient characteristics stratified by permanent pacemaker dependency after TAVR.

Permanent Pacemaker Dependency	Overall, N = 301	No, N = 133	Yes, N = 168	p-value
Age	81 (77, 85)	82 (76, 84)	80 (77, 86)	0.816
Sex (F)	97 (32.2 %)	49 (36.8 %)	48 (28.6 %)	0.127
Duration from TAVR to PPM-implantation (d)	6 (3, 8)	6 (4, 8)	5 (3, 7)	**0.045**
Right atrial pacing percentage (%)	8 (2, 30)	7 (2, 15)	8 (3, 76)	0.231
Right ventricular pacing percentage (%)	4 (0, 90)	0 (0, 0)	79 (10, 99)	**<0.001**
Prosthesis diameter (mm)				0.051
23	62 (20.6 %)	34 (25.6 %)	28 (16.7 %)	—
26	121 (40.2 %)	56 (42.1 %)	65 (38.7 %)	—
29	118 (39.2 %)	43 (32.3 %)	75 (44.6 %)	—
Maximum diameter of the AOA (mm)	29 (27, 31)	29 (27, 32)	30 (27, 31)	0.855
Minimum diameter of the AOA (mm)	22 (21, 24)	22 (21, 24)	22 (20, 24)	0.980
Area of the AOA (mm^2)	507 (442, 565)	505 (441, 563)	517 (443, 566)	>0.999
Maximum perimeter of the AOA (mm)	82 (77, 87)	82 (76, 88)	82 (77, 87)	0.737
Prosthesis oversizing (%)	6.7 (0.5, 13.7)	2.9 (0.8, 7.2)	10.5 (3.7, 14.9)	**<0.001**
Eccentricity index of the AOA ($^{-1}$)	25 (20, 29)	24 (20, 29)	25 (20, 29)	0.832
Sinotubular junction height (mm)	23 (21, 25)	23.0 (21, 25)	23.0 (21, 25)	0.752
Diameter of the sinus of Valsalva (mm)	35 (32, 37)	35 (31, 37)	35 (32, 37)	0.495
Distance from AOA to left coronary ostium (mm)	15 (13, 18)	15 (13, 17)	15 (13, 18)	0.247
Distance from AOA to right coronary ostium (mm)	18 (15, 21)	17 (15, 21)	18 (15, 20)	0.897
Angle of the left ventricle to the aortic root (°)	52 (46, 58)	52 (47, 59)	52 (46, 57)	0.529
Length of the left ventricular outflow tract (mm)	15 (13, 18)	15 (13, 18)	16 (13, 18)	0.978
Calcification of the LCC (mm^3)	241 (117, 435)	210 (110, 374)	255 (124, 448)	0.105
Calcification of the RCC (mm^3)	204 (116, 377)	188 (121, 368)	219 (109, 391)	0.826
Calcification of the NCC (mm^3)	304 (176, 448)	319 (186, 432)	285 (171, 464)	0.671
Calcification below the LCC (mm^3)	1 (0, 37)	0 (0, 4)	5 (0, 75)	**<0.001**
Calcification below the RCC (mm^3)	0 (0, 1)	0 (0, 1)	0 (0, 1)	0.554
Calcification below the NCC (mm^3)	0 (0, 11)	0 (0, 6)	1 (0, 13)	0.227
Atrial fibrillation prior to TAVR (yes)	133 (44.2 %)	55 (41.4 %)	78 (46.4 %)	0.379
LBBB prior to TAVR (yes)	36 (12.0 %)	17 (12.8 %)	19 (11.3 %)	0.696
LAHB prior to TAVR (yes)	26 (8.6 %)	9 (6.8 %)	17 (10.1 %)	0.304
AVB prior to TAVR (yes)	87 (28.9 %)	36 (27.1 %)	51 (30.4 %)	0.532
Bifascicular block prior to TAVR (yes)	4 (1.3 %)	1 (0.8 %)	3 (1.8 %)	0.633
RBBB prior to TAVR (yes)	80 (26.6 %)	24 (18.0 %)	56 (33.3 %)	**0.003**
Indication for PPM-implantation post TAVR				0.115
AVB	177 (58.8 %)	74 (55.6 %)	103 (61.3 %)	—
Atrial fibrillation	21 (7.0 %)	7 (5.3 %)	14 (8.3 %)	—
Asystole	9 (3.0 %)	6 (4.5 %)	3 (1.8 %)	—
Bradycardia	22 (7.3 %)	7 (5.3 %)	15 (8.9 %)	—
LBBB	72 (23.9 %)	39 (29.3 %)	33 (19.6 %)	—
Mitral insufficiency prior to TAVR (yes)	159 (52.8 %)	68 (51.1 %)	91 (54.2 %)	0.600
COPD prior to TAVR (yes)	40 (13.3 %)	16 (12.0 %)	24 (14.3 %)	0.567
Chronic renal dysfunction prior to TAVR (yes)	100 (33.2 %)	42 (31.6 %)	58 (34.5 %)	0.590
Arterial hypertension prior to TAVR (yes)	281 (93.4 %)	124 (93.2 %)	157 (93.5 %)	0.940
Diabetes mellitus prior to TAVR (yes)	99 (32.9 %)	42 (31.6 %)	57 (33.9 %)	0.667
Smoking history prior to TAVR (yes)	61 (20.3 %)	24 (18.0 %)	37 (22.0 %)	0.415
Obesity prior to TAVR (yes)	22 (7.3 %)	12 (9.0 %)	10 (6.0 %)	0.309

Note.- Values are median and interquartile range (Q1, Q3) or frequencies and percentages unless otherwise specified. AOA = aortic annulus, AVB = atrioventricular block, COPD = chronic obstructive pulmonary disease, LAHB = left anterior hemiblock, LBBB = left bundle branch block, LCC = left coronary cusp, NCC = non coronary cusp, PPM = permanent pacemaker, RBBB = right bundle branch block, RCC = right coronary cusp, TAVR = transcatheter aortic valve reconstruction

4. Discussion

This study aimed to identify ECG, clinical, and CT-derived parameters predictive of pacemaker dependency among patients who underwent PPM implantation following SAPIEN 3-TAVR. From a cohort of 2,105 patients undergoing transfemoral TAVR, we included only those who received a SAPIEN 3 prosthesis, developed new conduction disturbances requiring PPM implantation, and had complete imaging and follow-up data. Using multivariate logistic regression, we differentiated patients who were truly pacing-dependent (ventricular pacing ≥ 1 %) from those who were not. The limited prediction model—comprising sex, prosthesis oversizing, calcification below the LCC, pre-TAVR RBBB, and the angle between the left ventricle and aortic root—demonstrated the highest predictive accuracy (AUC 0.752), offering a clinically applicable and focused tool for risk stratification. These findings provide a clinically applicable tool for identifying pacemaker dependency among TAVR patients with postprocedural PPM implantation and may help refine post-TAVR management and device programming, with implications for reducing unnecessary procedures, complications, and healthcare resource utilization [3,10,14].

A key strength of this study lies in its exclusive focus on patients treated with balloon-expandable SAPIEN 3 valves and its comparison of PPM-dependent versus non-dependent patients after device implantation. Prior studies have predominantly evaluated predictors of PPM implantation per se, without assessing pacing dependency [3,10,14]. By isolating true pacing dependency as the clinical endpoint and limiting the analysis to a single valve type, we reduce heterogeneity and confounding observed in earlier research involving mixed prosthesis populations [13,14,16].

The SAPIEN 3 represents a newer-generation balloon-expandable valve with enhanced radial strength and an external sealing skirt designed to minimize paravalvular leak while avoiding excessive interaction with the interventricular septum. These design features may explain the comparatively lower rates of PPM implantation consistently reported for balloon-expandable valves compared with self-expanding or mechanically expanding systems [28]. In the randomized CHOICE trial, the balloon-expandable SAPIEN XT (Edwards Lifesciences, Irvine, California) was associated with a markedly lower PPM implantation rate than the self-expanding CoreValve (Medtronic, Minneapolis, Minnesota) (25.4 % vs. 40.4 %) [29]. Likewise, data from the REPRISE III trial

Table 2
Univariate and multivariate analysis of potential predictors for permanent pacemaker dependency after TAVR.

Regression Analysis Characteristic	Univariate OR	95 % CI	p-value	Multivariate OR	95 % CI	p-value
Age	1.01	0.97, 1.04	0.729	—	—	—
Sex (F)	0.69	0.42, 1.11	0.128	0.67	0.34, 1.31	0.240
Duration from TAVR to PPM-implantation	0.97	0.92, 1.01	0.178	—	—	—
Prosthesis oversizing	1.05	1.02, 1.08	<0.001	1.09	1.05, 1.14	**<0.001**
Maximum perimeter of the AOA	0.99	0.97, 1.02	0.643	—	—	—
Eccentricity index of the AOA	1.00	0.97, 1.03	0.955	—	—	—
Sinotubular junction height	1.00	0.94, 1.07	0.889	—	—	—
Diameter of the sinus of Valsalva	1.02	0.96, 1.09	0.435	—	—	—
Distance from AOA to left coronary ostium	1.03	0.96, 1.10	0.462	—	—	—
Distance from AOA to right coronary ostium	0.98	0.93, 1.04	0.607	—	—	—
Angle of the left ventricle to the aortic root	0.99	0.96, 1.01	0.312	0.97	0.94, 1.00	0.061
Length of the left ventricular outflow tract	1.00	0.95, 1.05	0.955	—	—	—
Calcification of the LCC	1.00	1.00, 1.00	0.043	—	—	—
Calcification of the RCC	1.00	1.00, 1.00	0.657	—	—	—
Calcification of the NCC	1.00	1.00, 1.00	0.852	—	—	—
Calcification below the LCC	1.02	1.01, 1.03	<0.001	1.02	1.02, 1.04	**<0.001**
Calcification below the RCC	1.00	1.00, 1.01	0.641	—	—	—
Calcification below the NCC	1.01	1.0, 1.03	0.222	—	—	—
Atrial fibrillation prior to TAVR (yes)	1.23	0.78, 1.95	0.379	—	—	—
LBBB prior to TAVR (yes)	0.87	0.43, 1.76	0.696	—	—	—
LAHB prior to TAVR (yes)	1.01	0.88, 1.22	0.612	—	—	—
AVB prior to TAVR (yes)	1.17	0.71, 1.95	0.532	—	—	—
Bifascicular block prior to TAVR (yes)	2.40	0.30, 48.8	0.451	—	—	—
RBBB prior to TAVR (yes)	2.27	1.33, 3.97	0.003	2.20	1.12, 4.44	**0.025**
Indication for PPM-implantation post TAVR						
AVB	—	—	—	—	—	—
Atrial fibrillation	1.44	0.57, 3.95	0.457	—	—	—
Asystole	0.36	0.07, 1.41	0.157	—	—	—
Bradycardia	1.54	0.62, 4.20	0.371	—	—	—
LBBB	0.61	0.35, 1.05	0.077	—	—	—
Mitral insufficiency prior to TAVR (yes)	1.13	0.72, 1.78	0.600	—	—	—
COPD prior to TAVR (yes)	1.22	0.62, 2.44	0.567	—	—	—
Chronic renal dysfunction prior to TAVR (yes)	1.14	0.70, 1.86	0.590	—	—	—
Arterial hypertension prior to TAVR (yes)	1.04	0.41, 2.58	0.940	—	—	—
Diabetes mellitus prior to TAVR (yes)	1.11	0.69, 1.81	0.667	—	—	—
Smoking history prior to TAVR (yes)	1.28	0.73, 2.30	0.394	—	—	—
Obesity prior to TAVR (yes)	0.64	0.26, 1.53	0.313	—	—	—

Note.- Values are odds ratios (OR) with 95 % confidence intervals (CI) unless otherwise specified. AOA = aortic annulus, AVB = atrioventricular block, COPD = chronic obstructive pulmonary disease, LAHB = left anterior hemiblock, LBBB = left bundle branch block, LCC = left coronary cusp, NCC = non coronary cusp, PPM = permanent pacemaker, RBBB = right bundle branch block, RCC = right coronary cusp, TAVR = transcatheter aortic valve reconstruction

demonstrated higher PPM implantation rates with the mechanically expanding Lotus valve (Boston Scientific Corporation, Marlborough, MA) compared with CoreValve (34 % vs. 18 %) [30].

However, regarding pacemaker dependency, valve type itself did not emerge as a significant predictor in the REPRISE III trial [30]. Similarly, Nai Fovino et al. reported that valve type was not independently associated with pacemaker dependency after TAVR, suggesting that other factors—such as implantation depth exert a stronger influence on long-term pacing requirements [8]. These inconsistencies may in part reflect heterogeneous definitions and follow-up intervals used to determine pacing dependency across studies, as well as differences in patient selection and implantation techniques. Nevertheless, evaluating a homogeneous SAPIEN 3 cohort enables a more controlled analysis of device-specific anatomical and procedural predictors while minimizing confounding by mixed valve designs.

In our cohort, the PPM implantation rate was 15.3 %—slightly higher than in the PARTNER trial but consistent with rates reported in other balloon-expandable valve studies [10,14,31]. Of those receiving a PPM, 55.8 % were pacing-dependent at follow-up, which exceeds proportions reported in prior literature [8,17–19]. This difference may reflect stricter implantation criteria, a higher baseline burden of conduction disease, or variations in how pacing dependency was defined across studies. In the present analysis, dependency was defined as ≥ 1 % ventricular pacing to capture both intermittent and continuous pacing needs, thereby reflecting any persistent conduction abnormality requiring pacing support. However, this inclusive threshold may also include patients with minimal pacing activity who are not truly dependent in clinical terms. Conversely, 44 % of PPM recipients exhibited no relevant pacing at follow-up, suggesting that a notable proportion of implantations may have been avoidable. Given the known association between PPM placement and prolonged hospitalization, increased procedural risks, and elevated long-term costs [32], developing accurate predictive models for true dependency is essential to optimize clinical decision-making.

Prosthesis oversizing, calcification below the LCC, and pre-existing RBBB emerged as independent predictors of pacing dependency—findings consistent with prior studies linking these factors to post-TAVR conduction disturbances [6,8,15,16,31]. These parameters likely represent surrogate markers for mechanical trauma to the atrioventricular conduction system, which is anatomically adjacent to the membranous septum and highly susceptible to compression during valve deployment [6]. In contrast to findings from self-expandable valve cohorts—such as the study by Ruiz-Hernandez et al. [19], which reported an association between female sex and pacing dependency—sex was not a significant predictor in our SAPIEN 3 cohort. This discrepancy may reflect differences in patient selection, valve type, or cohort characteristics, and highlights the importance of validating predictors in prosthesis-specific populations.

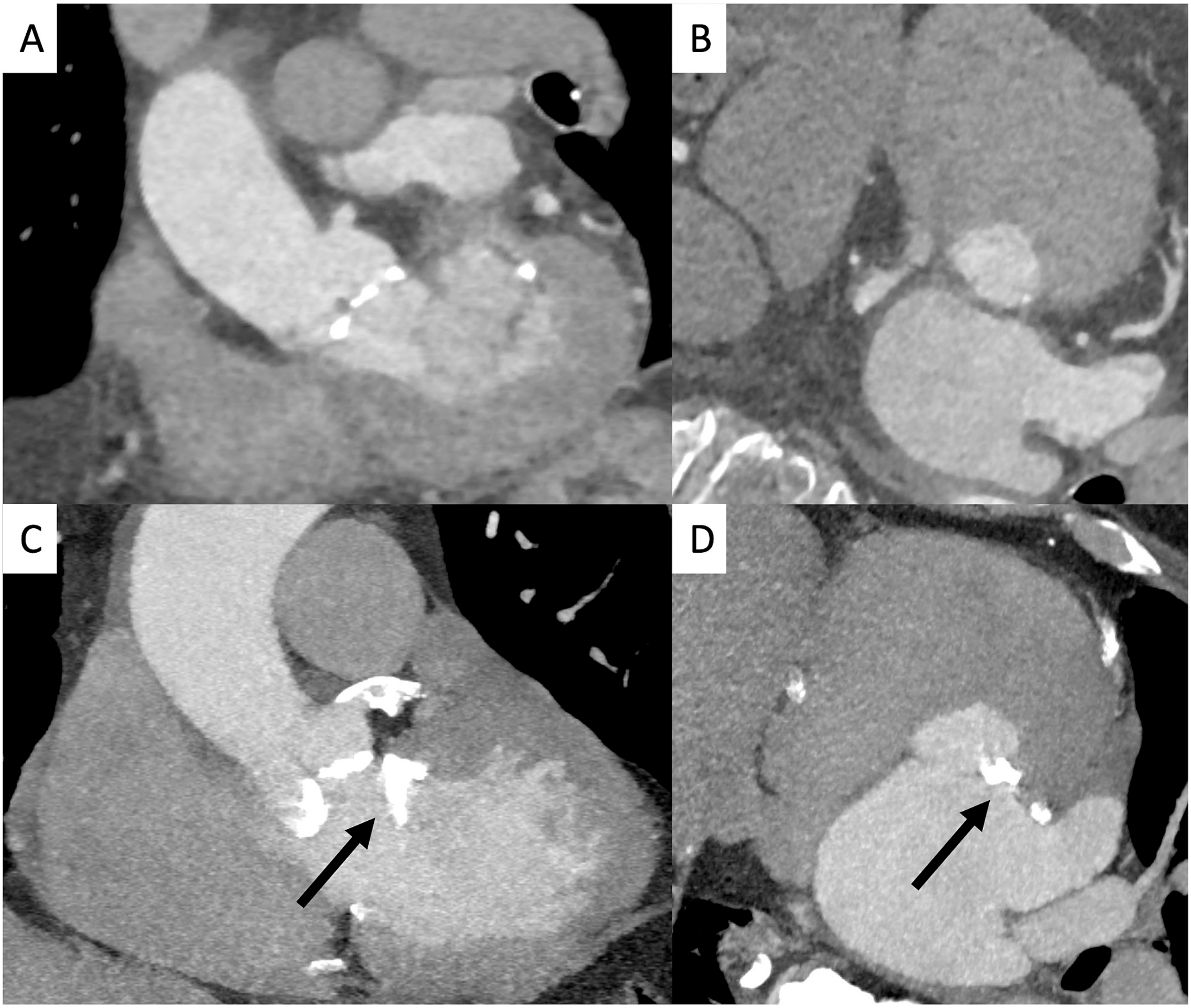

Fig. 3. Illustrative CT angiography examples of calcification below the left coronary cusp (LCC) as a significant predictor of pacemaker dependency after transcatheter aortic valve replacement (TAVR). Panels A and C show coronal views of the left ventricular outflow tract (LVOT), and panels B and D show corresponding axial reconstructions. A, B: Ninety-one-year-old female patient (non–pacemaker dependent) with no calcification below the LCC. C, D: Eighty-seven-year-old male patient (pacemaker dependent) with 345 mm^3 of calcification below the LCC (black arrows).

As transcatheter valve therapies continue to expand into lower-risk and younger populations, the clinical stakes of unnecessary PPM implantation grow increasingly relevant [10,14]. Although our model demonstrated high sensitivity (93 %), its lower specificity (47 %) limits immediate clinical applicability, as it may overestimate the risk of dependency in some patients. Nevertheless, this trade-off prioritizes the identification of truly pacing-dependent individuals, where missed detection could have serious clinical consequences. Future refinement and external validation in prospective, multicenter cohorts—ideally incorporating procedural and electrophysiological variables or advanced computational approaches such as artificial intelligence applied to imaging and rhythm data—may improve model specificity and overall predictive accuracy [3]. Additionally, observational strategies like delayed pacing or extended telemetry monitoring could help identify patients at low risk of dependency and avoid premature device implantation without compromising safety [17,18]. These advances may ultimately support more personalized and resource-conscious care in contemporary TAVR practice.

4.1. Limitations

First, this retrospective, single-center study may limit external generalizability. Nonetheless, the large, homogeneous SAPIEN 3 cohort with standardized imaging and clinical protocols provided a robust foundation for internal model development and validation. However, although this cohort is comparatively large, the overall sample size remains modest, which may restrict statistical power for some subgroup analyses. Second, CT measurements were performed in consensus by two experienced readers, although inter-reader variability was not formally assessed. Third, as noted above, PPM dependency was defined as $\geq$ 1 % ventricular pacing at follow-up, possibly including patients with minimal pacing requirements and not representing absolute dependency, and fourth, the limited model showed high sensitivity but low specificity, and is therefore not yet fully refined for excluding patients from PPM implantation. Fifth, coronary artery disease, including stenoses and calcium burden, was not systematically assessed. Further research should investigate whether coronary imaging adds predictive value for post-TAVR pacing dependency. Sixth, although the study

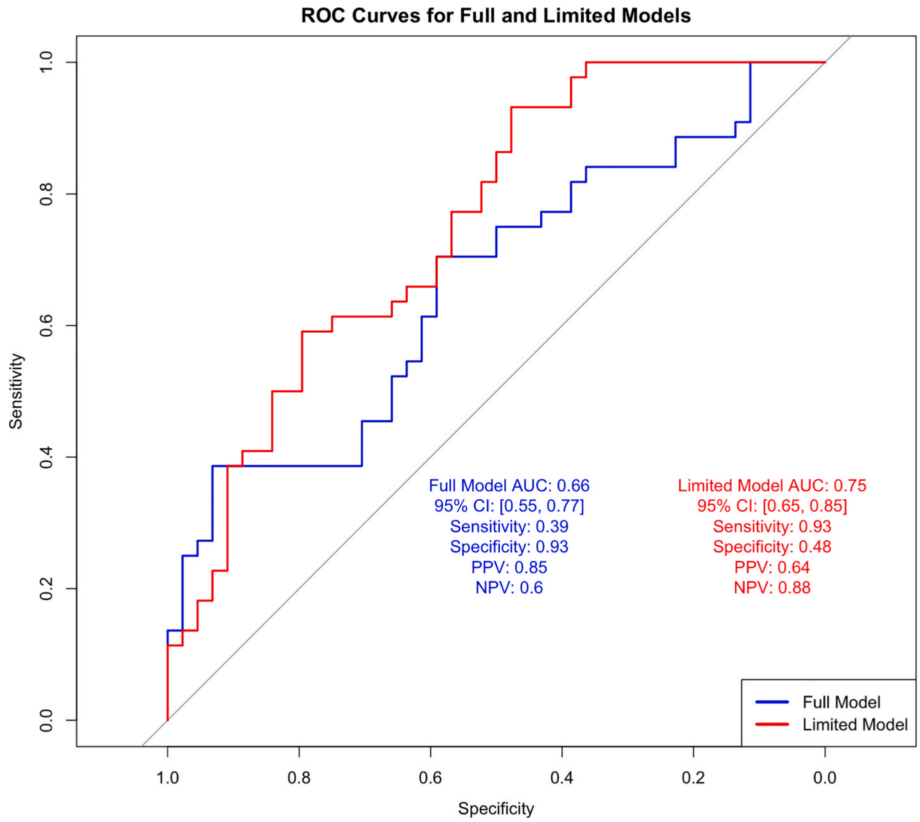

Fig. 4. ROC curves comparing full and limited prediction models for permanent pacemaker dependency after transcatheter aortic valve reconstruction (TAVR). Colored areas represent confidence intervals of prediction models. AUC = area under the curve, full model = prediction model with all variables, limited model = prediction model with selected variables through stepwise elimination, CI = confidence interval, NPV = negative predictive value, PPV = positive predictive value, ROC = receiver operator characteristic.

period (2012–2019) spanned seven years, the SAPIEN 3 valve design remained stable. Minor procedural refinements over time were not captured but are unlikely to have introduced substantial bias. Seventh, these findings apply specifically to transfemoral TAVR using balloon-expandable SAPIEN 3 valves and may not extrapolate to other valve types or access routes. Finally, It should be emphasized that this study included only patients who underwent permanent pacemaker implantation after TAVR. Therefore, the identified predictors apply specifically to pacemaker dependency within this subgroup and cannot be generalized to the overall TAVR population.

4.2. Conclusion

In this study, we applied a multivariate prediction model to a SAPIEN 3-only TAVR cohort to identify predictors of PPM dependency following post-TAVR device implantation. We identified three independent predictors: prosthesis oversizing, calcification below the LCC, and pre-existing RBBB. These findings may support improved risk stratification and help reduce unnecessary PPM implantations in future clinical practice.

CRediT authorship contribution statement

Konstantin Klambauer: Writing – review & editing, Writing – original draft, Visualization, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Konstantinos D Rizas:** Writing – review & editing, Methodology, Conceptualization. **Matthias P Fabritius:** Investigation, Data curation. **Nicola Fink:** Investigation, Data curation. **Verena Schäfer:** Investigation, Data curation. **Nabeel Mansour:** Writing – review & editing, Formal analysis. **Christina Utz:** Writing – review & editing, Software, Data curation. **Fabian Grathwohl:** Visualization, Software, Data curation. **Wolgang G Kunz:** Writing – review & editing, Supervision. **Judith Spiro:** Writing – review & editing, Supervision. **Jens Ricke:** Writing – review & editing, Supervision. **Adrian Curta:** Writing – review & editing, Supervision, Methodology. **Daniel Puhr-Westerheide:** Writing – review & editing, Supervision, Resources, Project administration, Methodology.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejrad.2025.112534.

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