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Identifying Clinical Predictors for Permanent Pacemaker Implantation: A Single-Center Risk Score Development

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Abstract

Background: Permanent pacemaker implantation carries considerable risks, yet tools for identifying high-risk individuals for primary prevention are lacking. We aimed to identify predictors and develop a clinical risk score to predict the need for permanent pacemaker implantation.

Methods: We conducted a retrospective case-control study of 800 participants (550 cases with pacemakers, 250 controls). Data on demographics, comorbidities, and ECG findings were extracted. Logistic regression was used to identify independent predictors and create a point-based risk score, whose performance was assessed using ROC analysis.

Results: Seven independent predictors were identified: chronic kidney disease (CKD), NYHA class III-IV heart failure, atrial fibrillation (AF), diabetes mellitus (DM), age >75, complete heart block (CHB), and temporary pacemaker use. A 9-point risk score successfully stratified patients into low, intermediate, and high-risk groups, demonstrating excellent discrimination (AUC 0.87).

Conclusion: This simple, point-based score is a practical tool for identifying patients at high risk for pacemaker implantation, potentially guiding closer monitoring and preventative strategies.

Keywords: Pacemaker implantation; risk stratification; risk score; bradyarrhythmia; conduction disorders; case-control study

Introduction

Permanent pacemaker implantation is the established definitive treatment for disorders of bradyarrhythmia and heart block ^[1]. The use of pacemakers in the current clinical practice is common, with recent reports indicating that more than 200,00 devices are implanted annually worldwide ^[2]. However, despite the advances in the technology and technique of pacemaker implantations, they are still associated with relatively considerable risk of complications, particularly directly after and within the first two months after the implantation ^[3]. Complication rates can rise up to 9% in post-pacemaker implantation patients ^[4].

Therefore, to avoid the burden of pace-maker implantation, primary prevention of conduction system disorders is a promising and attractive strategy. However, current literature and clinical practice both lack robust tools to identify high-risk patients, who might benefit from targeted risk-factors modification, which could help in reducing their need for future pacemakers ^[1, 2].

Previous studies identified advanced age, female sex, and underlying heart disease as potential risk factors for developing conduction cardiac disorders, such as high-grade atrioventricular block and symptomatic bradyarrhythmia's ^[5]. Other studies demonstrated the potential role of metabolic dysfunctions such as, hypothyroidism and renal dysfunction in the progressive slowing of the conduction system ^[6].

Nevertheless, a lack of integrative risk models combining relevant demographic, clinical and biochemical markers to predict the need for pacemaker implantation is currently present. Existing tools, such as the TAVI PACER score, only focus on the post-TAVI need for a pacemaker and thus cannot be generalized to other vulnerable populations ^[7].

Therefore, we conducted this retrospective study of patients who underwent pacemaker implantation at our local institute to identify the potential risk factors and develop a multivariable risk stratification model, with the ultimate aim to enable early identification of high-risk individuals.

Methodology

This was a retrospective, single-center, case-control study conducted at Mabbarra Masr ElKadema hospital by utilizing prospectively maintained medical records of patients at this facility. We retrospectively identified and extracted data for patients who underwent pacemaker implantation during the two-year period between January 2021 and December 2023. The protocol for the study was approved by the local Institutional Review Board (IRB) of the hospital. Due to the retrospective nature of the study, the need for informed consent was waived.

Eligibility Criteria

This study included a total of 800 participants; a case group comprising 550 patients who underwent pacemaker implantation for various clinical conditions, and a control group of 250 age- and gender- matched individuals without history of pacemaker implantation were included to enable a logistic regression analysis. In the case group, the inclusion criteria focused on patients who received a conventional pacemaker (dual-chamber [DDD] or single-chamber ventricular [VVI]) during the specified study period. Exclusion criteria for both groups included patients who were associated with a pre-existing clear and absolute indication for pacemaker implantation, presenting with acute coronary syndrome, documented history of dementia or major mental disorder that could have interfered with the clinical assessment. We also excluded patients with incomplete or missing essential data in the medical records.

Data Collection and Variables

Data were retrospectively extracted from the hospital's electronic medical records using a standardized data collection form designed for this study. Data collection was performed by trained researchers to ensure consistency and accuracy.

The following variables were collected for all participants:

- 1. Demographics:** Age, gender, and current smoking status.
- 2. Comorbidities and Clinical History:** Presence of hypertension (HTN), diabetes mellitus (DM), ischemic heart disease (IHD), chronic kidney disease (CKD), cerebrovascular disease, hypothyroidism, and New York Heart Association (NYHA) functional class for heart failure (HF).
- 3. ECG Findings:** Data from baseline 12-lead ECGs and available Holter monitoring reports were reviewed for findings such as complete heart block (CHB), atrial fibrillation (AF), sick sinus syndrome (SSS), sinus bradycardia, high-degree AV block, and bundle-branch blocks.
- 4. Procedural Variables (for cases only):** Type of pacemaker, use of a temporary pacemaker (TPM) prior to permanent implantation and use of low-dose AV-blocking agents.

Statistical Analysis

All statistical analyses were performed using SPSS software, Version 28.0 (IBM Corp., Armonk, NY). A two-sided p-value of ≤ 0.05 was considered statistically

significant. Descriptive statistics were used to summarize the baseline characteristics of the case and control groups. Continuous variables were presented as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequencies and percentages (n, %). To identify independent predictors of pacemaker implantation, a two-step logistic regression analysis was performed (univariate and multivariate analyses). The results of the regression analyses were reported as unadjusted and adjusted odds ratios (OR) with their corresponding 95% confidence intervals (CI), β coefficient and p-value. Based on the final multivariate model, a clinical risk-stratification score was developed, in which Integer points were assigned to each independent predictor by doubling and rounding its β -coefficient to the nearest integer, then the total score for each patient was calculated by summing the points for each factor present. Furthermore, the predictive performance for each risk score was assessed by calculating its sensitivity, specificity and then by performing a receiver operating characteristic (ROC) curve analysis and was reported as the area under the curve (AUC) with a 95% CI.

Results

This study included a total number of 800 participants (550 cases and 250 controls). Regarding the demographic data of the included cases, the average mean age was 76 years old, and approximately half of the patients (52%) aged more than 75 years old. Males were the slight majority (52%) and smoking was prevalent among 21% of the cohort. Analysis of the morbidities revealed that HTN was the most common (62%), followed by DM (29%), CKD (21%), hypothyroidism (10.4%) and cerebrovascular disease (9.7%). Among the cases included, the most commonly reported presenting complaint was presyncope or syncope, which was present in 41% of the sample. Additionally, 31% of the patients had a history of heart block, 29% had a history of coronary syndrome, 21% were heart failure with advanced stages and nearly 4.9% were associated with neuromuscular cardiomyopathy. Notably, the most common ECG finding in our analysis was CHB (31%), followed by AF (29%), SSS (21%), sinus bradycardia (21%) and high-degree AV block (19.5%). Contrary, the least common ECG findings were intermittent BBB (4.9%) and Holter PR prolongation (5.3%). Furthermore, among the 550 included cases who underwent pacemaker implantation, the most commonly used device was by far the DDD (72%), while VVI was used in 20% and CRT-P was used in 8% of the cases. Interestingly, approximately third of the cases received TPB before the procedure and low-dose AV-blocking agent usage was prevalent in 21% of the cases. Table 1 the control group (n=250) was age- and gender-matched to the cases and had a significantly lower prevalence of comorbidities, including HTN (30% vs. 62%) and DM (10% vs. 29%), and fewer major ECG abnormalities like CHB (5.2% vs. 31%). Full data are presented in Supplementary Table 1.

Our logistic regression model revealed that several variables were strong predictors of the outcome event (pacemaker implantation). Among them, the strongest predictor was CKD (OR 2.3, $p = 0.001$), followed by NYHA class III-IV (OR 2.6, $p < 0.001$), AF (OR 2.0, $p = 0.002$), DM (OR 1.9, $p = 0.006$), age >75 years (OR 1.7, $p = 0.018$), CHB (OR 1.8, $p = 0.021$), and use of a temporary pacemaker (OR 1.6, $p = 0.045$). On the other hand, other variables such as HTN,

smoking, female gender and LBBB did not remain independent predictors of pacemaker implantation in the multivariate analysis.

Based on the multivariate β -coefficients, a simple point-based risk score was constructed. NYHA class III-IV and CKD each received 2 points; DM, AF, CHB, age >75 years, and use of a temporary pacemaker each received 1 point. The total possible score ranged from 0 to 9. Table 3

When applied to the combined cohort of 800 patients (550 cases and 250 controls), the risk score stratified patients into low (0-2), intermediate (3-5), and high (≥ 6) risk categories. In the low-risk group, 22% experienced the event; in the intermediate-risk group, 78%; and in the high-risk group, 95%. The distribution of patients was 29% low risk, 32% intermediate risk, and 39% high risk. Furthermore, for identifying patients with elevated risk (≥ 3), our model showed a sensitivity of 91% and specificity of 72% (AUC=0.801), indicating its excellent ability for screening and identifying individuals who are elevated risk. For identifying patients with high risk (≥ 6), our model showed a sensitivity of 55% and specificity of 94% (AUC=0.762), indicating its ability in confirming high-risk status. Finally, the overall model performance demonstrated excellent performance with AUC of 0.87 (95% CI, 0.82-0.91). Table 4, Figure 1-3

Discussion

In this study we demonstrated that a combination of demographic, clinical and procedural factors can reliably predict and stratify patient's risk of developing a need for future pacemaker implantation. In this model, we identified the following variables as strong predictors of pacemaker implantation: old age (>75 years), CKD, AF, DM, CHB, HF with NYHA class III-IV and use of a temporary pacemaker.

In consistent with our findings, a nationwide cohort study of 155,934 patients diagnosed with new onset AF demonstrated that old age (>80 years) was alone associated with an approximately 4-fold increase in the risk of pacemaker implantation compared to younger patients [8]. Another study reported that the cumulative incidence of pacemaker implantation significantly increased from 0.03 at age 50 to 0.27 at age 68 in the general population, indicating a potential age-related increase in the need for pacemaker [9]. This potential role of old age could be related to the age-related degeneration of the cardiac conduction system, leading to progressive bradyarrhythmias and conductive dysfunctions.

We observed that CKD demonstrated the strongest predictive ability among all of the analyzed variables. Previous studies stated that CKD has the ability to accelerate structural and electrical remodeling of the heart, leading to higher risks of conduction system disease and bradyarrhythmias. This could be related to the electrolyte disturbances, chronic inflammation and uremia that are typically associated with CKD [10]. In accordance with our findings, Mitacchione *et al.* reported that patients with CKD were associated with a statistically significant higher incidence of bradyarrhythmias and 1.8-fold increase in the odds of requiring permanent pacemaker implantation [11].

We also observed in our analysis that both AF and NYHA class III/IV HF were strong predictors for the need for a

pacemaker. Miyazaki *et al.* reported in their analysis of 128 patients with unexplained syncope, that paroxysmal AF was a significant independent predictor of pacemaker implantation (HR 2.54) [12]. Following the same trend, Barrett *et al.* investigated 362 AF patients and found that the presence of HF caused a 2.72-fold increase in the odds of requiring pacemaker implantation for bradycardia compared to patients without HF [13]. Generally, we can conclude that AF increases the risk of pacemaker requirement by causing atrial remodeling and progressive conduction system deterioration. On the other hand, HF-related cardiac dysfunction substantially increases pacemaker dependency risk.

In accordance with our findings, Rautio *et al.* reported in their nationwide registry study of 14,822 patients with type 2 diabetes that DM was associated with a 1.6-fold increase in the risk of permanent pacemaker implantation [14]. Similar findings were also observed by Fauchier *et al.* in both type 1 and type 2 DM [15]. The association between DM and pacemaker could be related to the multitude of pathologies that are related to hyperglycemic status, including diabetic cardiomyopathy, accelerated coronary atherosclerosis, myocardial fibrosis, and metabolic disturbances [14, 15].

Unlike prior risk scores limited to specific subpopulations, such as post-transcatheter aortic valve replacement patients, our model integrates readily available variables applicable across a broader clinical spectrum. Our model demonstrated that the risk score is a viable screening tool, evident by its high sensitivity (91%) for detecting patients at elevated risk (score ≥ 3). Moreover, the high specificity (94%) at the upper threshold (score ≥ 6) supports its role as a confirmatory test for high-risk patients that could benefit from close monitoring. Interestingly, our choice to stratify patients into low (0-2), intermediate (3-5), and high (≥ 6) risk groups reflects a clinically meaningful grading, as in our study we observed that only 22% of the patients in the low-risk group were indicated to receive pacemaker implantation compared to 78% and 95% in the intermediate and high-risk groups, respectively. Thus, we can conclude that our suggested model and stratification scores could be an efficient tool in the decision-making process regarding the timing and need for device implantation.

While this study has multiple strength points, such as the inclusion of a large sample size of 800 participant, alongside its rigorous case-control methodology, it still had some limitations that should be considered. First, the retrospective and observational nature of the study introduces potential spaces for selection and confounding biases. Second, the exclusion of patients presented with acute coronary syndrome and those with pre-existing absolute indications could limit the generalizability of our findings to these populations. Third, the single center setting of the study and the inclusion of mainly elderly cohort might also limit the generalizability of the findings to younger or diverse subgroups of patients. Therefore, we recommend future efforts to focus on prospective multi-center studies with a more broad-spectrum eligibility criterion. Also, future studies should investigate the validity of our findings by replicating our results and adding to them, by assessing the impact on clinical outcomes, such as reduction in mortality and morbidity.

Table 1: Characteristics of the included cases (n=550)

Variable	Value
Demographics	
Age, mean $\pm$ SD (years)	76 $\pm$ 11
Age > 75 years	283 (52%)
Female	267 (48%)
Current smoker	114 (21%)
Comorbidities	
Hypertension	340 (62%)
Diabetes mellitus	170 (31%)
Ischemic heart disease	160 (29%)
Chronic kidney disease (eGFR < 60 mL/min)	114 (21%)
Cerebrovascular disease	53 (9.7%)
Hypothyroidism	57 (10.4%)
Clinical History	
Presyncope/syncope	226 (41%)
History of heart block	170 (31%)
Chronic coronary syndrome (CCS I-IV)	160 (29%)
NYHA class III-IV	114 (21%)
Neuromuscular cardiomyopathy	27 (4.9%)
ECG Findings	
Left bundle-branch block (LBBB)	53 (9.7%)
Bifascicular block	57 (10.4%)
Complete heart block (CHB)	170 (31%)
High-degree AV block (HB)	107 (19.5%)
Sick sinus syndrome	114 (21%)
Atrial fibrillation	160 (29%)
Sinus bradycardia	114 (21%)
Holter PR prolongation	29 (5.3%)
Intermittent BBB (Holter/stress)	27 (4.9%)
Chronotropic incompetence	53 (9.7%)
Procedural Variables	
Pacemaker type (DDD)	396 (72%)
Pacemaker type (VVI)	110 (20%)
Pacemaker type (CRT-P)	44 (8%)
Use of temporary pacemaker (TPM)	170 (31%)
Low-dose AV-blocking agent use	114 (21%)

Data is presented as either mean $\pm$ SD or frequency (percentage), NYHA; new york heart classification, DDD; dual chamber pacing/ dual chamber sensing/ dual chamber response, VVI; ventricular pacing/ ventricular sensing, inhibited response, CRT-P; cardiac resynchronization therapy pacemaker.

Table 2: Univariate and Multivariate Logistic Regression Analysis

Variable	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	β -Coefficient	p-value
Age > 75 years	2.1 (1.4-3.1)	1.7 (1.1-2.6)	0.53	0.018*
CKD	2.8 (1.8-4.3)	2.3 (1.4-3.6)	0.83	0.001*
DM	2.3 (1.5-3.5)	1.9 (1.2-3.0)	0.64	0.006*
NYHA class III-IV	3.2 (2.0-5.1)	2.6 (1.6-4.2)	0.96	<0.001*
AF	2.5 (1.7-3.7)	2.0 (1.3-3.1)	0.69	0.002*
CHB	2.0 (1.3-3.0)	1.8 (1.1-2.9)	0.59	0.021*
Use of temporary pacemaker	2.2 (1.5-3.3)	1.6 (1.0-2.7)	0.47	0.045*
Hypertension	1.4 (0.9-2.1)	1.1 (0.7-1.7)	0.1	0.680
Current smoker	1.3 (0.8-2.0)	1.2 (0.7-2.0)	0.18	0.510
Female	1.2 (0.8-1.8)	1.0 (0.7-1.5)	0	0.990
LBBB	1.5 (0.9-2.7)	1.2 (0.7-2.2)	0.18	0.530

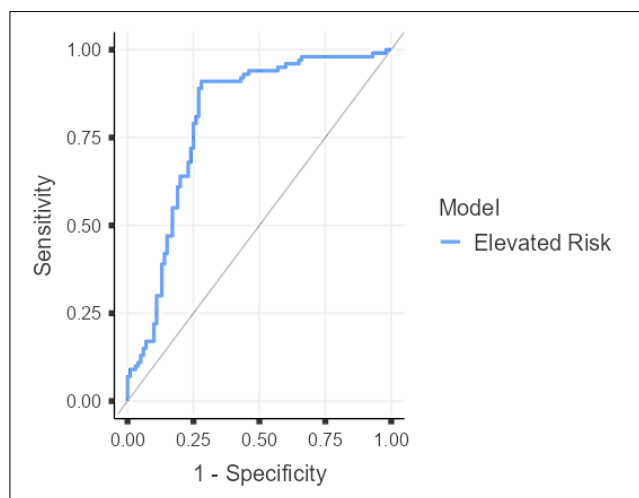
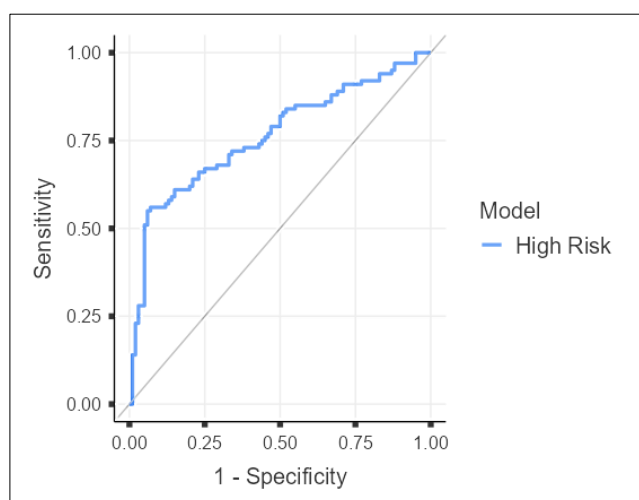
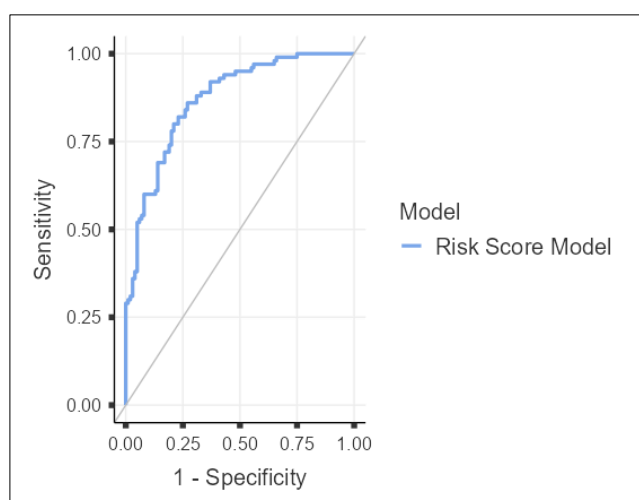
CKD; chronic kidney disease, DM; diabetes mellitus CHB; complete heart block, AF; atrial fibrillation, LBBB; left bundle branch block, OR; odds ratio, *, statistically significant ≤ 0.05 .

Table 3: Clinical Risk-Stratification Score

Risk Factor	Assigned Points
NYHA class III-IV	2
Chronic kidney disease	2
Diabetes mellitus	1
Atrial fibrillation	1
Complete heart block	1
Age > 75 years	1
Use of temporary pacemaker	1
Total Score	0-9

Table 4: Performance of the Risk Score

Risk Category	Score Range	Cases (N=550)	Controls (N=250)	Total N (%)	Event Rate (%)
Low	0-2	50	180	230 (29%)	22%
Intermediate	3-5	200	55	255 (32%)	78%
High	≥6	300	15	315 (39%)	95%
Total		550	250	800 (100%)	

**Fig 1:** ROC curve of Elevated Risk Score**Fig 2:** ROC curve of High Risk Score**Fig 3:** ROC curve of Overall Risk Score Model

Conclusion

This study developed a simple risk score using seven predictors (age, CKD, HF, AF, DM, CHB, TPM use) that accurately stratifies patients for future pacemaker need. The model showed excellent performance, serving as a practical tool for early identification and management of high-risk individuals.

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Author contribution

Authors contributed equally to the study.

Conflicts of Interest

No conflicts of interest

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