

Peri and Post-Procedural Complications of Permanent Pacemaker Implantation: Experience from an Indian Tertiary Care Centre

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Abstract

Background: Permanent Pacemaker Implantation (PPI) is a standard intervention for symptomatic bradyarrhythmias. Although the procedure is generally safe, peri- and post-procedural complications may affect outcomes, especially in patients with comorbidities.

Objective: To evaluate the incidence, spectrum and clinical impact of complications associated with PPI in a tertiary care setting.

Methods: This retrospective study included 375 patients who underwent PPI between [March 2022-March 2025] at a tertiary care centre. Data regarding patient demographics, comorbidities, procedural details and peri/post-procedural complications were extracted from institutional records. Outcomes were analysed using descriptive statistics.

Results: Of 375 patients, 363 (96.8%) had an uneventful recovery. Complications were observed in 12 patients (3.2%). The most frequent was pacemaker pocket infection (n=4), followed by pneumothorax (n=2), pericardial effusion (n=2), atrial fibrillation (n=1), ventricular fibrillation (n=1), lead displacement (n=1) and cardiorespiratory arrest (n=1). No re-implantation procedures were required and no procedure-related mortality was reported. All complications were managed successfully with appropriate medical or minor interventional measures.

Conclusion: PPI remains a safe and effective intervention with a low complication rate in routine clinical practice. Most complications were non-fatal and manageable. These findings highlight the need for meticulous technique, careful patient monitoring and early identification of adverse events to maintain optimal outcomes.

Keywords: Permanent Pacemaker; Complications; Bradyarrhythmia; Cardiac Device Therapy; Post-Procedure Safety

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Introduction

Permanent Pacemaker Implantation (PPI) is an established and widely performed procedure for the management of symptomatic bradyarrhythmias, including complete heart block, sick sinus syndrome and trifascicular block [1,2]. The advent of transvenous pacing systems and advancements in device technology have significantly improved the safety and efficacy of this life-saving intervention [3]. In India, with the increasing burden of cardiovascular diseases and an aging population, the number of patients requiring PPI has steadily risen [4].

Despite its minimally invasive nature, PPI is not devoid of complications. Adverse events may arise during or after the procedure and can include lead dislodgement, pocket hematoma, pneumothorax, infections and arrhythmias [5,6]. The incidence of such complications varies across centres and is influenced by operator experience, patient comorbidities and the type of device implanted [7]. Although most complications are minor and manageable, some may lead to prolonged hospitalisation, device

revision or even mortality if not promptly addressed [8]. There is a paucity of comprehensive Indian data evaluating the real-world complication rates associated with PPI, especially in the context of diverse patient populations and variable healthcare infrastructure. This study aims to assess the incidence, types and outcomes of peri- and post-procedural complications following permanent pacemaker implantation in a tertiary care setting. The findings are intended to guide clinical practice, enhance procedural safety and inform strategies to minimize risk.

Methodology

Study Design and Setting

This retrospective observational study was conducted at a tertiary care teaching hospital in India. The study included patients who underwent Permanent Pacemaker Implantation (PPI) from March 2022 to March 2025.

Study Population

All adult patients (≥ 18 years) who underwent PPI for symptomatic bradyarrhythmias, including Complete Heart Block (CHB), Sick Sinus Syndrome (SSS), trifascicular block and symptomatic Left Bundle Branch Block (LBBB), were included. Patients undergoing temporary pacing were excluded.

Data Collection

Data were extracted from hospital records, including inpatient charts, procedure logs and electronic discharge summaries. Variables recorded included age, sex, comorbidities (diabetes mellitus, hypertension, dyslipidemia, smoking status, thyroid disorders), prior cardiac interventions (e.g., CABG, PTCA, temporary pacing), device type (VVIR, DDDR), indication for implantation and procedural complications.

Outcome Measures

The primary outcome was the incidence and type of peri- and post-procedural complications. Complications were categorized as:

- Peri-procedural: occurring within 24-48 hours (e.g., pneumothorax, lead displacement, pocket hematoma)
- Post-procedural: occurring within 30 days (e.g., infection, arrhythmias, pericardial effusion)

Secondary outcomes included the need for re-implantation, in-hospital mortality and early follow-up status.

Statistical Analysis

Data were analyzed using descriptive statistics. Categorical variables were expressed as frequencies and percentages. Complication rates were calculated as proportions of the total number of procedures. Analyses were performed using Microsoft Excel and cross-verified by manual tabulation.

Results

A total of 375 patients underwent permanent pacemaker implantation (PPI) during the study period. The mean age of the cohort was 64.4 years and the majority were male (282 males [75.2%], 91 females [24.3%]). The most common device type implanted was dual-chamber pacemakers (DDDR), including MRI-safe variants. The most frequently recorded device description was "PPI (DDDR, MRI SAFE)", accounting for 232 implants, followed PPI VVIR (n=31).

Out of 375 patients, 363 (96.8%) had an uneventful post-procedural course. A total of 12 patients (3.2%) experienced complications, which included:

- Pacemaker pocket infection (n=4)
- Pneumothorax (n=2)
- Ventricular fibrillation (n=1)
- Cardiorespiratory arrest (n=1)
- Atrial fibrillation (n=1)
- Pericardial effusion (n=1)
- Lead displacement (n=1)
- Massive pericardial effusion post TPI lead removal (n=1)

All complications were managed conservatively or with minor intervention. No patients required re-implantation and no mortality was recorded during hospitalisation or follow-up.

Follow-up data were available for 356 patients (94.9%), with 16 patients lost to follow-up and 3 marked ambiguously. These results reflect a high procedural success rate and a low rate of adverse outcomes.

Association Analysis: Patient Characteristics and Complications

We compared patient characteristics between those with complications (n=12) and without complications (n=363) after permanent pacemaker implantation. Here's a summary of the findings (Table 1):

Variable	No Complications (Mean ± SD)	Complications (Mean ± SD)	p-value	Interpretation
Age (years)	64.4 ± 14.3	65.3 ± 14.9	0.8388	Similar age distribution
Female (%)	24.2%	23.1%	1.0000	No gender difference
Diabetes (%)	40.7%	7.7%	0.0187	Lower in complications group
Hypertension	51.4%	30.8%	0.1669	Lower trend in complications group
Smoker (%)	3.4%	7.7%	0.3776	Slightly higher in complications
Thyroid (%)	0.8%	0.0%	1.0000	Very low overall

Table 1: Patient characteristics and complications.

We tested for statistically significant differences in patient characteristics between those with and without complications using Fisher's exact test (for categorical variables) and independent t-test (for age). Age and gender were not significantly different between groups. Diabetes Mellitus (DM) showed a statistically significant inverse association with complications ($p = 0.0187$). Interestingly, fewer patients with diabetes developed complications. Smoking showed a slightly higher rate in the complications group (7.7% vs 3.4%), but numbers are small. Thyroid disorders were rare and not present in any patient with complications.

Bar chart comparing patient characteristics between those with and without complications (Fig. 1).

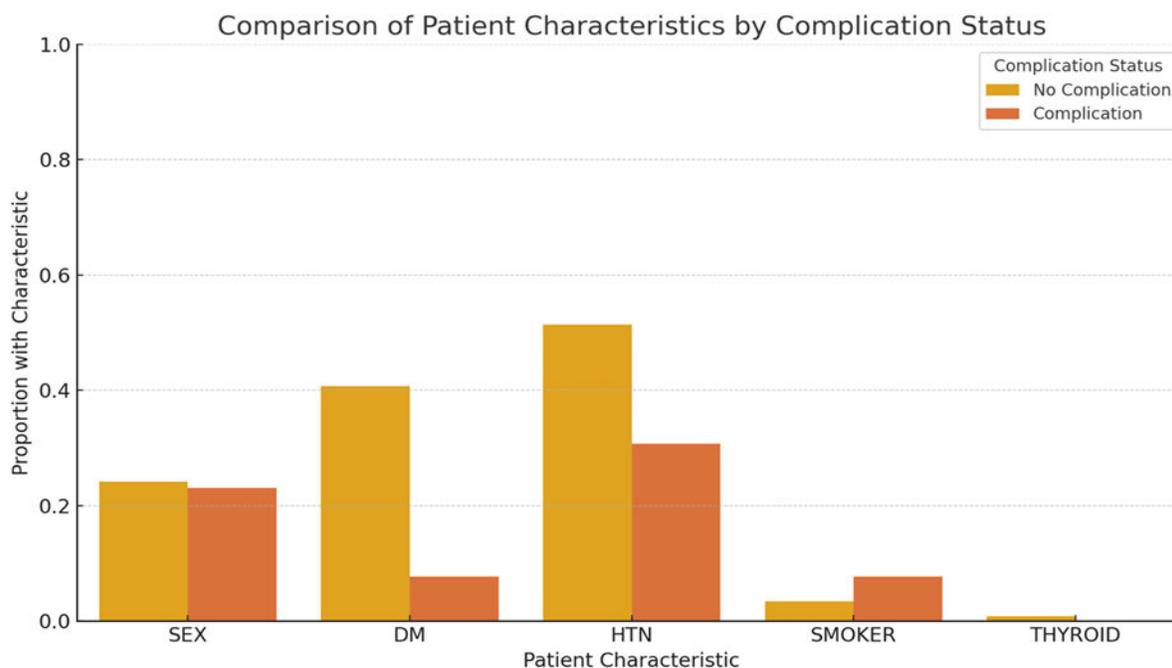


Figure 1. Comparing patient characteristics between those with and without complications.

Discussion

This retrospective study evaluated the peri- and post-procedural complications of Permanent Pacemaker Implantation (PPI) in a tertiary care setting and explored associations between patient characteristics and complication risk. The overall complication

rate was low (3.2%), consistent with prior international studies, which report rates ranging from 3% to 7% depending on patient population and procedural complexity [3,5,8].

The most commonly observed complications were pocket infections and pneumothorax, each of which required prompt but non-surgical intervention. Other complications, such as lead displacement, pericardial effusion and arrhythmias, were rare and managed conservatively. Importantly, there were no re-implantation procedures or mortality events recorded, highlighting the safety and procedural success at our centre.

Interestingly, diabetes mellitus was significantly less common in patients who experienced complications (7.7% vs 40.7%, $p = 0.0187$). This finding contrasts with existing literature, where diabetes is often considered a risk factor for wound infections and delayed healing [6,9]. This inverse association may be due to sample variation, tighter glycaemic control or closer monitoring in diabetic patients and warrants further investigation in larger, multicentric datasets.

Other variables such as age, sex, hypertension, thyroid disorders and smoking did not show statistically significant associations with complications. These findings are in line with other studies suggesting that procedural and anatomical factors (e.g., venous access, lead positioning) may play a more direct role in complication risk than baseline comorbidities alone [10]. The high follow-up rate (94.9%) and zero procedure-related mortality further affirm the quality of care delivered.

Limitations

This study has several limitations. First, its retrospective and single-centre design may introduce selection and documentation biases, limiting the generalizability of findings to other populations and settings. Second, complications were identified from hospital records, which may underreport minor or delayed adverse events, particularly those occurring after discharge or managed elsewhere. Third, the relatively small number of complication cases ($n=12$) limited the statistical power for detecting associations with baseline variables and precluded multivariate regression analysis.

Finally, the study did not include long-term follow-up, so delayed complications such as late lead dislodgement, device erosion or chronic infections could not be assessed. Future prospective, multicentric studies with standardised data collection and long-term follow-up are recommended to validate and expand upon these findings.

Conclusion

Permanent Pacemaker Implantation (PPI) is a safe and effective intervention for the management of symptomatic bradyarrhythmias, with a low incidence of peri- and post-procedural complications. In this study, the overall complication rate was 3.2% and all adverse events were managed successfully without the need for re-implantation or resulting mortality. While most patient characteristics were not significantly associated with complications, an unexpected inverse association with diabetes mellitus was observed, warranting further investigation. These findings reinforce the importance of meticulous procedural technique, patient monitoring and early complication detection to ensure optimal outcomes.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Data Availability Statement

Not applicable.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Informed Consent Statement

Informed consent was taken for this study.

Authors' Contributions

All authors contributed equally to this paper.

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