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Original Article

Assessing the Effectiveness of the PADIT Score in Predicting CIED Infections: Insights from a Tertiary Care Center

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Abstract

Objectives: To assess the utility of the PADIT score in identifying patients at higher risk of developing CIED-related infections within a six-month follow-up period at a tertiary academic medical center.

Methodology: This prospective, descriptive, single-center study enrolled 168 consecutive adult patients who underwent pacemaker, implantable cardioverter-defibrillator (ICD), or cardiac resynchronization therapy defibrillator/pacemaker (CRT-D/CRT-P) placement or generator renewal between June and December 2023 at a tertiary medical center in Pakistan. The primary outcome was hospital admission due to confirmed CIED or pocket infection within six months post-implantation.

Results: The study analyzed data from 168 patients (mean age: 64.6 ± 14.43 years; 50.7% male, 49.3% female), revealing a generally low prevalence of pre-existing risk factors. The mean PADIT (Prevention of Arrhythmia Device Infection Trial) score was 1.18 ± 1.65, indicating a predominantly low-risk profile. Three patients (1.7%) developed CIED infections, and only one of these cases was classified as high-risk with a PADIT score >7. The score demonstrated poor predictive performance, with a C-statistic of 0.413 (95% CI).

Conclusion: The PADIT score did not effectively identify patients at increased risk of CIED-related infections within a six-month follow-up in this single-center prospective study. Further research may be needed to explore additional risk factors and improve risk stratification models for this patient population.

Keywords: Cardiac Implantable Electronic Devices, Infection Control, Prevention of Arrhythmia Device Infection Trial (PADIT), Implantable Cardioverter Defibrillators, Cardiac Resynchronization Therapy

INTRODUCTION

Healthcare-associated infections of cardiac implantable electronic devices (CIEDs) remain a significant challenge in modern clinical practice. These infections, much like those seen with any implanted foreign object, are most likely to occur within the first year post-implantation, with reported rates ranging between 1% and 2% [1-4]. Beyond their immediate health implications, CIED infections contribute to a marked increase in healthcare costs, morbidity, and even mortality [5-7]. Treatment often necessitates prolonged hospitalization, extended courses of intravenous antibiotics, and in severe cases, complete device removal and eventual re-implantation [5,6].

Mitigating the economic and clinical impact of CIED infections calls for a twofold strategy: robust infection prevention protocols and precise identification of high-risk individuals. The PADIT (Prevention of Arrhythmia Device Infection Trial) study explored the effectiveness of different antibiotic regimens. It compared a standard prophylactic pre-procedural cefazolin regimen against an intensive regimen incorporating vancomycin, bacitracin, and oral cephalexin. Although this intensive protocol led to a 23% reduction in infection-related hospitalizations, the result was not statistically significant [2].

Numerous studies (approximately 50-60) have sought to identify risk factors associated with CIED-related infections, giving rise to several risk assessment tools. Each tool integrates a variety of risk factors, making them user-friendly and easy to calculate. Among these, the PADIT score stands out for its validation in multiple studies, though it has demonstrated lower predictive accuracy compared to other models like RI-AIAC, SHARIFF, PACE DRAP, and KOLEK.

Prevention strategies are indispensable in reducing CIED infection rates. The pivotal WRAP-IT trial (World-wide Randomized Antibiotic Envelope Infection Prevention) in 2019 examined the effectiveness of an absorbable, biocompatible envelope designed to minimize infection risk [8]. This envelope, which provides a sustained release of antibiotics, achieved a significant 40% reduction in severe CIED infection risk among high-risk patients, especially during re-implantations or initial CRT-D placements [9]. Further cost-effectiveness analyses have reinforced the utility of this approach, with the European Heart Rhythm Association (EHRA) endorsing the use of antibacterial envelopes for high-risk patients [10].

Risk stratification tools, such as the PADIT score, have gained traction as practical methods for predicting CIED infection risk. The PADIT score incorporates five well-established clinical and procedural risk factors [5,10]. This study aims to evaluate the utility of the PADIT score in identifying patients at risk for device-related infections over a six-month post-implantation period in an outpatient setting.

In our healthcare context, identifying high-risk patients is paramount. Implementing targeted infection prevention measures, including the strategic use of prophylactic antibiotics, diligent wound care through routine follow-up, and extended intravenous antibiotic coverage for selected cases, could optimize resource utilization. Given the limitations inherent in our developing country's healthcare infrastructure, emphasizing a high-risk, preventive approach is crucial for maximizing the efficiency and impact of our available healthcare resources.

METHODOLOGY

Study Design: This was a prospective cohort study conducted from June to December 2023. The study aimed to evaluate the risk of hospitalization due to cardiac implantable electronic device (CIED) infections within one year, using the PADIT (Prevention of Arrhythmia Device Infection Trial) score as the primary assessment tool. A structured approach ensured standardized data collection and analysis across all participants.

Ethics: The study was approved by the Institutional Ethical Review Board of the Rawalpindi Institute of Cardiology (RIC), Rawalpindi, Pakistan (Approval No: RIC/RERC/76/23). Due to the non-invasive and observational nature of the research, participants faced no additional risk beyond their routine medical care. All patients provided written informed consent before enrollment.

Setting: The research was conducted in the Department of Electrophysiology at RIC, a leading cardiac care center in Rawalpindi, Pakistan. This setting was chosen for its high volume of CIED

procedures, ensuring a diverse and comprehensive patient sample.

Participants: A total of 168 consecutive adult patients undergoing CIED implantation were recruited. Eligible devices included pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy devices (CRT-Ds/CRT-Ps). Inclusion criteria comprised adults (≥18 years) undergoing primary or secondary CIED implantation during the study period. Exclusion criteria involved patients with incomplete medical records or those unwilling to provide consent.

Variables: The primary exposure variable was the PADIT score, which integrates five key risk factors influencing CIED infection susceptibility. These factors include the number of prior CIED implantation procedures, patient age, and impaired renal function defined by a glomerular filtration rate (GFR) of less than 30 mL/min. Immunocompromised status was evaluated based on the PADIT trial criteria, such as current use of immunosuppressive treatments or advanced immune-suppressing conditions.

Data Sources/Measurement: The PADIT score, ranging from 0 to 13, was calculated using an online tool (https://padit-calculator.ca) to ensure accurate and standardized assessment. Patients were classified into low (≤4 points), intermediate (5-6 points), or high (≥7 points) risk categories [5,10]. Clinical endpoints were identified based on the 2019 International CIED Infection criteria [11], and the primary outcome was hospitalization for CIED infection within one year. Follow-up data were collected at both six months and one year to account for the time constraints and to provide an interim analysis.

Bias: To minimize selection bias, consecutive patients meeting the inclusion criteria were enrolled. Information bias was reduced by using the online PADIT calculator for consistent scoring and standardized diagnostic criteria for CIED infections. Efforts were also made to mitigate measurement bias by employing rigorous data collection protocols.

Study Size: The sample size of 168 patients was determined based on the expected incidence of CIED infections and the feasibility of patient recruitment within the study period. This number was deemed sufficient to provide reliable risk estimates across the different PADIT score categories.

Quantitative Variables: Key quantitative variables included the PADIT score and patient demographics such as age, renal function (GFR), and the number of prior CIED procedures. Continuous variables were assessed for normality to guide appropriate statistical methods. Additionally, categorical data such as immunocompromised status were analyzed using relevant descriptive statistics.

Statistical Methods: Data analysis was conducted using SPSS software version 27. Continuous variables were summarized as mean ± standard deviation (SD) for normally distributed data or as median with interquartile range (IQR) for non-normally distributed data. Categorical variables were presented as frequencies and percentages. Comparative analyses were performed to explore associations between PADIT score categories and infection outcomes. Significance levels and confidence intervals were reported where applicable to provide robust statistical insights.

RESULTS

Participants: The study was conducted from June to December 2023 using non-probability consecutive sampling. A total of 168 patients undergoing cardiac implantable electronic device (CIED) procedures were included. The mean age of participants was 64.66 ± 14.43 years, with a balanced gender distribution of 50.7% males and 49.3% females. The demographic and clinical characteristics of the study population are summarized in Table 1. All participants were followed for a duration of six months to assess outcomes.

Descriptive Data: The distribution of CIED procedures performed is detailed in Figure 1. The most frequently conducted procedure was the DDDR pacemaker (new implant), which accounted for 47.3% of the total. This was followed by VVIR pacemakers (new implant) at 36%. Less common procedures included CRT-P (2.7%), VVIR generator replacements (2.7%), ICD single chamber implants with lead adjustments (2.7%), and rare cases like His bundle pacing or DDDR generator replacements, each comprising less than 1.3% of the total.

Table 1: Characteristics of the Patients Enrolled in the Study

Variables	Summary
Age (years); Mean ± SD	64.66 ± 14.43
Gender	
Male	76 (50.7)
Female	74 (49.3)
ECG Diagnosis	
None	2 (1.3)
Acquired Complete Heart Block (CHB)	130 (86.7)
Sick Sinus Node (SND)	2 (1.3)
Trifascicular Block	2 (1.3)
Left Bundle Branch Block (LBBB) QRS > 150	4 (2.7)
Ventricular Tachycardia	3 (2.0)
Congenital Complete Heart Block (CHB)	1 (0.7)
Secondary Prevention of Sudden Cardiac Death (SCD)	1 (0.7)
Mobitz II Atrioventricular Block (AVB)	4 (2.7)
LVEF; Mean ± SD	52.41 ± 11.38
PADIT Score; Mean ± SD	1.18 ± 1.65
PADIT Categories	
Low Risk	141 (94.0)
Intermediate Risk	6 (4.0)
High Risk	3 (2.0)
Rate of Hospitalization; Mean ± SD	0.46 ± 0.44

LVEF: Left Ventricular Ejection Fraction, PADIT: Prevention of Arrhythmia Device Infection Trial, SD: standard deviation

The clinical diagnoses at the time of device implantation included complete heart block (CHB) in 86.7% of cases, sinus node dysfunction (1.3%), trifascicular block (1.3%), and other conditions like Mobitz II atrioventricular block and ventricular tachycardia. Left ventricular ejection fraction (LVEF) had a mean of 52.41 ± 11.38. The PADIT score, a predictor of infection risk, averaged 1.18 ± 1.65, with 94.0% of patients classified as low risk, 4.0% as intermediate risk, and 2.0% as high risk.

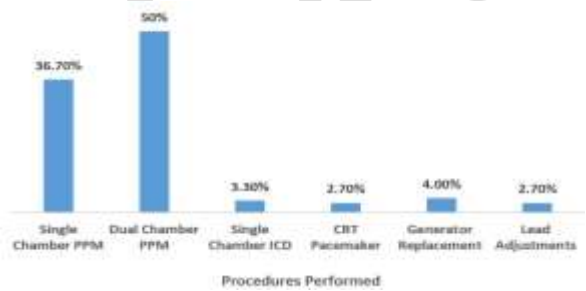

Figure 1: Procedure distribution

Outcome Data: The primary outcome was the incidence of CIED infections requiring hospitalization within six months. Overall, three out of 168 patients (1.7%) developed a CIED infection. The majority of infections were superficial skin infections (66.7%), which were managed with extended courses of intravenous antibiotics. However, one case (33.3%) involved Methicillin-resistant Staphylococcus aureus (MRSA) and required device removal and reimplantation on the contralateral side after a course of intravenous antibiotics.

Main Results: The median PADIT score for the study population was low, at 1. The distribution of PADIT scores is depicted in Figure 2, indicating that most patients were in the low-risk category. The C-statistic for PADIT score performance in predicting infection risk was 0.413 (95% CI), indicating a poor discriminative ability in this cohort.

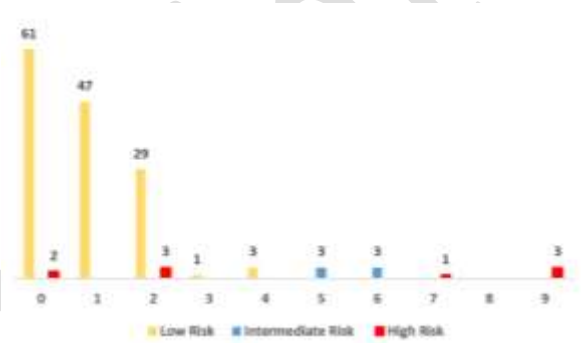

Figure 2: Distribution of PADIT Scores

Hospitalization rates and infection trends are summarized in Figure 3. Among the patients classified as high risk (PADIT score ≥7), only one out of four experienced a serious infection, contradicting the expectation of a higher rate of complications. The detailed cases of infection are described in Table 2, highlighting the variability in infection severity and management. The overall rate of hospitalization due to infection was low (0.46 ± 0.44).

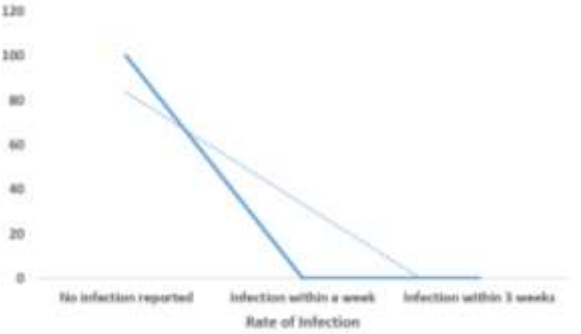

Figure 3: Trend of infection cases among total population

Table 2 provides individual patient details, including age, sex, index procedure, PADIT score, infection

type, timing, causative agent, and management strategies. For example, the most severe case involved a 47-year-old female with a PADIT score of 9, who developed an MRSA infection necessitating device extraction and subsequent re-implantation.

Table 2: List of Patients with reported device infection

Case	Age/ Sex	Index Procedure	PADIT Score	CIED Infection	Timing of Infection	Causative Agent	Management (Days after the Procedure)
1	61/F	DDDR Lead Adjustment	1	Superficial skin infection	Infection at 3rd month	MRSA	Hospitalization for administration of IV antibiotics for extended period (>1 week)
2	47/F	DDDR	9	Infection in 1st week	7	MRSA	Hospitalization and device extraction followed by IV antibiotics for 2 weeks and reimplantation on right side
3	50/M	DDDR	2	Infection in 1st week	7	-	Hospitalization for administration of IV antibiotics

DISCUSSION

CIED-related infections are a significant complication, often necessitating device extraction followed by re-implantation on the contralateral side after 1-2 weeks of intravenous antibiotic therapy [2, 10]. This process imposes a considerable financial burden on the healthcare system, prolongs hospital stays, and is associated with reduced patient survival. Such complications contribute to increased healthcare resource utilization, particularly in tertiary care settings.

By leveraging the PADIT score which incorporates five independent patient and procedural risk factors our study aimed to develop a predictive model for effectively managing and reducing infection rates in our population [12].

Our analysis revealed interesting associations. Our study participants were notably younger, with a mean age of 64.6 years compared to the average of 72 years reported in the PADIT study. Patients who developed infections were even younger, with a mean age of 52 ± 7.2 years, indicating a higher infection incidence in this demographic. This finding is consistent with multicenter trials, which demonstrated a progressively lower risk of infection with advancing age. Although the biological mechanism for this association remains unclear, one hypothesis suggests that older adults may have a diminished immune response to low-virulence bacteria, reducing their infection risk.

We also observed a lower percentage of immunocompromised individuals in our study (1.4% compared to 1.6% in other studies) and a higher proportion of patients receiving DDDR pacemaker (PPM) implantations or replacements (47.3%). Despite these recognized risk factors, our observed infection rate was 1.7%, with a 95% confidence interval. This relatively low rate aligns with findings from another single-center study, which reported an infection rate of 0.36% at one year in a real-world patient population with a median age of 77 and a median PADIT score of 2 [13]. These results suggest that consistent and rigorous implementation of infection prevention strategies can potentially maintain infection rates below 1%, even across a broader patient cohort.

Generator replacement, device revision, and system upgrades are well-established risk factors for infection. In our study, 6 out of 168 patients underwent these procedures, yet only one developed an infection. Although this outcome was not statistically significant, it reinforces the need for continued vigilance and robust preventive measures for patients requiring repeat procedures.

Other factors such as the type of procedure, immunocompromised status, and renal insufficiency demonstrated limited association with infection risk in our study. However, these risk factors are well-supported in the existing literature as important contributors to infection risk [1,2,5].

While our study focused on the five primary factors identified by the PADIT score, numerous additional risk factors have been validated in meta-analyses and could be relevant for our population [12]. Host-related risk factors such as diabetes mellitus, chronic obstructive pulmonary disease (COPD), corticosteroid use, malignancy, heart failure, and anticoagulant therapy (e.g., heparin) warrant further investigation. Additionally, procedural factors like hematoma formation, lead dislodgement, and extended procedure duration should also be considered as they have been shown to elevate infection risk in various contexts.

Limitations: Our study has several limitations that should be acknowledged. First, the prospective design inherently requires a longer follow-up period for more robust and validated outcomes; however, due to time constraints, our initial analysis was conducted at six months. Future reassessments of this cohort could yield more definitive results. Additionally, the single-center design and the relatively low incidence of infections at our center limited the sample size and the number of events, which restricted our ability to achieve statistically significant findings. Thus, our results warrant confirmation through larger, multicenter prospective studies.

CONCLUSION

The PADIT score did not demonstrate strong utility as a clinical tool for identifying individuals at heightened risk of CIED-related infections within a six-month follow-up period in our single-center prospective study. Despite this, the implementation of strict preventive measures contributed to a notably low infection rate. The score's lack of predictive effectiveness may be due to the unexpectedly low infection incidence in our setting. Future risk stratification should consider additional potential factors beyond those included in the PADIT score to improve identification of high-risk patients.

AUTHORS' CONTRIBUTION

FN, MTBN, QHK, MUJ: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. FN, MTBN, QHK, MUJ: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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