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Original Article

Utility of Novel Padit and Pace Drap Scores as Predictors of Cied Infection Post Implantation In A Tertiary Care Cohort

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ABSTRACT

Objective: To systematically assess prognostic accuracy and clinical applicability of PADIT score as well as PACE DRAP scores in predicting long-term infectious complications following cardiac implantable electronic device (CIED) procedure.
Study Design: Prospective analytical study
Place and Duration of Study: Electrophysiology department of Armed Forces Institute of Cardiology and National Institute of Heart Diseases at Rawalpindi, Pakistan from Jan 2024 to Jan 2025.
Methodology: The study included 405 patients undergoing cardiac devices implantation. Demographic, clinical and laboratory characteristics were assessed. Patients were categorized in groups based on predetermined criteria in accordance with guidelines.
Results: Overall incidence of cardiac device infection (CDI) was 3.2% (n=13). The PADIT score correlated better with presence of device infections. PADIT score demonstrated better discriminative ability for device infections (AUC of 0.975; 95% CI: 0.941–1.000; $p < .001$) as compared with PACE DRAP score which showed poor predictive performance for CIED infction (AUC: 0.637; 95% CI: 0.491–0.783; $p = .066$).
Conclusions: Our study depicted that PADIT score discriminated patients at greater risk for CDI better as compared to PACE DRAP score. Type of procedure including lead revision and system upgrade as well as number of procedures on same pocket increased odds of infection significantly.

Keywords: Cardiac implantable electronic device (CIED) infection; and PACE DRAP score, PADIT score.

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INTRODUCTION

Global use of implantable cardiac electronic devices (CIEDs) has significantly increased over the past decades due to evolving indications, rising life expectancy, and growing prevalence of cardiac rhythm disorders and heart failure.[1,2] Despite advancements in technology and procedural expertise, device-related complications, particularly infections remain a significant concern, contributing to increased morbidity, mortality, and healthcare burden.[1]

CIED-related infections occur in approximately 1% to 4% of procedures.[3,4] with higher rates reported in patients undergoing repeat interventions or receiving cardiac resynchronization therapy (CRT) or receiving implantable cardioverter-defibrillators (ICD), where infection rates may reach up to 4.8%.[5,6] However, more recent prospective studies and clinical trials, including PADIT and WRAP-IT, have reported lower infection rates, ranging from 0.6% to 1.3%.[7]

In-hospital mortality rate for these patients has been reported as high as 4.7%.[8] Hence, accurate risk prediction models are essential for preoperative planning, individualized prophylaxis, and informed shared decision-making.

The PADIT score, derived from a large multicenter cohort, incorporates clinical and procedural variables to estimate infection risk7. More recently, the PACE DRAP score has emerged, integrating additional procedural and patient-related factors to enhance sensitivity and specificity in risk prediction.[9]

While both tools have demonstrated predictive value independently, their comparative performance and real-world applicability, particularly in diverse populations, remain underexplored. There is an utmost need to evaluate whether these risk scores can be reliably integrated into routine clinical workflows to improve infection prevention strategies.

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This study aims to assess and compare the prognostic utility of PADIT and PACE DRAP scores in predicting long-term infectious complications following CIED implantation in our population.

METHODOLOGY

This prospective analytical study was conducted at Electrophysiology department of Armed Forces Institute of Cardiology and National Institute of Heart Diseases, Pakistan, from Jan 2024 to Jan 2025 vide IERB letter reference number 9/2/R&D/2025/365 dated 26 June 2025. Sample size of n=28 was calculated using WHO sample size calculator, taking 1.84% prevalence of CIED infection, [10] 95% confidence level and 5% margin of error. However for purpose of study all patients undergoing CIED implantation during study period were included in study with non-purposive consecutive sampling .Thus a total of 405 patients were included in study.

Inclusion Criteria: Patients of either gender undergoing CIED procedures willing to undergo study with completed one year of follow up were included in study.

Exclusion Criteria: Patients who failed to follow-up and who were unwilling to undergo study were excluded from study. After obtaining written informed consent, demographic details were recorded. Relevant clinical history was collected, including comorbidities. A history of prior device implantation, revisions, previous infections, immunosuppressive therapy and current medication use was noted. Laboratory investigations included complete blood count (CBC), renal function tests, C-reactive protein (CRP), renal function tests, and blood glucose or HbA1c levels in diabetic patients. Blood cultures were obtained if there was clinical suspicion of infection.

During CIED implantation procedure, various intraoperative factors including type of device being implanted as well as whether procedure is a primary implantation, revision or upgrade, or generator replacement was documented. Any concurrent use of anticoagulants or antiplatelet agents was also recorded. Management of anticoagulation therapy (ACT) was carried out in accordance to current scientific statement of American Heart association recommendations. 11 All patients were administered intravenous antibiotic prophylaxis within an hour of undergoing procedure with either intravenous cefazolin (2 g) or intravenous Vancomycin. Skin preparation was carried out with 0.5% chlorhexidine digluconate in combination with 70% alcohol.

Post-procedural monitoring included inspection of device pocket site for erythema, warmth, discharge, or swelling, as well as continuous monitoring of vital signs and fever charts. Any early complications such as hematoma formation or lead dislodgement, was documented. Before discharge, patients received wound care instructions and follow-up schedule.

Patients were followed-up at regular intervals for at least 12 months after CIED implantation to monitor for development of infections. Follow-up visits were be scheduled at 3 months and 6 months up to one year. At each follow-up, device pocket site was examined, and patients were assessed for evidence of local infection or systemic infection, including fever, malaise, or discharge. In cases where infection was suspected, additional laboratory investigations such as repeat complete blood count (CBC), C reactive protein (CRP), blood cultures, and imaging studies were conducted. Any interventions, such as antibiotic treatment, hospitalization, or device removal, was recorded

Extent and presence of Device related infection was defined using predetermined criteria as specified by European Heart Rhythm Association (EHRA) consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections.3'Definite' CIED clinical pocket or generator infection was described as : device pocket showing swelling, warmth, pain, redness and pus discharge or formation of sinus tract or deformation of device pocket accompanied with adherence and erosion or exposed proximal leads or generator regardless of results of microbiology 3 CIED related systemic infections including CIED-related bloodstream infection (positive blood cultures with no other source) and CIED-related infective endocarditis (CIED-IE): involving leads, valves, or cardiac endothelium often associated with positive blood cultures and signs of sepsis were defined using 2019 International CIED Infection Criteria combining modified Duke criteria and European society of cardiology (ESC) 2015 criteria. As specified by EHRA consensus statement on CIED infections 2019 3

All patients who developed CDI were managed with intravenous antibiotics appropriately and complete explant was achieved whenever possible. Each patient's factors for CIED infection were assessed using both PADIT 4 score as well as PACE DRAP

score. 9 these scores will be calculated based on available clinical and procedural information, as per standardized criteria. Methodology is summarized in Figure-1.

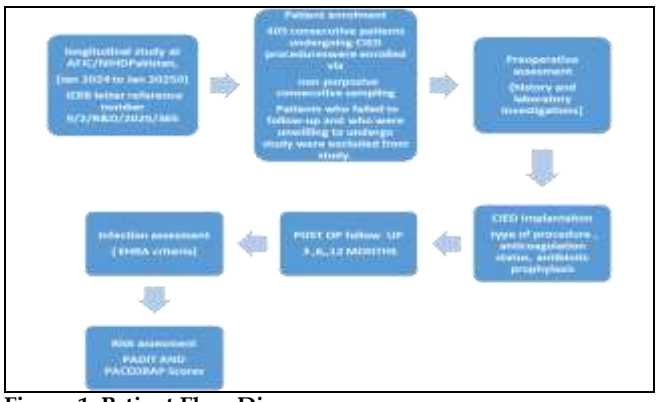

Figure-1: Patient Flow Diagram

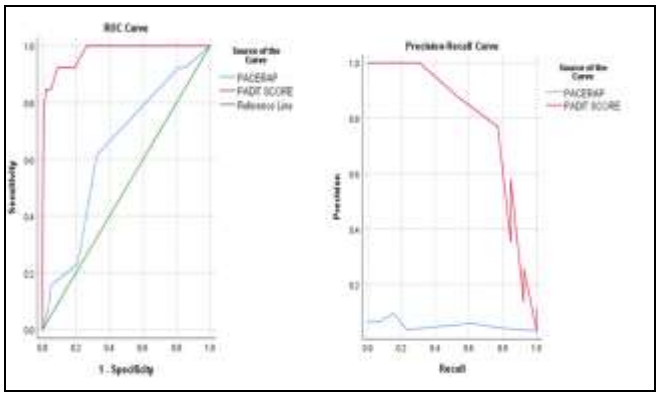

Figure-2: ReceiveR Operating Characteristic (ROC) Curve For Padit and Pace Drap Score

Data was analyzed on Statistical Package for the Social Sciences version 26(SPSS-26). Categorical data was represented as percentages and frequencies. Continuous data was represented as median and inter quartile range (IQR). Continuous data was compared using the Mann-Whitney U test after affirming non-normal distribution through Shapiro- Wilk test. Chi-square test was applied for association of categorical variables including gender, diabetes, hypertension, CKD with CIED infection. Rest of categorical data was compared with Fisher exact test. Receiver Operating Characteristic curve (ROC) curve was drawn and area under curve (AUC) was evaluated for discriminative ability of PADIT and PACEDRAP score for CIED infections. *p*-value <0.05 was taken as significant.

RESULTS

Over one year follow up 13(3.2 %) cases of CDI were identified. Baseline features of patients with Cardiac implantable device infections and those without CIED infection are presented in Table-I.

Lead revision as well as procedures for device Upgrade were present more frequently in CDI group 11(84%) than in non-CDI group 12(3.1%), $p<0.001$. The device-related superficial incisional infection were present in 1(7.69 %) patient with growth of Staphylococcus Epidermidis which was followed with wound debridement .Device related isolated pocket infection was present in 10 cases (69.2% of CDI group) with growth of Burkholderia cepacia in three cases, Klebsiella pneumonia , Ecoli and pseudomonas in one case each with no growth in rest of patients. All of these patients underwent explant. CIED related infective endocarditis was present in 1 patient (7.7 %.) with staphylococcus Aureus bacteremia and underwent device explantation.

Patients PADIT and PACE DRAP scores were assessed before surgery. Median PADIT score in patients without CDI was 1(0-3) and median PADIT SCORE in patients with CDI was 8.5(7.5-9.5). Median PACE DRAP score in non CDI group was 3(2-4) and median PACE DRAP score in CDI group was 4(3-4.5). Owing to non-normal distribution of PACE DRAP and PADIT scores, Area under the Receiver Operating Characteristic (ROC) curve (AUC) was estimated using non-parametric approach. PADIT score demonstrated better discriminative ability for device infections (AUC of 0.975; 95% CI: 0.941–1.000; p < .001) as compared with PACE DRAP score which showed poor predictive performance (AUC: 0.637; 95% CI: 0.491–0.783; p = .066). Details are presented in Figure-2 and Table-II.

DISCUSSION

Clinical data from complete Danish device-cohort (1982–2018) by Thomas Olsen including 99105 patients showed incidence of infection of 3.35% for CRT-D 2.18% for CRT-P, 1.91% for ICD and 1.19% for pacemakers. Increased incidence of device infections related with CRT can be attributed to advanced procedural complexity as well as number of leads and also patient comorbidities .However, this study likely underestimated true incidence of CIED infection as it only registered infections that lead to hardware removal.[12] Another recent study by John de Heide on Device infection in patients implanted with CIED between 2016 January and 2021 November demonstrated device infection developed in 10 patients (0.43% of a total of 2333) implanted devices.[3]

Table-I: Clinical and procedural characteristics of patients (n=405)

Variables		Non-CDI Group (n=392)	CDI Group (n=13)	*p*-value
Demographic Characteristics				
Median Age (IQR)		70.0 (60.0-76.0)	68.0 (51.0-74.0)	0.169
Gender n (%)	Male	257 (65.6%)	9 (69.2%)	
	Female	135 (34.4%)	4(30.8%)	0.784
Comorbidities				
Diabetes Mellitus, n (%)		160 (40.8%)	3(23.1%)	0.199
Hypertension, n (%)		222(56.6%)	5(38.5%)	0.194
Immuno-compromised, n (%)		37(9.4%)	3(23.0%)	0.361
Malignancy, n (%)		7(1.8%)	0(0.0%)	1.000
Prosthesis, n (%)		15(3.8%)	3(16.7%)	0.016
Atrial Fibrillation, n (%)		62(15.8%)	2(15.4%)	1.000
Stroke, n (%)		28(7.1%)	1 (7.7%)	1.000
CKD, n (%)		193(49.2%)	4(30.8%)	0.190
Antiplatelets And Anticoagulation Therapy, n (%)				
Aspirin		135 (34.4%)	6 (46.2%)	0.388
P2Y12 inhibitors	Clopidogrel	29(7.4%)	0(0.0%)	0.624
	Ticagrelor	1(0.3%)	0 (0.0%)	
NOACS		23 (5.9%)	1 (7.7%)	0.554
Antiplatelet/anticoagulation during index procedure		20 (5.1%)	21(7.7%)	0.505
VKA		11(2.8%)	0 (0%)	1.000
Baseline Investigations				
Median Hemoglobin g/dl , (IQR)		12.7 (11.5-14.0)	13.2 (10.1-13.6)	0.638
Median Platelets count, (IQR)		196 (151.0-240.0)	195.0(109.0-250.0)	0.501
Median Creatinine mg/dl, (IQR)		1.10 (0.90-1.51)	1.0 (0.8-1.8)	0.435
Median HBA1C % , (IQR)		5.5 (5.0-6.5)	6.0 (5.4-6.4)	0.167
Median Ejection fraction %, (IQR)		55.0 (45.0-50.0)	60 (52.5-60.0)	0.112
Indication				
Complete AVB, n (%)		286 (73.0%)	12 (92.3%)	0.477
Sinus node dysfunction, n (%)		40 (10.2%)	0 (0.00%)	
Second or high degree AVB, n (%)		17 (4.3%)	1 (7.7%)	
Heart failure, n (%)		9 (2.3%)	0 (0.0%)	
Ventricular tachycardia, n (%)		40 (10.2%)	0 (0.0%)	
Type Of Device, n (%)				
Dual chamber pacemaker		306(78.1%)	11(84.6%)	0.749
Single chamber pacemaker		30 (7.7%)	1(7.7%)	
ICD single chamber		27 (6.9%)	0 (0%)	
ICD dual chamber		12 (3.1%)	1 (7.7%)	
CRT P		8 (2.0 %)	0(0.0%)	
CRT D		9 (2.3%)	0(0.0%)	
Type of Procedure, n (%)				
Denovo		337 (85.5%)	1(7.7%)	< 0.001
Generator replacement		43 (11.0%)	1 (7.7%)	
Lead revision replacement/system upgrade		12(3.1%)	11 (84.0%)	
Number Of Previous Procedures on same pocket, n (%)	None	321 (81.9%)	1(7.7%)	< 0.001
	1	62(15.8%)	4(30.8%)	
	≥2	9 (2.3%)	8 (61.5%)	
Pocket hematoma n (%)		14 (3.6%)	1 (7.7%)	0.392
Median PADIT score (IQR)		1 (0.0-3.0)	8.5 (7.5-9.5)	<0.001
PADIT score categories, n (%)	0-4	353 (90.1%)	1.0(7.7%)	< 0.001
	5-6	29 (7.4%)	1.0 (7.7%)	
	≥7	10.0 (2.6%)	11.0 (84.6%)	
Median PACE DRAP score, IQR		3.0 (2.0-4.0)	4.0 (3.0-4.5)	0.087

Atrioventricular block (AVB), Cardiac device infection (CDI), Chronic kidney disease (CKD), Novel oral anticoagulants (NOACS), Glycosylated Hemoglobin (HBAIC), ,Implantable cardiac defibrillator (ICD), cardiac resynchronization therapy pacing (CRT P), cardiac resynchronization therapy defibrillator (CRT D), Prevention of Arrhythmia Device Infection Trial (PADIT), P: valvular Prosthesis A: Uncontrolled Arterial hypertension C: Cancer E: Elderly ,age ≥75 years D: Device type -CRT/ICD R: Renal failure A: Antiplatelet (certain types like clopidogrel, ticagrelor) P:Procedure type -system upgrade

In present study, CIED infection rate was 3.2 % (13 of 405 CIED recipients), with 3.44 % (12 of 348 patients) incidence of CIED infection in pace maker group which is much higher than studies discussed, however, data from study on Epidemiology of cardiac implantable electronic device infections in the United States by Elissa Rennert-May MD, including 191,610 CIED implantations in 2016 showed 8060 infections (4.2%) which corroborates well with our findings.[14]

Recent data from study by Ghulam Kubra, carried out at National Institute of Cardiovascular Diseases, Karachi Pakistan, from Jul 2019 to Jun 2020 showed incidence rate of CIED infections of 2.1% (34 of 1046 patients developed CIED infection.[15] Another contemporary study by Muhammad Asad in Pakistan showed that of 356 devices implanted 14 patients developed infection with infection rate being 3.9% 2 which is in line with our findings.

Our study showed 2.5% incidence of CIED infection in ICD group (1 of 40 patients) which corroborates with recent studies.[12] None of patients undergoing CRT developed device infection in our

Table-II: CIED-Related Infection Rate and Negative and Positive Predictive Values for Infection Development Based on the PADIT and PACE DRAP Risk Assessment Models (n=405)

	CDI						
Risk score	Present	Absent	PPV %	NPV %	Sensitivity %	Specificity %	Accuracy
PADIT > 7							
≥ 7	10	7	58.82	99.22	76.92	98.21	97.53
1-6	3	385					
PADIT > 6							
≥6	11	137	7.41	99.22	84.62	65.00	65.68
1-5	2	255					
PACE DRAP ≥6							
≥6	2	18	9.97	97.15	15.38	95.41	92.84
1-5	11	374					

Prevention of Arrhythmia Device Infection Trial (PADIT), P: valvular Prosthesis A: Uncontrolled Arterial hypertension C: Cancer E: Elderly-age ≥75 years D: Device type -CRT/ICD R: Renal failure A: Antiplatelets (clopidogrel, ticagrelor) P: Procedure type -system upgrade (PACE DRAP), cardiac device infection (CDI), positive predictive value (PPV), negative predictive value (NPV)

study in contrast to recent studies 12 likely attributable to small number of patients undergoing CRT procedure (only 17 of 405 patients underwent CRT placement) . Moreover, in our study cohort all complex procedures including ICD placement and CRT implantation procedures were deliberated by experts, reducing CDI incidence in this group.

Results from complete Danish device-cohort (1982–2018) by Thomas Olsen showed that risk of CIED infection was highest in device upgrade procedures (PM = 2.40 %, ICD = 1.66%, CRT-P = 3.88 %, and CRT-D = 3.94 %). Incidence of CDI in present study was higher for lead revision and system upgrade procedures 2.71 %(11 of 405 patients) which is in agreement with contemporary data.[12]

PADIT risk score with PADIT acronym has been recently introduced as novel tool for predicting CIED infections. Patients having 7 points in PADIT score or more are considered at high risk of CIED infection (4.33%) 16 Recently PACE DRAP score has also been introduced in literature. Score of 6 points or more in PACE DRAP indicates increased risk of subcutaneous pocket hematoma (SPH) 9 and hence CDI infection due to association between SPH and device infection as supported by previous literature.[17] However there was low incidence of pocket hematoma in our population 3.7% in total (n=15) likely due to less frequency of antiplatelet use during index procedure 5.2 %(n=21) and only one patient was on ticagrelor as well as avid use of cautery in patients in dual antiplatelet treatment (DAPT) group. Besides bridging therapy with heparin was avoided in patients on anticoagulation .These findings are in accordance with findings of combined analysis of Bruise control trial by Vidal Essebag in 2019 which showed increased risk of pocket hematoma when heparin bridging was used (16.8%) and also that concomitant antiplatelet therapy doubled the risk of clinically significant pocket hematoma (CSH) during device surgery (9.8%) 18 Besides no significant relation was found for pocket hematoma with PACE DRAP score p=0.87.

A recent study at Rawalpindi Institute of Cardiology (RIC) on CIED Infections by Fauzia Nazir on 168 CIED patients demonstrated weak predictive ability of PADIT score (C-statistic of 0.413; 95% CI) 19 which is in contrast to our study which showed high accuracy of PADIT score for predicting CIED infections, AUC= 0.975.This is likely due to smaller patient population in the recent study involving low risk patients only with mean PADIT score of study 1.18 ± 1.65 ,whereas median PADIT score of CDI group patients in our study was 8.5(7.5-9.5), and non CDI group was 1 (0-3).[21]

A single-center study on stratifying risk with utilization of PADIT score of 2333 patients who underwent device procedure from 2016 and 2021 by John de Heide showed that PADIT score had great discriminative ability in predicting device infection (C-statistic 0.70; 95% confidence interval [CI] :0.54 to 0.86, p = 0.03) which is in agreement with our study findings.[13]

Recent data from Sylwia Sławek-Szmyt on 1100 consecutive patients who underwent CIED implantation between June 2015 and June 2018 in single center in Poland showed PACE DRAP score ≥6 was able to identify patients at high risk of CIED infection with good predictive ability (area under the curve, 0.95;p<0.001).which is in contrast with our study where PACE DRAP score showed poor discrimination ability with AUC 0.637 which is likely due to lower incidence of subcutaneous pocket hematoma in our population with incidence of 3.7 %

vs 4.5 % in contemporary study as well lower incidence of other risk factors in PACE DRAP score.[9]

Study on Utility of Novel PADIT and PACE DRAP Scores by Sylwia Sławek-Szmyt on 1,000 patients undergoing ICD placement or CRT implantation procedures carried out between 2016 and 2020 in a tertiary-care settings showed PACE DRAP score had greater ability to discriminate for incidence of CDI (with an area under curve (AUC 0.72) in comparison to PADIT score (AUC 0.63).[1]

These findings are in contrast to our study which depicted advantage of PADIT score over PACE DRAP risk assessment score, with AUC 0.975 for PADIT SCORE as compared to PACE DRAP score, with AUC of 0.637 for predicting device infection. which is attribute to fact that majority of infection cases had higher prevalence of risk factors present in PADIT score including system upgrade procedure/ lead revision and increased number of procedure on same pocket .

Study on risk factors for infections in patients who underwent device placement in Denmark between 1996 and 2018 with total of 108494 CIED surgeries by Thomas Olsen showed greatest risk of CIED infection with reoperations 3.40(2.84-4.06)*p* value <0.001 , device replacement 3.44(2.98-3.98)*p* value<0.001 along with CIED type and age, [hazard ratio (HR): 1.83(1.25-2.67)p value 0.002 10 .Another study by Hironori Ishiguchi, MD on risk factors for CDI in a Japanese population involving 1749 patients undergone CIED operations between 1999 and 2019 demonstrated lead Revision (OR: 7.4, 95% CI: 1.6–33.5, p = 0.008) as well as patient age younger than 50 years (OR: 10.8, 95% CI: 2.2–51.6, *p* = 0.003) as predisposing risk factors for CIED infection which is in consistence with our study.[21]

Risk factors leading to CDI are well-established and their assessment by using a validated risk score can help in predicting patients as high risk for device infection. The PADIT score is a simple tool for predicting patients at increased risk for CIED infection development .[13] Utilizing precautionary measures in these patients like antibacterial envelope can be a cost-effective way to curtail incidence of CIED infections [22]

In WRAP-IT trial, patients in control group (2803 patients) who did not receive antibiotic envelope however received standard preoperative antibiotics, provisions like pocket wash with antibiotic and meticulous skin preparation with chlorhexidine showed reduced infection risk. In contrary, complete removal of device capsule was accompanied with increased infection risk due to increased hematoma formation and infection.[23]

In multicenter randomized clinical trial that enrolled 6983 patients undergoing CIED revision, replacement, or upgrade, or de novo implantation of cardiac resynchronization therapy devices, major CIED-related infections occurred in 32 patients in envelope group and 51 patients in control group, conferring relative risk reduction of 40% over period of 12 months follow-up. Tarakji et al16 assessed relation between hematoma and antibiotic envelope use in CDI patients who were included in WRAP-IT trial and demonstrated 82% reduction in risk of CDI in patients who were given antibiotic envelope who developed hematoma when compared with control group who did not receive antibiotic envelope.[24]

Implementing antimicrobial envelope placement can be considered in case of patients who are at high risk of CDI. With optimal implementation of preventive techniques, CIED infection risk can be mitigated.

LIMITATION OF STUDY

Study is a single center study with small study group for a relatively short one year of follow-up which may be insufficient to delineate late complications. Although pocket is generally considered as primary source of infection, other portals of entry for infection cannot be excluded definitely which may result from secondary seeding.

CONCLUSION

Our study demonstrated that PADIT score was better able to discriminate patients at increased risk of CDI as compared to PACE DRAP score. Type of procedure including lead revision and system upgrade as well as number of procedures on same pocket increased odds of infection significantly

Conflict of Interest: None.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SM & AA: Data acquisition, data analysis, critical review, approval of the final version to be published.

MS & MA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

AK & MF: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity

of any part of the work are appropriately investigated and resolved.

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