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The Predictive Value of Inflammatory Indices in Complications Following Lead Extraction: A Retrospective Analysis

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Abstract

Objectives: Lead extraction is a critical procedure for managing complications in patients with cardiovascular implantable electronic devices. The potential predictive value of inflammatory indices, such as the systemic immune-inflammation index (SII), pan-immune-inflammation value (PIV), and prognostic nutritional index (PNI), in determining procedural outcomes remains unclear. This study aimed to evaluate the relationship between complications following lead extraction and inflammatory indices in patients undergoing the procedure, with a particular focus on those treated for infectious versus non-infectious causes.

Materials and Methods: This retrospective, single-center study analyzed patients who underwent lead extraction between 2019 and 2020. Complications, including hematoma, pericardial effusion, and sudden cardiac death, were assessed. Multivariate logistic regression identified predictors of adverse outcomes, and ROC curve analysis evaluated the predictive value of SII, PIV, and PNI.

Results: Among the 234 patients included (mean age 62, 81% male), complications occurred in 25.6% (n=60), with mortality recorded in 3.8%. Hematoma and pericardial effusion were observed in 12% and 14.5% of patients, respectively. ROC analysis revealed no significant association between the inflammatory indices (SII, PIV, PNI) and complications. Multivariate logistic regression identified diabetes mellitus (DM) as a significant independent predictor of complications ($p<0.05$). No differences in outcomes were noted between infectious and non-infectious lead extraction subgroups.

Conclusion: While inflammatory indices showed limited predictive utility, DM emerged as a critical risk factor for complications following lead extraction. Comprehensive preprocedural risk stratification, with attention to metabolic

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conditions such as diabetes, is essential to improving procedural outcomes. Further studies are needed to refine predictive models incorporating both systemic and procedure-specific variables.

Keywords: Antiarrhythmics, cardiology, heart, heart failure

Introduction

Cardiovascular implantable electronic devices (CIEDs) such as pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices play crucial roles in the management of various cardiac conditions. These devices form a vital component of contemporary therapeutic strategies addressing arrhythmias, heart failure (HF), and conduction disorders to improve survival and quality of life among affected patients[1]. Previous studies have shown that using CIEDs is associated with improved survival, reduced hospitalisation and improved quality of life in patients with various heart conditions[2]. The expanded utilization of CIEDs has inevitably led to an increase in the incidence of complications[3]. Challenges such as electrode malfunction, infection, and inappropriate shocks remain for patients with CIEDs. Ongoing advancements in device technology are targeted at mitigating these challenges, thereby enhancing patient outcomes[4].

The relationship between inflammatory conditions and CIEDs is clinically significant, as the presence of inflammation can affect both device performance and patient outcomes[5]. Inflammatory conditions, such as systemic autoimmune diseases or localized infections, can lead to complications such as device-related infections or increased thromboembolic risk[5,6]. In particular, patients with conditions such as rheumatoid arthritis or vasculitis may experience an exaggerated immune response to foreign devices, such as pacemakers or ICDs. This immune reaction can manifest as fibrosis or granuloma formation around the device leads, which may impair the functionality of the device, lead to increased resistance in electrical conduction, or necessitate device replacement[7]. These risks highlight the need for careful management of inflammatory conditions in patients using intracardiac devices, with close monitoring for signs of infection and potential device malfunction. Monitoring inflammatory indexes in patients with signs of device erosion or lead exposure is crucial for early detection and management, which often necessitates prompt lead extraction, antibiotic therapy, or device revision to prevent severe complications. Understanding the role of inflammation in lead extraction can help guide clinical decision-making and improve patient outcomes through timely intervention. Lead extraction has become increasingly significant in the follow-up of CIED patients. Although technical facilities have reduced the risk of complications during lead extraction, the success of the procedure is still significantly affected by individual comorbidities[8]. In this study, patients who developed complications following lead extraction were analyzed to evaluate the relationship between these complications and inflammatory indices that have gained prominence in the cardiovascular field in recent years.

Materials and Methods

This was a single-center, retrospective study conducted in our hospital between 2019 and 2020. Data from all the patients who underwent lead extraction for any reason were retrospectively reviewed. Cardiac rupture during the procedure, sudden cardiac death, postprocedural hematoma, and pericardial effusion were defined as cardiac complications. The baseline demographic and laboratory values of patients with and without complications were compared. Patients who developed mechanical complications during intracardiac device implantation, those with malignancy, those on oral anticoagulant therapy, and those with a history of pericardial effusion were excluded from the study.

The predictive value of the inflammatory indices was evaluated in patients who underwent lead extraction due to infection, and in those who underwent the procedure for non-infectious reasons. To account for potential fluctuations in inflammatory status, preoperative blood samples drawn within 24 hours prior to the procedure were used to calculate the inflammatory indices. Manual extraction, which included traction with locking stylets or standard instruments without additional mechanical support, was preferred for recently implanted leads (<1 year). However, detailed procedural variables, such as lead dwell time, lead type, extraction technique, and operator expertise, were not available, which may constrain the interpretation of results.

The systemic immune-inflammation index (SII) was determined using the formula, platelet count × neutrophil-to-lymphocyte ratio × 10^9/L[9]. The prognostic nutritional index (PNI) was calculated as 10 × serum albumin value (g/dL) + 0.005 × peripheral lymphocyte count (per mm^3)[10]. The pan-immune-inflammation value (PIV) was calculated using the formula: neutrophil count (10^9/L) × platelet count (10^9/L) × monocyte count (10^9/L) / lymphocyte count (10^9/L)[11].

Cardiac rupture was defined as rupture of the tricuspid valve, right atrium, or right ventricle, identified during or immediately after lead extraction. Sudden cardiac death was defined as a rapid, unforeseen fatal event of cardiovascular origin, occurring with a loss of consciousness within one hour after the onset of symptoms. Hematoma was defined as a localized area of bleeding that developed post-procedure at the site of lead extraction. Pericardial effusion was defined as the accumulation of fluid in the pericardial space following lead extraction, in patients without a history of pericardial effusion.

This study was approved by the Scientific and Ethical Review Board for Medical Research No. 1 (TABED) under the chairmanship of the Ethics Committee (approval no.: 1-24-11, date: 14.02.2024).

Statistical Analysis

All data analyses were conducted using the IBM SPSS Statistics software. The study population was divided into two groups: those with complications and those without. The Kolmogorov-Smirnov test was employed to assess the normality of the distribution. Variables with a normal distribution were reported as mean ± standard deviation, while variables with a non-normal distribution were presented as median with interquartile range. Categorical variables were expressed as frequencies and percentages. For all patients who underwent lead extraction, the predictive value of complications in relation to the SII, the PIV, and PNI was analyzed using ROC curve analysis. Additionally, for patients who underwent lead extraction solely due to infection, the predictive value of the SII, PIV PNI were assessed using ROC curve analysis. Multivariate logistic regression analysis was performed to assess the independent predictors of complication development following lead extraction.

Results

The mean age of the study population was 62 years, with a percentage of males of 81%. The mean left ventricular ejection fraction was 32%. More patients were classified as New York Heart Association functional capacity II. The prevalence of diabetes mellitus (DM) was significantly higher in the group with complications (p=0.011). No significant differences in hypertension, chronic kidney disease, or HF were observed between the groups. Additionally, there were no differences in the rates of ICD, CRT, or pacemaker implantation (Table 1). Lead extraction was performed in 190 patients due to infection, and in 44 patients for non-infectious indications. The total incidence rate of adverse events was 25.6%, affecting 60 patients. Mortality was recorded in 3.8% of patients (a total of 9 patients). No cases of cardiac rupture have been reported. Hematoma occurred in 12% of the patients (29 patients), while pericardial effusion was observed in 14.5% (34 patients) (Table 2).

Table 3 presents the laboratory values of the study population. There were no significant differences between the groups in terms of laboratory values and inflammatory indices.

Table 1. Baseline demographic and clinical characteristics of the study population

Characteristic	Total (n=234)	No complication (n=174)	Complication (n=60)	p-value
Age (years)	62±14	62±14	63±12	0.904
Male, n (%)	190 (81.2)	145 (83.3)	45 (75.0)	0.180
LVEF (%), Mean ± SD	32±20	31±14	32±19	0.615
LVEDD (mm), Mean ± SD	57±11	58±11	57±13	0.325
NYHA FC (%)				0.281
Class I	81 (34.6)	65 (37.4)	16 (26.7)	
Class I-II	6 (2.6)	5 (2.9)	1 (1.7)	
Class II	124 (53.0)	85 (48.9)	39 (65.0)	
Class II-III	9 (3.8)	7 (4.0)	2 (3.3)	
Class III	14 (6.0)	12 (6.9)	2 (3.3)	
DM, n (%)	115 (49.1)	77 (44.3)	38 (63.3)	0.011 (*)
HT, n (%)	172 (73.5)	126 (72.4)	46 (76.7)	0.612
CKD, n (%)	71 (30.3)	55 (31.6)	16 (26.7)	0.518
HF, n (%)	179 (76.5)	133 (76.4)	46 (76.7)	0.562
ICD, n (%)	138 (59.0)	103 (59.2)	35 (58.3)	0.512
CRT, (%)	69 (29.5)	52 (29.9)	17 (28.3)	0.871
PM, n (%)	28 (12.0)	20 (11.5)	8 (13.3)	0.818

**P-values less than 0.05 were considered statistically significant, indicating a meaningful difference between the complication and non-complication groups. LVEF: Left ventricular ejection fraction, LVEDD: Left ventricular end-diastolic diameter, NYHA FC: New York Heart Association Functional Classification, DM: Diabetes mellitus, HT: Hypertension, CKD: Chronic kidney disease, HF: Heart failure, ICD: Implantable cardioverter-defibrillator, CRT: Cardiac resynchronization therapy, PM: Pacemaker, SD: Standard deviation*

Table 2. Indications, adverse events, and outcomes in patients undergoing lead extraction

Before extraction	
Primary prevention of SCD	180 (76.9)
Secondary prevention of SCD	26 (11.1)
ICMP	123 (52.6)
DCMP	73 (31.2)
HCMP	6 (2.6)
Infection	190 (81.2)
Non-infection	44 (18.8)
After extraction	
Total adverse event	60 (25.6)
Death	9 (3.8)
Cardiac rupture	0
Hematoma	29 (12)
Pericardial eff	34 (14.5)

SCD: Sudden cardiac death, ICMP: Ischemic cardiomyopathy, DCMP: Dilated cardiomyopathy, HCMP: Hypertrophic cardiomyopathy

In Figure 1, ROC analysis of the entire cohort did not identify a significant cut-off value for predicting complications based on the SII, the PIV, or PNI. Evaluation of the group that underwent lead extraction due to infection did not reveal a significant cut-off value for predicting complications based on the SII, the PIV, or PNI (Figure 2). Figure 3 shows that the scatter plots did not exhibit statistically significant associations. As shown in Table 4, a multivariate logistic regression analysis was conducted to evaluate the clinical parameters predicting complications following lead extraction. Among these parameters, DM has emerged as a significant independent predictor of postprocedural complications.

Table 3. Comparison of laboratory parameters between patients with and without complications

Parameter	Total (mean ± SD)	No complication (n=174)	Complication (n=60)	p-value
Glucose (mg/dL)	149.8±88.4	144.0±71.8	151.8±93.6	0.898
Creatinine (mg/dL)	1.2±1.0	1.2±1.1	1.1±0.6	0.237
Total protein (g/dL)	67.3±6.6	67.2±6.8	67.5±6.1	0.972
Albumin (g/dL)	40.8±5.4	41.3±4.6	39.0±6.9	0.079
Triglycerides (mg/dL)	183.2±111.9	185.2±115.8	177.4±100.4	0.926
Total cholesterol (mg/dL)	159.5±37.5	159.3±38.0	160.0±36.5	0.837
LDL (mg/dL)	90.4±28.9	89.5±29.1	93.0±28.5	0.352
HDL (mg/dL)	35.9±10.4	35.7±10.4	36.4±10.6	0.605
Hemoglobin (g/dL)	13.3±1.9	13.3±1.9	13.1±2.0	0.780
Neutrophils (/μL)	5691.1±2936.2	5836.2±3183.2	5272.8±2030.1	0.286
Lymphocytes (/μL)	1871.0±680.5	1875.5±700.2	1858.0±625.5	0.826
Platelets (10^3/μL)	252.2±194.8	245.4±177.8	271.5±237.9	0.661
WBC (10^3/μL)	8436.2±3302.8	8576.6±3565.6	8031.3±2367.7	0.452
CRP (mg/L)	16.7±33.9	18.5±36.5	11.6 ±24.6	0.283
Monocytes (/μL)	532.6±209.1	539.9±214.4	511.3± 192.9	0.406
PNI	50.9±9.9	51.2±8.7	50.2±12.2	0.069
SII	955.8±624.3	965.9±665.1	926.6±596.7	0.811
PIV	509.5±391.0	926.6±596.7	521.8±400.4	0.623

LDL: Low-density lipoprotein cholesterol, HDL: High-density lipoprotein cholesterol, WBC: White blood cell, CRP: *C-reactive protein, PNI: Prognostic nutritional index, SII: Systemic immune-inflammation index, PIV: Pan-immune-inflammation value*

Table 4. Multivariate logistic regression analysis identifying predictors of postprocedural complications following lead extraction

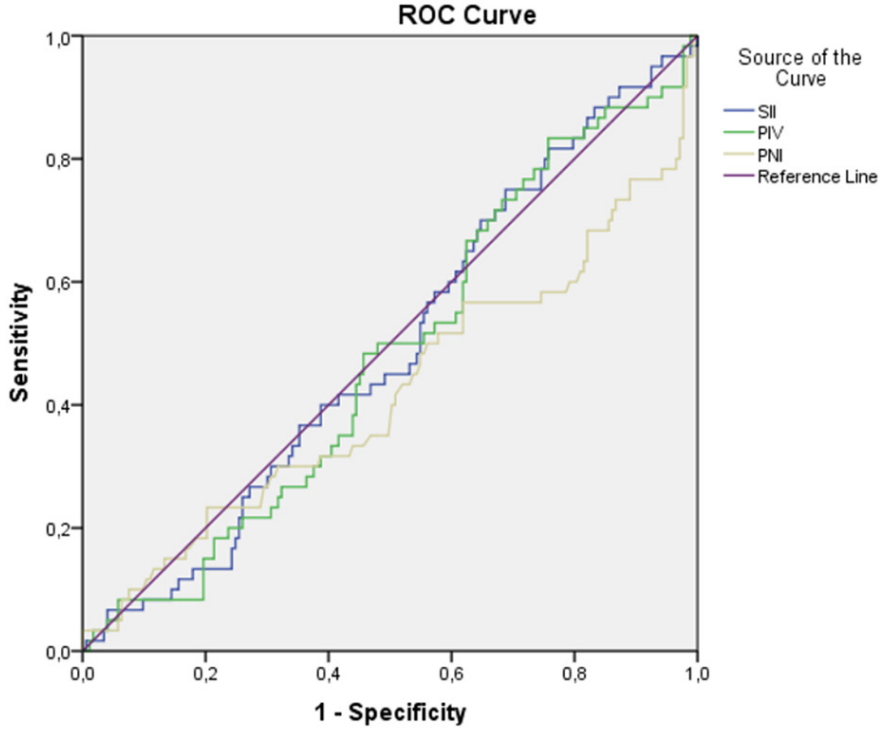
Variable	Odds ratio	95% Confidence interval for exp. (B)	p-value
Age	1.000	0.976-1.024	0.989
Male	0.649	0.307-1.372	0.258
LVEF	1.007	0.985-1.031	0.522
DM	2.396	1.235-4.647	0.010
HT	1.078	0.489-2.377	0.853
CKD	0.661	0.324-1.349	0.256

LVEF: Left ventricular ejection fraction, DM: Diabetes mellitus, HT: Hypertension, CKD: Chronic kidney disease

Discussion

In this study, we evaluated a population of patients who underwent lead extraction and divided them into two groups based on the presence or absence of complications: complicated and uncomplicated groups. Our analysis aimed to investigate the significance of demographic parameters and inflammatory markers in predicting the development of complications after the procedure. Interestingly, no significant association was identified between the inflammatory markers and the occurrence of complications.

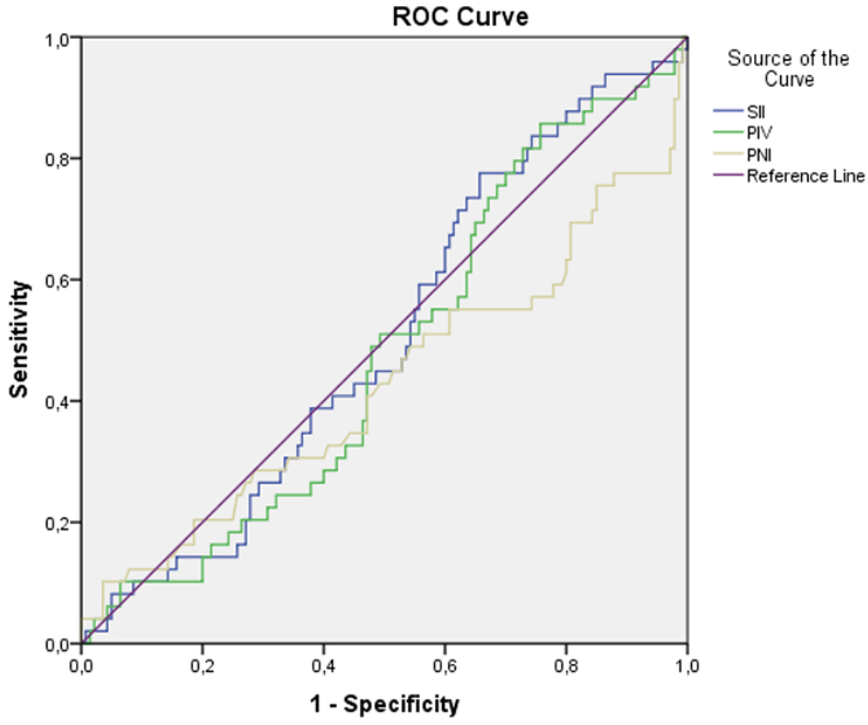
Inflammatory markers, including indices such as the SII, the PIV, and PNI, have been widely studied in cardiovascular research for their potential role as predictors of adverse events[12-15]. The SII, derived from platelet, neutrophil, and lymphocyte counts, has been proposed as a robust indicator of the balance between proinflammatory and anti-inflammatory processes. Elevated SII levels have been associated with worse outcomes in various cardiovascular conditions, such as HF and coronary artery disease, owing to their implication in thrombogenesis and immune dysregulation[16,17].



Test Variable	Area	Asymptotic Significance (p-value)	95% Confidence Interval (Lower Bound)	95% Confidence Interval (Upper Bound)
SII	492	855	410	574
PIV	479	623	396	561
PNI	419	63	328	510

SII: Systemic Immune-Inflammation Index, PIV: Pan-Immune-Inflammation Value , PNI: Prognostic Nutritional Index,

Figure 1. ROC curve analysis of systemic immune-inflammation index, pan-immune-inflammation value, and prognostic nutritional index for predicting post-procedural complications
SII: Systemic immune-inflammation index, PIV: Pan-immune-inflammation value, PNI: Prognostic nutritional index



Diagonal segments are produced by ties.

Test Variable	Area	Asymptotic Significance (p-value)	95% Confidence Interval (Lower Bound)	95% Confidence Interval (Upper Bound)
SII	503	942	414	593
PIV	477	636	387	568
PNI	426	125	325	528

SII: Systemic Immune-Inflammation Index, PIV: Pan-Immune-Inflammation Value , PNI: Prognostic Nutritional Index,

Figure 2. ROC curve analysis of systemic immune-inflammation index pan-immune-inflammation value, and prognostic nutritional index for predicting complications in patients undergoing lead extraction
SII: Systemic immune-inflammation index, PIV: Pan-immune-inflammation value, PNI: Prognostic nutritional index

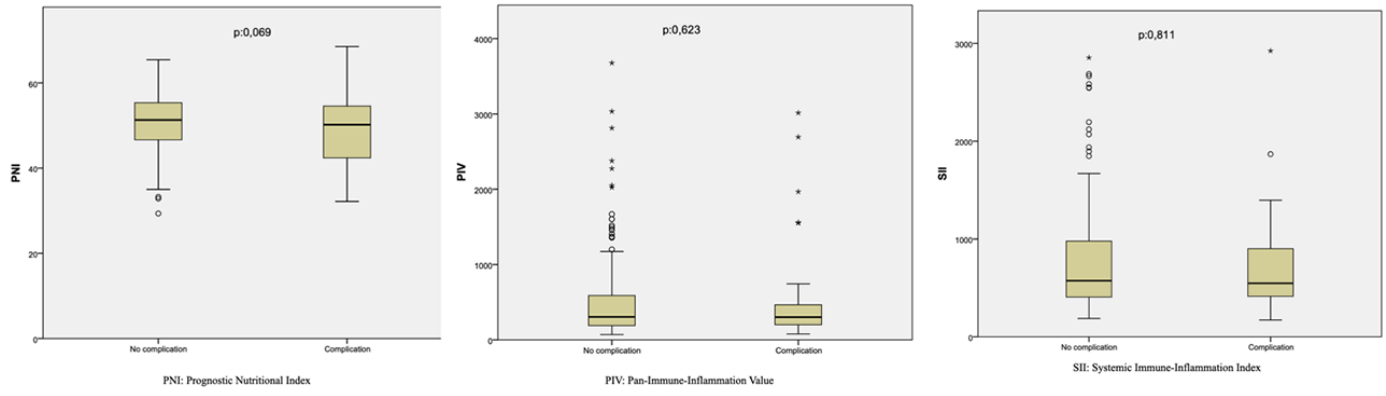


Figure 3. Boxplots comparing systemic immune-inflammation index, pan-immune-inflammation value, and prognostic nutritional index between patients with and without complications
SII: Systemic immune-inflammation index, PIV: Pan-immune-inflammation value, PNI: Prognostic nutritional index

Although there is substantial evidence supporting the role of inflammation in predicting adverse outcomes in cardiovascular conditions, most studies have focused on generalized inflammatory markers rather than establishing a specific association between the SII and complications in patients with intracardiac devices. Lead extraction, a critical procedure performed to address infections or lead malfunctions, is associated with significant risks including vascular injury, cardiac rupture, and systemic complications. Elevated levels of the SII have been linked to increased long-term mortality, which is potentially attributable to the underlying pro-inflammatory and pro-thrombotic states that these patients often exhibit[18]. Oliveira et al.[19] identified predictors of mortality in patients with cardiac device-related infective endocarditis, emphasizing the role of systemic inflammation in patient outcomes. Lead extraction, a necessary procedure in cases of infection or lead malfunction, carries inherent risks including vascular injury, cardiac rupture, and systemic complications. To our knowledge, the prognostic value of the SII in predicting procedural outcomes in patients with ICED has not been investigated previously. Similarly, the PIV is a marker of inflammation and thrombosis. Higher PIV values are thought to signify a heightened inflammatory state and predisposition to adverse events, such as vascular complications and impaired tissue healing[20]. Several studies have explored the relationship between PIV and the prognosis of patients with CIEDs, with a focus on its predictive value for complications, such as device-related infections, endocarditis, and long-term mortality. Elevated PIV levels have been associated with poorer outcomes in terms of infection rates, reflecting the inflammatory and immune response activation that could predispose patients to infections or delayed recovery post-procedure[21]. In a cohort of patients with pacemakers and defibrillators, high PIV values correlated with an increased risk of pocket infections, a common complication following device implantation[21]. Moreover, the role of PIV in predicting long-term mortality in patients treated with CIEDs has been highlighted in several retrospective analyses. Studies suggest that a higher PIV is a reflection of a systemic inflammatory state that may contribute to cardiovascular deterioration, possibly through mechanisms like endothelial dysfunction, atherosclerosis, and pro-thrombotic tendencies[22]. Habib et al.[23] further highlighted predictors of mortality in patients with CIED infections, supporting the association between inflammation and adverse outcomes. On the other hand, the PNI, which incorporates serum albumin levels and lymphocyte counts, provides insight into the patient's nutritional and immunological status. Lower PNI values have been linked to poor outcomes, including increased susceptibility to infection and delayed recovery following invasive procedures[24]. Despite their increasing relevance in cardiovascular research, these markers showed no significant association with complications in the current study. This lack of association suggests that the inflammatory burden captured by these indices is insufficient for predicting procedural complications in the context of lead extraction**.** Inflammatory indices, such as the SII, PIV, and PNI, did not predict complications in patients undergoing lead extraction, which may stem from several factors. First, these indices are composite markers that capture systemic inflammatory and nutritional status but may not adequately reflect localized or procedure-specific inflammatory processes. Lead extraction procedures involve mechanical disruption within the vascular and cardiac environments, potentially triggering localized inflammatory or thrombotic responses that are not directly proportional to systemic inflammatory levels. Technical and procedural factors during lead extraction can independently influence complication rates, overshadowing the impact of systemic inflammatory markers. The complexity of lead characteristics, operator experience, and procedural techniques might play pivotal roles in determining outcomes, rendering systemic inflammation indices less predictive. A recent study investigated predictors of percutaneous lead extraction complications, reinforcing the importance of procedural and technical factors in determining patient outcomes[25]. We identified DM as a significant independent predictor of complication development, a finding that aligns with

its well-established role in worsening cardiovascular disease outcomes. Diabetes is a multifactorial condition that affects cardiovascular health through a range of mechanisms, including chronic hyperglycaemia, systemic inflammation, and oxidative stress[26]. These processes contribute to endothelial dysfunction, reduced nitric oxide bioavailability, and prothrombotic states, all of which exacerbate cardiovascular morbidity and mortality[26,27]. Furthermore, diabetes impairs wound healing due to alterations in collagen synthesis, diminished angiogenesis, and persistent low-grade inflammation. These factors collectively increase the risk of adverse outcomes following both medical and surgical interventions in diabetic patients[26]. In our study, the chronic systemic effects of diabetes, such as microvascular and macrovascular complications, appeared to play a critical role in the development of procedural complications. Impaired microvascular circulation, coupled with a heightened inflammatory state, may predispose patients with diabetes to localized tissue injury, delayed healing, and increased susceptibility to infection, thereby elevating the risk of both immediate and long-term complications. This finding is particularly relevant to our study's primary hypothesis, which aimed to evaluate the predictors of adverse outcomes following lead extraction. Additionally, our results suggest that diabetes should be carefully considered a critical risk factor during the preprocedural assessment of patients undergoing lead extraction. The identification of diabetes as a significant predictor underscores the importance of individualized risk stratification and highlights the need for meticulous perioperative management in patients with diabetes. Moreover, the long-term consequences of lead extraction, particularly in high-risk populations, such as those with diabetes, warrant further investigation to develop targeted strategies to optimize patient outcomes and minimize procedural risks. Carlini et al.[28] investigated predictors of cardiac implantable electronic device infections and readmissions, providing further evidence on the clinical significance of diabetes in post-procedural complications.

Study Limitations

This study has several limitations. Primarily, it is a single-center retrospective analysis, which inherently restricts the generalizability of the findings. Furthermore, the relatively small sample size limits the statistical power and may impact the robustness of the conclusions drawn. The timing of biomarker assessment is critical. The indices were likely measured preoperatively and thus may not account for the acute inflammatory surge or other physiological changes occurring during or immediately after the procedure. Monitoring the real-time inflammatory responses perioperatively may provide better predictive insights.

Future research should focus on refining the utility of these biomarkers by incorporating real-time inflammatory data, exploring localized inflammatory markers, and integrating procedural variables to develop comprehensive predictive models tailored to the context of lead extraction.

Conclusion

Our findings emphasize the importance of a thorough preprocedural risk assessment, particularly in patients with diabetes, to optimize outcomes. Future studies with larger sample sizes and prospective designs may help to further elucidate the interplay between systemic inflammation, metabolic conditions, and procedural complications, ultimately contributing to the development of targeted strategies to improve patient safety in lead extraction procedures.

Ethics

Ethics Committee Approval: This study was approved by the Scientific and Ethical Review Board for Medical Research No. 1 (TABED) under the chairmanship of the Ethics Committee (approval no.: 1-24-11, date: 14.02.2024).

Informed Consent: This was a single-center, retrospective study conducted in our hospital between 2019 and 2020.

Authorship Contributions

Surgical and Medical Practices: Çakmak Karaaslan Ö, Güray Ü, Concept: Çakmak Karaaslan Ö, Özilhan MO, Güray Ü, Design: Çakmak Karaaslan Ö, Güray Ü, Data Collection and/or Processing: Çakmak Karaaslan Ö, Girgin Dirliktutan G, Kaplan Z, Analysis and or Interpretation: Çakmak Karaaslan Ö, Güray Ü, Literature Search: Çakmak Karaaslan Ö, Girgin Dirliktutan G, Kaplan Z, Özilhan MO, Güray Ü, Writing: Çakmak Karaaslan Ö, Güray Ü.

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