

Survival of patients with cardiac implantable electronic device infections after transvenous lead extraction

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ABSTRACT

Background: Cardiac implantable electronic device (CIED) infections, particularly CIED-associated infective endocarditis (CIED-associated IE), are associated with a high 1-year mortality rate of 14%–35%, reduced quality of life, and increased burden on the healthcare system.

Aims: In this prospective, single-center, high-volume referral study, we aimed to analyze and compare 3 groups of patients who underwent transvenous lead extraction (TLE): patients with CIED-associated IE, patients with pocket infection (PI), and both.

Methods: This study included all consecutive patients with CIEDs who underwent TLE due to device-related infection at a tertiary referral hospital between 2011 and 2023. Patients were divided into 3 groups (CIED-associated IE, PI, and both indications) based on the modified Duke criteria.

Results: A total of 253 consecutive patients underwent TLE. Of these, 135 (53%) were treated for PI, 90 (36%) for CIED-associated IE, and 28 (11%) for both indications. Almost all procedures (97%) were completed without complications. Patients with CIED-associated IE had significantly higher mortality than patients in the CIED-associated IE + PI group, and patients in the PI group had the lowest mortality. One-year, 2-year, and 5-year overall survival rates in the CIED-associated IE group were 61%, 49%, and 32%, respectively, compared with 77%, 73%, and 56% in the CIED-associated IE + PI group and 90%, 86%, and 67% in the PI group ($P < 0.001$).

Conclusions: Patients with CIED-associated IE had almost 4-fold higher 1-year mortality compared to those with PI. Patients with CIED-associated IE and PI had about 2-fold higher 1-year mortality compared to those with PI.

Key words: cardiac implantable electronic devices, CIED-associated infective endocarditis, transvenous lead extraction

INTRODUCTION

The global use of cardiac implantable electronic devices (CIEDs), particularly implantable cardioverter-defibrillators (ICDs), continues to rise worldwide, mainly in emerging regions (Asia-Pacific) [1, 2]. In devices that utilize transvenous endocardial leads, the chronic intravascular presence of the leads contributes to a growing burden of complications, broadly categorized as infectious or non-infectious [3]. Infectious indications constitute a class I recommendation for transvenous

lead extraction (TLE) in both past and current consensus guidelines [4]. These infections range from localized surgical site involvement to CIED-associated infective endocarditis (IE). The Duke criteria have been adapted to support the diagnosis of CIED-associated IE and to help distinguish it from more limited pocket infections (PI) [5].

Infectious complications, particularly CIED-associated IE, are associated with significantly increased mortality, reduced quality of life, and greater strain on the healthcare

WHAT'S NEW?

In this analysis of patients with cardiac implantable electronic devices (CIED) who underwent transvenous lead extraction due to device-related infection, we compared those with CIED-associated infective endocarditis (CIED-associated IE), pocket infection (PI), and both. Patients with CIED-associated IE had more comorbidities and lower left ventricular ejection fraction. One-year, 2-year, and 5-year overall survival rates in the CIED-associated IE group were 61%, 49%, and 32%, respectively, compared with 77%, 73%, and 56% in the CIED-associated IE + PI group and 90%, 86%, and 67% in the PI group ($P < 0.001$). Patients with CIED-associated IE had almost 4-fold higher 1-year mortality compared to those with PI. However, patients with CIED-associated IE and PI had about 2-fold higher one-year mortality compared to those with PI.

system [6]. Reported CIED infection rates range from 1% to over 5% of patients [7–10], with such infections increasing the risk of in-hospital mortality by more than 2-fold. The estimated in-hospital 30-day mortality associated with CIED infections is 5% to 8%. Prognosis is particularly poor for patients with CIED-associated IE, while those with PI show survival rates similar to those of patients undergoing TLE for non-infectious indications [11].

Despite clear class I recommendations, utilization of TLE among hospitalized patients with CIED-associated IE remains low. A US study using the Nationwide Readmissions Database reported that only 11.5% of eligible patients underwent TLE [12].

Given that many CIEDs are implanted in older adults with multiple comorbidities, the incidence of infections and related complications is expected to rise. CIED infections often necessitate complete device removal and are associated with substantial financial costs and burden on the global healthcare system. These considerations highlight the need for greater emphasis on both infection prevention and timely, evidence-based treatment strategies [3, 13].

In this prospective, single-center, high-volume referral study, we aimed to analyze and compare 3 groups of patients who underwent TLE: CIED-associated IE, PI, and CIED-associated IE with PI.

METHODS

This prospective, single-center study included all patients with CIEDs who underwent TLE due to device-related infection at a tertiary referral clinical hospital between 2011 and 2023. Among the patients' CIED, there were no subcutaneous ICD or leadless devices. All patients with infectious indications for TLE were qualified for the procedure as a priority at our center. In cases of CIED-associated IE (also coexisting with PI), the time from diagnosis to TLE was less than 10 days, while in PI it was up to 14 days. Appropriate antibiotic therapy was administered according to the European Heart Rhythm Association consensus [11]. The study protocol was approved by the Ethics Committee of Jagiellonian University (KBET/259/B/2011), and written informed consent was obtained from all patients for the anonymous use of their clinical data. The study conformed to the principles outlined in the Declaration of Helsinki and followed Good Clinical Practice guidelines. Patients with

endocardial leads implanted less than 1 year prior to the procedure were excluded from the analysis.

TLE procedures were performed using Byrd Dilator Sheaths Telescoping Polypropylene and Evolution® RL Controlled-Rotation Dilator Sheath (Cook Medical LLC, Bloomington, IN, US). A detailed description of the TLE procedure has been provided in our previous study [14].

All patients were followed up in the cardiology outpatient clinic following the TLE procedure. The initial follow-up visit occurred 1–2 months post extraction, with subsequent visits scheduled at 6–12-month intervals. In cases of missed visits, clinical status was verified *via* telephone contact. All data were prospectively collected and stored in a secure database. Patient follow-up continued until the end of 2024. The exact date of death was obtained from the PESEL register. A detailed flowchart representing the study population is presented in [Figure 1](#). The analysis included patient demographics and clinical data at admission, device-related information, indications for implantation and lead extraction, procedural characteristics, inpatient treatment, and follow-up outcomes. Collected variables included age at index admission and at first implantation, sex, weight, height, survival status at the end of follow-up, and date of death where applicable. Clinical variables included the presence of an ICD, arterial hypertension, diabetes mellitus, dyslipidemia, ischemic heart disease, prior myocardial infarction, chronic heart failure, atrial fibrillation, chronic kidney disease (CKD), and history of ischemic stroke or transient ischemic attack. The Charlson Comorbidity Index (CCI) and the age-adjusted CCI (ACCI) were calculated for each patient.

Patients were divided into 3 groups based on the indication for TLE: CIED-associated IE, PI, and CIED-associated IE with PI. CIED-associated IE was diagnosed using the modified Duke criteria [5]. Comparative analysis between groups included clinical and demographic characteristics as well as long-term outcomes obtained from outpatient follow-up.

Statistical analysis

Statistical analysis was performed using Statistica 13.3 (StatSoft Europe GmbH, Hamburg, Germany). Standard descriptive statistics were used to summarize the data. Continuous variables were reported as mean (standard deviation) or median with interquartile range (IQR),

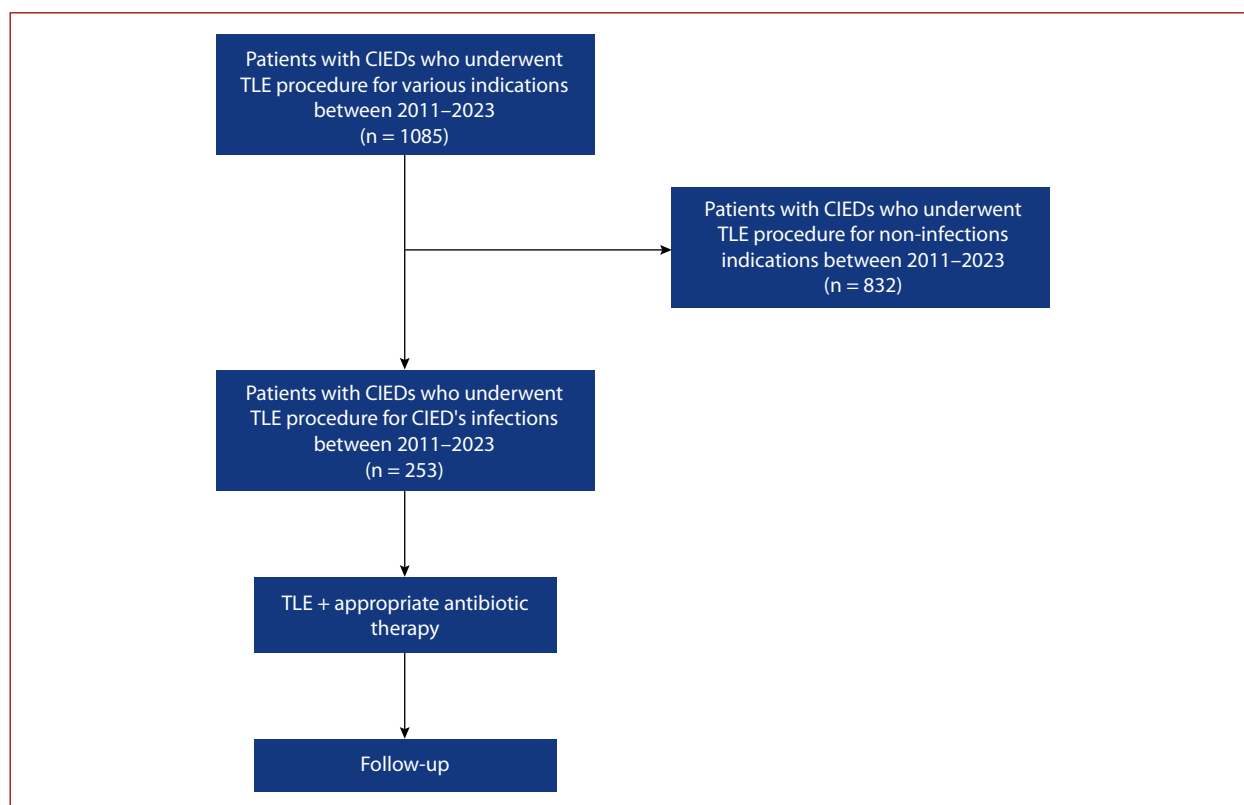


Figure 1. Flowchart representing the study population

Abbreviations: CIED, cardiac implantable electronic device; TLE, transvenous lead extraction

depending on distribution. Normality was assessed using the Kolmogorov–Smirnov test. For comparisons between groups, the Kruskal–Wallis analysis of variance with *post hoc* tests was used. Categorical variables were compared using the χ^2 test or Fisher’s exact test. Logistic regression analysis was performed to identify predictive factors for death within one year. All variables with *P*-values ≤ 0.1 on univariable analysis were entered into the multivariable model. The backward elimination method was used. The independent variables were expressed as odds ratios (ORs) with 95% confidence intervals (CIs). After performing multivariable analysis, the collinearity of predictors was assessed using the variance inflation factor, which did not show any significant collinearity. Survival analysis was conducted using the Kaplan–Meier method, and group differences were evaluated using the log-rank test. A 2-sided *P*-value of <0.05 was considered statistically significant.

RESULTS

A total of 253 consecutive patients underwent TLE. Of these, 135 (53%) were treated for PI, 90 (36%) for CIED-associated IE, and 28 (11%) for both indications for TLE surgery. Women accounted for 67 patients (26.5%). The median (IQR) age at the time of TLE was 72.2 (63.0–79.2) years. The median (IQR) total age of the extracted leads was 7.5 (3.5–15.6) years. The oldest extracted lead was 25.4 years old, and the youngest was 0.3 years old.

The types of extracted CIED systems were as follows: 23 (9%) single-chamber pacemakers, 107 (42%) dual-chamber pacemakers, 6 (2%) cardiac resynchronization therapy pacemakers, 50 (20%) single-chamber ICDs, 30 (12%) dual-chamber ICDs, and 37 (15%) cardiac resynchronization therapy defibrillators. Data on the analyzed types of CIEDs are presented in [Table 1](#).

The analyzed groups did not differ significantly in the number of prior CIED procedures. The time from the last CIED procedure to the occurrence of infection is noteworthy. It was significantly shorter in the PI group and in the CIED-associated IE + PI group compared to the CIED-associated IE group ($P < 0.001$; [Table 1](#)). A significant number of cultures were non-diagnostic due to prior antibiotic therapy at the referring centers. However, the predominant pathogens were as follows: *Staphylococcus epidermidis* and *Staphylococcus aureus* in the PI group, *Staphylococcus aureus*, *Enterococcus spp.*, and *Klebsiella pneumoniae* in the CIED-associated IE group, and *Staphylococcus aureus* in the CIED-associated IE + PI group.

A total of 246 procedures (97%) were completed without complications. Pericardial tamponade requiring pericardiocentesis occurred in 3 patients. In 4 cases, post-procedural anemia or pocket hematoma required blood transfusion ([Table 1](#)). All patients underwent appropriate antibiotic therapy.

In almost half of the patients (47.8%), an active fixation lead for temporary cardiac stimulation/defibrillation was

Table 1. Patient characteristics

Variable	All patients (n = 253)	Pocket infection ^a (n = 135)	CIED-associated IE ^b (n = 90)	CIED-associated IE + PI ^c (n = 28)	P-value
Sex (female), n (%)	67 (26.5)	37 (27.4)	25 (27.8)	5 (17.9)	0.55
Patient age, years	72.2 (63.0–79.2)	73.7 (65.7–80.0)	68.4 (60.6–77.2)	74.3 (57.9–82.1)	0.06
Device type:					
PM, %	130 (51.4)	77 (57.1)	36 (40.0)	17 (60.7)	0.03
ICD, %	80 (31.6)	35 (25.9)	37 (41.1)	8 (28.6)	0.052
CRT-P, %	6 (2.4)	3 (2.2)	3 (3.3)	0 (0.0)	0.59
CRT-D, %	37 (14.6)	20 (14.8)	14 (15.6)	3 (10.7)	0.81
Number of total leads	273	145	98	30	—
Number of ICD-leads	118	55	52	11	—
Number of pacing/left ventricular leads	155	90	46	19	—
Number of abandoned lead	20	10	8	2	—
Total lead age, months	90.1 (41.8–187.41)	70.9 (36.8–182.9)	102.0 (48.9–196.4)	113.0 (46.4–187.6)	0.52
Charlson Comorbidity Index	3.0 (1.0–4.0)	2.0 (1.0–4.0)	4.0 (2.0–5.0)	3.0 (1.0–4.0)	<0.001 ^{a,b}
Age-adjusted Charlson Comorbidity Index	6.0 (5.0–8.0)	6.0 (5.0–7.0)	7.0 (6.0–8.0)	6.0 (4.0–7.5)	0.01 0.02 ^{a,b}
Arterial hypertension, n (%)	201 (79.5)	110 (81.5)	70 (77.8)	21 (75.0)	0.66
Diabetes, n (%)	104 (41.1)	53 (39.3)	44 (48.9)	7 (25.0)	0.07
Dyslipidemia, n (%)	221 (87.4)	121 (89.6)	77 (85.6)	23 (82.1)	0.45
Ischemic heart disease, n (%)	154 (60.9)	78 (57.8)	60 (66.7)	16 (57.1)	0.37
Previous myocardial infarction, n (%)	103 (40.7)	47 (34.8)	46 (51.1)	10 (35.7)	0.04
Atrial fibrillation, n (%)	133 (52.6)	68 (50.4)	53 (58.9)	12 (42.9)	0.25
Chronic kidney disease, n (%)	65 (25.7)	28 (20.7)	28 (31.1)	9 (32.1)	0.15
Previous stroke or TIA, n (%)	30 (11.9)	14 (10.4)	14 (15.6)	2 (7.1)	0.36
LVEF, %	40.0 (26.0–55.0)	45.0 (34.0–55.0)	33.0 (23.0–48.0)	46.0 (33.0–56.0)	<0.001 ^{a,b} 0.03 ^{b,c}
eGFR, ml/min/1.73 m ²	61.0 (47.0–81.0)	65.0 (53.0–81.0)	56.0 (39.0–77.0)	60.5 (48.3–76.5)	0.08
BMI, kg/m ²	27.1 (24.1–30.4)	28.1 (25.0–30.5)	26.3 (23.1–30.1)	26.9 (22.8–29.3)	0.10
Number of previously performed procedures	1.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–2.0)	2.0 (1.0–2.0)	0.06
Last CIED-related procedure, months	21.0 (12.0–45.1)	17.5 (8.5–33.1)	35.9 (17.4–64.4)	14.8 (5.2–38.6)	0.001 <0.001 ^{a,b} 0.011 ^{b,c}
Active fixation lead as a bridge to next device implantation, n (%)	121 (47.8)	74 (54.8)	32 (35.6)	15 (53.6)	0.02
TLE results					
Complete success, n (%)	247 (97.6)	132 (97.8)	87 (96.7)	28 (100.0)	0.09
Clinical success (excluding complete success), n (%)	3 (1.2)	3 (2.2)	0 (0.0)	0 (0.0)	
Failure, n (%)	3 (1.2)	0 (0.0)	3 (3.3)	0 (0.0)	
Complications					
No complications, n (%)	246 (97.2)	132 (97.8)	86 (95.6)	28 (100.0)	0.51
Minor complications, n (%)	4 (1.6)	1 (0.7)	3 (3.3)	0 (0.0)	
Major complications, n (%)	3 (1.2)	2 (1.5)	1 (1.1)	0 (0.0)	

The data are given as a number (percentage) for categorical data and as median (interquartile range) for continuous variables

Abbreviations: BMI, body mass index; CIED, cardiac implantable electronic device; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacing; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; PM, pacemaker; TIA, transient ischemic attack; TLE, transvenous lead extraction

implanted as a bridge to CIED implantation, most frequently in the PI group (54.8%) and least frequently in the CIED-associated IE group (35.6%) (Table 1).

The median follow-up duration was 18.2 months (range 0.1–131.3 months). Baseline clinical characteristics of the 3 groups of patients are summarized in Table 1. Most patients in the groups were male. The median (IQR) age of patients with PI was 73.7 (65.7–80.0) years, for patients with CIED-associated IE it was 68.4 (60.6–77.2) years, and for patients with both indications it was 74.3 (57.9–82.1) years. Patients in the CIED-associated IE group had a higher (than

PI and both indications) median CCI (4.0 vs. 2.0 and 3.0), prior myocardial infarction (51.1% vs. 34.8% and 35.7%), lower median left ventricular ejection fraction (LVEF; 33% vs. 45% and 46%), and lower estimated glomerular filtration rate (56 ml/min/1.73 m² vs. 65 ml/min/1.73 m² and 60.5 ml/min/1.73 m², respectively).

Patients with CIED-associated IE had significantly higher mortality at 1-, 2-, and 5-year follow-up. One-year, 2-year, and 5-year overall survival rates in the CIED-associated IE group were 61%, 49%, and 32%, respectively, compared with 77%, 73%, and 56% in the CIED-associated IE + PI

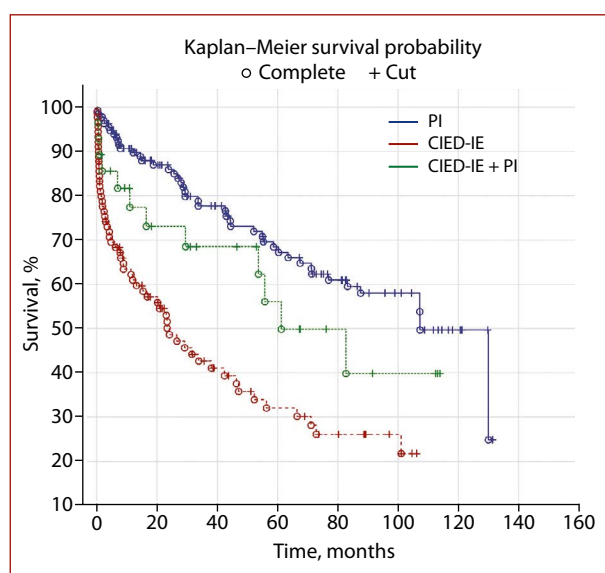


Figure 2. Kaplan-Meier survival probability

Abbreviations: CIED-IE, cardiac implantable electronic device-associated infective endocarditis; PI, pocket infection

group and 90%, 86%, and 67% in the PI group ($P < 0.001$). Kaplan-Meier survival curves are shown in [Figure 2](#).

Univariable and multivariable logistic regression analyses were performed to identify predictors of 1-year mortality. On univariable analysis, the following factors were associated with increased risk of death: CIED-associated IE, CIED-associated IE + PI, higher CCI, dyslipidemia, previous myocardial infarction, CKD, lower LVEF, lower estimated glomerular filtration rate, lower body mass index, and higher B-type natriuretic peptide level. In multivariable analysis, CIED-associated IE and CIED-associated IE + PI,

major TLE-related complications (OR, 42.57; 95% CI, 1.75–1037.13; $P = 0.02$), higher CCI (OR, 3.07; 95% CI, 1.89–5.00; $P < 0.001$), and diabetes (OR, 0.29; 95% CI, 0.09–0.95; $P = 0.04$) remained statistically significant predictors. Detailed regression results are presented in [Table 2](#).

DISCUSSION

Infections related to CIEDs, particularly CIED-associated IE, are associated with significantly increased mortality, substantial financial costs, and burden on the healthcare system [15]. With the growing number of device implantations and ageing populations, early recognition and evidence-based treatment are essential. The 2020 European Heart Rhythm Association consensus recommends TLE followed by 10–14 days of antibiotics for PI and 4–6 weeks for CIED-associated IE [11]. All patients in our center were managed in line with these recommendations, which is still not a global standard.

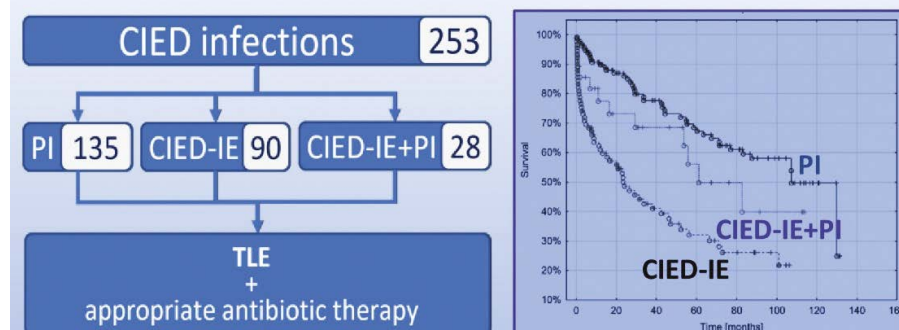
In our study, 97% of procedures were completed without complication and with no procedure-related perioperative deaths. Similarly, data from the Silesian Cardiovascular Database showed a 93.3% rate of procedures without complications [16]. Achieving an even lower percentage of complications was obtained in the group of patients with TLE of His bundle pacing leads [17]. In our cohort, patients with CIED-associated IE had a 1-year mortality rate of 39%, almost 4 times higher than the 10% observed in those with PI. This disparity underscores the systemic burden of CIED-associated IE and its prognostic implications. CIED-associated IE patients also had higher CCI, higher prevalence of CKD, prior myocardial infarction, and lower LVEF — each of which contributes to increased risk of adverse outcomes.

Table 2. Predictive factors for death within one year

Variable	Univariable OR (95% CI)	P-value	Multivariable OR (95% CI)	P-value
Sex (male)	1.53 (0.74–3.18)	0.25	—	—
CIED-associated IE vs. PI	3.89 (1.98–6.18)	<0.001	3.82 (1.69–8.60)	<0.001
CIED-associated IE vs. CIED-associated IE + PI	2.05 (1.59–2.48)	<0.001	2.36 (1.37–3.42)	0.010
CIED-associated IE + PI vs. PI	1.89 (1.22–2.56)	0.03	1.38 (1.15–4.64)	0.04
Patient age at TLE, years	1.01 (0.99–1.03)	0.48	—	—
Lead age at TLE, months	1.00 (0.99–1.00)	0.54	—	—
Minor TLE complications	3.79 (0.52–27.54)	0.19	—	—
Major TLE complications	7.62 (0.68–85.63)	0.10	42.57 (1.75–1037.13)	0.02
Charlson scale, points	1.95 (1.57–2.43)	<0.001	3.07 (1.89–5.00)	<0.001
Arterial hypertension	1.18 (0.55–2.53)	0.68	—	—
Diabetes	1.74 (0.95–3.19)	0.07	0.29 (0.09–0.95)	0.04
Dyslipidemia	4.62 (1.07–19.97)	0.04	4.18 (0.70–25.00)	0.12
Ischemic heart disease	1.70 (0.89–3.25)	0.11	—	—
Previous myocardial infarction	3.20 (1.72–5.98)	<0.001	0.38 (0.01–1.43)	0.15
Atrial fibrillation	1.56 (0.84–2.87)	0.16	—	—
Chronic kidney disease	3.08 (1.63–5.83)	0.001	1.16 (0.43–3.15)	0.77
Previous stroke/TIA	1.14 (0.46–2.82)	0.78	—	—
LVEF, %	0.96 (0.94–0.98)	0.001	0.98 (0.94–1.01)	0.23
eGFR, ml/min/1.73 m ²	0.97 (0.96–0.99)	<0.001	1.01 (0.97–1.03)	0.87
BMI, kg/m ²	0.93 (0.87–0.99)	0.03	0.95 (0.85–1.06)	0.39

Abbreviations: IE, infective endocarditis; OR, odds ratio; PI, pocket infection; other — see [Table 1](#)

Survival of patients with cardiac implantable electronic device infections after transvenous lead extraction



Patients with CIED-associated IE had almost a **four-fold** higher one-year mortality compared to those with PI. However, patients with CIED-associated IE and PI had about **twice** higher one-year mortality compared to those with PI.

Graphical abstract

Abbreviations: see Figures 1 and 2

Comparing our findings with international data, the Medicare database study reported that only 16.7% of 4215 patients with CIED-associated IE underwent TLE. One-year mortality was 31.4% in those who did not undergo TLE and 24.9% among patients who received extraction within 7 days of diagnosis [18].

Several other studies have reported similar findings. Cahill et al. [19] observed 30% annual mortality in IE of all types. The University of Lausanne reported 31% annual mortality in patients with prosthetic valve endocarditis [20]. At Rigshospitalet in Copenhagen, where all patients underwent TLE, mortality was 14%, with no difference between CIED-associated IE and PI [21]. The lower mortality may reflect a generally healthier patient population with fewer comorbidities and higher LVEF.

Tarakji et al. [22] found 31% mortality for CIED-associated IE and 12% for PI at Cleveland Clinic. Similarly, Australian data from Barwon Health showed 23% 1-year mortality for CIED-associated IE [23]. Polewczyk et al. [24] reported identical CIED-associated IE mortality of 23% in Kielce, Poland. Despite similar age profiles, their patients had lower prevalence of diabetes and CKD compared to our cohort.

Toriello et al. [25] emphasized that TLE for infection carries higher risk of complications than TLE for non-infectious indications. However, urgent extraction significantly reduces 1-year mortality by up to 3-fold [25]. A notably high 1-year mortality rate of 83% was reported by Ząbek et al. [26] from our institution in a case series involving patients with concomitant CIED infection and mechanical left ventricular assist devices. These results are consistent with previously published data by Krishnamoorthy et al. [27]. Overall, variability in outcomes across studies likely reflects differences in patient selection, timing of TLE, infection severity, and local treatment protocols.

Study limitations

The primary study limitation was the relatively small sample of patients with different types of CIED infections and single-center experience. Another limitation was the high rate of sterile/non-diagnostic blood cultures.

CONCLUSIONS

This study confirms the high safety and efficacy of TLE, with 97% of procedures completed without complication and with no procedure-related perioperative deaths. However, significant differences in patient survival were observed between those with CIED-associated IE and those with PI. One-year mortality for CIED-associated IE was almost a 4-fold higher compared to PI (39% vs. 10%). However, patients with CIED-associated IE and PI had about 2-fold higher 1-year mortality compared to those with PI. CIED-associated IE, major procedural complications, and higher CCI were independently associated with worse outcomes.

These results highlight the importance of early diagnosis, risk stratification, and aggressive, guideline-directed management for patients with CIED-associated IE. Future research should focus on developing optimized post-extraction treatment algorithms to reduce long-term mortality in this high-risk population.

Article information

Conflict of interest: None.

Declaration of artificial intelligence use: Nothing to disclose.

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