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Cardiac Implantable Electronic Device Infections at a Tertiary Center in Southern Chile (2015–2021): A Retrospective Cohort Study

Alban Landeros B. [1,2], Mauricio Soto V. [1,3], Cheryld Mutel G. [1] and Luis Quiñiñir S. [1,3,*]

[1] Department of Internal Medicine, Faculty of Medicine, Universidad de La Frontera, Temuco, Araucanía Region, 4811230, Chile

[2] Hospital de Pitrufquén, Pitrufquén, Araucanía Region, 4920000, Chile

[3] Department of Cardiology, Hospital Dr. Hernán Henríquez Aravena, Manuel Montt 115, Temuco, Araucanía Region, 4781151, Chile

* Correspondence: lrquininir@ufrontera.cl

Abstract

Background/Objectives: Cardiac implantable electronic device (CIED) infections are infrequent but clinically significant, and Latin American — particularly Chilean — data remain scarce. We aimed to describe the clinical and microbiological profile, complications, mortality, and local infection burden of CIED infections at a tertiary center in southern Chile. Methods: Retrospective descriptive cohort study of all patients treated for CIED infection at Hospital Dr. Hernán Henríquez Aravena between January 2015 and December 2021. Crude per-procedure infection proportions were calculated using locally implanted devices as the denominator; approximate incidence rates per 100 patient-years were estimated for comparison with international cohorts. Results: Fifty-four patients were included (77.8% men; mean age 69 ± 14 years). Predominant comorbidities were arterial hypertension (79.6%), heart failure (40.7%), atrial fibrillation (27.8%), and type 2 diabetes mellitus (24.1%). Pacemakers accounted for 59.3% of infections, and late-onset cases predominated (48.2%). The overall infection proportion was 1.4% (95% confidence interval [CI] 1.1–1.9%), reaching 5.5% for implantable cardioverter-defibrillators (ICDs) and 4.3% for cardiac resynchronization therapy (CRT) devices. Approximate incidence rates per 100 patient-years were 0.32, 1.57, and 1.24 for pacemakers, ICDs, and CRT devices, respectively. Coagulase-negative Staphylococcus (43.2%) and Staphylococcus aureus (24.3%) were the leading isolates. Complete system extraction was attempted in all patients and achieved in all but one case; recurrence occurred in 9.3% and in-hospital mortality in 1.9%. Conclusions: The clinical and microbiological profile mirrored international cohorts, but approximate incidence rates for complex devices exceeded those of major nationwide registries. Findings identify clear targets: optimizing microbiological sampling, expanding pre-procedural echocardiography, and strengthening long-term follow-up of CIED carriers.

Keywords: cardiac implantable electronic devices; device-related infections; pacemaker; implantable cardioverter-defibrillator; cardiac resynchronization therapy; staphylococcal infections; lead extraction; Latin America; Chile

1. Introduction

Cardiac implantable electronic device (CIED) infections are an infrequent but clinically significant complication associated with substantial morbidity, prolonged hospitalization, and considerable healthcare costs. Large population-based and hospital cohorts have reported cumulative infection rates of approximately 1–2% over the device lifespan, with two- to four-fold higher figures for defibrillators and resynchronization systems than for conventional pacemakers [1–

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4]. This rising burden reflects the expanding global use of CIEDs, the older age of recipients, and the increasing comorbidity profile of contemporary candidates [4–6].

Recognized risk factors include chronic kidney disease (CKD), heart failure (HF), diabetes mellitus (DM), anticoagulant use, pocket hematoma, and procedural factors such as device revisions and generator or lead replacements [6–9]. CIED infections are conventionally classified by their temporal pattern as early (<30 days after implantation), delayed (30 days to 12 months), or late (>12 months), a distinction with pathophysiological and prognostic relevance [4,6].

Despite this growing body of evidence, data from Latin America remain limited and are largely derived from small institutional series focused on overall procedural complications rather than on infection-specific outcomes [10]. Published evidence from Chile is particularly scarce, hindering accurate estimation of the local burden and its epidemiological particularities. Characterizing the experience of high-volume referral centers in the region is therefore essential to inform regional benchmarks, identify modifiable risk factors, and guide preventive strategies.

The primary aim of this study was to describe the clinical and microbiological profile, complications, and mortality of CIED infections managed at Hospital Dr. Hernán Henríquez Aravena (HHHA; Temuco, Chile) between 2015 and 2021. Secondary objectives were to identify common risk factors, isolated microorganisms, and complications, and to estimate the local infection burden in devices implanted at the center during the same period..

2. Materials and Methods

2.1. Study Design and Setting

We conducted a retrospective descriptive cohort study including all consecutive patients treated for CIED infection at HHHA, a tertiary referral center for cardiac electrophysiology in southern Chile, between January 2015 and December 2021. The manuscript was prepared in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for cohort studies (see Supplementary Materials, Table S1).

2.2. Case Identification and Selection

Cases were identified through the institutional electrophysiology registry and systematic review of the hospital information system using International Classification of Diseases, 10th Revision (ICD-10) codes compatible with CIED infection. Data were extracted from physical and electronic medical records. Because the study began in 2015, prior to publication of the standardized European Heart Rhythm Association (EHRA) 2020 diagnostic criteria [6], formal application of the definite/possible/rejected EHRA classification was not feasible. The diagnosis of CIED infection was therefore established by the treating electrophysiologist on the basis of one or more of the following: (i) clinical signs of pocket infection (erythema, swelling, purulent discharge, dehiscence, or device exposure); (ii) microbiological isolation of an organism from pocket tissue, lead tip, or blood cultures in the context of clinical suspicion; or (iii) echocardiographic evidence of lead or valvular vegetation.

Of the 71 cases initially identified by ICD-10 screening, 13 were excluded after expert review because the final clinical diagnosis was not CIED infection (alternative diagnoses included cellulitis unrelated to the device, surgical wound dehiscence without infection, and superficial skin irritation), and 4 were excluded due to insufficient clinical information, yielding a final analytic cohort of 54 patients (Figure 1).

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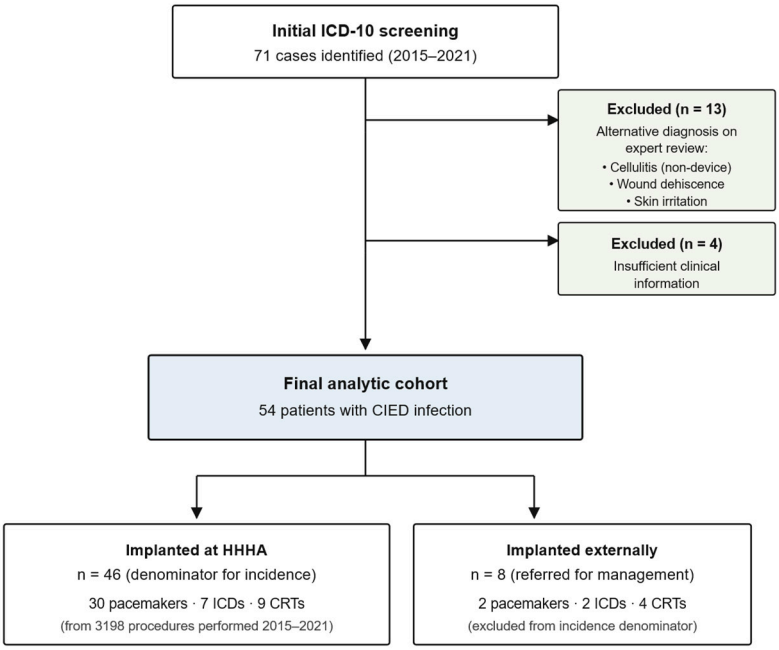

Figure 1. STROBE flow diagram of case selection. Of 71 cases initially identified through ICD-10 screening of the institutional electrophysiology registry and hospital information system, 13 were excluded after expert review (alternative diagnoses) and 4 were excluded due to insufficient clinical information, yielding 54 patients for analysis. CIED, cardiac implantable electronic device; HHHA, Hospital Dr. Hernán Henríquez Aravena; ICD-10, International Classification of Diseases, 10th Revision; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

2.3. Operational Definitions and Local Burden Estimation

Recurrence was defined as any new device-related infection occurring within two years after reimplantation. Recurrences were ascertained from subsequent hospital admissions and outpatient electrophysiology visits documented in the institutional medical record system. No active systematic post-discharge surveillance was performed, and recurrences managed at external centers would not have been captured.

The local infection burden was calculated using only infections occurring in devices implanted at HHHA. During the study period, 3198 procedures were performed at the center — including primary implants, generator replacements, and upgrades — distributed as 2686 pacemakers (PMs), 127 implantable cardioverter-defibrillators (ICDs), 208 cardiac resynchronization therapy (CRT) devices, and 177 procedures whose device type could not be determined. Forty-six of these locally implanted devices subsequently developed confirmed infection.

The crude per-procedure infection proportion (referred to throughout as cumulative incidence for brevity, while recognizing that it is not a formal cumulative incidence in the epidemiological sense) was calculated as the number of infections divided by the corresponding number of procedures. Because the denominator combines primary implants with generator replacements and upgrades (events that may recur in the same patient), and because annual implant volumes were not retrievable from the registry, this metric reflects an infection proportion per procedure rather than a per-patient cumulative incidence. To enable approximate comparison with cohorts reporting time-adjusted rates, exploratory incidence rates per 100 patient-years were also estimated, assuming a uniform distribution of implants across the seven-year period and a mean follow-up per device equal to half the period (3.5 years). These estimates do not account for individual follow-up duration, censoring, competing events, or growth in annual implant volume, and should be interpreted as exploratory benchmarks rather than formal incidence-density estimates.

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2.4. Variables

The following variables were collected: age, sex, and comorbidities (arterial hypertension [AHT], type 2 diabetes mellitus [T2DM], atrial fibrillation [AF], CKD defined as stage V or requiring hemodialysis, HF, and use of anticoagulants or corticosteroids). Procedural and microbiological variables included antibiotic prophylaxis, type of implanted device, type of infection (local infection or cardiac device-related infective endocarditis [CDRIE]), isolated microorganism, and antimicrobial treatment (regimen and duration). Outcome variables comprised device extraction (technique and timing), associated complications (sepsis, osteomyelitis, embolism), and in-hospital mortality.

2.5. Statistical Analysis

The statistical analysis was descriptive. Categorical variables were summarized as absolute frequencies and percentages. The distribution of continuous variables was assessed with the Shapiro–Wilk test; normally distributed variables are presented as mean ± standard deviation (SD), and non-normally distributed variables as median with interquartile range (IQR). Ninety-five percent confidence intervals (95% CIs) for proportions were computed using the Wilson score method for the overall and device-specific infection proportions reported in Table 2, and using the Clopper–Pearson exact method for the microbiological proportions reported in Table 4, where the smaller subgroup denominator (n = 37) made exact intervals preferable. No inferential analyses were performed. All analyses were conducted using Stata software, version 16 (StataCorp LLC, College Station, TX, USA). No generative artificial intelligence tools were used for data analysis.

2.6. Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Scientific Ethics Committee of the Servicio de Salud Araucanía Sur (CEC SSAS; accredited by Resolución Exenta N° 2309584491 of 12 December 2023) under Official Letter (Oficio) N° 370 of 30 October 2024, with formal approval dated 28 October 2024. The study was approved under its original Spanish title, *Infecciones asociadas a dispositivos electrónicos cardiacos implantables en el Hospital Dr. Hernán Henríquez Aravena entre los años 2015–2021, experiencia en un centro de referencia* (principal investigator: Dr. Alban Landeros Bravo). Given the retrospective design and the exclusive use of an anonymized institutional database extracted by an independent third party not involved in the analysis, the requirement for written informed consent was waived by the Ethics Committee.

3. Results

3.1. Demographics and Comorbidities

A total of 54 patients with CIED infection were included; 77.8% were male and 22.2% female, with a mean age of 69 ± 14 years. Of these, 46 (85.2%) had been implanted at HHHA and 8 (14.8%) had been implanted at external centers and referred for management. AHT was present in 79.6%, T2DM in 24.1%, CKD stage V or on hemodialysis in 7.4%, AF in 27.8%, and HF in 40.7%. The median left ventricular ejection fraction (LVEF) was 46% (IQR 27–60). Anticoagulant use (vitamin K antagonists or direct oral anticoagulants) was documented in 18.5% of patients, recent device manipulation (any pocket or lead intervention within the 30 days preceding the diagnosis of infection) in 6 patients (11.1%), and previous use of a temporary pacing lead in 5 patients (9.3%). Detailed baseline characteristics are presented in Table 1.

Table 1. Demographic characteristics and comorbidities of patients with CIED infection (n = 54).

Variable	Value
Age, years (mean ± SD)	69 ± 14

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Variable	Value
Male sex, n (%)	42 (77.8%)
Female sex, n (%)	12 (22.2%)
Arterial hypertension, n (%)	43 (79.6%)
Type 2 diabetes mellitus, n (%)	13 (24.1%)
Heart failure, n (%)	22 (40.7%)
LVEF, % (median, IQR)	46 (27–60)
Atrial fibrillation, n (%)	15 (27.8%)
Anticoagulant use, n (%)	10 (18.5%)
Chronic kidney disease (stage V or hemodialysis), n (%)	4 (7.4%)
Previous device manipulation, n (%)	6 (11.1%)
Previous temporary pacing lead, n (%)	5 (9.3%)

CIED, cardiac implantable electronic device; IQR, interquartile range; LVEF, left ventricular ejection fraction; SD, standard deviation.

3.2. Device Type, Timing, and Infection Proportion

Among the 54 infected devices, 32 were pacemakers (59.3%), 9 implantable cardioverter-defibrillators (16.7%), and 13 cardiac resynchronization therapy devices (24.1%). The 46 locally implanted infected devices (30 PMs, 7 ICDs, 9 CRTs) constituted the analytic denominator for incidence calculations, whereas the 8 externally implanted devices (2 PMs, 2 ICDs, 4 CRTs) were excluded from this denominator but retained in the descriptive analyses.

By temporal classification, 12.9% (n = 7) were early-onset, 38.8% (n = 21) delayed-onset, and 48.2% (n = 26) late-onset. The median time from implantation to diagnosis was 448 days (IQR 122–1252), with a mean of 858 ± 1003 days.

A total of 3198 CIEDs were implanted at HHHA during 2015–2021 (2686 PMs, 127 ICDs, 208 CRTs, and 177 unclassified procedures). Of these, 46 developed confirmed infection (30 PMs, 7 ICDs, and 9 CRTs), yielding an overall infection proportion of 1.4% (95% CI 1.1–1.9%). Device-specific infection proportions were 1.1% for PMs (95% CI 0.8–1.6%), 5.5% for ICDs (95% CI 2.7–10.9%), and 4.3% for CRTs (95% CI 2.3–8.0%) (Table 2). When restricted to infections occurring within the first post-implantation year (early plus delayed cases), the infection proportion was 1.6% for ICDs (2/127) and 2.4% for CRTs (5/208).

To enable comparison with cohorts reporting time-adjusted rates, approximate incidence rates per 100 patient-years were estimated. Assuming a uniform distribution of implants across the seven-year period and a mean per-device follow-up of 3.5 years, the corresponding patient-time accruals were approximately 9400, 445, and 728 patient-years for PMs, ICDs, and CRTs, respectively. The resulting approximate incidence rates were 0.32 per 100 patient-years for PMs, 1.57 per 100 patient-years for ICDs, and 1.24 per 100 patient-years for CRTs. These estimates should be interpreted with caution: they rely on the assumption of uniform implantation and do not account for individual follow-up duration, censoring, or competing events. They are presented to facilitate comparison with previously published cohorts rather than as formal incidence-rate estimates.

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Table 2. Crude per-procedure infection proportion of CIED infection by device type, 2015–2021.

Device type	Total implants (n)	Infections (n)	Infection proportion (%)	95% CI
Pacemaker (PM)	2686	30	1.1	0.8–1.6
Implantable cardioverter-defibrillator (ICD)	127	7	5.5	2.7–10.9
Cardiac resynchronization therapy (CRT)	208	9	4.3	2.3–8.0
Unclassified	177	—	—	—
Total	**3198**	**46**	**1.4**	**1.1–1.9**

CI, confidence interval; CIED, cardiac implantable electronic device; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; PM, pacemaker. Infection proportion = (infections / total implants) × 100. The denominator includes primary implants, generator replacements, and upgrades. Unclassified procedures were excluded from device-specific estimates but retained in the overall denominator. First-year infection proportions (early plus delayed infections) were 1.6% for ICDs (2/127) and 2.4% for CRTs (5/208). Approximate incidence rates per 100 patient-years (assuming uniform implantation across the seven-year period and 3.5 years of mean per-device follow-up) were 0.32 for PMs, 1.57 for ICDs, and 1.24 for CRTs.

3.3. Type of Infection

Pocket infection was the most frequent clinical presentation (n = 36, 66.7%), followed by lead infection (n = 9, 16.7%) and a single case of infective endocarditis (1.9%); in 8 cases (14.8%) the anatomical type of infection could not be classified. The interval between implantation and diagnosis ranged from 2 to 4253 days (Table 3).

Table 3. Type of infection, timing, and interval from implantation to diagnosis.

Variable	Value
Type of infection	
Pocket infection, n (%)	36 (66.7%)
Lead infection, n (%)	9 (16.7%)
Device-related infective endocarditis, n (%)	1 (1.9%)
Unclassifiable, n (%)	8 (14.8%)
Timing	
Early (<30 days), n (%)	7 (12.9%)
Delayed (30 days–12 months), n (%)	21 (38.8%)
Late (>12 months), n (%)	26 (48.2%)
Time from implantation to diagnosis	

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Variable	Value
Median (IQR), days	448 (122–1252)
Mean ± SD, days	858 ± 1003

IQR, interquartile range; SD, standard deviation.

3.4. Microbiology

Microbiological samples were obtained from 37 patients (68.5%). Coagulase-negative *Staphylococcus* was the most frequently isolated organism (n = 16, 43.2%), of which 6 (37.5%) were oxacillin-resistant. *Staphylococcus aureus* was recovered in 9 patients (24.3%), all oxacillin-susceptible. Gram-negative bacilli were identified in 2 patients (5.4%) and *Enterococcus* spp. in 1 patient (2.7%); cultures were negative in 9 patients (24.3%). Microbiological findings are summarized in Table 4.

Table 4. Microorganisms isolated from microbiological cultures (n = 37).

Microorganism	n (%)	95% CI
Coagulase-negative *Staphylococcus* (total)	16 (43.2%)	27.1–60.5
Oxacillin-susceptible	10 (27.0%)	14.6–43.1
Oxacillin-resistant	6 (16.2%)	6.2–31.3
Staphylococcus aureus (all oxacillin-susceptible)	9 (24.3%)	11.8–41.2
Gram-negative bacilli	2 (5.4%)	0.7–18.2
Enterococcus spp.	1 (2.7%)	0.1–14.2
Negative cultures	9 (24.3%)	11.8–41.2

CI, confidence interval (Clopper–Pearson exact method). Percentages calculated over the 37 patients with microbiological samples.

3.5. Echocardiographic Assessment

Echocardiographic assessment was incomplete in this cohort: 17 patients (31.5%) underwent transthoracic echocardiography (TTE), of whom only 2 (3.7% of the full cohort) also underwent transesophageal echocardiography (TEE); 27 patients (50.0%) had no echocardiographic study performed, and in 10 cases (18.5%) no information regarding echocardiography was retrievable.

3.6. Antimicrobial Treatment

Antibiotic treatment information was available for 50 patients (92.6%). The most frequent empirical regimen was vancomycin monotherapy (n = 17, 34.0%), followed by cephalosporin monotherapy with cefazolin or cefadroxil (n = 15, 30.0%), vancomycin combined with a cephalosporin (n = 9, 18.0%), cloxacillin (n = 6, 12.0%), and other regimens (n = 3, 6.0%). The median duration of antibiotic therapy was 14 days (IQR 10–21), with a range of 0 to 65 days. The median hospital stay was 13 days (IQR 4–17).

3.7. Device Extraction and Reimplantation

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Complete system extraction was attempted in all 54 patients. Simple manual traction was used in 38 cases (70.4%), complex extraction techniques in 6 cases (11.1%), and the extraction technique was not documented in 10 cases (18.5%). In one patient, lead extraction was not feasible because of the unavailability of an advanced extraction device, with no subsequent complications. No surgical extractions were required, and no major peri-procedural complications (hemopericardium, pneumothorax, or peri-procedural death) were recorded. The median time from infection diagnosis to device extraction was 6.5 days (IQR 1.25–15.75; mean 12.1 ± 16.4 days; range 0–76 days). Reimplantation was performed in 41 of the 54 patients (75.9%).

3.8. Recurrence and Mortality

Five patients (9.3%) developed recurrent infection, with a mean age of 74 years. Four were pocket infections and one a case of CDRIE. The mean time to recurrence was 9 months, distributed as: one case within the first month after implantation, three between 1 and 12 months, and one beyond the first year after definitive implantation. No fatal outcomes or major complications were documented in association with recurrence.

In-hospital mortality occurred in a single patient (1.9%, 95% CI 0.3–9.6%), corresponding to the only case of sepsis observed in the cohort. This patient had chronic kidney disease, multiple comorbidities, and a severe clinical course complicated by septic shock. No additional cases of sepsis, osteomyelitis, or embolic events were recorded.

4. Discussion

In this retrospective cohort from a tertiary referral center in southern Chile, the demographic and microbiological profile of CIED infections paralleled that of major international series [5,6], whereas crude per-procedure infection proportions for complex devices (ICDs and CRTs) appeared higher than those reported in large nationwide registries. The cohort also reveals locally relevant gaps in diagnostic workup, microbiological yield, and procedural surveillance that represent concrete opportunities for quality improvement.

4.1. Demographic and Microbiological Profile

The demographic profile observed in our cohort, with male predominance (77.8%) and a mean age of 69 years, mirrors that of previously published series, in which the higher comorbidity burden and broader indication for CIEDs among men may explain the observed pattern [5]. The prevalence of AHT, T2DM, HF, and AF was also consistent with the literature. The low proportion of patients with CKD (7.4%) is unexpected and likely reflects underreporting in the pre-digitization period rather than a true epidemiological difference [5,7,8].

Staphylococci predominated, with coagulase-negative *Staphylococcus* accounting for 43.2% of isolates and *Staphylococcus aureus* for 24.3%, the majority oxacillin-susceptible. These figures are in line with international series in which these two groups jointly represent 60% to 85% of CIED infections [4,6,12]. Microbiological documentation was nonetheless incomplete: 17 patients had no cultures obtained, and 24.3% of those cultured remained culture-negative. These gaps likely reflect early initiation of empirical antibiotic therapy before sampling, incomplete retrieval of prior microbiological records, and inconsistent collection of lead or deep-tissue specimens — patterns also reported in other cohorts [11]. Empirical regimens were dominated by vancomycin and cephalosporin monotherapy, with a median treatment duration of 14 days (IQR 10–21), matching the prevailing susceptibility profile. These findings support a systematic diagnostic protocol prioritizing pre-antibiotic blood cultures, routine deep-tissue sampling, and selective use of molecular diagnostics in culture-negative cases.

4.2. Device-Specific Infection Burden

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Pacemakers accounted for the majority of infected devices (59.3%), reflecting their greater procedural volume rather than a higher per-device risk, in keeping with previous series [5]. More complex devices showed a proportionally higher infection burden (5.5% for ICDs and 4.3% for CRTs versus 1.1% for pacemakers), figures in the upper range of the published literature [4,5,9]. When compared with the Danish nationwide cohort reported by Olsen et al., which reported incidence rates after de novo implantation of 0.20 per 100 patient-years for PMs, 0.38 per 100 patient-years for ICDs, and 0.68 per 100 patient-years for CRT-defibrillators [1], our approximate estimates appear higher, with rates roughly 4-fold higher for ICDs and 2-fold higher for CRTs. This discrepancy is consistent with the elevated per-procedure infection proportions observed in these device categories and may reflect a combination of patient comorbidity burden, procedural volume, and operator experience in a regional referral setting; it also points to a need for targeted procedural quality improvement in complex device implantation. These estimates should nonetheless be interpreted cautiously, since the absence of complete implantation dates precluded formal exposure-time adjustment, the denominator includes primary implants together with replacements and upgrades (which carry higher infection risk than de novo procedures), and the comparison is therefore not strictly equivalent.

4.3. Temporal Pattern and Prevention

The temporal distribution was dominated by late-onset (48.2%) and delayed-onset (38.8%) infections, which are typically attributed to transient bacteremia or distant infectious foci rather than to peri-implant contamination [6,8]. This pattern argues for long-term surveillance, comorbidity control, and prompt evaluation of any febrile or systemic infection in CIED carriers, particularly in elderly patients and those with multiple risk factors.

Regarding prevention, the elevated infection proportion observed for complex devices in our cohort highlights the relevance of contemporary preventive strategies. The Worldwide Randomized Antibiotic Envelope Infection Prevention (WRAP-IT) trial demonstrated that an absorbable antibacterial envelope reduced major CIED infections by approximately 40% in high-risk patients undergoing replacement, revision, or de novo CRT or ICD implantation [13]. Other measures recommended by current consensus documents include strict pre-procedural skin antisepsis, weight-adjusted intravenous antibiotic prophylaxis administered within 60 minutes of incision, meticulous hemostasis, axillary or cephalic venous access where feasible to minimize the number of cannulations, and timely treatment of pocket hematomas [6]. Leadless pacemakers, which eliminate both pocket and transvenous lead-related infections in selected single-chamber pacing indications, were not available at our institution during the study period; the leadless pacemaker program at HHHA was initiated in 2022, so these devices are not represented in the present cohort.

4.4. Extraction, Recurrence, and Mortality

Complete system extraction was attempted in all patients, in accordance with international recommendations that establish full hardware removal as the cornerstone of treatment to minimize recurrence and mortality [6,11]. Thirteen patients (24.1%) did not undergo subsequent reimplantation, suggesting that the original device indication warrants reassessment in the context of an infection. The specific reasons for non-reimplantation were not systematically captured but may include loss of clinical indication, clinician judgment regarding short life expectancy, patient preference, in-hospital death, or other causes; this question merits prospective investigation.

Recurrence occurred in 9.3% of patients, comparable to the 5–15% range typically reported in the literature, depending on cohort characteristics and recurrence definitions [4,11]. The mean age of patients with recurrence (74 years) was slightly higher than that of the overall cohort, which may signal an additional contribution from frailty, immunosenescence, or accumulated comorbidities. Three recurrences occurred in patients who had undergone single-stage explantation and reimplantation, a practice subsequently discouraged by international guidelines and discontinued at our center [6]. No fatal outcomes or major complications were associated with recurrence, an

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observation that likely reflects early antibiotic therapy, timely device extraction, and, in part, the limited sample size.

A single case of sepsis was documented and corresponded to the only in-hospital fatal outcome, yielding an in-hospital mortality of 1.9% (95% CI 0.3–9.6%). Although this figure appears at the lower end of the in-hospital mortality range reported in CIED infection cohorts [4,5], a single event provides limited statistical precision and the confidence interval remains compatible with substantially higher mortality. The literature also reports much higher mortality at longer time horizons — between 8% and 20% at 1 year and up to 25–35% at 5 years in patients with device-related infective endocarditis [6,12] — which the in-hospital denominator used here cannot capture. No osteomyelitis or embolic events were observed in the cohort. The fatal case had CKD, multiple comorbidities, and prior use of a temporary pacing lead, factors that increase both the risk of infection and the risk of poor outcome, and that highlight the importance of careful patient selection and timely definitive device implantation. The absence of systematic post-discharge follow-up is therefore a significant limitation that precludes reliable estimation of medium- and long-term mortality in this cohort.

4.5. Limitations

This study has several limitations inherent to its retrospective single-center design. First, the case definition relied on clinical, microbiological, and imaging-based judgment by the treating electrophysiologist rather than on a standardized scheme, since the EHRA 2020 diagnostic criteria were not available at study initiation [6]; retrospective reclassification of cases against these criteria would be valuable in future work. Second, the denominator used for incidence estimates combines primary implants with generator replacements and upgrades (events that may recur in the same patient), so the resulting figures represent infection proportions per procedure rather than true cumulative incidences per patient; annual implant volumes were not retrievable, precluding a more refined time-stratified estimation. Third, several established risk factors were not captured systematically in the medical record, including body mass index, post-implant pocket hematoma, antibiotic prophylaxis regimen, corticosteroid use, vascular access route, total procedural time, and operator-level volume; this limits both descriptive completeness and the ability to identify modifiable predictors. Fourth, the low rate of TEE (3.7%) and the absence of any echocardiographic study in half of the patients almost certainly led to underdiagnosis of CDRIE [6]; the single endocarditis case (1.9%) is markedly below the 10–23% range reported in international series and should be interpreted with this diagnostic gap in mind, particularly because eight infections (14.8%) remained anatomically unclassifiable. Fifth, microbiological documentation was incomplete: 17 patients had no cultures obtained and 24.3% of cultured cases remained culture-negative, which may have biased the apparent microbiological spectrum. Sixth, as a tertiary referral center receiving externally implanted devices, long-term follow-up of the referred subgroup was challenging, and no systematic post-discharge surveillance was performed, restricting mortality reporting to the in-hospital period and likely undercounting recurrences. Seventh, the small number of events (one death, five recurrences, one endocarditis) yields wide confidence intervals and limits the robustness of comparisons with larger international cohorts. Finally, imaging confirmation of complete system extraction was not available in 10 cases (18.5%). These limitations should be addressed in future prospective work incorporating standardized diagnostic criteria, complete person-time accounting, structured collection of risk factors, and active post-discharge surveillance.

5. Conclusions

In this seven-year cohort from a tertiary referral center in southern Chile, CIED infections occurred with a crude per-procedure infection proportion of 1.4%, reaching 5.5% for ICDs and 4.3% for CRT devices. Although the overall clinical and microbiological profile was consistent with that of published series, approximate time-adjusted rates for ICDs and CRT systems were notably higher than those reported in major European nationwide registries. System extraction was attempted in all patients and achieved in nearly all cases, with low in-hospital mortality (1.9%, 95% CI 0.3–9.6%) and

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a recurrence rate (9.3%) within the expected range, although the absence of long-term follow-up precludes assessment of medium- and long-term outcomes. The findings identify concrete opportunities for quality improvement, particularly the systematic collection of microbiological cultures, pre-procedural echocardiographic assessment, structured documentation of antibiotic prophylaxis and pocket hematoma, and selective use of antibacterial envelopes in high-risk patients [6,13]. Translating these contemporary preventive strategies into standardized local protocols, together with prospective assessment of the recently initiated leadless pacing program, will be essential to reduce the elevated infection burden observed for complex devices in our setting.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org, Table S1, STROBE Statement Checklist for Cohort Studies.

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Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to institutional data-protection policies and patient confidentiality considerations.

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Abbreviations

Abbreviation	Definition
AF	Atrial fibrillation
AHT	Arterial hypertension
CDRIE	Cardiac device-related infective endocarditis
CEC SSAS	Comité de Ética Científica, Servicio de Salud Araucanía Sur
CI	Confidence interval
CIED	Cardiac implantable electronic device
CKD	Chronic kidney disease
CRT	Cardiac resynchronization therapy

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Abbreviation	Definition
DM	Diabetes mellitus
EHRA	European Heart Rhythm Association
HF	Heart failure
HHHA	Hospital Dr. Hernán Henríquez Aravena
ICD	Implantable cardioverter-defibrillator
ICD-10	International Classification of Diseases, 10th Revision
IQR	Interquartile range
LVEF	Left ventricular ejection fraction
PM	Pacemaker
SD	Standard deviation
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
T2DM	Type 2 diabetes mellitus
TEE	Transesophageal echocardiography
TTE	Transthoracic echocardiography
WRAP-IT	Worldwide Randomized Antibiotic Envelope Infection Prevention (trial)

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