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MAJOR ARTICLE

Risk of Cardiovascular Implantable Electronic Device Infection in Patients Presenting With Gram-Negative Bacteremia

Supavit Chesdachai,[1] Larry M. Baddour,[1,2] M. Rizwan Sohail,[1,3] Bharath Raj Palraj,[1] Malini Madhavan,[2] Hussam Tabaja,[1] Madiha Fida,[1] Brian D. Lahr,[4] and Daniel C. DeSimone[1,2]

[1]Division of Public Health, Infectious Diseases and Occupational Medicine, Department of Medicine, Mayo Clinic, Rochester, Minnesota, USA, [2]Department of Cardiovascular Disease, Mayo Clinic, Rochester, Minnesota, USA, [3]Section of Infectious Diseases, Department of Medicine, Baylor College of Medicine, Houston, Texas, USA, and [4]Division of Clinical Trials and Biostatistics, Mayo Clinic, Rochester, Minnesota, USA

Background. Gram-negative bacteremia (GNB) as a manifestation of cardiovascular implantable electronic device (CIED) infection is uncommon. Moreover, echocardiography may be nonspecific in its ability to differentiate whether CIED lead masses are infected. We aimed to determine the rate of CIED infection in the setting of GNB.

Methods. All patients with CIED who were hospitalized with GNB during 2012–2019 at Mayo Clinic were investigated. The definition of CIED infection was based on criteria recommended by the 2019 European Heart Rhythm Association document.

Results. A total of 126 patients with CIED developed GNB. None of them had signs of pocket infection. Twenty (15.9%) patients underwent transesophageal echocardiography. Overall, 4 (3%) patients had definite CIED infection. None of them underwent CIED extraction; 3 died within 12 weeks and 1 received long-term antibiotic suppression. Ten (8%) patients had possible CIED infection; despite no CIED extraction, no patient had relapsing GNB. We observed a higher rate of CIED infection in patients with *Serratia marcescens* bacteremia as compared to that in patients with other GNB.

Conclusions. The rate of CIED infection following GNB was relatively low. However, accurate classification of CIED infection among patients presenting with GNB remains challenging, in part, due to a case definition of CIED infection that is characterized by a low pretest probability in the setting of GNB. Prospective, multicenter studies are needed to determine accurate identification of CIED infection among GNB, so that only patients with true infection undergo device removal.

Keywords. bacteremia; cardiovascular implantable electronic device; gram-negative bacilli; infection; outcome.

Infection is a major complication of cardiovascular implantable electronic device (CIED) implantation and associated with significant morbidity, mortality, and financial burden [1–3]. In contrast to bacteremia due to *Staphylococcus aureus*, gram-negative bacteremia (GNB) linked to CIED infection has been characteristically uncommon [4]. For example, in 2006, Uslan et al [5] reported CIED infection in 6% of patients with GNB. More recently, however, Maskarinec et al [6], reported cardiac device–related infection that included CIED, prosthetic valves, and left ventricular assist devices (LVADs) in 17% of patients with GNB, with both *Pseudomonas aeruginosa* and *Serratia marcescens* being prominent.

These more recent findings, coupled with updated criteria used in defining CIED infection [7], and limitations regarding the lack of specificity of CIED lead masses visualized by transesophageal echocardiography (TEE) to identify infected vegetations versus uninfected thrombi to support a diagnosis of CIED-related endocarditis, have impacted diagnostic and management strategies [8, 9]. It is within this backdrop that we conducted a retrospective analysis of GNB in patients with CIED to determine the rate of CIED infection and whether certain gram-negative bacilli are more likely to be associated with CIED infection. These findings are of importance as we consider management strategies, in particular the recommendation for complete device removal in cases of CIED infection to achieve cure of infection.

METHODS

Study Design and Participants

The retrospective cohort study was conducted at Mayo Clinic, Rochester, Minnesota. The inclusion criteria included all adult patients aged ≥18 years with CIED who were hospitalized with

Received 14 July 2022; editorial decision 22 August 2022; accepted 23 August 2022; published online 25 August 2022

Correspondence: Supavit Chesdachai, MD, Division of Public Health, Infectious Diseases and Occupational Medicine, Department of Medicine, Mayo Clinic, 200 First Street SW, Rochester, MN 55905 (chesdachai.supavit@mayo.edu).

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https://doi.org/10.1093/ofid/ofac444

GNB from 1 January 2012 to 31 December 2019. Exclusion criteria included patients with LVAD, patients with polymicrobial bacteremia, patients who did not require hospitalization, and patients who declined an authorization to use their medical record for research purposes. The Mayo Data Explorer software was used to identify all patients with CIED who had GNB. Mayo Data Explorer retrieves data from multiple Mayo Clinic clinical databases that contain >30 years of electronic medical record systems, including CIED and microbiology data. The medical records of all patients who had CIED placement, monitoring, or received CIED-related medical care at Mayo Clinic were generated by the software. The CIED patient list was cross-checked with the list of patients with blood cultures that had GNB. Patient data were then manually abstracted from electronic medical records by 2 authors (S. C. and H. T.). All data were collected and managed using REDCap electronic data capture tools [10, 11] hosted at Mayo Clinic.

Patient Consent Statement

The study protocol was reviewed and approved by the Mayo Clinic Institutional Review Board (study institutional review board number 20-009376). The study was granted an exemption from patient consent, as it does not include factors necessitating patient consent.

Definitions

Cardiovascular implantable electronic devices included automatic implantable cardioverter-defibrillators, cardiac resynchronization therapy devices, and permanent pacemakers. The definition of CIED infection was based on the 2019 European Heart Rhythm Association (EHRA) International Consensus document [7] and was categorized into definite, possible, and rejected CIED infection. "Definite CIED infection" criteria were met if (*i*) there was evidence of clinical signs of pocket or generator infection or (*ii*) 2 major criteria or 1 major criterion plus 3 minor criteria were met. "Possible CIED infection" criteria needed either 1 major criterion plus 1 minor criterion or 3 minor criteria. "Rejected CIED infection" was defined as patients who did not meet the aforementioned criteria. Major and minor criteria were adopted from modified Duke criteria and European Society of Cardiology 2015 guidelines criteria [12]. Imaging portion of major criteria consisted of echocardiography (including intracardiac echocardiography), positron emission tomography–computed tomography (PET-CT), or cardiac computed tomography (defining paravalvular leakage). Evidence of CIED infection based on echocardiographic finding included lead vegetation, valve vegetation, perivalvular extension of infection, abscess, pseudoaneurysm, intracardiac fistula, valvular perforation or aneurysm, new partial dehiscence of prosthetic valve.

Other definitions that included contaminated blood culture, time to positivity, type of bacteremia, duration of bacteremia, and complete/partial CIED extraction were adopted from previous studies [13, 14]. Only bacteremias due to aerobic gram-negative bacilli were included. Relapse of GNB was defined as a new episode of bacteremia with the same organism within 12 weeks after the initial blood culture date of GNB. Twelve-week follow-up data were determined by reviewing the clinic or hospital encounters at 12 weeks or after 12 weeks timepoint.

Statistical Analysis

Descriptive statistics were reported as median (interquartile range [IQR]) for continuous variables and number (percentage) for categorical variables. The rate of CIED infection was calculated by the number of definite and possible CIED infection divided by number of all the patients in the cohort. Differences in CIED infection rate between *P aeruginosa*, *S marcescens*, and other groups were determined using Fisher exact test. Both hospital length of stay and 1-year survival were analyzed as censored response data using Kaplan-Meier survival probability or quartile estimates. All analyses were performed using R statistical software (version 4.0.3, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Baseline Demographics

During the study period, 149 patients with CIED developed GNB. Twenty-three patients were excluded due to presence of an LVAD (n = 16), outpatient treatment (n = 4), and concomitant *S aureus* bacteremia (n = 3). Overall, 126 patients were included, and detailed baseline patient demographic characteristics are listed in Table 1. The median age was 76.5 years (IQR, 68.5–84.0 years); 119 (94.4%) patients were of White race and 81 (64.3%) were male. The median age-weighted Charlson Comorbidity Index was 3.0 (IQR, 2.0–4.8). Ninety-six (76.2%) patients had heart failure and 25 (19.8%) patients had a prosthetic heart valve. A history of recurrent urinary tract infection was present in 13 (10.3%) patients. The median time from initial device implantation to bacteremia was 4.2 years (IQR, 1.5–7.1 years).

Microbiology

Gram-negative bacilli identified were *Escherichia coli* (60 [47.6%]), *P aeruginosa* (20 [15.9%]), *Klebsiella* species (15 [11.9%]), *S marcescens* (11 [8.7%]), *Proteus* species (4 [3.2%]), *Acinetobacter* species (3 [2.4%]), *Enterobacter* species (2 [1.6%]), *Haemophilus influenzae* (2 [1.6%]), and miscellaneous isolates (9 [7.1%]) (Supplementary Table 1). Follow-up blood cultures were obtained in 108 (85.7%) patients and the median duration of bacteremia was 1.0 day (IQR, 1.0–2.0 days).

Table 1. Baseline Demographics of Patients With Cardiovascular Implantable Electronic Devices Who Developed Gram-Negative Bacteremia

Characteristic	No.[a] (%)
Comorbidities	
Diabetes mellitus	39 (31.0)
Prosthetic heart valve	25 (19.8)
Central venous/PICC/PA catheter at the time of bacteremia	25 (19.8)
ESRD with dialysis	4 (3.2)
History of infective endocarditis	2 (1.6)
History of prior CIED infection	1 (0.8)
History of injection drug use	1 (0.8)
Type of CIED	
PPM	75 (59.5)
AICD	47 (37.3)
CRT	4 (3.2)
Type of bacteremia	
Community-acquired	85 (67.5)
Nosocomial	25 (19.8)
Healthcare-associated	16 (12.7)
Most likely source of bacteremia	
Urinary tract	47 (37.3)
GI/hepatobiliary source	35 (27.8)
Central venous catheter–related	14 (11.1)
Unknown source	12 (9.5)
Pneumonia	9 (7.1)
Other sources	9 (7.1)

Abbreviations: AICD, automatic implantable cardioverter-defibrillator; CIED, cardiovascular implantable electronic devices; CRT, cardiac resynchronization therapy; ESRD, end-stage renal disease; GI, gastrointestinal; PA, pulmonary artery; PICC, peripherally inserted central catheter; PPM, permanent pacemaker.

[a]Number of nonmissing values.

Hospital Course and Diagnostic Procedures

Median length of stay was 7.0 days (IQR, 4.0–15.0 days) and 60 (47.6%) patients required intensive care support during their hospitalization. The median Pitt Bacteremia Score was 0.0 (IQR, 0.0–3.0). Forty-four (34.9%) patients underwent transthoracic echocardiography (TTE), of whom none demonstrated CIED infection or valve endocarditis. Twenty (15.9%) patients underwent TEE and vegetations were seen in 4 (20.0%) patients: 2 aortic valve, 1 tricuspid valve, and 1 CIED lead. Only 2 patients (1.6%) underwent PET-CT scanning and was negative in both cases. Overall, 4 (3.2%) patients had definite CIED infection and 10 (7.9%) had possible CIED infection. Details of each patient are provided in Supplementary Table 2 and 3. The frequency of CIED infections based on species is demonstrated in Figure 1. When comparisons were made between *P aeruginosa*, *S marcescens*, and other species of gram-negative bacilli, the proportion of patients with CIED infections (15.0% vs 45.5% vs 6.3%) was statistically different ($P = .002$). Specifically, those with *S marcescens* had marginally to significantly higher rates of CIED infection than those with *P aeruginosa* ($P = .095$) and other species of gram-negative bacilli ($P = .002$) (Table 2).

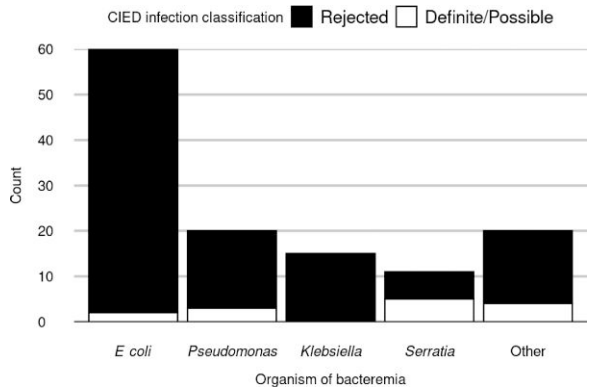

Figure 1. Proportion of cardiovascular implantable electronic device (CIED) infection based on type of gram-negative bacilli. Distribution of *Escherichia coli*, *Pseudomonas* spp, *Klebsiella* spp, *Serratia* spp, and other type of gram-negative bacilli in patients with and without CIED infection.

Treatment and Outcome

Four patients underwent complete CIED extraction: 2 in the possible CIED infection group and 2 in the rejected CIED infection group. There was no bacterial growth in cultures from all 4 extracted devices; all 4 had been on systemic antibiotic therapy at the time of complete device removal. Indications of extraction for 4 cases in the possible and rejected CIED infection groups were (*i*) prolonged *Brucella* bacteremia without an alternative diagnosis (1 possible case) and (*ii*) heart transplantation (1 possible and 2 rejected cases) rather than CIED infection. Twenty-two (17.5%) patients died during hospitalization. Three patients developed relapsing GNB within 12 weeks. Two patients in the rejected CIED infection group had unknown status at 12 weeks. The relapsing episodes were in the rejected CIED infection group (Supplementary Table 4). None of the patients in the definite and possible CIED infection groups suffered relapsing GNB, despite no device extraction. The median duration of antibiotic therapy was 30.5 days (IQR, 22.8–39.5 days), 22.0 days (IQR, 16.2–43.5 days), and 15.0 days (IQR, 13.0–16.0 days) in the definite, possible, and rejected CIED infection groups, respectively. There

Table 2. Cardiovascular Implantable Electronic Device Infection in Patients With *Pseudomonas aeruginosa* Versus *Serratia marcescens* Versus Other Gram-Negative Bacteremia

Organism	Fraction	Estimate, %	(95% CI)[a]
Overall	14/126	11.1	(6.7–17.8)
Pseudomonas aeruginosa	3/20	15.0	(5.2–36.0)
Serratia marcescens	5/11	45.5	(21.3–72.0)
Other	6/95	6.3	(2.9–13.1)

Abbreviations: CI, confidence interval.

[a]Wilson 95% CIs, $P = .002$ for overall Fisher exact test testing whether there are any differences in infection rate between the 3 subtypes. Pairwise tests: *P aeruginosa* vs *S marcescens*, $P = .095$; *P aeruginosa* vs other, $P = .189$; *S marcescens* vs other, $P = .002$.

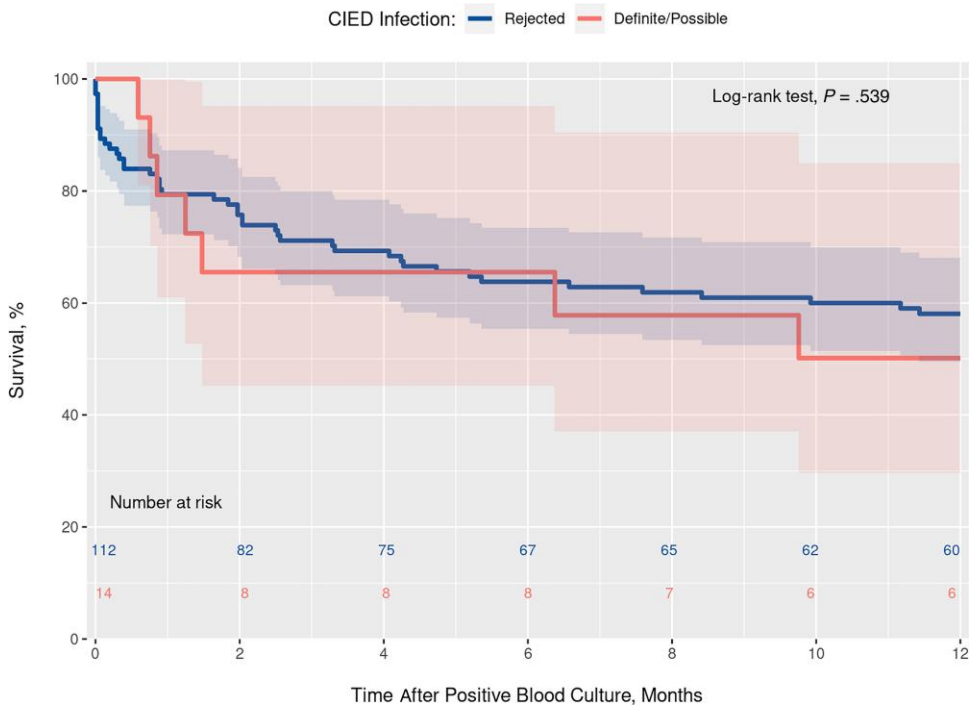

Figure 2. Survival curves by cardiovascular implantable electronic device (CIED) infection group. There was no difference in 1-year survival rates between the definite/possible CIED infection group and the rejected CIED group (log-rank test, $P = .539$).

was no difference in 1-year survival rates between the definite/possible CIED infection group and the rejected CIED infection group (Figure 2).

DISCUSSION

Our investigation represents the largest contemporary profile of 126 patients with CIED who developed GNB during 2012–2019. The rate of CIED infection using the 2019 EHRA criteria was 11% (3% definite and 8% possible). CIED removal was rarely undertaken in the absence of definite CIED infection and recurrent bacteremia was rare in those who did not undergo device removal.

The reported incidence of 11% CIED infection in our study compares to 6% (3 of 49 patients) and 17% (22 of 132 patients) from a study previously conducted at our institution with cases between 1998 and 2005 [5] and from Duke University Medical Center with cases between 2002 and 2014 [6], respectively. There are several factors that make it difficult to compare these rates. These include relatively small sample sizes for a range of pathogens, inclusion of cardiac devices (LVADs, prosthetic valves) other than CIED in calculations of the Duke data, and, importantly, the application of different case definitions used by the 3 studies between 1998 and 2019.

The variability of case definitions, perhaps, is the most important factor as we analyze CIED infection rates in patients with GNB and this deserves additional analysis. Of note, both earlier studies [5, 6] used clinical evidence of pocket infection, modified Duke criteria for infective endocarditis, and a positive device culture to define device infection, which was similar to the criteria used for defining definite CIED infection in the 2019 EHRA document [7]. However, there are concerns about application of the EHRA recommendations in patients with definite CIED infection identified in the current investigation. First, there were only 4 patients and 3 of them had vegetations on prosthetic valves, not on CIED leads. Second, none of them underwent CIED extraction, mainly because they were poor surgical candidates, and 3 of them died within 12 weeks of a GNB diagnosis; the remaining patient received long-term oral antibiotic suppressive therapy. Thus, our ability to verify a diagnosis of CIED infection in this small cohort with documentation of GNB relapse in patients without complete device removal was not feasible.

The possible and rejected CIED infection criteria deserve further comment. Possible CIED infection was not used in prior studies and the rejected criteria were different. A diagnosis of possible CIED infection was made if a patient met 3 minor criteria of the 2019 EHRA document. Unlike the definite CIED infection group, none had vegetations seen from echocardiography. Additionally, 8 of 10 possible CIED infection patients did not undergo CIED extraction and did not relapse, and no patient received long-term oral antibiotic suppression.

Therefore, it is possible that diagnostic criteria of possible CIED infection in the 2019 document [7] may be less specific in the setting of GNB with a low pretest probability of CIED infection. Previous studies rejected a CIED infection diagnosis if patients who did not undergo CIED extraction failed to develop GNB relapse during 12 weeks of follow-up. The rejected CIED infection criteria of the 2019 EHRA document, however, did not include relapse in any of the criteria.

Some have recommended that a more aggressive diagnostic approach be conducted in patients with underlying CIED and GNB due to *P aeruginosa* or *S marcescens* to determine if CIED infection is present [8]. While we observed a higher rate of CIED infection in the setting of *S marcescens* bacteremia relative to other types of bacteremia due to gram-negative bacilli, most of the GNB due to *S marcescens* in our study was relegated to the possible CIED infection group and none of the possible CIED infection cases relapsed despite device retention. Therefore, the diagnosis of possible CIED infection based on the 2019 EHRA document is less specific, as mentioned above, and it may not be suitable to link *S marcescens* bacteremia to enhanced risk of CIED infection. Regarding GNB due to *P aeruginosa* and CIED infection rate, the absolute rate was much lower (15%) in our study as compared to that (54%) in the Duke investigation [6]. The critical difference in our study was that LVAD patients were excluded, a group that is well-recognized to be at risk of *P aeruginosa* causing LVAD infections. Hence, it is not surprising to see a higher rate of device-related infection in the previous study [6] that included LVAD patients.

The decision to remove a CIED is the most important aspect of patient management in the setting of bloodstream infection and a "negative" pocket site. Based on our contemporary results in patients with GNB and CIED, a conspicuous challenge exists regarding what case definition of CIED infection should be used in patients presenting with GNB as these cases have a low pretest probability. In addition, TEE findings cannot be used as a major criterion as TEE has low specificity in distinguishing lead "vegetations" versus "noninfectious echodensities" as demonstrated in a blinded TEE evaluation [9, 15]. Based on these observations, we believe that routine device removal be reserved for patients with definite CIED infection due to gram-negative bacteria while cases with possible CIED infection due to gram-negative bacteria be managed on case-by-case basis.

Our study has some limitations. First, the relatively small number of patients who developed CIED infection and diagnostic uncertainty prevented an evaluation of true rate of CIED infection following GNB and associated risk factors. Second, selection bias and confounders were unavoidable in the retrospective review that was conducted at a referral center. In addition, the generalizability of results may be limited. It is also worth noting that the proportion of prosthetic heart valves in CIED patients in our cohort was higher than that in the general population. Third, new criteria included novel diagnostic tools such as PET-CT and intracardiac echocardiography, but it was not possible to determine the role, if any, of these tools in our study due to the use of historical data with a limited number of procedures being done.

In conclusion, the rate of CIED infection following GNB in our study was 11%. The overall rate remains relatively low compared to that of *S aureus*. Despite study limitations, we believe that our data suggest that routine removal of these devices in cases classified as possible CIED infection in the setting of GNB is not necessary as no relapses were noted in our cohort despite device retention. Moreover, a reassessment of case definition of CIED infection is warranted as gram-negative bacteria are not "typical" pathogens for CIED infection. Perhaps along the lines of modified Duke criteria for infective endocarditis, a listing of "typical" pathogens of CIED infection in diagnostic classification schemes may be warranted. A larger prospective observational study is needed to provide evidence-based guidance for accurate clinical definition of cases.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Acknowledgments. The authors are extremely grateful for the philanthropic support provided by a gift from Eva and Gene Lane (to L. M. B.), which was paramount in our work to advance the science of cardiovascular infections, an ongoing focus of investigation at Mayo Clinic for over 60 years.

Disclaimer. The contents of this work are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.

Financial support. This research was made possible by a Clinical and Translational Science Award (number UL1TR002377) from the National Center for Advancing Translational Sciences, a component of the National Institutes of Health.

Potential conflicts of interest. L. M. B. has received royalty payments for author duties from UpToDate and has served as a consultant for Boston Scientific and Roivant Sciences. M. R. S. has received research funding from Medtronic and honoraria/consulting fees from Medtronic, Spectranetics, Boston Scientific, and Philips. B. R. P. has received consulting fees from Armor Health. M. M. has received research funding from Boston Scientific and has served as a consultant for Convatec, Biotronik, and Biosense Webster. All other authors report no potential conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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