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Major article

Infection and readmission rate of cardiac implantable electronic device insertions: An observational single center study

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Background: Infection is one of the most serious complications following surgical placement of cardiac implantable electronic devices (CIEDs). Infection prevention efforts are necessary in reducing CIED infectious outcomes. These devices, however, are commonly inserted in higher risk patients, which may explain the ongoing risk of surgical site infection (SSI) in this population. The rates of CIED infection and utilization vary widely in the literature. The definitions of infection may also vary between clinical definitions and the National Healthcare Safety Network (NHSN) criteria.

Methods: The primary objective of this study was to review patient data to identify risk factors for infection and readmission after CIED placement at an academic medical center. The secondary objectives were to compare the rates of SSI identified by NHSN criteria compared to that obtained by applying clinical infection definitions.

Results: The overall rate of infection (SSI) was 1.9%, which was identical in both the clinical definition and NHSN reported data. The 30 day readmission rate and the 90 day readmission rate were 12.7% and 25.6% respectively with the most readmissions related to the patients' underlying medical conditions. A lower ejection fraction (EF) was identified as an independent risk factor for readmission, inpatient procedures, smoking and device infection were also significantly associated with readmission after CIED insertion.

Cardiovascular implantable electronic devices (CIEDs) are extremely important in the management of numerous cardiovascular conditions, including, but not limited to, life-threatening cardiac dysrhythmias and heart failure. The implantation of these devices has resulted in a significant improvement in both patient quality of life and longevity.[1] Over the years, the incidence of CIED infection has been rising because the number of patients with these devices is increasing.[2,3] It has been suggested that these devices are inserted in higher risk patients. Infections represent serious complications of CIED implantation, which frequently require removal of all hardware and prolonged intravenous antibiotic therapy. CIED infection is associated with high fatality that ranges from 3%-19% of patients.[4] CIED infection rates vary significantly between studies but are commonly reported to be between 1% and 7%.[5]

There are no formal infection prevention guidelines for CIED insertion. Preoperative antibiotics prior to CIED insertion is a strong recommendation that is based on multiple clinical studies.[6,7] Patients with chronic comorbidities, such as diabetes mellitus, heart failure, long-term corticosteroid use, anticoagulation, and renal dysfunction, are reported to be at higher risk of CIED infection.[8] Complicated procedures with multiple leads and device revision or replacement were previously identified as independent correlates of device infection.[9,10]

CIED complications, particularly infection, are very costly. In 2004 the average cost per patient of combined medical and surgical treatment of CIED-related infections was estimated at $35,000.[11]

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The financial impact is the result of multiple factors, which include readmission and prolonged critical care stay, cost of device removal, insertion of a new device, diagnostic procedures, and medical therapy for infection.[1]

METHODS

The study was performed at a 500-bed academic medical center located in Pittsburgh, Pennsylvania. This single center observational study reviewed all CIEDs implanted (initial or revision) between February 1, 2013, and March 31, 2014. The information reviewed included patient demographic data, medical comorbidities, Charlson comorbidity index, and anticoagulation profiles. Preoperative infection prevention data was also collected, which included preoperative hair removal when necessary, the use of preoperative chlorhexidine wipes, methicillin-resistant *Staphylococcus aureus* (MRSA) screening, and preoperative antimicrobial prophylaxis. Procedural data collected included the type of CIED implanted (pacemaker or defibrillator), number of leads placed, duration of the procedure, initial placement versus revision, and physician performing the procedure. Inpatient versus outpatient procedures were noted based on whether the patient had been admitted to the hospital or scheduled as an outpatient.

Infection and readmission data within 30 and 90 days were obtained from patient chart review. Clinical definition of infection was used to identify the presence and extent of infection.[12] Infection was categorized as local infection at the generator pocket (erythema, warmth, wound dehiscence, erosion, or purulent drainage) or CIED-related bacteremia and endocarditis. These conditions were confirmed by the presence of positive blood cultures and valvular or lead vegetation on echocardiography using the modified Duke criteria.[13] Bacterial cultures are used to confirm both types of CIED infections by positive cultures from the device pocket, extracted electrode leads, or blood. The definition also includes cases of positive blood cultures without local inflammatory signs, no other source of bacteremia, and resolution of bacteremia after device extraction.[14-16] These data were compared with National Health Safety Network (NHSN)—reported device infection data within the same time frame using their specific definition.[17]

CIED infection rate was calculated during the 14-month study period, and readmission rate was measured for 30 and 90 days after CIED implantation. Readmissions were broadly categorized as medical or surgical. Medical readmissions were defined as patients who were readmitted to a medicine service for conditions which included congestive heart failure, cardiac dysrhythmias, infections not related to the CIED (eg, pneumonia), and procedural-related complications (eg, hematoma, infection, device malfunction). Surgical readmissions were defined as patients admitted to a nonmedicine service for an unrelated problem (eg, trauma, fractured bone requiring operative intervention).

A univariate logistic regression was performed to look for risk factors for readmission to the hospital for medical reason at 90 days. Factors that had a P value $<.20$ in the univariate analysis were eligible for inclusion in the multivariable analysis. A stepwise multivariable logistic regression was performed to determine independent risk factors for readmission to the hospital within 90 days. A P value $< .05$ was considered statistically significant. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC).

RESULTS

Between February 1, 2013, and March 31, 2014, 316 patients with CIEDs implanted for the first time or with pre-existing device manipulations were included in the study. Baseline characteristics of the study population, procedural data, and, infection control measures are described in Table 1.

Table 1
Baseline patient characteristics, preoperative infection prevention data, and procedural data

Variable	Value
Sex	
Male	205 (64.9)
Female	111 (35.1)
Age, y	74 (29-92)
Charlson comorbidity index	6 (1-15)
Ethnicity	
White	279 (88.3)
Black	31 (9.8)
Other	6 (1.9)
Anticoagulation	
Yes	147 (46.5)
No	169 (53.5)
Smoking	
Yes	50 (15.8)
No	266 (84.2)
Ejection fraction	
<30	94 (29.7)
31-40	62 (19.6)
>40	160 (50.6)
MRSA and MSSA screening*	
Performed	86 (27.2)
Not performed	230 (72.8)
Preoperative antibiotics	
Yes	315 (99.7)
No	1 (0.3)
Hair clipping for male patients	
Yes	205 (100)
No	0 (0)
Type of antibiotic used	
Cefazolin	270/315 (85.7)
Vancomycin	40/315 (12.7)
Other	5/315 (1.59)
Type of CIED	
AICD	175 (55.4)
Pacemaker	141 (44.6)
Setting	
Inpatient	156 (49.4)
Outpatient	160 (50.6)
No. of leads implanted	
1	84 (26.6)
2	183 (57.9)
3	49 (15.5)
Initial versus manipulation of pre-existing device	
Initial	189 (59.8)
Manipulation	127 (40.2)

NOTE. Values are n (%) or median (range).
AICD, automated implantable cardiac defibrillator; *CIED*, cardiovascular implantable electronic device; *MRSA*, methicillin-resistant *Staphylococcus aureus*; *MSSA*, methicillin-sensitive *S aureus*.
*After screening for MRSA and MSSA, none of the patients who tested positive for *S aureus* received a preoperative decolonization regimen of intranasal mupirocin and chlorhexidine bathing.

In total, 6 cases (1.9%) of CIED infections were identified, and each case is highlighted in Table 2. Three patients had a clinical diagnosis of pocket site infection without bacteremia, 1 patient had a pocket site infection with bacteremia, and 2 patients had bacteremia with lead vegetation. There were not enough infections to identify any association between specific risk factors and CIED infection.

Regarding all-cause readmissions, 12.7% (40/316) and 25.6% (81/316) of patients were readmitted within 30 and 90 days, respectively. Medical readmissions accounted for 10.1% (32/316) of patients within 30 days and 20.3% (63/316) of patients within 90 days. Acute exacerbation of underlying heart failure was the most frequent cause for medical readmission in both subgroups (34.4% at 30 days and 42.2% at 90 days). Dysrhythmia was the second most