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Rates of post procedural prophylactic antibiotic use following cardiac implantable electronic device insertion and the impact on surgical site infections in Alberta, Canada

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Abstract

Background The necessity of post procedural prophylactic antibiotics following clean surgeries is controversial. While most evidence suggests that there is no benefit from these additional antibiotics and guidelines do not support their use, there is a paucity of evidence as to how often they are still being used and their impact on infection outcomes. The current study assessed the use of prophylactic antibiotics following cardiac implantable electronic device (CIED) implantations in the province of Alberta, and their impact on infection and mortality.

Methods We conducted a population-based cohort study in the province of Alberta. Administrative data was used to link all patients ≥ 18 who underwent outpatient CIED implantation from January 1, 2011 through December 31, 2019 to antibiotics commonly used for surgical prophylaxis which were prescribed within 48 h of implantation. The primary outcome, explored with an adjusted Poisson model, was incidence of complex surgical site infection within one year of device implantation. All-cause mortality was a secondary outcome.

Results Post implantation prophylactic antibiotics were used 41% of the time overall, though the rate has been decreasing over time. The most commonly used prophylactic antibiotic was cefalexin (52%). When adjusted analyses were completed, there was no difference in the outcome of infection between those who did and did not receive post implantation prophylactic antibiotics (Relative Risk 0.74, 95% CI 0.46–1.17) and there was no difference in mortality (Relative Risk 0.8, 95% CI 0.63–1.02).

Conclusions The use of prophylactic antibiotics following CIED implantation does not correlate to a reduced rate of complex surgical site infection or reduced mortality. The widespread use of these antibiotics, which is not guideline concordant, suggests the need for targeted antimicrobial stewardship interventions for surgical prophylaxis to ensure that antibiotic use is being optimized. Further work should explore other adverse outcomes associated with this antibiotic usage and stewardship programs should explore interventions to educate and reduce antibiotic use for this indication.

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Keywords Antibiotic Prophylaxis, CIED infections, Surgical Site infections, Antimicrobial stewardship

Introduction

The use of postoperative prophylactic antibiotics following clean surgical procedures has been a controversial issue for many years. When medical devices are implanted, such as in cardiac and orthopedic procedures, the balance between uncertain benefit versus relative harms of postoperative prophylactic antibiotics becomes an even more important consideration due to difficulty eradicating infections associated with prosthetic material [1]. Surgical site infections (SSIs) associated with hardware and prosthetic materials often require repeated surgeries to remove materials, prolonged courses of antibiotics and repeat hospital admissions [2].

The rate of cardiac implantable electronic device (CIED) infections ranges from approximately 1 to 4% [2, 3]. The most common causative organisms are *Staphylococcus aureus* and coagulase negative Staphylococci [4, 5]. These pathogens have a propensity to form a biofilm on prosthetic material generally requiring removal of the entire CIED in order to achieve cure [6]. These infections reduce patient quality of life and are very costly to the healthcare system [7, 8]. While prevention of infection is important, there is limited evidence to suggest that prophylactic antibiotics following CIED implantation are linked to improved outcomes. The Prevention of Arrhythmia Device Infection Trial (PADIT) was a randomized controlled trial that compared conventional (i.e., pre-operative antibiotics alone) to incremental (i.e., addition of intraoperative antibiotic washes plus post-operative oral cefalexin for 2 days) periprocedural antibiotics for CIED implantations [9]. Notably, there was no difference between groups in the 1 year rates for device infection [9].

While guidelines do not recommend the routine use of post-CIED implantation antibiotics as a method to prevent infection, evidence suggests antibiotics are often being inappropriately used following surgery [10, 11]. However, antibiotic use is not benign and is associated with increased risk of adverse events including *Clostridioides difficile* infection, antibiotic-associated diarrhea, drug allergy and perhaps most concerning selection of antimicrobial resistance in the etiologic organism, rendering infections more difficult to treat and creating substantial patient morbidity and economic burden [12–14]. The objective of the current study was to explore the association between post CIED procedure prophylactic antibiotics outcomes, including SSI and all-cause mortality, in the province of Alberta, Canada. This will help to inform optimal antimicrobial stewardship strategies in this area.

Methods

Study design and patient cohort

This was a population-based cohort study conducted in Alberta, Canada, a province of approximately 4.4 million people with a single healthcare system, Alberta Health Services (AHS). Using linked administrative data, we identified a cohort of adults (i.e., age ≥ 18 years) who underwent surgery for CIED implantation (including pacemaker (PM), implantable cardioverter defibrillator (ICD), or cardiac resynchronization therapy (CRT)) in an outpatient day surgery setting between January 1, 2011, and December 31, 2019. We excluded any adults who underwent CIED implantation within the inpatient setting or required admission (>48 h) from their initial outpatient day surgical encounter. The rationale for this exclusion criteria was that prolonged admission following implantation likely had a more complex admission and it would have been difficult to determine if any antibiotics given were for prophylaxis or treatment of an active infection.

Patients were categorized based on whether or not prophylactic antibiotics were prescribed post procedure, and followed for 1 year to ascertain outcomes of all-cause mortality and complex CIED SSI.

Administrative data sources

Paceart™

CIED implantations were identified using the Paceart™ database which contains all device-related clinical encounters for patients followed within the province of Alberta, Canada. Paceart™ contains information regarding indications for device implantation, type of device, date of operation and basic demographic information including sex. To avoid double counting patients that may have multiple revisions in the setting of operative complications, repeat procedures within a two-year period from the index surgical date were censored.

AHS analytics

Index CIED implantation surgeries, identified using the PaceArt database, were linked to administrative data housed within AHS Data & Analytics, including Discharge Abstract Database (DAD) for inpatient and outpatient hospitalization visits, the National Ambulatory Care Reporting System (NACRS) for ambulatory visits including emergency department encounters and the Pharmaceutical Information Network (PIN) for dispensed medications [15]. PIN is a central repository of prescription drugs dispensed from community pharmacies and is inclusive of all drugs regardless of supplementary drug plan coverage; in-hospital dispensations are not included.

Currently, at least 95% of all community pharmacies in Alberta submit records to this database. The data is patient identifiable and includes data elements such as patient identification data, drug name, drug identification number, drug dose, quantity dispensed, and number of days supplied [15]. All-cause mortality was ascertained from vital statistics. Elixhauser comorbidities of included patients were obtained from DAD and NACRS using a 2-year look back window from index date [16]. Additionally, specific comorbidities validated using cardiac registry data were looked at individually [17].

Prophylactic antibiotic use

Prophylactic antibiotics were defined as any oral antibiotic that was prescribed for >1 day, and tracked within PIN within 48 h of CIED implantation. These antibiotics included cefalexin (also commonly known as cephalexin), amoxicillin, clindamycin, amoxicillin-clavulanate, sulfamethoxazole-trimethoprim, doxycycline, ampicillin, penicillin, cefadroxil, and cloxacillin.

Outcomes

The primary outcome was presence of a complex SSI following CIED implantation identified using Discharge Abstract Database (DAD) and International Classification of Disease 10th revision Canada codes (T827, T857, I330, I339, I38, I398, L0330, L0339, L038, L039) that were previously validated as able to identify complex CIED SSIs (i.e. deep and organ space but not superficial SSIs) with sensitivity and specificity >90% [18]. All SSIs that occurred within one year from the index date of CIED implantation were tracked. Secondary outcomes included one year all-cause mortality also stratified by whether prophylactic antibiotics were used.

Statistical analyses

Descriptive statistics, including frequencies and percentages were used to describe baseline characteristics of patients with and without SSIs and with and without usage of antibiotics within 48 h. For our primary method, we assessed the relationship between prophylactic antibiotic prescription on the rate of SSI for the total cohort using multivariable generalized linear models with a Poisson distribution and a logit/log link function. Adjusted models included the covariates of age, sex, location of CIED implantation, type of CIED device, and medical comorbidities. All statistical analyses were performed using R Statistical Software (Version 1.4.0). This research was approved by the University of Calgary Health Research Ethics Board (REB20-2186).

Results

Baseline cohort characteristics

There were 14,718 CIED implantations occurring in the outpatient setting that met inclusion criteria. Of these 14,718 surgeries, 69% ($n=10,148$) were for pacemakers, 17% ($n=2,525$) for implantable cardioverter defibrillators, and 13% ($n=1,962$) for cardiac resynchronization therapy (Table 1). The average age of the cohort was 73.6 (standard deviation 13.4), 36% were female, and 79% had 2 or greater Elixhauser comorbidities. The most common comorbidities included hypertension (56%), heart failure (40%), and diabetes (26%).

Prophylactic antibiotic use

Of the 14,718 CIED implantations, 5,978 (41%) had a prophylactic antibiotic prescription that was dispensed within 48 h of CIED implantation. The most prescribed antibiotic for prophylaxis was cefalexin at 52% (Fig. 1), which was prescribed for an average of 7 days (standard deviation 5.4, see Table 2). The percentage of prophylactic antibiotics prescribed annually following CIED implantation has been decreasing with 54% of patients with CIED implantation receiving them in 2011 and 31% receiving them in 2019 (Fig. 2).

Clinical endpoints

Of the 5,978 CIED implantations associated with prophylactic antibiotics within 48 h post CIED implantation, 0.8% ($n=46$) developed a complex SSI at 1 year. In the group that did not receive post procedural prophylactic antibiotics within 48 h, 1.1% ($n=99$) developed a complex SSI ($p<0.05$). One year mortality in the group that received prophylactic antibiotics was 2.0% ($n=122$). In the group that did not receive prophylactic antibiotics one year all-cause mortality was 3.4% ($n=293$) ($p<0.05$).

Relationship between prophylactic antibiotic prescription and clinical endpoints

Two tables demonstrating the results of the univariable and multivariable analyses can be found in additional file 1. In the adjusted multivariable models, there was no difference in SSI rates between the group that received prophylactic antibiotics compared to the group that did not receive antibiotics (relative risk (RR) 0.74, 95% confidence interval (CI) 0.46–1.17, $p=0.20$) (Fig. 3). In the adjusted model for all-cause mortality, there was no significant difference in mortality between those who did and did not receive antibiotics (RR 0.80, CI 0.63–1.02, $p=0.07$). It was noted that trimethoprim-sulfamethoxazole was prescribed for a mean duration longer than anticipated for post procedural prophylaxis. Therefore, the adjusted analyses were also completed excluding this antibiotic as a sensitivity analyses. However, this did not impact the

Table 1 Baseline characteristics for entire cohort stratified by those who did and did not receive prophylactic antibiotics within 48 h of CIED implantation

Factors	ABX within 48 h N= 5978	Non-ABX within 48 h N= 8740	All N= 14,718
Age			
18–29	72 (1.2)	57 (0.65)	129 (0.88)
30–39	120 (2.01)	90 (1.03)	210 (1.43)
40–49	218 (3.65)	220 (2.52)	438 (2.98)
50–59	637 (10.66)	734 (8.4)	1371 (9.32)
60–69	1275 (21.33)	1679 (19.21)	2954 (20.07)
70–79	1747 (29.22)	2469 (28.25)	4216 (28.65)
80+	1909 (31.93)	3491 (39.94)	5400 (36.69)
Sex			
Female	2071 (34.64)	3283 (37.56)	5354 (36.38)
Male	3889 (65.06)	5440 (62.24)	9329 (63.38)
Unknown	18 (0.3)	17 (0.19)	35 (0.24)
Device Type			
PM	3798 (63.53)	6350 (72.65)	10,148 (68.95)
CRT	1144 (19.14)	818 (9.36)	1962 (13.33)
ICD	1023 (17.11)	1502 (17.19)	2525 (17.16)
LPM	0 (0)	43 (0.49)	43 (0.29)
S-ICD	13 (0.22)	27 (0.31)	40 (0.27)
Generator Replacement	2281 (38.16)	3157 (36.12)	5438 (36.95)
Site/Location of CIED Care			
Site 1	575 (9.62)	4538 (51.92)	5113 (34.74)
Site 2	5126 (85.75)	2708 (30.98)	7834 (53.23)
Site 3	149 (2.49)	159 (1.82)	308 (2.09)
Site 4	65 (1.09)	855 (9.78)	920 (6.25)
Site 5	61 (1.02)	478 (5.47)	539 (3.66)
Number of Elixhauser Comorbidities			
0–1	1531 (25.61)	1576 (18.03)	3107 (21.11)
2–3	2216 (37.07)	3138 (35.9)	5354 (36.38)
4–5	1308 (21.88)	2109 (24.13)	3417 (23.22)
6+	923 (15.44)	1917 (21.93)	2840 (19.3)
Cardiac Comorbidities			
Cerebrovascular Diseases	433 (7.24)	931 (10.65)	1364 (9.27)
Chronic Obstructive Pulmonary Disease	996 (16.66)	1524 (17.44)	2520 (17.12)
Congestive Heart Failure	2335 (39.06)	3568 (40.82)	5903 (40.11)
Peripheral Vascular Disease	298 (4.98)	642 (7.35)	940 (6.39)
Liver Disease	183 (3.06)	371 (4.24)	554 (3.76)
Renal Disease	494 (8.26)	876 (10.02)	1370 (9.31)
Malignancy	399 (6.67)	789 (9.03)	1188 (8.07)
Hypertension	3035 (50.77)	5217 (59.69)	8252 (56.07)
Hyperlipidemia	648 (10.84)	744 (8.51)	1392 (9.46)
Diabetes	1484 (24.82)	2321 (26.56)	3805 (25.85)
Myocardial Infarction	724 (12.11)	820 (9.38)	1544 (10.49)
Coronary Artery Bypass Grafting	462 (7.73)	537 (6.14)	999 (6.79)
Percutaneous Coronary Intervention	479 (8.01)	633 (7.24)	1112 (7.56)

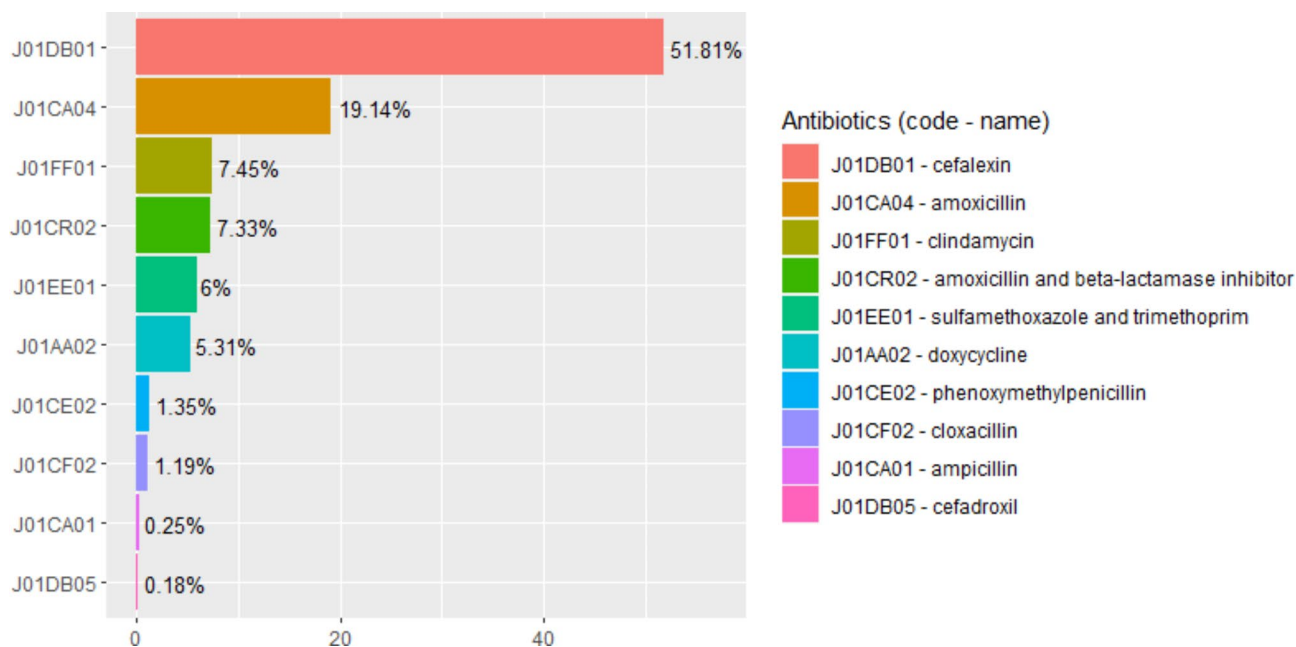


Fig. 1 Relative percentages of prophylactic antibiotics prescribed within 48 h of CIED implantation

Table 2 Average duration of antibiotics (days prescribed) with standard deviation

Antibiotic	Mean days of therapy prescribed	Standard deviation
Cefalexin	7	5.4
Amoxicillin	6	6.1
Clindamycin	6	3.5
Amoxicillin-clavulante	9	8.5
Sulfamethoxazole-Trimethoprim	21	25.4
Doxycycline	14	17.0
Penicillin	15	21.0
Cloxacillin	9	4.0
Ampicillin	6	6.9
Cefadroxil	13	8.2

clinical outcomes or p values as it accounted only for a small percentage of prescribed antibiotics.

Discussion

This work demonstrated that approximately 40% of patients received postoperative antibiotic prophylaxis following CIED implantation between 2011 and 2019. The most common antibiotic used for prophylaxis was cefalexin. Antibiotic prophylaxis was neither associated with a lower risk of complex SSI nor all-cause mortality at 1 year, after adjusting for medical comorbidities, device type, or implanting site. Although absolute rates of antibiotic prophylaxis are substantial, the rate of prescribing has been decreased overall since 2011. Reasons for the decreased use of post-operative antibiotic prophylaxis is unclear and there were no widely accepted

guidelines published during the study period that would have accounted for the change in trajectory in antibiotic use. The results of the PADIT trial were published in 2018 demonstrating that an enhanced antibiotic strategy including post procedural use did not reduce the risk of CIED infections significantly [9]. The decreasing use of antibiotic prophylaxis in our work was observed well before the completion of PADIT.

Our findings are in keeping with prior studies describing the use of prophylactic post-operative antibiotics [10]. The WRAP-IT (Worldwide Randomized Antibiotic Envelope Infection Prevention Trial) trial assessing the efficacy of an intraoperative antimicrobial envelope at time of CIED implantation, found that 30% of patients in both trial arms received post-operative antibiotics [3]. Although not specific to CIED implantation surgeries, a global point prevalence survey including 53 countries found that prophylaxis post operatively (prescribed for >1 day) was very common in all regions ranging from 40.6 to 86.3%.¹⁹ However, they found that sulfamethoxazole-trimethoprim was the most commonly prescribed antibiotic globally at 63.4% compared to our finding of cefalexin being used the most frequently [19]. This is potentially due to greater rates of methicillin resistant *Staphylococcus aureus* colonization globally compared to Alberta.

A notable finding of our study is that post-operative antibiotic prophylaxis did not reduce the risk of developing a complex CIED infection at 1 year. This finding is despite probable selection bias as to who received prophylactic antibiotics. That is, implanting operators may prescribe antibiotics due to perceived increased risk of

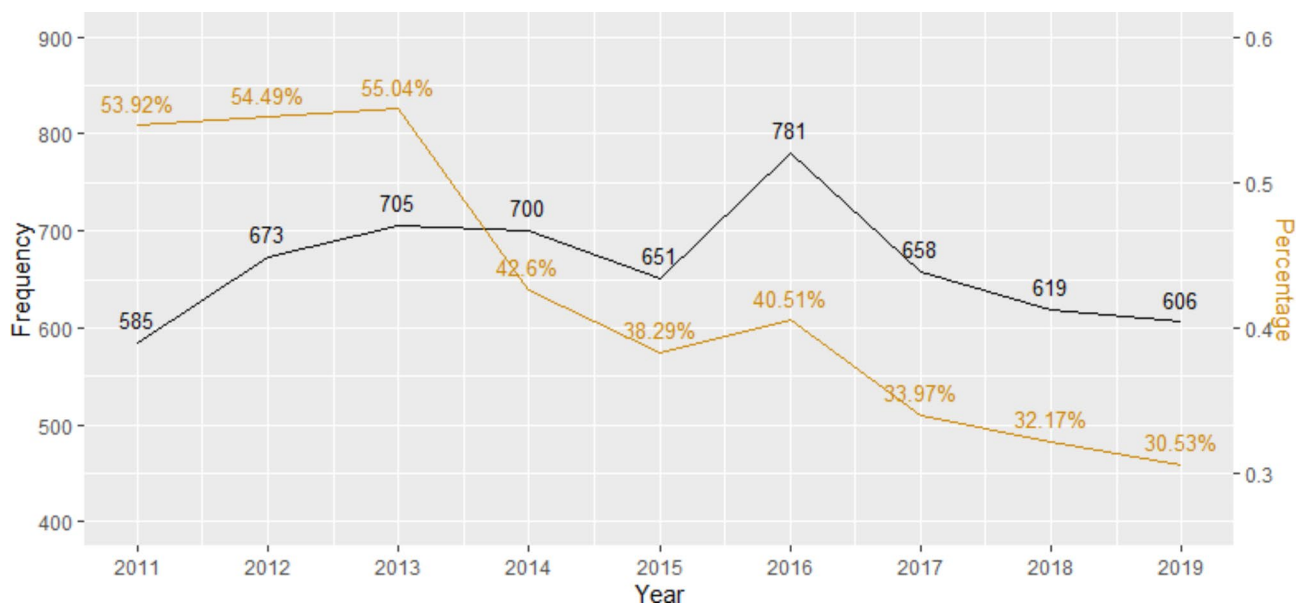


Fig. 2 The frequency and percentage of prophylactic antibiotics prescribed within 48 h after CIED implantation by year

developing infection, which may be related to length of CIED surgery and patient comorbidities. Indeed, higher comorbidity burden was one of the strongest predictors of increased risk of infection. For those with greater than 6 comorbidities, there was a 17-fold increased risk of developing a complex CIED SSI at 1 year. Validated risk scores, which incorporate patient risks (such as comorbidities) and operative factors (such as redo intervention and device type), can help identify patients at greatest risk of post-operative infection complications and provide opportunities for implementation of evidence-based infection prevention strategies, such as intraoperative antibiotic envelopes [20, 21] or use of novel device technologies associated with lower risk of infection, such as leadless pacemakers or non-transvenous defibrillators [21].

Nevertheless, our study suggests that post-operative antibiotics are not one of these evidence-based strategies that prevent CIED infection. Our findings are in keeping with prior work comparing use of pre-procedural antibiotics alone to a strategy of incremental antibiotics consisting of added intraoperative antibiotic washes and post-operative antibiotics. In the Prevention of Arrhythmia Device Infection (PADIT) study of 19,603 patients undergoing CIED implantation, there was no difference in the group treated with peri-procedural antibiotics alone compared to those treated with the incremental antibiotic strategy [9].

Finally, previous work done by our group in Alberta has demonstrated that overall annual complex SSI rates following CIED implantation have decreased from 2011 to 2019 [22]. The current work has shown a reduction in prophylactic antibiotic prescribing over this same

time frame further underscoring the lack of relationship between prophylactic antibiotics and SSI rates. Consistent with our prior work as well as the PADIT trial, our multivariable analysis did highlight that older age had a lower relative risk of infection [9, 22]. The exact explanation for this is unclear but reduced immune response with age has been postulated as one mechanism [23]. We also found that generator replacement was associated with lower risk of infection. This is also concordant with our previous work and may be related to the shorter procedural time for generator replacement as well as enhanced vigilance due to the risks with a revision procedure [22].

These findings highlight the importance of antimicrobial stewardship programs targeted at surgery, specifically postoperative prophylaxis. Prior work has shown that even when guidelines and protocols exist around postoperative prophylaxis there is poor adherence [24]. However, when antibiotic stewardship programs are implemented for surgery specific indications antibiotic appropriateness improves demonstrating the success of such programs [24]. One study found that implementation of an antibiotic stewardship program targeting perioperative surgical prophylaxis resulted in significant improvements ($p < 0.001$) in appropriate antibiotic prescribing, including for indication, antibiotic selection and dosing, timing and duration [25].

Strengths of this work include that it was population based and a large dataset over an eight-year period, and that we had access to outpatient antibiotic prescriptions for the entire population as frequently this data is only available in select populations based on age.

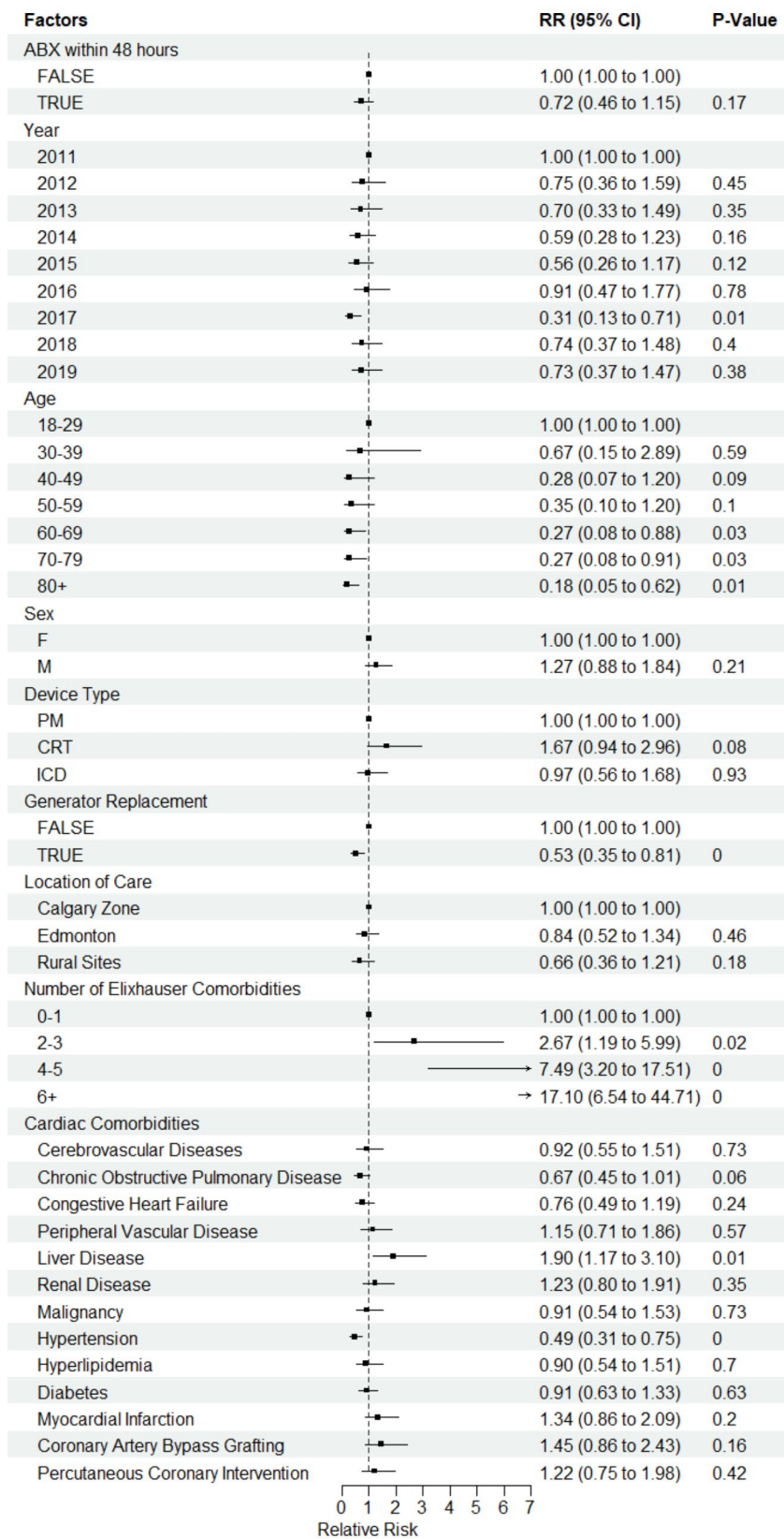


Fig. 3 Forest Plot demonstrating the relative risk of infection using an adjusted Poisson model with location of care as a fixed factor

We recognize limitations in our findings. Antibiotics were presumed to be prophylactic based on choice of class and duration, from expert opinion. However, no chart review was performed to confirm this as this work was based on administrative data. However, these antibiotics were all started within 48 h of CIED implantation which would be too early for infection and the choices are ones commonly associated with postoperative prophylaxis. Additionally, our data did not contain information on adverse antimicrobial associated events such as allergic reaction or antibiotic associated diarrhea and so these outcomes could not be assessed. Finally, we did not have data on the use of intraoperative antibiotic impregnated envelopes which may be utilized in certain patient populations. However, the data on the effectiveness of these envelopes was not published until 2019³ and therefore less likely to have impact the findings of the current study.

Conclusion

Our findings are important as they highlight that despite lack of evidence that they reduce SSIs, antibiotics are still commonly being used for postoperative prophylaxis. While their use does appear to be decreasing with time, over a quarter of patients still receive them post CIED implantation. Further work should endeavor to look at all adverse antibiotic related outcomes, and antimicrobial stewardship programs should consider exploring and targeting of postoperative antibiotic prophylaxis, not only in CIED procedures but in all clean surgical procedures. Eliminating unnecessary post procedural prophylaxis has the potential to improve optimization of antibiotic utilization, and importantly, from a global and population perspective, reduce selection pressure on the development of antibiotic resistance.

Abbreviations

CIED	Cardiac Implantable Electronic Devices
PM	Pacemaker
ICD	Implantable Cardioverter Defibrillator
CRT	Cardiac Resynchronization Therapy
SSI	Surgical Site Infection
AHS	Alberta Health Services
DAD	Discharge Abstract Database
NACRS	National Ambulatory Care Reporting System
RR	Relative Risk
CI	Confidence Interval

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13756-024-01512-3>.

Supplementary Material 1

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Author contributions

The original project was conceived by authors ER, DC and JL. Authors JL, DC, and ER completed data collection and validation. All statistical analyses were completed by author ZZ. ER completed the manuscript with input and revision from authors DC, SS, JC, DE, VK, JL, IR and ZZ.

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Data availability

The data that support the findings of this study are available from Alberta Health Services but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Alberta Health Services and appropriate ethics.

Declarations

Ethics approval

This study was approved by the University of Calgary Health Research Ethics Board (REB20-2186).

Competing interests

The authors declare no competing interests.

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