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# Implementing Evidence Based Practices for Preventing Cardiac Implantable Electronic Device (CIED) Infection and the Role of Post-Operative Oral Antibiotics

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# ABSTRACT

Cardiac pacemakers and implantable cardioverter defibrillators (ICD) are standard therapy for patients with a bradyarrhythmia, tachyarrhythmia or heart failure (HF) with a left bundle branch block (LBBB) (Wilkoff, et al., 2008). Millions of cardiac implantable electronic devices (CIED) have been implanted worldwide and this clinical practice has improved the quality of life for millions (Epstein, DiMarco, & Ellenbogen, 2008). With the increase of implants there has been an increase in the infection rates (Klug et al., 2007). Research studies have evaluated pre-procedure, during procedure and after procedure risk and protocols. Studies have also evaluated operative factors, procedural related factors, intravenous preoperative and postoperative prophylaxis and topical antibiotics (Padfield et al., 2015). There is no consensus on the use of oral antibiotics post CIED implant at discharge to reduce the rate of infection. With no clear consensus, protocols vary greatly among institutions and clinical practice to reduce the rate of infections. The purpose of this study was to address gaps in the literature and determine whether prophylactic oral post-operative antibiotic administration reduced the incidence of infection related to device implantation. In addition, an evaluation of institutional infection prevention program. The study describes the clinical practice at a single center tertiary care hospital for implanting CIED's including initial and replacement pacemaker, ICD's and loop recorders (ILR). The study compared infection rates before and after the institution of prophylactic oral post-operative antibiotics.

Statistically- Sample size N= 1200 ± 25 between 2013 and 2016, ICD's 50.6%, Pacemakers 42.2%, ILR 5.5, lead revision 1.8%. Both pacemaker and ICD initial implants were 64.3%, replacement 35.2% and upgrades 11%. Patient characteristics were male 57.9%, female 42.1%, mean age was 65.8 years old. Use of oral antibiotics consisted of Keflex 8.2%, Doxycycline 17.6%, other 3.8% and no antibiotic usage was 70.5%.

Findings note the use of prophylactic post-operative oral antibiotics in whole was not statistically significant with CI of 95%. Statistical significance (P .030) was noted in provider and incisional assessment and interaction between provider and antibiotic (P .019). No statistical difference was noted in implants between years for incisional site assessment.

Recommendations include adherence to pre-operative, peri-operative and post-operative protocols. In addition we recommend adherence to infection prevention by consistently cleaning device programmer heads with antiseptic wipes between patients interactions



Ingrid Mitchell
April 2017

# IMPLEMENTING EVIDENCE BASED PRACTICES FOR PREVENTING CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) INFECTION AND THE ROLE OF POST-OPERATIVE ORAL ANTIBIOTICS

by

Ingrid Mitchell

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APPROVED

For the Department of Nursing:

We, the undersigned, certify that the thesis of the following student meets the required standards of scholarship, format, and style of the university and the student's graduate degree program for the awarding of the master's degree.

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# CHAPTER 1: INTRODUCTION

The population of interest for this project was patients implanted with Cardiac Implantable electronic devices (CIED), pacemaker or an implantable cardioverter defibrillator (ICD) for an arrhythmia. Cardiac implantable electronic devices are life saving devices, the clinical benefit of CIED's has been long proven through numerous studies. Cardiac pacemakers and ICD's are standard therapy for patients with a bradyarrhythmia, tachyarrhythmia, or heart failure with a left bundle branch block (Wilkoff, et al., 2008). Millions of CIED's have been implanted worldwide and this clinical practice has improved the quality of life for millions (Epstein, DiMarco, & Ellenbogen, 2008).

With the increase of implants there has been an increase in the infection rates (Klug et al., 2007). Research studies have evaluated pre-procedure, during procedure and after procedure risk and protocols and risk factors. Few studies have assessed or did not identify a consensus on prophylactic use of oral post-op antibiotics after CEID implantation at hospital discharge to further reduce the rate of infection. Additional studies that specifically investigate the effectiveness of of this practice needed.

The aim of this project was to evaluate the efficacy of prophylactic post-operative oral antibiotics at discharge and reduction in the rate of infection after device implantation.

**Problem statement**

A surgical site infection is an infection that occurs after surgery in the area of the body where procedure was performed. Surgical site infection is defined by the Center for disease control as superficial incisional, deep incisional or organ or space infection (CDC, 2016; De Angelis, 2011; Metais et al., 2011) (Appendix 1).

Surgical site infections remain a significant cause of morbidity, prolonged hospitalization, and death (Skoufalos, Clarke, & Napp, 2012). Surgical site infections are associated with a mortality which can be directly attributable to the SSI (Awad, 2012). Infection rates in pacemakers and ICD's range from 1% to 7% for initial implants and replacements respectively (Skoufalos, Clarke & Napp, 2012). There are known risk factors associated with an increased risk for surgical site infection, diabetes, anticoagulation resulting in hematoma, end stage renal disease and temporary pacemaker wires (Rohacek & Baddour, 2015).

Studies have evaluated operative factors, procedural related factors, intravenous preoperative and postoperative prophylaxis and topical antibiotics (Padfield et al., 2015). The Prevention of arrhythmia device infection trial (PADIT) utilized a combination approach of preoperative antibiotics, wound pocket irrigation with an antibiotic and a 2-day course of oral postoperative antibiotics in a targeted population of higher risk procedures (Connolly et al.,

2013). With no clear consensus, protocols vary greatly among institutions and clinical practice to reduce the rate of infections.

**Objectives and Aims**

The study was to determine whether prophylactic oral post-operative antibiotic administration reduces the incidence of infection related to device implantation. In addition, evaluate institutional infection prevention program. The study aimed to:

1. Describe the clinical practice at a tertiary care hospital for implanting CIED's including initial and replacement pacemaker, ICD's and ILR.
2. Compare infection rates before and after the institution of prophylactic oral post-operative antibiotics. Evaluate infection rate and interventions
3. Develop a protocol that includes or excludes prophylactic oral post-operative antibiotics based on findings.

## CHAPTER 2: LITERATURE REVIEW

A literature search for key words; cardiac electronic implantable device, implantable cardiac defibrillator, pacemaker and infection was completed. Articles were identified relevant to this project with a compendium summarized. Studies identified ranged from one year to forty years, sample sizes were as small as thirteen up to over four thousand patients. Study designs were prospective, retrospective and mixed method.

Khalighi, Aung and Elmi (2014) evaluated the efficacy of topical antibiotic prophylaxis in the prevention of surgical site infection after CEID implantation procedures. A prospective randomized, placebo-controlled, single-center, single-operator study randomized 1,008 patients into four groups and received various topical prophylaxes after procedure. Fifty-eight patients developed surgical site inflammation and infection. Fourteen patients had culture-positive wound infections. Among them, 13 patients had superficial wound infections with Staphylococcus species (Khalighi, Aung & Elmi, 2014)

Metais et al. utilized a standardized survey form adapted from a prior research study, a prospective evaluation of pacemaker lead endocarditis study (people) cohort. The study noted that optimal compliance with antibiotic prophylaxis was not reached and attempts should be made to obtain full adherence to preventive measures in device implantation (2011). Uslan et al. Conducted an analysis to identify contributing clinical factors, infection prevention practices, and practice site differences associated with infectious complications (Uslan et al., 2012).

A single center study completed by Tischer et al. investigated the management and outcome of patients with pacemaker infections in a single center over four decades. Authors noted antibiotic regimes have changed over a period of time and assimilation of the guidelines improved the outcome of pacemaker infections (2014). In another study early recognition and treatment of infections,

aggressive management of hematomas, and use of antibiotic therapy with device revisions might help reduce the rate of infection (Raad et al., 2012).

Each of the studies recommends intravenous antibiotic prophylaxis and protocols to reduce the risk. Few studies have assessed prophylactic use of oral post-op antibiotics after CEID implantation at discharge to further reduce the rate of infection (D. Uslan, Dowsley, & Sohail, 2010). With these gaps in the literature further research has been recommended and will be addressed in this project.

**Theoretical framework**

Benner's clinical wisdom in nursing practice was the theoretical framework applied to analyze the population and data reviewed. Each of Benner's seven domains could easily be applied however, the one domain specific to this study was monitoring and ensuring quality of healthcare practices (Masters, 2014). This domain was applicable in patient education post implant to identify signs and symptoms of infection, utilized in assessment of the patients incisional sites post procedure at follow-up appointments and evaluating if current practices was the consistent with evidenced based practices.

## CHAPTER 3: METHODOLOGY AND METHODS

A retrospective population based cohort of patients was evaluated in a single center teaching institution over a three year period 2013-2016. This time frame was chosen as it coincided with the implementation of institutional electronic medical record (EMR) system for both clinic and hospital. Two patient

groups were evaluated, prophylactic post-operative oral antibiotics (Keflex and Doxycycline) compared with no prophylactic oral antibiotic at discharge to determine rate reduction of surgical site infection in CIED implants. Inclusion criteria included patients implanted with an initial or replacement pacemaker, ICD or ILR by four Electrophysiologist (EP) within the group. Exclusion criteria; simple interventions on the scar; devices not implanted by Electrophysiologist team, device extraction, intervention on the same surgical site $\leq$ 30 days after the first implantation for devices implanted in outside hospitals (OSH).

The project included an evaluation of the each implanting physician and protocols for CIED implants of four EP (Figure 2). The intervention was antibiotic prophylaxis implemented by a single implanting EP after a designated period, September 2015 to end of study period. Data collection for patients implanted with a CIED will be through a retrospective chart review. Evaluation included time frame of an in-office visit post procedure by a physician or Advanced practice registered Nurse (APRN)/Nurse Practitioner (NP) on EP team. No subjects were recruited for this retrospective study, they were identified in the manner described above. There was no direct compensation to subjects. No consent was required as this was a retrospective chart review. There were no direct risks or benefits to subjects recruited to this study. There was no direct contact with patients additionally; the patients' identities will not be identifiable in results from this investigation. Potential risk may include having the patient's privacy or

confidentiality compromised. But every reasonable effort was made to protect the patient's information while their data is used as part of this study.

**Data Analysis**

Data collection was gathered in a tertiary care university hospital by the primary investigator, and two research assistants, a Cardiology Nurse practitioner, and clinic medical assistant assigned to the EP team. The primary investigator conducted one on one training sessions with individuals assisting in data retrieval prior to data collection.

Patients were identified through a Cardiovascular lab specific data base and the EMR system. The project has approval by the institutional Nursing research council and California State University Nursing institutional review board. Variables included in the statistical analysis were; procedure date, length of stay, provider, device type, risk factors, initial or replacement devices, days to follow-up and if antibiotics were prescribed at discharge. Data collection included patient location before and after the procedure, and if the patient was inpatient or outpatient through the EMR (Appendix A). Procedures or infections not clearly defined were excluded.

## CHAPTER 4: RESULTS

Standard infection control methods were observed in pre-operative, intraoperative and post-operative period. Pre-operatively patients were screened for risk factors increasing risk of infection, patients showered in chlorhexidine the

night before and the morning of the procedure, chest hair was clipped, patients received intravenous antibiotics one hour before incision. Vancomycin was the antibiotic of choice unless allergies, as this institution has been deemed to have an increased risk for methicillin resistant streptococcus aureus (MRSA). Intra-operatively patients chest were cleansed with betadine scrub neck to nipple, sterile techniques were observed by CVL or operating room staff, a sterile dressing was applied to incisional site before leaving the operative area. Post-operatively patients received a second dose or intravenous antibiotics as applicable and extensive wound care instructions were provided by an APRN with written instructions provided to patient and/or family. It was noted during post-op office visits that staff were not consistently utilizing infection prevention with equipment use. An additional intervention included educating staff to cleanse programmer head between each patient before application. There was no pre and post data analysis for this intervention.

Continuous variables were assessed with categorical variables using one - way, two-way Anova and Tukey method to evaluate oral post op antibiotic use, incisional assessment, infection rates and time frame for follow-up as appropriate. Standard statistical methods were used in analysis of data collected using SPSS 23 statistical program to run data analysis.

Patient demographics included male 57.9%, female 42.1%. The youngest was nineteen years old, the oldest was ninety-seven years old 47.3% were between

sixty-one and eighty years old, mean age was 65.8 years old, other characteristics are shown in Table 1.

Table 1. Patient demographics

| **Age Groups** | **Percentage** |
|---|---|
| **19-30 y.o.** | 5.2% |
| **31-40 y.o.** | 4.0% |
| **41-50 y.o.** | 8.0% |
| **51-60 y.o.** | 17.1% |
| **61-70 y.o.** | 20.4% |
| **71-80 y.o.** | 26.9% |
| **81-97 y.o.** | 18.4% |
| | |
| ***Gender*** | *Percentage* |
| **Male** | 57.9% |
| **Female** | 42.1% |
| ***Ethnicity*** | ***Percentage*** |
| **African American** | 10.8% |
| **Hispanic** | 19.8% |
| **Caucasian** | 62.5% |
| **Asian** | 4.8% |
| **Other** | 2.2% |

Twelve-hundred patient CIED patient encounters were implanted between 2013 and 2016, ICD's 50.6%, Pacemakers 42.2%, ILR 5.5, lead revision 1.8%. Both pacemaker and ICD initial implants were 64.3%, replacement 35.2%, and upgrades 11%. Statistical significance (P .030) was noted in provider and incisional assessment and interaction between provider and antibiotic (P .019). Meaning, based on the provider and use of antibiotic there was a significance on incisional assessment.

Table 2. Tests of Between-Subjects Effects Two way ANOVA results

| Source | df | Sig. | Partial Eta Squared |
|---|---|---|---|
| Corrected Model | 12 | .000 | .180 |
| Intercept | 1 | .001 | .036 |
| Provider | 3 | **.030** | **.028** |
| Antibiotics | 3 | .169 | .016 |
| Provider * Antibiotics | 6 | **.019** | **.047** |

For this study infection was diagnosed based on incisional assessment by provider evaluation for symptoms of pain 17.8%, fever 1.0% and no symptoms 81.2%. Patients incision were assessed for- no symptoms 79%, drainage 1.0%, swelling 10.4%, fluctuance 0.4%, erythema 0.2%, hematoma 1.4%, bruising 1.4%, patients with more than one finding was 5.8% as shown in Table 2. While symptoms were noted as outlined, no surgical site infections were identified in the population during the study time frame. Follow-up was within 6-15 days 71.2% (Nurse Practitioner 34.5%, Physician 56.1%, no follow-up 9.4%) in outpatient setting.

Table 3 . Incisions assessed at post-op visit

| **Incisional assessment** | **Percentage** |
|---|---|
| | |
| **None** | 79.4 % |
| **Drainage** | 1.0 % |
| **Swelling** | 10.4 % |
| **Fluctuance** | 0.4 % |
| **Erythema** | 0.2 % |
| **Hematoma** | 1.4 % |
| **Bruising** | 1.4 % |
| **More than one symptom** | 5.8 % |

The use of antibiotics in whole was not statistically significant when evaluating incisional assessment with a 95% confidence interval (CI). Use of oral antibiotics consisted of Keflex 8.2%, Doxycycline 17.6%, other 3.8% and no antibiotic usage was 70.5%. No statistical difference was noted in implants between years for incisional site assessment.

Risk factors to infection identified in analysis of this patient population consisted of diabetes 13.4%, dialysis 0.2%, anticoagulation 25.7%, temporary wires 0.8%. Patients also had multiple factors for increased risk of infection with the largest population figure in combined diabetes and anticoagulation 7.8% as detailed in Table 4.

Table 4. Risk factors associated with increased risk of SSI

| Comorbidities | Percentage |
|---|---|
| **Diabetes** | 13.4 % |
| **Dialysis** | 0.2 % |
| **Anticoagulation** | 25.7 % |
| **Temporary Wires** | 0.8 % |
| **DM, Dialysis** | 1.6 % |
| **DM, Anticoag** | 7.8 % |
| **DM, Temp Wires** | 0.2 % |
| **DM, Dialysis, Anticoag** | 1 .0 % |
| **Anticoag, Temp wires** | 0.6 % |

# CHAPTER 5: CONCLUSION

The increase in infections for patients implanted with a CIED has been identified in the literature. The project evaluated the use of oral post-op antibiotics in reducing the rate of infection. No infections were identified during the study period. The use of prophylactic post operative oral antibiotics in whole was not statistically significant.

This was a retrospective analysis from a single center and thus subject to inherent limitations. However, the comparisons made were in subjects performed by the similar operators and facility. In addition, the large subject size may allow for application to the general public.

Implications for Nursing and APRN practice includes improved patient outcomes, utilization evidenced based practice to prevent or minimize infection by adhering to infection control practices. Nursing will be able to apply knowledge obtained in the post-operative care of CIED patients through enhanced knowledge of cardiac device infection identification, appropriate use of antibiotics and when to refer to cardiac specialty.

Recommendations for future research a prospective analysis of prophylactic oral antibiotics in low and high risk populations, adherence to pre-operative, peri-operative and post-operative protocols. In addition we recommend consistently cleaning device programmer heads between patients as a part of infection prevention.

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# APPENDICES

# APPENDIX A: DATA COLLECTION TOOL

| **Implanting Physician** | | | | | |
|---|---|---|---|---|---|
| **Name** | | **ID number** | | | |
| **Patient description** | | | | **Risk factors** | |
| Patient MRN | | Age (on date of procedure) | | Diabetes | |
| | | | | Dialysis | |
| Gender | | Ethnicity | | Anticoagulation | |
| | | | | Temporary Pacing wires | |
| **Event details** | | | | | |
| Date of procedure | | | | | |
| Procedure | | # of leads with initial | | | |
| Inpatient / Outpatient | | Initial/Replacement | | | |
| Location/Unit | | Upgrade | | | |
| Antibiotic prescribed | | Early Reintervention | | | |
| **Incision Evaluation** | | | | | |
| **Assessment** | | **Symptoms** | | **Follow up** | |
| Drainage | | Pain or tenderness | | # of days to follow up appoint. | |
| Swelling or Fluctuance | | fever | | Physician /NP (APRN) | |
| Erythema | | | | | |
| Hematoma | | | | | |
| Warmth to touch | | | | | |
| Clinical diagnosis of Infection | | | | | |
| **Legend** | | | | | |
| **Physician ID** | | **Antibiotic Use** | | **Secondary ID** | |
| Provider 2 | 2 | Doxy | 2 | Patient initials and age | |
| Provider 1 | 1 | Keflex | 1 | | |
| Provider 3 | 3 | None | 0 | | |
| Provider 4 | 4 | Other | 3 | **Number of Leads** | |
| **Procedure** | | **Follow- up** | | Dual | 2 |
| Pacemaker | 1 | Physician | 1 | Single | 1 |
| ICD | 2 | NP | 2 | None | 0 |
| Implantable loop recorder | 3 | | | Bi - Ventricular | 3 |

APPENDIX B: CDC- SURGICAL SITE INFECTION

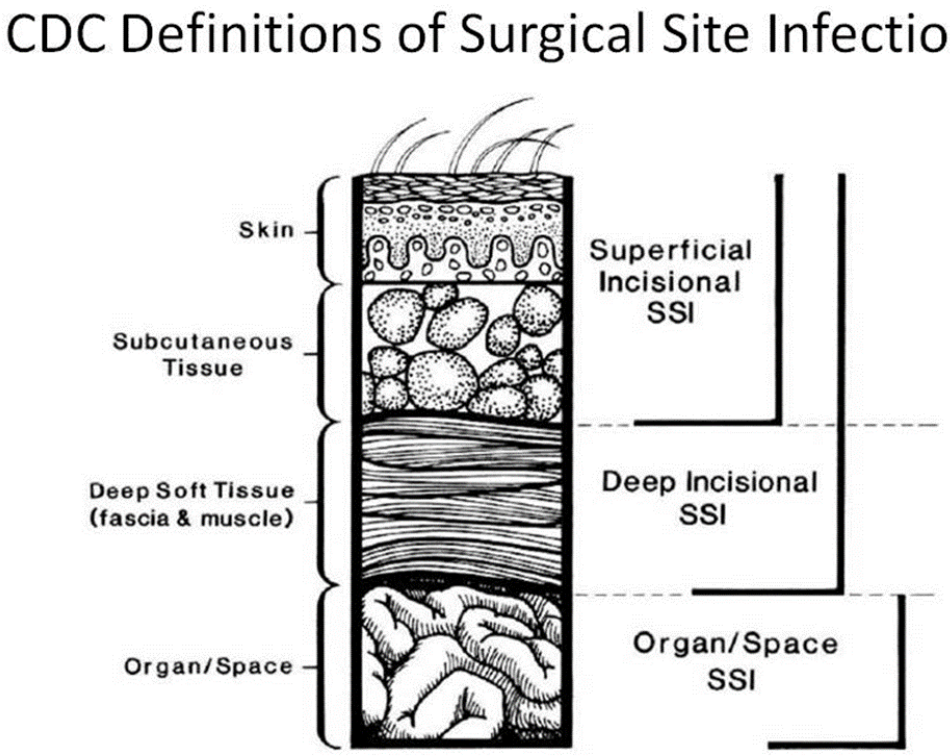


Figure 1 Surgical site infection Centers for disease control – Retrieved from https://www.cdc.gov/hicpac/pdf/guidelines/SSI_1999.pdf

APPENDIX C: RESEARCH DESIGN

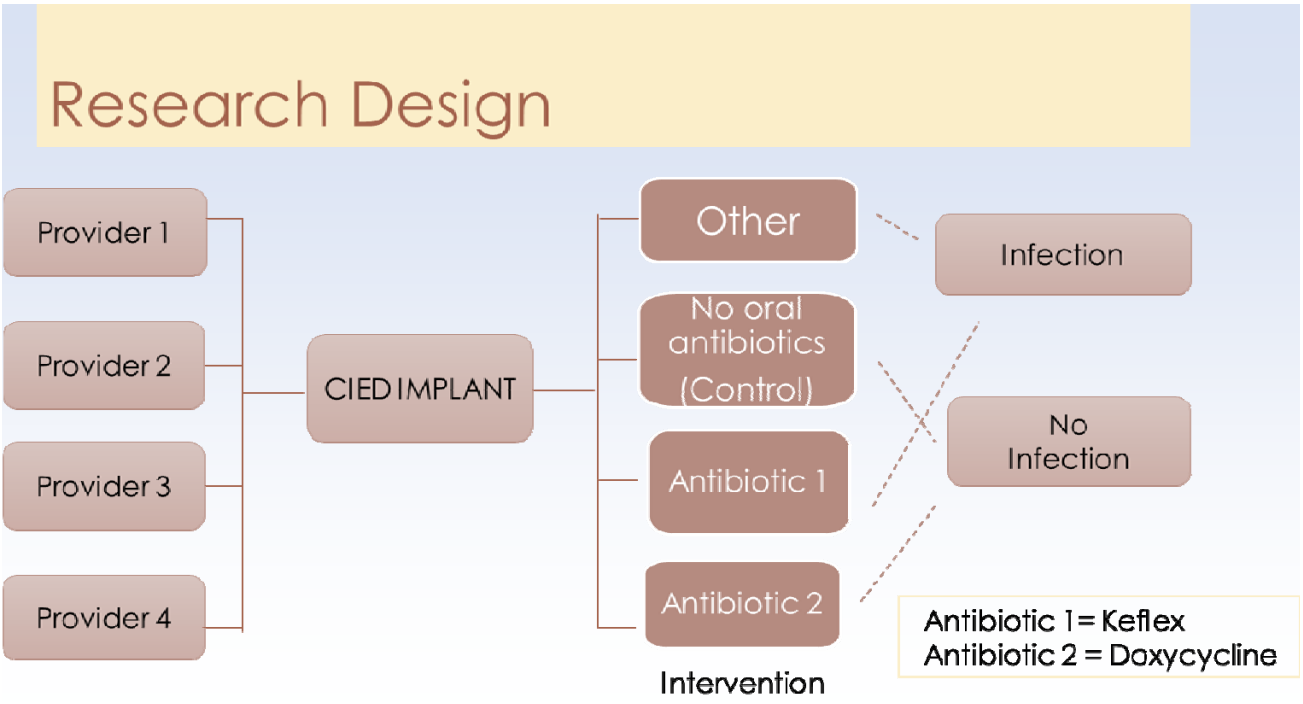


Figure 2. Overview of study design