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Journal of Arrhythmia

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Review

Perioperative management for the prevention of bacterial infection in cardiac implantable electronic device placement

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ARTICLE INFO

Article history:

Received 18 May 2015

Accepted 19 June 2015

Available online 8 August 2015

Keywords:

Implantation technique

CIED complication

CIED infection

ABSTRACT

Cardiac implantable electronic devices (CIEDs) have become important in the treatment of cardiac disease and placement rates increased significantly in the last decade. However, despite the use of appropriate antimicrobial prophylaxis, CIED infection rates are increasing disproportionately to the implantation rate. CIED infection often requires explantation of all hardware, and at times results in death. Surgical site infection (SSI) is the most common cause of CIED infection as a pocket infection. The best method of combating CIED infection is prevention. Prevention of CIED infections comprises three phases: before, during, and after device implantation. The most critical factors in the prevention of SSIs are detailed operative techniques including the practice of proper technique by the surgeon and surgical team.

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1. Background

The development of transvenous electrodes and downsized generators over the past two decades has permitted physicians to place cardiac implantable electronic devices (CIEDs), and even high voltage devices such as implantable cardioverter-defibrillators or cardiac resynchronization therapy devices with a defibrillator, using

techniques similar to those employed for permanent pacemaker insertion [1–5]. As a result, CIED implantation rates have increased significantly in the last decade and these devices gained importance in the treatment of cardiac disease for their ability to reduce morbidity and mortality in selected patients [6,7]. CIED implantation by a cardiologist in an electrophysiology laboratory has several advantages including support by specialized staff and the availability of appropriate monitoring and radiological equipment. However, these beneficial procedures are associated with risks, including infection.

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Infection is the most serious complication of CIED implantation and requires explantation of all hardware, with fatalities occurring in 3–19% of patients [8]. CIED infections are associated with significant morbidity, mortality, and cost [9–11]. Infection rates associated with device implantation are reported to be between 1% and 7% [12]. The majority of CIED infections are caused by staphylococcal species, which account for 60–80% of cases in most reported series [13–15]. Coagulase-negative staphylococcal species, often *S. epidermidis*, are the most common pathogens (42%) reported to cause CIED infections [16]. *Staphylococcus aureus* is the second most common pathogen (25%).

The current American Heart Association (AHA)/Heart Rhythm Society (HRS) recommendation for prophylaxis at the time of CIED placement is an antibiotic that possesses in vitro activity against staphylococci [9]. Recent large studies indicate that the vast majority of patients receive antimicrobial prophylaxis with CIED placement [17,18]. However, despite the widespread use of appropriate antimicrobial prophylaxis, CIED infection rates are increasing disproportionately to implantation rates [19].

2. Surgical site infection

The Centers for Disease Control and Prevention (CDC) has developed criteria for defining surgical site infection (SSI) [20], which replaced the previous term ‘surgical wound infection’. This guideline became the worldwide standard and is widely used for surveillance, including in Japan (i.e., Japan Nosocomial Infections Surveillance; JANIS). These criteria define SSIs as infections related to the operative procedure that occur at or near the surgical incision (incisional or organ/space) within 30 days of an operative procedure or within 1 year if an implant is left in place. Incisional SSIs are further divided into those involving only the skin and subcutaneous tissue (superficial incisional SSIs) and those involving deeper soft tissues (deep incisional SSIs). Organ/space SSIs involve any part of the anatomy (e.g., organ or space), other than the incised body wall layers, that was opened or manipulated during an operation. These definitions should be universally followed for the surveillance, prevention, and control of SSIs.

Along with this guideline, cardiac device infections can also be defined and classified as ‘pocket infections’ and ‘deeper infections’. The term ‘pocket infection’ is used when the infection involves the subcutaneous pocket containing the device and the subcutaneous part of the leads. The term ‘deeper infection’ is used when the infection involves the transvenous portion of the lead, usually in association with bacteremia and/or endovascular infection. Alternatively, device infections may be classified by the mode of infection. Primary infections, in which the device and/or pocket itself is the source of infection, are usually due to contamination at the time of implantation. A secondary infection occurs when the leads (and sometimes the device and pocket) are seeded by bacteremia from a different source (i.e., hemodialysis vascular access or dental abscesses).

Table 1

Interventions that have been used to reduce the risk of SSIs.

✓	Preoperative showering with antimicrobial soaps ^a
✓	Preoperative application of antiseptics to the skin of the patient
✓	Washing and gloving of the surgeon's hands
✓	Use of sterile drapes
✓	Use of gowns and masks by operating room personnel

^a Not available in Japan

3. Prevention of CIED infection

The prevention of CIED infections comprises three phases: before, during, and after device implantation. The most critical factors in the prevention of SSIs are detailed operative techniques including the practice of proper technique by the surgeon and surgical team. Table 1 shows interventions that have been used to reduce the risk of SSIs [20]. Most interventions were developed to reduce contact with normal microbial flora from hospital personnel, believed to be the source of microorganisms causing SSIs.

3.1. Preoperative prevention

Fever elevation within 24 h before implantation is associated with the development of CIED infection [17]. Therefore, patients should be screened for evidence of infection prior to implantation. All remote infections should be adequately treated before elective operations, and implantation should be postponed until the infection has resolved. If urgent surgery is required, the risk of infection must be weighed against the timing of surgical intervention on an individual basis.

3.1.1. Hair removal and skin sterilization (anti-sepsis)

In the past, hair removal was commonly performed before most surgical procedures to provide a clean operative field and prevent bacteria in hair follicles from entering the surgical site.

However, most studies have found an increased risk of SSIs in patients undergoing preoperative hair removal [21]. Therefore, it is not recommended to remove hair perioperatively unless the hair at or around the incision site will interfere with the operation [20].

The CDC also recommends that patients be required to shower or bathe with an antiseptic agent at least on the night before surgery [20]. However, the benefit of bathing with an antiseptic preparation prior to surgery to reduce the risk of SSIs has been questioned. In a meta-analysis of six trials involving 10,007 participants, preoperative bathing with chlorhexidine conferred no benefit in terms of SSI reduction over preoperative bathing with other products such as non-antiseptic washing agents [22].

The CDC also recommends thoroughly washing and cleaning at and around the incision site to remove contamination before performing an antiseptic skin preparation. The application of antiseptics to the skin immediately prior to surgery is a routine practice in almost all operations, and perioperative antiseptic preparation of the skin of the surgical site should be performed with an approved antiseptic agent. The antiseptic should be applied over the incision site in concentric circles starting from the incision site and moving toward the periphery.

3.1.2. Antibiotic prophylaxis

In a clean operation such as cardiovascular or brain surgery, the incidence of SSIs is relatively low. However, once it occurs, it becomes increasingly severe. Therefore, systemic prophylactic antibiotics at the time of CIED implantation are recommended. At present, there are no guidelines on systemic prophylactic antibiotic use in CIED implantation and no trials comparing systemic prophylactic antibiotic regimens. Data from some studies [17,23–25] support the administration of antibiotic prophylaxis for CIED implantation. The CDC recommends that vancomycin should not be used routinely for antimicrobial prophylaxis because of the risk of postoperative methicillin-resistant *S. aureus* infection [20]. In a clean operation, ceftazolin, which is effective for skin flora, is usually used for prophylaxis.

Table 2

Patients background risk factors associated with CIED infection.

- ✓ Advanced patient age
- ✓ Congestive heart failure
- ✓ Diabetes mellitus
- ✓ Immunosuppression (corticosteroid use)
- ✓ Oral anticoagulation use
- ✓ Patient coexisting illnesses
- ✓ Failure to administer perioperative antimicrobial prophylaxis
- ✓ Preprocedural temporary pacing
- ✓ Renal dysfunction
- ✓ The amount of indwelling hardware (leads)
- ✓ The microbiology of bloodstream infection
- ✓ Underlying malignancy
- ✓ Current smoke

Table 3

Good surgical technique reducing the risk of SSIs.

- ✓ Gentle traction
- ✓ Effective and obsessive hemostasis
- ✓ Removal of devitalized tissues
- ✓ Obliteration of dead space
- ✓ Enough irrigation of tissues with saline
- ✓ Use of non-absorbed monofilament suture material
- ✓ No or judicious use of closed suction drains
- ✓ Wound closure without tension

Modified from Altemeier et al. [27], 54.

3.1.3. Preoperative disease and status control (including smoking cessation)

Several preoperative host factors associated with a greater risk of CIED infection were described previously (Table 2) [9,17]. When possible, these risks should be mitigated. The CDC recommends that serum blood glucose levels be adequately controlled in all diabetic patients and in particular, that preoperative hyperglycemia be avoided. The CDC also recommends instructing patients to abstain from smoking cigarettes, cigars, or pipes and avoid any other form of tobacco consumption (e.g., chewing/dipping) for at least 30 days (at minimum) before elective surgery [20].

3.2. Intraoperative prevention

The most important factors for the prevention of SSIs are detailed operative techniques including the practice of proper technique by the surgeon. Before starting the surgery, operating room personnel should be equipped with barrier devices (masks, caps, gowns, drapes, and shoe covers) as protection against exposure to infectious blood or body fluids. Prior to surgery, physicians should perform a surgical scrub including the hands and forearms for at least 2–5 min with an appropriate antiseptic agent. This is an accepted practice, and guidelines support using either an antimicrobial soap or an alcohol-based hand rub with persistent activity for surgical hand antisepsis [26]. Cleaning underneath each fingernail prior to performing the first surgical scrub of the day is recommended. After performing the surgical scrub, physicians should keep their hands up and away from their body. Hands should be dried with a sterile towel before donning a sterile gown and gloves.

3.2.1. General surgical technique

There is general agreement that good surgical technique reduces the risk of SSIs (Table 3) [27]. However, the role of these techniques in SSI prevention in relation to CIEDs is not supported by strict study. Intraoperatively, compulsive or obsessive attention to sterile technique is mandatory. Usually, CIEDs can be implanted in pockets fashioned in the prepectoral subcutaneous space.

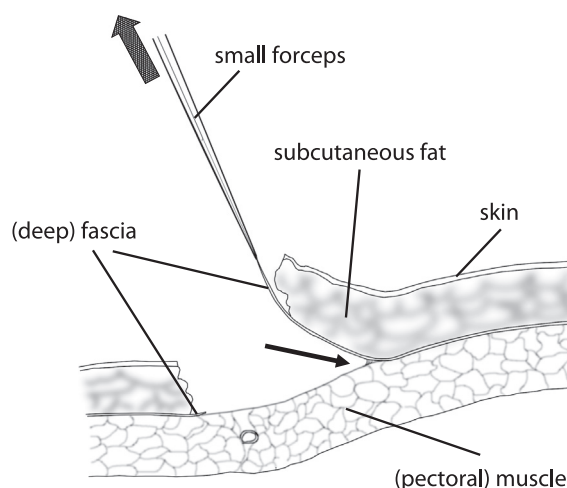


Fig. 1. To minimize traumatic pocket complications such as hematoma formation, prepectoral subfascial implantation has been employed. By chipping off the entire muscle body, using the fingers to gently spread the tissues apart slightly medially and caudally, the pocket is formed simply by the reduced adhesion between the fascia and muscle.

However, in lean or small subjects, especially in Japanese people, who are thought to be at risk of pocket erosion, the formation of deep pockets beneath the major pectoral muscle has been recommended [28–30]. Because such pockets require deep dissection, traumatic injury to the small vessels or nerve system, accidental bleeding, or postoperative hematoma can occur. To minimize such traumatic pocket complications, prepectoral subfascial implantation has been employed since the early 1990s mainly for large devices (Fig. 1) [31,32], although limited data support this practice. In any and all circumstances, hematoma formation should be avoided by meticulous cautery of bleeding sites since hematoma involving a pocket has been identified as a risk factor in device placement [33]. Therefore, hematoma prevention during the procedure is desirable. Frequent irrigation of the pocket is useful for removing tissue debris and may reveal persistent bleeding that could lead to a pocket hematoma. The effectiveness of prophylactic intrapocket antibiotics in CIED implantation has not been evaluated in randomized controlled trials. The presence of antibiotics in irrigation solutions is unlikely to be necessary. Rather, the mechanical action of debris removal and dilution of any contaminant are due to the flow and volume of irrigation. The use of monofilament sutures for closure of the subcuticular layer may prevent superficial postoperative cellulitis. A pressure dressing applied postoperatively for 12–24 h after skin closure may help prevent infection and further decrease the risk of hematoma formation.

3.3. Postoperative prevention

In cases of hematoma formation, it is recommended that the hematoma only be evacuated in the presence of increased skin tension, suggesting a risk of dehiscence. In general, needle aspiration should be avoided because of the risk of introducing skin flora into the pocket, which may subsequently develop into infection. Prolonged pressure dressing (> 3 days) of the pocket can help prevent hematoma formation even if anticoagulation or anti-platelet agents were administered. Recent AHA guidelines recommend early follow-up in a clinic setting as well as thorough patient education to achieve early identification of CIED-related infectious complications [9].

Postoperative prophylactic systemic antibiotics are commonly used, although there is wide variation in the duration of treatment. One study that investigated the duration of postoperative

antibiotics compared short-term (2 days) with longer-term (7 days) use [34]. This study suggested that a short course is just as effective as a longer course in preventing CIED infections. Currently, there is insufficient evidence to support the administration of postoperative antibiotic therapy, and the use of postimplantation antibiotics is not recommended in the recently updated AHA guidelines [9]. There is currently no scientific basis for the use of prophylactic antibiotics before routine dental, gastrointestinal, or genitourinary procedures to prevent CIED infections.

4. Conclusions

Infection is the most serious complication of CIED implantation. Once it develops, it often requires explantation of all hardware with strong invasion and sometimes results in death. The best method of combating CIED infection is prevention. The most critical factors in the prevention of CIED infection are detailed operative techniques including the practice of proper technique by the surgeon and surgical team. Improved antimicrobial prophylaxis is one approach to reducing the morbidity, mortality, and expense associated with infection after CIED implantation.

Conflict of interest

The author of this manuscript has no conflicts of interest to declare.

References

- [1] Camunas J, Mehta D, Ip J, Gomes JA. Total pectoral implantation: a new technique for implantation of transvenous defibrillator lead systems and implantable cardioverter-defibrillator. *Pacing Clin Electrophysiol* 1993;16:1380–5.
- [2] Fitzpatrick AP, Lesh MD, Epstein LM, et al. Electrophysiological laboratory, electrophysiologist-implanted nonthoracotomy-implantable cardioverter/defibrillators. *Circulation* 1994;89:2503–8.
- [3] Stanton MS, Hayes DL, Munger DM, et al. Consistent subcutaneous prepectoral implantation of a new implantable cardioverter-defibrillator. *Mayo Clin Proc* 1994;69:309–14.
- [4] Zipes DP. The implantable cardioverter-defibrillator revolution continues. *Mayo Clin Proc* 1994;69:395–6.
- [5] Tung RT, Bajaj AK. Safety of implantation of a cardioverter-defibrillator without general anesthesia in an electrophysiology laboratory. *Am J Cardiol* 1995;75:908–12.
- [6] Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. *Circulation* 2008;117:e350–e408.
- [7] Hunt SA, Abraham WT, Chin MH, et al. 2009 Focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. *Circulation* 2009;119:e391–479.
- [8] Cacoub P, Leprince P, Nataf P, et al. Pacemaker infective endocarditis. *Am J Cardiol* 1998;82:480–5.
- [9] Baddour LM, Epstein AE, Erickson CC, et al. Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association. *Circulation* 2010;121:458–77.
- [10] Ferguson TBJ, Ferguson CL, Crites K, et al. The additional hospital costs generated in the management of complications of pacemaker and defibrillator implantations. *J Thorac Cardiovasc Surg* 1996;111:742–51 [discussion 751–2].
- [11] Reynolds MR, Cohen DJ, Kugelmass AD, et al. The frequency and incremental cost of major complications among Medicare beneficiaries receiving implantable cardioverter-defibrillators. *J Am Coll Cardiol* 2006;47:2493–7.
- [12] Lai KK, Fontecchio SA. Infections associated with implantable cardioverter-defibrillators placed transvenously and via thoracotomies: epidemiology, infection control and management. *Clin Infect Dis* 1998;27:265–9.
- [13] Uslan DZ, Sohail St MR, Sauver JL, et al. Permanent pacemaker and implantable cardioverter-defibrillator infection: a population-based study. *Arch Intern Med* 2007;167:669–75.
- [14] Chua JD, Wilkoff BL, Lee I, Juratli N, Longworth DL, Gordon SM. Diagnosis and management of infections involving implantable electrophysiologic cardiac devices. *Ann Intern Med* 2000;133:604–8.
- [15] Sohail MR, Uslan DZ, Khan AH, et al. Management and outcome of permanent and implantable cardioverter-defibrillator infections. *J Am Coll Cardiol* 2007;49:1851–9.
- [16] Kloos WE, Bannermann TL. Update on the clinical significance of coagulase-negative staphylococci. *Clin Microbiol Rev* 1994;7:1451–9.
- [17] Klug D, Balde M, Pavin D, et al. Risk factors related to infections of implanted pacemakers and cardioverter defibrillators: results of a large prospective study. *Circulation* 2007;116:1349–55.
- [18] Gould PA, Gula LJ, Champagne J, et al. Outcome of advisory implantable cardioverter-defibrillator replacement: one-year follow-up. *Heart Rhythm* 2008;5:1675–81.
- [19] Voigt A, Shalaby A, Saba S. Continued rise in rates of cardiovascular implantable electronic device infections in the United States: temporal trends and causative insights. *Pacing Clin Electrophysiol* 2010;33:414–9.
- [20] Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. *Am J Infect Control* 1999;27:97–132.
- [21] Mishriki SF, Law DJ, Jeffery PJ. Factors affecting the incidence of postoperative wound infection. *J Hosp Infect* 1990;16:223–30.
- [22] Webster J, Osborne S. Meta-analysis of preoperative antiseptic bathing in the prevention of surgical site infection. *Br J Surg* 2006;93:1335–41.
- [23] Sohail MR, Uslan DZ, Khan AH, et al. Risk factor analysis of permanent pacemaker infection. *Clin Infect Dis* 2007;45:166–73.
- [24] Da Costa A, Kirkorian G, Cucherat M, et al. Antibiotic prophylaxis for permanent pacemaker implantation: a meta-analysis. *Circulation* 1998;97:1796–801.
- [25] de Oliveira JC, Martinelli M, Nishioka SA, et al. Efficacy of antibiotic prophylaxis before the implantation of pacemakers and cardioverter-defibrillators: results of a large, prospective, randomized, double-blinded, placebo-controlled trial. *Circ Arrhythm Electrophysiol* 2009;2:29–34.
- [26] Boyce JM, Pittet D. Guideline for Hand Hygiene in Health-Care Settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Infect Control Hosp Epidemiol* 2002;23:S3–40.
- [27] Altemeier WA, Burke JF, Pruitt BA, et al. Manual on control of infection in surgical patients. Philadelphia: JB Lippincott; 1984.
- [28] Bardy GH, Raitt MH, Jones GK. Unipolar defibrillation systems. In: Singer I, editor. Implantable cardioverter-defibrillator. Armonk, NY: Futura Publishing Co; 1994. p. 365–76.
- [29] Foster AH. Technique for implantation of cardioverter-defibrillators in the subpectoral position. *Ann Thorac Surg* 1995;59:764–7.
- [30] Eastman DP, Selle JG, Reames Sr MK. Technique for subpectoral implantation of cardioverter-defibrillators. *J Am Coll Surg* 1995;181:475–6.
- [31] Pacifico A, Wheelan RK, Nasir Jr N, et al. Long-term follow-up of cardioverter-defibrillator implanted under conscious sedation in prepectoral subfascial position. *Circulation* 1997;95:946–50.
- [32] Imai K. Pocket creation in the prepectoral subfascial position for the implantation of a cardiac implantable electrical device. *J Arrhythmia* 2014;30:92–4.
- [33] Lekkerkerker JC, van Nieuwkoop C, Trines SA, et al. Risk factors and time delay associated with cardiac device infections: Leiden device registry. *Heart* 2009;95:715–20.
- [34] Dwivedi SK, Saran RK, Khera P, et al. Short-term (48 h) versus long-term (7 days) antibiotic prophylaxis for permanent pacemaker implantation. *Indian Heart J* 2001;53:740–2.