Heliyon 9 (2023) e22229

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Do barrier dressings reduce cardiac implantable device infection: Protocol for a randomized controlled trial (BARRIER-PROTECT)

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ARTICLE INFO

Keywords:
Cardiac implantable electronic device
Pacemaker
ICD
Infection
Prevention
Swab
Barrier
Dressing
Drape

ABSTRACT

Background: Cardiac implantable electronic device (CIED) procedures can be associated with serious complications, including infection with significant mortality and morbidity, necessitating removal of the device and prolonged hospitalization. One potential pathophysiological mechanism is pocket contamination at the time of device implantation. Therefore, steps taken to prevent contamination at this stage can potentially reduce CIED infections.

The barrier dressing, an adhesive material applied to the skin, has the potential to reduce the colonization of the surgical site with host flora that can predispose to infection. There are a limited number of randomized prospective studies on barrier dressing use during various surgeries, but it has never been systematically studied in CIED implantation.

Objectives: Do Barrier Dressings Reduce Cardiac Implantable Device Infection? (BARRIER-PROTECT trial; NCT04591366) is a single-centre, prospective, double-armed, single-blinded, randomized controlled trial designed to evaluate the use of an intra-operative adhesive barrier dressing to reduce the risk of end-of-procedure pocket swab positivity. We hypothesize that adhesive draping during implant procedures will reduce the risk of contamination from the skin flora. Also, we aim to investigate if the end-of-procedure pocket swab culture positivity can be used as a potential surrogate marker of CIED infection.

Methods and Design: Patients undergoing a second or later procedure on the same device pocket (pulse generator change, lead/pocket revision or upgrade) will be enrolled. Eligible and consenting patients will be equally randomized to the use of barrier dressing or not using an automated web-based system. Patients, but not the operator, will be blinded to the arm. The person performing the pocket swabs will also be blinded. The primary endpoint is the end-of-procedure pocket swab culture positivity. The main secondary endpoint is the CIED infection rate.

Discussion: This is the first randomized controlled trial to assess the effectiveness of using a barrier adhesive draping on reducing the end-of-procedure pocket swab culture positivity. In this study, we are exploring a low-cost intervention that may significantly reduce CIED infection. Also, having a valid surrogate marker for CIED infection at the time of implant will facilitate design of future clinical trials.

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https://doi.org/10.1016/j.heliyon.2023.e22229
Received 17 September 2023; Received in revised form 3 November 2023; Accepted 7 November 2023
Available online 10 November 2023

1. Background

PAcemaker and implantable cardioverter defibrillator (ICD) therapies are vital for treating bradycardia, heart failure and preventing sudden cardiac death [1]. These and other implantable prosthetic devices are increasingly used in the aging population. Implantable devices can be associated with serious complications, including infections. Infection-related to CIEDs is a serious complication with significant mortality and morbidity, necessitating removal of the device and prolonged hospitalization [2]. Although several studies have focused on the mechanism of CIED infection, there is considerable uncertainty about the sources [3,4]. One potential pathophysiological mechanism is pocket contamination at the time of device implantation. Therefore, steps taken to prevent contamination at this stage can potentially reduce CIED infections, decreasing morbidity and mortality.

Preventing CIED infections comprises three phases: before, during, and after device implantation. Preoperative prevention includes screening the patients for active infection, hair removal around the implant site and thorough skin cleaning prior to antiseptic skin preparation. Additionally, antibiotic prophylaxis at the time of the procedure is recommended by the relevant guidelines [1].

The barrier dressing, an adhesive material applied to the skin, is used in some surgeries to reduce the colonization of the surgical site with host flora that can predispose to infection. The adhesive barrier, usually containing an antibacterial material such as iodine, is applied prior to incision and removed at the time of or after skin closure. There are a limited number of randomized prospective studies assessing adhesive dressing use during various surgeries to reduce surgical site contamination by skin flora [5–8]. These randomized studies failed to demonstrate a benefit from the barrier dressing. It should be noted that none of these trials involved pacemaker or ICD implantation and CIED infections are importantly different from most other types of surgical site infections. Several factors contribute to the development and persistence of CIED infection, including the presence of foreign material and biofilm formation allowing bacteria to remain on the surface of a device indefinitely [9,10].

Hence in summary, in this RCT we aim to understand whether adhesive barrier dressing during implant procedures reduces the risk of contamination from the skin flora and, whether that is associated with a reduced risk of CIED infection.

2. Methods

This is a prospective, double-armed, single-blinded, randomized controlled trial. Study steps are shown in Fig. 1.

2.1. Objectives

Primary objective: To compare the risk of pocket swab positivity with or without an intra-operative adhesive barrier dressing during cardiac implantable device procedures.

Secondary objectives: To investigate the end-of-procedure pocket swab culture positivity as a potential surrogate marker of CIED infection.

2.1.1. Study population

Inclusion criteria: Any patient aged ≥18 undergoing a second or later procedure on the same device pocket (i.e., pulse generator

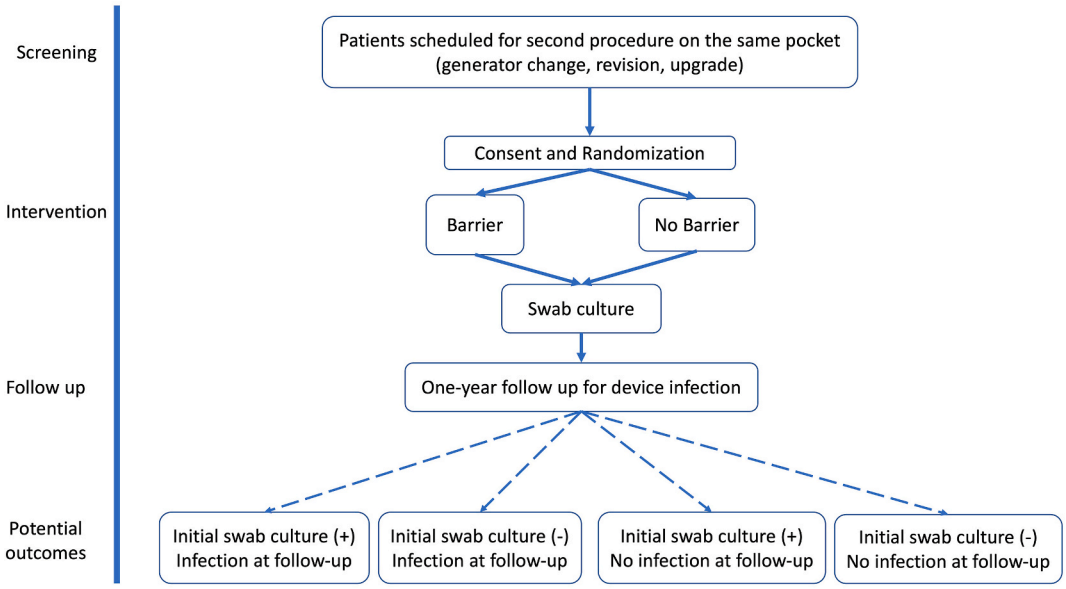

Fig. 1. Flow diagram on study steps and possible outcomes.

change or lead replacement or pocket revision, or device upgrade).

Exclusion criteria: Unable or unwilling to provide informed consent, active CIED infection, iodine allergy, life expectancy less than two years.

2.1.2. Institutional review board

The study was approved by the University of Ottawa Heart Institute review board (20200369-01H).

2.1.3. Randomization

Eligible and consenting patients will be equally randomized to use a barrier or not with an automated web-based system. Patients, but not the operator, will be blinded to the arm. The individual performing the pocket swab and the microbiology lab technicians will also be blinded.

2.1.4. Operative preparation

All patients will receive skin preparation, antibiotic prophylaxis and be prepped and draped as per the Ottawa Heart Institute protocols. Skin will be scrubbed with a chlorhexidine gluconate sponge 2 h before the procedure. Then before applying sterile drapes, the chlorhexidine gluconate sponge will be repeated, and after a 2-min wait, chlorhexidine will be wiped with a sterile towel, and the area will be further cleaned by chlorhexidine 2 % and isopropyl alcohol 70 % solution twice. Following, the patient will be covered by sterile drapes as usual. The barrier dressing (3 M™ Ioban™ 2 Antimicrobial Incise Drape, 6661EZ, 10.5 in x 8 in) will be applied in the barrier arm after draping and before the incision. All physicians will be trained on how to apply the barrier dressing. All patients will receive antibiotic prophylaxis according to the Prevention of Arrhythmia Device Infection Trial (PADIT) score [11].

2.2. Pocket swab procedure

The swab will be performed at the end of the procedure, immediately prior to the skin closure. A barrier dressing will be applied prior to taking the swab in the control arm. This is to prevent inadvertent contamination from the skin and for blinding purposes. An individual not involved in the procedure (brought into the electrophysiology lab after application of the barrier in the control arm and therefore will be blinded) will take the swab. The swab will be placed at the most caudal portion of the pocket on top of the generator. The swab will then be wiped back and forth four times until it is almost completely removed from the pocket. It will then be placed

Table 1
Relationship between intraoperative swab positivity and subsequent infection -CIED surgery.

.	patients	sample	Positive culture rate	How many infections
Dy Chua [12] 2015	71 pts requiring lead extraction with no evident infection in 36 (51 %)	Swab specimen from the deep portion of the pocket and a large piece of the fibrotic capsule. Follow up for nine weeks.	69 % with clinical infection 42 % with no sign of infection (10 (67 %) tissue vs 8 (53 %) swabs)	3 (all in pts with positive culture)
Pichlmaier [13] 2008	108 patients requiring pulse generator change	Swabs from patients electively admitted due to battery depletion. A tissue biopsy from the device pocket was also performed. Follow up for 24.6 months (7.5–33.1).	51 (47.2 %) specimens showed bacterial DNA.	All three patients with positive DNA for Staphylococcus developed infection. No infection otherwise
Kleeman [14] 2010	122 patients undergoing pulse generator change or lead revision	A swab specimen was obtained from the deep portion of the pocket after the removal of the device from the pocket. Microbiological cultures were taken from the extracted leads as well. 2/3rd had extracted leads.	Positive cultures from the generator pocket and leads were found in 40 (33 %) patients.	3/40 with positive cultures (7.5 %) had subsequent infections) Two (2.4 %, CI 0.3–8.5 %) patients with a negative culture had a subsequent infection (P = 0.33)
Rohacek [15] 2010	121 patients undergoing pulse generator change (6 patients with evidence of infection)	Swabs from the generator pocket were collected after the device's removal and culture of the sonication fluid of the devices.	44 (38 %) in sonication fluid 30 (27 %) in swab culture	No data
Okada [16] 2015	100 patients (49 de novo, 51 replacements	Three swab cultures [1] immediately after the creation of a new pocket or removal of the old generator [2], after connection of leads to the new generator, and [3] after pocket lavage. 25-month follow-up for infection.	272 (45 %) of 600 samples	One infection with different bacteria (P. acnes in swab culture, Staphylococci at the time of infection)
Mason [17] 2011	86 patients with generator explantation (16 due to infection)	A swab from the deep portion of the pocket, device sonication fluid and tissue sample. Follow up for 311 ± 144 days	15 (94 %) of the infected patients 14 (21 %) of the non-infected patients	No infection in the asymptomatic colonization group
Da Costa [3] 1998	103 elective pacemaker implantations	Three swabs (1) from the skin before cut (2), after pocket is created (3) after device insertion before skin closure.	88 % skin, 48 % before insertion and 37.1 % before closure Four infections (3.9 %) in 16-month F/U.	No data

underneath the device again to the most caudal portion of the pocket and sweeping motion will be repeated and then the swab will be removed. Before closing the pocket, it will be routinely soaked with bacitracin solution. All physicians will be trained on correct swabbing process as per this instructional video. (https://youtu.be/aEzr-gJkiYQ).

2.3. Swab culture and analysis

This will be performed in the microbiology lab using routine culture methods by blinded individuals.

2.4. Patient follow up

All patients will be followed for one year for the secondary endpoint (CIED infection). After discharge, all patients will have standard visits to the device clinic as per the routine Ottawa Heart Institute follow-up protocol. The infection data will be collected using electronic medical record system (EPIC and Cardio-core (PACEART) by text scraping of routine device clinic visits. All potential CIED infections will be adjudicated by a blinded endpoint committee (i.e., blinded to randomization). A CIED infection will be microbiologically confirmed based on positive cultures from the generator pocket, lead(s), or blood. The type of organism and its antibiogram will then be compared with the cultures obtained from the implant procedure. A CIED infection with the same organism will be decided based on the biotype and the antimicrobial susceptibility pattern.

2.5. Sample size calculation

We conservatively estimate a 30 % primary endpoint rate in the control arm (based on the data in Table 1). We hypothesize a 40 % relative risk reduction, with 80 % power and alpha equals 0.05, requiring a sample size of 396 patients in total. There are no anticipated crossovers or drop-outs.

2.6. Planned recruitment rate

We estimate that 15–20 patients per week will potentially be eligible for the study. The predicted date for completion of recruitment is within 12 months.

2.7. Planned analysis

Descriptive statistics, including 95 % confidence intervals, will be calculated for all baseline variables using means, medians, standard deviations and interquartile ranges for continuous outcomes and rates and proportions for discrete outcomes for each treatment arm. For the primary outcome, pocket swab culture positivity, drape versus no drape, will be compared using the chi-square test. The baseline characteristics of the treatment arms will be compared. If any clinically significant differences are identified, a logistic regression analysis will be conducted to compare swab culture positivity between the two treatment arms, adjusting for these differences. The same analysis plan for the primary outcome will be followed for the secondary outcome an to complete the recruitment of the study in 12 months.

3. Discussion

The use of CIEDs can be associated with serious complications, including infections. Any preventive measure would have significant impacts on the economic burden of the health care system and patient outcomes since CIED infections are associated with significant morbidity and mortality (3.7–8.1 % mortality rate) [18].

Although several studies have focused on the mechanism of CIED infection, there is considerable uncertainty about the sources of CIED infection [3,4]. The most common bacteria isolated from the patients with CIED infection was coagulase-negative staphylococcus which is a typical skin flora member and can be a result of contamination during the implant procedure [19]. Despite the conflicting results of the studies, one may suggest bacteria may remain dormant, possibly in the state of equilibrium with the host defence mechanisms, until this equilibrium changes in favour of bacteria and infection become overt [20].

There are a limited number of randomized prospective studies on adhesive barrier dressings used during various surgeries to reduce surgical site contamination with the skin flora [5–8]. A recent Cochrane systematic review evaluated the impact of adhesive barrier dressing on wound infections [21]. This systematic review included randomized controlled trials examining the use of barrier dressing in various types of surgeries, including general or abdominal surgeries [5,8,22], hip surgeries [6], and cardiac surgeries [23] in addition to obstetric surgeries [7,24] and showed no significant difference in the incidence of wound infection with the use of iodine-impregnated adhesive incisional drapes (RR 1.03; CI 0.66–1.6) and an increased incidence of wound infection with the help of adhesive incisional drapes that were not iodine-impregnated (RR 1.23; CI 1.02–1.48) [10].

The use of barrier dressings has never been studied systematically in CIED implantation. Although the meta-analysis did not show a reduction in the risk of infections with the help of barrier dressings in other surgeries, CIED infections are, very importantly, different in a number of ways from most other types of surgical site infections. Several factors contribute to the development and persistence of CIED infection, including the presence of foreign material and biofilm formation [10]. The bacteria can form a biofilm on the device, which traps bacteria allowing them to remain on the surface of a device indefinitely [9,10]. The biofilms limit the penetration of

antibiotics to microorganisms in deeper layers and the microorganisms may stay in a dormant state [10]. This microbial persistence is the primary reason for high rates of relapse and increased mortality in patients who do not have their device removed [9,25]. Implantation of a CIED also provokes an inflammatory reaction that results in the formation of a fibrous capsule. Also, the device and the leads usually come in contact with the skin around the incision site during the implant procedure. CIED infections cannot be treated with simple debridement of the tissue. The requirement for the removal of the system is complex and carries the risk of life-threatening complications.

The potential clinical relevance of per-implant pocket cultures has also been addressed by a few studies with small numbers of patients [12,13,15–17,26]. (see Table 1). The summary of the current body of data suggests swab culture positivity is common (between 21 and 47 % of patients) in the clinically non-infected device pockets with the most common bacteria isolated from the patients being coagulase negative staphylococcus which is a normal skin flora member thought to be contaminated during the implant procedure. Also, a group of patients with positive swab cultures (between 4.5 % and 7.5 %) develops clinical CIED infection with the same bacteria [13,15,14].

Two recent large randomized clinical trials on CIED infections have shown that infection rates have fallen when compared with the studies from the previous decade [11,27]. A large randomized study investigating the efficacy of an antibiotic-coated absorbable mesh on CIED infections demonstrated the infection rate was between 0.7 and 1.2 % [27]. Another large randomized study investigating the effect of standard or escalated prophylactic antibiotics to prevent CIED infections reported the infection rate was between 0.78 and 1.03 % [11]. Hence, it follows that future trials to further reduce CIED infections will require some combination of very large sample sizes, populations at increased risk of infection, innovative study designs and/or the development of validated surrogate endpoints. Intraoperative swab culture is a potential surrogate that has been studied in other types of surgeries, such as chronic wounds [28], diabetic foot infection [29], burns [30] and postoperative wound infections [31]. These studies have shown a good correlation between the isolated microorganisms with swabs and tissue biopsy cultures. Based on the previous literature on the other types of surgeries and the most common microorganism isolated from patients with CIED infections being the skin flora members, a simple swab has the potential to be the surrogate marker for CIED infection prevention trials.

3.1. Limitations

We expect to see a reduction in end-of-procedure swab culture positivity in the barrier arm. We also expect that more infections will occur in patients with end-of-procedure swab culture positivity. However, due to the small sample size, we do not expect to show a statistically significant reduction in CIED infection with barrier drape. Future studies with larger sample sizes will be required to further explore end-of-procedure swab culture positivity as a potential clinically relevant surrogate endpoint.

4. Conclusion

This will be the first randomized controlled study to assess the effect of barrier adhesive dressing on reducing skin contamination during device procedures. In this study, we are exploring a low-cost intervention that may significantly reduce the mortality, morbidity and costs related to CIED infection if found successful. Also, having a valid surrogate marker for future CIED infection at the time of implant will facilitate future studies' design to decrease the infection rate.

Funding

The trial is supported by peer-reviewed grant funding from the University of Ottawa Heart Institute Catalyst Fund. The authors are solely responsible for the design and conduct of the trial, all study analyses, interpretation of the data, drafting and editing of the manuscript, or decision to submit results.

Data availability statement

Data associated with the study has not been deposited into a public available repository. Since this is a methods paper, no data was used.

CRediT authorship contribution statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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