Comparison of Outcomes between the Use of Silverlon® Dressing and AQUACEL® AG dressing Post Cardiac Device Implant

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Protocol Summary

Silver impregnated dressings have been used widely since their introduction in the 1990s. A few studies have been done which showed that they may decrease the risk of post-operative infections of the wound sites. As a result of these studies there are several commercial available options, however we do not have any data on which ones are better. However, many aspects of the patient and the surgical wound may influence outcomes with respect to each dressing, one product may be more suitable for some patients. For example, given their lax skin texture, dressings with less adhesive may be better for elderly patients. This protocol describes our aim to prospectively study the two widely used dressings (namely Silverlon® and AQUACEL®AG) used at the University of Kansas Hospital for post-operative wound coverage and to assess which one has better patient outcomes.

Background

Implantation of cardiac implantable electronic devices has exploded in recent years. A nationwide analysis revealed that from 1997 through 2004, the number of pacemaker implants increased by 19% and that of automated implantable cardioverter defibrillators (AICDs) increased by 60% (1). Although cardiac implantable electronic devices (CIEDs) have made significant impacts in outcome of majority of implanted patients, these devices bought us a whole new set of problems due to both hardware issues and programing issues. Infections related to these devices have also increased from 5,308 in 2003 to 9,948 in 2011. The average mortality rate is 4.5% for patients with device infections which is high (2).

There are numerous ways of minimizing the rate and severity of post-operative infections. These include sterile technique including appropriate hand washing techniques, intra operative antibiotic administration, appropriate wound care and post-operative antibiotic coverage. Infections do happen and there is a continued need to improve all aspects of the surgery and post-operative care. Wound coverage with appropriate dressings is one aspect that has not been studied in the CIED implant patient population.

Silver is a well-known bacteriostatic agent. Silver impregnated dressings as opposed to standard dressings have been shown to reduce post-operative infections in patients post-CABG (3), post-laminectomy (4) and even post colo-rectal surgery (5). The above data was obtained from randomized studies using the Silverlon® dressings (short for Silver Nylon dressings). AQUACEL®AG, a product which touts a combination of patented Hydrofiber® Technology with ionic silver. The Hydrofiber® Technology has been shown to form a gel on contact with body fluids. This happens inside of the wound crevices and eliminating these crevices which could potentially be home for bacteria. AQUACEL® AG in in-vitro studies has been shown to lessen bacterial colony count (6). AQUACEL® AG has also been shown in randomized trials to be more effective than non-silver impregnated dressings (7, 8). It has been shown to be more effective post Incision and Drainage (I & D) of abscesses compared to iodoform (9).

Another aspect of wound care that is important is how easily dressings can be removed from of the wound at the time of dressing removal; 7 to 10 days post procedure. Some dressings are easier to remove than others. For example AQUACEL® AG has been shown to be less traumatic at removal than povidone iodine gauze, a dressing that was widely used in the past (10).

Rationale and Justification

Given our two options of the dressings, and lack of evidence on which of these is a better option for our post-operative Cardiac Implantable Electronic Device (CIED) implant patients, we sought to conduct a prospective study of outcomes with the Silverlon and Aquacel dressings.

Description of the Research Project

Objectives

1. To assess the efficacy of each of the two dressings (Silverlon® and AQUACEL® AG) in preventing post-operative wound infections (primary outcome).
2. To assess the safety of each of the two dressings in terms of traumatic skin tears at the time of removal (secondary outcome).
3. To assess end points such as patient comfort at the time of removal (using a 1-10 pain scale), ease of removal (using a 1-5 scale completed by the operator), adherence of

the dressing at the post-op incision check 7 to 10 days post procedure (secondary outcome).

4. To access skin breakdown and assigning a category/stage 1 – IV (using the National Pressure Ulcer Advisory Panel Pressure Ulcer States and Categories)

Design

This is a single-center, prospective, 2-arm randomized, non-blinded study involving about 200 patients total, 100 patient in the Silverlon arm and 100 patients in the AQUACEL® AG arm.

Location:

This study will be conducted at the University of Kansas Hospital, Kansas City, KS and Mid-America Cardiology locations.

Study inclusion and exclusion criteria

Inclusion:

1. All patients aged 18 or more who can give valid informed consent.
2. All patients who are scheduled for a CIED implant, generator change, upgrade at the University of Kansas Hospital.

Exclusion:

1. Patients who are already on antibiotics for another reasons.
2. Immunocompromised patients such as those on immunosuppressant's and HIV positive patients.
3. Patients who are post device explant for lead infection.
4. Patients with an allergy to adhesive, silver or an allergy to the dressing(s) or their components.

Subject Enrollment

Potential subjects at the University of Kansas Hospital will be identified from daily EP procedure list. Subjects will be before their procedure or while in clinic for pre-op visit. All eligible patients will be offered to participate irrespective of sex, age, race, ethnicity or disability.

Subject Consent

Informed consent will be obtained from each patient. Participation in this study is voluntary and subject can decline at any stage. Participation in this study will have no impact on the patient's relationship with Mid America Cardiology or University of Kansas Hospitals or their associated facilities. After explaining the risks and benefits, informed consent will be obtained to participate in the study. They will be randomized into either Silverlon or AQUACEL® AG arm.

Randomization:

Block randomization will be used to permit uniform sample sizes at the end of our study. Randomization will be done with the aid of a computer based algorithm.

Intervention:

Arm 1:Subjects randomized to this arm will receive Silverlon® dressing post operatively.

Arm 2: Subjects randomized to this arm will receive AQUACEL® AG dressing post operatively.

Follow-Up:

No modifications are required for follow-up visits. All subjects will have their dressing evaluated in the cardiology office for an incision check at 7-10 days post procedure.

Photographs:

Photographs of the incision site will be taken immediately post-procedure and during the 7-10 days post procedure visit. Images of the incision site and the area immediately surrounding it will be visible. No identifying features of the patient will be visible in the photographs. The purpose of the photographs is to document the appearance of the skin surrounding the wound. Photographs will taken by the [redacted] performing the incision check on a digital camera that is kept in a secure, locked cabinet when the camera is not in use. Images will be labeled with the subject number, stored electronically (.jpg, .png or other relevant format) and uploaded to the secure KUMC server. Photographs may be used for [redacted] purposes or in academic presentation or publication. Photographs will be stored [redacted] finitely. [redacted]

Data Collection

The following variables will be collected by electronic medical record query or during the interview with the subject. Patient information will be coded with the following system: 001,002,003 etc.

Variables:

1. Demographics: Age, Sex, Race, Height, Weight, BMI.
2. Past Medical History: HTN, CAD, Thyroid status, OSA, DM, HLD, CVA, CKD, Valvular Diseases, Smoking History, COPD, CHF, peripheral vascular disease
3. Medication History: Antiplatelet agents, anticoagulants, steroids, hypoglycemic,
4. Indication for procedure.
5. Procedure notes.
6. Complications including post op hematoma
7. Discharge medications including antibiotics used for generator exchanges
8. Follow up post op Day 7 -10: Appearance of skin surrounding wound including grading of swelling (mild swelling compared to the contralateral side vs significant swelling), presence of any erythema (compared to skin on the contralateral side), patient comfort level (from 1-5). Incidence of frank infection and ease of dressing removal (from 1-5) by nurse practitioner, Skin laxity (firm skin vs lax skin which is prone to tearing), presence

or absence of leg edema (a surrogate indicator of subcutaneous edema at the wound site which would predispose to evisceration of skin at the time of dressing removal)

Statistical Considerations

The primary efficacy outcome of the study is the prevention of infection. Secondary outcomes include the side-effects such as trauma at the time of removal, ease of removal and patient discomfort at the time of removal.

Standard statistical tools will be utilized. SPSS and STATA® version 9.0 will be used to analyze the data. Continuous data will be described as the mean value ± SD, and categorical data will be described as frequencies. The association between a clinical event/ endpoint and specific clinical and laboratory variables will be evaluated using the t test for continuous variables or the Fischer exact test for categorical variables. A p value <0.05 will be considered statistically significant.

Confidentiality

The data will be collected on data sheets and will be stored in a locked cabinet. This data will be transferred to an access database within the KUMC Cardiovascular Research Institute, which has a secure password protected main frame. Once all the data is analyzed, the data will be deleted and the paper records will be shredded.

Study Records

All records relative to the research will be treated in confidence and stored in the CVRI Department. The records will be available only to the investigators and any agents of the University or federal government who oversee research involving human subjects.

Safety Monitoring

All incidences of serious adverse events observed will be reported to the principal investigator. These events will be reviewed against the HSC reporting criteria; all events meeting the reporting criteria will be forwarded to the HSC.

Risks, Benefits and Justification of the Research Study

Risks:

There are no additional risks for patients that participate in this study. Each of the patients would have received one of the two dressings even if they were not part of this study.

Benefits:

This study will help in identifying new methods of improving the efficacy and outcomes of the dressings used for CIED patients at the University of Kansas Hospital.

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