Salvage of focally infected implantable cardioverter-defibrillator system by in situ hardware sterilization

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Introduction

Cardiovascular implantable electronic device (CIED)-related infections have increased in frequency over the past 2 decades out of proportion to the rise in device implantations.[1] This has occurred despite an improvement in technology, which includes smaller device profiles, improvement in battery life, prepectoral systems, and greater operator experience. Much of what is driving this trend is the greater implantation rate of implantable cardiac defibrillators (ICD), which are more likely to become infected than permanent pacemakers, possibly owing to greater surface area for bacterial adherence.[2]

The current recommended treatment for CIED infection includes the removal of all hardware, including subcutaneous and transvenous components. This is true even in the setting of a localized pocket infection without signs of systemic infection.[3] Complete removal of all components, including the device generator and leads, is required owing to high infection relapse rates when retained hardware is in place.[4]

Percutaneous lead extraction has become the preferred method for removal of CIED hardware, which often requires the use of laser sheath technology extraction systems or mechanical telescopic sheaths. Extraction of chronic pacemaker and ICD leads involves small but serious potential risks, including cardiac tamponade, hemothorax, pulmonary embolism, lead migration, vascular laceration, and death, even in experienced hands.[5] The performance of these procedures has generally been limited to centers with the appropriate facilities and training in order to minimize procedural risks and be able to initiate an immediate surgical rescue in the event of a complication.

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Because of the potential risks associated with lead extraction, other effective infection management options would be appealing in certain high-risk patients. In this report, we demonstrate the employment of a unique lead salvage strategy in the setting of a localized infection and a strong desire to avoid extracting the patient's chronic lead.

Case report

Our patient was diagnosed with a mild form of muscular dystrophy. Cardiac manifestations included paroxysmal atrial fibrillation and progressive atrioventricular block. She subsequently underwent implantation of a dual-chamber pacemaker at age 23 for high-grade atrioventricular block. The pacemaker was upgraded to a dual-chamber ICD 5 years later for inducible ventricular tachycardia during an electrophysiologic study, at which point the patient had also progressed to permanent atrial fibrillation and complete heart block with pacemaker dependence. Two years later, at age 30, owing to a high-voltage lead advisory in the setting of pacemaker dependence, she underwent laser lead extraction of her 3 indwelling leads (right atrial pacer lead, right ventricular pacer lead, right ventricular advisory ICD lead) and reimplantation of a submuscular, single-lead ICD system. During this procedure, there was evidence of complete ipsilateral venous occlusion, and vascular access was maintained through the occluded segment via the extraction sheath.

Three months later, she required replacement of the ICD lead owing to intermittent diaphragmatic stimulation, and the ICD generator was placed back in its submuscular pocket. After this procedure, a focal area at the mid portion of the wound failed to fully heal (Figure 1A). Her local physician used local wound care, minor outpatient debridement, and multiple courses of oral antibiotics. This conservative management was continued for 12 months, but she had recurring cycles of flare-ups, with local erythema, scant serous drainage, and then temporary scabbing over before the sequence repeated. The inability to fully heal indicated that the infection involved the underlying foreign material; however, the lack of signs or symptoms related to the ICD pocket

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KEY TEACHING POINTS

- Standard of care for all cardiovascular implantable electronic device (CIED) infections, both local pocket infections and bloodstream/lead-associated endocarditis infections, is complete system removal with lead extraction.
- In young patients with long lives ahead, it is advisable to delay the use of both subclavian veins for intravascular leads for as long as possible, to preserve future venous access options.
- In very unique circumstances, with extremely localized hardware infection, it may be possible to achieve a long-term resolution of clinical infection with precise and meticulous techniques, recognizing the known principles of the bacterial–foreign body interface.
- CIED-associated infections are best managed by physicians with experience in lead extraction and device infections, both at the time of infection presentation and in follow-up.

and absence of systemic findings suggested the possibility that the infection was limited to the local aspect of the lead.

Customary treatment for lead infection would involve a full device and lead extraction and contralateral implantation of a new device and lead. In this situation, however, given the young age of the patient and the chronic occlusion of the ipsilateral subclavian vein that would preclude future use after abandonment (Figure 1B), we considered trying to salvage the left pectoral site in order to postpone switching over to the right venous system. After a detailed discussion with the patient about the risks and benefits of our unconventional plan, including emphasizing the chance of recurrent infection that would necessitate reoperation, full extraction, and a new contralateral device implantation, we together agreed to attempt to manage the local infection without extracting the lead or device.

The patient was brought to the electrophysiology laboratory in a fasting, postabsorptive state. After sterile preparation of the pectoral site, an elliptical skin incision was made around the wound to excise the devitalized skin. When the ellipse of skin was excised, the suture sleeve was seen immediately beneath the spot of recurrent ulceration, suggesting focal infection of the sleeve preventing full wound healing (Figure 2). The silk ties were fully removed and the local scar capsule was fully resected. The suture sleeve was then longitudinally cut and removed in an attempt to debulk the amount of foreign material remaining. Given that there was no visual evidence of infection extension along the lead in either direction, the submuscular pocket was not entered, and further dissection along the lead was not performed.

Having consulted with the lead engineers (St. Jude Medical, St. Paul, MN) regarding what antimicrobial agents could safely be used in the wound without damaging the silicone rubber outer lead insulation, we performed pocket irrigation through sequential wound and lead lavage with diluted hydrogen peroxide, diluted povidone-iodine solution, and diluted alcohol. Each agent was instilled into the wound, completely submerging the exposed lead segment, left to sit for 1–2 minutes, and then removed with suction. Each agent was used several times. Neomycin solution was then used to vigorously irrigate the wound, as per our usual device implantation protocol.

After wound irrigation, an attempt was made to limit reexposure of the pocket to infected material by sterilizing the field with alcohol and draping with new sterile towels. Additionally, new sterile gloves were worn and the previously used surgical instruments were exchanged for new ones for the remainder of the procedure.

In order to achieve high local concentrations of antibiotic, a strip was cut from an AIGISRx nonabsorbable antibacterial envelope that was available at the time of this procedure in 2009 (TyRx Pharma, Inc, Monmouth Junction, NJ), which was impregnated with rifampin and minocycline. This mesh strip was wrapped around the exposed segment of lead, with the goal of preventing any remaining live skin flora from multiplying and creating a recurrent local clinical infection (Figure 3).

The wound was fully closed in 3 layers with absorbable suture (using new, sterile instruments) followed by adhesive Steri-Strip skin closures (3M, St. Paul, MN) applied across the closed incision. Intravenous vancomycin was used pre- and postprocedure, and was continued for 24 hours. An oral antibiotic was used for 2 weeks after discharge, which was the planned time for a follow-up outpatient assessment, as well as a time frame consistent with post-CIED removal recommendations in the latest scientific statement from the American Heart Association and Heart Rhythm Society regarding CIED infection and management.[3] The excised tissue and suture sleeve were sent to the microbiology lab for culture and subsequently grew rare *Staphylococcus epidermidis*.

Over the following weeks, the incision fully healed, without erythema, drainage, or recurrent ulceration. The submuscular device pocket remains free of erythema, swelling, warmth, or other signs of infection over a 7-year follow-up period, including the time after an ICD generator change that was performed via a new incision 1 inch caudal to the old incision and infection site.

Discussion

As indications and implantation of CIEDs has grown, the diagnosis and management of device-related infections has become more challenging. The treatment of infection depends on the extent of infection, the device and lead location and characteristics, and patient comorbidities. When a device system becomes colonized with bacteria, full device and lead extraction is the standard of care, largely owing to the

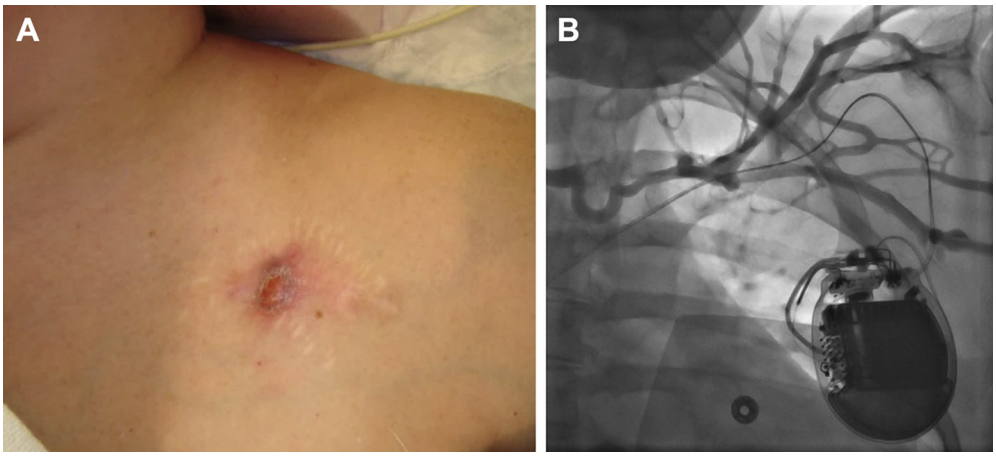

Figure 1 **A:** Left pectoral implantable cardiac defibrillator wound, failing to heal in a focal spot, even after 12 months. **B:** Left arm venogram showing total occlusion of the left subclavian vein and vigorous venous collaterals.

formation of a bacterial biofilm on the intravascular and/or extravascular surfaces of the foreign body, which protects the bacteria from antibiotics and the body's immune system. In very specific situations, it appears to be possible to either eliminate the infection or dramatically reduce the organism burden to below a critical clinical infection threshold without full removal of the hardware.

The principles that appear to be important to the success of this case include (1) the complete removal of braided silk suture with its large internal surface area that could harbor bacteria, (2) the elimination of a lumen by complete removal of the suture sleeve, (3) the small foreign body surface area involved, likely facilitated by the proximity to the skin surface with the ability for the infection to freely drain outward rather than be forced further inward along the lead toward the device pocket and/or intravascular segment, (4) the ability to safely expose the entire affected surface of the hardware to high concentrations of potent bactericidal agents without creating injury to the device or surrounding tissue, (5) the utilization of newly available antibiotic-impregnated mesh to maintain a high local concentration of antibiotic for 7–10 days after pocket closure, and (6) meticulous operative technique to avoid the reinoculation of the "sterilized" hardware with bacteria from the removed infected material and biologic tissue or from the surfaces, tools, and gloves that were exposed to the infection.

The concept of treating a local device infection by "salvaging" the existing hardware without device removal or lead extraction has great hypothetical appeal. The procedural risks are lower if lead extraction is not necessary; conservation of vascular access is greater if a contralateral implant is not needed; management of pacemaker-dependent patients is simpler if temporary and replacement pacing systems are not needed; and costs are substantially

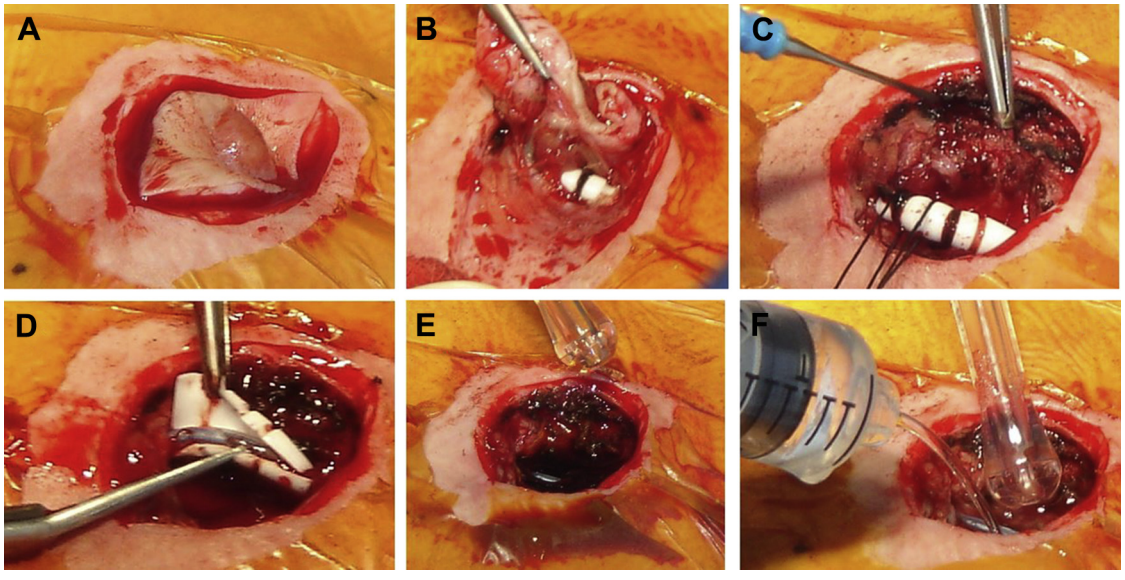

Figure 2 Stages of the first part of the procedure. **A:** Elliptical incision around the nonhealing wound site. **B:** Discovery of the suture sleeve immediately beneath the spot of recurrent ulceration. **C:** Debridement of the local scar capsule tissue around the suture sleeve and lead. **D:** The suture sleeve was longitudinally cut and removed. **E:** Irrigation with diluted povidone-iodine solution. **F:** Irrigation with diluted alcohol.

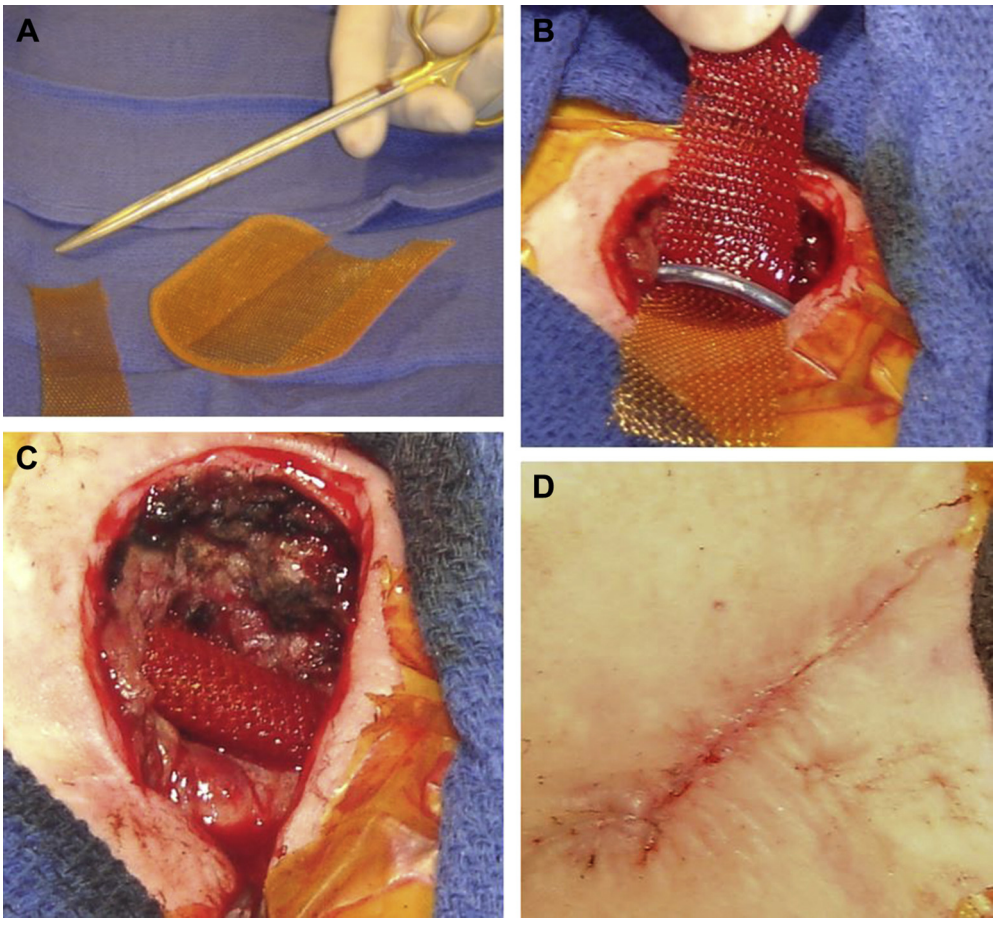

Figure 3 Stages of the second part of the procedure. **A:** A strip was cut from a nonabsorbable antibiotic mesh pouch (rifampin + minocycline) that was available at the time of the procedure in 2009. **B:** Wrapping the mesh antibiotic strip around the exposed lead segment. **C:** Wrapped lead in the wound. **D:** Full closure of the wound with 3 layers of absorbable suture.

reduced with shorter procedure times, reduced length of hospital stay and interim management needs, and elimination of the costs of a new device, leads, and implantation procedure.

In frail patients with poor quality of life, significant comorbidities, or limited life expectancy, local device infections are sometimes managed conservatively. An open, draining wound may be managed with dressing changes alone, with or without antibiotics, with the philosophy that tolerating a local, chronic infection is the "lesser of evils" in patients with an overall poor prognosis.

Device "salvage" procedures that involve wound debridement, pocket enlargement, generator cleansing or replacement, aggressive prolonged irrigation with antibiotic solution in "closed-loop" systems, and a course of intravenous antibiotics have been associated with freedom from clinical infection with mean follow-up time frames of up to 2 years.[6–9] Furman and colleagues[6] reported clinical success in 5 patients, with 5- to 23-month follow-up, using pocket debridement, prolonged closed-loop pocket irrigation, and a mean hospital stay of 9 days. Hurst and colleagues[8] followed 19 patients for 3–70 months (mean 24 months) after a similar approach that included 7 days of intravenous antibiotics and 5 days of closed-loop pocket irrigation with detergent and antibiotic, with freedom from overt clinical infection. These strategies have not always been able to be replicated,[10] suggesting that the details of surgical techniques, pocket management, and specifics of the irrigation protocol may be critical to infection control. Without full removal of the infected material, if a salvage approach is attempted and fails, there is a significant risk for recurrent or worsening infection either locally or systemically, with the possibility of a more serious outcome even if definitive device and lead extraction is undertaken at the time of repeat presentation. It should be noted that lead extraction risks are often greatly overestimated by nonextracting physicians, and elderly or sick patients with device infections should almost always be referred to an experienced lead extractor for evaluation before a path of tolerating a smoldering infection or a salvage approach is selected.

If there were a reliable way to effectively manage a device infection without lead extraction, overcoming the challenges of bacterial biofilms and eliminating the need for chronic antibiotic suppression, then "lead salvage" treatment would not be relegated to the frail or those at high risk for lead extraction, but—to the contrary—could be quite valuable to all patients, especially those with decades of life ahead, in whom preserving vascular access is critical. The current case demonstrates the proof of concept that an infected lead

can be "sterilized" without chronic antibiotics, with no evidence of clinical infection for more than 7 years and counting. Our technique took advantage of the focal nature of the hardware infection and leveraged the use of antibiotic-impregnated mesh, which may have served as a substitute for prolonged antibiotic irrigation in the salvage techniques previously discussed. At present, this technique should be exclusively reserved for unique situations and experts in infected device management, observing the principles that anecdotally appear to be important for success, and only with robust informed consent, extreme postoperative vigilance, and a backup plan of lead extraction in case clinical infection recurs. But with additional in vitro and in vivo investigation to help us understand the relationship between infectious organisms and foreign materials, and techniques and new materials to reduce and overcome foreign-body infection, lead salvage could potentially become a viable future therapeutic option for patients with device pocket infection.

Conclusions

This case demonstrates the feasibility of achieving long-term freedom from clinical infection without removal of an infected ICD lead. The circumstances that motivated this unconventional strategy and led to procedural success are unique, and this technique is not currently a replacement for lead extraction, which is the standard of care for device infections. As always, the risks and benefits of any treatment, particularly those that are nontraditional, should be weighed in the context of each individual patient, with strong consideration given to referring patients with a pacemaker or ICD infection to a physician with expertise in device infections, lead management, and lead extraction. Future investigation of how to effectively treat infected foreign materials, as well as the development of new infection-resistant products, will, it is hoped, lead to fewer infections and simpler approaches to device infection management.

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