Strategies to reduce infections during the cardiac implantable electronic device implant: a time to name and shame

David G. Wilson*, Arthur Yue, John M. Morgan, and Paul R. Roberts

University Hospital of Southampton NHS Foundation Trust, Tremona Road, Southampton SO16 6YD, UK

Received 12 June 2014; accepted after revision 27 November 2014; online publish-ahead-of-print 8 January 2015

Introduction

The adage that prevention is better than cure is held to be true by many. An infected cardiac implantable electronic device (CIED) is a disaster for the patient and can reflect a failure of effective healthcare. For the patient it often means risk of significant morbidity and mortality, suffering symptoms of sepsis, courses of antimicrobial medication, and admission to hospital and additional procedures—usually for system extraction and re-implantation. While system extraction has traditionally been thought to carry significant morbidity and mortality, recent data from high-volume centres describe very low rates of mortality. Nevertheless, extraction for an infective indication tends to confer worse prognosis. For the healthcare provider, the cost is measured in pounds/dollars/euros and in hospital bed occupancy.

In this article, we discuss the trends in CIED infection and current inadequacy in guidelines addressing the prevention of CIED infection. We draw parallels with surgical specialties and learn from their experience in dealing with and reducing rates of surgical site infections (SSIs). Finally, we propose a mechanism to comprehensively address the issue of reducing the incidence of CIED-related infections.

Increasing the trend of cardiac implantable electronic device infection

In spite of the costs of CIED infection detailed above, strategies to implement ‘upstream’ CIED infection prevention are inconsistently applied and are variably successful. In the USA, worrying data demonstrate an increase in the incidence of CIED infection, up from a baseline of 1.6 – 2.5% over recent years. The increased rate is thought to reflect the trend of implanting more complex devices into patients with greater co-morbidities. Also, patients are living longer and therefore have more device revisions. It is well recognized that with each device revision there is an incremental risk of complication. European data are more piecemeal. In a prospective multicentre study involving 6300 procedures (4465 de novo) in 44 medical centres in France performed over 1 year and followed up for a further 12 months, proven CIED-related infection was 0.68%. Studies with longer follow-up capture the ‘late infections’ as demonstrated by a Danish report of over 45 000 permanent pacemaker (PPM) implants over a 25-year period, which reported a surgical site infection rate of 4.82/1000 patient-years for de novo PPM implants and 12.12/1000 patient-years for generator exchanges. Delayed infection (> 365 days post implant) occurred in 1.02/1000 patient-years and 3.26/1000 patient-years, respectively, in the de novo PPM and replacement populations.

The collection and reporting of CIED-related infection in the UK is recommended but not mandated and not reported (NICOR 2012). Therefore, the current rate of CIED-associated infection across the UK is not known and limited to single-centre retrospective studies.

Current recommendations for prevention of cardiac implantable electronic device-related infection

A Class I recommendation for antibiotic prophylaxis for the prevention of CIED-related infection comes from the American Heart Association in 2010, which states that ‘antibiotic that has activity against staphylococci should be administered’. This is rather underwhelming.

Whilst anti-microbial agents are important in preventing CIED infection, we believe these recommendations are incomplete. There is a lack of evidence base in this area that may contribute to the paucity of recommendations. However, we believe that they could be improved by addressing the different aspects of the CIED implant, for instance, pre-procedural antibiotics—skin preparation, draping, policy towards antiplatelet agents and anticoagulants; intra-procedural—diathermy use, suture choice, use of antibacterial envelopes, closing technique, dressings; and post-procedural—dressings.

The opinions expressed in this article are not necessarily those of the Editors of Europace or of the European Society of Cardiology.

* Corresponding author. Tel: +023 8120 8646; fax: +023 8120 5102, E-mail address: drdgwilson@gmail.com

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2015. For permissions please email: journals.permissions@oup.com.
and antibiotic policy. The concept that there is a variety of causes of CIED-related infection is evidenced by the implementation of simple infection-control protocols that can lead to significant (54%) reduction in CIED-related infections.7

What are the known risk factors for cardiac implantable electronic device-associated infection?

The evidence suggests a number of risk factors that are associated with CIED infection4,8,9 (see Figure 1). Experience and intuition suggests that there are a multitude of variables that are potentially important in the prevention of CIED infections. These can be thought of as patient factors (including immune system integrity and colonization with staphylococcal species), procedural factors (including timing of anti-microbial prophylaxis, surgical technique of doctor, and length of procedure), and operating room and environmental factors (including staff adherence to aseptic principles and discipline, personal hygiene of all staff, operating room disinfection, quality and recycling of air). Some of these factors cannot be modified. Many of these practices also have little evidence base and once a pre-/peri-operative routine is established among staff it tends not to change. Instigating change, therefore, requires clear benefit and goals for both staff and patients. Reduction in infection rates benefits patients and should reflect improvement in healthcare delivery and that should be motivation enough to change.

What happens in other specialities?

Implanting CIEDs is a surgical technique and, therefore, it is logical to look at other surgical specialities to understand how they have addressed the problem of SSIs. Parallels can be drawn with orthopaedic surgery and CIED implantation surgery, in that both involve implanting prosthetic material into a similar cohort of patients (elderly, frail, often with co-morbidities), Staphylococcus aureus is the responsible pathogen in the majority of cases of SSIs, and finally, SSIs are associated with complications with high morbidity and mortality (osteomyelitis and infective endocarditis respectively). Over the last 10 years, NHS hospitals performing high-volume orthopaedic surgery have been mandated to report rates of SSI. The results are published annually by the Health Protection Agency and Public Health England. Broadly speaking, the incidence of SSI has diminished in the main orthopaedic procedures to rates approaching 0.5%. This is thought to be due to two main factors. First, the introduction of bundles of care introduced to prevent SSI has ensured that all elements of infection prevention measures are being performed consistently and allowed for auditing and cycles of review to improve care. Secondly, the process of surveillance and feedback at a national level appears to be a motivational factor in achieving reductions and maintaining a low incidence of SSI. Theoretically, CIED implants could also be subjected to similar scrutiny.

The NICE quality standard (QS49) published in October 2013 identified six high priority areas that are amenable for quality improvement in SSIs. These are recommendations on hair removal; antibiotic prophylaxis in accordance with the local antibiotic formulary; maintenance of normothermia during general or regional anaesthesia; maintenance of operating room best practice for all theatre staff; provision of information regarding wound care; early recognition of infection to patient and care providers and treating SSIs with appropriate antibiotics and the surveillance of rates of SSI (including post-discharge infections) and the provision of feedback to relevant staff and stakeholders for continuous improvement through adjustment of clinical practice.

Goals and best practice in preventing cardiac implantable electronic device-associated infection

It is aspirational to have an incidence of CIED infection of <0.5%. We believe that this is possible. In a 2011 European survey of
high-volume implanting centres, the incidence of CIED infection of $<0.5\%$ was achieved by 27% centres.\textsuperscript{10} There exists significant variation, with 22% of centres reporting infection rates of $>2\%$ in the same time period.

**Mechanisms to reduce incidence of cardiac implantable electronic device infection**

In order to achieve a target of an incidence of CIED infection of $<0.5\%$, a number of small changes to current practice are required. First, best practice guidelines to prevent CIED-associated infections need to be established. This includes agreeing what constitutes optimal pre-procedure, intra-procedure, and post-procedural care for CIED implants. In the absence of robust data from randomized controlled trials (and with the exception of anti-microbial prophylaxis, infection prevention in CIED is largely an evidence-free zone), this is best accomplished by consensus among a panel of experts. Second, the definition of what constitutes CIED-associated infections needs to be clarified. For the purposes of public reporting, a clear, unambiguous definition of what constitutes CIED-related infection is mandatory prior to engagement in such a process. Thirdly, data for CIED infection need to be collected prospectively at all implanting hospitals. Lastly, these data need to be collected centrally by National and European Heart Rhythm Associations, who would in turn publish these data annually. This would clearly identify which hospitals are performing well in preventing CIED infection and which are not.

By way of comparison, in the USA in 2015, electrophysiologists must participate in mandatory Physician Quality Reporting System. This system requires clinicians to report infection within 90 days of implant, replacement, or revision as a complication. This will be publicly reported and linked to reimbursement. Financial penalties are in place for those who do not report such complications.

While we consider financial penalties to be counterproductive, we believe that this ‘naming and shaming’ is a necessary evil in order to measure and benchmark performance and improve patient care.

**More evidence required**

To date, a lot of published literature has focused on the detection and management of CIED-related infections rather than the prevention of such infections. However, the Prevention of Arrhythmia Device Infection Trial (PADIT) will change this. The PADIT is a 10 800 patient high-volume prospective trial, designed to test the comparative effectiveness of an existing pre-procedural antibiotic regimen vs. a novel dosing regimen for higher risk procedures. A single dose of intravenous (IV) cefazolin 1–2 g (or vancomycin 1–1.5 g IV in penicillin-allergic patients) (control arm) is compared with pre-, intra-procedural (intraoperative wound pocket wash with Bacitracin) and post-procedural antibiotic regime of oral cephalaxin 500 mg four times per day, or cephradroxil 1000 mg twice per day (penicillin-allergic patients will receive clindamycin 150–300 mg three times per day) for 2 days. High-risk patients are defined as any patient undergoing cardiac resynchronization therapy implant or any re-intervention on an incumbent device.\textsuperscript{11} The results of this trial are awaited and will no doubt add a useful knowledge base to the multiple areas of conjecture that seem to best practice in this area.

We believe that infections in CIED are avoidable, but require a multisystem approach to tackle them. Until more evidence of effective infection-prevention strategies are known, we conclude that it is incumbent on the CIED implanting community to establish a code of best practice to prevent CIED-related infections, to collect and report rates of CIED infection at a national level in order to improve outcomes for our patients and continue to drive up standards.

**Conflict of interest:** None declared.

**Funding**

D.W. is supported by an educational grant from Medtronic, Inc. J.M.M., A.Y. and P.R.R. have received Honoraria and research grants from Medtronic, St Jude, Sorin and Boston Scientific. No funding was required for the preparation of this manuscript.

**References**

1. Maytin M, Jones SO, Epstein LM. Long-term mortality after transvenous lead extrac-

2. Rickard J, Taraki J, Cheng A, Spragg D, Cantillon D, Martin DO et al. Survival of patients with biventricular devices after device infection, extraction, and reimplanta-
6. Baddour LM, Epstein AE, Erickson CC, Knight BP, Levison ME, Lockhart PB et al. Update on cardiovascular implantable electronic device infections and their manage-
10. Bongorno MG, Marinakis G, Lip GYH, Swendsen JH, Dobranu D, Blomstrom-
11. Connolly SJ, Philippoff F, Longtin Y, Casanova A, Birnie DH, Exner DV et al. Rando-