

Cardiac Implantable Electronic Devices (CIEDs) Infection, What To Do?

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Cardiac Implantable Electronic Devices (CIEDs) which include permanent pacemaker (PPM) or implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT), have turned out to be very useful treatment of current era. In these days, an ICD is used not only to save survivors of cardiac arrest, but it also came out to be the first-line primary prevention to save patients with severe cardiac dysfunction. Furthermore, the advanced medical technology has resulted in resynchronization therapy, leading to higher rate of device implantation [1,2]. As the device implantation has increased, the CIED infection has also increased leading to increase in fatal and serious complications [3-7]. Prutkin, *et al.* reported that a total of 3390 (1.7%) out of 200,909 implanted ICDs, when followed for first six months, developed infection of device [6]. Other literature revealed a similar rate of CIED infection (0.7 - 2.2%) [5,8,9]. It is difficult to manage the infection of CIEDs, requiring good knowledge and special efforts by the doctors. CIED infections are needed to be treated aggressively, including appropriate antibiotics and complete removal of the infected device [5,10]. Prompt and complete device removal in combination with antimicrobial therapy is also endorsed by consensus reports and statements [11-13].

Most researchers conclude infections that occur within 1 year of implantation are most likely related to contamination at the time of surgery, while those occurring after 1 year are related to the device manipulation, like change of generator or due to a blood-borne infection. It has been demonstrated that 25% of CIED infections occur early (0 - 28 days after device placement), 33% late (29 - 364 days after device placement), and 42% delayed (364 days after the device placement) [14]. Latest research supports this view showing that 45% of patients with CIED pocket infection presented more than 12 months after their last procedure [15].

These data show that operative procedures are related to more than half of CIED infections. Sohail, *et al.* showed a significant difference in the median time from implantation to infection between PPMs and ICDs (415 vs. 125 days, respectively) [16].

All these data points toward the implementation of strict protocols for prevention of CIED infections. Generally, All the major professional societies have focused more on the management and less on the prevention strategies [11,17]. Recently, British scientific societies have reported specific prevention guidelines on CIED infections [18]. In addition, new data on this topic are continuously adding up [19-22].

It is a common practice to administer antibiotic around the time of CIEDs implantation to prevent infection [23]. In 1998, a meta-analysis included seven prospective randomized trials and evaluated the value of antibiotics in this setting [24-30]. This meta-analysis showed that systemic antibiotic prophylaxis significantly reduces the incidence of serious infective complications after PPM implantation (OR: 0.256) [31]. These findings showed that the use of antibiotics at the time of implantation may prevent short-term pocket infection, skin erosion, or septicaemia. Hence, the majority of implanting electrophysiologists have adopted this practice.

In CIEDs implantation, another strategy for infection control is local antibiotic irrigation. Several irrigation protocols have been proposed using one or more antibiotics. However, no study to date has examined the efficacy of this approach.

Another approach that greatly reduced risk of CIED infection, especially in high-risk patients, is the utilization of an antibacterial envelope [32-34]. This absorbable envelope covers the device and extravascular parts of the leads releasing antibiotics into the pocket for at least 7 days. Despite the financial cost of this device, it seems to be a cost-effective preventive measure if used wisely in high-risk procedures [35].

In November 2007 a protocol, based on recent evidence, was advised by multi-disciplinary team. Following are the main points of the protocol

1. Screening of Methicillin-resistant *Staphylococcus aureus*
2. Antibiotic cover: Flucloxacillin 1 g and gentamicin 1.5 mg/ kg are administered intravenously within 30 min of the start of the procedure so that optimal bactericidal concentration of the drugs is achieved at skin incision. Antibiotics are not delivered directly into the pocket or continued post-procedure.
3. Skin preparation: Double gloving is mandatory during draping and outer gloves are removed prior to skin incision. Betadine is replaced by a 2% chlorhexidine gluconate/70% isopropyl alcohol solution in a preloaded applicator.
4. Hair removal
5. Glycaemic control
6. Sutures: Antibacterial-coated vicryl sutures impregnated with triclosan is used for subcutaneous closure.
7. Surgical scrub: A scrubbing time of 2 minutes is recommended.
8. Diathermy: Cutting diathermy at 40W is used after incision for cutting and haemostasis.
9. Raised inflammatory markers or fever within 24h: Patients with clinical signs of sepsis or raised infective markers [fever, leucocytosis (WCC \geq 10) or C reactive protein \geq 30] had their procedure deferred.
10. Intravenous access
11. Closed system intravenous access cannulas: Are used in all patients, with meticulous attention to sterility before use.
12. Body temperature control: A Bair Hugger was recommended in all patients who are undergoing complex device implant.
13. Wound dressings: Wound dressings were left intact for 3 days post procedure. Removal of dressings and bathing that result in soiling over the wound site is discouraged.

This specific protocol led to a 54% reduction in CIED infection incidence [36].

There are many risk factors for CIED infection which have been identified in the past years [37]. Some of them relate to patient characteristics, such as male sex, diabetes mellitus, renal failure, and oral anticoagulation, whereas others are device- or procedure-related (a non-de novo procedure, more than 2 lead device, and ICD or CRT compared with PPM) [38-43]. However, the risk of infection in each individual may have a greater relationship with a combination of certain risk factors than with the sum total of the risk factors presented in each case. To my knowledge, there are 2 studies that show a composite score to stratify the risk of infection [34,44]. In the first, only patients with ICD or CRT were included as PPMs are supposed to be less prone to get infected. In the second, there was no statistical significance difference between low-risk and high-risk patients.

A score, "CIED-AI score" (Charlson Index, more than 2 leads/Electrodes, Device revision/replacement, oral Anticoagulation, previous Infection), corresponding to the acronym of Cardiac Implantable Electronic Device-Associated Infection was developed from a study of 2323 procedures [45].

The growing implantations of CIEDs as well as emerging evidence of a disproportionate increase in device-related infections underscore the importance of an effective periprocedural prophylactic strategy. The perioperative systemic use of antibiotic agents significantly reduces the incidence of infections. However, further studies are needed to elucidate the role of post-operative antibiotic prophylaxis, the

specific value of each agent in different clinical settings as well as the optimal duration of therapy. On the contrary, the merit of local pocket irrigation with antibiotic and/or antiseptic agents remains unproved. The application of antibacterial envelopes into the device pocket is very promising especially in high-risk patients. Moreover, limited reports on strict integrated infection control protocols show a dramatic reduction in infection rates in this setting and therefore deserve further attention. Finally, the relative impact of particular factors on the infection risk, including the type of the CIED, patients' individual characteristics and comorbidities, should be further examined since it may facilitate the development of tailored prophylactic interventions for each patient.

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