

Prevention of cardiac implantable electronic device infections: guidelines and conventional prophylaxis

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Received 20 January 2021; editorial decision 6 March 2021; accepted after revision 9 March 2021

Abstract

Cardiac implantable electronic devices (CIED) are potentially life-saving treatments for several cardiac conditions, but are not without risk. Despite dissemination of recommended strategies for prevention of device infections, such as administration of antibiotics before implantation, infection rates continue to rise resulting in escalating health care costs. New trials conveying important steps for better prevention of device infection and an EHRA consensus paper were recently published. This document will review the role of various preventive measures for CIED infection, emphasizing the importance of adhering to published recommendations. The document aims to provide guidance on how to prevent CIED infections in clinical practice by considering modifiable and non-modifiable risk factors that may be present pre-, peri-, and/or post-procedure.

Keywords

CIED • Pacemaker • Defibrillator • Infection • Endocarditis • Risk

Introduction

Infection remains one of the most serious complications of CIED implantations leading to substantial morbidity, hospitalizations, and mortality with associated health-care costs.^{1–6} Expanding indications and use of more complex systems, such as CRTs are suggested explanations for the increasing infections rates even outweighing the rise in device implantations.^{1,7–10} The observation that complication and infection rates are higher for re-interventions than for *de novo* implantations,^{9,11–16} further underlines that primary prevention of infection is particularly important for CRTs and other complex multi-lead procedures and reoperations.

Despite publications of several practice guidelines and consensus documents on prevention and management of CIED infection^{17–20} along with multiple attempts to improve their dissemination and implementation, major gaps in knowledge and insufficient adherence to guidelines still remain a challenge as evident in a recent worldwide survey on CIED infection.²¹ Major gaps in physicians' knowledge and skills across all stages of CIED care were also identified in a recent

EHRA survey.²² The finding of physicians' lack of confidence and certain system barriers (mainly logistic and attitudinal) for correct referral, may also limit adequate prevention measures of device infections.

Given this background and the knowledge that device complications are common and device infections require complete system removal²³ both generating substantial healthcare costs,²⁴ novel strategies for the prevention of CIED infection are urgently needed. This section gives an overview of recommended strategies for preventing CIED infections in line with recent EHRA international consensus document on how to prevent, diagnose, and treat CIED infections.²⁰ Check lists on actionable risk factors and subsequent actions for preventing CIED infections are presented.

Prevention

Prevention of CIED infection encompasses risk evaluation and efforts to avoid complications at several steps in good time before, during, and after the implantation procedure, as outlined in the published

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EHRA international consensus document on how to prevent, diagnose and treat Cardiac Implantable Electronic Device infections.²⁰ Risk stratification for device infection is important because it increases awareness of risk factors that can be eliminated or minimized by various preventive actions at various levels. Many known risk factors for CIED infection can be *modified* and are thus amenable to preventive actions for risk reduction.^{9,14,16} An example of such actionable risk factor is the presence of a temporary pacing lead at the time of the implant procedure, which often can be avoided or replaced by other techniques. Although many risk factors *cannot* be *modified*, particularly those related to certain comorbidities, some of them can be targeted for optimized therapy or minimized by using alternative approaches. An example is diabetes, which albeit being non-modifiable, can be optimally treated prior surgery to lower the risk.²⁵ Another strong non-actionable risk factor is end-stage renal disease, which cannot per se be modified, but by using alternative techniques or devices, such as a leadless- or subcutaneous system, the risk for infection may be substantially reduced.

Seasonal variations in pocket infections associated with elevated temperatures and precipitation were reported for subgroups including women, elderly people (>75 years), late CIED infection, and skin commensal bacterial infections.²⁶ Specific prevention strategy should be discussed in these high-risk patients.

Risk factors and preventive actions for CIED infections may further be categorized as patient-, procedure-, or device-related factors. Environmental-, organizational-, and staff-related risk factors can in general be subject to standardized preventive measures, such as facility barriers, quality of environmental cleaning, and access to dedicated operating rooms. A checklist of risk factors for device infection and recommended actions is shown in *Table 1*.

Pre-procedural actions

Mechanisms of infection—preventing contamination

The most common mechanism of CIED infection is local contamination of leads, pulse generator, or pocket during the implantation procedure when crossing the skin barrier.²⁷ Contamination may occur by introducing the patient's normal skin flora into the wound at the time of skin incision, via the air in the operating room (both host and staff) prior to implantation or via the hands of those implanting or assisting the procedure. Subsequent bacterial colonization results in pocket infection, which then spreads along the leads and cause secondary blood stream infection with progress to systemic infection and endocarditis.^{4,28} *Staphylococcus* species, which are far more prone to adhere to non-biological material than other species, cause nearly 70% of device infections.²⁹ Device-related infections after initial implant occur earlier, more aggressively, and are often due to *Staphylococcus aureus*, while those after reoperations have more indolent manifestations and are due to coagulase negative staphylococci.³⁰ The second less common mechanism is haematogenous spread from a distant focal infection with secondary involvement of the CIED system.³¹ Gram-negative pathogens and other microbes are found in <10% of cases.^{4,31}

Patient selection

Whether the benefit of the device implantation outweighs the risks should always be carefully considered on an individual basis in good

time before the procedure. Up to 50% of patients undergoing device removal for infection may not require device re-implantation.³² The timing and indication for a particular device should be meticulously chosen in order to minimize risk of infection. It is preferable to postpone an implantation and give time for preventive measure rather than neglecting an increased risk for infection that could have been prevented. Alternatives to conventional transvenous systems for high-risk patients are described below.

Patient risk factors for device infection

A thorough clinical history carefully identifying the *presence of comorbidities* as risk factors for infection and corresponding possible preventive actions to reduce the risk is of paramount importance (*Table 1*). Particularly end-stage renal disease and a history of previous device infection have consistently been associated with the highest risks, emphasizing the importance of a careful evaluation whether CIED therapy is absolutely indicated in these patients and which measures can be undertaken to minimize the risk (*Table 1*).^{7,11,15,33} Optimized treatment of various conditions may lower the risk for infection, as shown with better glycaemic control in the peri-procedural period in surgical patients with diabetes.²⁵

A procedure should always be postponed until a patient has been afebrile for at least 24 h since *pre-procedural fever* has been associated with a higher risk for device-related infection (adjusted OR: 4.8).^{12,15} The importance of isolated leucocytosis for device infection is, however, less clear according to a recent study showing no significant association between device infections and preoperative isolated leucocytosis in the absence of other infectious markers, such as bacteraemia, fever, or physical examination suggesting an ongoing infectious process.³⁴

Temporary transvenous pacing is associated with a two-fold increased risk for device infections and should therefore be avoided and alternatives sought for (backup transthoracic pacing or infusion of rate-accelerating drugs) if possible (*Table 1*).¹² Temporary pacing via a jugular route may confer a lower risk of infection than access via the groin. Removal of all central venous lines, a well-recognized risk factor for infection, should always be considered before device surgery (*Table 1*).¹⁵

Choice of alternative device system in high-risk patients

'Leadless' pacemakers may be less prone to infection and can be used in high-risk patients.^{35,36} The absence of a pacemaker pocket and transvenous lead may theoretically reduce the risk of device infection although bloodstream seeding of the device by a remote-site infection may still be possible. Whether leadless pacing technology reduces the long-term risks of CIED infection remains to be proven. Subcutaneous ICD (S-ICD) is an option in patients requiring sudden death protection.^{37,38} Implanting an epicardial system may be an alternative in high-risk patients.³⁹

Medications

The patient's medication, particularly corticosteroids and antithrombotic drugs, may confer an increased risk for infection.¹⁵

Anticoagulation and antiplatelet drugs. Since clinically significant pocket haematoma, defined as requiring reoperation or interruption of OAC, is associated with >seven-fold increased risk for subsequent

Table 1 Check list of actionable risk factors for prevention of CIED infections

| Actionable risk factor | Actions to prevent device infection |
|--|--|
| Pre-operative actions | |
| <ul style="list-style-type: none"> • Comorbidities? • Renal insufficiency • Chronic skin disease • COPD • Diabetes • Heart failure | Optimize medical treatments prior implant: <ul style="list-style-type: none"> • consider device alternatives • check for skin infections—wounds • optimize respiratory medication • better glycaemic control • optimize heart failure treatment |
| <ul style="list-style-type: none"> • Fever/systemic infection? | Postpone procedure until afebrile for ≥ 24 h or values normalized. Check dental status |
| <ul style="list-style-type: none"> • Central venous line? • Temporary transvenous pacing? | <ul style="list-style-type: none"> • Remove indwelling lines. • Avoid or consider pacing alternatives (isoproterenol, transthoracic pacing, change port) |
| <ul style="list-style-type: none"> • Anticoagulation therapy? | <ul style="list-style-type: none"> • Do not use heparin bridging • Continue or interrupt temporarily if possible |
| <ul style="list-style-type: none"> • Antiplatelets? | <ul style="list-style-type: none"> • Discontinue 5-10 d prior surgery (particularly P2Y12 inhibitors) & avoid DAPT if possible |
| <ul style="list-style-type: none"> • Steroid treatment? | <ul style="list-style-type: none"> • Is withdrawal or dose reduction possible? |
| <ul style="list-style-type: none"> • Is procedure complex/expected to be lengthy? | <ul style="list-style-type: none"> • Consider experienced operator and/or supervisor to shorten procedure time or consider referral to experienced operator/high volume centre |
| <ul style="list-style-type: none"> • CIED replacement? • Upgrade to more complex CIED? • Early re-intervention? | <ul style="list-style-type: none"> • Re-evaluate indication for replacement/upgrade. • Does the benefit of device implantation outweigh the risks? • Consider alternative approach to transvenous system. • Postpone procedure if possible |
| <ul style="list-style-type: none"> • Presence of many leads and/or abandoned leads? | <ul style="list-style-type: none"> • Consider extraction on individual basis |
| <ul style="list-style-type: none"> • High-risk patient for infection? | <ul style="list-style-type: none"> • Consider LPM, S-ICDs or epicardial system if appropriate. • Reconsider indication for device implant • Consider experienced operator or refer to high volume centre if complex procedure |
| <ul style="list-style-type: none"> • <i>S. aureus</i> colonization | <ul style="list-style-type: none"> • -Consider nasal swabs and nasal treatment with mupirocin and chlorhexidine skin washing in selected patients |
| <ul style="list-style-type: none"> • Is i.v. antibiotic therapy given? | <ul style="list-style-type: none"> • i.v. flucloxacillin (1–2 g) or cefazolin (1–2 g) within 1 h prior to surgery |
| <ul style="list-style-type: none"> • Is procedure scheduled as 'out-of-hours' procedure? | <ul style="list-style-type: none"> • Postpone procedure to be performed during office hours |
| Intra-operative actions | |
| <ul style="list-style-type: none"> • High-risk patient for infection? | <ul style="list-style-type: none"> • Consider antibiotic-impregnated mesh envelope (minocycline/rifampicin) • Ensure short procedure times and low complication rate by selecting experienced operators and well-trained staff |
| <ul style="list-style-type: none"> • High risk for peroperative haematoma (antithrombotic therapy)? | <ul style="list-style-type: none"> • Consider pressure dressings • Consider pulsed electron avalanche knife instead of traditional electrocautery • Avoid sub-pectoral pocket unless strongly indicated |
| <ul style="list-style-type: none"> • Re-operation? | <ul style="list-style-type: none"> • Avoid capsulectomy at re-interventions |
| <ul style="list-style-type: none"> • Has staff and operating theatre conditions been checked/prepared? | <ul style="list-style-type: none"> • Restrict number- and exchanges of personnel during procedures • Proper ventilation system, air-quality optimization, • Temperature control |
| Post-operative actions | |
| <ul style="list-style-type: none"> • Is there a high wound dehiscence risk due to haematoma? | Consider surgical pocket evacuation |

Reduce risk for pocket haematoma

device infection over 1-year follow-up⁴⁰ every attempt should be made to avoid such complication. Surgery performed with continued perioperative warfarin vs. interruption with heparin bridging results in 80% fewer clinically significant pocket haematomas (3.5% vs. 16%).⁴¹ Continued vs. interrupted direct oral anticoagulants have similar low risks of pocket haematoma (2.1% in both groups)⁴² and direct oral anticoagulants vs. continued warfarin do not seem to differ either while concomitant antiplatelet use doubles that risk.⁴³

Given this knowledge, a 'bridging' approach with heparin should not be used during surgery for CIEDs (Table 1).^{20,41,44,45} Withholding anticoagulation for the procedure and restarting when the bleeding risk is reduced seems reasonable in patients with low risk for stroke, while continuing oral anticoagulants is recommended in higher risk patients (prior embolic event or mechanical valve).²⁰

Since antiplatelet therapy doubles the risk of pocket haematoma during device surgery, particularly P2Y12 inhibitors (clopidogrel, prasugrel, and ticagrelor), they should preferably be discontinued for 5–10 days before the surgical intervention.^{20,43,46}

Long-term steroid therapy suppressing immunity and delaying wound healing has been associated with device-related infection but is often difficult to withdraw as it usually implies the presence of another coexisting disease, such as chronic obstructive pulmonary disease and rheumatologic diseases.^{7,15,30} Conditions that compromise the patient's immune status, which often necessitate steroid use, and malnutrition are also strong risk factors for CIED infection.⁷

Leads

The decision to abandon or extract a lead must be made on an individual basis weighing all known risks and benefits.^{47,48} There is a greater risk of infection with increasing number of implanted leads and if abandoned leads are present.^{49,50}

Staphylococcus aureus decolonization of patients

Nasal swabs can detect *S. aureus* colonization by means of a real-time polymerase chain reaction (PCR) assay in patients scheduled for elective procedures. Nasal treatment with mupirocin and chlorhexidine skin washing has been shown to reduce the risk of hospital-associated *S. aureus* infection from 7.7% in placebo groups to 3.4%.⁵¹

Pre-procedure skin preparation

Data are diverse regarding benefits of routine pre-surgical washing with an anti-microbial agent.⁵² Studies on preoperative chlorhexidine skin preparation indicate a reduced risk for infection in patients undergoing knee and hip arthroplasty though.⁵³ Electronic clippers with a single-use head (not razors) should be used if chest hair removal is required (Table 2).⁵⁴

Pre-procedure antibiotic prophylaxis

Prophylactic intravenous antibiotic therapy is standard-of-care for prevention of CIED infection, based on randomized controlled trials and meta-analysis showing 70% relative risk reduction in device-related infections.^{54,55} The lack of preoperative antibiotics prophylaxis is the strongest predictor of CIED infection.¹⁵ Prophylactic systemic antibiotics covering at least *S. aureus* species,⁵⁵ including i.v. flucloxacillin (1–2 g) and first-generation cephalosporins, such as cefazolin

(1–2 g), is recommended based on randomized trials^{54–56} and must be completed within 1 h of incision to ensure adequate tissue levels. In case of allergy to cephalosporins, vancomycin (15 mg/kg) may be used and administered slowly over 1 h starting 90–120 min prior to the incision. Routine methicillin-resistant *S. aureus* (MRSA) coverage should be guided by the prevalence of MRSA in the implanting institution and patient risk. Repeat dosing of antimicrobials is not recommended after skin closure.

Re-intervention, upgrade, and replacement

Every effort should be made to avoid procedure-related complications, particularly re-intervention for lead dislodgement, which increases the risk for infection by sixth-fold.^{9,15,57} Since generator change is associated with a roughly two-fold risk for infection, the decision to replace a device should be made by weighing benefits and risks for device-related infection and death.

The timing of re-intervention is important and seems to correlate with the risk of CIED infections. Early re-interventions, defined as repeat procedures performed within the index admission period prior to discharge, dramatically increases the risk of CIED infection with >15-fold increased risk.¹² All measures must therefore be taken to avoid an early re-intervention. Whether a strategy of postponing a re-intervention by weeks (e.g. for lead repositioning) can effectively reduce the risk of infection is unclear though and requires further research.

Risk stratification for prevention

Several studies developing risk scores to predict patients at higher pre-procedural risk of device infection have mainly aimed to identify those who would benefit from antibacterial envelope.^{56,58–60} Such *risk stratification* score may better identify patients at risk than individual factors, but further validation is warranted in independent prospective cohorts (see specific section below). The PADIT risk score, aiming to identify higher risk patients that can benefit from targeted interventions to reduce the risk of CIED infection, may provide additional predictive value, particularly if prior CIED infection is considered.⁶¹

Pre-procedure-related preventive actions for high-risk patients are described in Tables 1 and 2.

Intra-operative actions

Surgical skin preparation

Pre-operative antiseptic skin cleansing aims to eliminate colonizing bacteria on the skin. The optimal choice of topical antiseptic is unclear since no randomized data exist for CIED implantation procedures. Alcoholic 2% chlorhexidine was superior to povidone-iodine for skin preparation in one randomized trial prior to surgery⁶² or intra-vascular catheter insertion⁶³ and is therefore recommended (Table 2).²⁰ A single-centre retrospective cohort study of patients receiving a CIED failed to observe a difference in infection rates between these topical antiseptics, but the infection rate was small.⁶⁴ The antiseptic should be left until dried completely before incision to give sufficient time for it to be effective. There are no data suggesting that iodine-impregnated adhesive incise drapes reduce infection rates.⁶⁵

Double-gloving

Table 2 Recommended actions for prevention of device infections according to EHRA consensus document

| Consensus statement | Scientific evidence coding |
|--|----------------------------|
| Pre-procedural actions | |
| Confirm indication for CIED | E |
| Delay CIED implantation in patients with infection | E |
| Avoid temporary transvenous pacing and central venous lines, which should ideally be removed prior to introducing new hardware, whenever possible | O, M |
| Measures to avoid pocket haematoma are recommended (avoid heparin bridging, discontinue antiplatelets if possible) | R |
| Periprocedural use of therapeutic Low-molecular-weight-heparin | R, M, O |
| Perform the CIED procedure in an operating room/suite with complete sterile environment as required for other surgical implant procedures. | E |
| Procedure should be performed or supervised by an operator with sufficient training and experience | O |
| • Operators with <100 CIED procedures experience should work under close supervision of more experienced operators | O, E |
| • An annual minimum operator volume of ~50 CIED procedures is recommended for all operators | |
| Topical <i>S. aureus</i> decolonization may be performed | E |
| Pre-procedural skin wash may be performed | E |
| Hair removal with electric clippers (not razors) is recommended | O |
| Antibiotic prophylaxis is recommended within 1 h of incision for cefazolin and flucloxacillin, within 90–120 min for vancomycin | R, M |
| A continuous surveillance program of infection rates and associated microbiology should be set-up at the level of each implanting centre | E |
| Intra-procedural actions | |
| Surgical preparation with alcoholic chlorhexidine should be used rather than povidone-iodine | R |
| Allow sufficient time for the antiseptic preparation to dry | E |
| Adhesive iodophor-impregnated incise drapes may be used | E |
| Perform the procedure with adequate surgical technique—minimize tissue damage, haemostasis, adequate wound closure | E |
| Antibiotic envelope in high-risk situations is recommended* | R |
| If the operator performs the prepping and draping, glove change/re-scrub or remove outer glove of a double-glove before incision | E |
| Using local instillation of antiseptic and antibiotics in the pocket | R, E |
| Use of braided sutures for final skin closure | E |
| Post-procedural actions | |
| Use of post-operative antibiotic therapy | R |
| Adequate dressing for 2–10 days is recommended | E |
| Patient instructions on wound care should be provided | E |
| Delay or reconsider indication for re-intervention if possible | E |
| Haematoma drainage or evacuation (unless tense, wound dehiscence is present or pain is severe) | O |
| Prevention of infections related to device implantations in elderly, paediatric patients and in adults with congenital heart disease | |
| Implanting physicians should be aware of the higher CIED infection risks in frail and elderly patients. Submuscular position of PM or ICD generators is recommended in selected elderly patients with limited subcutaneous tissue to prevent device erosion. | O |
| Implanting physicians should be skilled in multiple and alternative surgical approaches performed in paediatric, congenital heart disease, and ACHD patients related to a higher risk of CIED infection due to multiple procedures, lead addition, and revisions and upgrade procedures. | M, O |
| The entirely S-ICD should be considered as an alternative to transvenous or epicardial approaches in the older child, patients with congenital heart disease, and those with limited or no venous access. Patients with a bradycardia indication, anti-tachycardia pacing, or cardiac resynchronization therapy requirements are not appropriate candidates. | O |

Modified table from EHRA international consensus document on how to prevent, diagnose, and treat CIED infections.²⁰

EHRA Statement classes; turquoise = recommended/indicated or 'should do this'; red = may be used or recommended; and green = should not be used or recommended.

EHRA ROME coding: R, randomized trials; O, observational studies; M, meta-analysis; E, expert opinion.

CIED, cardiac implantable electrical devices; LPM, leadless pacemaker; S-ICD, subcutaneous implantable defibrillator; *S. aureus*, *Staphylococcus aureus*.

*As defined in the WRAP-IT study population (ref 74) (patients undergoing pocket or lead revision, generator replacement, system upgrade, or an initial CRT-D implantation) and patients with other high risk factors, considering also the local incidence of CIED infections.

Glove change when draping the patient and before handling the generator may reduce risk for infection, although large-scale randomized clinical trials are lacking.²⁰ There is some support that bacterial glove contamination before handling the generator is common⁶⁶ and that double-gloving reduces the rate of inner glove perforation, but it is unclear whether microbial transmission and the rate of post-operative infectious complications are reduced. Non-powdered gloves may reduce the risk of infection by reducing local inflammation.⁶⁷

Good surgical technique

Actions to avoid pocket haematoma. Special focus should be given to avoid pocket haematoma, particularly in patients with increased risk for bleeding.⁶⁸ Sub-pectoral pockets double the risk for pocket haematoma and should only be reserved for selected patients, such as those with low body mass.⁶⁸

Adequate haemostasis by minimizing tissue damage and adequate wound closure are all important actions to reduce infection. Intraoperative administration of haemostatic agents has been suggested to give better haemostasis and less tissue damage, although there is little evidence to support such actions on a routine basis.^{20,69,70} Pulsed electron avalanche knife, may potentially be beneficial compared with traditional electrocautery, in patients receiving antithrombotic therapy with respect to prevention of bleeding complications.⁷¹

Capsulectomy, excision of the fibrous capsule formed in the pocket, should not be performed routinely at re-interventions as it could result in more pocket bleeding/haematoma.^{20,72} Moreover, pocket haematoma aspiration for diagnostic or therapeutic purpose is contraindicated given the risk of 'inoculating' the pocket and causing an infection (Table 2).^{12,40} Haematoma evacuation should only be performed operatively in rare selected cases if pain is unmanageable or wound closure is threatened.^{12,20,40} Vigorous pocket irrigation is important to remove devitalized tissue as well as dilute any contaminants.⁷³

Pressure dressing may be used for the first 24 h to give better haemostasis, although there is little evidence to support it on a routine basis.²⁰

Local intraoperative antibiotics or antiseptics

There is limited support for the use of *antiseptic or antibiotic pocket irrigation* as indicated by the PADIT trial⁵⁶ and is not recommended.²⁰

Recommendation for an *antibacterial mesh envelope* (TYRX™, Medtronic, MN, USA) shown to significantly reduce major CIED infections in high-risk patients (WRAP-IT trial),^{74,75} and be cost-effective⁷⁶ is discussed in more detail below (Tables 1 and 2).²⁰

Closure of pocket

Closure in layers minimizes wound tension and reduces the risk of dehiscence and infection.^{20,77} If skin closure is performed with non-absorbable material, it must be removed in a timely manner (usually 7–14 days) and if performed by absorbable sutures, they must be placed to allow for absorption and avoidance of a 'stitch abscess'. Whether the type of suture material impacts the risk of infection is unclear. The preventive effects of sutures impregnated with antibiotics are also unclear and they are therefore not recommended over

standard sutures.²⁰ Abdominal pocket should not be used as it is associated with a four-fold risk for infection.¹⁵

Procedure-related preventive actions are described in Tables 1 and 2.

Post-procedural actions

Post-procedure antibiotic therapy is not recommended²⁰ given the results of the PADIT trial, showing no benefit of incremental perioperative antibiotics using preprocedural cefazolin and vancomycin, intraoperative bacitracin pocket wash and 2-day postoperative oral cephalexin.⁵⁶

Wound care, such as changing the dressing, is not recommended unless it becomes impregnated. Patients should be advised to avoid soaking the wound until it is entirely healed after approximately a month.²⁰

Staff training, physician skill, centre volume, and patient education

All personnel involved in CIED implantations must have the required competence and skills for strict sterile techniques and behaviour in operating room settings including scrubbing, setting up tables, patient preparation, and strict limitation of operating room traffic. They should further be aware of all risk factors for complications and infections so that preventive actions can be made.

Short procedure times should be secured by ensuring adequate equipment, room facilities, well-trained staff, and operators with access to supervisors since long procedure time has been associated with infectious complications (85 vs. 60 min)^{14,15} and was shown to increase the risk of infection stepwise as compared to durations shorter than 30 min, with increases 1.5 times for durations 60–90 min and 2.4 times for those exceeding 120 min.¹¹ Inexperienced operator, in particular thoracic surgeon, was associated with an almost three-fold risk for device infection,⁷⁸ and was shown to be an independent risk factor for any complication (adjusted risk ratio of 1.9, 95% confidence interval 1.4–2.6) if the annual volume was <50 procedures.⁹ The higher infection rates observed for CRT devices²⁸ and the nearly six-fold higher infection risk for CRT-Ds vs. CRT-Ps, underlines the need for adequately trained operators,^{7,9,10,14,15,33,49,50,57} and the need for supervision for each type of device implant procedure.⁷⁹

Patients should be educated about the risks and signs of infection and instructed to seek medical attention in case of signs of infection.

Higher complication rates and higher risks for CIED infections have been observed for centres with <750 device implantations annually,⁹ whereas others reported that high-volume centres (>200 per year) were protected against device infections, observations that emphasize the importance of securing adequate implantation volumes annually at the hospital level.⁸⁰

Environmental, organizational, and surveillance actions

Standards for sterile procedures in operating rooms and Electrophysiology/Catheterization laboratories must be met as for other surgical procedures associated with implants.⁸¹ This includes standards for cleaning, room design, presence of proper ventilation system with positive pressure in operating rooms, optimization of air

quality with filtered air and frequent air exchanges, restricting area traffic and access to the operating room during working hours. 'Out-of-hours procedures' must be avoided as it increases the risk for infection by 1.5.⁹

Existing surveillance structures for CIED infections are lacking in many institutions. A continuous surveillance program for recording of procedure-related complication- and infection rates and flora involved should be in place in all centres performing implantations in order to increase awareness, reduce reluctance of reporting complications and give incentive for preventive measures. The registration must include clinical data on the individual patient, procedure, staff and device implanted including all reoperations. Since device complication rates are frequently underreported in registries, with three-fold lower reported total major complication rates as compared with randomized trials,⁸² cross checking of data is encouraged to minimize risk of both underreporting and misclassification of events. A semi-automated detection algorithm based on diagnosis codes and structured electronic medical records for identifying device infections may potentially be a useful tool for surveillance of CIED infections with feedback to clinicians.⁸³ A similar algorithm, based on structured and free text diagnostic—therapeutic data using electronic medical records, was constructed to more reliably and efficiently measure CIED infections, and resulted in a positive predictive value of 43.5% with an overall sensitivity and specificity of 94.4% and 48.8%, respectively.⁸⁴

Conclusions

The continued rise in device-related infections, particularly in CRT recipients and patients with high comorbidity burden, highlights the need for novel and more extensive preventive strategies to stop this development.

A greater awareness and improved actions to prevent device infections may be achieved by a comprehensive effective surveillance of infections on centre level collecting data on procedures, treatments, outcomes, and costs. Such registries should be user-friendly and standardized, and apart from device infections also focus on procedure-related complications. Educational activities focusing on preventive actions with tools for better implementation of guidelines, targeting not only physicians but also patients, are also needed. While preventive actions are exceedingly important, monitoring risks, and acknowledging them may be even more challenging.

Funding

This article was published as part of a supplement supported by an educational grant from Medtronic.

Conflict of interest: C.B.-L. declares direct personal payment from Bayer, Sanofi Aventis, MSD, Medtronic, Cathprint, Pfizer, Johnson-Johnson, Phillips, and Boston Sci. B.O. has nothing to disclose.

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