

PROCEDURAL ISSUES AND COMPLICATIONS OF IMPLANTABLE DEVICES

Implantation-related Complications

The incidence of complications following implantation of permanent pacemakers and ICD is 0.5-5%, and ICD or biventricular pacemakers implantation carries an in-hospital mortality of 0.05-0.5% (Table 1).¹⁻³ Chronic heart failure as an indication, inexperienced operators, CRT or DDD devices and passive fixation atrial leads are independent risk factors for lead complications.⁴ Patients >75 years have a considerably higher average complications rate (5.1% vs 3.4%) than younger patients, mainly driven by pneumothorax and lead dislodgement.⁵

Pneumothorax occurs in 1.5-2% after subclavian puncture.

Haematomas of the pocket requiring evacuation occur in 1-5% of implants. Pocket hematoma is after lead dislodgement, the second more frequent complication of device implantation.⁶ Hematoma formation, regardless of size, is associated with a high risk of CIEDI; thus, prevention is critical.⁷

Tamponade has an incidence of 0.35%. It is the most common cause of death (up to 40%) during device implantation procedures.¹ Female sex, dual-chamber pacemakers and chronic liver disease are risk predictors.⁸

Deep venous thrombosis/venous occlusion, air embolism, and perforation of cardiac chambers are rare complications. Venous thrombosis leading to SVC syndrome may be seen in 0-6% of patients, but asymptomatic pulmonary embolism may be detected in up to 20% of patients. Mobile thrombi on device leads can be detected in up to 30% of patients with intracardiac echocardiography but their clinical significance is not known.⁹ Increasing age predicts worsening outcomes in the elderly, but the absolute rates are modest, even in nonagenarians, and comorbidity is a stronger predictor of complications following implantation of permanent pacemakers.¹⁰ A clinical model that predicts risks for in-hospital events in patients undergoing ICD implantation has been proposed.¹¹

Tricuspid regurgitation may be caused by the lead,¹² with a 5% increase in the prevalence of moderate or severe TR within a year after implantation.¹³ However, device lead implantation in patients with a bioprosthetic TV has not always been associated with an increased incidence of significant prosthetic TR.¹⁴ Three-D echocardiographic guidance may be considered for placement in a commissural position without interfering with normal leaflet mobility.¹⁵ Transcatheter TV interventions are possible in the presence of leads.¹⁶

Device-related infections

Cardiac implantable electronic device (CIED) infections occur in 1-2% of pacemaker implants and are higher with ICD, and, especially, CRT.¹⁷⁻²¹ In a report from the US ICD registry, the infection rate was 1.4%, 1.5%, and 2.0% for single, dual, and biventricular ICDs, respectively. Clinical definitions of device infections are provided in Table 2. Peri-ICD implant complications requiring early reintervention, previous valve surgery, device replacement for reasons other than battery depletion, and increased comorbidity such as renal failure, lung disease, and cerebrovascular accidents were predisposing factors for infection that was associated with a twice as high 6-month mortality rate (12 vs 6.5%).²² Older patient age, and immunocompromised patient are also significant predictors of device infection.²³ The BLISTER risk score (https://qxmd.com/calculate/calculator_876/the-blister-score-for-cied-infection) is a valid predictor of CIED infection (Table 3).²⁴ In the Danish Registry report, infection rates for ICD, CRT and CRT-D were 1.2%, 2.2%, and 3.3%, respectively. Majority of risk factors for DRI were patient- and operation-related such as total number of operations, type of operation, young age, and male sex.²⁵ One-year mortality in patients with device infections is 17-24%.^{17, 26} In a more recent Danish study, pocket CIED infections were associated with device reoperations, young (<50) or very old (>80) age and more complex type of device, whereas systemic CIED infections were associated with risk factors predisposing to bacteraemia, such as renal insufficiency, prior valvular surgery, and dermatitis/eczema.²⁷ The majority of patients (up to 60%) present with localized infection involving the device pocket, and the rest with blood stream infection with or without evidence of inflammation of the device pocket.^{17, 28} A negative transoesophageal echo does not rule out lead infection. Intracardiac echocardiography is superior to transoesophageal echocardiography in detecting intracardiac vegetations, especially around the tricuspid valve, in this respect.²⁹ Renal failure, hematoma formation, poor wound healing, and implantation of devices with multiple leads are risk factors. Several studies have identified device revision or replacement as a risk factor for infection,²² although the REPLACE registry showed a low rate of major infection (0.8%).¹⁸ Perioperative antibiotic prophylaxis with cefazolin reduces the risk of device-related infections.^{3, 7, 30} Vancomycin is an alternative. It should be administered 120 minutes before incision in a dose of 20 mg/kg.⁷ The use of antibacterial envelope results in a lower occurrence of device-related infections, particularly in patients undergoing CRT reoperations that face a particularly high risk of device-related infection.³¹ The use of antibiotic pocket irrigation and postoperative oral antibiotics provides no additional benefit to the prophylactic measures of chlorhexidine skin preparation, preoperative intravenous antibiotics, and an antibiotic envelope in reducing infection.^{7, 32}

Main causes are staphylococci (60-80%, and up to half of them methicillin-resistant) (Figure 1).²¹ Gram-positive cocci (15%), gram-negative bacilli and polymicrobial infections are rare. Infections due to coagulase-negative staphylococci usually have an indolent presentation, whereas *S. aureus* infections, particularly those complicated by bloodstream infection or infective endocarditis, develop more rapidly, with more severe systemic manifestations. Device infection will be confirmed in 35% or more of patients with bacteremia due to staphylococcal species, whereas its likelihood is lower (20% or less) in patients with bacteremia caused by non-staphylococcal gram-positive cocci or by gram-negative bacilli. A single blood culture that is positive for coagulase-negative staphylococci usually represents contamination rather than infection; multiple blood cultures that are positive for coagulase-negative staphylococci should prompt consideration of a device-related infection even if there are no other suggestive symptoms or signs.³⁰

In patients with left ventricular assist devices, device infection occurs in 22% of patients per year despite the use of newer, smaller devices, and affects mortality. Staphylococci are the most common pathogen (approximately 50%), but pseudomonas or other Gram-negative bacteria cause up to 30% of infections.³³

Among patients who have received a resterilized and reused pacemaker or defibrillator, the reported incidence of infection or device-related death at 2 years is 2.0%. This did not differ significantly from that seen among matched control patients with new devices.³⁴

The ESC algorithm for diagnosis of cardiac device-related infective endocarditis is presented in Figure 2.

Therapy

Aspiration of the pocket should be avoided because it could result to infection. If the pocket has to be surgically explored deep tissue and lead tips rather than swab cultures are obtained. Device removal is not required for superficial or incisional only infection at the pocket size if there is no involvement of the device. Seven to 10 days of oral antibiotic therapy with antistaphylococcal activity is recommended. However, if localized pocket infection is established or blood cultures become positive, early and complete removal of the device and leads is necessary.^{30, 35, 36} Biofilm formation on the leads without obvious vegetations is a distinct possibility and precludes eradication of the infection without system extraction. The high frequency of leads extracted in patients with findings limited to the pocket indicates that the spread of the infection from the pocket site is common, and complete removal of the device is usually necessary to prevent relapse. Most pacemaker leads implanted within a year can be explanted without the use of any specialized equipment. Postextraction wound management is crucial to eradication of infection and timely healing. Complete debridement of the infected and avascular tissue or foreign materials can be accomplished by surgical

dissection and electrocautery. Vacuum-assisted closure therapy may also be useful.³⁷

In established pocket infection IV vancomycin should be given pending culture results, and therapy should last up to 14 days if there is no evidence of infective endocarditis. A new device should be implanted in the contralateral side at least 72 hours after the infected device has been removed. Clinical manifestations of pocket infection are present in the majority of patients with early lead-associated endocarditis. However, late lead-associated endocarditis (>6 months after device implantation) should be considered in any patient who presents with fever, bloodstream infection, or signs of sepsis, even if the device pocket appears uninfected. Prompt recognition and management may improve outcomes.³⁸ Development of lead vegetations >2 cm in diameter may require surgical removal to avoid pulmonary embolism. The presence of PFO, especially with right-sided vegetation with right-to-left shunting, is associated with an increased risk of stroke.³⁹ In patients too sick to be subjected to lead extraction, a conservative approach may be adopted by extensive resection of infected and non-viable tissue, mechanical and chemical sterilization of all remaining hardware and local antibiotics by a closed irrigation system, and oral antibiotics upon discharge.^{40, 41} After completion of initial antibiotic therapy, chronic antimicrobial suppression with antibiotics may be considered in patients who are not candidates for complete device removal.⁷ A summary of prevention, diagnosis and management by the 2024 Update of the AHA Statement on CIED Infection is presented in Figure 3. Recommendations for management of infections are also presented in Table 4 and Figure 4. Recommendations by the ESC and AHA/ACC about cardiac device-related endocarditis are also provided in the Chapter on infective endocarditis.

Reimplantation

Lead complications are the main reason for reoperation after implantation of pacemakers or cardiac resynchronization therapy devices (Table 5).^{4, 42, 43} Sprint Fidelis (Medtronic) and Riata (St Jude Medical) defibrillator leads have a failure rate at 2.6-2.7% per year and have been removed from the market. Fracture of a pace-sense conductor is the most widely studied failure mode of the Fidelis ICD lead. Fractures of high voltage conductors are much less common but, unlike pace-sense conductor fractures, may result in failed defibrillation.⁴⁴ Patients with an ICD-CRT have a significantly higher Fidelis fracture rate than patients with an ICD.⁴⁵ The Riata ST and Riata (especially) ICD leads are prone to high-voltage failures that have resulted in death. These failures appeared to have been caused by insulation defects that resulted in short circuiting between high-voltage components.⁴⁶ Early extraction of Riata leads with externalized conductors has been proposed to avoid the potential for large organized thrombus formation that has been recently described.⁴⁷ however, fluoroscopic

detection of externalized conductors does not necessarily imply electrical dysfunction, and an individualized approach is probably reasonable.⁴⁸

Lead dislodgment for primary implantation is approximately 0.8-1% per procedure-year for pacemakers and ICDs, and 3% for CRT.⁴⁹

Lead extraction, more than 4-6 months after implantation, requires extensive experience and can be accomplished in 90% of cases with the use of various dedicated devices. Mechanical non-powered (polypropylene or similar plastic material) or powered sheaths (laser, radio-frequency electrosurgical or controlled-rotational with threaded tip devices) are used. For older leads, mechanical non-powered (teflon, polypropylene, and stainless steel) sheaths were initially used for removal, but have largely been replaced by powered sheaths (laser, radio-frequency electrosurgical or controlled-rotational with threaded tip devices), which are easier and safer to use. Lead extraction is associated with a 12% complications rate including a 0.2-4% mortality, depending on the cases volume of the center.^{1, 20, 50, 51} Extraction for noninfectious indications offers similar long-term survival with capping and abandoning of leads.⁵² Unfunctional leads should be abandoned in a condition that will permit future extraction and prevents retraction into the vessel.²⁰ Indications for noninfected lead removal such as vein thrombosis or chronic pain are discussed in detail in the HRS 2017 statement.²⁰

Pacemaker and ICD generator replacements are associated with a notable complication risk (1-2% and 4-6%, respectively), particularly those with lead additions.⁵³ Pacemaker reuse, although not allowed in most countries, is an interesting opportunity for elimination of resources waste.⁵⁴ Pacemaker reuse has an overall low rate of infection and device malfunction but there is a higher rate of device malfunction as compared with new device implantation.⁵⁵ Admission for heart failure within the prior 12 months, NYHA III or IV, antiarrhythmic drug use, chronic kidney disease, cerebrovascular disease, are independently associated with 6-month mortality after replacement (REPLACE DARE Score).⁵⁶

Strategies for avoiding complications as well as the optimum management of patients with electronic devices during and after medical and surgical procedures have been described.^{55, 57}

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