

How European centres diagnose, treat and prevent CIED infections: Results of an European Heart Rhythm Association survey

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Received 24 September 2012; accepted after revision 26 September 2012

The purpose of our survey is to analyse the clinical approach used to prevent and treat cardiovascular implantable electronic device (CIED) infections in Europe. The survey involves high-volume implanting centres. According to the survey the incidence of CIED infections shows a slight decrease in most centres and is substantially under 2% in the majority of centres interviewed. However, there are still differences in terms of prophylactic antibiotic therapy: 8.9% of the centres administer oxacillin as preoperative treatment, 4.4% of them do not give any antibiotic therapy, all centres use some kind of skin antiseptic, but only 42.2% use chlorhexidine. In case of local infection, 43.5% of centres perform lead extraction as first approach. In the case of systemic infection or evidence of lead or valvular endocarditis, 95% of centres treat these conditions by extracting the leads, which indicates that the adherence to the lead extraction guidelines is quite good.

Keywords CIED infections • Pacemaker • ICD • Pocket infection • Lead extraction • Guideline knowledge • EHRA survey

Introduction

An increasing number of patients are receiving cardiovascular implantable electronic devices (CIEDs).^{1,2} Even though the use of a CIED is associated with a lower risk of death and a better quality of life, the growing burden of comorbidities in CIED patients, the greater complexity of the devices and the increased duration of procedures, have led to an increased risk of infections.

Infections after the implantation of CIED significantly increase the morbidity and mortality rates in CIED patients and affect costs of the worldwide health systems.³ Early and correct diagnosis of systemic and local infections is crucial since CIED infections often require a complete removal of the system (device and leads) as well as adequate antibiotic therapy.^{4–7} The aim of this survey was to analyse the clinical approach used to prevent, diagnose, and treat CIED infections in different European with special emphasis on their adherence to guidelines.

Methods and results

Characteristics of centres

Responses were received from 48 of the European Heart Rhythm Association (EHRA) Research Network Centres. Centre distribution by nation was: Italy 7, UK 6, Netherlands 5, France 4, Spain 3, Poland 3, Denmark 3, Germany 2, Austria 2, Greece 2, Romania 2, Armenia 1, Belgium 1, Helvetic Confederation 1, Estonia 1, Georgia 1, Norway 1, Portugal 1, Sweden 1, and Tunisia 1.

Sixty-seven percent of centres were university hospitals; 12.8% were private and 25.5% other type of hospitals. The annual implantation rate was >200 pacemakers (PM) [including cardiac resynchronization therapy-pacemaker (CRT-P)] in 62.5% of centres, while 31.3% reported rates between 50 and 200 and 6.3% less than 50. Seventy-nine percent of centres declared an

annual implantation rate >50 implantable cardioverter-defibrillator (ICD) [including cardiac resynchronization therapy-defibrillator (CRT-D)] while 21% less than 50.

Prevalence of CIEDs infections

The prevalence of CIEDs infection was:

- <0.5% for 11 centres in 2010 and 13 centres in 2011;
- >0.5 ≤ 1% for 12 centres in 2010 and 13 in 2011;
- >1 ≤ 2% for 8 centres in 2010 and 10 in 2011;
- >2 ≤ 5% for 15 centres in 2010 and 11 in 2011;
- >5% for 1 centres in 2010 and 0 in 2011.

No centre reported a prevalence > 10%.

The incidence of CIEDs infection from 2010 to 2011 decreased in 9 centres, remained the same in 34 centres, and increased in 4 centres (1 centre did not respond). Infection rates in 2010 and 2011 are represented in Figure 1.

Cardioverter-defibrillator implantation was the procedure with the highest incidence of infection according to 55.3% of centres, followed by PM implantations according to 27.7% of centres and equally CRT-P and ICD for 23.4%.

In 48% of centres replacement of devices was the intervention associated with the highest incidence of infection, followed by revision in 40.4%, upgrading in 27.7%, and first implants in 23% of centres (Figure 2).

Diagnosis of infections

Suspected pocket infection

In presence of pain, swelling and erythema at the site of device pocket (local infection). In all, 68.1% of centres would undertake hospitalization for laboratory tests, echocardiographic examination, and adequate treatment; 28.8% would start empiric antibiotic therapy, while 14.9% would prefer to 'wait and see' for the development of clinically relevant conditions. Only 2.1% perform pocket needle aspiration for bacterial culture.

Suspected systemic infection

In the case of suspected systemic infection and absence of local signs, the centres chose the tests reported in Table 1 to diagnose CIEDs infections.

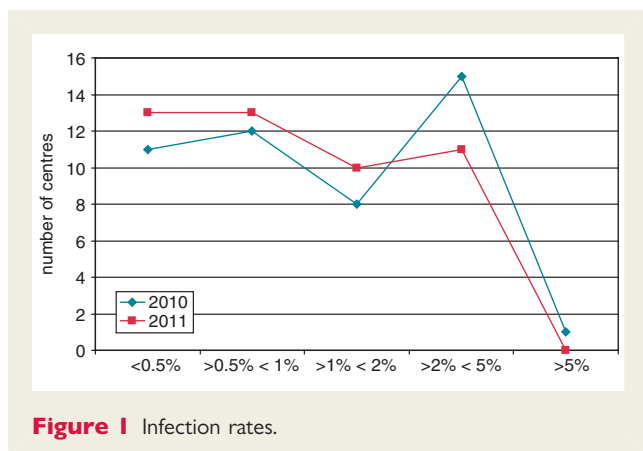


Figure 1 Infection rates.

To the following question: do you usually consult an infectious disease specialist to diagnose and treat CIEDs infections? The centres stated: 21.3% always, 39.9% in most of cases, 40.4% sometimes, and 6.4% never.

Fifty-five percent of centres would find positive blood cultures in not more than 50% of cases, 25.5% of centres between 50 and 70%, 15% between 70 and 90%, and 4.5% of centres in more than 90% of cases.

Treatment of CIEDs infections

Indications to complete hardware removal

Centres were asked to attribute a class of indication (from I to III) to complete hardware removal according to major clinical manifestations of infection; Table 2 shows the results of centres' choice.

Conservative treatment in case of local infection

In case of local infection, 45.7% of centres had a conservative strategy only when lead extraction was considered at high risk, but 43.5% avoided a conservative approach.

In case of CIEDs infection treated conservatively, 65.2% of centres do not ever perform pocket irrigation, while 19.6% do it only sometimes and 15% do it only after PM/ICD replacement.

Prophylaxis of CIEDs infections

Risk factors for CIEDs infections

Replacement and Upgrading are considered as important risk factors, respectively, in 95 and 90.2% of centres. Diabetes mellitus was considered a risk factor by 97.6% of centres, procedure duration by 92.9%, fever within 24 h before procedure by 90.2%, chronic renal failure by 85% of centres, CRT-D or CRT-P recipients by 82.5%, anticoagulation or antithrombotic therapy by 70.0%, temporary pacing 67.5%, elderly subjects in 66.7%, and ICD (not CRT) recipients 34.3%.

Preventive measures

Cardiovascular implantable electronic device implantations are performed in a cardiac catheterization laboratory in 51.1% of

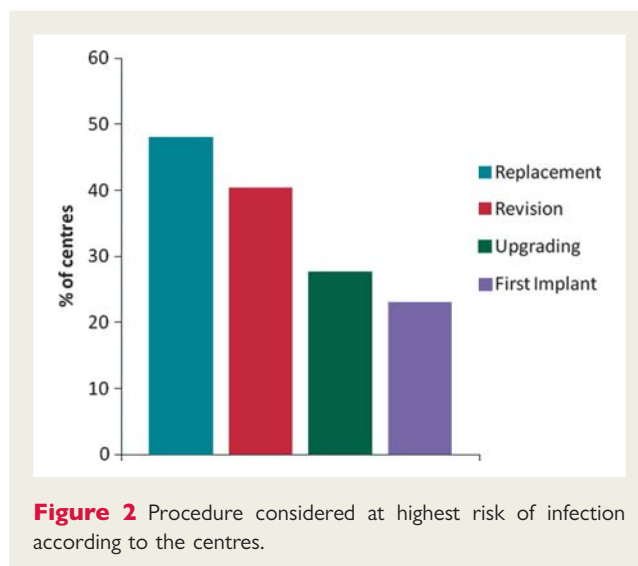


Figure 2 Procedure considered at highest risk of infection according to the centres.

Table 1 Tests used to diagnose cardiovascular implantable electronic devices infections

Laboratory analysis	%
Complete blood cell count	100.0
C-Reactive protein	97.8
Two sets of blood culture	92.9
Erythrocytes sedimentation rate	88.9
One set of blood culture 72%	72.0
Procalcitonin	32.3
Instrumental diagnostic tests	
Trans-thoracic echocardiography:	97.5
Trans-oesophageal echocardiography	89.9
Scintigraphy using labeled leukocytes	23.1
Intracardiac and intravascular echocardiography	4.2
Pulmonary scintigraphy	4

Table 2 Percentage of centres choosing class of indication for complete hardware removal

	I (%)	II (%)	III (%)
Valvular or lead endocarditis, or sepsis	96	2	2
Pocket abscess, device erosion or chronic draining sinus	91	7	2
Signs of skin adherence	12	59	29
Valvular endocarditis without definite lead(s) involvement	53	40	7
Occult Gram-positive bacteriemia (not contaminant)	21	67	12
Occult Gram-negative bacteriemia	5	73	22
Incisional infection without device and/or leads involvement	14	33	53
Chronic bacteriemia due a source other than the CIED	14	34	52

centres, in an operating room with ventilation in 35.6% of centres and in a hybrid room in 13.3% of centres.

Antibiotics are administered in 95.6% of centres of which 71.1% prescribed intravenous (i.v.) cephazoline as preoperative antibiotic treatment, 15.6% of centres used i.v. oxacillin, 8.9% of hospitals used i.v. vancomycin, while 4.4% do not give any antibiotic.

In 80% of centres the antibiotic treatment is started 60–120 min before the implantation procedure, in 20% during the procedure.

A total of 57.8% of centres reported to use povidone–iodine solution as skin antiseptic, while chlorhexidine is used in 42.2% of centres.

Pocket haematoma management

In the case of pocket haematoma, 4.4% of centres would always perform a surgical revision, 4.4% a drainage puncture, 82.2%

would perform a surgical revision and 8.9% would perform a drainage puncture but only in the case of painful and under tension haematoma.

Discussion

The data of this survey represent the European clinical practice in the diagnosis and treatment of CIEDs infections at high-volume centres. One limitation is the low representativeness of small-volume centres that may be associated with higher rates of infections.

The majority of centres reported an incidence of CIED infections <2%, which is quite low compared with data from the published literature.^{1,2} In addition, the analysis of the trends between 2010 and 2011 showed that at least in 13 centres the incidence of CIEDs infection has decreased.

The survey shows that CRT-D implantation is associated with the highest incidence of infection (55.3% of centres), followed by PM (27.7%) and then both CRT-P and ICD (23.4%). Our observations are in agreement with previous studies.^{1,2}

On the other hand, the replacement of implanted devices was the procedure associated with a higher incidence of infections, followed by the revision and upgrading of CIEDs, which is consistent with the current reports. In the presence of signs/symptoms of pocket infection, the majority of centres recruited in the study (68.1%) would proceed with hospitalization in order to perform laboratory assays, echocardiographic assessment (to exclude lead or valvular vegetations) and provide adequate treatment. Conversely, the remaining centres reported different practice and diagnostic options than what is outlined in published guidelines.^{4–6}

In the presence of systemic infections, all centres employed the basic diagnostic approaches and only a small group used second-level diagnostic tools (intracardiac/intravascular echocardiography and scintigraphy with labelled blood cells). The majority of centres were able to isolate the infectious agent in ≤50% of blood cultures which underscore the difficulty in finding the agent of CIEDs infection in many cases. Probably more accurate diagnostic tools are necessary to face with this topic.

When asked to give the class of indication for complete hardware removal in some clinical situations, not all the centres reported a complete adherence to the guidelines despite their high experience. The occurrence of skin adherence was considered a Class I indication to lead extraction (correct one according to the guidelines) in only 12.2% of centres. Valvular endocarditis without definite lead(s) involvement was correctly considered as a Class I indication in 50% of the centres, but it was erroneously identified as Class II indication in 33%. The presence of occult Gram-positive bacteriemia (not contaminant), which is a Class I indication in the guidelines, was considered a Class II indication for lead extraction in the majority of the centres and only a smaller group considered it as Class I. These data suggest that a significant number of centres, even high-volume centres, do not adhere to guidelines for hardware removal.

In the case of local infection, almost half of the centres reported to avoid conservative treatment as guidelines would advise.

Considering prophylaxis, the centres showed a good knowledge of the main risk factors related to CIED infections and reported good management of pocket haematoma.

Seventy-one percent of centres prescribed intravenous cephalosporins as preoperative antibiotic treatment. There is a large controversy about the selection of the right antibiotic. However, in the majority of the centres the timing of antibiotic administration was correct.

Chlorhexidine was used in only 42.2% of centres as antiseptic, which is in contrast to the current knowledge suggesting that chlorhexidine-based antiseptic approach is the most effective one.⁸

Conclusions

This survey on clinical practice in the management of CIED infections has shown good knowledge among the majority of the centres. Surprisingly, some centres reported an approach that is not evidence based regarding the prevention and treatment of CIEDs infections. A more widespread knowledge of these critical aspects would most likely reduce the incidence of infections and improve the effectiveness of the treatment.

Acknowledgements

The production of this EP Wire document is under the responsibility of the Scientific Initiative Committee of the European Heart Rhythm Association: Carina Blomstrom-Lundqvist (chair), Philippe Mabo, Maria Grazia Bongiorno, Nikolaos Dages, Dan Dobreanu, Isabel van Gelder, Thorsten Lewalter, Gregory Y H Lip, Germanas Marinskis, Laurent Pison, Alessandro Proclemer, and Jesper Hastrup Svendsen. We acknowledge the EHRA

Research Network centres participating in this EP Wire. A list of the Research Network can be found on the EHRA website.

Conflict of interest: none declared.

References

1. Kurtz SM, Ochoa JA, Lau E, Shkolnikov Y, Pavri BB, Frisch D *et al.* Implantation trends and patient profiles for pacemakers and implantable cardioverter defibrillators in the United States:1993–2006. *Pacing Clin Electrophysiol* 2010;**33**:705–11.
2. Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT *et al.* 16-year trends in the infection burden for pacemakers and implantable cardioverter-defibrillators in the United States: 1993–2008. *J Am Coll Cardiol* 2011;**58**:1001–6.
3. Ferguson TB Jr, Ferguson CL, Crites K, Crimmins-Reda P. The additional hospital costs generated in the management of complications of pacemaker and defibrillator implantations. *J Thorac Cardiovasc Surg* 1996;**111**:742–51.
4. Wilkoff BL, Love CJ, Byrd CL, Bongiorno MG, Carrillo RG, Crossley GH III *et al.* Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA). *Heart Rhythm* 2009;**6**:1085–104.
5. Baddour LM, Epstein AE, Erickson CC, Knight BP, Levison ME, Lockhart PB *et al.* American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee; Council on Cardiovascular Disease in Young; Council on CardiovascularSurgery and Anesthesia; Council on Cardiovascular Nursing; Council on Clinical Cardiology; Interdisciplinary Council on Quality of Care; American. Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association. *Circulation* 2010;**121**:458–77.
6. Deharo JC, Bongiorno MG, Rozkovec A, Bracke F, Defaye P, Fernandez-Lozano I *et al.* Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper. *Europace* 2012;**14**:124–34.
7. Bongiorno MG, Blomström-Lundqvist C, Kennergren C, Dages N, Pison L, Svendsen JH *et al.* Current practice in transvenous lead extraction: a European Heart Rhythm Association EP Network Survey. *Europace* 2012;**14**:783–6.
8. Darouiche RO, Wall MJ Jr, Itani KMF, Otterson MF, Webb AL, Carrick MM *et al.* Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. *N Engl J Med* 2010;**362**:18–26.