

Infections liées aux DECI (PM/DAI): l'ablation doit-elle être systématique ? Sinon, que faire ?

Eric Bonnet

Membre du groupe des recommandations de la SPILF

Service des Maladies Infectieuses

CHU Toulouse

Introduction

- Fréquence relativement faible des infections de dispositif électronique cardiaque implantable (DECI) : 0,6-1,3%.
- Nombreuses situations de gravité variable. Diversité des entités cliniques individualisées selon les « guidelines »
- Nécessité d'une prise en charge pluridisciplinaire.

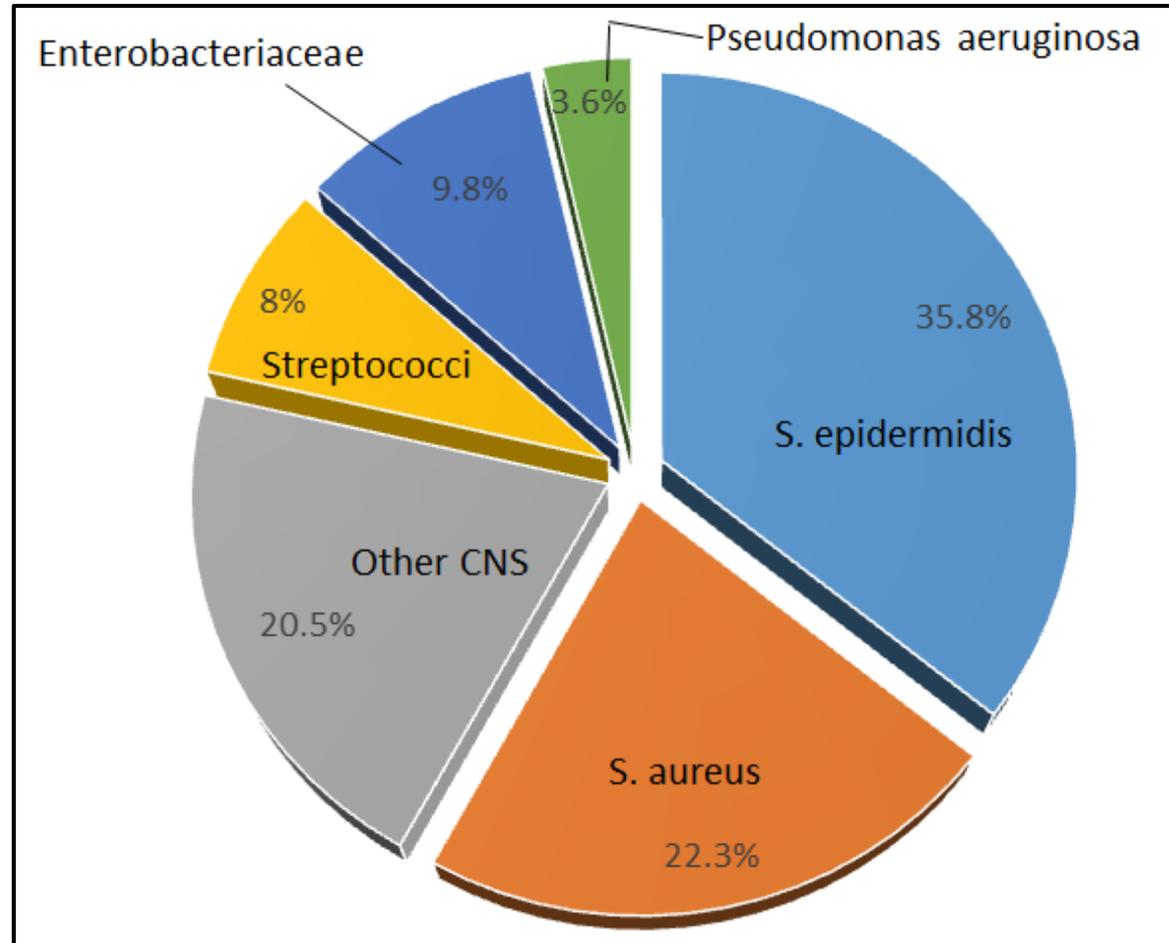
Entités cliniques

- **Extériorisation du matériel** : effraction cutanée avec exposition à la vue du boîtier et/ou des sondes, sans signes d'inflammation
- **Infection du site d'implantation = signes locaux d'inflammation**
 - **superficielle** : **dans les 30 jours** suivant l'implantation, sans fièvre et sans autres signes généraux, limitée à la peau et au tissu sous-cutané de la zone d'incision et n'atteignant pas le fascia et/ou les muscles
 - **profonde** : toute **collection au contact du matériel** avec ou sans fièvre
- **Infection de sonde(s) = « ~~endocardite~~ sur sonde(s)** : végétation visualisée par échocardiographie et/ou hyperfixation sur le trajet d'une sonde (Pet scan/ scintigraphie aux leucocytes marqués)
- **Endocardite** (sous-entendu valvulaire) définie selon les guidelines de l'ESC 2015

Données microbiologiques

Staphylocoques : 60 à 80% des cas, quel que soit le délai de survenue

- Staphylocoques à coagulase-négative : prédominant si infection de loge
- polymicrobien dans 13% des cas



Bactéries isolées de culture de la partie distale des sondes (123 souches)
Eric Bonnet et al. ENDO 06. Journées Nationales d'Infectiologie. Lyon 2019.

Microbiology of cardiac implantable electronic device (CIED) infections

Organism	Pacemaker endocarditis Number of patients (percent) [1]*	All CIED infections (pocket and bloodstream) Number of pathogens (percent) [2]
Coagulase-negative staphylococci	99 (61)	183 (44)
<i>Staphylococcus aureus</i>	49 (30)	148 (36)
Enterobacteriaceae	8 (5)	18 (4)
Streptococci	7 (4)	12 (3)
<i>Pseudomonas</i>	6 (4)	12 (3)
Other gram-negative bacteria	-	8 (2)
<i>Candida</i>	3 (2)	2 (<1)
Enterococci	3 (2)	20 (5)
<i>Corynebacterium</i>	2 (1)	2 (<1)
<i>Cutibacterium</i> (formerly <i>Propionibacterium</i>) <i>acnes</i>	1 (<1)	1 (<1)
<i>Listeria</i>	1 (<1)	-
Anaerobes	-	5 (1)
Micrococci	1 (<1)	-
<i>Mycobacterium</i> spp	-	2 (<1)
<i>Apergillus</i>	-	1 (<1)

7 à 9%

* Polymicrobial infection occurred in 11 percent of cases.

References:

- Arber N, Pras E, Copperman Y, et al. *Medicine (Baltimore)* 1994; 73:299; Duval X, Selton-Suty C, Alla F, et al. *Clin Infect Dis* 2004; 39:68; Klug D, Lacroix D, Savoye C, et al. *Circulation* 1997; 95:2098; and Cacoub P, Leprince P, Nataf P, et al. *Am J Cardiol* 1998; 82:480.
- Tarakji KG, Chan EJ, Cantillon DJ, et al. Cardiac implantable electronic device infections: Presentation, management, and patient outcomes. *Heart Rhythm* 2010; 7:1043.

Recommandations internationales

		AHA 2010	BHRS 2015	ESC 2015	AHA 2015	HRS 2017	EHRA 2019
Treatment—CIED management							
Early post-implantation inflammation	In superficial or early inflammation, the CIED can initially be left <i>in situ</i> .	✓	✓	NA	NA	NA	8
Isolated pocket infection/erosion	The CIED must be removed completely within 2 weeks after diagnosis	✓	✓	NA	NA	NA	8
CIED lead infection	Complete device system must be removed in CIED lead infection.	✓	✓	NA	NA	✓	8
CIED infective endocarditis	Complete removal is mandatory in CIED infective endocarditis	✓	✓	✓	✓	✓	8
Occult bacteraemia	Complete device removal is recommended in occult bacteraemia	✓	NA	NA	NA	✓	8
Device reimplantation	New transvenous lead implant should be postponed if possible, to allow a few days or weeks of antibiotic therapy	✓	✓	✓	NA	✓	10
Device reimplantation	The replacement device implantation should not be ipsilateral to extraction site. Preferred locations are contralateral side, iliac vein, or epicardial	✓	✓	NA	NA	✓	10

NA : Not available

Quand et comment extraire le matériel ?

- Quand ?
 - A réaliser le plus précocement possible, une fois l'indication retenue :
 - idéalement dans les 3 jours suivant le diagnostic
 - indépendamment de la durée du traitement antibiotique préalable
- Comment ?
 - Extraction complète (boitier et sondes)
 - Extraction percutanée :
 - si végétations < 2 cm
 - à discuter au cas par cas si végétations > 2 cm (aspiration ? chirurgie ?)
 - Extraction chirurgicale si sondes épiscopardiques

European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections

Table 8 Recommendations for device and lead removal

Consensus statement	Statement class	Scientific evidence coding
In patients with definite CIED infection (systemic and local), complete device removal is recommended (including abandoned leads, epicardial leads, and lead fragments)		O
After diagnosis of CIED infection, the device removal procedure should be performed without unnecessary delay (ideally within 3 days)		O
The recommended technique for device system removal is percutaneous, transvenous extraction technique. <u>Epicardial leads require surgical removal</u>		O
In patients with systemic infection and lead vegetations of approximately >20 mm, <u>percutaneous aspiration of vegetations prior to and during transvenous lead extraction or alternatively surgical extraction may be considered</u>		O
After device removal, meticulous debridement of the generator pocket (complete excision of the fibrotic capsule and complete removal of all non-absorbable suture material) and subsequent wound irrigation with sterile normal saline solution is recommended		E
Cultures of extracted CIED should be performed		E, O

Pourquoi enlever le matériel ?

- Si infection de DECI avérée, pas de guérison avec une antibiothérapie seule en raison de la présence de biofilm sur le matériel (sondes, boitier)

Situations où l'ablation du matériel est indiscutable

- **Infection certaine du site d'implantation**
(présence de signes locaux d'inflammation)
=> ceci exclut l'extériorisation « simple » du matériel
(effraction cutanée avec exposition à la vue du boîtier et/ou des sondes, sans signes d'inflammation)
- **Infection de sonde(s) = « ~~endocardite~~ » sur sonde(s)**
- **Bactériémie à *S. aureus*, staphylocoque à coagulase négative, *Candida*, *Cutibacterium*, sans infection de DECI et sans source identifiée,**

Staphylococcus bacteremia without evidence of cardiac implantable electronic device infection ^e

Ikutaro Nakajima, MD, PhD, Ryohsuke Narui, MD, PhD, Kenichi Tokutake, MD, PhD, Caleb A. Norton, MD, William G. Stevenson, MD, FHRS, Travis D. Richardson, MD, Christopher R. Ellis, MD, FHRS, George H. Crossley III, MD, FHRS, Jay A. Montgomery, MD

Conclusion: For patients with SB without evidence of CIED infection, relapse is predicted by the duration of bacteremia. Empirical CIED removal appears to be associated with a survival benefit, although there are likely clinical situations in which this could be deferred.

Table 2 Multivariable model to predict death by 1 y in patients without evidence of CIED infection

Clinical feature	1-y mortality	
	Hazard ratio (95% CI)	P
Age	1.02 (0.99–1.04)	.094
Charlson Comorbidity Index	1.08 (0.97–1.20)	.170
Presentation with hypotension	2.43 (1.38–4.26)	.002
Age of the oldest lead	1.00 (0.94–1.06)	.856
Source of the infection		
Primary focus unknown	1.06 (0.57–1.98)	.855
Presumed source of the infection	1.0 (reference)	
Empirical CIED removal	0.28 (0.08–0.95)	.041

CI = confidence interval; CIED = cardiac implantable electronic device.

Situations où l'ablation du matériel est discutable (RCP)

- Bactériémie à streptocoque alpha ou bêta-hémolytique ou entérocoque sans signe évident d'infection de DECI, ni autre source identifiée => 2 attitudes:
 - Ablation d'emblée
 - Ablation si bactériémie persistante ou récidivante sous ou après une antibiothérapie adaptée
- Endocardite valvulaire sans atteinte identifiée à l'imagerie (ETO, Pet-Scan, Scinti aux leuco marqués) du matériel.
- Infection « superficielle » du site d'implantation (signes locaux modérés)

Enterococcus faecalis bacteremia, cardiac implantable electronic device, extraction, and the risk of recurrence

Andreas Berge^{1 2}, Ludvig Arkel³, Bo Nilson^{4 5}, Magnus Rasmussen^{3 6}

Abstract

Purpose: In all patients with cardiac implantable electronic devices (CIED) and *Enterococcus faecalis* bacteremia (EfsB), endocarditis (IE) and CIED infection should be suspected. Guidelines recommend extraction of the CIED when CIED infection or IE is diagnosed. Whether extraction of the CIED should be done in other situations with EfsB is not known. We aimed to describe the management and outcome of patients with CIED and monomicrobial EfsB, in relation to extraction and recurrent EfsB.

Methods: A population-based cohort of patients with monomicrobial EfsB from January 2014 to November 2020 was identified through microbiology registers in the Region Skåne, Sweden. Data on CIED and other clinical features were collected from medical records.

Results: Among 1087 episodes of EfsB, 72 patients with CIED and monomicrobial EfsB were identified. Five of these patients were diagnosed with IE (7%), three of whom had echocardiographic changes on the CIED. Four CIED were extracted (6%). Recurrences were found in seven of 68 patients (10%) not subjected to extraction and in none of the extracted. In the group of patients without extraction, community acquisition and predisposition for IE were significantly associated with recurrent infection in univariate analyses. No infections involving the CIED were diagnosed during the recurrences.

Conclusions: In patient with monomicrobial EfsB, it seems safe to omit extraction if no structural changes are found on the CIED.

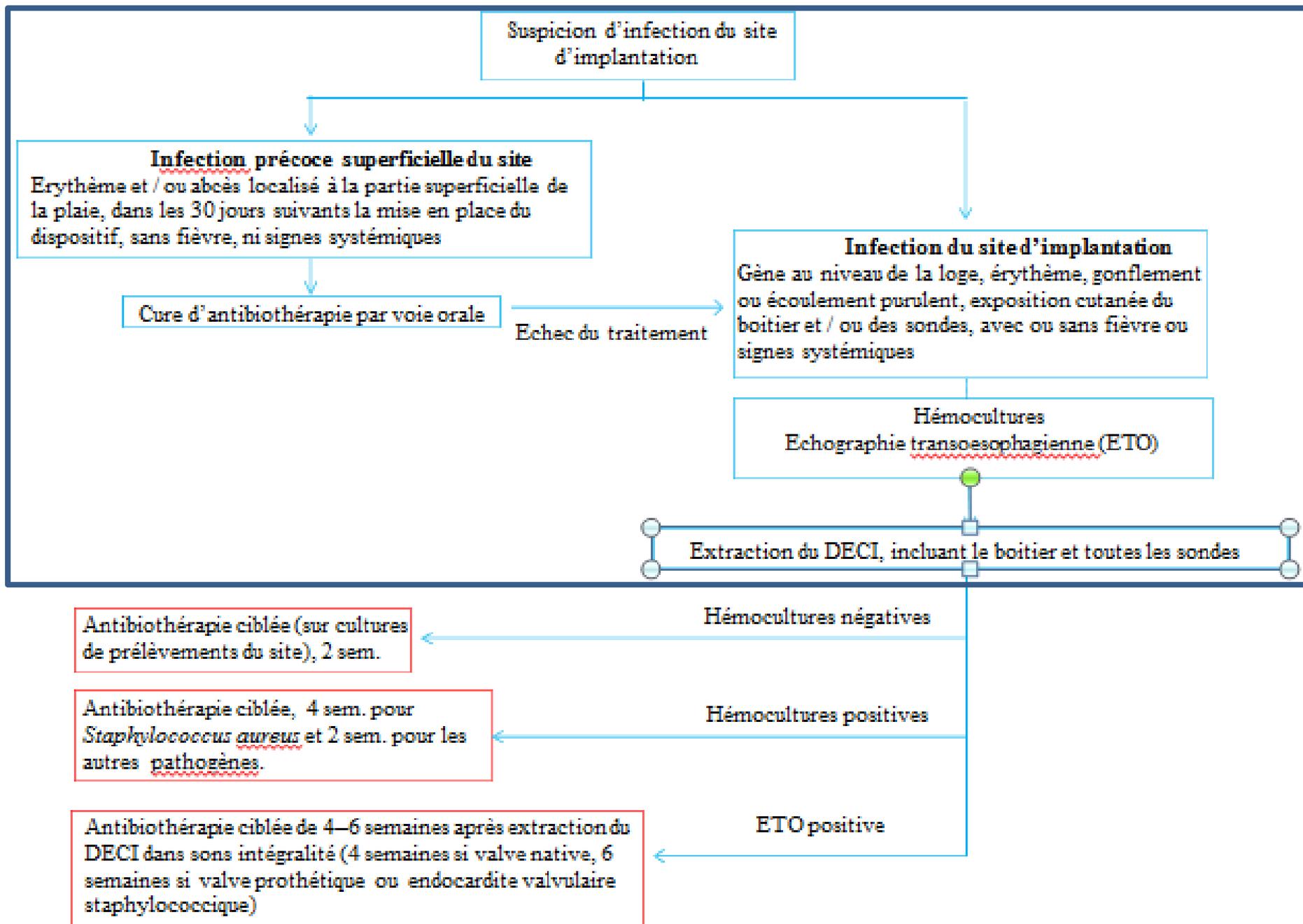


Figure 3 Algorithme décisionnel en cas de suspicion d'infection du site d'implantation du DECI.

Situations où l'ablation du matériel n'est pas indiquée (d'emblée)

- Simple extériorisation du matériel sans signes inflammatoires locaux.
- Premier épisode de bactériémie à BGN ou à pneumocoque

Mais si, malgré une antibiothérapie adaptée et en l'absence de source identifiée il existe une bactériémie récidivante ou persistante => ablation indiquée

Echocardiography and FDG-PET/CT scan in Gram-negative bacteremia and cardiovascular infections

Dahl, Anders^{a,b}; Hernandez-Meneses, M.^a; Perissinotti, A.^c; Vidal, B.^d; Quintana, E.^e; Miro, Jose M.^a

Author Information 

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Recent findings

Most evidence focuses on characteristics of diagnosed cardiovascular infections and the proportion caused by GNBSI. These proportions are low (1–5%) when it comes to native and prosthetic valve endocarditis as well as cardiac implantable electronic device (CIED) infections whereas the proportion of vascular graft infections caused by GNBSI seems substantially higher (30–40%). Information on the prevalence of cardiovascular infection in patients with GNBSI is limited to a few studies finding around 3% endocarditis in patients with GNBSI and a prosthetic heart valve and 4–16% device-related infection in patients with CIED and GNBSI.

Summary

Patients with GNBSI and native or prosthetic valves should only undergo work-up for endocarditis (TEE and FDG-PET/CT) if they present GNBSI relapse or signs suggestive of endocarditis. CIED patients with GNBSI with *Pseudomonas* or *Serratia* spp. should undergo TEE and PET/CT because of the high prevalence of device-related infection. In other GNBSI without IE suggestive signs, normal BSI treatment is reasonable and only cases with relapse need work-up. GNBSI in patients with vascular grafts should lead to consideration of PET/CT.

Bactériémie sans signe évident d'infection du DECI

Enlever toutes les sources d'infection autre que le DECI

Préoccupation clinique persistante sans preuve d'infection du DECI ni aucune source d'infection identifiable

Staphylococcus aureus, SCN,
Propionibacterium spp., *Candidas*
spp.

Retrait du DECI

Streptococcus ssp.
Enterococcus spp.

Retrait du DECI ou surveillance sans retrait
et retrait seulement si bactériémie
récidivante ou persistante malgré une
antibiothérapie adapté

BGN
Pneumocoque

surveillance sans retrait et retrait
seulement si bactériémie récidivante ou
persistante malgré une antibiothérapie
adapté antibiothérapie adapté

Situation où l'ablation est indiquée mais non réalisable

- Antibiothérapie curative usuelle de 6 semaines, suivie d'une antibiothérapie suppressive de durée non déterminée (> 1 an)
 - Principaux antibiotiques utilisés en suppressif :
 - Céphalosporine de première génération
 - Doxycycline
 - Cotrimoxazole
 - Suivi sous antibiothérapie suppressive : à M2 et M3 puis tous les 6 mois

Définition infection de DECI. Consensus EHRA 2019

Table 5 Recommendations for diagnosis of CIED infections and/or infective endocarditis: the Novel 2019 International CIED Infection Criteria

- Major criteria



E

systemic

- Microbiology

- A. Blood cultures positive for **typical microorganisms found in CIED** infection and/or IE((Coagulase-negative staphylococci, *S. aureus*)
 - B. **Microorganisms consistent with IE** from 2 separate blood cultures:
 - a. Viridans streptococci, *Streptococcus gallolyticus* (*S. bovis*), HACEK group, *S. aureus*; or
 - b. Community-acquired enterococci, in the absence of a primary focus
 - C. **Microorganisms consistent with IE from persistently positive blood cultures:**
 - a. ≥ 2 positive blood cultures of blood samples drawn >12 h apart; or
 - b. All of 3 or a majority of ≥ 4 separate cultures of blood (first and last samples drawn ≥ 1 h apart); or
 - c. Single positive blood culture for *Coxiella burnetii* or phase I IgG antibody titre $>1:800$

Définition infection de DECI. Consensus EHRA 2019

Recommendations for diagnosis of CIED infections and/or infective endocarditis: the Novel 2019
International CIED Infection Criteria

systemic

- **Major criteria**  **E**
 - **Imaging** positive for CIED infections and/or IE
 - D. **Echocardiogram** (including ICE) positive for:
 - a. CIED infection:
 - » i. Clinical pocket/generator infection
 - » ii. Lead-vegetation
 - b. Valve IE
 - » i. Vegetations
 - » ii. Abscess, pseudoaneurysm, intracardiac fistula
 - » iii. Valvular perforation or aneurysm
 - » iv. New partial dehiscence of prosthetic valve
 - E. **[18F]FDG PET/CT** (caution should be taken in case of recent implants) or radiolabelled WBC SPECT/CT detection of abnormal activity at pocket/generator site, along leads or at valve site
 - F. Definite paravalvular leakage by **cardiac CT**

Définition infection de DECI. Consensus EHRA 2019

Recommendations for diagnosis of CIED infections and/or infective endocarditis: the Novel 2019
International CIED Infection Criteria

systemic

- **Minor criteria.** 
 - a. Predisposition such as **predisposing heart condition** (e.g. new onset tricuspid valve regurgitation) or injection drug use
 - b. **Fever** (temperature >38C)
 - c. **Vascular phenomena** (including those detected only by imaging): major arterial emboli, septic pulmonary embolisms, infectious (mycotic) aneurysm, in- tracranial haemorrhage, conjunctival haemorrhages, and Janeway's lesions
 - d. Microbiological evidence: **positive blood culture which does not meet a major criterion** as noted above or **serological evidence of active infection with organism consistent with IE or pocket culture or leads culture (extracted by non-infected pocket)**

Définition infection de DECI. Consensus EHRA 2019

- **'Definite'** CIED clinical **pocket/generator infection** = generator pocket shows swelling, erythema, warmth, pain, and purulent discharge/sinus formation **or** deformation of pocket, adherence and threatened erosion **or** exposed generator or proximal leads
- **'Definite'** CIED/**IE or systemic CIED infection** = presence of either 2 major criteria or 1 major + 3 minor criteria
- **'Possible'** CIED/**IE or systemic CIED infection** = presence of either 1 major + 1 minor criteria or 3 minor criteria
- **'Rejected'** CIED/**IE or CEID infection** diagnosis = patients who did not meet the afore mentioned criteria for IE

EHRA 2019

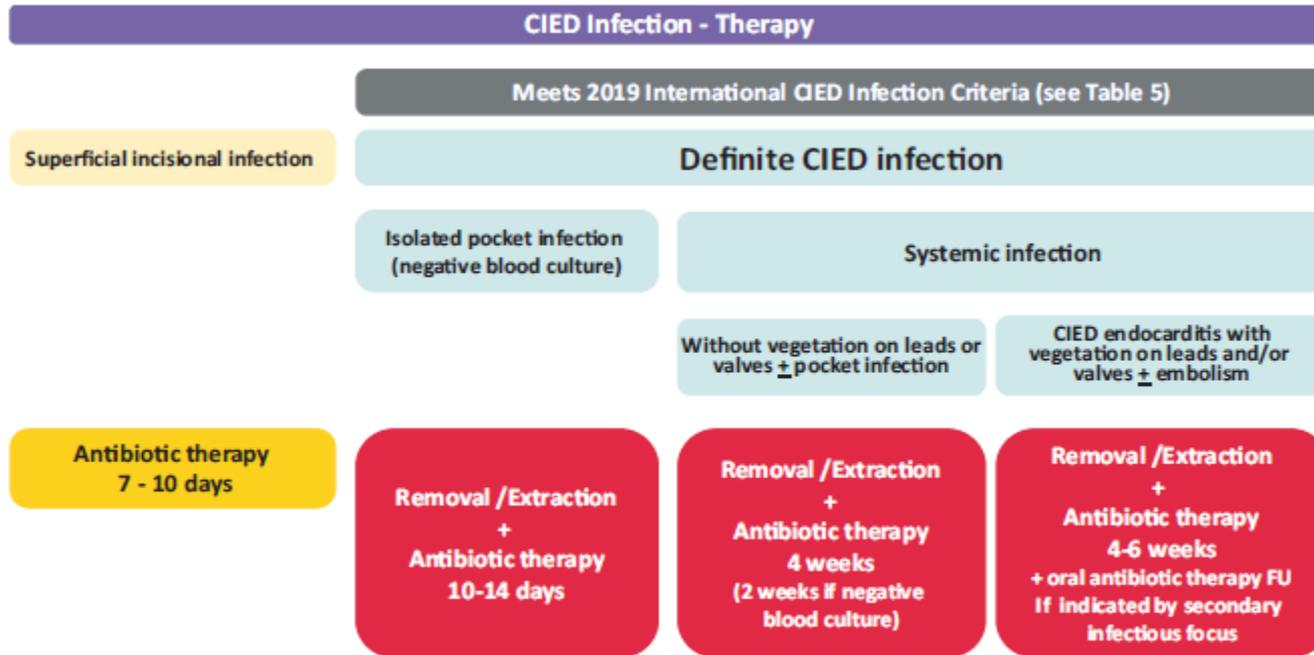


Figure 3 Therapeutic strategies for patients with CIED infections. CIED, cardiac implantable electronic device; FU, follow-up; IE, infective endocarditis.

Réimplantation du matériel-HRS 2017

EHRA 2019

- L'évaluation de l'indication de réimplantation est impérative (30 % de non indication)
- Réimplantation possible :
 - au plus tôt 72 heures après la première hémoculture négative = **hémocultures quotidiennes en cas de bactériémie**
 - plus tardivement si présence d'une autre source d'infection non traitée (abcès du psoas)
 - Réimplantation possible le jour même (dans un autre site) si infection localisée au site d'implantation (hémocultures négatives)

Réimplantation du matériel-HRS 2017

EHRA 2019

- Site de réimplantation
 - Choisir un site de réimplantation différent du site initial
 - Controlatéral
 - Veine iliaque (exceptionnelle)
 - Epicardique
 - Sous-cutané
- Alternatives au PM « traditionnel » (permanent)
 - PM semi-permanent
 - PM sans fil
 - Life vest →



Table 12 Recommendations on minimum volume requirements of cardiac implantable electrical device (CIED) procedures for centres and operators

Consensus statement	Statement class	Scientific evidence coding	References
Operators with less than approximately 100 CIED procedures experience should work under close supervision of more experienced operators		O, E	181–184
An annual minimum operator volume of approximately 50 CIED procedures is recommended for all operators		O, E	185–188

CIED, cardiac implantable electrical device; E, expert opinion; M, meta-analysis; O, observational studies; R, randomized trials.

Conclusion

- Beaucoup de situations où les données sont ténues => attitude variable selon les centres, mais, dans tous les cas, prise en charge pluridisciplinaire, si possible par une équipe expérimentée, souhaitable.