Centre Hospitalier Universitaire de Nice

RHYTHM

Cardiac implantable electronic device infection prevention ?

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Disclosure

Speaker name:

Sok-Sithikun BUN

I have the following potential conflicts of interest to report:

~~Consulting~~

~~Employment in industry~~

~~Shareholder in a healthcare company~~

~~Owner of a healthcare company~~

~~Other(s)~~

I do not have any potential conflict of interest

CIED infection: Incider

CIED-related infections, <12 months[354,639,641,645,685,695,702]	0.7 – 1.7
Superficial infection[354]	1.2
Pocket infections[354]	0.4
Systemic infections[354]	0.5
CIED-related infections, >12 months[702 – 709]	1.1 – 4.6
Pocket infections[702]	1.3
Systemic infections[702,705]	0.5 – 1.2

Glikson M et al. ESC Guidelines Cardiac Pacing 2021

CIED Infection: a major concern

- Stable or ↗ incidence
  - 1.45 to 3.41 % from 2000 to 2012 (USA National survey)

Joy PS et al. Heart Rhythm 2017

- Significant morbidity and mortality : in-hospital or 30-day mortality of 5-8 %
  - Long-term mortality = 1.5-2.4 x in comparison with non-infected patients
  - 6-15 % at 1 year / 14-33 % at 3 years.

Maytin M et al. Circ AE 2012
Sohail MR et al. PACE 2015

- Financial healthcare burden
  - 20623-23234 euros in France
  - 36931 euros in the UK
  - 15516 to 337886 euros in the USA

Clementy N et al. Europace 2018

Risk factors

Factors	Prospective + retrospective studies				Prospective studies only			
	Studies (*n*)	Total (*n*)	Pooled estimate	*P*-value	Studies (*n*)	Total (*n*)	Pooled estimate	*P*-value
Patient-related factors								
ESRD[a]	8	3045	8.73 (3.42–22.31)	0.00001	NA			
History of device infection	4	463	7.84 (1.94–31.60)	0.004	NA			
Fever prior to implantation	3	6652	4.27 (1.13–16.12)	0.03	2	6580	5.34 (1.002–28.43)	0.05
Corticosteroid use	10	3432	3.44 (1.62–7.32)	0.001	3	1349	2.10 (0.47–9.32)	0.33
Renal insufficiency[b]	5	2033	3.02 (1.38–6.64)	0.006	NA			
COPD	6	2810	2.95 (1.78–4.90)	0.00003	2	2393	2.30 (0.97–5.48)	0.06
NYHA class ≥2	3	2447	2.47 (1.24–4.91)	0.01	2	2393	2.77 (1.26–6.05)	0.01
Skin disorders	4	6810	2.46 (1.04–5.80)	0.04	2	6519	2.60 (0.88–7.70)	0.08
Malignancy	6	1555	2.23 (1.26–3.95)	0.006	NA			
Diabetes mellitus	18	11 839	2.08 (1.62–2.67)	<0.000001	7	9815	1.88 (1.19–2.98)	0.007
Heparin bridging	2	6373	1.87 (1.03–3.41)	0.04	NA			
CHF	6	1277	1.65 (1.14–2.39)	0.008	NA			
Oral anticoagulants	9	8527	1.59 (1.01–2.48)	0.04	3	7271	1.18 (0.44–3.11)	0.75
Procedure-related factors								
Procedure duration	9	4850	9.89 (0.52–19.25)	0.04	6	4508	13.04 (-0.64 to 26.73)	0.06
Haematoma	12	14 228	8.46 (4.01–17.86)	<0.000001	6	9715	9.33 (2.84–30.69)	0.0002
Lead repositioning	5	1755	6.37 (2.93–13.82)	0.000003	4	1659	7.03 (2.49–19.85)	0.0002
Inexperienced operator[c]	2	1715	2.85 (1.23–6.58)	0.01	2	1715	2.85 (1.23–6.58)	0.01
Temporary pacing	10	10 683	2.31 (1.36–3.92)	0.002	4	8683	3.29 (1.87–5.80)	0.00004
Device replacement/revision/upgrade	26	21 214	1.98 (1.46–2.70)	0.00001	8	8793	0.95 (0.49–1.87)	0.89
Generator change	20	12 134	1.74 (1.22–2.49)	0.002	6	2139	0.91 (0.37–2.22)	0.83
Antibiotic prophylaxis	16	14 166	0.32 (0.18–0.55)[d]	0.00005	11	10 864	0.29 (0.13–0.63)	0.002
Device-related factors								
Epicardial leads	3	623	8.09 (3.46–18.92)	0.000001	NA			
Abdominal pocket	7	4017	4.01 (2.48–6.49)	<0.000001	2	2268	5.03 (1.96–12.91)	0.0008
≥2 leads	6	1146	2.02 (1.11–3.69)	0.02	NA			
Dual-chamber device	14	45 224	1.45 (1.02–2.05)	0.04	7	12 102	1.28 (0.73–2.25)	0.38

Blomström-Lundqvist C et al. International consensus document on how to prevent, diagnose, and treat CIED infections. Eur Heart J 2020

Risk factors

- **Procedure-related:**
  - Haematoma: Risk x 9
  - Early reintervention
  - Device replacement / Upgrade procedures
  - CRT/ICD compared with simple pacemaker implantation
  - Procedure duration
  - Operator experience: risk ↗ when allocating generator changes to inexperienced operators

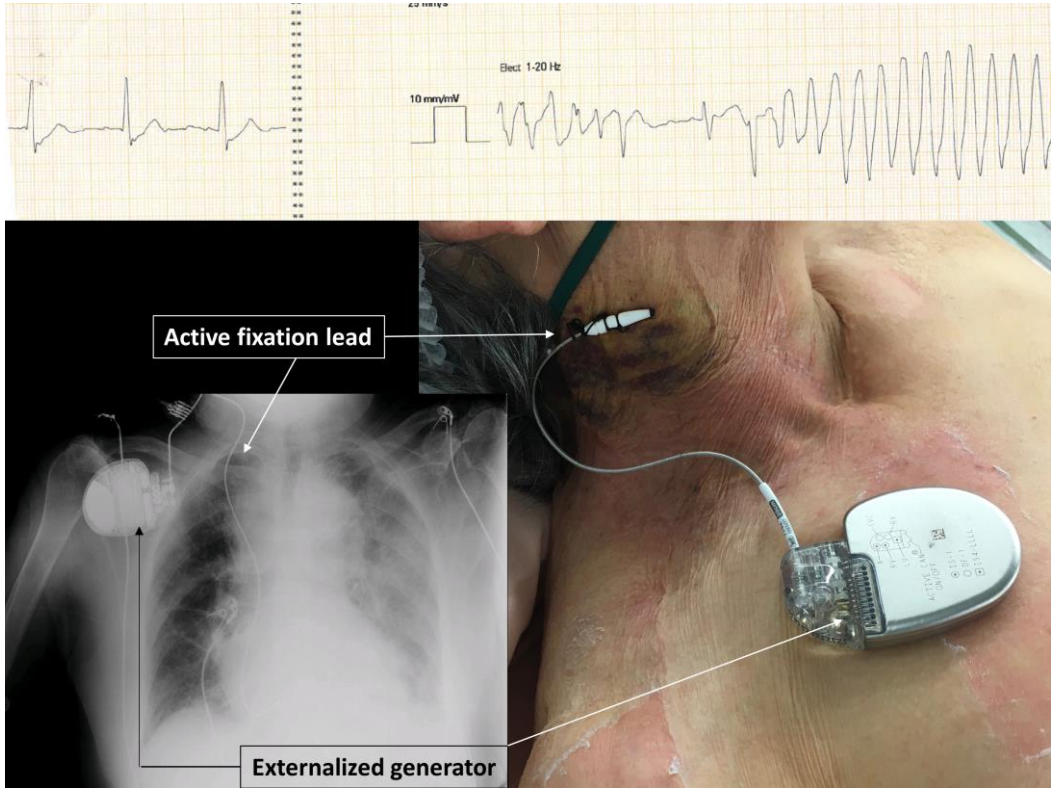
- **Patient-related:**
  - End-stage renal disease
  - Diabetes
  - COPD
  - Younger age
  - Prior device infection
  - Malnutrition

Olsen T et al. Danish device-cohort study. Eur Heart J 2019

Blomström-Lundqvist C et al. International consensus document on how to prevent, diagnose, and treat CIED infections. Eur Heart J 2020

General considerations (1)

- Delay implantation if clinical signs of active infection and/or fever until afebrile > 24 h
- Avoid temporary transvenous pacing / prefer jugular or axillary vein access



Bun SS et al. Ann Cardiol Angeiol 2020

- Temporary pacing positively correlated to infection (OR 2.46) / fever within 24 h (OR 5.83) in a survey of 6319 patients

Traykov V et al. Europace 2019

General considerations (2)

Recommendations	Class[a]	Level[b]
Administration of pre-operative antibiotic prophylaxis within 1 h of skin incision is recommended to reduce risk of CIED infection.[641,643.686]	I	A
Chlorhexidine—alcohol instead of povidone-iodine—alcohol should be considered for skin antisepsis.[647,648]	IIa	B
In patients undergoing a reintervention CIED procedure, the use of an antibiotic-eluting envelope may be considered.[685,688]	IIb	B

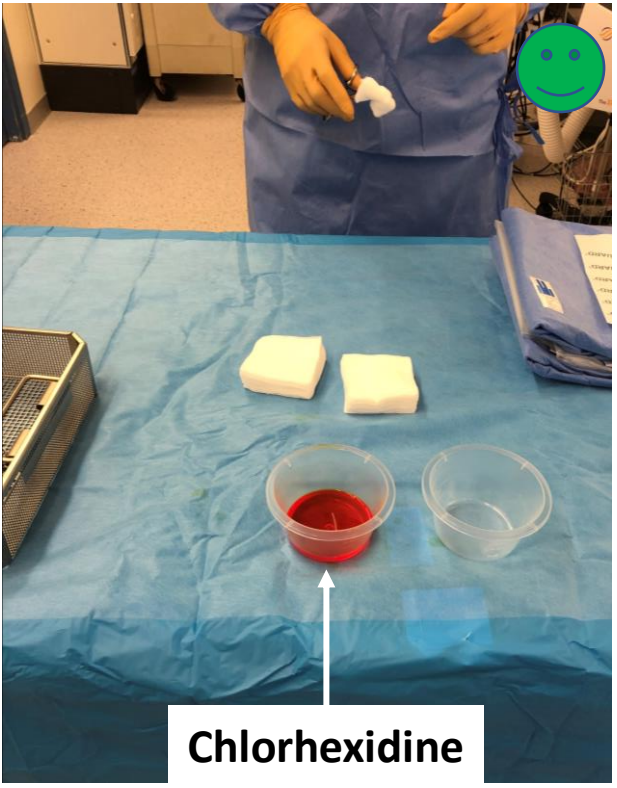
- **1-2 g i.v. Cefazolin/Flucoxacillin 30-60 min before**
- **15 mg/kg Vancomycin 90-120 min before**
- **Post-operative antibiotics do not ↘ infection**

Glikson M et al. ESC Guidelines Cardiac Pacing 2021

Chlorhexidine preferred

- RCT including 2456 patients:

Chlorhexidine-alcohol ↘ short-term intravascular catheter related-infections (vs povidone-iodine-alcohol)



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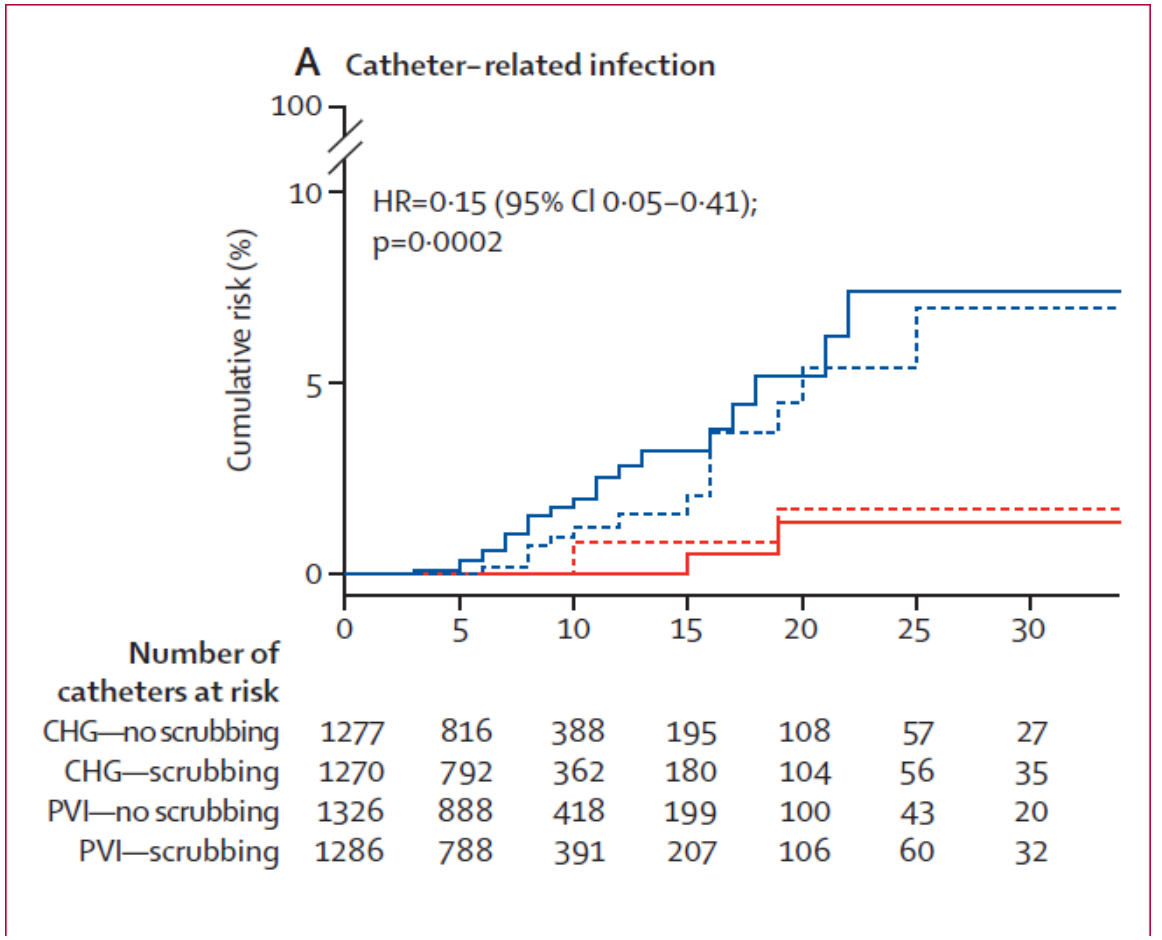

Mimoz O et al. Lancet 2015

Measures to decrease infections

Pre-procedural	Peri-procedural	Post-procedural
Confirm indication	Alcoholic chlorhexidine Adhesive iodophor-impregnated drapes	Post-operative antibiotic
Delay implantation if infection	Glove change/ Remove outer glove of a double-glove before incision	Adequate dressing for 2-10 d
Avoid haematoma: Discontinue antiplatelets (1 w) / VKA in higher-risk patients LMWH/Bridging	Antibiotic envelope in high-risk patients	Patient instructions on wound care
Hair removal with electric clippers	Local instillation of antiseptics/antibiotics in the pocket	Reconsider indication for reintervention
Avoid temporary transvenous pacing and/or central venous lines	Braided sutures	Haematoma evacuation
Antibiotic prophylaxis	Non-powdered gloves recommended Capsulectomy may not be performed	
Continuous surveillance programme of infection rates	Vigourous pocket irrigation	

Measures to decrease infections

Pre-procedural

Confirm indication

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Post-procedural

Post-operative antibiotic

Adequate dressing for 2-10 d

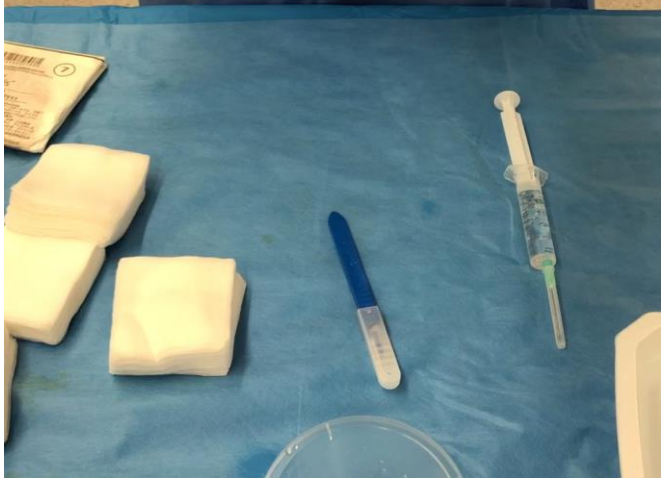
Patient instructions on wound care

Suture types

Absorbable					Non-absorbable		
Braided		Monofilament			Braided		Monofil ament
Vicryl	Vicryl rapide	Monocryl	Fast absorbing gut	Chromic gut	Ethibond	Silk	Ethilon

Per-procedural measures

Double your gloves



Rinsing the device pocket with normal saline solution before wound closure should be considered.[683,684]	IIa	C

Glikson M et al. ESC Guidelines Cardiac Pacing 2021

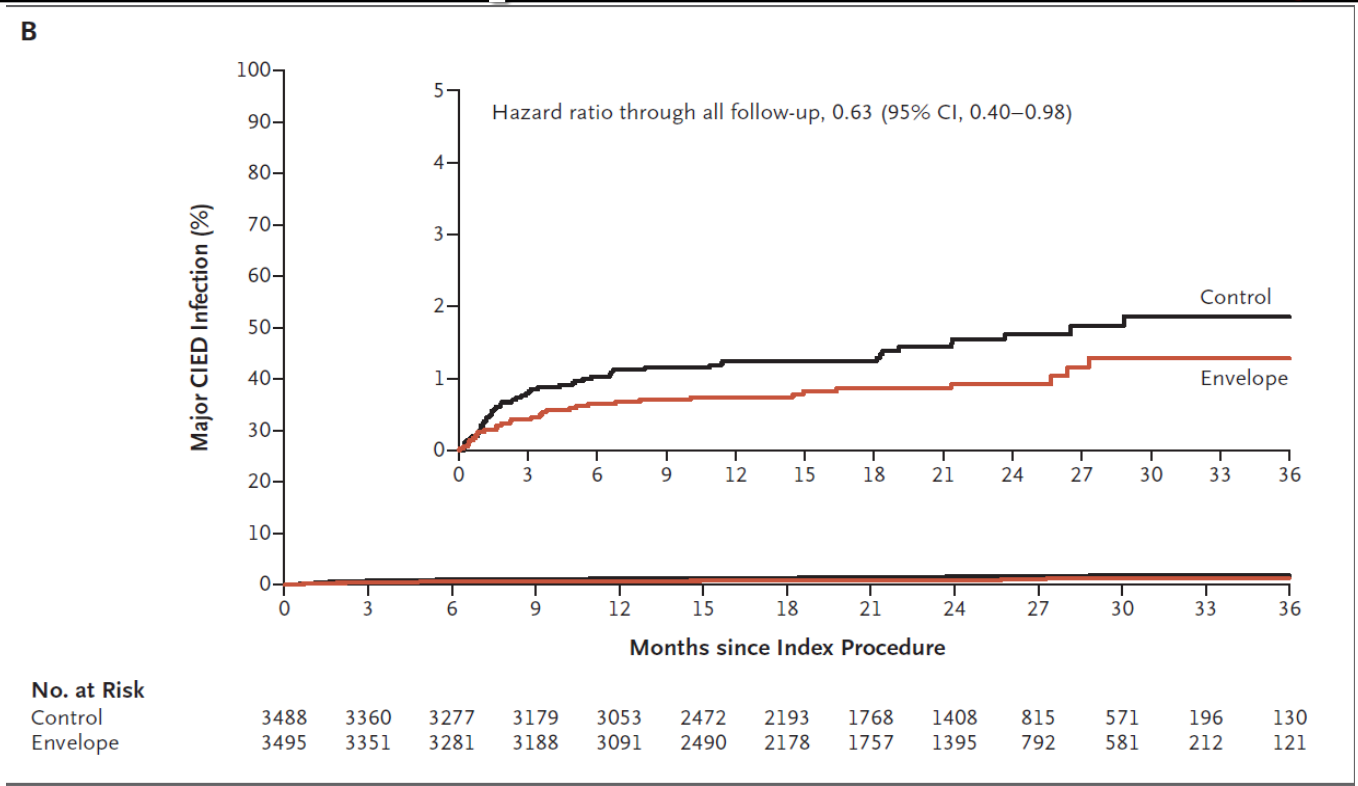
Vigourous irrigation with saline

Antibiotic envelope

- 6983 patients randomized : pocket revision / generator replacement / upgrade or initial CRT-D implantation (WRAP-IT study)
- Minocycline/Rifampicin
- Infections (system extraction):

25 in TYRX® (0.7 %) vs 42 (1.2 %) in control (HR 0.6)

- FU 20.7 ± 8.5 mo
- Lower-than-expected rate of infections (immunosuppressive treatments, dialysis excluded)



Tarakji KG et al. NEJM 2019

Risk factors

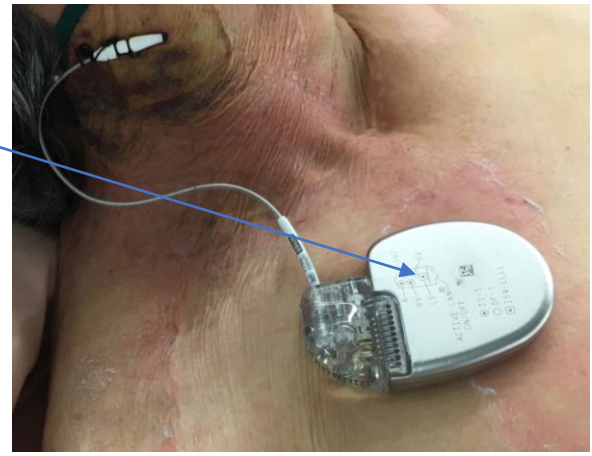
Procedure-related:		**Modifiable**
Haematoma: Risk x 9	→	No bridging / Careful haemostasis
Early reintervention	→	Reassess necessity
Device replacement / Upgrade	→	Reassess necessity
CRT/ICD	→	CSP ?
Procedure duration	→	Experienced operator
Operator experience	→	Experienced operator
Patient-related:	**ACTIONS**	**Modifiable**
End-stage renal disease		NA
Diabetes	→	Better glycaemic control
COPD		NA
Younger age	→	Leadless pacemaker / Epicardial ?
Prior device infection	→	Leadless pacemaker / Epicardial ?
Malnutrition	→	Optimal nutrition

Secondary prevention

- Reimplantation delayed until blood cultures are negative for at least > 72 h after extraction

- Reassess indication +++
  - 1/3 are not reimplanted after extraction

- Temporary pacemaker (ipsilateral active fixation strategy) in pacemaker-dependent patients requiring appropriate antibiotic treatment before reimplantation



- Leadless pacemakers / Entirely subcutaneous ICD
  - Wearable defibrillator (Life Vest, Zoll) as a bridge to reimplantation

- Antibiotic prophylaxis not recommended for CIED patients undergoing dental, respiratory, GI, genitourinary or cardiac procedures

Blomström-Lundqvist C et al. International consensus document on how to prevent, diagnose, and treat CIED infections. Eur Heart J 2020

Consider alternatives in high-risk patients…

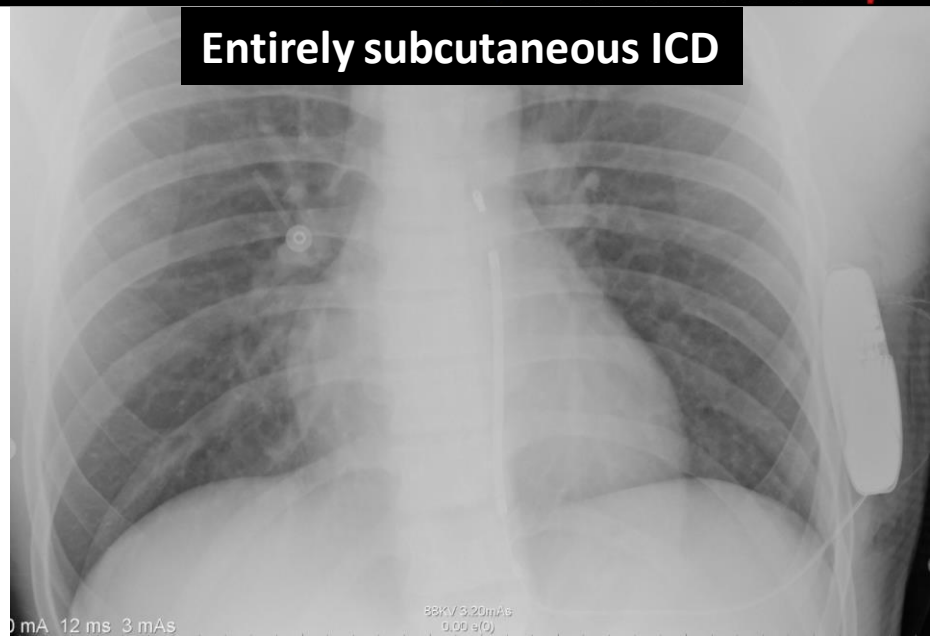
Leadless pacemaker

Reimbursement:
- Prior device infection
- Complex/complicated venous access (dialysis)

(Leadless pacemakers infection = 0.27 %)

Darlington D et al. Indian Pacing Electrophysiol J 2022

Entirely subcutaneous ICD



(S-ICD infection = 2.4 % over 3 years)

Boersma L et al. The EFFORTLESS study. JACC 2017

Secondary prevention

Modifiable

Patient-related factors
- Fever prior to implantation
- Skin disorders
- Heparin bridging
- Oral anticoagulants

Procedure-related factors
- Prolonged procedure
- Hematoma
- Prior procedure(s)
- Inexperienced implanter
- Temporary pacing wire

Device-lead-related factors
- Abdominal pocket

Non-modifiable

Patient-related factors
- End-stage renal disease
- Corticosteroid use
- Renal failure
- History of device infection
- COPD
- Heart Failure NYHA > II
- Malignancy
- Diabetes mellitus

Procedure-related factors
- Lead repositioning
- Device replacement/upgrade

Device-lead-related factors
- Device type: CRT or ICD
- More than 2 leads
- Abandoned / complex route leads
- Dual chamber device
- Presence of epicardial leads

Reassess indications for primary implantation, reoperation or re-implantation of a new device following lead extraction

Reduce risk by taking action on modifiable risk factors

- Postpone procedure if fever or infection
- Treat any comorbidity
- OAC uninterrupted Antiplatelets paused 1 w prior surgery if possible
- Experienced operator (shortens procedure duration & reduces lead dislodgement risk)
- Limit number of persons in operating room
- Follow outlined surgical field preparation /techniques
- Limit number of IV lines
- Replace temporary pacing by external pacing or drugs in non-dependent patient
- Evaluate need to use antibacterial envelopes

Administer preprocedural antibiotic prophylaxis as recommended

Consider epicardial pacing, leadless pacing, subcutaneous ICD

Blomström-Lundqvist C et al. International consensus document on how to prevent, diagnose, and treat CIED infections. Eur Heart J 2020

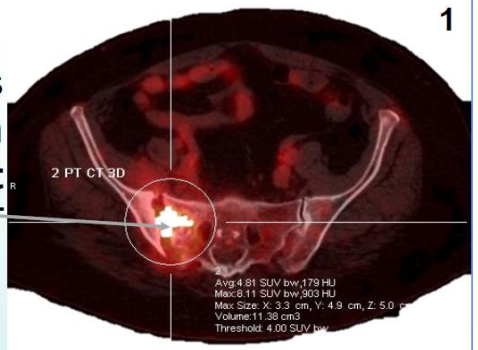
TEP scan before reimplantation

TEP Scan may help excluding « concealed » inflammatory/infectious process allowing safe reimplantation after lead extraction for endocarditis

Results

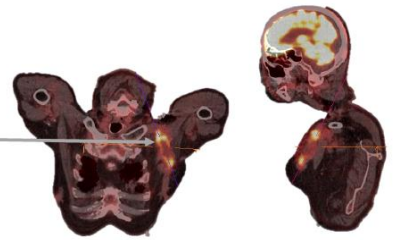
PET/CT performed 2 months after lead extraction for endocarditis complicating a DDD pacemaker in a 53-yo female revealed an uptake on the right coxofemoral joint, despite normal CRP. **Patient 1** received additional intravenous antibiotics and a second PET/CT still showed uptake, then delaying reimplantation.

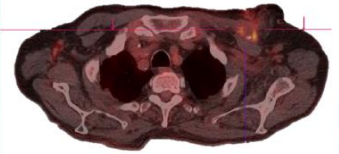
1



Patient 2, a 79-yo male with ischaemic cardiomyopathy and a significant uptake on the PET/CT 7 weeks after extraction, at the region of explantation, could be reimplanted endocardially with a CRT-D, after normalization of the uptake on a second PET/CT.

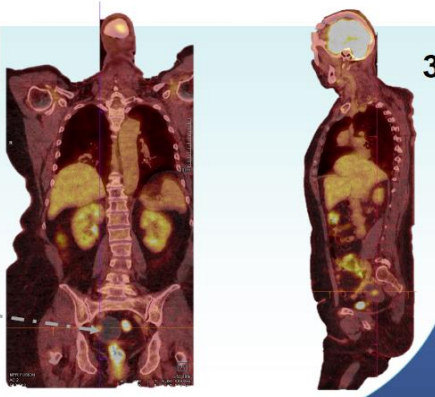
2

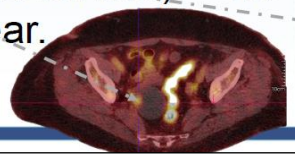




Patient 3, a 74-yo female with dilated cardiomyopathy could be reimplanted with a CRT-D after eradication of dental abscesses and removal of a benign ovarian tumor detected on the PET/CT realized 8 weeks after lead extraction (endocarditis). No complication occurred during the follow-up at one year.

3





Bun SS et al. Usefulness of Positon Emission Tomography to guide reimplantation after lead extraction for endocarditis. JESFC 2016.

Conclusion

- CIED Infections = Major concern
- Actions to modify risk factors
- « Prévenir plutôt que guérir »

PREVENT
by minimizing risk factors
for CIED infection

Patient-related | *Procedure-related* | *Device-lead-related*

Re-assess indications for primary implantation, reoperation or re-implantation following lead extraction

- **Preprocedural antibiotic prophylaxis as recommended**
- **Define strategies to prevent**
  - **pocket hematoma,**
  - **long procedure duration**
  - **re-intervention for lead repositioning.**

- Postpone procedure if fever or infection
- Treat any comorbidity
- OAC uninterrupted - Antiplatelets paused 1 w prior surgery if possible
- Experienced operator
- Limit number of persons in operating room
- Follow outlined surgical field preparation /techniques
- Limit number of I.V. lines, replace temporary pacing if possible
- Evaluate need to use antibacterial envelope
- *Consider epicardial pacing, leadless pacing, subcutaneous ICD*

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Thank you !

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