PRISE EN CHARGE DES ENDOCARDITES INFECTIEUSES SUR DISPOSITIFS ÉLECTRONIQUES INTRACARDIAQUES

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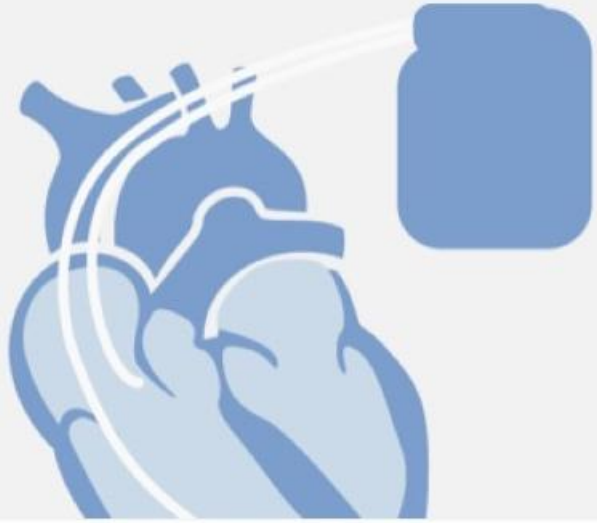
INTRODUCTION

Cardiovascular implantable electronic devices (CIEDs)

- Cardiac resynchronization therapy (CRT)
- Permanent pacemakers (PPMs)
- Implantable cardioverter defibrillators (ICDs)



INTRODUCTION

CIEDs are a cornerstone in modern management of cardiac arrhythmias, increasing both survival and quality of life

Infection is one of the most serious complications of CIED therapy

Associated with morbidity, mortality, and economic burden

QoL, quality of life.

Lakkireddy DJ, et al. J Am Coll Cardiol 2023;81:1283–1295.

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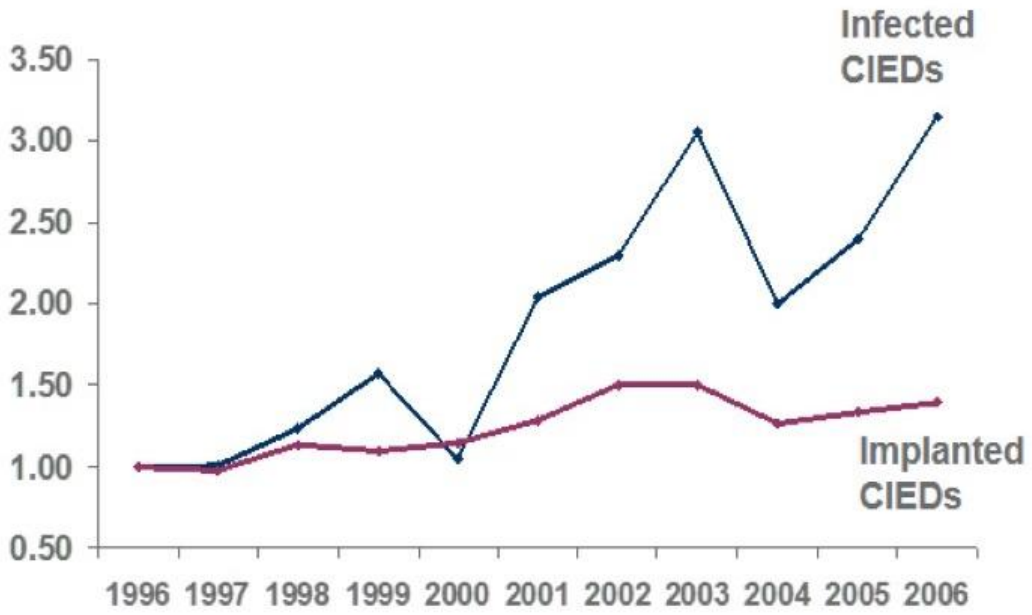
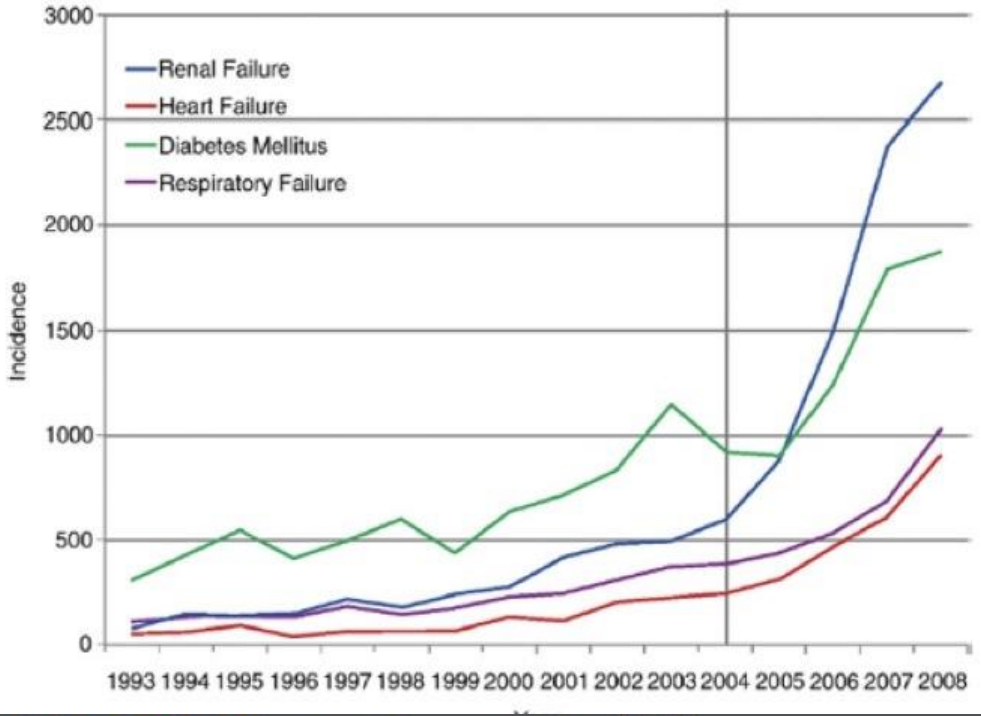
DEVICE INFECTION RATE RISING

National Hospital Discharge Survey[1]

Increase in CIED Implants and Hospitalizations for Infected CIEDs (Indexed to 1996)



Incidence of Comorbidities in Pts With CIED Infection[2]



Device infection jumped approximately 320% in a 10-y period[1,2]

Pt, patient.

1. Voigt, A. et al. Pacing Clin Electrophysiol. 2010;33:414-419. 2. Greenspon, A., et al. J Am Coll Cardiol. 2011;58:1001-1006.

National Tunisian Multicenter Prospective Study on Cardiac Implantable Electronic Devices (Tunisian NATURE-CIED study): One-Year Complications and Predictive Factors

Chabrak et al.

BACKGROUND & METHODS

The increasing prevalence of cardiac implantable electronic devices (CIEDs) in Tunisia is accompanied by complications related to vascular access, device pockets, leads, and patient characteristics.

This study aims to identify the prevalence, types, and predictors of complications within the first year of CIED implantation, and to characterize the demographic and epidemiological profiles of Tunisian patients with CIEDs.

The **Tunisian NATURE-CIED study** is a nationwide multicenter study that includes patients who underwent CIED implantation, replacement, or upgrade.

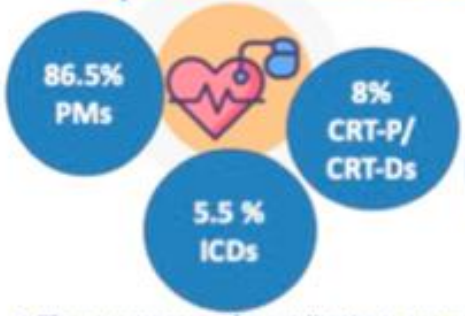
1500 patients enrolled
Mean age 70.1 ± 15.2 years
900 (60%) were treated in public hospitals, and 600 (40%) in private clinics
80 patients experienced 129 complications

Major Complications

A higher prevalence with:
- **CRT-D** (p=0,042)
- **System upgrade** (p=0.002)

Minor Complications

A higher prevalence with:
- **System upgrade**(p<0.001)



Complication rate

8.6%

517.4% in obese patients
179.3% in overweight patients
89.5% with non electrophysiologist implanter
62.7% in urgent procedures

Overall complications rate

56.2% in private clinics
64.2% in generator replacement

- The occurrence of complications was more prevalent in patients undergoing CRT-D devices implantation and upgrade procedures.
- Procedure-related variables influenced the incidence of both major and minor complications.
- These findings have implications for the development of personalized patient treatments and future CIED implantation strategies.

Table 2: Patients with complications according to Cardiac Implantable Electronic Devices type, procedure type and gender

Complications	Time of onset		CIED type							Procedure type				Gender		
			PM		CRTP	ICD		CRTD	P	De novo implantation	Generator replacement	Upgrade System	P	Male	Female	P
	3 Months 115 complications	12 Months 129 complications	Single 416	Dual 882	75	Single 30	Dual 52	45		1203	279	18		795	705	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)		N (%)	N (%)	N (%)		N (%)	N (%)	
Any major complication	53 (3,5)	59 (3.9)	17 (4.1)	32 (3.6)	4 (5.3)	-	1 (1.9)	5 (11.1)	**0.042**	53 (4.4)	5 (1.8)	1 (5.6)	**0.002**	31 (3.9)	28 (4)	0.943
Lead-related re-interventions	24 (1,6)	28 (1,9)	7 (1,7)	17 (1,9)	1 (1,3)	-	-	3 (6,7)	**0,037**	26 (2,2)	2 (0,7)	-	0,532	12 (1,5)	16 (2,3)	0,278
Procedure-related deaths	5 (0,3)	8 (0,5)	1 (0,2)	5 (0,6)	-	-	-	2 (4,4)	**0,012**	7 (0,6)	1 (0,4)	-	0,856	5 (0,6)	3 (0,4)	0,59
Probably procedure-related death	2 (0,1)	7 (0,5)	4 (1)	2 (0.2)	-	-	1 (1.9)	-	**<0,001**	5 (0,4)	2 (0,7)	-	0,768	3 (0,4)	4 (0,6)	0,59
Implantation failure	2 (0,1)	2 (0,1)	1 (0,2)	-	1 (1,3)	-	-	-	0,167	2 (0,2)	-	-	0,972	-	2 (0,3)	0,133
Tamponnade/Perforation	6 (0,4)	6 (0,4)	1 (0,2)	5 (0,6)	-	-	-	-	0,685	6 (0,5)	-	-	0,819	4 (0,5)	2 (0,3)	0,502
Pneumothorax requiring drainage	11 (0,7)	12 (0,8)	4 (1)	7 (0,8)	1 (1,3)	-	-	-	0,921	12 (1)	-	-	0,224	10 (1,3)	2 (0,3)	**0,023**
Hematoma requiring drainage	1 (0,1)	1 (0,1)	-	-	1 (1,3)	-	-	-	**0,002**	-	-	1 (5,6)	**<0,001**	1 (0,1)	-	0,346
Wound/Pocket infection	6 (0,4)	6 (0,4)	1 (0,2)	3 (0,3)	-	-	-	2 (4,4)	**0,004**	4 (0,3)	1 (0,4)	1 (5,6)	**0,003**	3 (0,4)	3 (0,4)	0,883
Systemic infections/endocarditis	1 (0,1)	1 (0,1)	-	-	-	-	-	1 (2,2)	**<0,001**	1 (0,1)	-	-	0,992	1 (0,1)	-	0,346
Twiddler's syndrome	1 (0,1)	1 (0,1)	-	1 (0,1)	-	-	-	-	0,986	1 (0,1)	-	-	0,992	-	1 (0,1)	0,288
Any minor complications	41 (2,7)	45 (3)	38 (2.9)		4 (5.3)	-	-	3 (6.7)	0.11	40 (3.3)	4 (1.4)	1 (5.6)	**<0.001**	24 (3)	21 (3)	0.964
Pneumothorax conservatively treated	7 (0,5)	7 (0,5)	2 (0,5)	4 (0,5)	-	-	-	1 (2,2)	0,590	7 (0,6)	-	-	0,42	6 (0,8)	1 (0,1)	0,082
Hematoma conservatively treated	4 (0,3)	4 (0,3)	1 (0,2)	2 (0,2)	1 (1,3)	-	-	-	0,606	4 (0,3)	1 (0,4)	-	0,967	2 (0,3)	3 (0,4)	0,6
Pericardial effusion	6 (0,4)	6 (0,4)	1 (0,2)	3 (0,3)	2 (2,7)	-	-	-	0,061	6 (0,5)	-	-	0,819	5 (0,6)	1 (0,1)	0,136
HF/LVFE decrease	5 (0,3)	5 (0,3)	2 (0,5)	3 (0,3)	-	-	-	-	0,966	1 (0,1)	-	-	0,992	1 (0,1)	-	0,795
Phrenic nerve stimulation	6 (0,4)	6 (0,4)	1 (0,2)	2 (0,2)	2 (2,7)	-	-	1 (2,2)	**0,011**	5 (0,4)	-	1 (5,6)	**0,002**	1 (0,1)	5 (0,7)	0,074
Pacing threshold increase	14 (0,9)	14 (0,9)	2 (0,5)	11 (1,2)	-	-	-	1 (2,2)	0,528	12 (1)	3 (1,1)	-	0,991	6 (0,8)	9 (1,3)	0,311
Rhythm/Conduction impairment	14 (0,9)	14 (0,9)	-	14 (1,6)	-	-	-	-	0,078	8 (0,7)	-	-	0,724	4 (0,5)	4 (0,6)	0,865

Journal Pre-proof

CIED INFECTION RATES

- It is difficult to give a precise rate of CIED infections because of divergent definitions, varied populations, and the range of rates in retrospective and prospective studies

- Infection rates in prospective observational studies registries and more recent cross-over cluster PADIT- and randomized WRAP-IT trials: **0.6–1.3%**
- Retrospective studies : **2.3–3.4%** in the first year after implantation

CIED INFECTION RATES

- First time implantation:
  0,5% to 1%
- Replacement/ Upgrade:
  1% to 5%

Year	Author	Study design	Study size	DRI rate
1994	Chauhan[60]	Case control	2019	0.8%
1994	Mounsey[63]	Open, RCT	656	2%
1998	Smith[112]	Case control	1821	1.2%
1998	Spinler[46]	Case control	202	4.5%
2001	Mela[113]	Case control	1700	1.7%
2006	Bloom[43]	Case control	4856	1.5%
2007	Sohail[22]	Nested case control	12770 (58)	0.2%
2007	Klug[33]	Case control	6319	0.6%
2009	Lekkerkerker[36]	Case control	3410	2.2%
2009	de Oliveira[55]	Blinded RPCT	649	2%
2009	Margey[114]	Case control	3105	1.26%
2010	Nery[35]	Nested case control	2417 (75)	0.99%
2010	Romeyer-Bouchard[44]	Case control	290	4.48%
2010	Cengiz[50]	Case control	833	6.84%
2010	Johansen[13]	Case control	46299	0.70%
2012	Raad[56]	Nested case control	NR (53)	NA
2014	Mittal[45]	Case control	1651	1.51%

Sandoe et at J Antimicr Chemother 2015
Pathfield et at HR 2015

PROGNOSIS OF CIED INFECTION

- 30-day mortality rate : **5%**
- 1-year mortality rate : **15%**
- **X7** increase in 30-day mortality if CIED is not removed
- **>95%** of patients with pocket infection or endocarditis can be cured with lead extraction and ATB
- Early diagnosis of CIED infection & lead extraction within **3 days** of diagnosis: lower in hospital mortality

ECONOMIC BURDEN OF CIED INFECTION

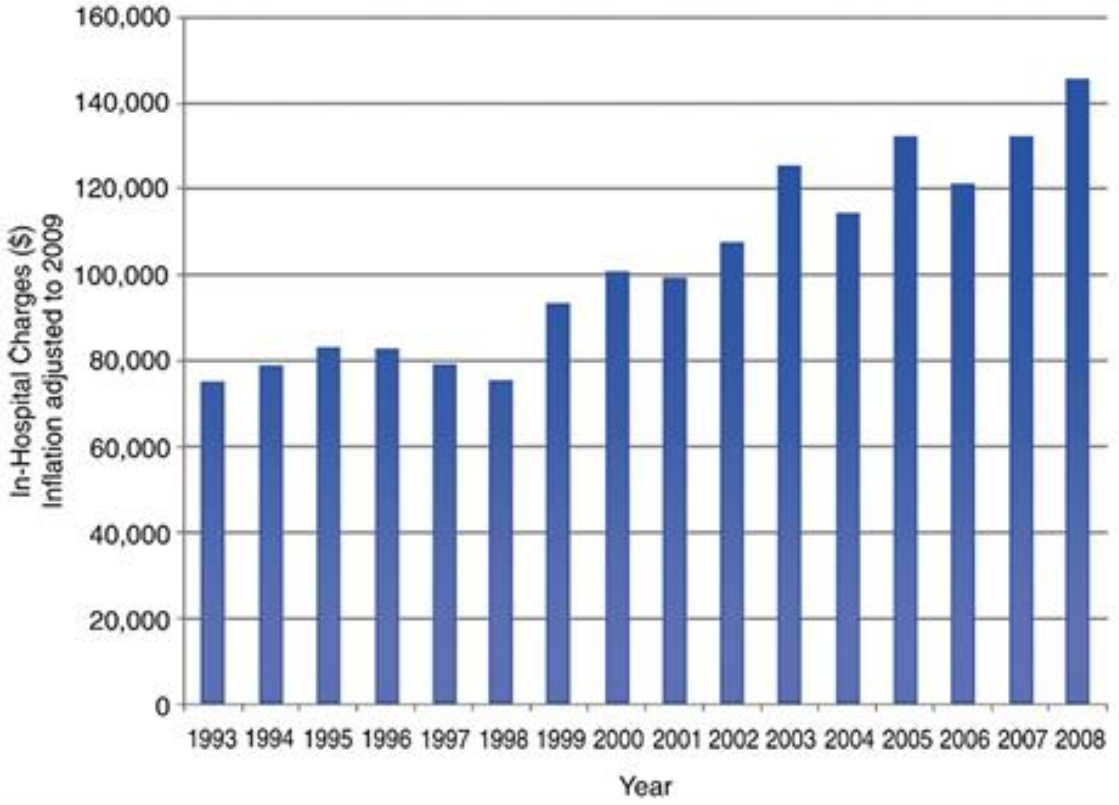


Figure 6 In-Hospital Charges Associated With CIED Infection (Inflation Adjusted to 2009)

Reasons for higher costs:

- High resource utilization
- Hospitalizations
- Cost increased with time to device extraction.
- Increased length of stay

Compared to endocarditis of prosthetic and native valves, patients with CIED infective endocarditis had the longest length of stay (17 days) and highest hospital costs (mean $56,000).[19]

RISK FACTORS FOR CIED INFECTION

Host-related risks factors

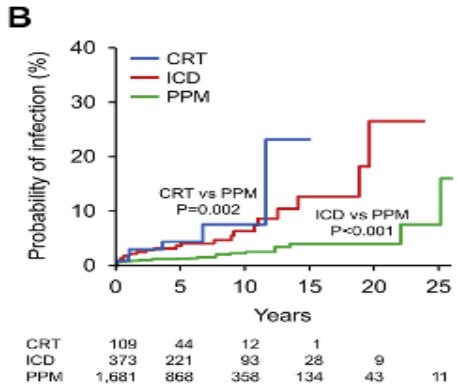
- End-stage kidney disease
- Previous device infection
- Corticosteroid use
- Chronic obstructive lung disease
- Malignancy
- Diabetes mellitus
- Heart failure
- Anticoagulant use
- Skin disorders
- Older age with comorbidities
- Pre-procedure fever

Procedure-related risk factors

- Procedure duration
- Postoperative hematoma
- Reintervention for lead dislodgement
- Operator inexperience
- Temporary pacing
- Device replacement/revision
- Lack of antibiotic prophylaxis

Device-related characteristics:

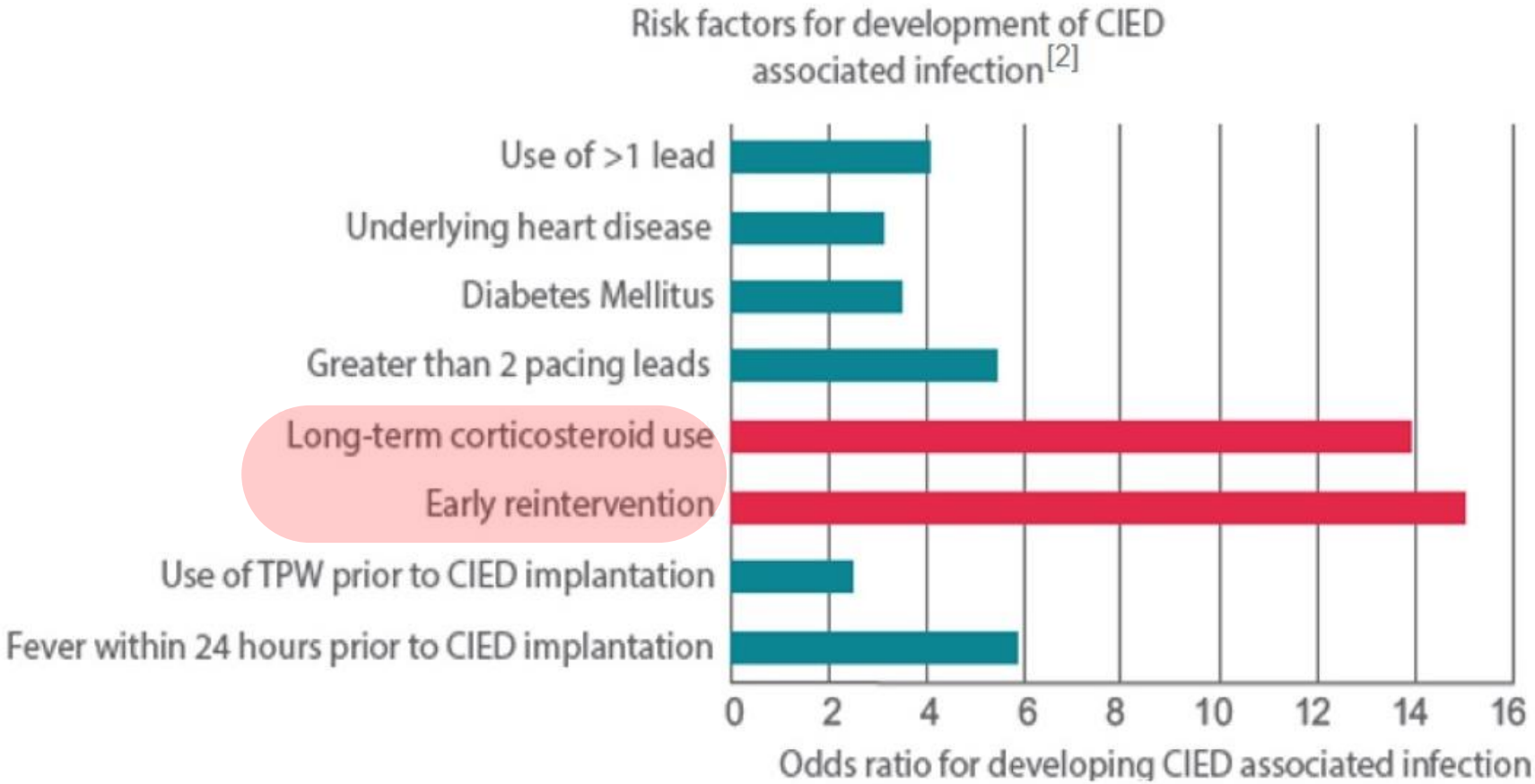
- Abdominal pocket
- Positioning of two or more leads
- ICD, CRT-P, or CRT-D greater risk than PPM



			Total CIED infections		
			Overall incidence		Incidence rate/1000 CIED-years
	CIED implants	CIED-years	*n* (%)	95% CI	(95% CI)
1st operation *De novo* implantation	80 430	344 165	869 (1.08)	1.01–1.15	2.52 (2.36–2.70)
2nd operation (1st reoperation)	20 759	86 079	407 (1.96)	1.78–2.16	4.73 (4.29–5.21)
3rd operation (2nd reoperation)	5292	20 361	170 (3.21)	2.75–3.72	8.35 (7.18–9.70)
4th operation (3rd+ reoperation)	2013	7651	110 (5.47)	4.51–6.55	14.38 (11.93–17.33)
Total	108 494	458 257	1556 (1.43)	1.36–1.51	3.40 (3.23–3.57)

Olsen, Thomas, Ole Dan Jørgensen, Jens Cosedis Nielsen, Anna Margrethe Thøgersen, Berit Thornvig Philbert, Maria Hee Jung Park Frausing, Niels Christian Foldager Sandgaard, et Jens Brock Johansen. « Risk Factors for Cardiac Implantable Electronic Device Infections: A Nationwide Danish Study ». *European Heart Journal* 43, nº 47 (14 décembre 2022): 4946-56. https://doi.org/10.1093/eurheartj/ehac576.

RISK FACTORS FOR CIED INFECTION



TPW, temporary pacing wire.

1. Lakkireddy DJ, et al. J Am Coll Cardiol. 2023;81:1283-1295; 2. Wilson DG, et al. Europace. 2015;17:511-513.

INFECTION TYPES

- CIED infections occur via two major mechanisms:

➢ The most common is contamination of leads and/or pulse generator during implantation or subsequent manipulation

➢ The second mechanism is a bloodstream infection.

INFECTION TYPES

Pocket Infection

- Local occurrence where device was implanted

Manifestations of Pocket Infections[2]

Signs/symptoms:

- Skin redness, pain/tenderness, swelling/warmth
- Drainage
- Skin ulceration
- Device erosion

Systemic Infection

- Bacteremia/fungemia
- Lead-associated endocarditis
- > 2 leads, ICD/CRT, device revision or upgrade

Signs/symptoms:

- Fever/chills
- Malaise
- Nausea
- Hypotension
- Murmur on examination
- Symptomatic HF

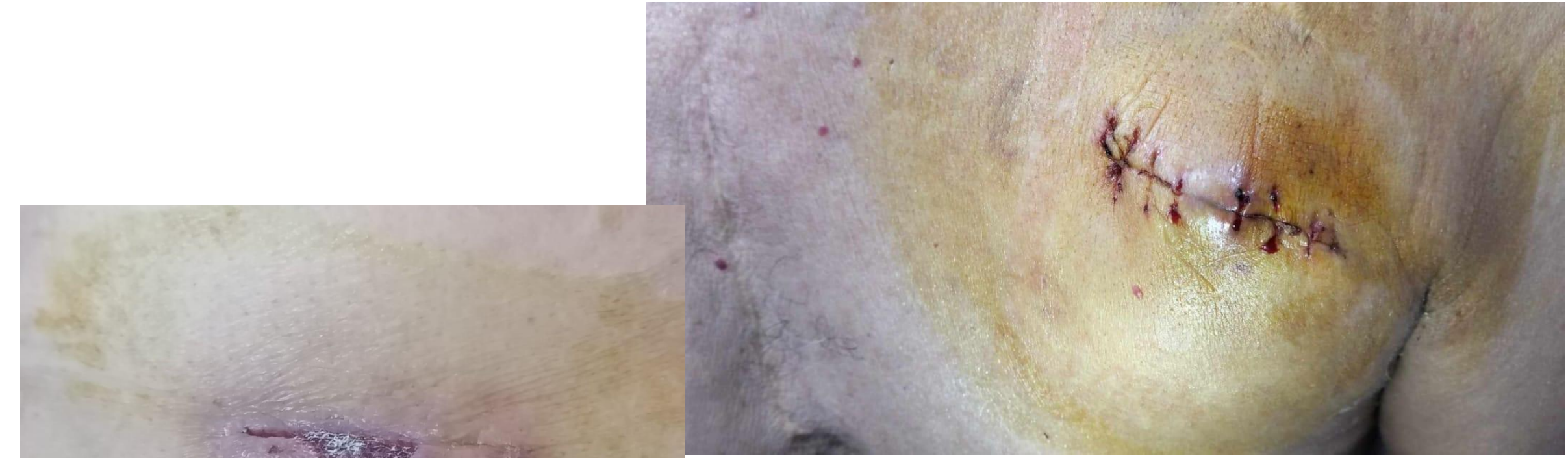
POCKET INFECTION

- More common in early-onset illness (< 1 year of device implantation)

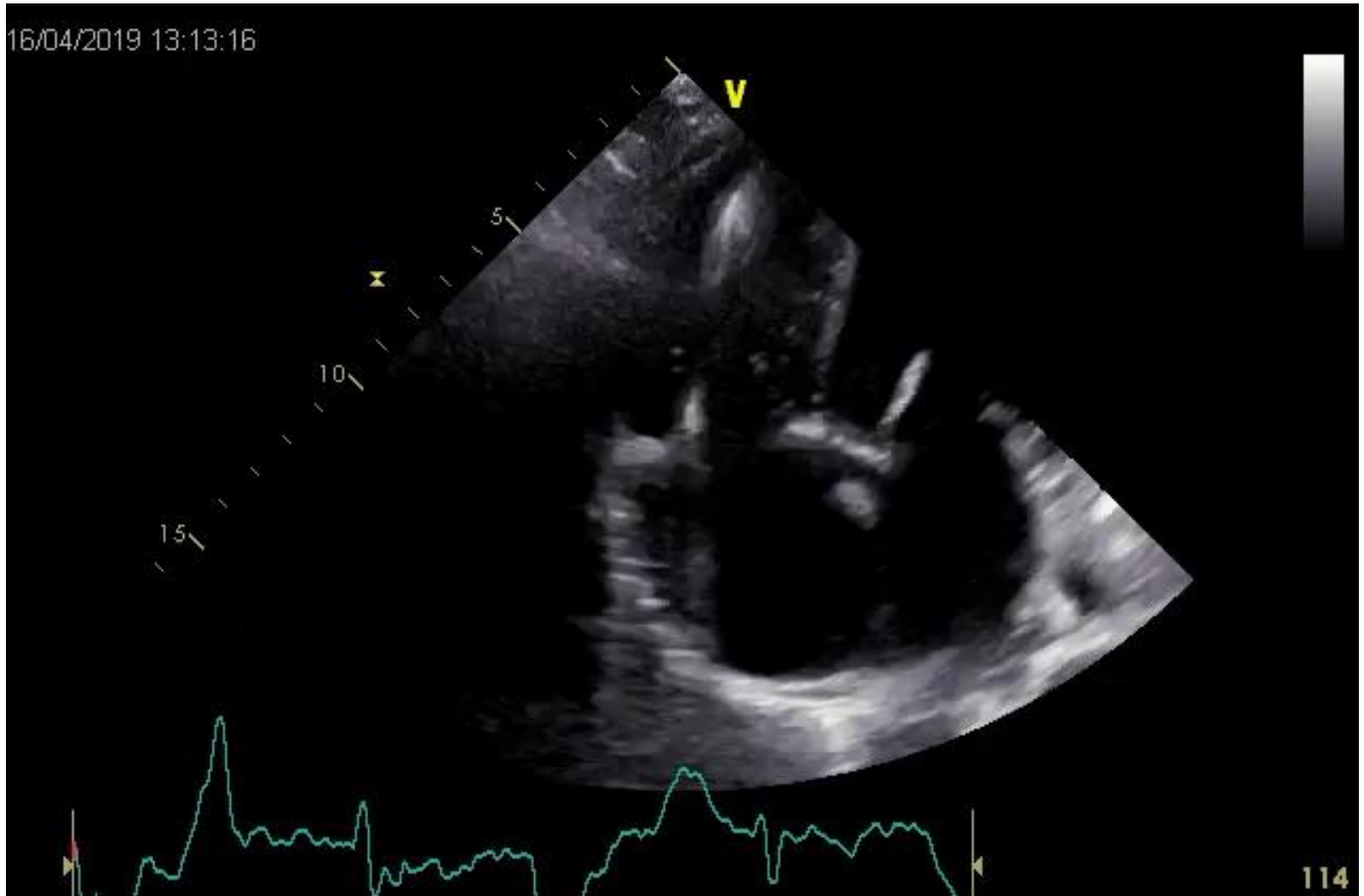
- Localized pocket warmth, tenderness, erythema, fluctuance, purulent drainage

POCKET INFECTION

Wound dehiscence or erosion of the generator or leads



CIED RELATED INFECTIVE ENDOCARDITIS



GUIDELINES

ESC European Society of Cardiology
European Heart Journal (2023) 44, 3948–4042
https://doi.org/10.1093/eurheartj/ehad193
ESC GUIDELINES

2023 ESC Guidelines for the management of endocarditis

Developed by the task force on the management of endocarditis of the European Society of Cardiology (ESC)

Update on Cardiovascular Implantable Electronic Device Infections and Their Prevention, Diagnosis, and Management: A Scientific Statement From the American Heart Association

January 9, 2024

Endorsed by the International Society for Cardiovascular Infectious Diseases

ESC European Society of Cardiology
Europace (2019) 0, 1–35
doi:10.1093/europace/euz246
EHRA CONSENSUS PAPER

European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections—endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)

2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction

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Duke modified Criteria – EHRA 2020

- **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** = presence of either 2 major criteria or 1 major + 3 minor criteria

- **Possible**
  minor c

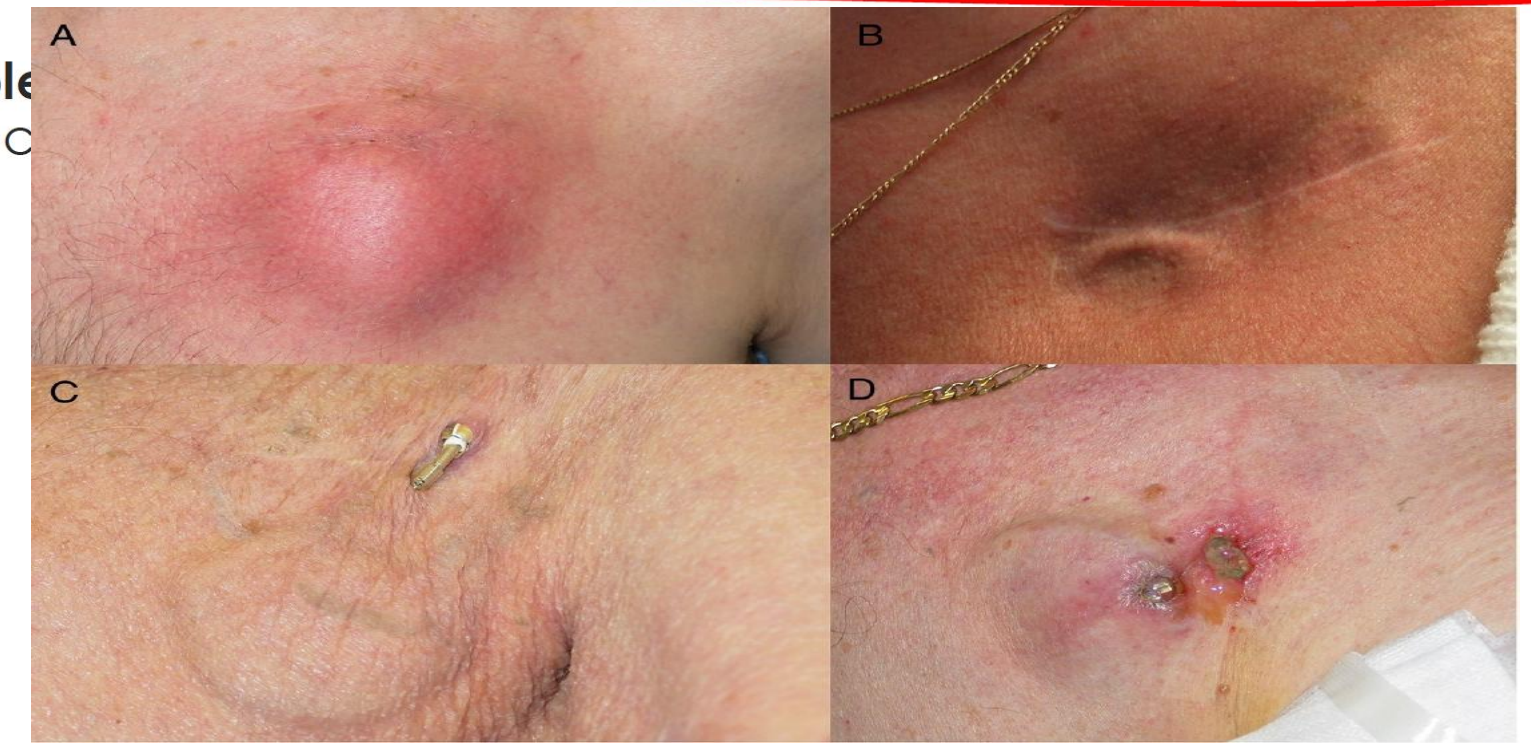


Table 5 Recommendations for diagnosis of CIED infections and/or infective endocarditis: the Novel 2019 International CIED Infection Criteria

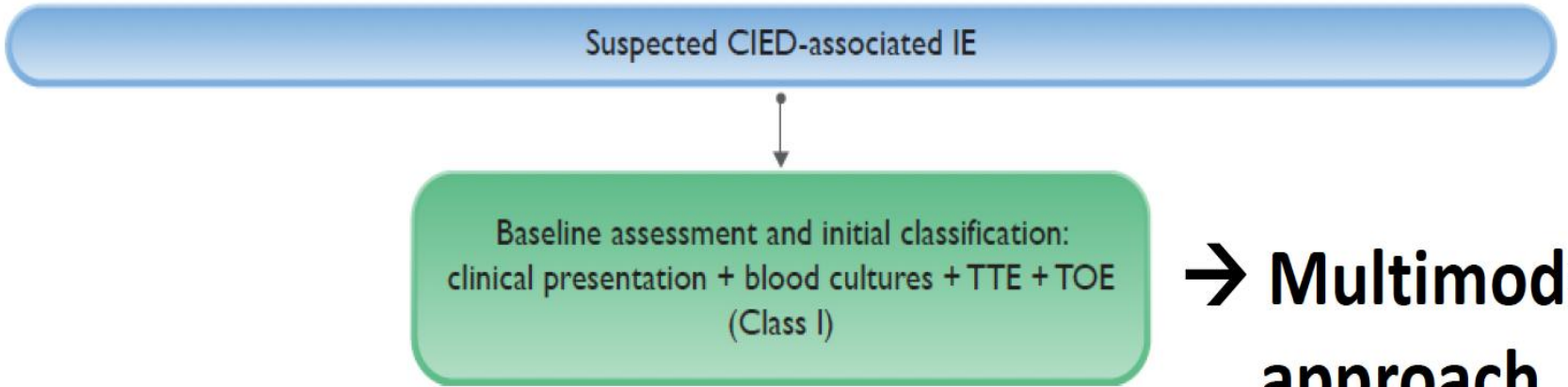
Major criteria		E	[59]
Microbiology	A. Blood cultures positive for typical microorganisms found in CIED infection and/or IE (*Coagulase-negative staphylococci*, *S. aureus*)		
	B. Microorganisms consistent with IE from 2 separate blood cultures:		
	a. Viridans streptococci, *Streptococcus gallolyticus* (*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		
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. [^{18}F]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		
Minor criteria		E	[59]

a. Predisposition such as predisposing heart condition (e.g. new onset tricuspid valve regurgitation) or injection drug use

b. Fever (temperature >38°C)

c. Vascular phenomena (including those detected only by imaging): major arterial emboli, septic pulmonary embolisms, infectious (mycotic) aneurysm, intracranial 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)



→ **Multimodal approach**

1. **Bacteriological culture**
   - Bloodstream - *Major criteria*
   - Extraded lead – CIED - *Minor criteria*

2. **Sign of infection**
   - Pocket infection - *Major criteria*
   - Intracardiac or intravascular image of CIED infection or valve IE- *Major criteria*
   - Secondary location - *Minor criteria*
   - Source of entry - *Minor criteria*
   - Fever > 38°C - *Minor criteria*

Delgado, Guidelines 2023 https://doi.org/10.1093/eurheartj/ehad193.

Blomström-Lundqvist, EHRA Concensus paper 2020 https://doi.org/10.1093/europace/euz246.

MULTYMODALITY IMAGING

TTE is recommended as the first-line imaging modality in patients with suspected CIED-related IE

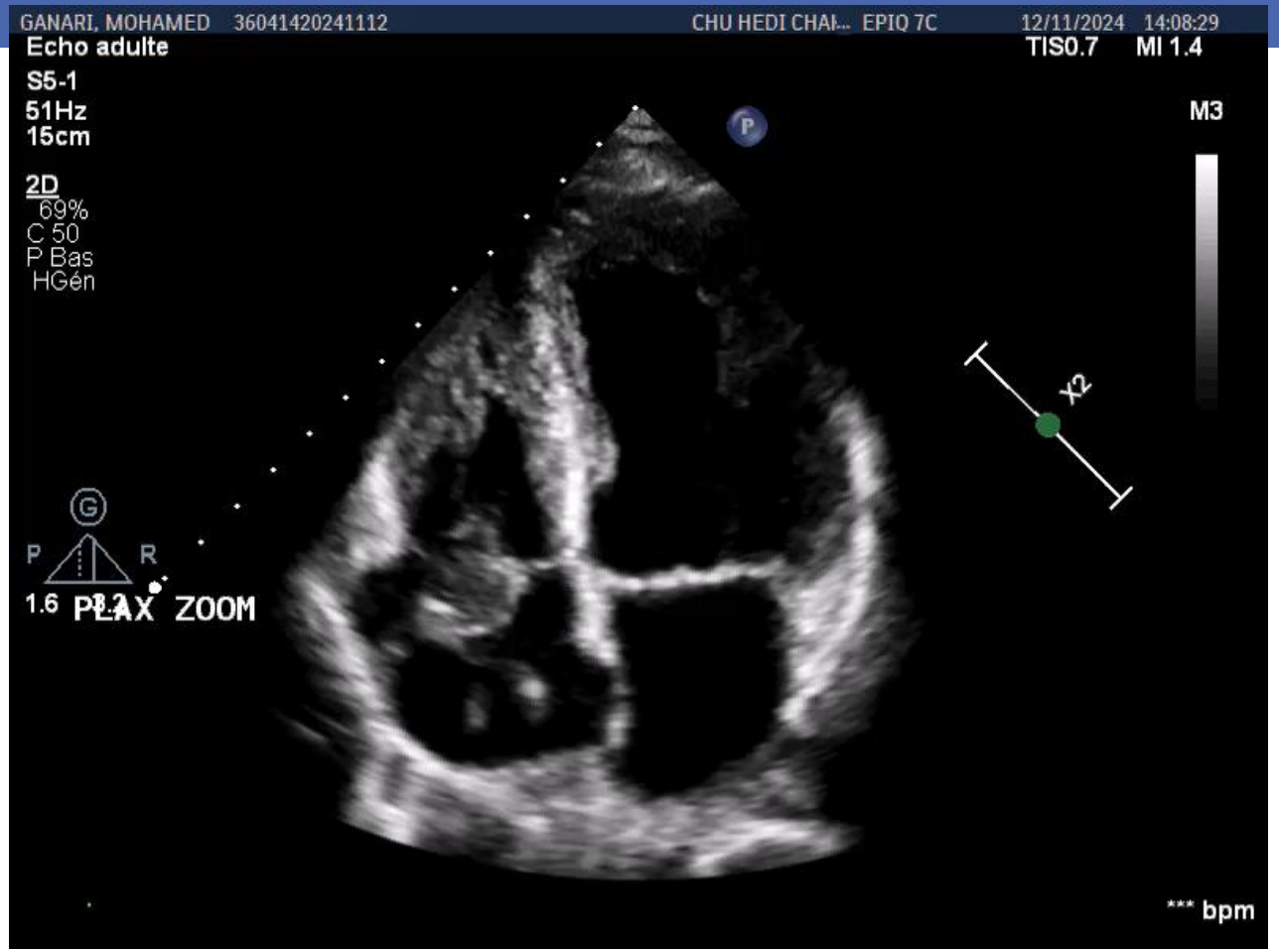
TEE is recommended in suspected CIED infection with positive or negative blood cultures, independent of TTE results before an extraction, to evaluate CIED infection and IE

Repeat TTE and/or TEE within 5–7 days is recommended in case of initially negative examination when clinical suspicion of CIED-related IE remains high

A chest X-ray should be performed in all patients with suspected CIED infection

EHRA 2020

TTE/TEE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1.6
PLAX ZOOM
*** bpm

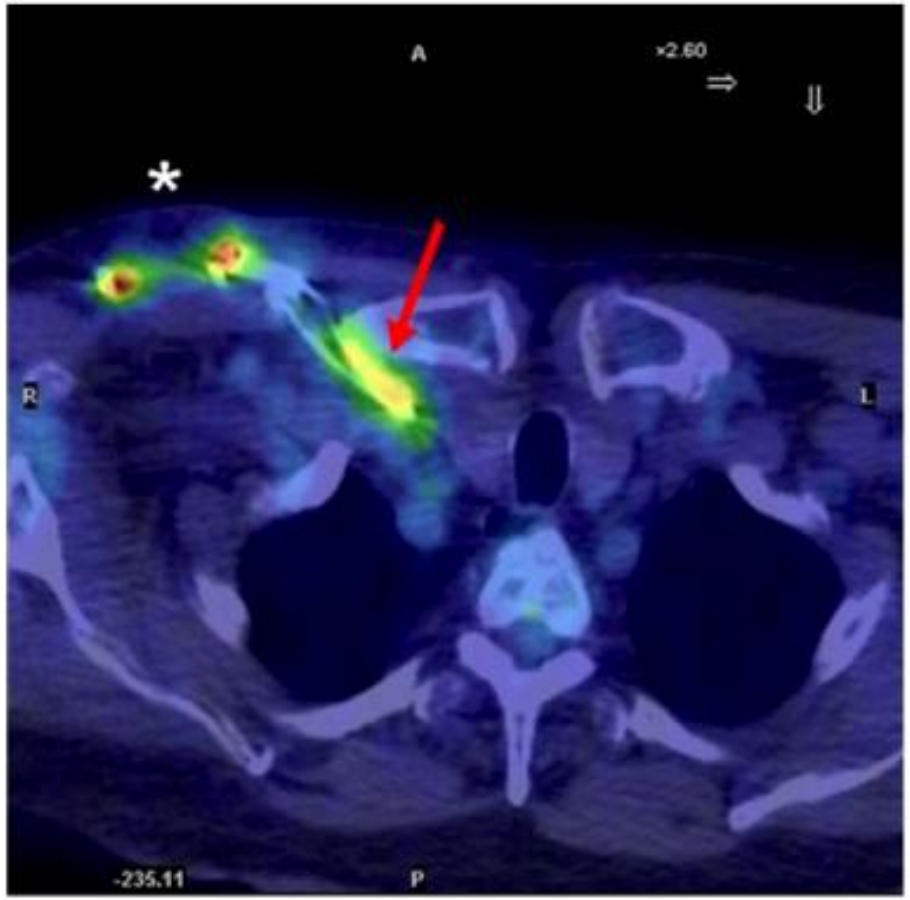
PET-SCANNER

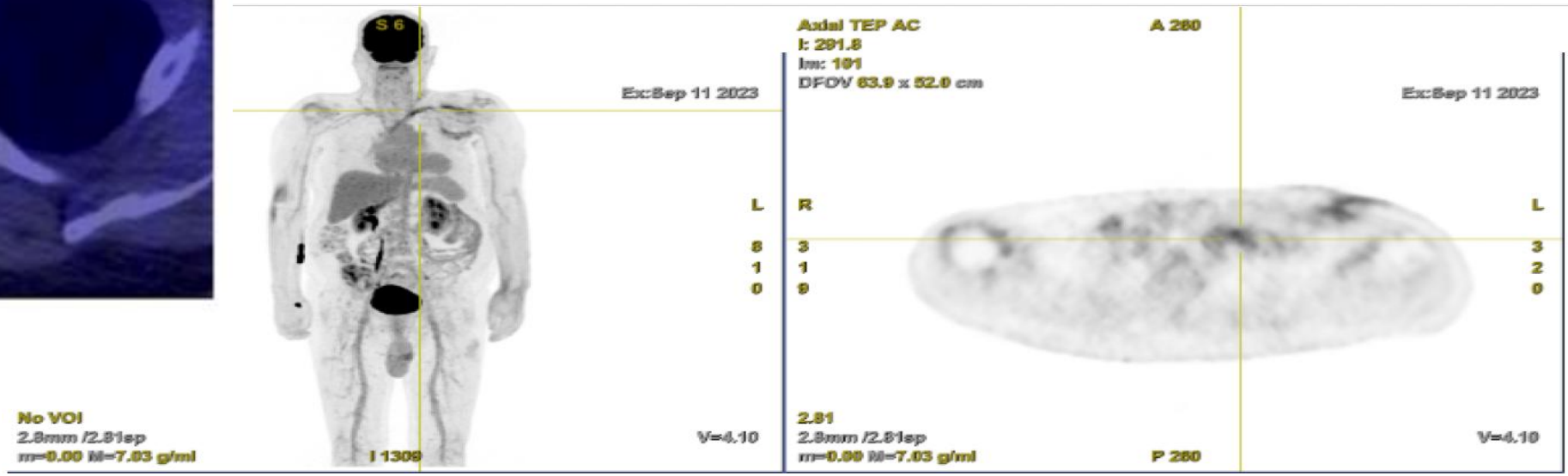
[^{18}F]FDG PET/CT scanning or radiolabelled WBC scintigraphy or contrast enhanced CT are recommended if suspected CIED-related IE, positive blood cultures, and negative echocardiography (attention in imaging interpretation early after device implant)

[^{18}F]FDG PET/CT should be performed in case of *S. aureus* bacteremia in CIED patients

[^{18}F]FDG PET/CT, radiolabelled WBC scintigraphy and/or contrast enhanced CT is recommended for identification of unexpected embolic localizations (i.e. lung embolism) and metastatic infections

EHRA 2020


A
×2.60
R
L
-235.11
P


S 6
Ex:Sep 11 2023
L
8
1
0
I 1309
No VOI
2.8mm /2.81sp
m=0.00 M=7.03 g/ml
V=4.10
Axial TEP AC
I: 291.8
Im: 101
DFOV 63.9 x 52.0 cm
A 280
Ex:Sep 11 2023
R
L
3
1
9
3
2
0
2.81
2.8mm /2.81sp
m=0.00 M=7.03 g/ml
P 280
V=4.10

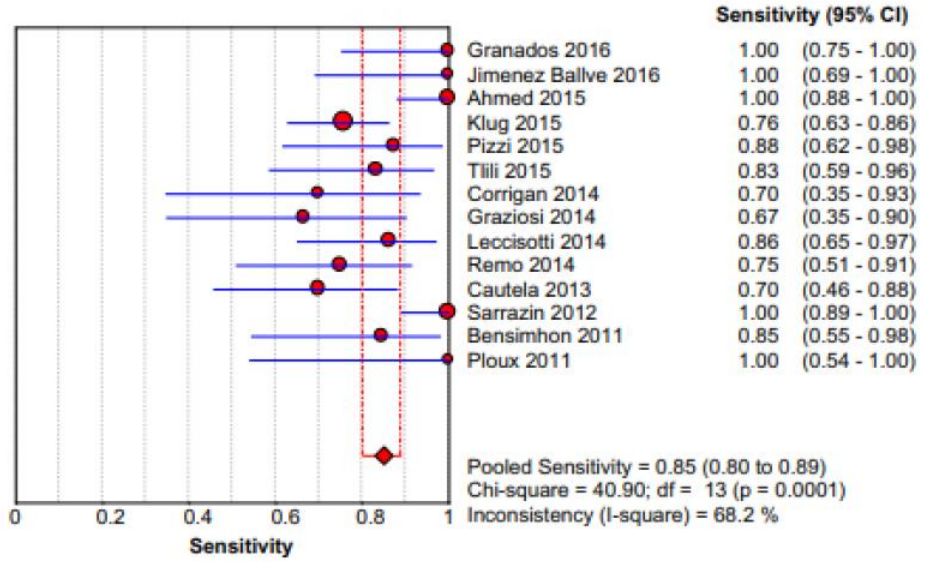
Role of 18F-FDG PET/CT in the Diagnosis of Cardiovascular Implantable Electronic Device Infections: A Meta-Analysis

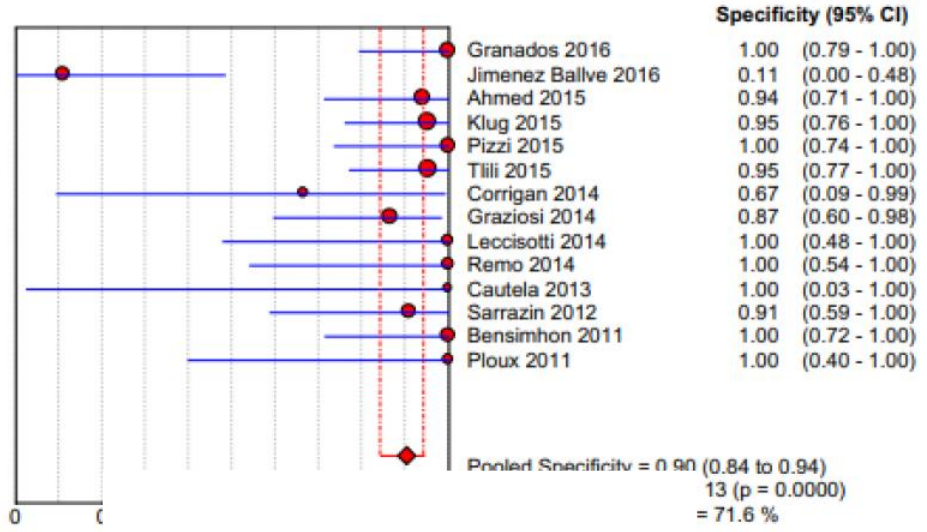
Diagnostic accuracy pocket infections:

- Pooled **sensitivity of 96%** *(95% CI 86%-99%; Q = 4.93, P = .085; I 2 = 59.4%)*
- Pooled **specificity of 97%** *(95% CI 86%-99%; Q = 1.70, P = .429; I 2 = 0.0%).*

Diagnostic accuracy for lead infections

- pooled **sensitivity of 76%** (*95% CI 65%-85%; Q = 30.87, P.01; I2 = 80.6%)*
- pooled **specificity of 83%** *(95% CI 72%-90%; Q = 40.53, P\.01;I2 = 85.2%)*





Mahmood, Maryam, Ayse Tuba Kendi, Saira Farid, Saira Ajmal, Geoffrey B. Johnson, Larry M. Baddour, Panithaya Chareonthaitawee, Paul A. Friedman, et M. Rizwan Sohail. *Journal of Nuclear Cardiology* 26, nº 3 (juin 2019): 958-70. https://doi.org/10.1007/s12350-017-1063-0.

MANAGEMENT

COMPLETE HARDWARE REMOVAL

+ ANTIBIOTICS

COMPLETE HARDWARE REMOVAL

Class I

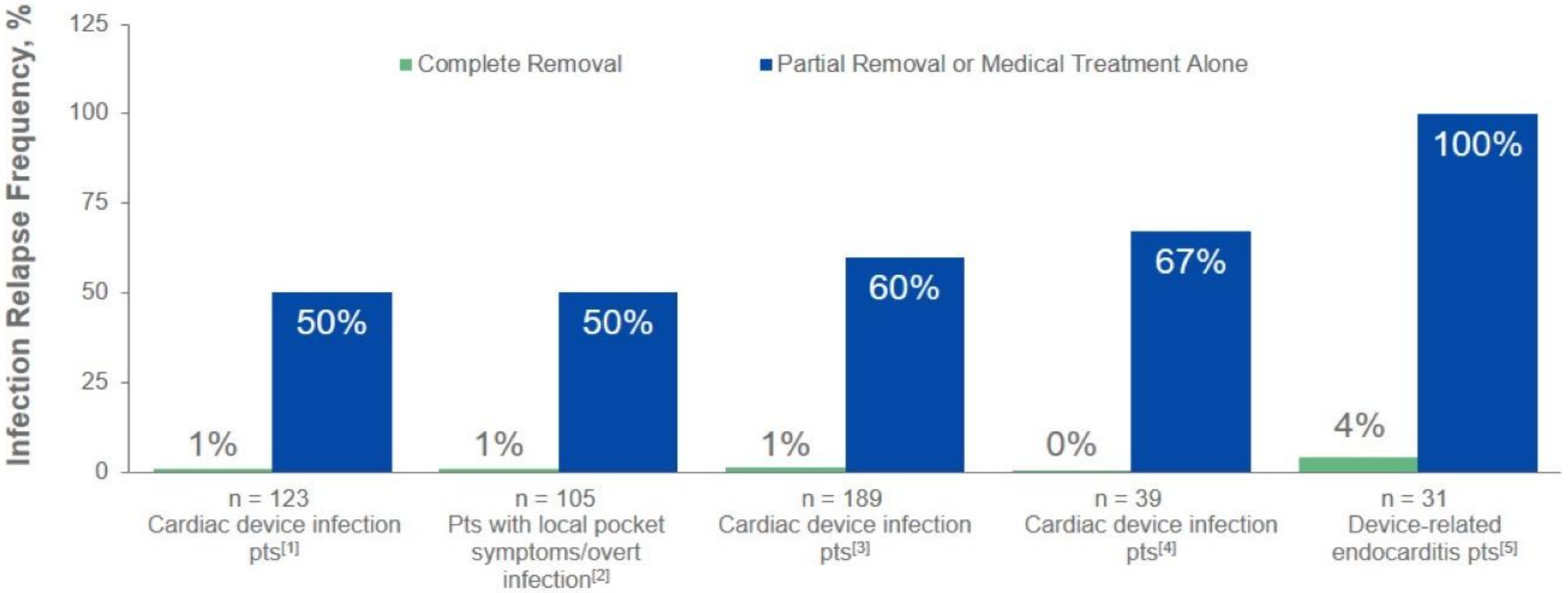
1. Complete device and lead removal is recommended for all patients with definite CIED infection, as evidenced by valvular and/or lead endocarditis or sepsis. (*Level of Evidence: A*)[1,a-b]

GUIDELINE	RECOMMENDATIONS	
	Complete Extraction	Prompt Extraction
AHA 2010[1]	x	x
BHRS 2014[2]	x	x
ESC 2015[3]	x	
HRS 2017[4]	x	x
EHRA 2020[5]	x	x

*"Delaying the definitive operation with removal of all of the components of the CIED system can be a **fatal choice** for the patient."*
2009 HRS/ACC/AHA Consensus Document

AHA, American Heart Association; BHRS, British Heart Rhythm Society; EHRA, European Heart Rhythm Association; ESC, European Society of Cardiology; HRS, Heart Rhythm Society.
a. Class I: benefit >>> risk. Procedure/treatment should be performed/administered. b. Level of evidence - Data derived from multiple randomized clinical trials or meta-analyses.
1. Baddour LM, et al. Circulation. 2010;121:458-477. 2. Sandoe JAT, et al. J Antimicrob Chemother. 2015;70:325-359. 3. Habib G, et al. Eur Heart J. 2015;36:3075-3128. 4. Kusumoto FM, et al. Heart Rhythm. 2017;14:e503-e551. 5. Blomström-Lundqvist C, et al. Europace. 2020;22:515-549.

RISK OF RELAPSE WITHOUT COMPLETE REMOVAL



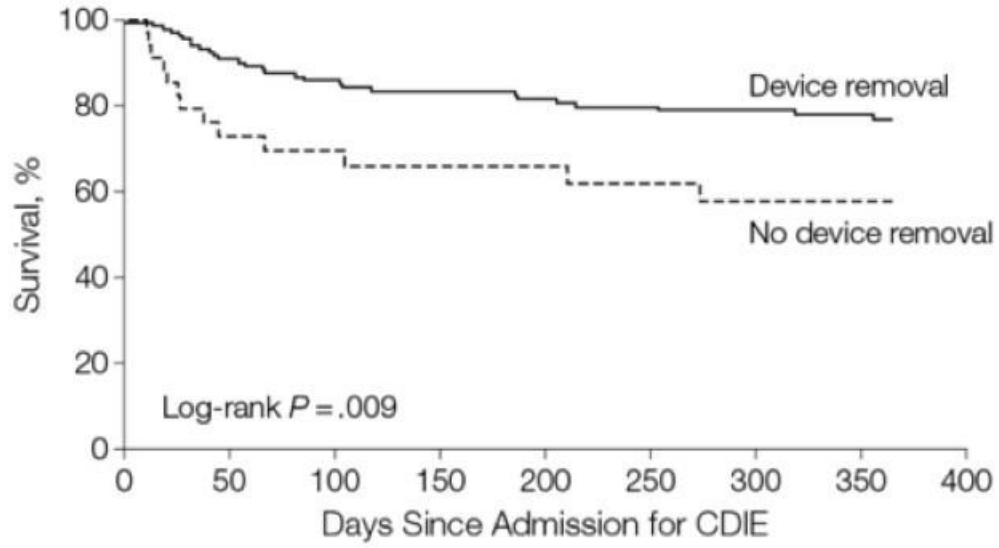
Infection relapse occurs in **50% to 100%** of cases with **partial removal or ABX treatment** alone compared to relapse of **0% to 4.2%** with **complete system removal**

ABX, antiobiotics.

1. Chua JD, et al. Ann Intern Med. 2000;133:604-608. 2.Klug D, et al. Heart. 2004;90:882-886. 3. Sohail MR, et al. J Am Coll Cardiol. 2007;49:1851-1859. 4. Margey R, et al. Europace. 2010;12:64-70. 5. del Rio A, et al. Chest. 2003;124:1451-1459.

SURVIVAL WITH CIED INFECTION

1-Y Survival in Pts With Cardiac Device Infective Endocarditis[1]



Δ 18.2%

	30-d mortality, HR (95% CI)	1-y mortality, HR (95% CI)
ABX Only vs Complete Removal[2]	6.97 (1.36, 35.6)	1.61 (0.37, 6.86)

SAFETY OF TLE

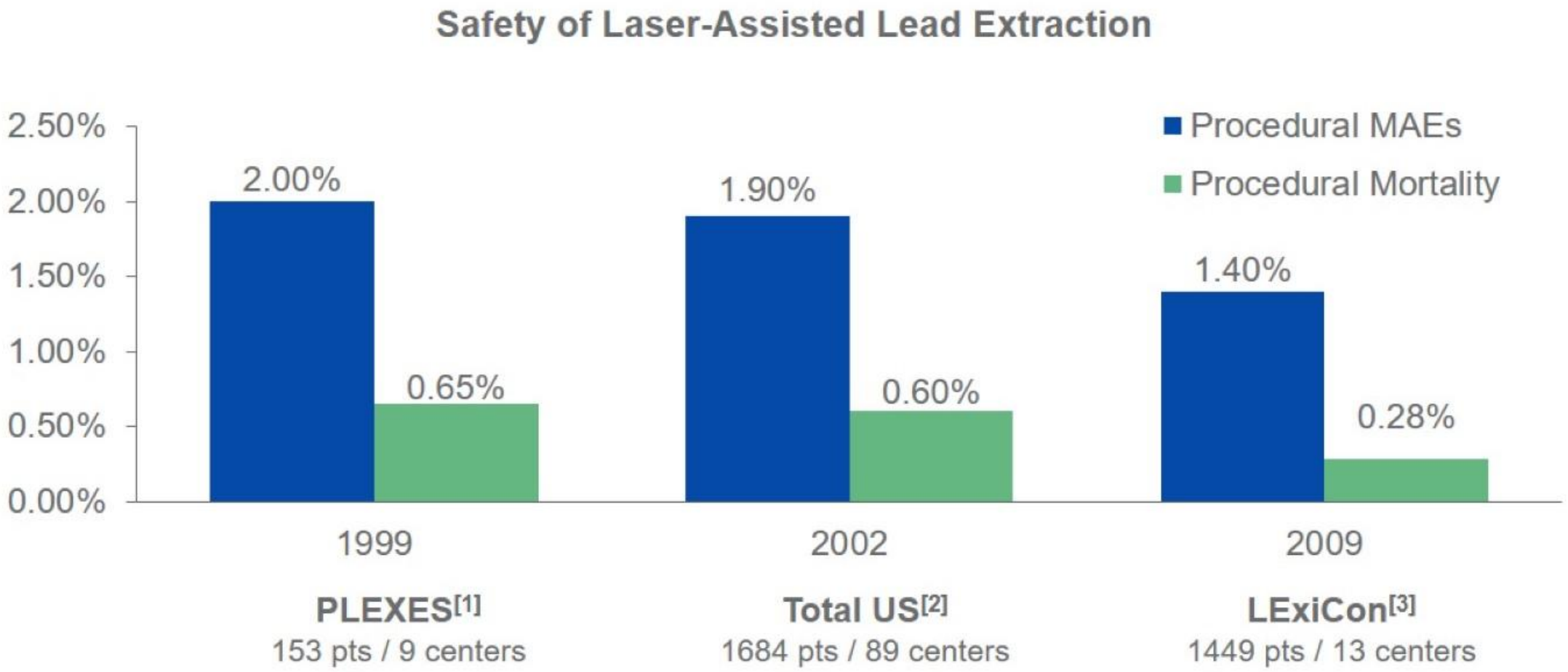
Safety and Success of Transvenous Lead Extraction
A Meta-Analysis of Over 1700 Pts

Outcomes of Transvenous Lead Extraction Using Excimer Laser Sheath

Variable	Outcomes of TLE (%)
Procedural success	96.8%
Clinical success	98.3%
Major complications	1.9%
Minor complications	1.9%
Procedure-related deaths	0.08%

Rinaldi CA, et al. Europace. 2023;25:euad298.

SAFETY OF LASER ASSISTED



MAE, major adverse event.

1. Wilkoff BL, et al. J Am Coll Cardiol. 1999;33:1671-1676. 2. Byrd CL, et al. Pacing Clin Electrophysiol. 2002;25:804-808; 3. Wazni O, et al. J Am Coll Cardiol. 2010;55:579-586.

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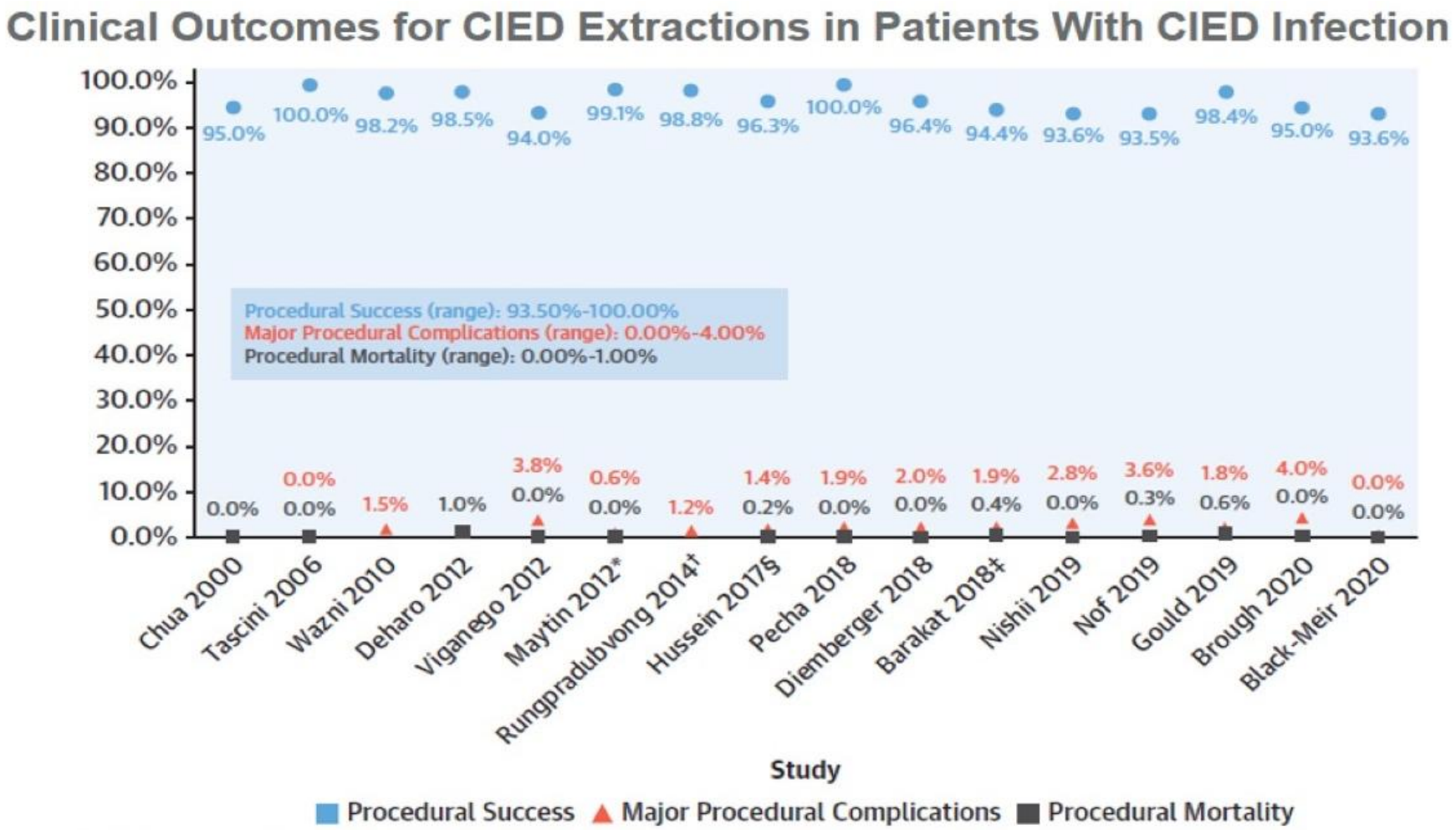
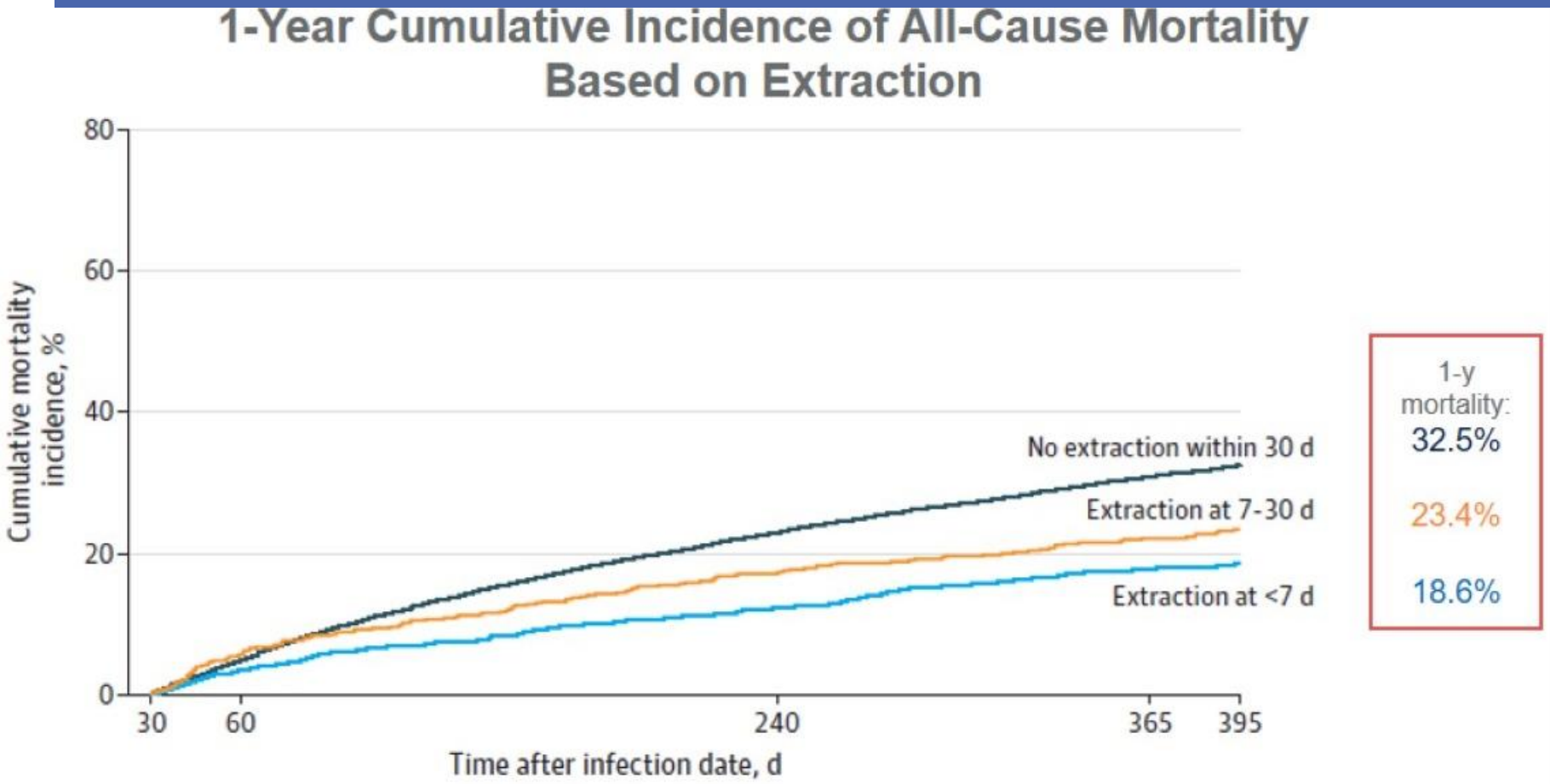
HIGH RATES OF PROCEDURAL SUCCESS



Lakkireddy DJ, et al. J Am Coll Cardiol. 2023;81:1283-1295.

MORTALITY BASED ON EXTRACTION



Earlier extraction was associated with lower mortality; there is a need to improve guideline-directed care of patients with CIED infection

TIA, transient ischemic attack.
Pokorney SD, et al. JAMA Cardiol. 2023;8:1165-1173.

Largest real-world analysis of CIED infection treatment including:

- 1,065,549 Medicare patients who underwent CIED implantation from 2006 to 2019 and lead extraction from 2007 to 2019
- Median age: 78 y
- 1.1% infection rate
- Female and Black patients and patients with diabetes, kidney disease, history of stroke or TIA, and frailty were less likely to undergo extraction within 30 d of CIED infection

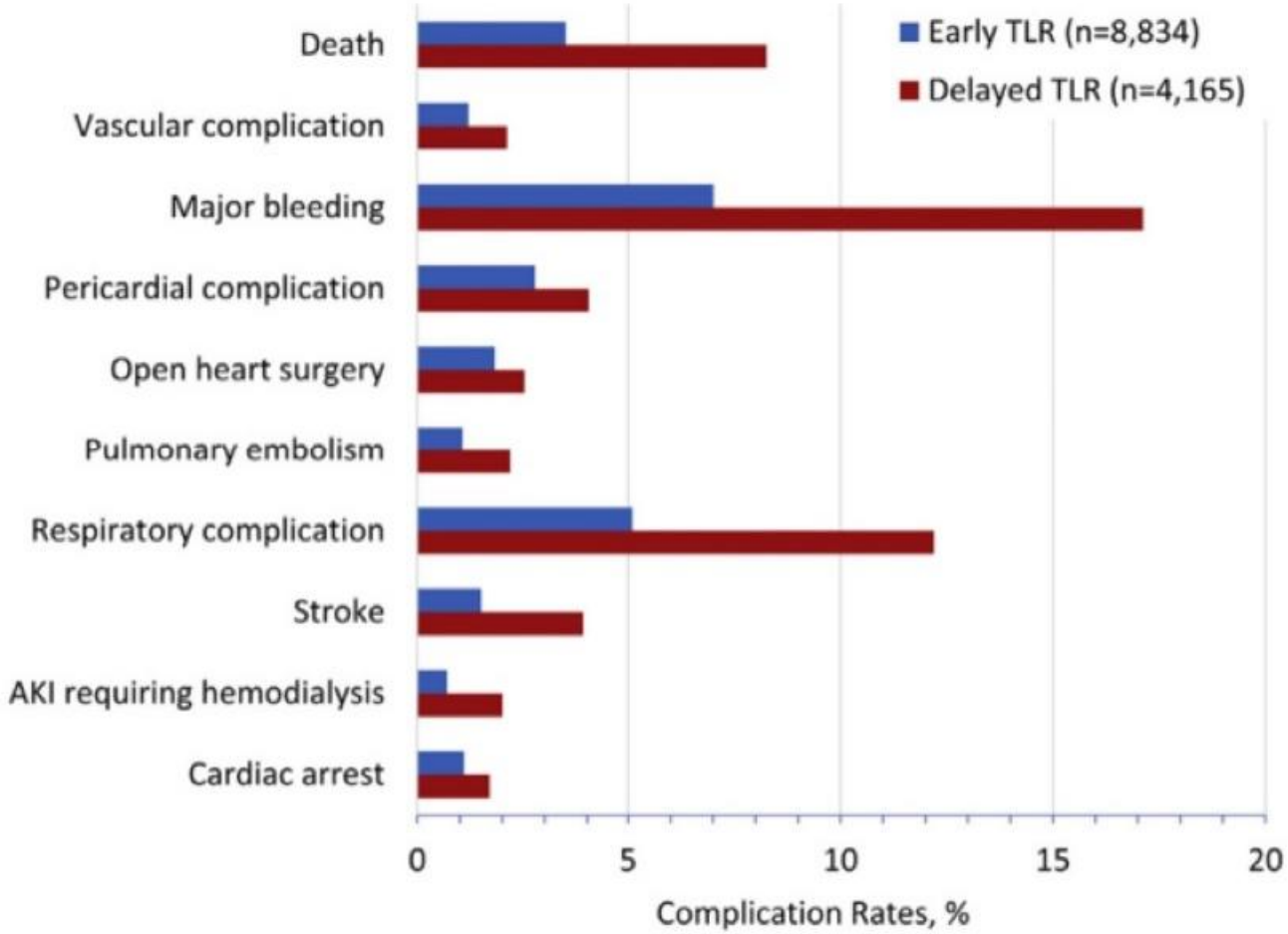
COMPLICATIONS BASED ON EXTRACTION

12,999 patients

8834 (68%) ≤ 7 d

4165 (32%) > 7 d

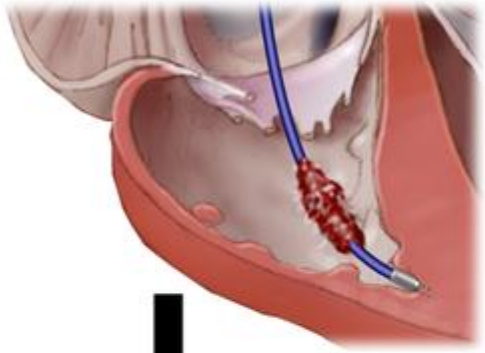
HR 1.55 for delayed TLR

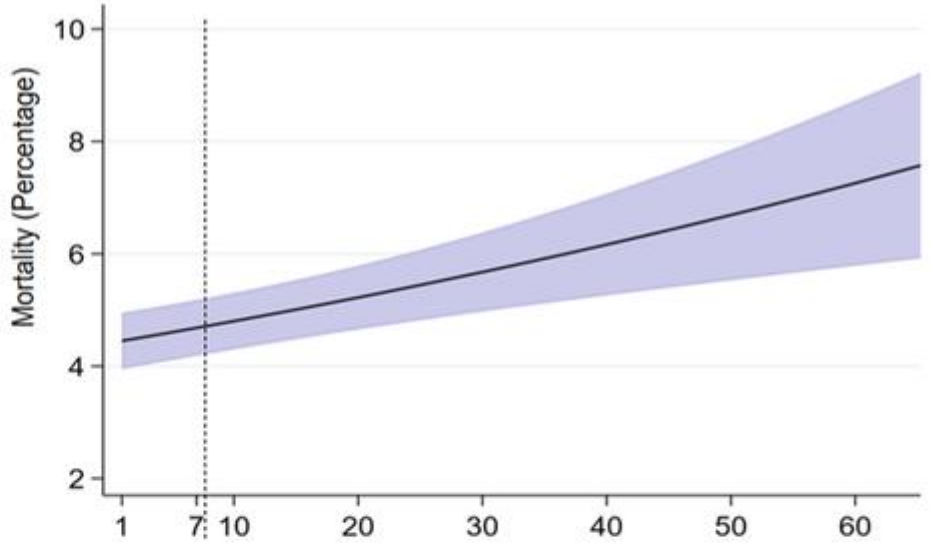


AKI, acute kidney injury; TLR, transvenous lead removal.
Lee JZ, et al. Heart Rhythm. 2022;19:768-775.

IMPACT OF TIMING OF TLE ON OUTCOMES

Admissions with Cardiac Implantable Electronic Device Infection





Timing of Transvenous Lead Removal

Day	Day	Day	Day	Day	Day	Day	Day	Day	Day	Day	Day	Day
1	2	3	4	5	6	7	10	20	30	40	50	60

Early Transvenous Lead Removal

↓ Mortality

↓ Major Adverse Events

Delayed Transvenous Lead Removal

↑ Mortality

↑ Major Adverse Events

Le et al.. Heart Rhythm. 2011;8:1678–1685.

MANAGEMENT

- **In all cases, the risk associated with the extraction procedure must be assessed by considering :**

- Age of the implanted leads
- Pacemaker dependency: need for temporary pacing?
- Patient frailty
- Presence or absence of comorbidities that could influence decision-making
- Risk of recurrence with the new implanted device

ANTIBIOTIC THERAPY

- **Empirical antibiotic therapy** (covering Staphylococcus aureus and Staphylococcus epidermidis)
- **Subsequently adjusted:**

  - MSSA/MSSE (Methicillin-sensitive Staph. aureus / Staph. epidermidis): Penicillin M or 1st-generation cephalosporin (C1G)
  - MRSA/MRSE (Methicillin-resistant Staph. aureus / Staph. epidermidis): Daptomycin
  - Enterococcus faecalis: Amoxicillin
  - Enterococcus faecium: Vancomycin
  - Streptococci: Amoxicillin

HARDWERE REMOVAL

- **Complete hardware removal +++**

In a center with cardiac surgery

- **Indications:**

➢ Systematic if infection is confirmed (local or systemic)

➢ Immediately if S. aureus, coagulase-negative Staphylococcus, Cutibacterium acnes, Candida are identified

➢ At a later stage in cases of recurrent or uncontrolled bacteremia: alpha- or beta-hemolytic Streptococcus, Enterococcus spp., P. aeruginosa, and Serratia

HARDWERE REMOVAL

- **What method?**
  - Percutaneous as first-line
  - Surgical approach to be considered in case of large vegetations (> 20 mm)
- **Post-extraction:**
  - TEE (residual vegetation?)
  - Follow-up blood cultures 48–72 hours later

- **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**

EHRA 2019

REIMPLANTATION: ALWAYS? WHEN AND HOW?

- **Indication to be re-evaluated +++ (30% may have no indication)**
- **Timing:**

  - After disappearance of local and systemic signs of infection and control of the entry point
  - 72 h after the first negative blood culture in cases of systemic infection without valve vegetations
  - Two weeks after the first negative blood culture in cases of valvular endocarditis
  - Reimplantation may be performed during the same procedure (at a different site) if the infection is limited to the device pocket
  - Different site from the original: contralateral side, epicardial placement

ALTERNATIVES

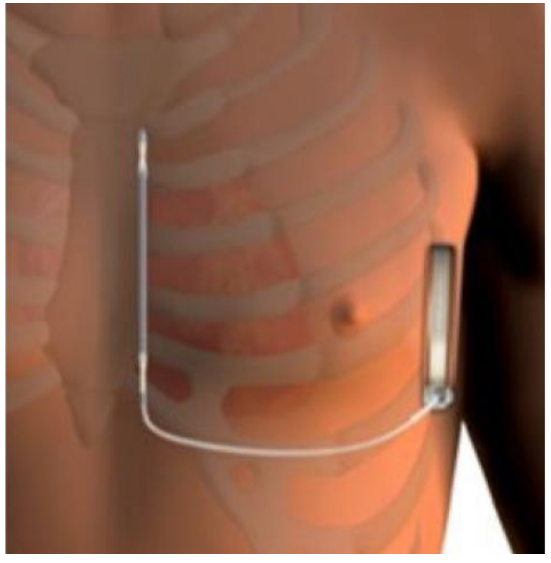
ESC European Society of Cardiology

European Heart Journal (2023) **44**, 3948–4042
https://doi.org/10.1093/eurheartj/ehad193

ESC GUIDELINES

2023 ESC Guidelines for the management of endocarditis

Developed by the task force on the management of endocarditis of the European Society of Cardiology (ESC)



Alternative devices such as leadless pacemakers or subcutaneous ICD may be implanted in selected patients if the risk of new infection is deemed high.

CHRONIC ANTIBIOTIC SUPPRESSION

Indication:

- Documented CIED infection with incomplete extraction.
- Decision made after multidisciplinary discussion

Protocol:

- 6 weeks of curative IV antibiotic therapy, Then well-tolerated oral monotherapy
- Agents: Doxycycline, Cotrimoxazole, C1G, Amoxicillin
- Close monitoring for tolerance: follow-up at 2 and 3 months, then every 6 months

Alternatives:

- PET-CT at 4–6 weeks in case of incomplete hardware removal (discontinue suppressive antibiotics if no hypermetabolism?)
- Regional/local antibiotic therapy?

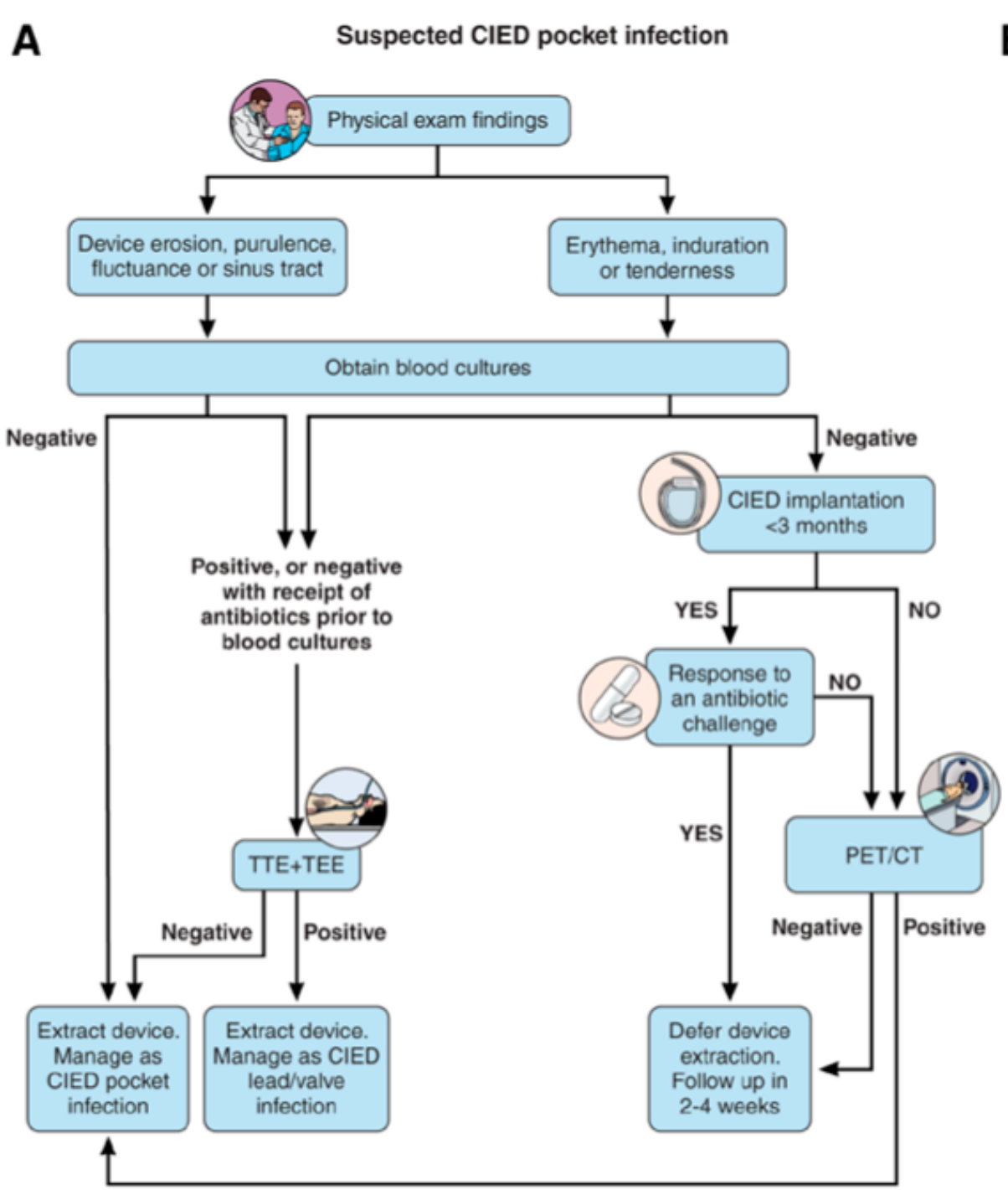
Clin Infect Dis. 2017 Jun 1;64(11):1516-1521. doi: 10.1093/cid/cix181.

Outcomes in Patients With Cardiovascular Implantable Electronic Device Infection Managed With Chronic Antibiotic Suppression

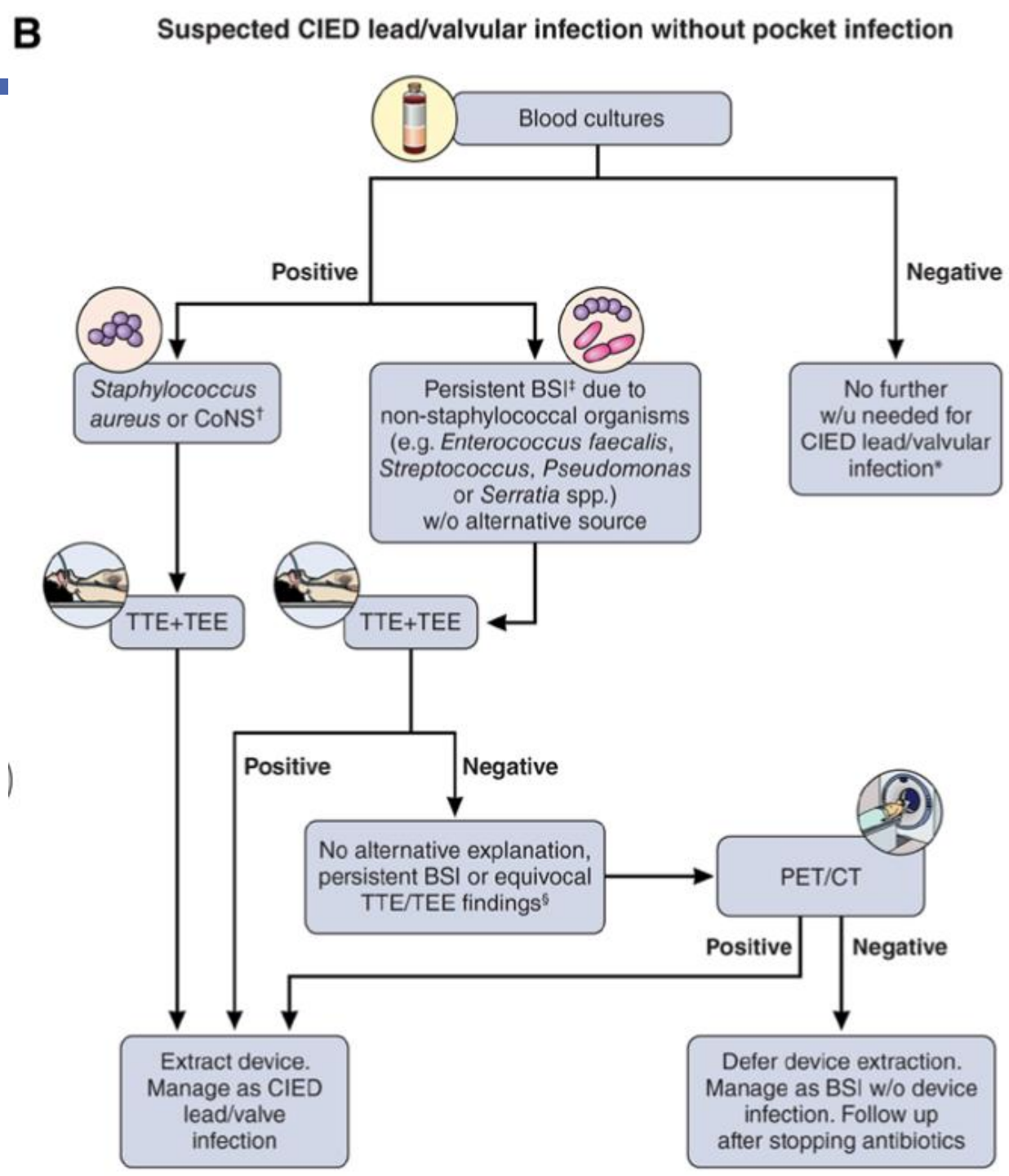
Eugene M Tan [1], Daniel C DeSimone [1], M Rizwan Sohail [1 2], Larry M Baddour [1 2], Walter R Wilson [1], James M Steckelberg [1], Abinash Virk [1]

Affiliations + expand

- Reviewed 660 CIEDI cases 2005 - 2015 48 patients prescribed CAS
- At 1 month after hospitalization, **25% had died**
- Overall survival was **1.43 years**
- **18% of survivors had infection relapse within 1 year**


A
Suspected CIED pocket infection
Physical exam findings
Device erosion, purulence, fluctuance or sinus tract
Erythema, induration or tenderness
Obtain blood cultures
Negative
Negative
Positive, or negative with receipt of antibiotics prior to blood cultures
CIED implantation <3 months
YES
NO
Response to an antibiotic challenge
NO
YES
PET/CT
TTE+TEE
Negative
Positive
Negative
Positive
Extract device. Manage as CIED pocket infection
Extract device. Manage as CIED lead/valve infection
Defer device extraction. Follow up in 2-4 weeks

AHA 2024


B
Suspected CIED lead/valvular infection without pocket infection
Blood cultures
Positive
Negative
Staphylococcus aureus or CoNS†
Persistent BSI‡ due to non-staphylococcal organisms (e.g. Enterococcus faecalis, Streptococcus, Pseudomonas or Serratia spp.) w/o alternative source
No further w/u needed for CIED lead/valvular infection*
TTE+TEE
TTE+TEE
Positive
Negative
No alternative explanation, persistent BSI or equivocal TTE/TEE findings§
PET/CT
Positive
Negative
Extract device. Manage as CIED lead/valve infection
Defer device extraction. Manage as BSI w/o device infection. Follow up after stopping antibiotics

AHA 2024

2024 AHA STATEMENT

CIED Infection

Prevention

Adherence to standard infection prevention measures

Single dose of preoperative cefazolin

Antimicrobial envelope for high-risk patients

Hematoma prevention

Diagnosis

Physical examination findings are key for pocket infection

TEE for diagnosis of valve infection in patients with bloodstream infection

PET/CT for cases with inconclusive findings or lead masses on TEE

Device sonication and molecular techniques* to enhance microbial detection

Management

Complete CIED removal

Chronic antimicrobial suppression for non-extraction candidates

New CIED implant once pocket is adequately debrided and blood cultures negative†

Consider subcutaneous ICD and leadless pacemakers in high-risk patients

*16S ribosomal RNA gene (rRNA) polymerase chain reaction (PCR)/sequencing or metagenomic next-generation sequencing (mNGS) of sonicate fluid may be helpful in select cases
†Some favor delaying new device placement for up to 14 days after initiation of antimicrobial therapy in the setting of valvular endocarditis
Baddour LM, et al. Circulation. 2024;149:e201–e216.

CONCLUSIONS

CIED infection is a real problem

CONCLUSIONS

CIED infection is a significant public health problem, often underdiagnosed, and is associated with increased morbidity, mortality, and costs

1 in 20
CIED pts will develop a CIED infection in over 3 y[1]

Diagnosis
of CIED infection can be difficult as presentation varies[2,3]

Up to 35%
1-y mortality rate with CIED infection[4]

50%-100%
infection relapse with ABX treatment alone[5,6]

Major gap in guideline adherence exists

> 8 in 10
CIED infection pts are not treated according to class I guidelines[7]

Early lead extraction
is associated with a 41% lower risk of death[7]

7x decrease
in 30-d mortality with extraction vs ABX alone[4]

1. Dai M, et al. JACC Clin Electrophysiol. 2019;5:1071-1080. 2. Blomström-Lundqvist C, et al. Europace. 2020;22:515-549. 3. Sandoe JAT, et al. J Antimicrob Chemother. 2015;70:325-359. 4. Le KY, et al. Heart Rhythm. 2011;8:1678-1685. 5. del Rio A, et al. Chest. 2003;124:1451-1459. 6. Tan EM, et al. Clin Infect Dis. 2017;64:1516-1521. 7. Pokorney SD, et al. Paper presented at: ACC Scientific Sessions; April 3, 2022; Washington, DC.

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CONCLUSIONS

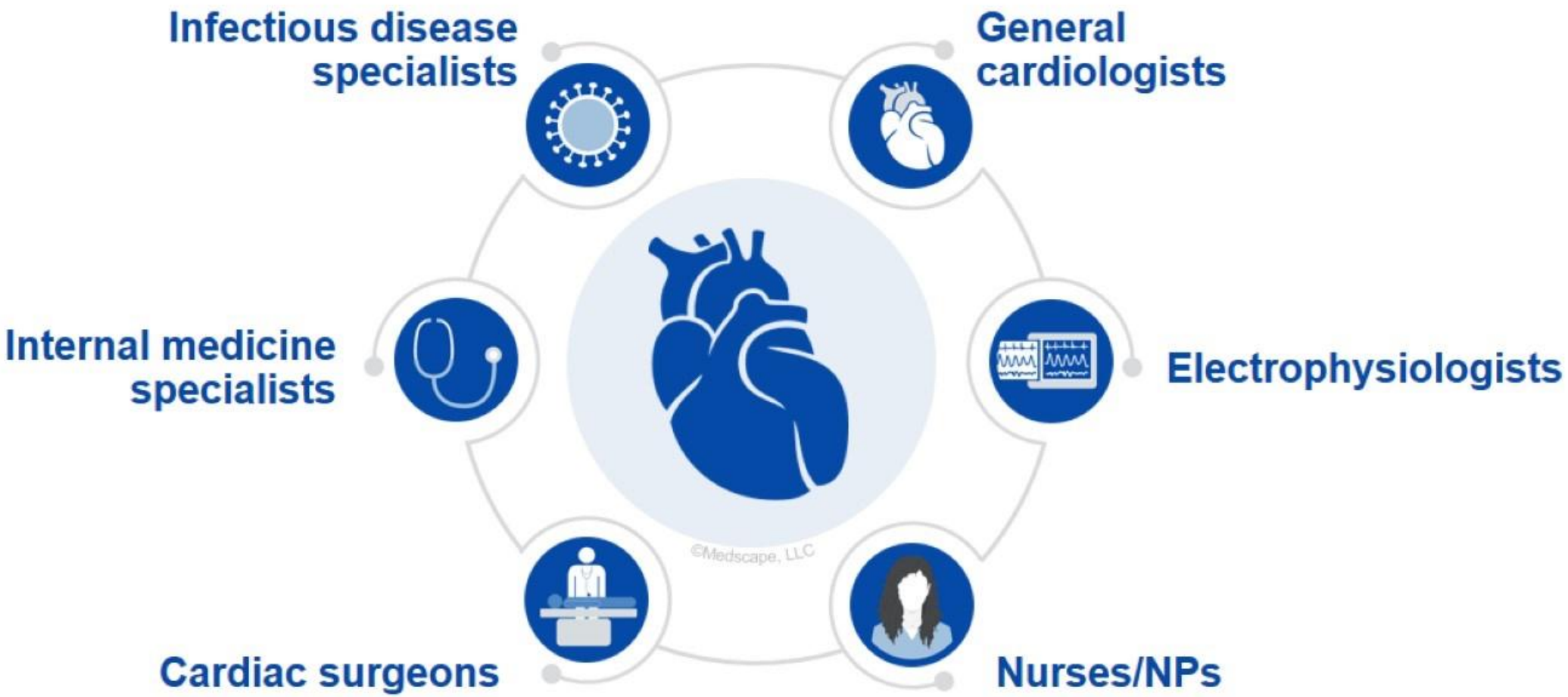
CIED infection is a real problem

Patients with CIED infections are being undertreated

Device extraction has a class I indication for patients with definite CIED infection

A team approach is required

CIED INFECTION TEAM



THANK YOU