

Gestione delle complicanze infettive CIED nel paziente fragile: più luci che ombre?

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ALESSANDRIA

DIAMO I NUMERI

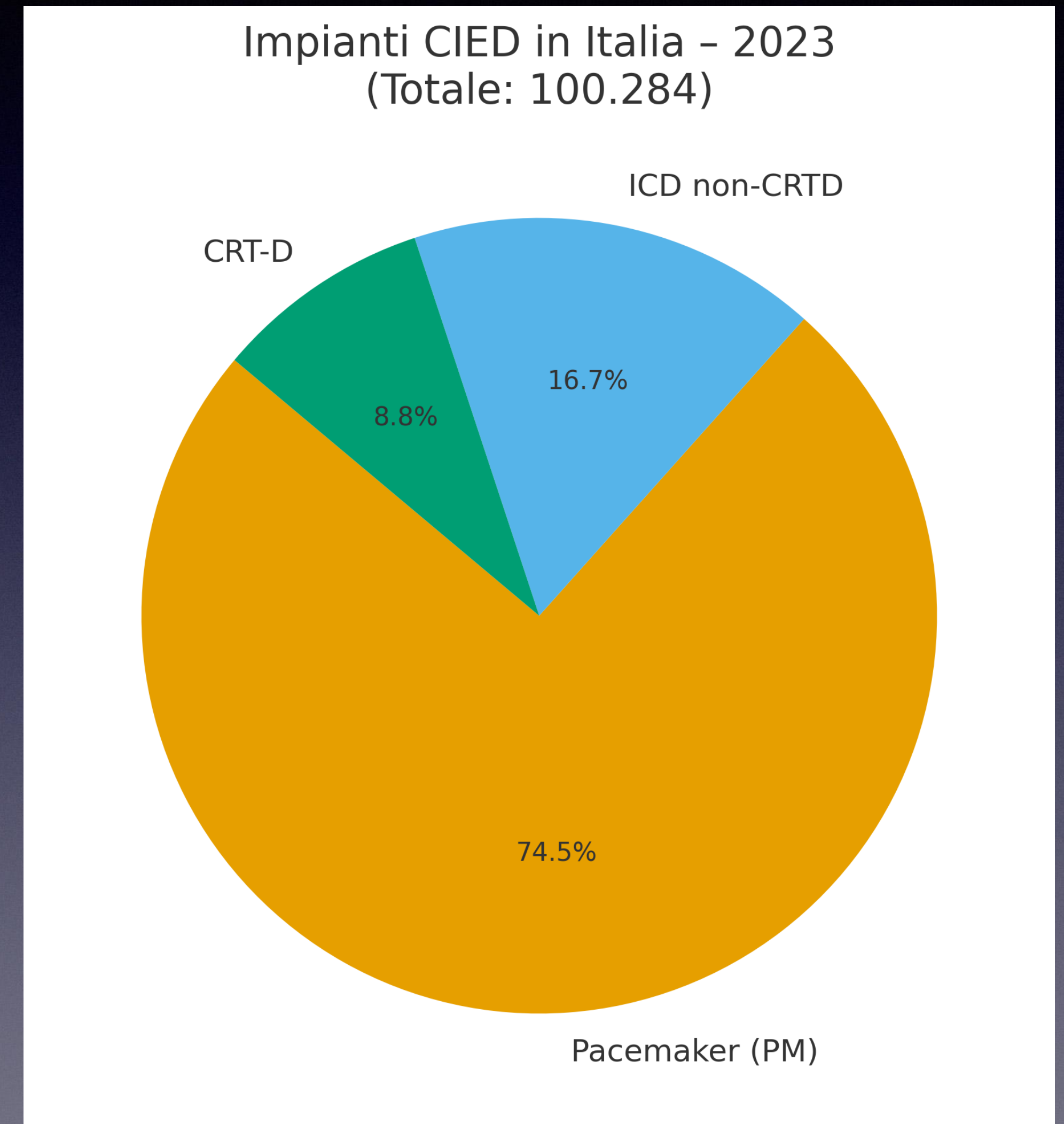
Impianti CIED in Italia nel 2023

Secondo il report dell'ISS basato sui dati SDO:

- Totale impianti: 100.284
 - Pacemaker (PM): 74.726
 - ICD totali: 25.558

Questi 25.558 ICD includono sia dispositivi ICD che CRT-D:

- ICD non-CRTD: circa 16.715
- CRT-D: circa 8.843



Trend negli anni precedenti (2001–2023)

Un altro studio basato sul database nazionale (anche questo ISS/RIDIPE):

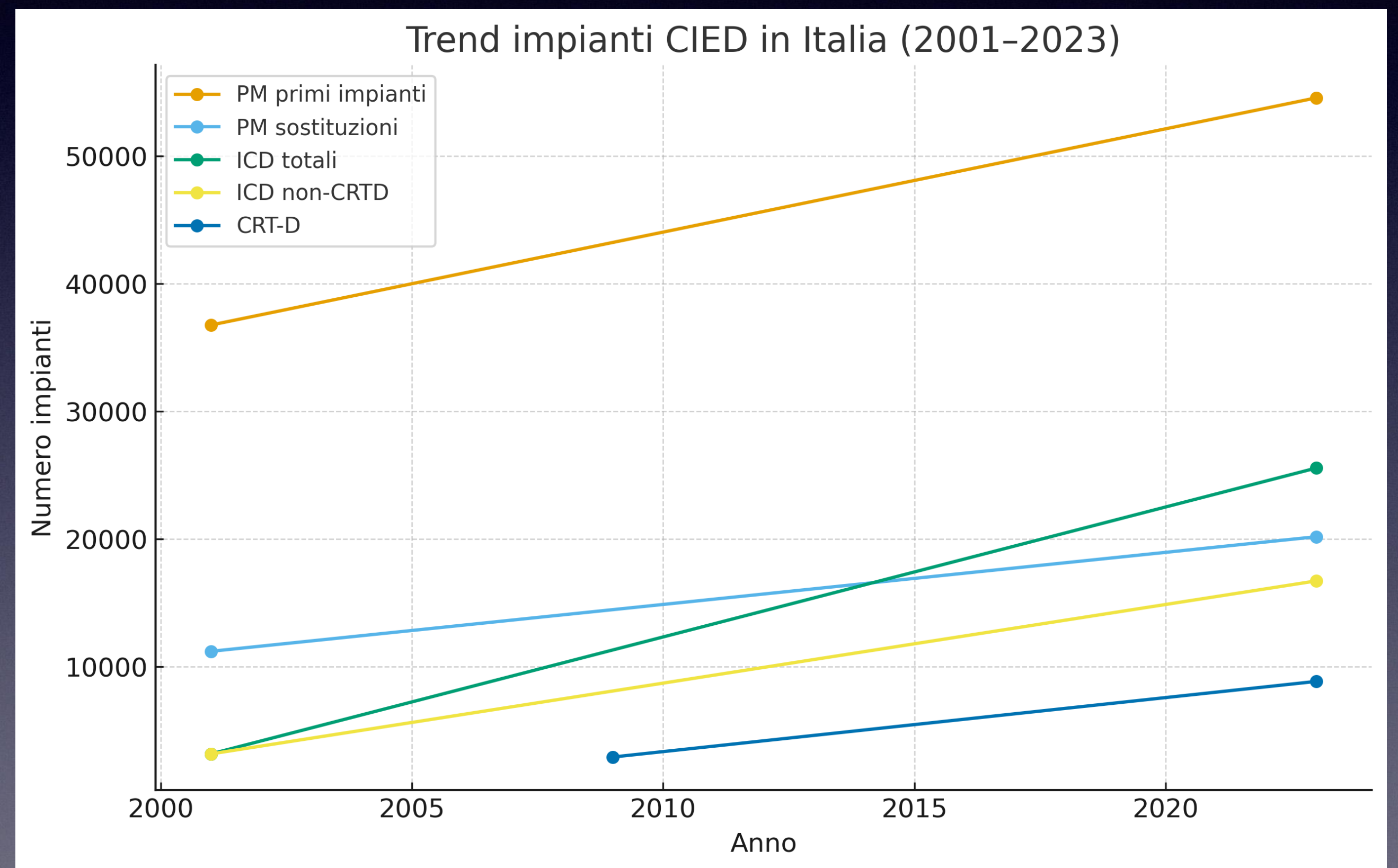
Primi impianti di PM: da 36.752 (2001) a 54.552 (2023), +48,4%

Sostituzioni di PM: da 11.197 (2001) a 20.174 (2023), +80,2%

Totalità di ICD impiantati: da 3.161 (2001) a 25.558 (2023), +708,5%

Di questi, ICD non-CRTD sono aumentati da 3.161 (2001) a 16.715 (2023), +428,8%

CRTD sono passati da 2.919 (2009, inizio registrazione) a 8.843 (2023), +202,9%



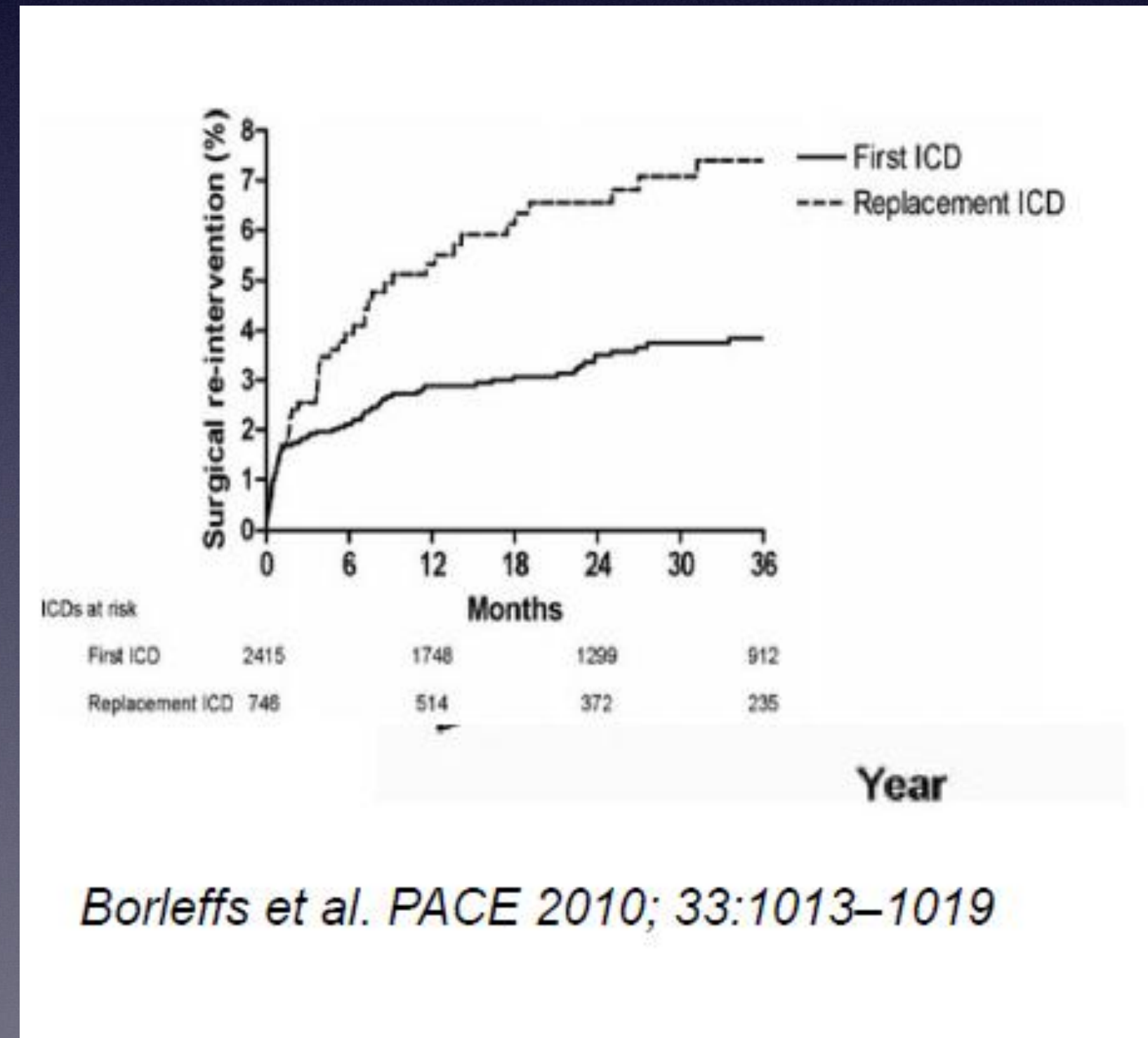
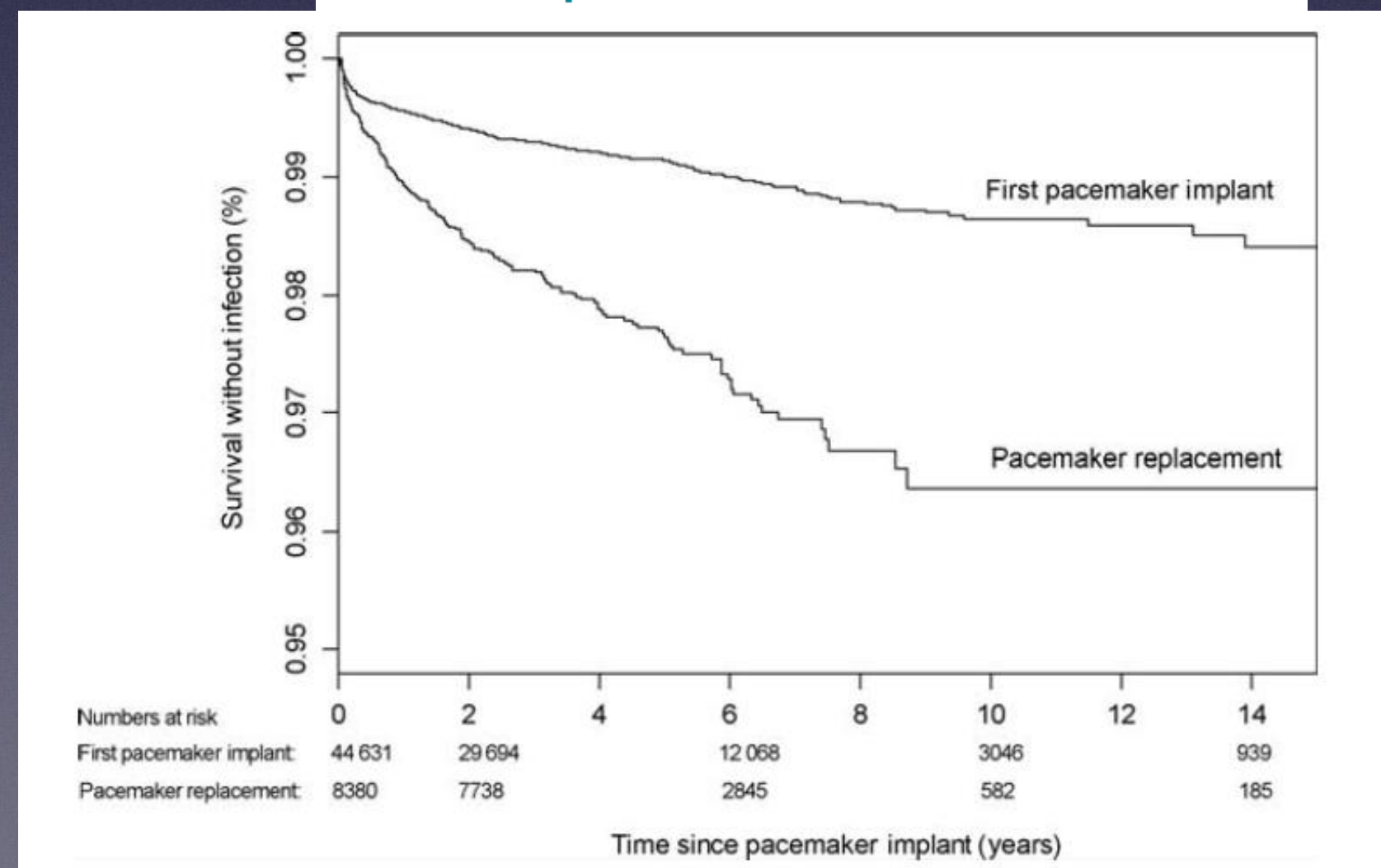
INCIDENZA DELLE INFEZIONI

Nel registro Danese che include 46299 pazienti consecutivi che hanno ricevuto un device tra 1982 e il 2007 l'incidenza di infezioni era di 4.82/1000 device/anno per il primo impianto e 12,12/1000 device/anno per le sostituzioni

European Heart Journal (2011) 32, 991–998
doi:10.1093/eurheartj/ehq497

CLINICAL RESEARCH
Arrhythmia/electrophysiology

Infection after pacemaker implantation: infection rates and risk factors associated with infection in a population-based cohort study of 46299 consecutive patients



Paziente fragile!

Table 3 Pooled effect estimates for potential risk factors predisposing to cardiac implantable electronic device infection

Factor	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	11839	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, 26.73]	0.06
Haematoma	12	14228	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	10683	2.31 [1.36, 3.92]	0.002	4	8683	3.29 [1.87, 5.80]	0.00004
Device replacement/revision/upgrade	26	21214	1.98 [1.46, 2.70]	0.00001	8	8793	0.95 [0.49, 1.87]	0.89
Generator change	20	12134	1.74 [1.22, 2.49]	0.002	6	2139	0.91 [0.37, 2.22]	0.83
Antibiotic prophylaxis	16	14166	0.32 [0.18, 0.55] ^d	0.00005	11	10864	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	45224	1.45 [1.02, 2.05]	0.04	7	12102	1.28 [0.73, 2.25]	0.38

FATTORI DI
RISCHIO

PAZIENTE FRAGILE



La fragilità è una sindrome clinica caratterizzata da:

Ridotta resilienza fisiologica → incapacità di mantenere l'omeostasi in seguito a stress.

Declino multidimensionale → fisico, cognitivo, funzionale e/o sociale.

Aumentato rischio di disabilità, complicanze, ospedalizzazioni e mortalità.

Criteri operativi più usati

Fenotipo di Fried (5 criteri): perdita di peso involontaria, debolezza muscolare, ridotta velocità del cammino, facile affaticabilità, bassa attività fisica. ≥ 3 criteri

Clinical Frailty Scale (CFS) di Rockwood: classifica da 1 (robusto) a 9 (terminalmente fragile).

Applicato ai CIED

Il paziente fragile con device cardiaco è tipicamente:

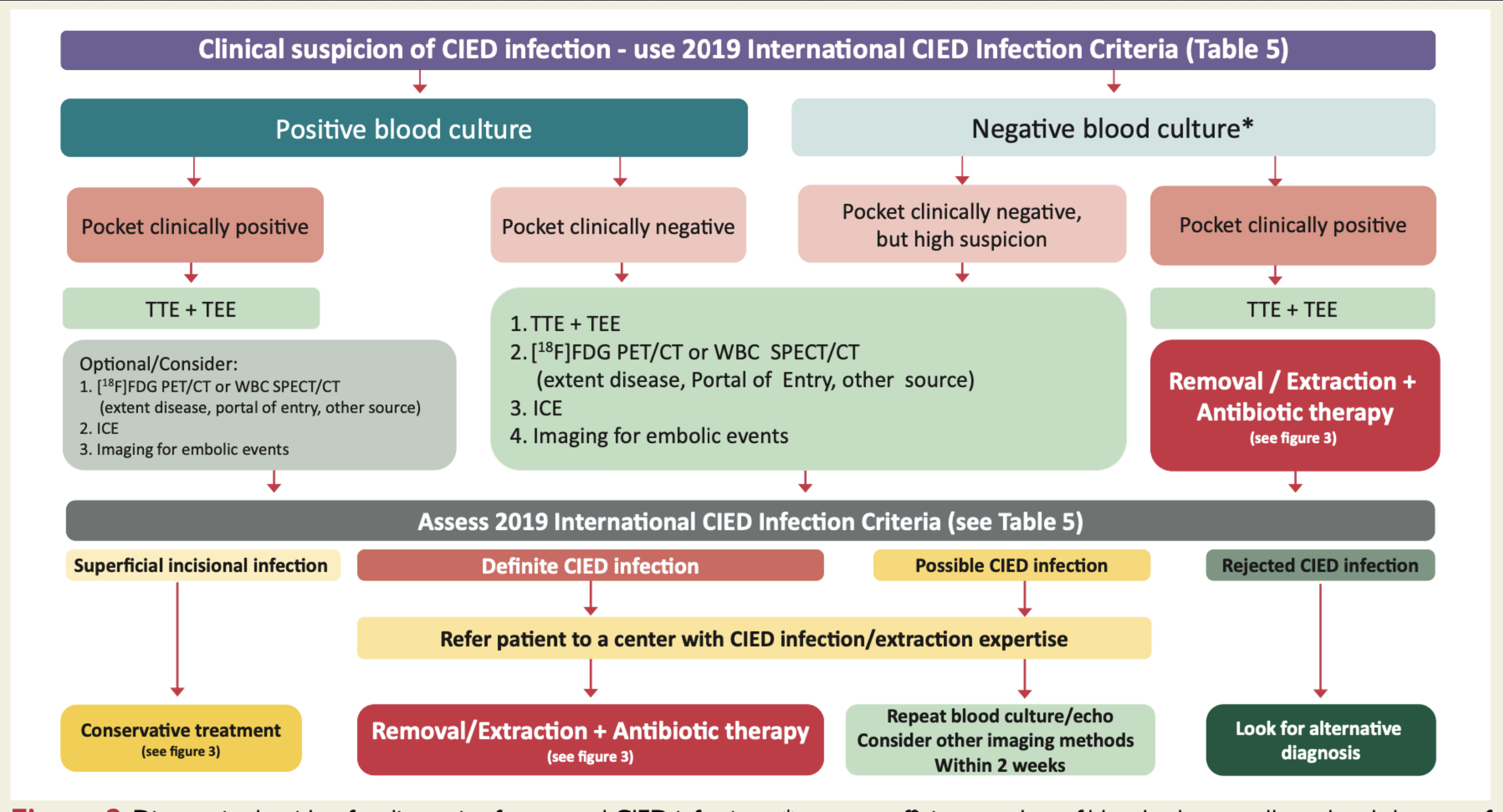
anziano con più comorbidità (diabete, IRC, BPCO, insufficienza cardiaca),

spesso polifarmacologico,

a rischio aumentato di infezioni e complicanze procedurali,

con riserva fisiologica ridotta che rende più complesso il bilancio rischio/beneficio delle terapie.

FLOW DIAGNOSTICO



Consensus statement	Statement class	Scientific evidence coding	Reference
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'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			
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'Definite' CIED/IE = presence of either 2 major criteria or 1 major + 3 minor criteria			
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'Possible' CIED/IE = presence of either 1 major + 1 minor criteria or 3 minor criteria			
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'Rejected' CIED/IE diagnosis = patients who did not meet the aforementioned criteria for IE			
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Major criteria			
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Microbiology			
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|--|--|--|--|
| A. Blood cultures positive for typical microorganisms found in CIED infection and/or IE (<i>Coagulase-negative staphylococci</i> , <i>S. aureus</i>) | | | |
| B. Microorganisms consistent with IE from 2 separate blood cultures: <ul style="list-style-type: none">a. Viridans streptococci, <i>Streptococcus gallolyticus</i> (<i>S. bovis</i>), HACEK group, <i>S. aureus</i>; orb. Community-acquired enterococci, in the absence of a primary focus | | | |
| C. Microorganisms consistent with IE from persistently positive blood cultures: <ul style="list-style-type: none">a. ≥2 positive blood cultures of blood samples drawn >12 h apart; orb. All of 3 or a majority of ≥4 separate cultures of blood (first and last samples drawn ≥1 h apart); orc. Single positive blood culture for <i>Coxiella burnetii</i> or phase I IgG antibody titre >1:800 | | | |

Imaging positive for CIED infections and/or IE			
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|--|--|--|--|
| D. Echocardiogram (<i>including ICE</i>) positive for: <ul style="list-style-type: none">a. CIED infection:<ul style="list-style-type: none">i. Clinical pocket/generator infectionii. Lead-vegetationb. Valve IE<ul style="list-style-type: none">i. Vegetationsii. Abscess, pseudoaneurysm, intracardiac fistulaiii. Valvular perforation or aneurysmiv. 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			
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|---|--|--|--|
| 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) | | | |

BACTERIEMIA OCCULTA

Complete CIED removal is indicated in bacteraemia or fungaemia with *S. aureus*, CoNS, Cutibacterium spp., and Candida spp.

In bacteraemia with alpha- or beta-haemolytic Streptococcus spp. and Enterococcus spp. complete CIED removal may be carried out as first-line treatment or as a second step in case of recurrent/continued bacteraemia despite appropriate antibiotic therapy.

In case of bacteraemia with non pseudomonal/Serratia Gram-negative bacteria or Pneumococci an appropriate antibiotic therapy is indicated first. In case of recurrent/continued bacteraemia, complete CIED removal should be performed in cases when no other identifiable source for recurrence or continued infection is found.

Complete CIED removal is furthermore indicated in patients with infective endocarditis without definite involvement of the CIED system.



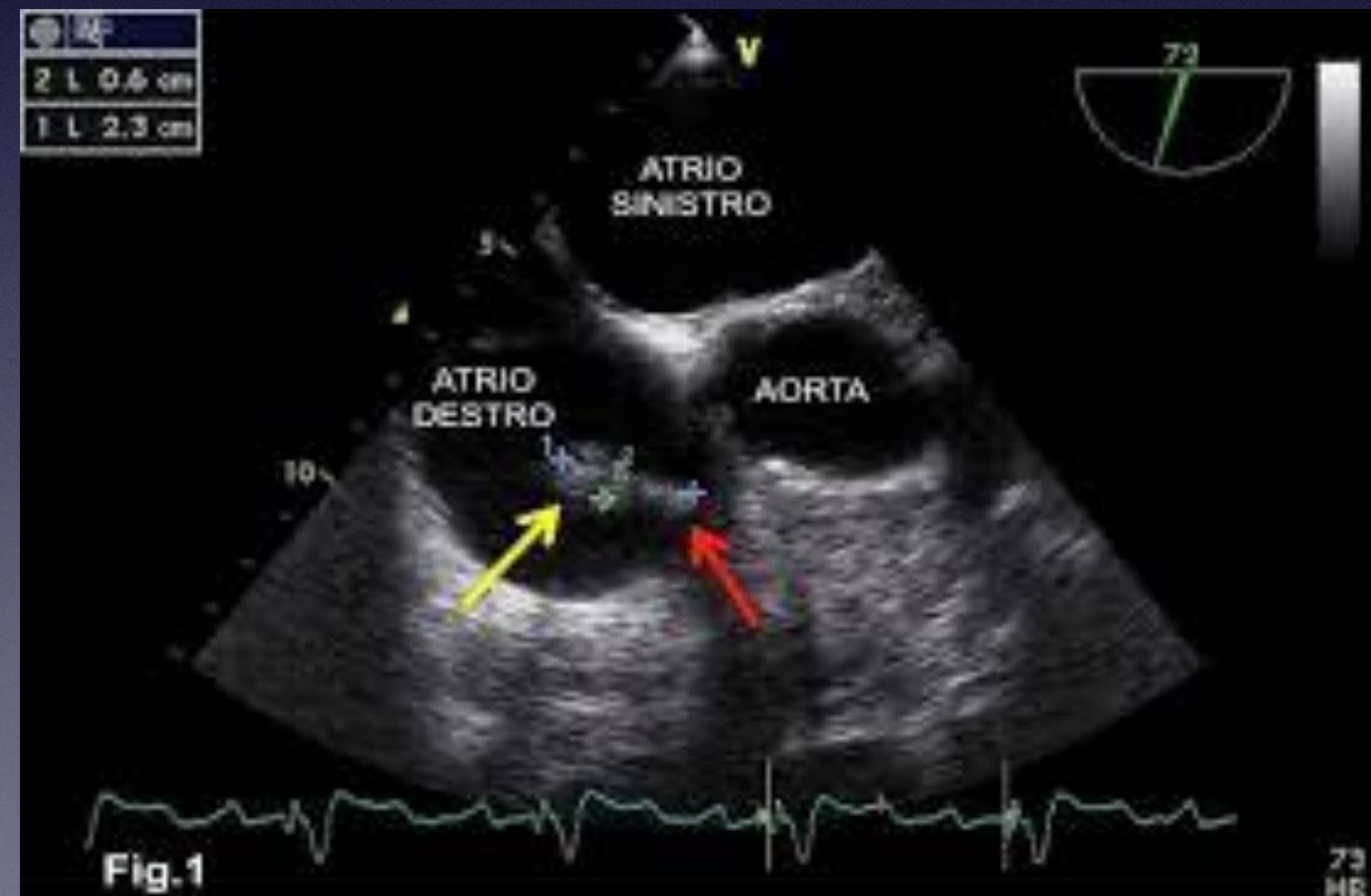
DIVERSI GRADI DI INFEZIONE



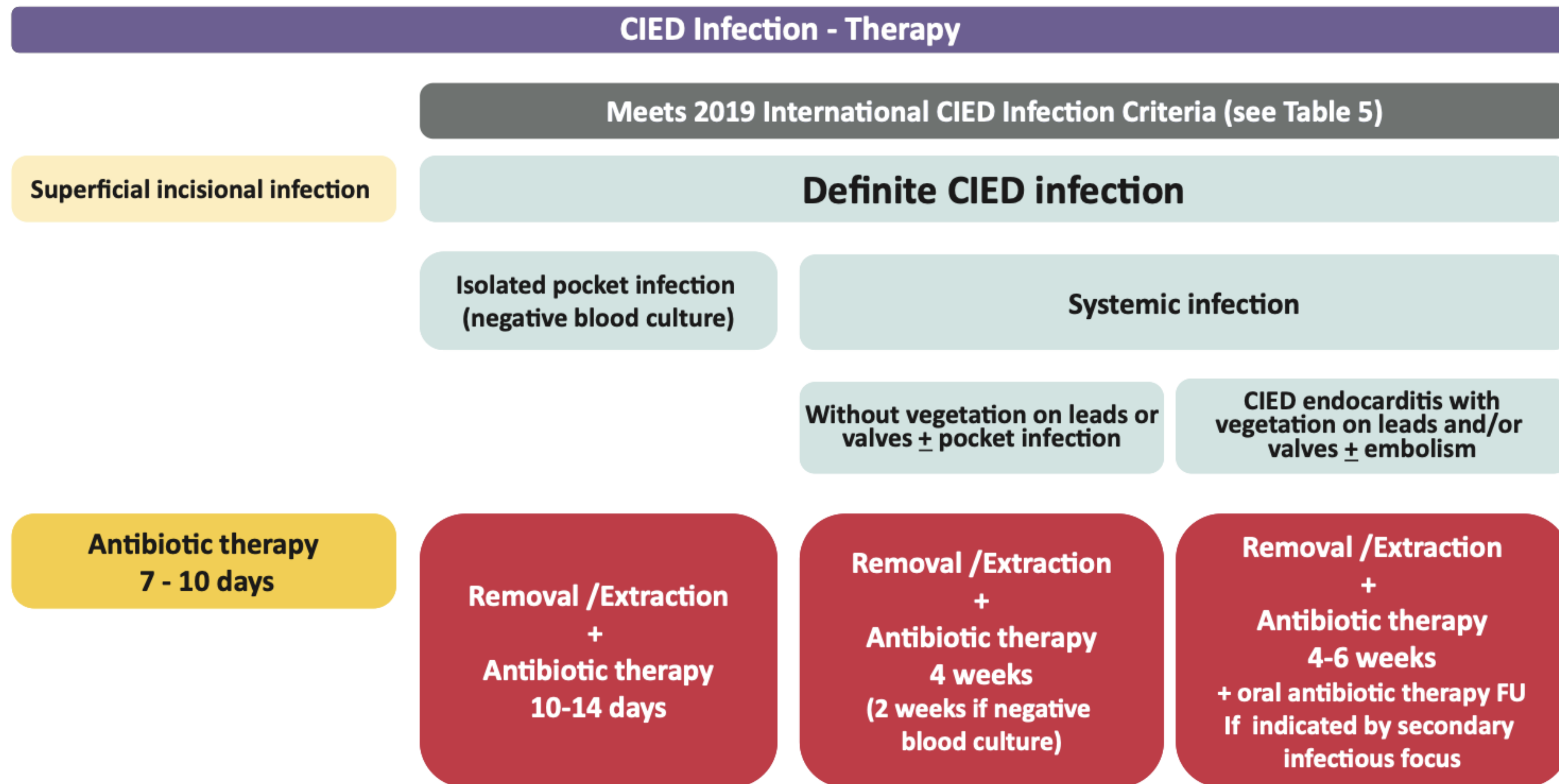
SHOCK SETTICO

FEBBRE E LEUCOCITOSI

ASSOLUTAMENTE NULLA



INDICAZIONI ALLA RIMOZIONE DEL DEVICE



DOVE e QUANDO?

Non è giustificabile perdere tempo dopo aver fatto la diagnosi.

I pazienti estratti nei primi tre giorni dall'ospedalizzazione hanno un outcome migliore e ricoveri più brevi

Consensus statement	Statement class
In patients with definite CIED infection (systemic and local), complete device removal is recommended (including abandoned leads, epicardial leads, and lead fragments)	
After diagnosis of CIED infection, the device removal procedure should be performed without unnecessary delay (ideally within 3 days)	
The recommended technique for device system removal is percutaneous, transvenous extraction technique. Epicardial leads require surgical removal	
In patients with systemic infection and lead vegetations of approximately >20 mm, percutaneous aspiration of vegetations prior to and during transvenous lead extraction or alternatively surgical extraction may be considered	
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	
Cultures of extracted CIED should be performed	

DOVE E QUANDO?

Cardiochirurgia in sede

Deve essere disponibile un team cardiocirurgico capace di intervenire entro pochi minuti in caso di complicanze maggiori (tamponamento, lacerazione cardiaca).

La presenza in sede (non solo in convenzione) è considerata requisito imprescindibile.

Terapia intensiva e anestesia dedicata

Sala operatoria ibrida o emodinamica con anestesista esperto.

Accesso immediato a terapia intensiva post-procedura.

Team multidisciplinare dedicato

Elettrofisiologi esperti in estrazioni (con numero minimo annuo di procedure).

Cardiologi, anestesisti e perfusionisti pronti all'intervento d'emergenza.

Strumentazione dedicata

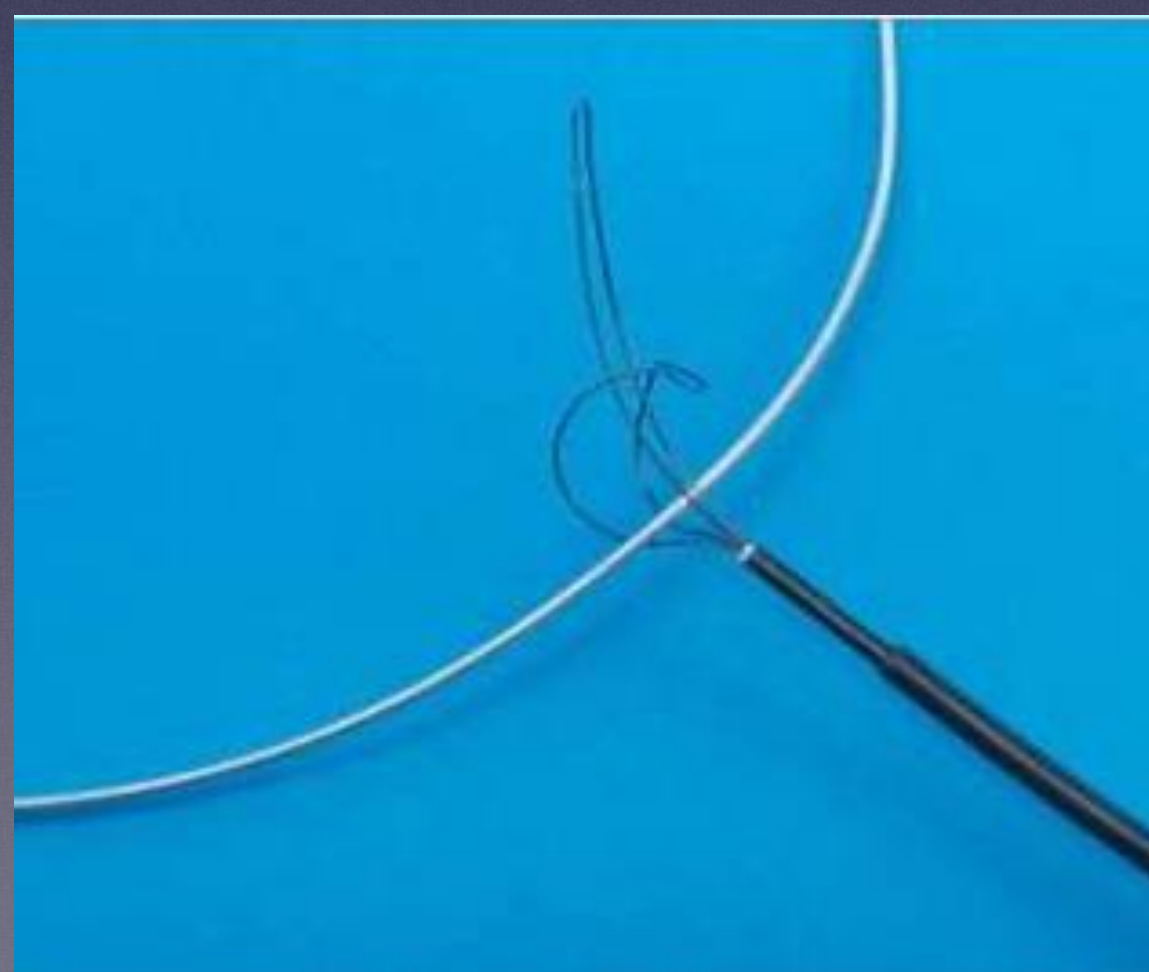
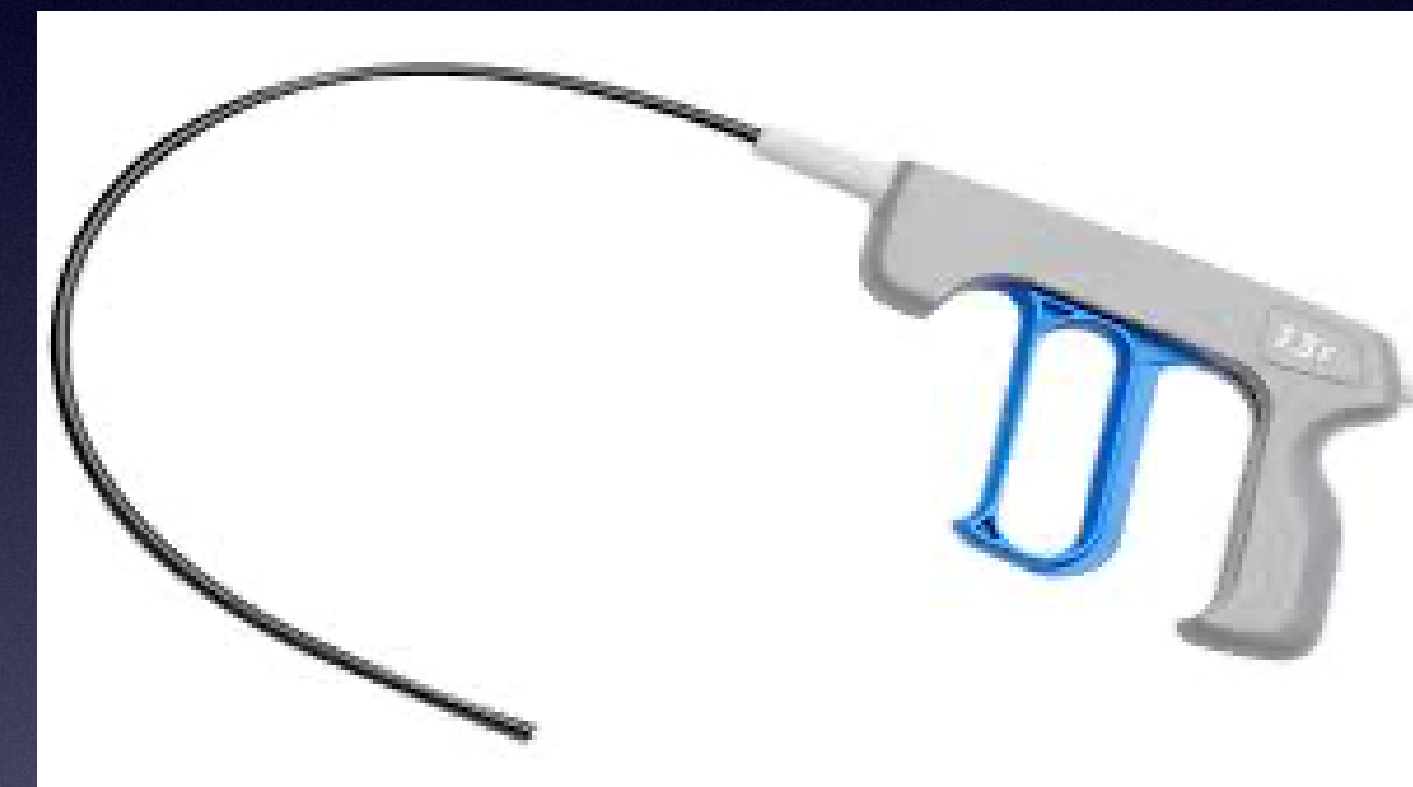
Disponibilità di sistemi di estrazione

Imaging intra-procedurale

Volume di attività

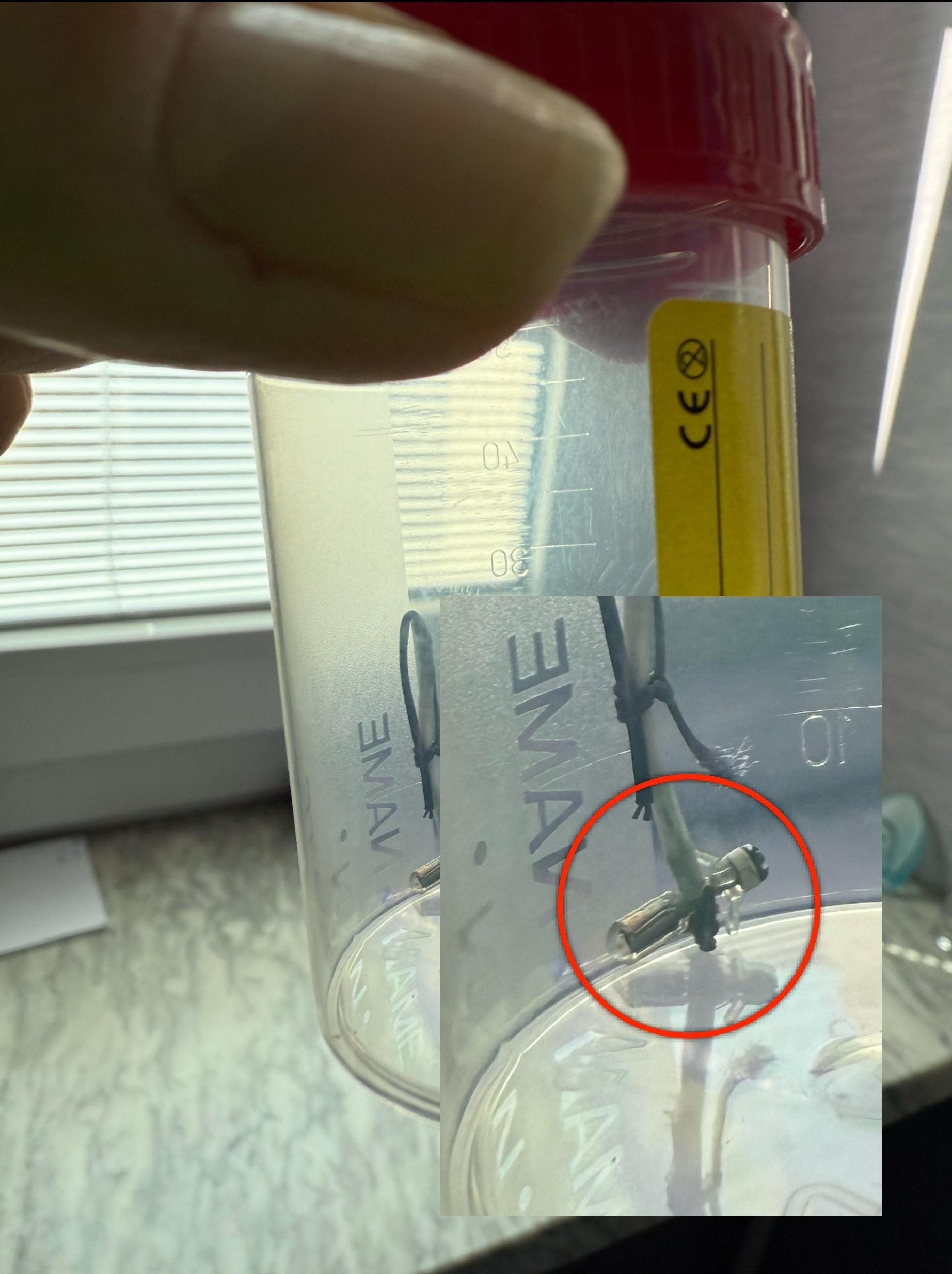
High-volume center = migliori outcomes e minore mortalità.

TECNICHE E MATERIALI



Punto chiave per la soluzione del quadro settico è la completa rimozione di ogni parte del sistema (tutti gli elettrocateri, compresi quelli rotti, vecchi ed abbandonanti) e di ogni frammento.

Consensus statement	Statement class
In patients with definite CIED infection (systemic and local), complete device removal is recommended (including abandoned leads, epicardial leads, and lead fragments)	♥
After diagnosis of CIED infection, the device removal procedure should be performed without unnecessary delay (ideally within 3 days)	♥
The recommended technique for device system removal is percutaneous, transvenous extraction technique. Epicardial leads require surgical removal	♥
In patients with systemic infection and lead vegetations of approximately >20 mm, percutaneous aspiration of vegetations prior to and during transvenous lead extraction or alternatively surgical extraction may be considered	♥
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	♥
Cultures of extracted CIED should be performed	♥



CRITICITA' PROCEDURALI

Paziente già compromesso alla malattia stessa

Sedazione profonda e intubazione

Multipli accessi vascolari

Ritmo di fondo non ottimale

Procedura non pianificabile

Criticità
accessorie

Gestione del pacing

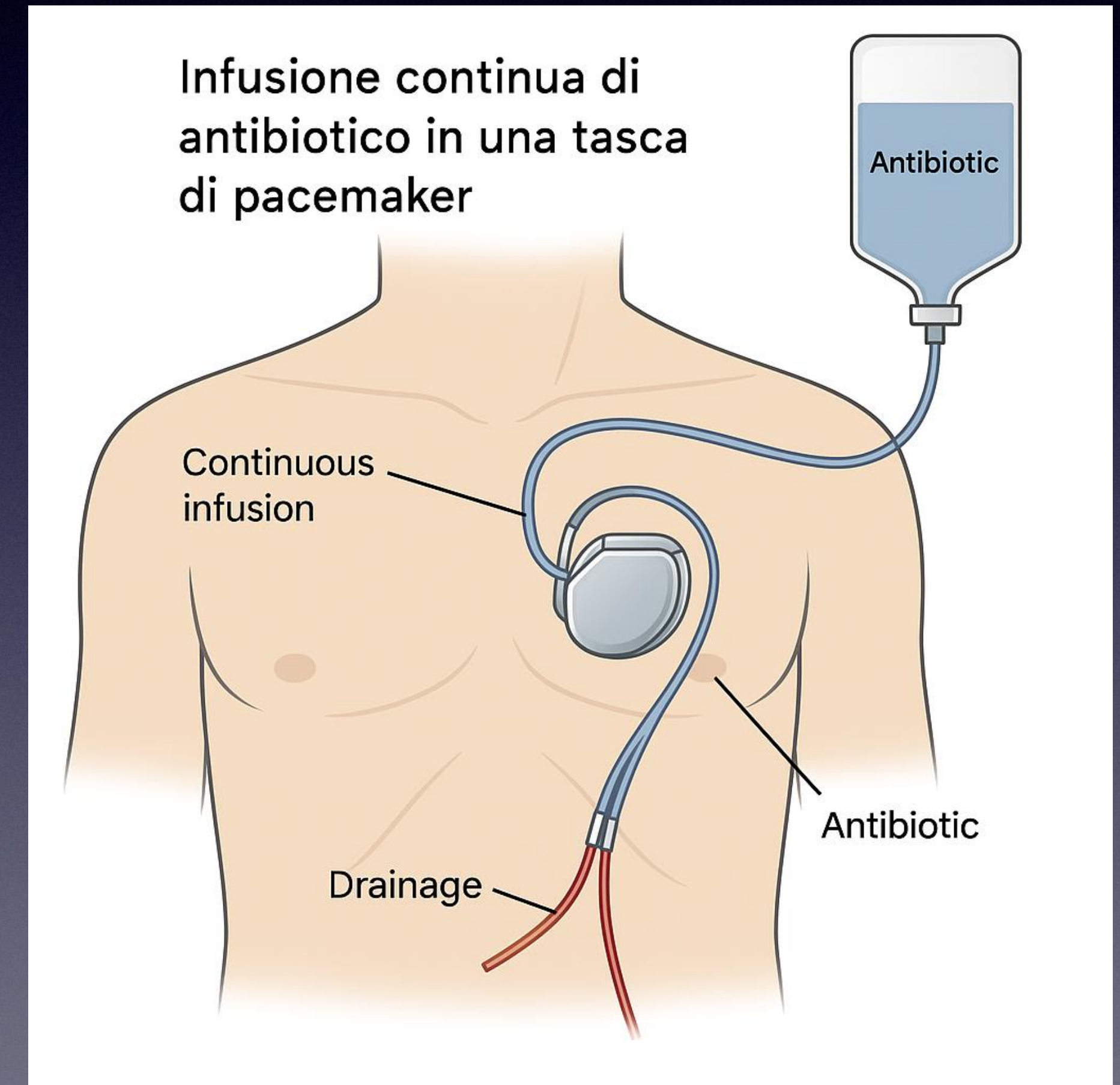
Gestione dell'antibiotico

Gestione dell'allettamento

TECNICHE ALTERNATIVE

Revisione

Lavaggio di antibiotico in continuo



MORTALITA' ESTRAZIONE VS TERAPIA CONSERVATIVA

ENDOCARDITE SU CIED trattata con antibiotici più estrazione

MORTALITA A 30 GIORNI 5-8% (inclusa la mortalità dovuta all'intervento di estrazione che si assesta allo 0,5%)

FATTORI DI RISCHIO:

Scompenso cardiaco

Insufficienza renale

Uso di steroidi

Presenza di vegetazioni

Estrazione non completa

Sekiguchi et al. (2015) –

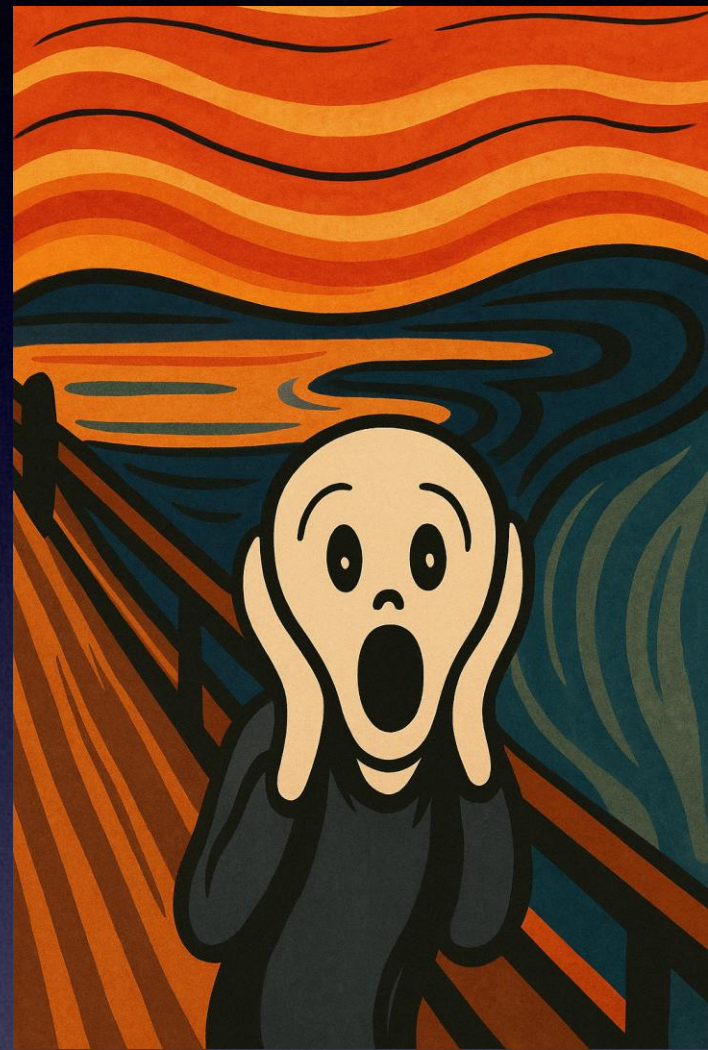
“Antibiotic therapy without device removal was associated with a 7-fold increase in 30-day mortality

Studio “Mortality and Costs ...” (Gutiérrez-Carretero et al. 2024)

Per le infezioni sistemiche trattate con antibiotici esclusivi: mortalità ~ 19,2%.

Athan et al. Soggetti con infezione sistemica che NON hanno subito rimozione del device avevano mortalità ad 1 anno del 38,2%

QUINDI LUCI O OMBRE?



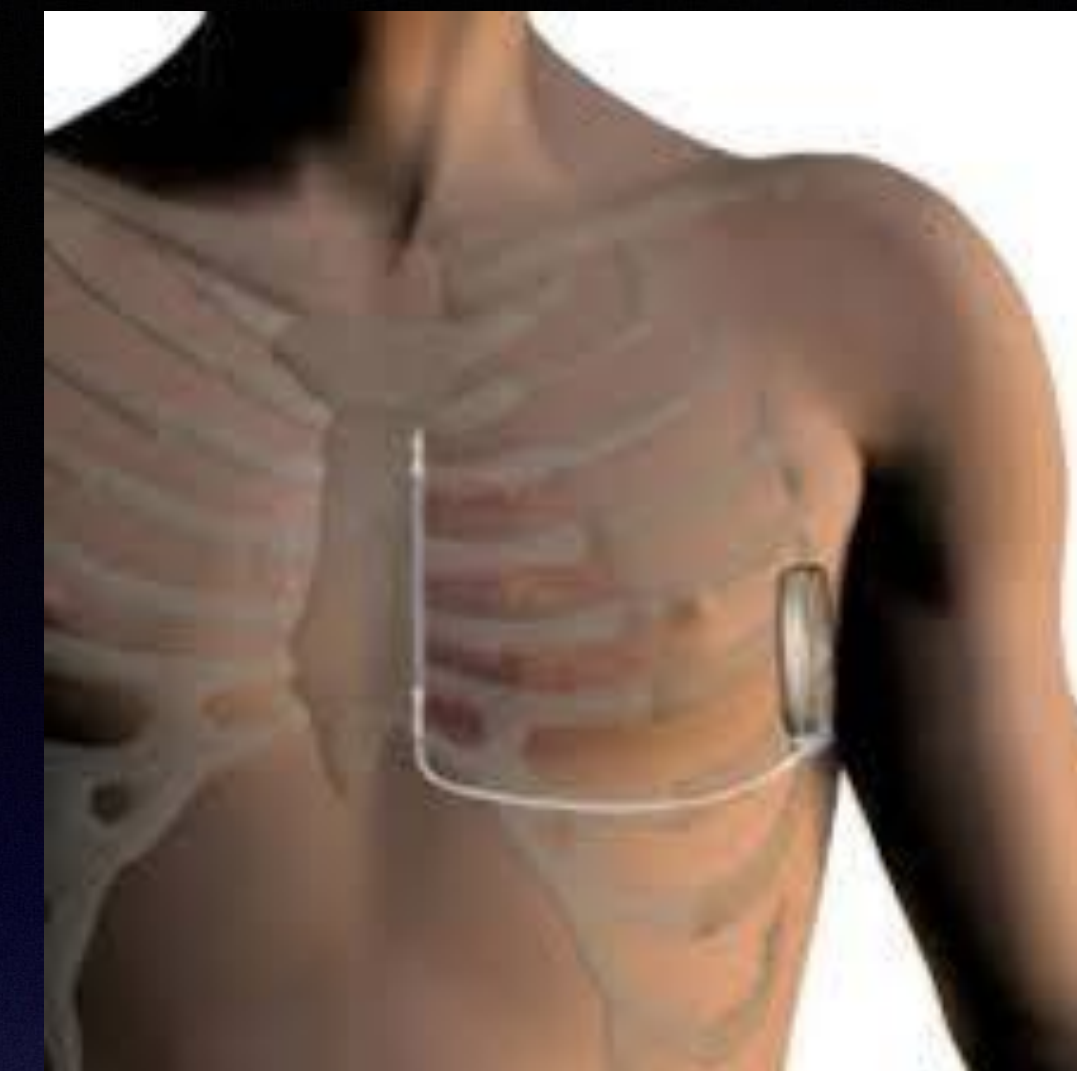
Intervento difficile e impegnativo
con importanti rischi associati,
Degenza lunga e debilitante

**MORTALITA' A 1 ANNO DEL
20-40%**

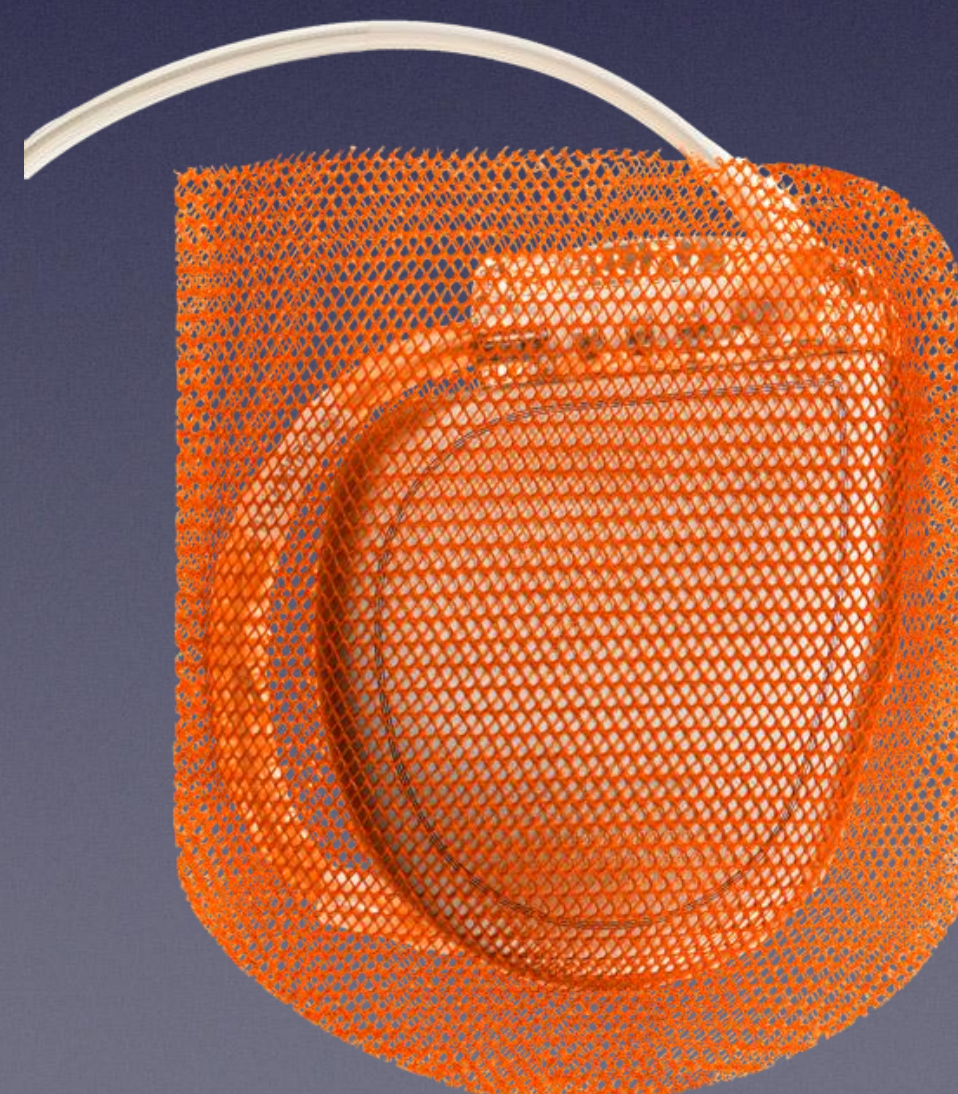
Consensus statement	Statement class	Scientific evidence coding	References
<i>Pre-procedural measures</i>			
<u>Confirm indication for CIED</u>		E	
Delay CIED implantation in patients with infection		E	28
Avoid temporary transvenous pacing and central venous lines, which should ideally be removed prior to introducing new hardware, whenever possible		O, M	21
<u>Measures to avoid pocket haematoma are recommended (avoid heparin bridging, discontinue antiplatelets if possible)</u>		R	21,29–31
Periprocedural use of therapeutic low-molecular-weight-heparin		R, M, O	30,32,33
Perform the CIED procedure in an operating room/suite with complete sterile environment as required for other surgical implant procedures		E	34
<u>Procedure should be performed or supervised by an operator with sufficient training and experience (Table 12)</u>		O	45
Topical <i>S. aureus</i> decolonization may be performed		E	
Pre-procedural skin wash may be performed		E	
<u>Hair removal with electric clippers (not razors) is recommended</u>		O	35
<u>Antibiotic prophylaxis is recommended within 1 h of incision for cefazolin and flucloxacilline, within 90-120 min for vancomycin</u>		R, M	21
A continuous surveillance program of infection rates and associated microbiology should be set-up at the level of each implanting centre		E	—
<i>Peri-procedural measures</i>			
Surgical preparation with alcoholic chlorhexidine should be used rather than povidone-iodine		R	36,37
<u>Allow sufficient time for the antiseptic preparation to dry</u>		E	
Adhesive iodophor-impregnated incise drapes may be used		E	
Perform the procedure with adequate surgical technique—minimize tissue damage, haemostasis, adequate wound closure		E	
<u>Antibiotic envelope in high-risk situations is recommended^a</u>		R	10
<u>If the operator performs the prepping and draping, glove change/re-scrub or remove outer glove of a double-glove before incision</u>		E	

RIDUZIONE DEL RISCHIO INFETTIVO

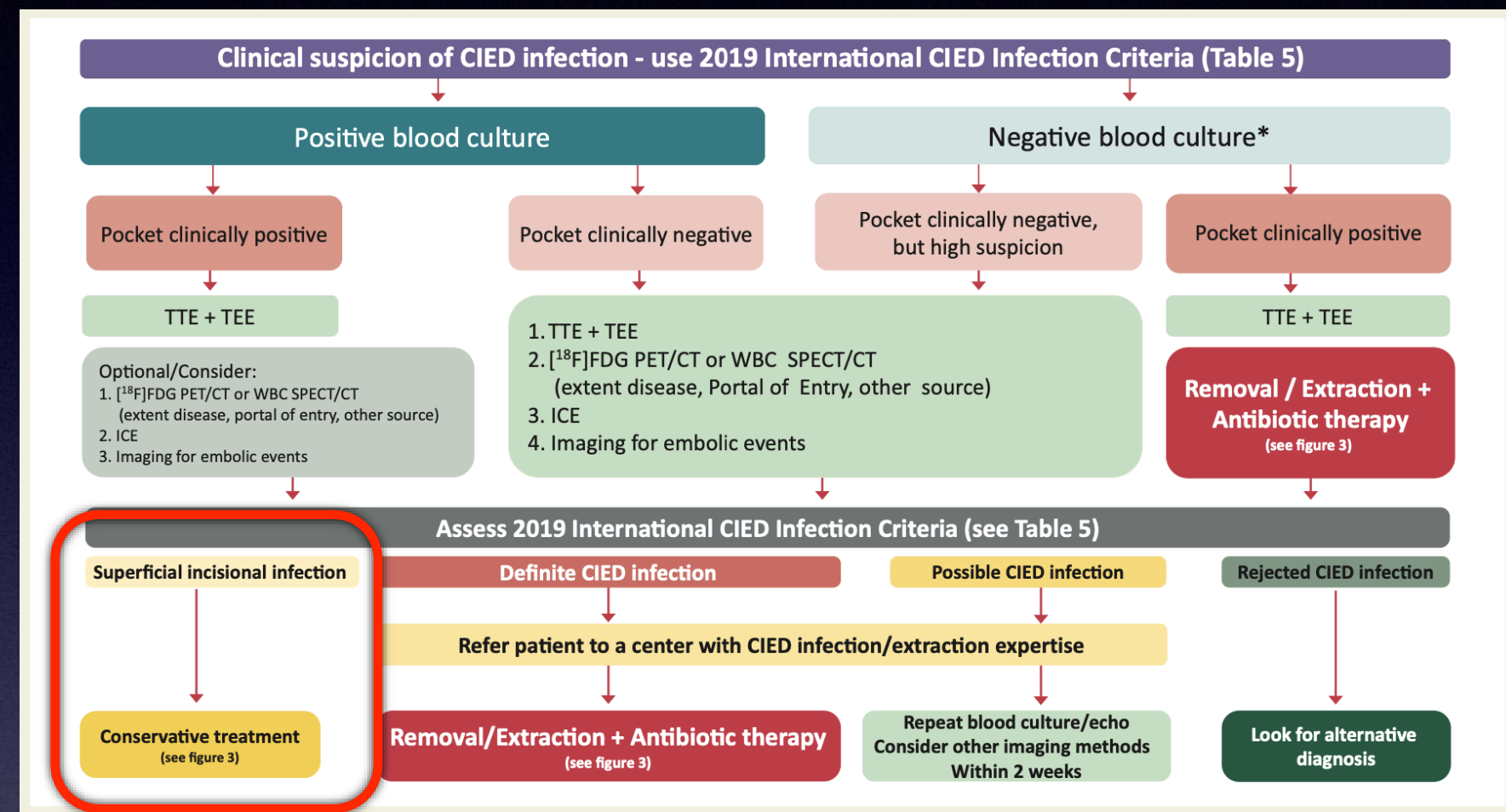
Consensus statement	Statement class	Scientific evidence coding	References
<u>Using local instillation of antiseptic and antibiotics in the pocket</u>		R, E	9
Use of braided sutures for final skin closure		E	
<i>Post-procedural measures</i>			
Use of postoperative antibiotic therapy		R	9
Adequate dressing for 2–10 days is recommended		E	
<u>Patient instructions on wound care should be provided</u>		E	
Delay or reconsider indication for re-intervention if possible		E	
<u>Haematoma drainage or evacuation (unless tense, wound dehiscence is present or pain is severe)</u>		O	24,28



NUOVI DEVICE



Necessario alert precoce



Gestione attenta delle complicanze locali
-infezione della ferita
-ematoma

Diagnosi precoce di infezione del sistema

Timing dell'estrazione per evitare polmonite e sepsi

CONCLUSIONI

Ombre: fragilità cronica, procedura complessa e pericolosa

Luci: nuove tecnologie

Messaggio chiave: diagnosi precoce e invio a centro hub