# 11° CONGRESSO NAZIONALE

CAMPUS Cuore

*Quello che le Linee Guida Non Dicono*

Napoli
5-6 aprile 2024

## INFEZIONI DI DEVICE IMPIANTABILI: PREVENZIONE E TRATTAMENTO

**Dr. Alberto Arestia**

In recent years the number of CIED complications increased because of:

- Increase of device implantation per year
- More complex procedures
- Sicker and high risk patients

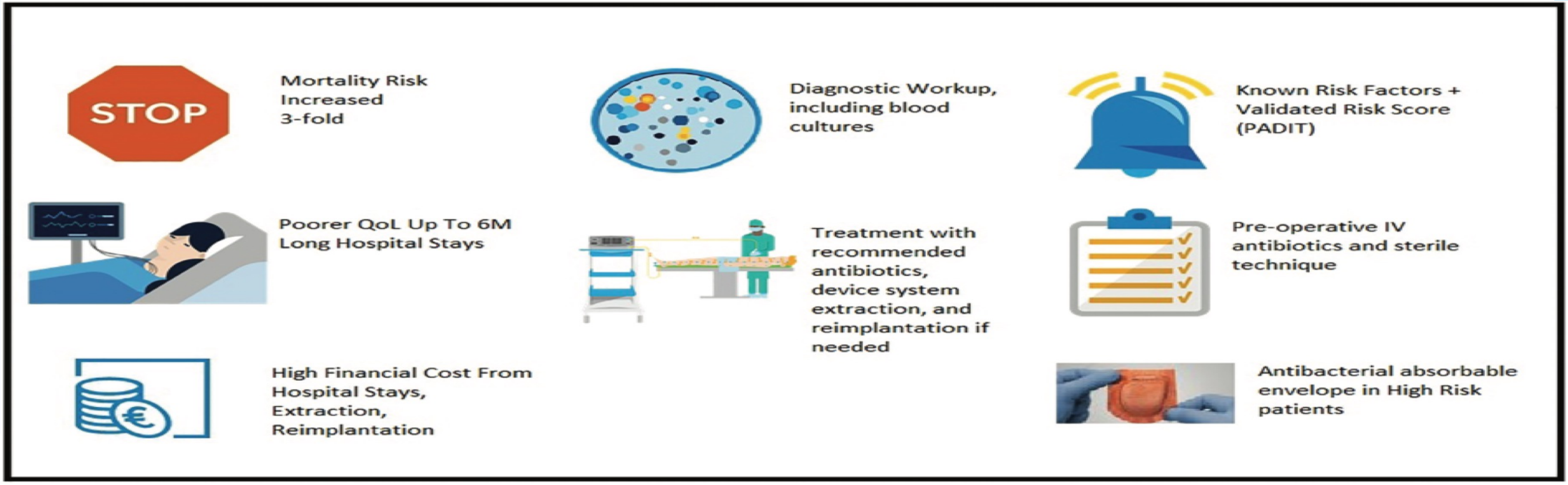
Transvenous Lead Extraction is the gold standard in the treatment of CIED-related infective complications and is often required in the management of lead malfunction

ESC European Society of Cardiology
Europace (2021) **23**, iv1–iv2
doi:10.1093/europace/euab139

EDITORIAL

# Infections of cardiac implantable electronic devices: still a cause of high mortality

**Andreas Goette [1]* and Philipp Sommer[2]**



ESC European Society of Cardiology

Europace (2020) **22**, 515–516
doi:10.1093/europace/euz246

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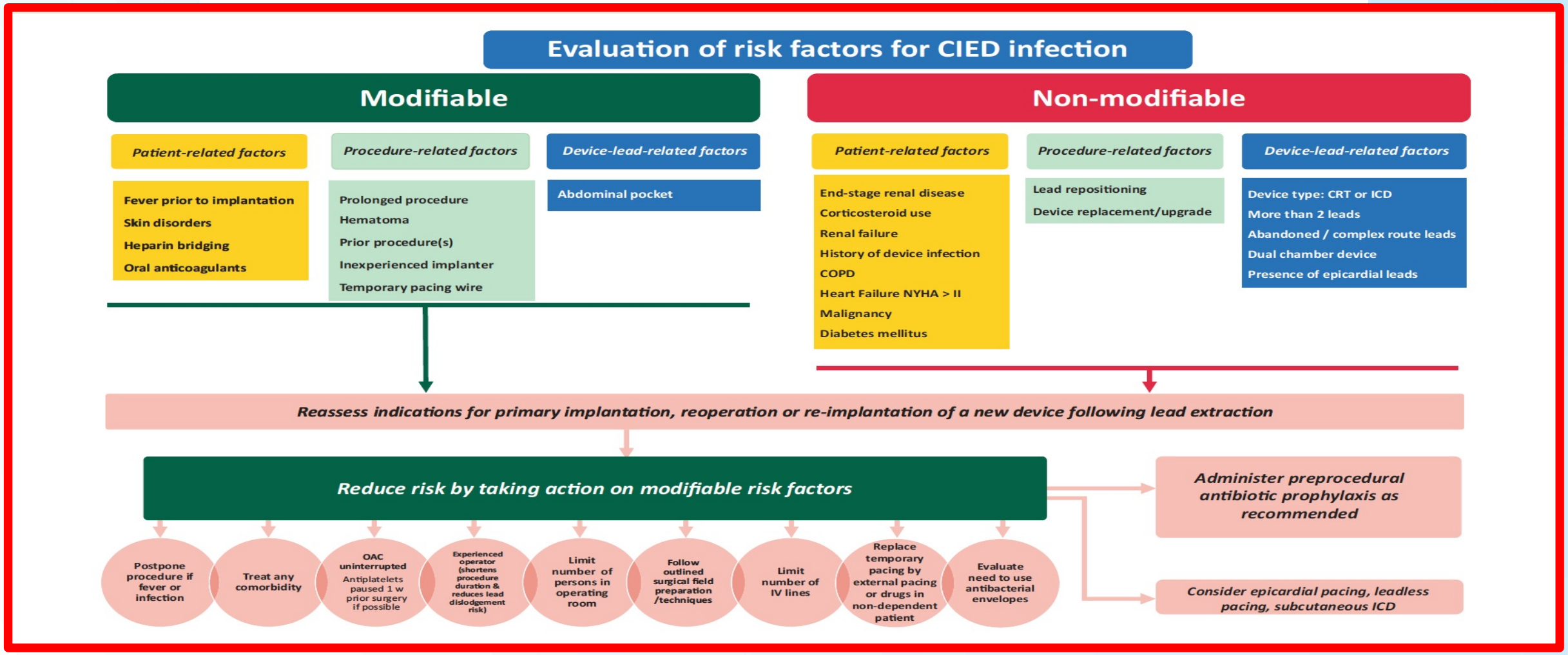

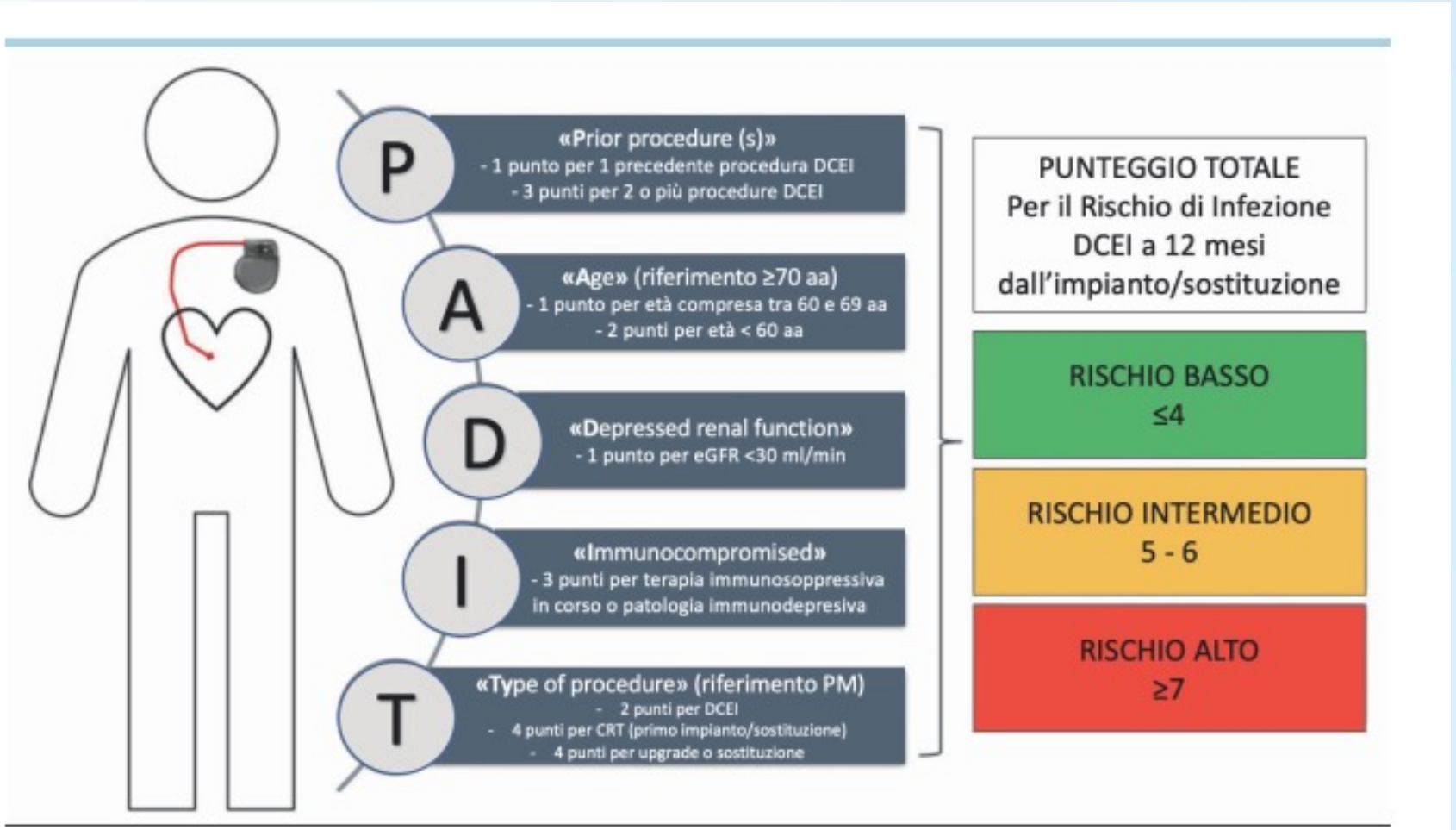
P
«Prior procedure (s)»
- 1 punto per 1 precedente procedura DCEI
- 3 punti per 2 o più procedure DCEI
A
«Age» (riferimento ≥70 aa)
- 1 punto per età compresa tra 60 e 69 aa
- 2 punti per età < 60 aa
D
«Depressed renal function»
- 1 punto per eGFR <30 ml/min
I
«Immunocompromised»
- 3 punti per terapia immunosoppressiva in corso o patologia immunodepresiva
T
«Type of procedure» (riferimento PM)
- 2 punti per DCEI
- 4 punti per CRT (primo impianto/sostituzione)
- 4 punti per upgrade o sostituzione
PUNTEGGIO TOTALE
Per il Rischio di Infezione
DCEI a 12 mesi
dall'impianto/sostituzione
RISCHIO BASSO
≤4
RISCHIO INTERMEDIO
5 - 6
RISCHIO ALTO
≥7

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le 2024

**Table 4** List of recommended preventive measures for CIED infections

| Consensus statement | Statement class | Scientific evidence coding | References |
|---|---|---|---|
| *Pre-procedural measures* | | | |
| Confirm indication for CIED | | 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 |
| Measures to avoid pocket haematoma are recommended (avoid heparin bridging, discontinue antiplatelets if possible) | | 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 |
| Procedure should be performed or supervised by an operator with sufficient training and experience (*Table 12*) | | O | 45 |
| Topical *S. aureus* decolonization may be performed | | E | |
| Pre-procedural skin wash may be performed | | E | |
| Hair removal with electric clippers (not razors) is recommended | | O | 35 |
| Antibiotic prophylaxis is recommended within 1 h of incision for cefazolin and flucloxacilline, within 90-120 min for vancomycin | | 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 | – |
| *Peri-procedural measures* | | | |
| Surgical preparation with alcoholic chlorhexidine should be used rather than povidone-iodine | | R | 36,37 |
| Allow sufficient time for the antiseptic preparation to dry | | 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 | |
| Antibiotic envelope in high-risk situations is recommended[a] | | R | 10 |
| If the operator performs the prepping and draping, glove change/re-scrub or remove outer glove of a double-glove before incision | | E | |

*Continued*

**Table 4** *Continued*

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

| | | | |
|---|---|---|---|
| Measures to avoid pocket haematoma are recommended (avoid heparin bridging, discontinue antiplatelets if possible) |  | R | 21,29–31 |
| Periprocedural use of therapeutic low-molecular-weight-heparin |  | R, M, O | 30,32,33 |

REVIEW

# Perioperative Anticoagulation Management in Patients on Chronic Oral Anticoagulant Therapy Undergoing Cardiac Devices Implantation: A Meta-Analysis

LING DU, M.M.,*,† YONG ZHANG, M.M.,* WEIZONG WANG, M.D.,*,‡ and YINGLONG HOU, M.D.*

tion is suggested in the guidelines.[26] Reducing the risk of hematoma with adequate management of anticoagulant therapy is also essential for infection risk. In a recent sub-analysis of the WRAP-IT study it is reported that hematoma increases infectious risk by up to 11 times.[27]

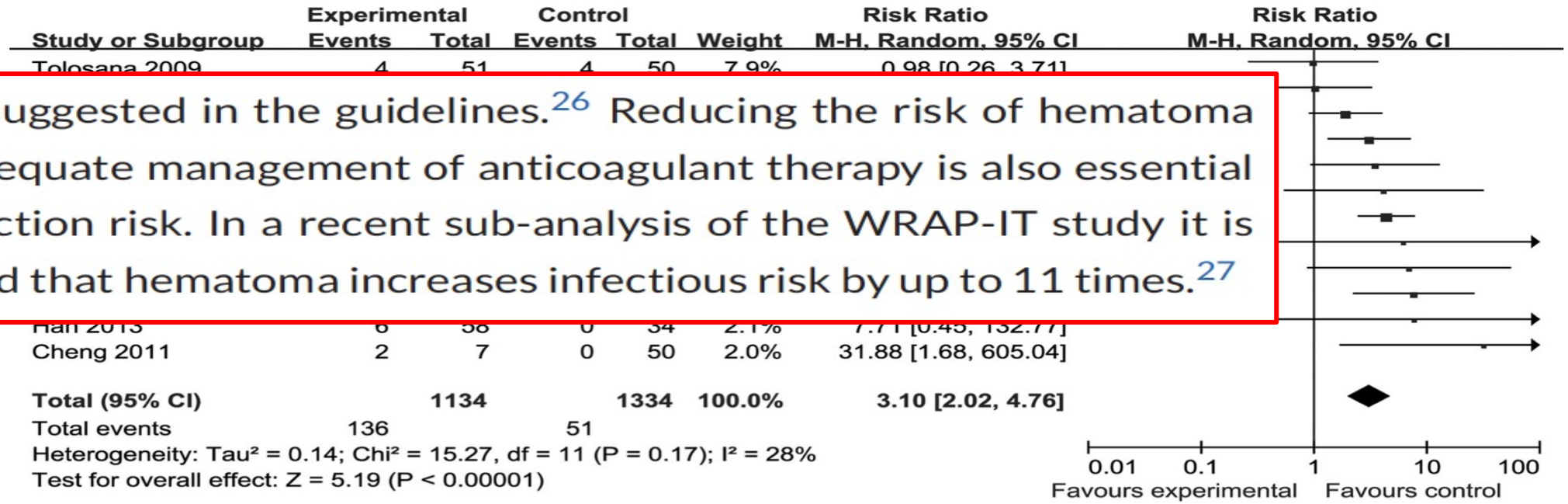


**Figure 2.** *Bleeding risk of heparin bridging versus OAC continuation; Experimental = bridging group; Control = OAC continuation group; CI = confidence interval; OAC = oral anticoagulant.*

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Europace (2020) **22**, 515–516
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—

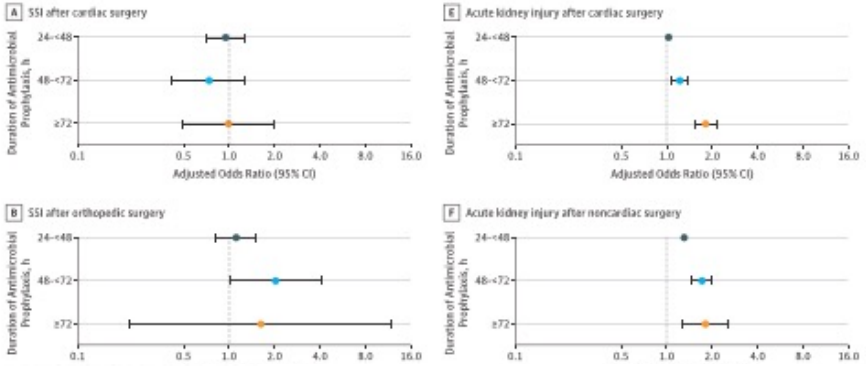
| | | | |
|---|---|---|---|
| Antibiotic prophylaxis is recommended within 1 h of incision for cefazolin and flucloxacilline, within 90-120 min for vancomycin |  | R, M | 21 |

JAMA Surgery | Original Investigation

# Association of Duration and Type of Surgical Prophylaxis With Antimicrobial-Associated Adverse Events

Westyn Branch-Elliman, MD, MMSc; William O'Brien, MS; Judith Strymish, MD; Kamal Itani, MD; Christina Wyatt, MD; Kalpana Gupta, MD, MPH

Figure 2. Adjusted Odds of Surgical Site Infection (SSI), Acute Kidney Injury, and *Clostridium difficile* Infection by Duration of Antimicrobial Prophylaxis




Incremento di incidenza di AKI, colite da C. Difficile nei gruppi trattati con antibioticoterapia prolungata senza avere una riduzione dell'infezione del sito chirurgico

*Post-procedural measures*

## Use of postoperative antibiotic therapy

R

# INFEZIONE CIED: COME DIAGNOSTICARLA?

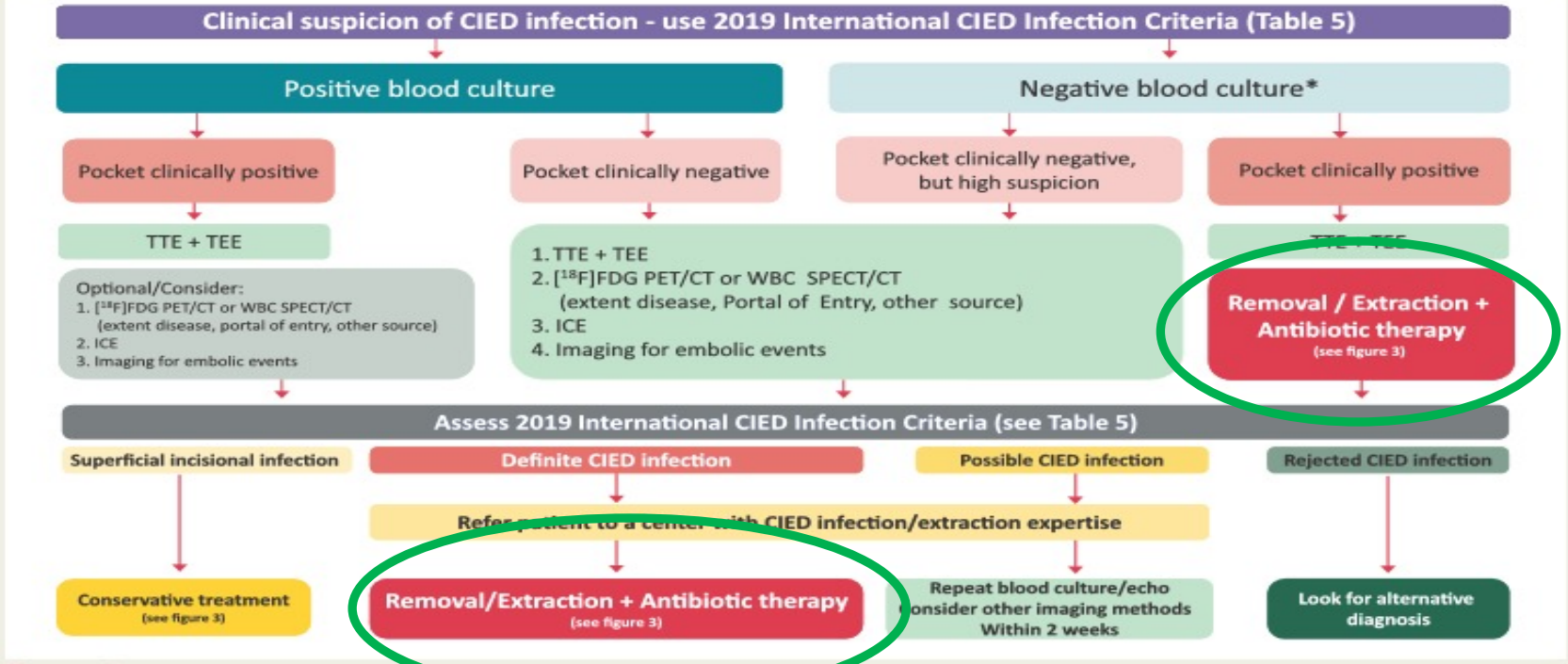


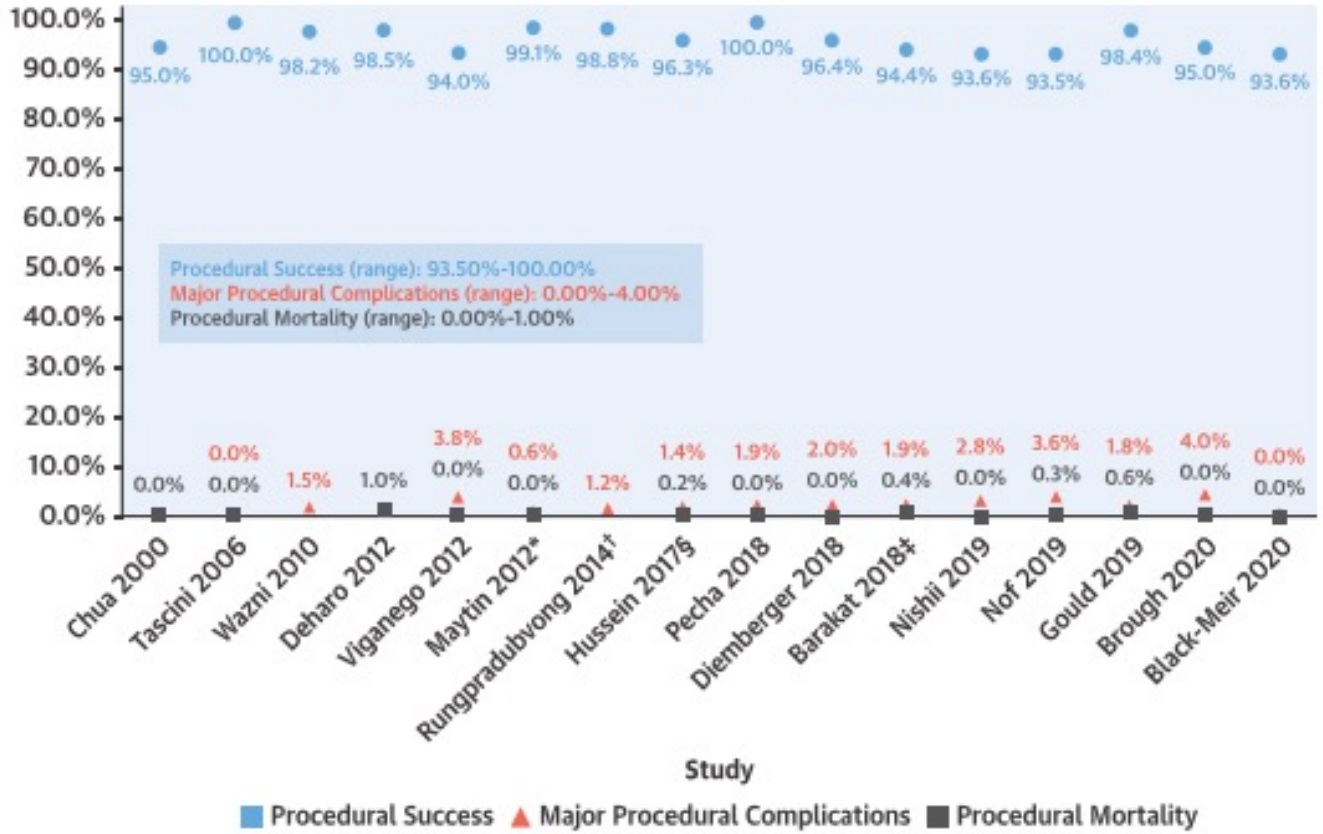

**Figure 2** Diagnostic algorithm for diagnosis of suspected CIED infection*, ensure sufficient number of blood cultures collected and absence of confounding antibiotic therapy prior to cultures. CIED, cardiac implantable electronic device; [18F]FDG PET/CT, fluorodeoxyglucose positron emission tomography—computed tomography; ICE, Intracardiac echocardiography; IE, infective endocarditis, TEE, transoesophageal echocardiography; TTE, transthoracic echocardiography; WBC SPECT/CT, white blood cell single-photon emission computed tomography—computed tomography.

**Table 8 Recommendations for device and lead removal**

| Consensus statement | Statement class | Scientific evidence coding | References |
|---|---|---|---|
| In patients with definite CIED infection (systemic and local), complete device removal is recommended (including abandoned leads, epicardial leads, and lead fragments) | ♥ | O | 81,102,104 |
| After diagnosis of CIED infection, the device removal procedure should be performed without unnecessary delay (ideally within 3 days) | ♥ | O | 104 |
| The recommended technique for device system removal is percutaneous, transvenous extraction technique. Epicardial leads require surgical removal | ♥ | O | 105 |
| Complete CIED removal is recommended in patients with infective endocarditis with or without definite involvement of the CIED system | ♥ | E | 113 |
| Blood cultures should be taken 48–72 h after removal of an infected CIED | ♥ | E | 19 |

CIED, cardiac implantable electronic device; E, expert opinion; M, meta-analysis; NA, not available; O, observational studies; R, randomized trials.

**FIGURE 2** Clinical Outcomes for Cardiac Implantable Electronic Device Extractions in Patients With Cardiac Implantable Electronic Device Infection




Extraction for cardiac implantable electronic device infection is associated with high procedural success (majority of studies showing rates of >95%), low major procedural complication (between 0% to 4%), and very low procedural mortality (0% to 1%). *Results reported for the local infection cohort. †Results reported for the early extraction cohort. ‡Results reported for the normal renal function group. §Results reported for patients without abandoned leads.

**Table 3 Definition of LE approaches, techniques and tools**

| Type |
| --- |
| Approach |
| Transvenous |
| Superior approa |
| Venous entry |
| Transjugular |
| Inferior approac |
| Surgical |
| Tools and techniques |
| Sheath |
| Non-powered |
| Powered |
| Stylet |
| Snares |
| Basket |
| Deflectable wires |
| Lead extenders |
| Compression coils |
| Occlusion balloons |

LE, lead extraction; RFA,

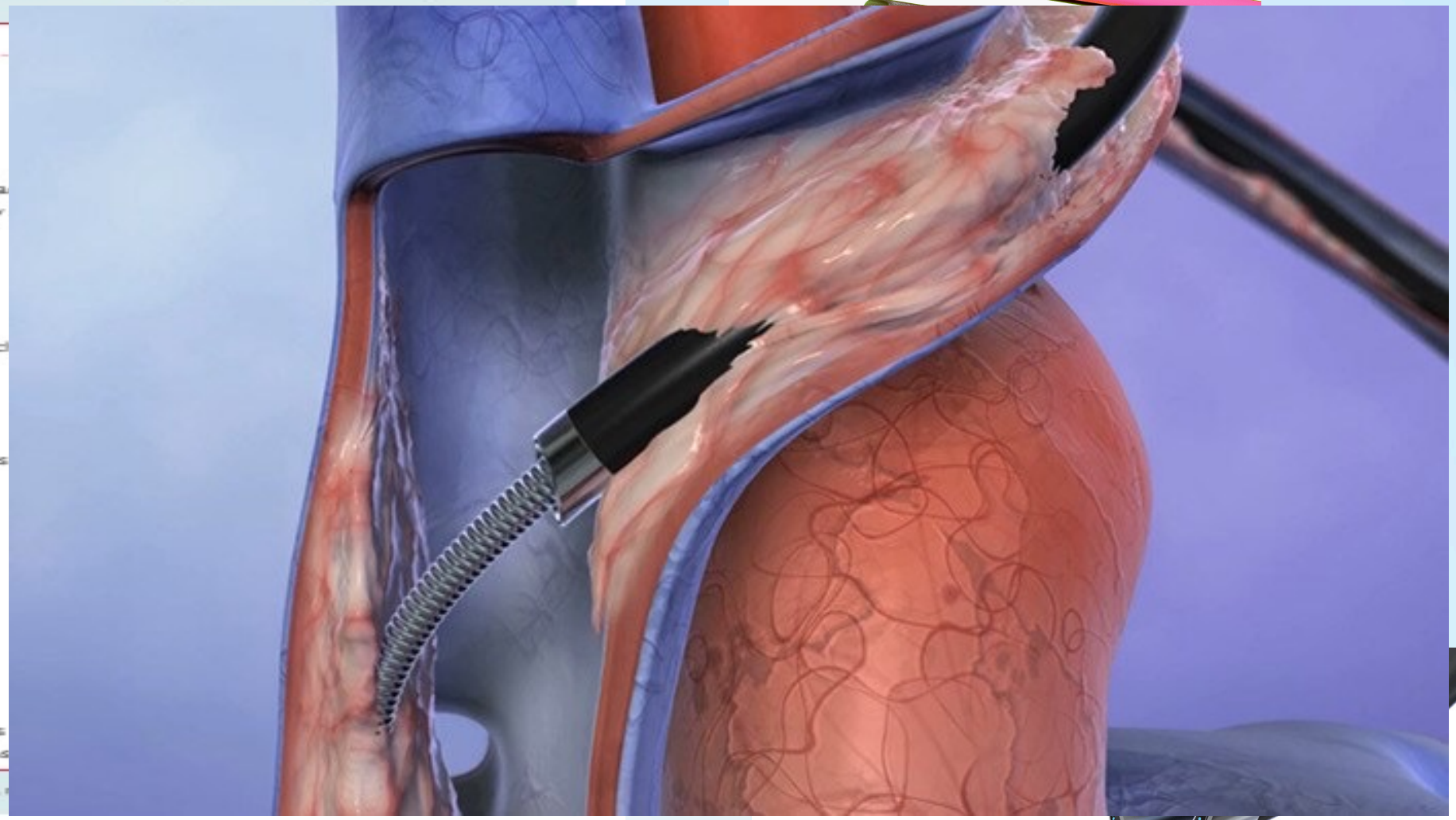
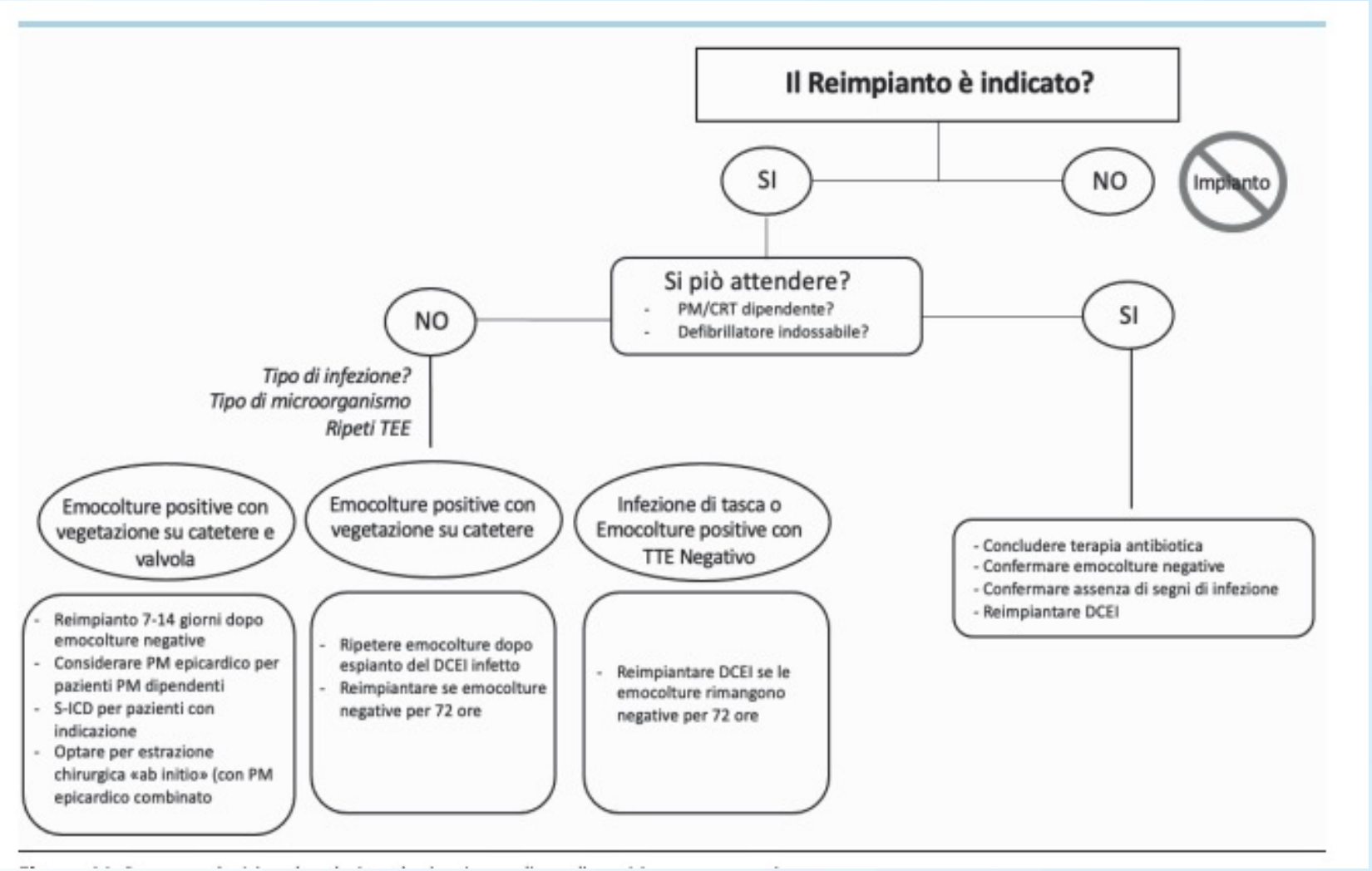


**Table 10** **Recommendations for preventive strategies after device implantation and for new re-implantations including alternative novel devices**

| Consensus statement | Statement class | Scientific evidence coding | References |
|---|---|---|---|
| After device extraction, re-assessment of the indication for re-implantation is recommended |  | O | 38,122 |
| Whenever possible, re-implantation may be avoided or delayed until symptoms and signs of systemic and local infection have resolved |  | O | 38,123 |
| A temporary pacemaker with ipsilateral active fixation strategy may be considered in pacemaker-dependent patients requiring appropriate antibiotic treatment before re-implantation |  | O | 124–127 |
| Preferred access sites for replacement device are the contralateral side, the femoral vein, or epicardially |  | E, O | 38,128,129 |
| Temporary pacing in patients who are not pacemaker dependent |  | O | 28 |
| Replacement device implantation ipsilateral to the extraction site |  | E | 38 |
| Alternative novel devices as LPM and S-ICD may be considered in selected patients with high infective risk or in patients in whom these devices are considered better options after an CIED infection |  | O | 129–133 |

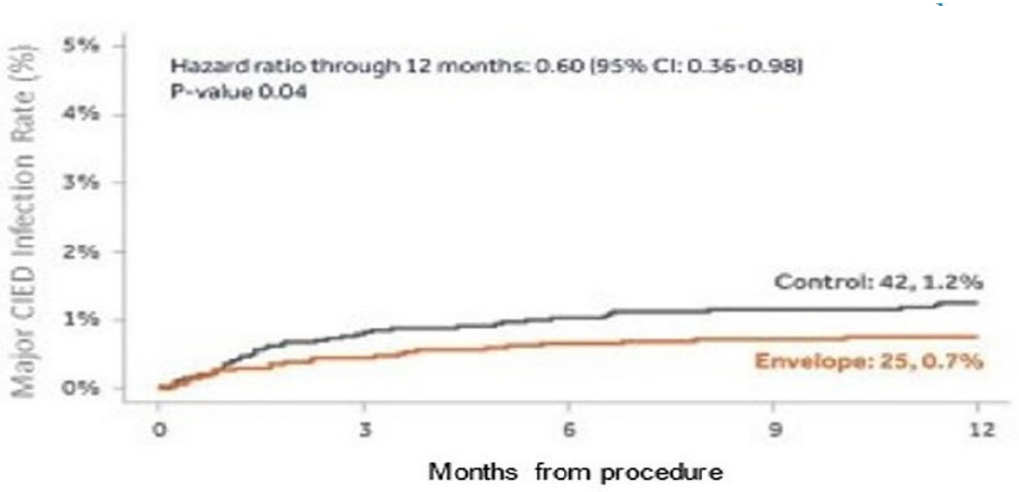
CIED, cardiac implantable electronic device; E, expert opinion; LPM, leadless pacemaker; M, meta-analysis; O, observational studies; R, randomized trials; S-ICD, subcutaneous implantable cardiac defibrillator.


Il Reimpianto è indicato?
SI
NO
Impianto
Si pió attendere?
- PM/CRT dipendente?
- Defibrillatore indossabile?
NO
SI
Tipo di infezione?
Tipo di microorganismo
Ripeti TEE
Emocolture positive con vegetazione su catetere e valvola
Emocolture positive con vegetazione su catetere
Infezione di tasca o Emocolture positive con TTE Negativo
- Concludere terapia antibiotica
- Confermare emocolture negative
- Confermare assenza di segni di infezione
- Reimpiantare DCEI
- Reimpianto 7-14 giorni dopo emocolture negative
- Considerare PM epicardico per pazienti PM dipendenti
- S-ICD per pazienti con indicazione
- Optare per estrazione chirurgica «ab initio» (con PM epicardico combinato
- Ripetere emocolture dopo espianto del DCEI infetto
- Reimpiantare se emocolture negative per 72 ore
- Reimpiantare DCEI se le emocolture rimangono negative per 72 ore

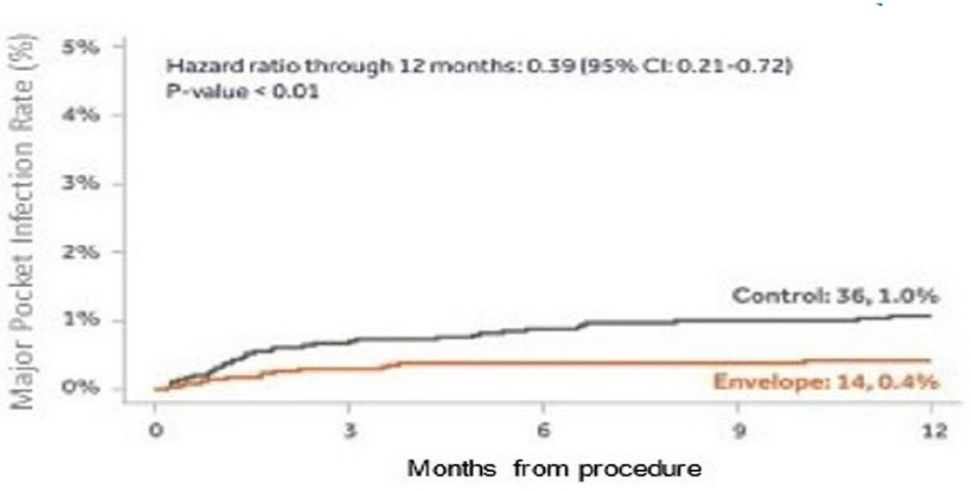
JACC: CLINICAL ELECTROPHYSIOLOGY


# Clinical Presentation, Timing, and Microbiology of CIED Infections

## An Analysis of the WRAP-IT Trial




**Included**
- CIED generator replacement, system upgrade, or overhaul
- Initial CRT-D




**Excluded**
- Hemodialysis or peritoneal dialysis
- Immunosuppressive agents (chronic oral or >20 mg of prednisone)
- Recent CIED infection (<12 months)

ESC European Society of Cardiology
Europace (2023) **25**, 1–8
https://doi.org/10.1093/europace/euad224

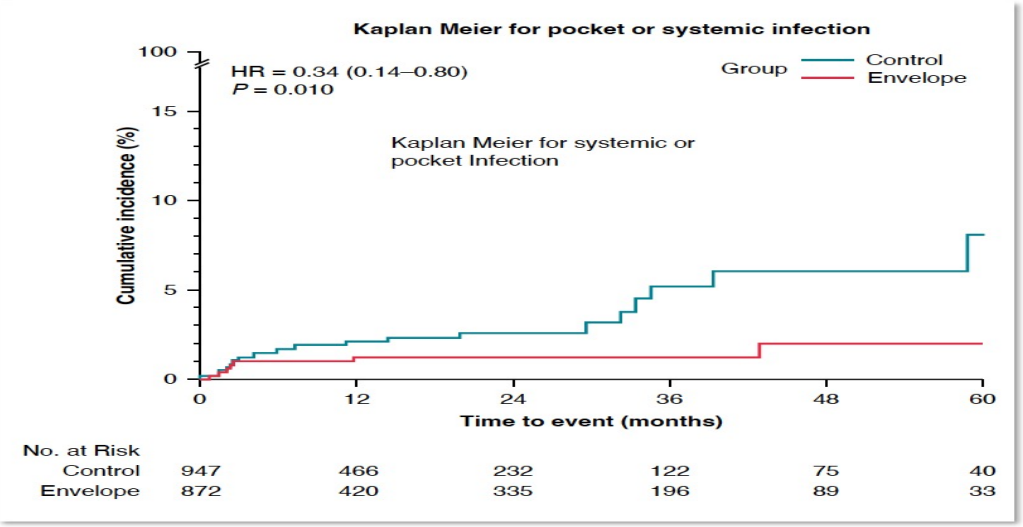
CLINICAL RESEARCH

# REducing INFectiOns thRough Cardiac device Envelope: insight from real world data. The REINFORCE project

The use of the Envelope was associated with a reduction of infection-related events of more than 60% in high, medium, and low risk populations and its protective effect was maintained over time.

| At least one infection-related clinical event (Pocket or Systemic infection) | TOTAL (n=1819) | Envelope (N = 872) | Control (N = 947) | P-value |
|---|---|---|---|---|
| PADIT Score = Low | 1.2% (11/903) | 0.0% (0/271) | 1.7% (11/632) | **0.029** |
| PADIT Score = Medium | 1.7% (8/483) | 0.7% (2/276) | 2.9% (6/207) | 0.064 |
| PADIT Score = High | 2.5% (11/433) | 1.5% (5/325) | 5.6% (6/108) | **0.022** |

Infective related events (Systemic or pocket infections) according to PADIT score.




Cumulative Event Rate of systemic or pocket infection in the Envelope and Control group by Kaplan-Meier estimate.

# CONCLUSIONI

- La prevenzione delle infezioni è un percorso che inizia fuori dalla sala operatoria ma continua dentro e dopo la dimissione perché l'evento infettivo è devastante

- L'adeguata preparazione del paziente e la corretta formazione del personale sanitario riducono l'esposizione al rischio infettivo

- Nel caso di un rischio elevato riconosciuto a priori bisogna tenere in considerazione la possibilità di utilizzare envelope antibatterici che abbassano significativamente la possibilità di infezioni

# CONCLUSIONI

- In caso di infezione CIED è di fondamentale importanza la corretta e tempestiva diagnosi data l'elevata mortalità

- Il trattamento percutaneo di estrazione dei CIED è sicuro nei centri specializzati ed è da considerare Gold Standard per il trattamento delle infezioni CIED-correlate
- Al momento del reimpianto di un CIED il corretto timing procedurale gioca un ruolo chiave al fine di evitare problematiche future