Device Infection the Nightmare
How to deal with?

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Incidence and mortality

- In the USA, the overall incidence of cardiac implantable electronic device (CIED) infections ranged from 0.5% to 2.2% of patients in 18 studies with follow-up or study periods between 6 weeks and 11 years.

![Graph showing change in CIED implants and infections between 1993-2008](image)

**Conclusions** Infection associated with CIED procedures resulted in substantial incremental admission mortality and long-term mortality that varied with the CIED type and occurred, in part, after discharge.

Cost for procedure of CIED without infection

Cost for procedure of CIED with infection
The aim of this study was to systematically summarize the literature on risk factors for infection after CIED implantation.

Sixty studies (21 prospective, 9 case–control, and 30 retrospective cohort studies) met the inclusion criteria.

The average device infection rate was 1–1.3%.

### Patient related risk factors
- Male gender
- Younger age
- DM
- Chronic Kidney Disease
- Renal Failure
- Haemodialysis
- COPD
- Congestive Heart Failure

### Procedure related risk factors
- Lack of antimicrobial prophylaxis
- Longer procedure duration
- Pocket haematoma
- More complex CIED
- Re-intervention for lead dislodgement

<table>
<thead>
<tr>
<th>Chronic skin disease</th>
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<td>Anticoagulation</td>
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<td>Corticosteroid treatment</td>
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<td>Fever in 24 hrs pre-implantation</td>
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<td>Early re-intervention (&lt;1 year)</td>
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<td>Number of prior procedures</td>
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<td>Low operator experience</td>
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<tr>
<td>Temporary pacing</td>
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<td>Device replacement</td>
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<td>Prior CIED infection</td>
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<td>Early infection</td>
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**Clinical presentation of CIED infection**

- **Early post-implantation inflammation**
  - Erythema affecting the box implantation incision site
  - Without purulent exudate, dehiscence, fluctuance or systemic signs of infection
  - occurring within 30 days of implantation.
  - Includes a small, localised area (<1 cm) of erythema and/or purulence associated with a suture ('stitch abscess')

- **Uncomplicated generator pocket infection**
  - Any one of:
    1. Spreading cellulitis affecting the generator site
    2. Incision site purulent exudate (excluding simple stitch abscess)
    3. Wound dehiscence
    4. Erosion through skin with exposure of the generator or leads
    5. Fluctuance (abscess) or fistula formation,
       AND **no systemic symptoms or signs of infection**
       AND **negative blood cultures**
Complicated generator pocket infection

- As for uncomplicated generator pocket infection but with any one of:
  1. Evidence of lead or endocardial involvement
  2. Systemic signs or symptoms of infection
  3. Positive blood cultures

CIED-lead infection (CIED-LI)

- Symptoms and signs of systemic infection without signs of generator pocket infection, but with:

  - Definite CIED-LI—either:
    1. Echocardiography consistent with vegetation(s) attached to lead(s) and major modified Duke microbiological criteria or
    2. Culture, histology or molecular evidence of infection on explanted lead

  - Possible CIED-LI—either:
    1. Echocardiography consistent with vegetation(s) attached to lead(s) but no major modified Duke microbiological criteria or
    2. Major modified Duke microbiological criteria but no echocardiographic evidence of lead vegetation(s)
CIED-associated infective endocarditis (CIED-IE)

- All of:
  1. CIED in situ
  2. Modified Duke criteria for definite infective endocarditis
  3. Echocardiographic evidence of valve involvement

**Microbiology**

- Pathogens were identified in the vast majority of patients (86.8%)
- Staphylococcal species remained the most common pathogens in CIED infections (68.4%)

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Identifying the pathogens

- Source
  1. lead material cultures (63.9%),
  2. Blood cultures (54.5%),
  3. pocket tissue cultures (52.9%),
  4. pocket swab cultures (44.2%).
  5. No growth -- remaining 13.2%

When should blood cultures be taken?

- Blood cultures should be taken prior starting antimicrobial therapy.
- On clinical suspicion of ICED infection:
  - **Chronic or subacute presentation**
    - 3 sets of aseptically collected, optimally filled blood taken from peripheral sites with ≥6 h between them
  - **Severe sepsis or septic shock at the time of presentation**
    - 2 sets of optimally filled blood cultures should taken from peripheral sites with 1 h between them
- Blood cultures should be taken from different peripheral sites
- Blood cultures should be taken 48–72 h after removal of an infected CIED.
- Apply meticulous aseptic technique when taking blood cultures to reduce the risk of contamination with skin commensals
Management of CIED infection

The biofilm (the growth of bacteria on solid surfaces) nature of CIED infection makes eradication of infection very unlikely without removal of the device.

In early post-implantation inflammation, should be determined on a case-by-case basis—either using a short course of an oral antimicrobial appropriate for soft tissue infection or monitoring closely.

In generator pocket infection, CIED-IL, CIED-IE or culture negative CIED infection, empirical IV antimicrobial therapy should be started until the results of the culture.

Anti-Gram-positive (Vancomycin or Daptomycin) & anti-Gram-negative agents (Aminoglycosides e.g. gentamicin or Meropenem) should be combined for Empirical IV antimicrobial therapy.
How should the device be managed?

- Infection relapse occurs in 50% to 100% of cases with partial removal or antibiotic treatment alone, compared to relapse of 0% to 4.2% with complete system removal.
- Device removal during the index hospitalization was associated with improved 1-year survival.

![Graph showing survival rates with and without device removal.](image1)

<table>
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<tr>
<th>No. at risk</th>
<th>Device removal</th>
<th>No device removal</th>
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<tbody>
<tr>
<td>141</td>
<td>112</td>
<td>98</td>
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<td>84</td>
<td>80</td>
<td>79</td>
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Log-rank *P* = .009

Athan E et al. JAMA 2012;307(16):1727-1735

**Consensus Recommendation for complete hardware removal**

![Flowchart showing class IIa and class I recommendations.](image2)

- **Systemic**
  - Persistent occult gram-negative bacteremia

- **Pocket**
  - Pocket abscess, device erosion, skin adherence, chronic draining sinus

- **Endocarditis**
  - Valvular endocarditis, lead endocarditis, sepsis with or without definitive lead involvement

**Consensus Recommendation for implantation of a new device in patients after removal of an infected CIED**

- Blood cultures (+) TEE (+)
  - Repeat blood cultures after CIED removal
  - Implant new CIED if repeat blood cultures remain negative for 72 hours
  - Implant new CIED after 14 days from first negative blood culture

- Blood cultures (+) TEE (-)
  - Repeat blood cultures after CIED removal
  - Implant if repeat blood cultures are negative for at least 72 hours

- Generator pocket infection/Generator or lead erosion
  - Negative blood cultures for 72 hours
  - Implant new CIED following adequate debridement of the generator pocket

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**Prevention of CIED infection**

**Pre-implantation**

- CIED treatment should be prescribe carefully with a balanced assessment of risks and benefits.

- In high risk group, good pre-operative preparation is warranted including blood sugar level, serum creatinine and acute phase reactants.

- Fever <24 h before implant is associated with higher infection risk. Therefore diagnose and treat ongoing infections before CIED implant.

- Wherever possible, temporary transvenous pacing should be avoided prior to implanting a permanent ICED.

- Central venous catheters and chest tubes should be removed in timely fashion before CIED implantation. Preferably >24 hs.

- Chronic skin conditions are associated with a higher infection risk and should be appropriately treated before implantation.
Peri-operatively

- General recommendations for reducing surgical site infection should be applied such as skin preparation ... etc.
- Peri-operative systemic antibiotic prophylaxis prior to CIED procedures is mandatory.
- Meticulous surgical technique to prevent tissue damage, assure haemostasis, and ensure secure subcutaneous cover for the device should be standard.
- During device replacement procedures, some authors support capsulectomy. No controlled studies have tested this strategy.
- In anti-coagulated patients, continued warfarin use is preferred to heparin bridging because of a lower risk of haematoma.
- A conservative approach when managing haematoma is often advisable, unless particularly tense or painful. Even large haematomas gradually soften and resorb over a few weeks.

Take home messages

- CIED infection rate is increasing with high incidence of mortality.
- Risk factors for CIED infection are related to patient and/or the procedure itself.
- Maintain a high suspicion for early recognition and management of CIED infection.
- Staphylococcal species is the most common pathogens in CIED infections.
- Empirical antimicrobial using anti-gram-negative and anti-gram positive agents.
- Complete removal of all hardware in CIED infection.
- Blood culture should be negative before implantation of a new device in patients after removal of an infected CIED.
- The key challenge in the management of CIED infection is prevention.
Aim for any case of cardiology