2017 HRS Expert Consensus Statement on CIED Lead Management and Extraction

Summary, Discussion, and Perspectives

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16-Year Trends in the Infection Burden for PM and ICD in the US: 1993 to 2008



Annual number of PM and ICD implantations: 1993 to 2008



PM vs ICD in % of all CIED implantations: 1993 vs 2008

16-Year Trends in the Infection Burden for PM and ICD in the US: 1993 to 2008



Annual rate of CIED infections

Incidence of comorbidities in patients with CIED infection

16-Year Trends in the Infection Burden for PM and ICD in the US: 1993 to 2008



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

Greenspon AJ, JACC 2011;58:1001

ACC/AHA Task Force Statement

Further Evolution of the ACC/AHA Clinical Practice Guideline Recommendation Classification System

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Class (strength) of recommendation

COR

- I Benefit >>> Risk STRONG
- IIA Benefit >> Risk MODERATE

HARM

- IIB Benefit ≥ Risk WEAK
- III Benefit = Risk NO BENEFIT
- III Risk > Benefit

Level (quality) of evidence LOE

- A high quality evidence from more than 1 RCT
- B-R moderate quality evidence from 1 or more RCT
- B-NR moderate quality evidence from observational study
- C-LD Limited data
- C-EO Expert opinion

Definitions

- Isolated generator pocket infection: localized erythema, swelling, pain, tenderness, warmth, or drainage with negative blood cultures
- Isolated pocket erosion: device and/or lead(s) are through the skin, with exposure of the generator or leads, with or without local signs of infection
- Bacteremia: positive blood cultures with or without systemic infection symptoms and signs
- Pocket site infection with bacteremia: local infection signs and positive blood cultures
- Lead infection: lead vegetation and positive blood cultures
- Pocket site infection with lead/valvular endocarditis: local signs and positive blood cultures and lead or valvular vegetation(s)
- CIED endocarditis without pocket infection: positive blood cultures and lead or valvular vegetation(s)
- Occult bacteremia with probable CIED infection: absence of alternative source, resolves after CIED extraction
- Situations in which CIED infection is not certain: impending exteriorization, isolated left heart valvular endocarditis in a patient with a CIED
- Superficial incisional infection: involves only skin and subcutaneous tissue of the incision, not the deep soft tissues (eg, fascia and/or muscle) of the incision

Clinical presentation of CIED infections



Sohail MR, JACC 2007;49:1851

The Multicenter Electrophysiologic Device Infection Cohort (MEDIC) study



Greenspon AJ, J Am Coll Cardiol 2012;59:681–7

Risk factors for CIED infection

| Patient-related factors | Procedure-related factors | Microbe-related factors |
|--|--|--|
| Age Chronic kidney disease Hemodialysis Diabetes mellitus Heart failure Chronic obstructive pulmonary disease Preprocedure fever Malignancy Skin disorder Immunosuppressive drug Prior CIED infection Anticoagulation | Pocket reintervention (generator change, upgrade, lead or pocket revision) Pocket hematoma Longer procedure duration Inexperienced operator ICD (compared with PM) Lack of use of prophylactic antibiotics | Highly virulent microbe (eg, staphylococci) |

CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter defibrillator; PM = pacemaker.

Diagnosis - Summary of recommendations (1)

| COR | LOE | Recommendations |
|-----|------|---|
| I | C-LD | If antibiotics are going to be prescribed, drawing at least two sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy. |
| I | C-LD | The sensitivity of tissue culture (69%) is higher than that of the swab culture (31%) of the pocket A connector culture provides a more than 90% positive yield |
| I | B-NR | TEE should be considered for all patients who have documented/suspected BSI or CIED pocket infection |
| I | C-EO | Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection. |

Diagnosis - Summary of recommendations (2)

| COR | LOE | Recommendations |
|-----|------|--|
| IIa | B-NR | TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations. |
| IIa | C-EO | Evaluation by physicians with specific expertise in CIED infection and lead extraction can be useful for patients with suspected CIED infection. |
| IIb | C-LD | Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods. |

Management- Summary of recommendations

| COR | LOE | Recommendations |
|-----|-----------------|---|
| I | of diagnosis is | s of CIED infection and performing lead extraction within 3 days associated with lower in-hospital mortality analysis found a 7-fold increase in 30-day mortality if the CIED was not removed |
| I | C-EO | Complete removal of epicardial leads and patches is recommended for all patients with confirmed infected fluid (purulence) surrounding the intrathoracic portion of the lead. |
| I | B-NR | Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. |
| I | B-NR | Complete device and lead removal is recommended for patients with persistent or recurrent bacteremia or fungemia, despite appropriate antibiotic therapy and no other identifiable source for relapse or continued infection. |
| I | C-EO | Careful consideration of the implications of other implanted devices and hardware is recommended when deciding on the appropriateness of CIED removal and for planning treatment strategy and goals. |

Infective Endocarditis in Patients with CIED

One-year survival

By concomitant valve

infection



By device removal

and device removal



Athan E, JAMA 2012;307:1727

Infective Endocarditis in Patients with CIED



Infective Endocarditis in Patients with CIED



Considerations for reimplantation

- Reassessment of the need for a new CIED is imperative after removal of an infected CIED
- The optimal timing of device replacement is unknown: there are no prospective trial data on the timing of new device replacement and risk of relapsing infection
- A new implantation can reasonably be postponed until blood cultures are negative for 72 hours, although implantation should be delayed if the patient has another undrained source of infection
- Replacement device implantation should be performed in an alternative location such as the contralateral side, the iliac vein, or using epicardial or subcutaneous implantation
- Single-center studies have suggested that same-day implantation is feasible for patients with isolated pocket infections and is not associated with adverse outcomes

Management of suspected CIED infection



Management of suspected pocket infection



Management of bacteremia without evidence of CIED infection



First-line, empirical Ab Rx



| Drug | Dosing and route | Duration | Comments |
|--|---|-----------------------|------------------------------------|
| Early isolated | oocket infection | | |
| Pristinamycin | 1gx3/d oral | | |
| or Clindamycin | 600 mgx3/d oral | 10 days | If body weight > 100kg: 600 mgx4/d |
| Suspected CIE | D infection | | |
| Sepsis (Quick | sofa ≥ 2) | | Alternative choice |
| Vancomycin + | 40 mg/kg/d, continuous IV infusion, after a loading dose of 30mg/kg IVL | Until culture | Daptomycin 10 mg/kg/d, qd IV |
| Cofotovimo | 150 mg/kg/d | results | β-lactam allergy: Aztreonam 100 |
| Cefotaxime | 150 mg/kg/u | | mg/kg/d tid IV |
| No sepsis: inititation of Ab Rx immediately after device removal and microbiology sampling | | | |
| Vancomycin | 40 mg/kg/d, continuous IV infusion, after a loading dose of 30mg/kg IVL | Until culture results | Daptomycin 10 mg/kg/d, qd IV |

Ab Rx, after documentation



| Drug | Drug Dosing and route | | | |
|--|---|-------------|--|--|
| Pocket infection with n | either endocarditis nor bacteremia: oral switch after dev | ice removal | | |
| | Staphylococcus spp. | | | |
| Pristinamycin or | 1gx3/d | | | |
| Clindamycin | 600 mgx3/d (x4/d if body weight > 100 kg) | | | |
| Streptococcus spp | | | | |
| Amoxicillin | 50 mg/kg/d tid | | | |
| St | 2 | | | |
| Pristinamycin 1gx3/d | | | | |
| Enterococcus spp. | | | | |
| Amoxicillin | 50 mg/kg/d tid | | | |
| Enterococcus spp. and β-lactam allergy | | | | |
| Linezolid | 600 mgx2/d | | | |

Ab Rx, after documentation



| Drug | Dosing and route | Duration (weeks) | Comments | |
|---------------------------------|--|---------------------|---------------------------------|--|
| Bacteremia an | id no IE | | | |
| | Strep | otococcus spp | | |
| Amoxicillin | 100 mg/kg/d, IV | 2 | | |
| | Streptococcus spp and | β-lactam allerg | gy, non anaphylaxis | |
| Ceftriaxone or Cefotaxime | 2g/d, IV 100 mg/kg/j, IV | 2 | | |
| Streptococc | Streptococcus spp and β -lactam allergy and anaphylaxis or allergy to cephalosporins | | | |
| Vancomycin | 40 mg/kg/d, IV | 2 | Plasma concentration 15-20 mg/l | |
| | Enterococcus spp. | | | |
| Amoxicillin | 200 mg/kg/d, IV | 2 | | |
| | Enterococcus spp | . Ampi-R or β-l | lactam allergy | |
| Vancomycin | 40 mg/kg/d, IV | 2 | Plasma concentration 15-20 mg/l | |

Ab Rx, after documentation (Cont')



| Drug | Dosing and route | Duration (weeks) | Comments |
|---|------------------------------------|---------------------|--|
| Bacteremia an | id no IE | | |
| | | MSSA | |
| (CI)oxacillin or Cefazolin | 150 mg/kg/d, IV 100 mg/kg/d, IV | 2-4 | Alternative choice: Clindamycin 600 mgx4/d if body weight > 100 kg |
| MSSA and β-lactam allergy (anaphylaxis) or MRSA | | | |
| Vancomycin or Daptomycin | 40 mg/kg/d, IV 10 mg/kg/d, IV | 2-4 | Plasma concentration 15-20 mg/l |

Ab Rx, after documentation (Cont')



If IE, follow 2015 ESC guidelines

How to optimize prevention of CIED infections?

Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators Results of a Large, Prospective, Randomized, Double-Blinded, Placebo-Controlled Trial

Julio Cesar de Oliveira, MD; Martino Martinelli, MD; Silvana Angelina D'Orio Nishioka, PhD; Tânia Varejão, PhD; David Uipe, MD; Anísio Alexandre Andrade Pedrosa, PhD; Roberto Costa, MD; Stephan B. Danik, MD

Methods and Results—This double blinded study included 1000 consecutive patients who presented for primary device (Pacemaker and implantable cardioverter-defibrillators) implantation or generator replacement randomized in a 1:1 fashion to prophylactic antibiotics or placebo. Intravenous administration of 1 g of cefazolin (group I) or placebo (group 2) was done immediately before the procedure. Follow-up was performed 10 days, 1, 3, and 6 months after discharge. The primary end point was any evidence of infection at the surgical incision (pulse generator pocket), or systemic infection related to be procedure. The safety committee interrupted the trial after 649 patients were enrolled due to a significant difference in favor of the antibiotic arm (group I: 2 of 314 infected patients—0.63%; group II: 11 of 335 to 3.28%; RR=0.19; P=0.016). The following risk factors were positively correlated with infection by univariate analysis: nonuse of preventive antibiotic (P=0.016); implant procedures (versus generator replacement: P=0.02); presence of antibiotic (P=0.037) and postoperative hematoma (P=0.023) as independent predictors of infection.

pacemakers or cardioverter-defibrillators. (Circ Arrhythmia Electrophysiol. 2009;2:29-34.)

Prevention of Arrhythmia Device Infection Trial The PADIT Trial

- High-risk patients undergoing a device procedure
- Hypothesis: incremental antimicrobial prophylaxis will reduce the risk of hospitalization for device infection, compared with a conventional strategy of a single dose of preprocedural antibiotic
- 2 interventions
 - Conventional: single dose of pre-operative antibiotics (cefazolin or vancomycin in allergic patients) within 120 min before skin incision
 - Incremental: conventional + intraoperative wound pocket bacitracin wash before skin closure and post-operative oral antibiotics for 2 days (cephalexin or clindamycin in allergic patients)
- Cluster randomized 4-period crossover design: each participating hospital was randomized to one of four 6-month sequences of incremental (I) and conventional (C) strategies (i.e., ICIC, ICCI, CICI, CIIC)
- Primary outcome: 1-year hospitalization for device infection in the high-risk group

Prevention of Arrhythmia Device Infection Trial The PADIT Trial



Krahn AD, J Am Coll Cardiol 2018;72:3098–109

Prevention of Arrhythmia Device Infection Trial The PADIT Trial

| | | | High-Risk Pat | ients | | | |
|--|--------------|--------------|---------------|------------------------------|------------|---------|--|
| | All | Conventional | Incremental | Incremental vs. Conventional | | | |
| | (N = 12,826) | (n = 6,285) | (n = 6,541) | OR† | 95% CI | p Value | |
| Hospitalization due to device infection | 143 (1.11) | 77 (1.23) | 66 (1.01) | 0.82 | 0.59-1.15 | 0.26 | |
| Subtype | | | | | | | |
| Skin, subcutaneous/pocket infection | 124 (0.97) | 67 (1.07) | 57 (0.87) | 0.82 | 0.57-1.17 | 0.27 | |
| Bloodstream infection | 34 (0.27) | 19 (0.30) | 15 (0.23) | 0.76 | 0.38-1.49 | 0.42 | |
| Endocarditis | 37 (0.29) | 22 (0.35) | 15 (0.23) | 0.66 | 0.34-1.27 | 0.21 | |
| Erosion of skin with device exposure | 3 (0.02) | 1 (0.02) | 2 (0.03) | 1.96 | 0.18-21.70 | 0.58 | |
| Bloodstream and/or endocarditis | 49 (0.38) | 28 (0.45) | 21 (0.32) | 0.72 | 0.41-1.28 | 0.26 | |
| Pocket infection and/or erosion | 94 (0.73) | 49 (0.78) | 45 (0.69) | 0.89 | 0.58-1.37 | 0.59 | |
| Requiring surgical intervention | | | | | | | |
| Yes | 128 (1.00) | 66 (1.05) | 62 (0.95) | 0.90 | 0.64-1.28 | 0.57 | |
| No | 15 (0.12) | 11 (0.18) | 4 (0.06) | 0.35 | 0.11-1.10 | 0.07 | |
| Antibiotics treatment for infection | 103 (0.80) | 57 (0.91) | 46 (0.70) | 0.79 | 0.52-1.20 | 0.27 | |
| Composite of primary outcome and any antibiotics treatment for infection | 239 (1.86) | 130 (2.07) | 109 (1.67) | 0.81 | 0.62-1.05 | 0.11 | |

Krahn AD, J Am Coll Cardiol 2018;72:3098–109

The Role of Prophylaxis Topical Antibiotics in CIED Implantation

• Patients

- 1008 high-risk patients who underwent transvenous implantation of CIED
- High-risk: diabetes mellitus, malignancy, advanced age, anticoagulation, corticosteroids use, and chronic renal failure
- Ab prophylaxis with IV gentamicin and cefazolin < 60 min before procedure
- Primary outcome: rate of inflammation and infection at the surgical site during the 12 months following the procedure



Khalighi K , PACE 2014; 37:304–311

The Role of Prophylaxis Topical Antibiotics in CIED Implantation

Factors Predictive of CEID Infection

| | Variable | | Single Variable | | | Multiple Variables | | |
|-------------|---|---|--|--|--|---|--|--|
| Percent-Age | Present | Absent | aOR | 95% CI | P Value* | aOR | 95% CI | P Value |
| 35.4 | 0.04 | 0.07 | 0.54 | 0.28-1.01 | 0.05 | 0.54 | 0.28-1.02 | 0.58 |
| 53.7 | 7.5 | 3.49 | 2.30 | 1.27-4.18 | 0.006 | 2.09 | 1.48-3.81 | 0.01 |
| 25.5 | 0.07 | 0.04 | 1.40 | 0.65-2.99 | 0.39 | | | |
| 26.1 | 0.05 | 0.04 | 1.03 | 0.46-2.29 | 0.95 | | | |
| 23.7 | 0.06 | 0.04 | 1.23 | 0.56-2.71 | 0.61 | | | |
| 24.7 | 0.05 | 0.04 | | | | | | |
| 15 | 0.02 | 0.06 | 0.31 | 0.09-1.0 | 0.05 | 0.35 | 0.11-1.16 | 0.086 |
| 23.7 | 0.06 | 0.05 | 1.08 | 0.58-2.01 | 0.81 | | | |
| 17.7 | 0.04 | 0.06 | 0.77 | 0.36-1.65 | 0.5 | | | |
| 25.5 | 0.06 | 0.05 | 1.65 | 0.96-2.83 | 0.07 | | | |
| 22.5 | 0.08 | 0.05 | 1.68 | 0.94-3.01 | 0.08 | | | |
| 6.3 | 0.08 | 0.05 | 1.51 | 0.58-3.93 | 0.4 | | | |
| 4.1 | 0.17 | 0.05 | 3.86 | 1.61-9.17 | < 0.01 | 3.63 | 1.51-8.74 | 0.004 |
| 2.6 | 0.04 | 0.06 | 0.67 | 0.09-5.07 | 0.7 | | | |
| 29.3 | 0.06 | 0.05 | 1.25 | 0.71-2.22 | 0.43 | | | |
| | | | | | | | Placebo | |
| | Solution | (%) | Ointm | ent (%) | Pad (%) | | (%) | Tota |
| | 9 (3.5) | | 10 | (3.8) | 7 (2.9) | | 7 (2.8) | 33 |
| ma | | | | | | | 5 E | 11 |
| | | | | | | | | |
| ve | 4 (1.5) | | 2 (| 0.7) | 4 (1.6) | | | 13 |
| fection | _ | | | _ | - | | 1 (0.4) | 1 |
| | 17/257 | | 14 | 263 | 14/240 | | 13/248 | 58 |
| | 35.4 53.7 25.5 26.1 23.7 24.7 15 23.7 17.7 25.5 22.5 6.3 4.1 2.6 | Percent-Age Present 35.4 0.04 53.7 7.5 25.5 0.07 26.1 0.05 23.7 0.06 24.7 0.05 15 0.02 23.7 0.06 24.7 0.05 15 0.02 23.7 0.06 22.5 0.08 6.3 0.08 4.1 0.17 2.6 0.04 29.3 0.06 Povidone log Solution 9 (3.5) arge 4 (1.5) ve 4 (1.5) | Percent-Age Present Absent 35.4 0.04 0.07 53.7 7.5 3.49 25.5 0.07 0.04 26.1 0.05 0.04 23.7 0.06 0.04 24.7 0.05 0.04 15 0.02 0.06 23.7 0.06 0.05 15 0.02 0.06 25.5 0.06 0.05 27.7 0.06 0.05 27.7 0.06 0.05 23.7 0.06 0.05 25.5 0.08 0.05 6.3 0.08 0.05 6.3 0.08 0.05 2.6 0.04 0.06 29.3 0.06 0.05 20.3 0.06 0.05 2.6 0.04 0.06 29.3 0.06 0.05 arge 4 (1.5) 4 (1.5) ve 4 (1.5) 4 (1.5) | Percent-Age Present Absent aOR 35.4 0.04 0.07 0.54 53.7 7.5 3.49 2.30 25.5 0.07 0.04 1.40 26.1 0.05 0.04 1.03 23.7 0.06 0.04 1.23 24.7 0.05 0.04 1.23 24.7 0.06 0.05 1.08 17.7 0.04 0.06 0.77 25.5 0.06 0.05 1.65 22.5 0.08 0.05 1.65 22.5 0.08 0.05 1.68 6.3 0.08 0.05 1.51 4.1 0.17 0.05 3.86 2.6 0.04 0.06 0.67 29.3 0.06 0.05 1.25 Povidone lodine Solution (%) Neon 9 (3.5) 10 0 arge 4 (1.5) 2 (ve | Percent-Age Present Absent aOR 95% Cl 35.4 0.04 0.07 0.54 0.28-1.01 53.7 7.5 3.49 2.30 1.27-4.18 25.5 0.07 0.04 1.40 0.65-2.99 26.1 0.05 0.04 1.03 0.46-2.29 23.7 0.06 0.04 1.23 0.56-2.71 24.7 0.05 0.04 1.23 0.56-2.71 23.7 0.06 0.04 1.23 0.56-2.71 23.7 0.06 0.05 1.08 0.58-2.01 17.7 0.04 0.06 0.77 0.36-1.65 25.5 0.06 0.05 1.68 0.94-3.01 6.3 0.08 0.05 1.51 0.58-3.93 4.1 0.17 0.06 0.67 0.09-5.07 29.3 0.06 0.05 1.25 0.71-2.22 | Percent-Age Present Absent aOR 95% Cl P Value* 35.4 0.04 0.07 0.54 $0.28-1.01$ 0.05 53.7 7.5 3.49 2.30 $1.27-4.18$ 0.006 25.5 0.07 0.04 1.40 $0.65-2.99$ 0.39 26.1 0.05 0.04 1.23 $0.56-2.71$ 0.61 24.7 0.06 0.04 1.23 $0.56-2.71$ 0.61 24.7 0.05 0.04 1.23 $0.56-2.71$ 0.61 24.7 0.06 0.04 1.23 $0.56-2.71$ 0.61 24.7 0.06 0.05 1.08 $0.58-2.01$ 0.81 17.7 0.04 0.06 0.77 $0.38-1.65$ 0.55 25.5 0.06 0.05 1.68 $0.94-3.01$ 0.08 6.3 0.08 0.05 1.25 $0.71-2.22$ 0.43 4.1 </td <td>Percent-Age Present Absent aOR 95% Cl P Value* aOR 35.4 0.04 0.07 0.54 0.28–1.01 0.05 0.54 35.7 7.5 3.49 2.30 1.27–4.18 0.006 2.09 25.5 0.07 0.04 1.40 0.65–2.99 0.39 2.09 25.7 0.06 0.04 1.23 0.56–2.71 0.61 0.05 0.39 24.7 0.05 0.04 1.23 0.56–2.71 0.61 0.35 0.35 23.7 0.06 0.05 1.08 0.59–2.01 0.81 0.35 25.5 0.06 0.05 1.65 0.96–2.83 0.07 2.5 25.5 0.08 0.05 1.51 0.58–2.93 0.07 2.6 25.5 0.08 0.05 1.58 0.94–3.01 0.08 0.63 25.5 0.08 0.05 1.51 0.58–3.93 0.4 4.1 0.06 0.67</td> <td>Percent-Age Present Absent aOR 95% Cl P Valuer aOR 95% Cl 35.4 0.04 0.07 0.54 $0.28-1.01$ 0.05 0.54 $0.28-1.02$ 53.7 7.5 3.49 2.30 $1.27-4.18$ 0.006 2.09 $1.48-3.81$ 25.5 0.07 0.04 1.40 $0.65-2.99$ 0.39 0.61 $1.48-3.81$ 26.1 0.05 0.04 1.23 $0.56-2.91$ 0.61 0.29 $1.48-3.81$ 24.7 0.06 0.04 1.23 $0.56-2.71$ 0.61 0.35 $0.11-1.16$ 23.7 0.06 0.05 1.08 $0.58-2.01$ 0.81 0.77 0.36 0.35 $0.11-1.16$ 23.7 0.06 0.05 1.68 $0.94-3.01$ 0.08 0.55 2.55 0.08 0.05 1.51 $0.58-3.93$ 0.4 4.1 0.17 0.01 3.63 $1.51-8.74$</td> | Percent-Age Present Absent aOR 95% Cl P Value* aOR 35.4 0.04 0.07 0.54 0.28–1.01 0.05 0.54 35.7 7.5 3.49 2.30 1.27–4.18 0.006 2.09 25.5 0.07 0.04 1.40 0.65–2.99 0.39 2.09 25.7 0.06 0.04 1.23 0.56–2.71 0.61 0.05 0.39 24.7 0.05 0.04 1.23 0.56–2.71 0.61 0.35 0.35 23.7 0.06 0.05 1.08 0.59–2.01 0.81 0.35 25.5 0.06 0.05 1.65 0.96–2.83 0.07 2.5 25.5 0.08 0.05 1.51 0.58–2.93 0.07 2.6 25.5 0.08 0.05 1.58 0.94–3.01 0.08 0.63 25.5 0.08 0.05 1.51 0.58–3.93 0.4 4.1 0.06 0.67 | Percent-Age Present Absent aOR 95% Cl P Valuer aOR 95% Cl 35.4 0.04 0.07 0.54 $0.28-1.01$ 0.05 0.54 $0.28-1.02$ 53.7 7.5 3.49 2.30 $1.27-4.18$ 0.006 2.09 $1.48-3.81$ 25.5 0.07 0.04 1.40 $0.65-2.99$ 0.39 0.61 $1.48-3.81$ 26.1 0.05 0.04 1.23 $0.56-2.91$ 0.61 0.29 $1.48-3.81$ 24.7 0.06 0.04 1.23 $0.56-2.71$ 0.61 0.35 $0.11-1.16$ 23.7 0.06 0.05 1.08 $0.58-2.01$ 0.81 0.77 0.36 0.35 $0.11-1.16$ 23.7 0.06 0.05 1.68 $0.94-3.01$ 0.08 0.55 2.55 0.08 0.05 1.51 $0.58-3.93$ 0.4 4.1 0.17 0.01 3.63 $1.51-8.74$ |

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Antibacterial Envelope to Prevent Cardiac Implantable Device Infection

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Worldwide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT)

Absorbable, multifilament mesh envelope (TYRX Absorbable Antibacterial Envelope, Medtronic)

Tarakji KG et al. NEJM. 2019 March 17th DOI: 10.1056/NEJMoa1901111

THE TYRX[™] ABSORBABLE ANTIBACTERIAL ENVELOPE TIME SEQUENCE SIMULATION OF ELUTION & ABSORPTION



Envelope after implantation¹

 Absorbable Envelope is eluting Minocycline & Rifampin



Envelope at 4 weeks²

 Absorbable Envelope is dissolving into fragments



Envelope at ~9 weeks³

 Mesh has no physical presence and is fully absorbed

1. Huntingdon Life Sciences Study TR-2013-001. 2. Data on File, 093013-1. 3. Huntingdon Life Sciences Study TR-2011-054.

Adjunctive use of an antibacterial envelope resulted in a 40% reduction of major CIED infections (pocket)



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Take home messages, in pictures and a few words

Complete removal of CIED including device generator and electrode leads is mandatory to achieve cure of infection, even in cases where - infection appears to be limited to the device pocket only - removal appears technically challenging!