

## SPOTLIGHT

# Continuous in situ targeted antibiotics for late cardiovascular implantable electronic device pocket perforation

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There is a steady rise in patients requiring Cardiac implantable electronic devices (CIED).<sup>1</sup> Indications include pacemakers for bradyarrhythmia, implantable cardioverter defibrillators for ventricular arrhythmias, and cardiac resynchronization therapy and physiological pacing. CIED-related infections are a dreaded complication associated with severe morbidity and mortality.<sup>2</sup> Infections may be systemic, or localized to the CIED pocket, known as “pocket infections.” International guidelines recommend extraction of system and all leads.<sup>3</sup> However, lead extraction is a complex procedure with serious complications including vessel injury, massive hemothorax, valve damage, cardiac perforation, tamponade, and death.<sup>2,4</sup>

A cohort study by an Israeli group<sup>5</sup> described using continuous, in situ-targeted, ultrahigh concentration of antibiotics (CITA) delivered into the CIED pocket as an alternative to extraction for the treatment of pocket infections. Eighty patients with pocket infections (including purulent pocket collections, protruding devices and lead coils, and dehiscence wounds) underwent the CITA protocol. 85% remained free of infection at median follow-up of three years. When compared with a case-controlled cohort who underwent standard management with extraction, rates of cure were higher in the extraction group at 96% versus 85% ( $p = .027$ ), but more serious complications were seen, 14.8% versus 1.5% ( $p = .005$ ), associated with a nonsignificantly higher 30-day mortality rate of 3.7% versus 0% ( $p = .25$ ). Lead extraction was avoided in 91% of patients treated with CITA.

We describe our initial experience and technique in two patients with localized infections who declined extraction in the first instance.

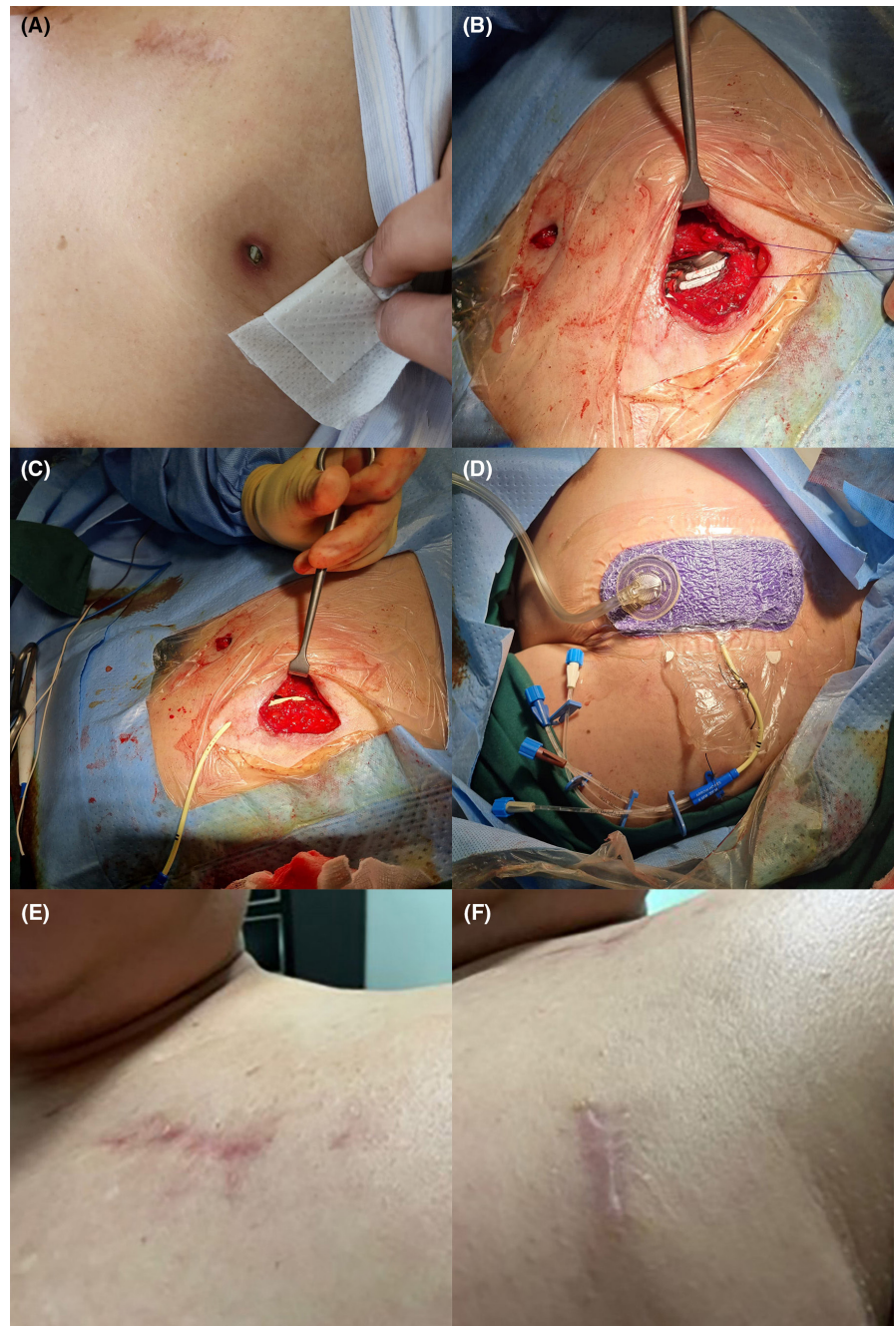
A 42-year-old Chinese male underwent a dual chamber pacemaker in 2019 for symptomatic complete heart block. In January 2023, he sustained trauma to his pacemaker pocket which developed into a 1 cm perforation (Figure 1A), exposing the pulse generator. He was asymptomatic and did not have evidence of systemic infection. No lead vegetations were seen on transthoracic echocardiogram. Extraction was offered, but he expressed reservations about the procedural risks. After an open discussion about CITA and its limitations, the patient opted for the CITA procedure, with a plan to proceed with extraction if CITA failed.

Wound revision was performed under local anesthesia by a team of Cardiologists and Plastic surgeons. A horizontal incision was made over the pocket. The pulse generator was removed, and the leads were preserved. The existing subcutaneous pocket capsule was fully excised, and all unhealthy tissue was debrided. Perioperative IV Cefazolin 2g was administered after obtaining tissue for microbiology. The pocket was washed with hydrogen peroxide 1.5% and povidone iodine 5%. A new total submuscular pocket (beneath the pectoralis major) was fashioned (Figure 1B). The generator was cleaned with iodine 5% and rinsed with saline before being reconnected to the leads and placed in the new pocket. An 8.5F central catheter was tunneled through to the new pocket for antibiotic infusion (Figure 1C). The new subpectoral pocket, the perforation defect and wound were closed with wide-spaced sutures to allow for free drainage of fluid through tiny gaps between the sutures. A Prevena™ suction dressing (3M™) was applied and set to continuous low-intensity suction pressure at 125mmHg (Figure 1D).

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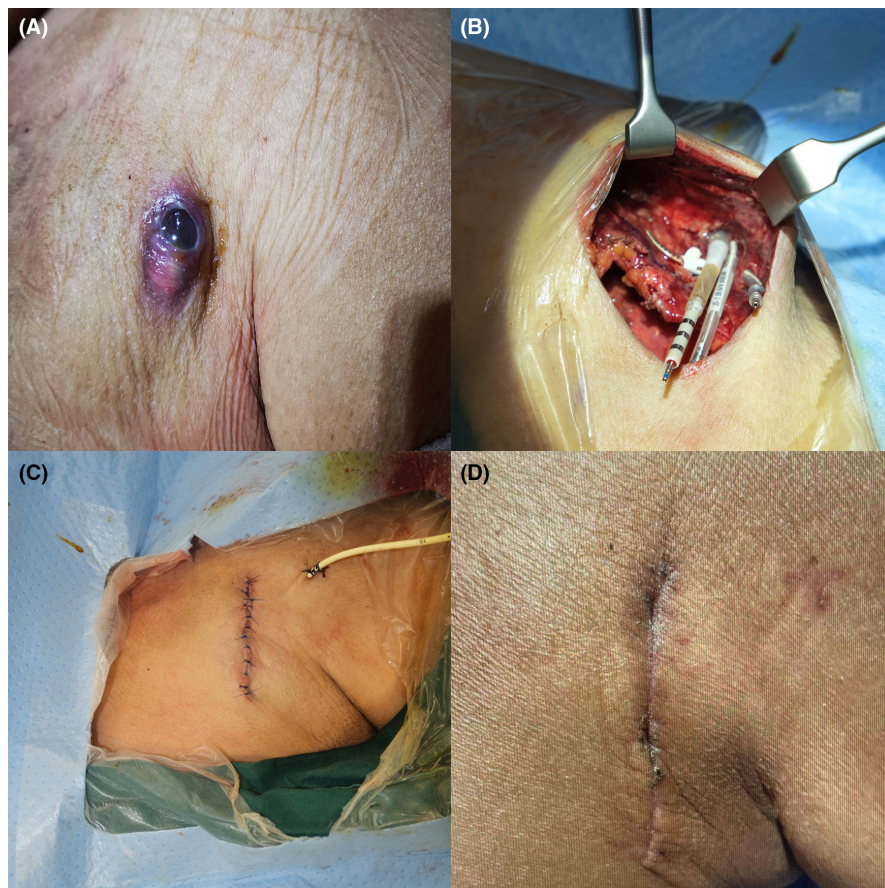
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**FIGURE 1** (A) 1cm perforation, exposing edge of pulse generator at lateral aspect of pocket. (B) Pulse generator placed in new total submuscular pocket (beneath pectoralis major). (C) Placement of 8.5F central catheter into submuscular pocket for antibiotic infusion. (D) Postrevision photograph, showing Prevena™ suction dressing (3M™) applied over wound and tunneled 8.5F central catheter for antibiotic infusion. (E) Wound well healed at six months with no evidence of infection. (F) Perforation site wound well healed at six months with no evidence of infection.



Working with the Infectious disease specialist, a continuous high-dose vancomycin and gentamicin regimen was developed. This was infused into pocket with a loading dose, followed by a slow infusion – 1-2mL/hour (40-80mg/h vancomycin and 3-10mg/h gentamicin). High concentrations of antibiotics used would result in systemic absorption. Daily serum levels of vancomycin and gentamicin guided infusion rates, aiming for median levels achieved in the publication.<sup>5</sup> Wound cultures returned negative, and the antibiotic infusion was continued for 10days, before removing the tunneled catheter and dressing. Wound healing was excellent, and there was no evidence of infection. At sixmonths, the patient remained well and asymptomatic (Figure 1E,F).

The second patient was a 75-year-old male ethnic Malay with ischemic cardiomyopathy who underwent a His Cardiac Resynchronization Therapy Defibrillator implant in 2020. He had significant comorbidities of moderate frailty (Clinical Frailty Scale 6), type 2 diabetes mellitus, chronic kidney disease, previous stroke, and vascular dementia. He presented in March 2023 with an inferior ST elevation myocardial infarction and underwent primary percutaneous coronary intervention. It was incidentally noted that his pulse generator had perforated through his skin (Figure 2A). There was no evidence of systemic infection or lead vegetations on echocardiogram. Device extraction was offered. The role of CITA was discussed with the patient and family because



**FIGURE 2** (A) Pulse generator edge perforating through skin at lateral aspect of pocket. (B) Pulse generator placed in new total submuscular pocket (beneath pectoralis major). (C) Postrevision photograph, vertical incision wound around perforation defect closed with prolene, prior to application of Prevena™ suction dressing (3M™). Tunneled 8.5F central catheter shown entering from a site separate from incision wound. (D) Wound well healed at three months with no evidence of infection.

of comorbidities and significant associated risk. It was agreed that CITA would be preferred.

A Cardiologist and Plastic surgeon performed the revision under local anesthesia. The patient was on dual antiplatelet therapy following the recent STEMI. An elliptical incision was made around the perforation. The pulse generator was removed, the pocket was debrided, excised tissue and biofilm were sent for culture, and IV cefazolin administered in a similar manner to the first case. It was then cleaned with hydrogen peroxide and iodine. A new submuscular pocket was created and an 8.5F central line was tunneled into the pocket. The pulse generator was cleaned with iodine and rinsed with saline. These were placed in the new pocket (Figure 2B). The pocket and wound were closed in layers (fascial layer, subcutaneous layer, dermis, and skin) and covered with a suction dressing and set to continuous low-intensity negative pressure. Wound cultures were negative, and the antibiotic infusion was terminated after 10 days. The wound healed well (Figure 2C) and there has been no evidence of infection at three months follow-up (Figure 2D).

CITA is a promising alternative for managing localized CIED pocket infections. The traditional treatment is extraction, which is associated with significant mortality and morbidity. This is further compounded by the significant frailty and comorbidities often seen in this population. If performed in a low volume center (<30 cases per year), complication rates and mortality from extraction procedures are significantly higher (complication rates 4.7% versus. 2.1%,

$p < .01$  and all-cause mortality 2.8% versus. 1.2%;  $p < .03$ ).<sup>4</sup> This makes CITA attractive in appropriately selected patients who have no evidence of systemic infection. To our knowledge, this is the first time the technique has been successfully adapted for Asian patients, through multidisciplinary collaboration.

#### CONFLICT OF INTEREST STATEMENT

All authors have no conflict of interest to disclose.

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