# An exposed Cardiovascular Implantable Electronic Device (CIED) complicated with infection: A case report of unconventional experience with 'Sealed CIED'

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## SUMMARY

The rate of infected Cardiovascular Implantable Electronic Device is alarming and causes substantial socio-economic burden. A common approach involves immediate extraction of the infected device. Here, we report an unorthodox approach to this problem by 'sealing' the generator inside a sterile container as a temporary permanent pacemaker while waiting for implantation of another device.

We report a 66 years old emaciated lady with underlying Sick Sinus Syndrome, who had an implanted single chamber pacemaker and presented with partial protrusion of her device. She underwent sub-pectoral implantation of the new device but subsequently re-presented with pocket site infection after a month. A decision was made to extract the infected generator from the sub-pectoral pocket and it was sealed inside a sterile container as 'bridging therapy' while awaiting arrival of a leadless pacemaker for implantation together with total extraction of the old infected device.

Our clinical vignette demonstrated the difficulties we encountered and influenced on our decision for this unconventional approach despite limited supporting evidence.

## INTRODUCTION

More than one million of Cardiovascular Implantable Electronic Device (CIED) are implanted on a yearly basis and contributed to the increasing prevalence of infected CIED.<sup>1,2</sup> A common approach involves immediate extraction of the infected device and new implantation placed at a different site. We report here an unorthodox approach and possibly the first to describe 'sealing' the device inside a sterile container for a temporary permanent pacemaker (TPPM).

#### **CASE REPORT**

A 66 years old lady with underlying Sick Sinus Syndrome and atrial fibrillation presented to the emergency department of the Hospital Sultanah Bahiyah, Kedah, Malaysia with partial protrusion of her CIED. She was diagnosed with Sick Sinus Syndrome in 2008 and a single chamber pacemaker (Verity ADx XL SC, St Jude Medical, Sylmar, CA, USA) was implanted.

This article was accepted: 13 November 2021 Corresponding Author: Mohd Ridzuan Mohd Said Email: ridzuan.said85@gmail.com She presented with gradual partial protrusion of the device in 2020 (Figure 1A) and underwent creation of a sub-pectoral pocket under general anesthesia by a plastic surgeon. The previous right ventricular lead was connected to a new generator (Endurity PM1162, Abbot, Sylmar, CA, USA) and implanted into the sub-pectoral pocket. Her recovery was uneventful, and she was discharged with regular follow-up.

Unfortunately, she re-presented with unhealthy discoloration of her skin (Figure 1B) and intravenous Ampicillin / Sulbactam was commenced. White cell count was normal (9 x  $10^3/uL$ ) and repeated blood cultures remained negative with no vegetations seen on transthoracic echocardiography. Hence, she underwent further wound exploration under general anesthesia.

Intraoperatively, unhealthy granulation tissue was observed confined only to the inside of the sub-pectoral pocket and this was excised, and a proper debridement was performed. Result of tissue culture demonstrated no growth of organism. Subsequently, the proximal part of the right ventricular lead and pacemaker generator were inserted into a sterile bag and sealed onto anterior chest (Figure 1C). The open wound was sutured and covered with a sterile dressing. Once financial approval was obtained, the Micra<sup>™</sup> (MC1VR01, Medtronic, Minneapolis, USA) was implanted (Figure 1D) three days later via a transvenous right femoral approach while simultaneous explantation of the old generator. Decision for immediate implantation of Micra™ (MC1VR01, Medtronic, Minneapolis, USA) was made considering contained infection within sub-pectoral pocket, negative tissue culture and unremarkable septic parameters. Consequently, her recovery was uneventful and she was discharged with close monitoring.

## DISCUSSION

Implantation of CIED has increased substantially due to growing evidence on indications plus heightened awareness amongst practitioners.<sup>1</sup> Unfortunately, complication rates remain elevated highest at 12%<sup>1</sup> and the reported rate of infection between 0.13% to 19.9%.<sup>2</sup> In addition, CIED infection is associated with substantial socio-economic burden due to prolonged hospital stays and expensive treatments.



Fig. 1: Images of patients' CIED, A; Protrusion of CIED device on left pectoral, B; Unhealthy discoloration and granulation tissue post sub-pectoral implantation, C; CIED (marked \*) was secured inside sterile container during second operation, D; Chest X-Ray post Micra™ (Arrow) insertion and extraction of pacemaker, previous lead was left in situ.

Current practice for CIED implantation is via a pre-pectoral approach for accessibility and better tolerability among patients but a sub-pectoral approach offers an alternative window with its own advantages.<sup>3</sup> Apart from providing aesthetic comfort with undetectable CIED, a sub-pectoral approach is advantageous for the underweight and ageing population with a deep seated CIED.<sup>3</sup>

For our patient, we opted for a sub-pectoral approach at the same site during the initial event because firstly, we noted a sterile healthy pocket and secondly, the patient's small body habitus (BMI 16.7 kg/m<sup>2</sup>) favored a sub-pectoral approach as recurrent device erosion was anticipated even with a right - sided pre-pectoral approach.

Subsequently, our decision for packaging the CIED within a sterile container as a functioning TPPM was made as the patient was dependent on the device and had low blood septic parameters. Secondly, the whole procedure was performed in the operation theatre with thorough debridement and a fully aseptic approach. Thirdly, a conventional approach of inserting a temporary pacing system as bridging therapy is preferred but increases the risk of device-related infection by two-fold,<sup>4</sup> especially via femoral approach.<sup>5</sup> In addition, safety and feasibility of TPPM has been demonstrated with minimal complications even for extended periods of months.<sup>5</sup> Collectively, these factors influenced our decision for externalization of the temporary permanent pacemaker as a bridging therapy. In addition, we also left the previous transvenous lead in situ to avoid any complication mainly right ventricular (RV) perforation.

Presently, reports on a similar approach is limited and we believe this to be the first case of 'sealing a CIED' inside sterile packaging as bridging therapy.

## CONCLUSION

In conclusion, our clinical vignette demonstrates the difficulties that can be encountered in dealing with CIED infection and highlights an unorthodox management by sealing the CIED outside the patient's body as bridging therapy.

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