CASE REPORT

Successful conservative management of a permanent pacemaker pocket infection: a less invasive approach

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SUMMARY

We present a successful conservative management strategy for a frail elderly patient with a cardiac resynchronisation pacemaker who presented with evidence of an *Enterobacter cloacae* pacemaker pocket infection. A device washout and debridement procedure was performed, with reburial of the device in a new prepectoral pocket and creation of a closed-loop continuous antibiotic infusion into the infected pacemaker pocket. This was followed by a 6-week course of ambulatory intravenous antibiotic therapy. This conservative management strategy avoided the need for a more invasive and high-risk full device extraction, which the patient clearly stated he did not wish to have. Up-to-date consensus management guidelines recommend extraction of the entire implanted system in this situation; however, in this case we demonstrate an alternative conservative management option, which may be suitable for frail elderly and comorbid patients or for patients who decline device extraction.

BACKGROUND

Infection of implantable cardiac electronic devices (ICED) is a devastating complication. The use of such devices in the UK is continuing to increase due to the expanding indications for their insertion, alongside an ageing population.¹ The incidence of ICED infection is <2% per year but is increasing in the USA.^{2–4} While comparable data from the UK are not available, the increasing use of ICEDs in the UK is likely to be accompanied by an increased burden of device infection.⁵

ICED infection can be categorised into early post-implantation inflammation, uncomplicated generator pocket infection, complicated generator pocket infection (with evidence of systemic infection, lead or endocardial infection), ICED lead infection and ICED-associated endocarditis.⁵ Regardless of the classification, removal of the entire device is recommended in all ICED infections except early post-implantation inflammation. The success rate in experienced centres for curing ICED-related infection with device extraction is >90%.⁵ The rationale for device removal is that the biofilm nature of ICED infection makes cure difficult with antimicrobial chemotherapy alone. The evidence to support this recommendation is derived from several observational studies comparing device extraction with conservative management. Relapse of infection is more common when an infected device is managed conservatively.^{6–8} In a single-centre retrospective

observational study conservative management was associated with a threefold increase in mortality at 1 year when an infected ICED was removed early compared with delayed removal.⁹ However, none of these studies analysed relapse and mortality for each category of ICED infection.

Device extraction carries significant risks including death, cardiac or vascular avulsion, stroke and pulmonary embolism. Several case series have reported outcomes for cases where device extraction was either clinically inappropriate or declined by patients. The cure rates in these series ranged from 13% to 80% and a wide variety of management strategies were employed.⁵ Two small case series of five and four patients respectively have reported on conservative management of ICED pocket infections with generator replacement, lead shortening and vacuum-assisted wound closure, with cure rates of 80% and 100%, respectively.^{10 11} Another case series of five patients describes conservative management with reburial of the generator with a closed antimicrobial irrigation system with an 80% cure rate.¹² While these case series are small, they have led several authors to speculate about an increasing role for conservative management of infected devices in cases that are deemed unsuitable for device extraction or in those who decline this management option.^{13 14}

In this case report, we describe the successful conservative management of a case of *Enterobacter cloacae* cardiac resynchronisation therapy pacemaker (CRT-P) pocket infection.

CASE PRESENTATION

An 89-year-old man was seen for a routine follow-up appointment in pacing clinic. He had known ischaemic cardiomyopathy with severe left ventricular (LV) systolic dysfunction following a previous anterior myocardial infarction. He had had a CRT-P implanted 2 years previously, having met the full criteria for this intervention. Prior to his device implantation, he had additionally demonstrated extensive conduction disease as evidenced by a trifascicular block with a profound first-degree atrioventricular (AV) block (PR interval of 440 ms) on 12-lead ECG and documented bradycardic episodes. The patient did not wish to have a defibrillator.

When seen in pacing clinic on this occasion, 2 years after his device implantation, the soft tissue overlying and surrounding his device was found to be erythematous and hot (figure 1). Clinical examination was otherwise unremarkable. He had not

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Figure 1 Initial clinical appearance of implantable cardiac electronic device site.

noticed fevers or systemic symptoms. The clinical suspicion was of a generator pocket infection, he was therefore admitted to the cardiac ward.

INVESTIGATIONS

Pacemaker interrogation revealed 100% atrial pacing and 100% biventricular pacing in line with his CRT. There was no underlying atrial or ventricular intrinsic sensed rhythm.

Blood tests showed white cell count of $8.3 \times 10^9/L$ (normal range $4\text{--}10 \times 10^9/L$), C-reactive protein of 14 mg/L (normal range $0\text{--}10\text{ mg/L}$). Peripheral skin swabs from the site overlying the device did not have any bacterial growth. Transthoracic echocardiogram did not identify any evidence of lead or valvular vegetation.

DIFFERENTIAL DIAGNOSIS

The most likely diagnosis was of an uncomplicated generator pocket infection. The differential diagnoses include associated ICED lead infection and ICED-associated endocarditis with the possibility of vegetation not visualised on transthoracic echocardiography. Overall however, his clinical condition was stable and he was not clinically septic, in keeping with uncomplicated generator pocket infection.

TREATMENT

The definitive guideline-recommended treatment in this situation would be for a full device system extraction. As already discussed, this procedure carries a significant risk of major complication leading to death or major surgery. In this patient's case, in addition to a device extraction, he would have required a temporary pacing system as he was entirely pacemaker dependant with no underlying intrinsic cardiac rhythm, and then a further device implantation after a period of intravenous antibiotics. Therefore, in addition to the risk of device extraction, this patient would have been subject to the additional risk of a temporary transvenous pacing system. This patient expressed a clear wish that he did want to have

Figure 2 Closed-loop continuous antibiotic infusion into the infected pacemaker pocket.

an extraction due to its invasive nature, fully understanding the implications of this. An alternative approach was therefore offered to him, which was less invasive. This was pacemaker washout and debridement procedure, with reburial of the device and creation of a closed-loop continuous antibiotic infusion into the infected pacemaker pocket. The patient was happy to proceed with this.

An incision was made over the infected pocket, revealing contained pus, the device was cleaned with iodine and the pocket was washed out with hydrogen peroxide and iodine. An antibiotic infusion drain was inserted into the pocket with a complementary suction drain and the pocket sutured up, creating a continuous contained closed-loop antibiotic infusion. The device was again cleaned with iodine and reburied by creating a separate prepectoral pocket that was not in direct communication with the infected site. A dressing was applied. Vancomycin and gentamicin were infused continuously via the closed-loop system for 48 hours (figure 2). Following this the drains were removed and the wound redressed.

A sample of the pus from the infected pocket was sent for microscopy, culture and sensitivity. This grew an *E. cloacae* species sensitive to ertapenem and gentamicin. The patient recovered well from the procedure. He remained afebrile. His pacemaker check was satisfactory. He was discharged with a 6-week course of once daily 1 g intravenous ertapenem delivered via a peripherally inserted central cannula facilitated by the outpatient antibiotic therapy team.

OUTCOME AND FOLLOW-UP

This patient was reviewed in pacing clinic 2 months after his procedure to conservatively manage his pacemaker pocket infection. After completing his course of intravenous antibiotics in the community, he remained clinically very well. His inflammatory markers remained normal off antibiotics. He was asymptomatic and the wound from his procedure had healed well with no evidence of redness, fluctuance or other signs of ongoing infection (figure 3). He has remained well at twice-yearly clinic review for 2½ years since the procedure with no evidence of ongoing pocket infection.

Figure 3 Appearance of implantable cardiac electronic device site at 2-year follow-up, with no further evidence of infection.

DISCUSSION

This case demonstrates the successful management of a pacemaker pocket infection without the removal of the entire ICED.

When making a decision about whether or not to remove the infected device several factors needed to be considered.

There was clear evidence of a generator pocket infection of the ICED both clinically, and later microbiologically. Consensus guidelines in this scenario would recommend the removal of the entire device, including removal of the pulse generator and extraction of pacemaker leads.⁵ It is not clear from the available evidence however, what the optimum management in this scenario should be. While several studies have demonstrated increased mortality without removing an infected ICED, none have performed subgroup analysis to determine whether this is true for less severe forms of device infection (such as uncomplicated generator pacemaker pocket infection or lead erosion).^{6–8} Furthermore all published studies comparing outcomes for conservative management versus device removal are observational studies and not randomised controlled trials, and ‘blinding’ (to compare device extraction with conservative management) in this scenario is clearly not feasible. Mortality associated with delayed pacemaker extraction and conservative management was largely due to uncontrolled sepsis, and delay in device removal resulted in a threefold increased mortality at 1 year of follow-up.⁹ However, in our patient there was no evidence of systemic infection, sepsis nor of intravascular infection, lead infection or endocarditis. It must be noted however that in one study of patients with pacemaker pocket infection alone, 72% have culture-positive pacemaker leads at device extraction.⁸ Therefore, without device removal and with inadequate sterilisation of the infected device there is a high risk of relapse of infection. Device removal significantly reduces these risks.

When considering the risks of extracting the entire device in this case it is important to note that the patient was entirely pacemaker dependant. This would mean that a temporary pacing system was required to bridge the gap between device removal and the insertion of a new device. Additionally, a temporary system would not have been a biventricular system, meaning the patient would not have had the benefit of CRT while the temporary system was in

Learning points

- ▶ Implantable cardiac electronic device (ICED) infection can be categorised as early postimplantation inflammation, uncomplicated generator pocket infection, complicated generator pocket infection, ICED lead infection and ICED-associated endocarditis.
- ▶ Consensus guidelines recommend early removal of the entire ICED in case of infection or lead erosion (with exception of early postimplantation inflammation), based on the best, although limited available evidence.
- ▶ In patients who are unsuitable for device extraction or who decline it, this novel approach to conservative management with device washout, reburial, closed antibiotic irrigation system and an appropriate antimicrobial chemotherapy course should be considered in cases of uncomplicated generator pocket infection.
- ▶ Further research is needed to determine if conservative management can be an effective and safe first-line option to manage uncomplicated generator pocket infection.

situ, putting him at risk of decompensated heart failure during this period. There is a small but not insignificant risk of death from the device extraction procedure. The overall risk is described as 1%–2.7%.^{15 16} Major complications that would not routinely be fatal but may require cardiothoracic intervention have been described at a rate of 1.4%–4.9%.^{15 16} His older age, his comorbidities and his frailty meant that his outcome would be poorer in the case that a complication occurred which required surgery.

In this case, the patient opted for conservative management as he was not prepared to undergo device extraction and therefore the decision was taken to adopt this novel conservative management strategy of device washout, reburial, closed antibiotic irrigation system and an appropriate antimicrobial chemotherapy course. This approach has been documented previously in a case series of five patients demonstrating an 80% cure rate.¹²

This case demonstrates that in selected patients who are unsuitable for, or decline device extraction, alternative approaches should be considered. Further research is clearly required to determine whether any group of patients with ICED infection may be safely managed with this conservative approach as a first-line treatment.

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