



## Review

# Conservative therapy for the management of cardiac implantable electronic device infection

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## ABSTRACT

Along with the increased frequency of implantation, the incidence of cardiac implantable electronic device (CIED) infection, which can have serious or fatal complications, has also increased. Although several successful conservative therapies for CIED infection have been reported, retained infected devices remain a source of relapse, which is closely related to a higher mortality rate. Presently, complete hardware removal is initially recommended for infected CIED patients, and indications for conservative therapy, including continuous administration of antibiotics, require careful consideration.

On the other hand, complete removal is not required for superficial or incisional infection at the device pocket if an infection does not involve the device, but the patient should be closely followed for progression to deeper infection, which would require extraction.

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## 1. Introduction

Treatment with a cardiac implantable electronic device (CIED), including a permanent pacemaker (PPM) or implantable cardioverter-defibrillator (ICD), is very useful. At present, an ICD is needed not only to rescue survivors of life-threatening ventricular arrhythmias, but is also first-line primary prevention to save patients with marked cardiac dysfunction. Moreover, medical technology for resynchronization therapy has advanced, with a resulting increased rate of device implantation [1,3]. Along with the increase in device implantation, the

incidence of CIED infection, which can have serious or fatal complications, has also increased [2,4–7]. Prutkin et al. reported that a total of 3390 (1.7%) out of 200,909 implanted ICDs developed a device infection within six months [6]. Other studies have reported a similar rate of CIED infection (0.7–2.2%) [5,8–10].

The management of infected CIED patients is difficult, and requires special knowledge and effort by physicians. Intensive treatment of CIED infections is recommended, including administration of appropriate antibiotics and complete removal of the infected device [5,11–22]. Consensus reports and statements from the literature also recommend prompt and complete device removal in combination with antimicrobial therapy [22–24]. In this article, we present the role of conservative therapy for the management of CIED infection.

Abbreviations: CIED, cardiac implantable electronic device

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## 2. Role of continuous antibiotic therapy

When CIED infection is diagnosed, early complete removal of the infected device is strongly recommended because of the high association with increased mortality. No prospective randomized studies have assessed the value of conservative antibiotic therapy alone, compared with combined complete device removal and administration of appropriate antibiotics. However, some reports cited the poor outcome using conservative antibiotic therapy in patients with CIED infection [11,25]. About 30 years ago, Lewis et al. reported on treatment of patients with permanent pacemaker infections [26]. Thirty-two patients received conservative antibiotic therapy without removal of the infected pacing system, which included limited debridement and irrigation or aspiration of the infected sites. This conservative therapy failed in all, but one of the 32 patients, and complete removal of the device system was needed in 31. Molina et al. subsequently reported the outcome of management in 38 patients with an infected CIED, including 17 ICDs [27]. Twelve patients received intravenous antibiotics without removal of the CIED, but with relocation to a different area, with or without aspiration of the infected area. Patients who received conservative therapy ultimately all remained infected. Two deaths occurred in these patients. On the other hand, the remaining 26 CIED patients who underwent primary removal of the entire device system were completely cured. No deaths occurred in these patients. These data supported the value of prompt complete device removal in infected CIED patients.

## 3. Mortality

Although complete removal of an infected CIED is first-line therapy, there can be a risk of device removal complications. It was reported that complications of device extraction were associated with increased mortality in patients with CIED infections at both 30 days (hazard ratio [HR]: 4.33, 95% confidence interval [CI]: 1.47–12.70) and one year (HR: 3.77, 95% CI: 1.88–7.55) [11]. However, delayed device removal was associated with a 3-fold increase in one-year mortality, and antibiotic therapy without device removal was associated with a 7-fold increase in 30-day mortality, compared to immediate device removal in the previous paper. Margery et al. also described outcomes and mortality in infected CIED patients [5]. Of 39 (82%) patients, 32 underwent device extraction, and complete device removal was accomplished in 27 (84%). Of these, none relapsed, and mortality was 7.4% during a median follow-up period of 36 months. Of those managed with only generator removal or conservative therapy, relapse occurred in 8 of 12 (67%), with mortality occurring in 8.4%. Using data on patients with infective endocarditis and a cardiac device, Athan et al. reported that 28 of 141 (19.9%) who underwent device removal during the index hospitalization died at one year, compared with 13 of 34 (38.2%) who did not undergo device removal (HR: 0.42, 95% CI: 0.22–0.82), which suggested that device removal was associated with improved survival at one year [12].

## 4. Possibility of successful conservative therapy

Some patients have severe complicated medical problems and are considered too ill to tolerate aggressive surgical intervention. In addition, some patients refuse surgery, or have a limited life span. In such cases, conservative treatment has been attempted. In 1985, Garcia-Rinaidi et al. successfully treated exposed pacemakers relocated to deeper subfascial planes without relapse of infectious signs in 10 patients [28]. They concluded that subfascial relocation of a properly functioning pacemaker generator should be considered as an alternative to complete replacement of the unit. Hurst et al. also reported that 19 infected or extruded pacemaker patients were

treated with local debridement and insertion of a closed irrigation system using solutions of tyloxapol and tobramycin [29]. In order to achieve successful treatment, they insisted on careful debridement of the infected pocket and large pocket space to ensure adequate closure without tension. Using this method, they have been successful in salvaging infected pacemaker pockets, and all 19 patients healed without complications after treatment (the maximum follow-up period was 70 months).

Clinical data on 51 patients with intravascular device-related infections who were administered long-term suppressive antibiotic therapy were also reported [30]. The categories included vascular graft infections in 30 (59%) patients, prosthetic valve endocarditis in 12, pacemaker-related infections in 5, aortic graft infections in 3, central venous catheter infections in 3, and venous filter infection in one. Therapy duration ranged from 3 months to 10 years. Of 41 followed-up patients, 3 (7%) had an infection relapse while on long-term antibiotic therapy. Three patients died, including one who had an infection relapse and died of the infection. Drug side effects occurred in the other 3 patients. The report stated that long-term antibiotic therapy was well-tolerated and efficacious in nonsurgical candidates. Segreti et al. reviewed 18 patients with infected orthopedic prostheses who had been treated with long-term antibiotic therapy. Although side effects related to antibiotics occurred in 22%, 15 (83%) patients with a mean follow-up of 5 years had a good response to suppression of infection and could retain a functional prosthesis [31]. Ortlor et al. experienced the case of one epileptic patient implanted with an infected vagus nerve stimulator system who underwent successful open wound treatment without removal of the system [32]. They reported that the deep wound was initially opened and debrided. With continuous antibiotic therapy and daily rinsing with 3% hydrogen peroxide solution and 5% saline, granulation tissue gradually appeared. In this case, relapse of infection never occurred during a follow-up of 1 year. The value of local treatment with 3% hydrogen peroxide for prevention of foreign body infection has been previously reported [33]. Of 990 CIEDs treated with 3% hydrogen peroxide during the implant procedure, 2 (0.2%) developed an infection, which was a significantly reduced infection rate compared to that of CIEDs treated without hydrogen peroxide during implantation (1.83%,  $p < 0.05$ ).

Although conservative therapies might be useful in limited cases, retained infectious devices have a risk of mortality. Additionally, these papers were published more than 10 years ago, and medical technology has advanced since then. The excimer laser has also been used for CIED lead removal in many countries. If possible, initial complete hardware removal is strongly recommended, and the indications for conservative antibiotic therapy for CIED infections should be determined with great caution.

## 5. Recent studies

In 2010, Satsu et al. reported the use of a vacuum-assisted wound closure (VAC) system as an option for treating an infected device [34]. The VAC system is comprised of polyurethane foam with an evacuation tube, a vacuum pump, and adhesive drape. Treatment with VAC has been reported to be an efficacious modality for chronic and difficult wounds [35,36]. After opening the wound, the polyurethane is cut and positioned on the defect area, with connection of the evacuation tube. The wound is then covered with an adhesive drape, and suction is continued with a negative pressure of 100 mmHg. The wound is treated by changing the foam every 2 or 3 days until healing occurs, or the incision is sutured when granulation appears. According to this paper, infections never relapsed after treatment with VAC in all 4 patients for 5–15 months, and CIED infection healed without complete removal of the pacemaker system in 2 patients.

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