

Leadless Pacemaker Implantation after Lead Extraction for Cardiac Implanted Electronic Device Infection

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Introduction:

As the clinical indications for cardiac implantable electronic devices (CIED) have expanded, especially in patient populations with significant co-morbid conditions, the prevalence of CIED infections has increased. CIED related infections present in many forms, that may or may not lead to sepsis, ranging from isolated pocket infection to CIED endocarditis with lead involvement. The morbidity and mortality associated with CIED infection is considerable. While the extraction procedure itself has significant morbidity and considerable mortality, even when performed with success [1], the morbidity and mortality of delayed CIED system

extraction may be significantly higher [2]. Therefore, the Heart Rhythm Society expert consensus recommends complete CIED system removal, including any previously retained hardware, in patients with a device pocket infection, bloodstream infection, and/or valvular endocarditis with or without lead involvement.

There are no randomized control trials defining the minimum duration for antibiotic therapy; however, the following durations are recommended: 10 days for pocket erosion; 2 weeks for closed pocket infection; 2 weeks for bloodstream infection, with the antibiotic course extended to 4 weeks for *Staphylococcus aureus* ; 2-4 weeks for lead vegetation, depending on pathogen; 4 weeks for native valvular endocarditis; and 6 weeks for prosthetic valve or staphylococcal valvular endocarditis[1].

There are also no prospective trial data on the timing of new device replacement and risk for recurrent infection. Patients should be evaluated on an individual basis for their ongoing CIED indication and device reimplantation should be tailored to a given patient’s situation. Attention should be paid to evidence of ongoing infection and especially bacteremia. Currently accepted waiting periods for new device reimplantation range from 72 hours in pocket and bloodstream infections to two weeks in cases of valvular endocarditis. For pacemaker-dependent patients, temporary pacing is required as a bridge to reimplanting a permanent device. A commonly adopted alternative is temporary pacing using a permanent pacing lead connected to an external re-used pulse generator, sometimes called a “temporary-permanent pacemaker”. While this provides the freedom of patient mobility, not all patients are good candidates for discharge with this device. Likewise, the majority of long-term care facilities and rehabilitation hospitals will not accept such a patient.

The Use of Leadless Pacemakers in Infected Patients:

The authors present an interesting report of the use of a leadless pacemaker in patients who have a need for continued pacing support and have had an extraction due to infection. While this concept has been previously described by others [2-4], this report provides further data to support the efficacy of this approach and provides for longer duration follow-up. The studied patient group is diverse with some patients having simple device pocket infections and others having complex lead-associated endocarditis. Likewise, the patients were treated differently with respect to the timing of leadless pacemaker implantation. Just under half were implanted as part of the extraction procedure and the rest were implanted soon thereafter. In follow-up there were no device related infections. [3-5]

Growing evidence supports the use of leadless pacemaker implantation in patients with high risk of infection recurrence. In addition to eliminating the device pocket, a leadless pacemaker has several inherent design features that make it resistant to infection. First, the intravascular surface area of the device is quite small as compared to a traditional transvenous pacemaker. In fact, most of the time the current Medtronic leadless pacemaker is buried deeply in the trabecula with very little device exposure to the blood pool. Secondly, it seems obvious that in many cases the course of the lead may be involved in the infection. This may include cardiac valves, as well as the fibrous tissue tract along the lead body. If that is the case, any new device, be it permanent or temporary, will be in contact with this potentially infected tissue. Thirdly, the Medtronic leadless pacemaker described in this report is almost entirely covered by parylene, a material that has been demonstrated to inhibit biofilm formation and should reduce device-associated infections[6].

In the more than 2500 patients enrolled in the Micra Transcatheter Pacemaker System pivotal and post approval studies [7, 8], there were no device-associated infection reports and no leadless pacemakers required extraction due to a reported infection. The post-approval study included a subset of patients considered at high risk for infection, including patients in whom transvenous device implantation was precluded due to previous infection, need for dialysis or cancer (22.4%). Rare case reports have been reported in the literature documenting Micra device removal for infection; however, the infection rate remains orders of magnitude lower than traditional transvenous systems. While utilization of a leadless pacemaker provides an attractive alternative to a transvenous system in patients with a recent CIED infection, only retrospective data on a limited sample size are described evaluating Micra implantation concomitant with CIED extraction.

Interpretation and Conclusions:

In summary, the care of patients with infected CIEDs is treacherous territory that is associated with significant morbidity and mortality. The use of leadless pacemakers, either as a permanent solution or possibly as a prolonged temporary solution, may be another small step forward in the improvement of outcomes in this difficult population of patients.

While caution and clinical judgement are required to evaluate the unique clinical scenario of each infected patient, the use of the Medtronic leadless pacemaker in this setting shows promise.

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