Comparison of delayed transvenous reimplantation and immediate surgical epicardial approach in pacing-dependent patients undergoing extraction of infected permanent pacemakers

Sana Amraoui, MD,[*] Manav Sohal, MBBS,[†] Adrian Li, MBBS,[†] Steven Williams, MBBS,[†] Paul Scully, MBBS,[†] Tom Jackson, MBBS,[†] Simon Claridge, MBBS,[†] Jonathan Behar, MBBS,[†] Philippe Ritter, MD,[*] Laurent Barandon, MD, PhD,[*] Sylvain Ploux, MD, PhD,[*] Pierre Bordachar, MD, PhD,[*] Christopher A. Rinaldi, MD[†]

From [*]Université de Bordeaux, Hopital Haut-Lévêque, LIRYC, Pessac, France, and [†]Guy's and St. Thomas' NHS Foundation Trust, London, United Kingdom.

BACKGROUND Pacemaker infection in pacing-dependent patients is challenging. After extraction, temporary pacing usually is utilized before delayed reimplantation (after an appropriate course of antibiotics), resulting in prolonged hospital stays. A single combined procedure of epicardial (EPI) pacemaker implantation and system extraction may prevent this.

OBJECTIVE The purpose of this study was to evaluate the feasibility and safety of these 2 approaches by comparing clinical outcome for both strategies over 1 year.

METHODS In center 1, 80 consecutive pacemaker-dependent patients underwent extraction with an externalized pacemaker and delayed implantation on the contralateral side (ENDO group). In center 2, 80 consecutive patients had 2 epicardial ventricular leads surgically implanted with extraction of the infected pacemaker during the same procedure (EPI group). Patients were followed-up for 12 months.

RESULTS One hundred sixty pacing-dependent patients were successfully implanted and extracted (ENDO group 71 ± 13 years vs EPI group 73 ± 14, P = NS). In the EPI group, 2 patients developed significant pericardial bleeding. In-hospital mortality was 0% in the ENDO group and 2.5% in the EPI group. Total hospitalization time was 15 ± 7 days in the ENDO group vs 9 ± 6 days in the EPI group (P <.001). At 1 year, no infection recurrences occurred in either group, and mortality was equal (5% in each group). Median 1-year pacing thresholds were lower in the ENDO vs the EPI group (0.8 ± 0.6 V vs 1.1 ± 0.6 V, P = .02).

CONCLUSION The ENDO and EPI strategies had an excellent success rate and low risk of complications. A single procedure using surgical epicardial lead implantation was associated with a shorter duration of hospital stay.

KEYWORDS Pacemaker infection; Pacing-dependent patients; Extraction; Endocardial reimplantation; Epicardial reimplantation

ABBREVIATIONS **AV** = atrioventricular; **CIED** = cardiac implantable electronic device; **CRT** = cardiac resynchronization therapy; **ENDO** = endocardial; **EPI** = epicardial; **HRS** = Heart Rhythm Society; **RV** = right ventricle

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Introduction

The rate of cardiac implantable electronic device (CIED) implantation continues to grow.[1] Patients who receive a CIED are living longer (with more comorbidities) and leads are remaining implanted for longer periods of time, thereby increasing the likely need for CIED extraction. The most common indication for CIED extraction is infection, which is increasing at a greater rate than CIED implantation.[2] Timing of CIED reimplantation after extraction for infection is often delayed to allow for a prolonged course of antimicrobial therapy. The American Heart Association scientific statement advocates an antibiotic treatment range from 7 days to more than 2 weeks depending on the presence of systemic infection.[3] The Heart Rhythm Society (HRS) consensus statement recommends new CIED implantation on the contralateral side in patients treated by antimicrobial therapy, 3 to 14 days after extraction, depending on clinical (local vs systemic infection) and biologic (bloodstream infection) parameters.[4] Management of pacing-dependent patients with infected CIEDs is particularly challenging, requiring maintenance of pacing between extraction and reimplantation. The 2009 HRS consensus document outlined the facilities and training required for a safe and successful extraction program but does not provide a firm consensus on the best

Address reprint requests and correspondence: Dr. Sana Amraoui, Hôpital Cardiologique du Haut-Lévêque, 33604 Bordeaux-Pessac, France. E-mail address: sana.amraoui@hotmail.com.

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approach for managing pacing-dependent patients undergoing extraction for CIED infection.

In pacing-dependent patients, interim pacing performed with a temporary pacing wire has a number of drawbacks, including the need for patient immobilization (to reduce the risk of lead displacement) and the need to change the wire at regular intervals to minimize the risk of infection. To circumvent these issues, implantation of a traditional active fixation permanent pacing lead connected to an externalized pacemaker generator has been used until permanent endocardial reimplantation can occur.[5,6] An alternative approach for patients who require pacing for bradycardia alone is a single procedure that combines implantation of an epicardial pacing system via the subxiphoid approach followed by extraction of the infected device (EPI-pacing strategy).[7]

We sought to compare these 2 strategies: interim pacing with an externalized pacing system and reimplantation on the contralateral side following antimicrobial therapy (ENDO-pacing) strategy and the EPI-pacing strategy. We hypothesized that EPI pacing would be associated with reduced length of hospital stay, and we sought to evaluate the feasibility and safety of such an approach and to compare infection rates and clinical outcome for both strategies at 1 year.

Methods

St. Thomas' Hospital (London, United Kingdom) and Haut-Lévêque Hospital (Bordeaux, France) are 2 regional centers for the investigation and treatment of patients with a CIED infection. Both centers serve a large geographic area, receiving patients with local or systemic device infection. Patients treated at St. Thomas' Hospital (center 1) underwent the ENDO-pacing strategy (externalized pacing device pending definitive CIED implant on the contralateral side), and patients treated at Haut-Lévêque Hospital (center 2) underwent EPI pacing with surgical epicardial CIED implant and extraction of the infected device during the same procedure. The study was approved by each local ethics committee, and all patients provided written informed consent.

Patients

A total of 160 consecutive pacing-dependent patients referred for extraction of infected bradycardia pacemakers (local or systemic) were compared in a case-controlled retrospective manner (80 in each group). Cardiac resynchronization therapy (CRT) and implantable cardioverter-defibrillator extractions were excluded from the analysis. Patients were considered pacing dependent as a result of complete heart block if interrogation of the pacemaker the day before extraction demonstrated $>95\%$ right ventricular (RV) pacing and/or an electrocardiogram demonstrated third-degree atrioventricular (AV) block.

Diagnosis and treatment of infection

CIED infection was diagnosed using standard criteria, including the presence of erythema or abscess formation over the CIED pocket or vegetations seen on the pacemaker leads (lead endocarditis). When there was a clinical suspicion of CIED infection, a standardized clinical pathway was followed in both centers, including a detailed history, clinical examination, routine blood tests with inflammatory markers, wound swabs, and multiple blood cultures (minimum of 3 sets). All patients underwent transthoracic echocardiography $\pm$ transesophageal echocardiography for the diagnosis of systemic infection.[8,9] A diagnosis of lead endocarditis was made according to the modified Duke criteria.[10] A diagnosis of local infection was made when the clinical manifestations were limited to signs of pocket infection.[11] All patients were treated with prolonged antimicrobial therapy tailored to microbiologic results when possible and in the absence of an identified pathogen vancomycin was used as first-line empirical therapy.

Extraction and ENDO pacing (center 1)

All extraction procedures were performed by cardiologists in a cardiac catheter laboratory with the patient under general anesthesia. A temporary pacing wire was introduced into the apex of the RV via the femoral vein before extraction. Lead extraction was performed via a transvenous approach[4,12] by a cardiologist experienced in lead extraction procedures.[13] When possible, extraction was performed initially from a superior approach using a combination of simple traction or laser sheath (CVX-300 Excimer laser system, Spectranetics, Colorado Springs, CO) as required.[14,15] When a superior approach failed or was not possible, extraction was performed from a femoral approach using a dedicated femoral workstation (Cook Vascular) utilizing a needle's eye or gooseneck snare as appropriate. All infected tissues and lead materials were separately sent for culture. Complete extraction was defined as removal of the entire lead and partial extraction as removal of most of the lead components, except for the electrode tip and less than 4 cm of wire or insulation. Procedures were classified as unsuccessful when these endpoints were not reached in accordance with the HRS consensus statement.[4]

Immediately after extraction, interim pacing was provided by an externalized pacing system on the side ipsilateral to the extraction site. If subclavian access was maintained via the laser sheath (where used), a 0.035-inch guidewire was brought out through the skin remote from the wound and a 7Fr sheath passed over it in typical Seldinger fashion. A 58-cm active fixation pace/sense endocardial pacing lead (Medtronic 5096, Medtronic, Minneapolis, MN) was then passed to the RV apex or interventricular septum and secured to the overlying skin after satisfactory pacing checks. If vascular access was not preserved, then a percutaneous subclavian vein puncture was made and the Seldinger technique used as described earlier. The removed generator was cleaned with hydrogen peroxide solution and the pace/sense lead connected to the RV pacing port. For dual-chamber generators the atrial port was capped. The generator was then secured to the overlying skin. Patients were