Epicardial leads in adult cardiac resynchronization therapy recipients: A study on lead performance, durability, and safety

Maurits S. Buiten, MD,[*] Aafke C. van der Heijden, MD,[*] Robert J.M. Klautz, MD, PhD,[†] Martin J. Schalij, MD, PhD,[*] Lieselot van Erven, MD, PhD[*]

From the [*]Department of Cardiology, Leiden University Medical Center (LUMC), Leiden, The Netherlands, and [†]Department of Cardiothoracic Surgery, LUMC, Leiden, The Netherlands.

BACKGROUND Transvenous left ventricular (LV) lead placement for cardiac resynchronization therapy–defibrillator (CRT-D) delivery is unsuccessful in 8% to 10% of cases. These patients might benefit from an epicardial lead. However, data on long-term epicardial lead performance are scarce. Furthermore, extracting an epicardial lead requires a rethoracotomy.

OBJECTIVE The purpose of this study was to determine data on almost a decade of experience with epicardial leads and investigate the safety of partially leaving this lead in place after device infection.

METHODS All adult patients receiving an epicardial lead (Medtronic CapSure Epi, model 4968) for CRT-D in the Leiden University Medical Center were included. Leads were implanted during a standalone procedure or in combination with other cardiothoracic procedures. Electrical lead parameters were assessed at implantation and every 6 months thereafter. In case of device infection the epicardial lead was cut off parasternal, just outside the thoracic cavity, leaving the distal part of the lead in place.

RESULTS Two-hundred sixteen patients were included with a median follow-up of 3 years (25th–75th percentile 1.0–5.5). LV pacing threshold decreased within 6 months after implantation [1.1 V (95% confidence interval [CI] 0.9–1.2) vs 0.8 V (95% CI 0.7–0.9), $P = .01$] and stabilized thereafter. Mean LV electrogram was 15.2 ± 7.5mV, and average lead impedance was 633.5 ± 174.0 Ω. Five-year cumulative incidence was 1.6% for lead failure and 9.6% for device infection. The retained epicardial lead caused skin erosion in 3 patients and fistula formation in 1.

CONCLUSION This study demonstrates that epicardial LV leads have an excellent long-term performance. Partially retaining the lead after device infection was associated with a risk of reinfection with limited long-term clinical implications for the patient.

KEYWORDS Cardiac resynchronization therapy–defibrillator; Cardiac resynchronization therapy; Left ventricular lead; Epicardial lead; Lead performance

ABBREVIATIONS **CABG** = coronary artery bypass grafting; **CI** = confidence interval; **CRT** = cardiac resynchronization therapy; **CRT-D** = cardiac resynchronization therapy–defibrillator; **ICD** = implantable cardioverter-defibrillator; **LV** = left ventricle; **RA** = right atrium; **RV** = right ventricle

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Introduction

Cardiac resynchronization therapy (CRT) improves both morbidity and mortality of selected patients with heart failure.[1,2] Most CRT recipients receive a transvenous lead in the right atrium (RA) and right ventricle (RV) as well as a lead placed through the coronary sinus on the left ventricular (LV) free wall. Unfortunately, transvenous LV lead placement is unsuccessful in 4.3% to 7.5% of patients because of venous anatomy, high stimulation thresholds, or phrenic nerve stimulation.[3–6] These patients need an alternative method of LV lead placement.

A lead placed on the epicardial LV wall by thoracotomy might represent an alternative for a transvenous lead.[7–10] Early CRT devices used epicardial LV leads, but both the incidence of lead failure and the reported complication rates were high.[11,12] Furthermore, in case of a device-related infection necessitating device removal, a rethoracotomy was necessary to extract the epicardial lead. Thus, epicardial LV lead placement was mostly abandoned in favor of the transvenous approach.[13]

With the increasing number of CRT recipients, the number of patients in whom transvenous LV lead placement is impossible continues to rise.[14] Consequently there has been a growing interest in alternatives for transvenous lead placement, such as video-assisted thoracoscopic LV lead

The Department of Cardiology receives unrestricted grants from Biotronik (Berlin, Germany), Boston Scientific (Natick, Massachusetts), and Medtronic (Minneapolis, Minnesota). **Address reprint requests and correspondence:** Dr. Lieselot van Erven, Department of Cardiology, Leiden University Medical Center, PO Box 9600, 2300 RC Leiden, The Netherlands. E-mail address: l.van_ervan@lumc.nl.

placement and transapical and transseptal endocardial lead implantation.[15–17] Moreover, there has been a renewed interest in epicardial LV leads, with the development of novel implantation techniques and new lead technologies.[8,18] However, because the available data on epicardial leads in adults consist of small patient groups or limited follow-up, concerns remain regarding long-term epicardial lead performance in adult patients.[9,18–20]

The aim of this study was to evaluate long-term performance of epicardial LV leads in a large population of adult CRT recipients. Therefore, the focus of the current study was on electrical parameters rather than echocardiographic response to CRT. In addition, whether it was safe to partially retain the epicardial lead in case of device infection, rather than surgically removing the lead by rethoracotomy, was investigated.

Methods

Patient population

All patients receiving a cardiac resynchronization therapy–defibrillator (CRT-D) in the Leiden University Medical Center were registered in the departmental cardiology information system (EPD-Vision, Leiden, The Netherlands). Clinical characteristics at baseline, data on the implant procedure, and follow-up were noted in this system. Electrocardiogram evaluation was performed by 1 of the authors (MSB) according to previously published guidelines.[21] For the current analysis, all adult patients receiving an epicardial lead, connected to a CRT between 2004 and 2013, were analyzed. In all patients, the epicardial lead was either connected to a CRT-D during the same hospital admission as the lead placement procedure or connected at a later point in time. In all cases, CRT was indicated or expected to be necessary in the future. The study is a retrospective report on clinical practice and therefore was exempt from ethics committee approval.

CRT-D

The CRT-D devices used were manufactured by Biotronik (Berlin, Germany), Boston Scientific (Natick, MA; formerly CPI, Guidant, St. Paul, MN), Medtronic (Minneapolis, MN), or St. Jude Medical/Ventritex (St. Paul, MN). The RA and RV leads were positioned conventionally.

Epicardial lead

All epicardial leads investigated were bipolar suture-on leads (Medtronic CapSure Epi, model 4968). The lead was placed concomitantly during another procedure necessitating a sternotomy such as coronary artery bypass grafting (CABG), tricuspid or mitral valve repair (valve repair), LV reconstruction, or aortic arch replacement. Alternatively, the lead was placed in a standalone procedure by lateral minithoracotomy. In all cases, care was taken to place the lead on a spot on the LV free wall with the least epicardial fat. Subsequently, the lead was brought through the thoracic cage and connected to a CRT-D already present or tunneled toward the site of a future device where it was sutured subcutaneously.

Lead performance

All CRT-D devices were interrogated directly after placement, every 3–6 months thereafter, or when clinically indicated. Device interrogation was performed by device technicians under supervision of device cardiologists and included determination of LV pacing threshold in volts (at an average pulse width of 0.5 ms), LV electrogram (mV), and lead impedance (Ω). The LV electrogram cannot be measured in Medtronic devices. Data on electrical parameters were collected until the end of follow-up, the final visit before referral to another hospital, death, or loss to follow-up. All epicardial lead problems that required lead disconnection, relocation, or replacement were considered as epicardial lead complications.

Device infection

Device infection was defined as any case of suspected device infection necessitating device removal regardless of the presence of a positive lead or device culture. In case of a device infection, a small parasternal skin incision was made separate from the pocket in order to prevent spread of infectious material to deeper tissue. Through this incision, the subcutaneous epicardial lead was located using fluoroscopy and palpation. Subsequently, the epicardial lead was locally freed from the surrounding tissue, and an effort was made to remove as much of the distal part of the lead as possible by using traction before cutting the lead. Usually only the intrathoracic part of the lead was left in place (Figure 1). After rinsing the wound with povidone–iodine, the parasternal incision was closed. Then, the ICD pocket was opened, and the device and proximal part of the epicardial lead were removed; the transvenous leads were extracted using manual traction or mechanical lead extraction tools. Finally, the ICD pocket was closed. After appropriate antibiotic treatment based on the bacterial pathogen and the extent of infection, a new CRT-D was implanted on the contralateral site.

Statistical analysis

Continuous data are reported as mean ± SD or as median with interquartile range (25th–75th percentile) if the data were not normally distributed. Categorical data are given as number and proportion (percentage).

Serial measurements of the electrical lead parameters were compared using a linear mixed model with a diagonal covariance matrix. Time was incorporated in the model as a categorical variable (0, 6, 12, 24, 36, 48, and 60 months after implant) to assess whether the lead parameters changed compared with the previous measurement. Subsequently, time was implemented in the mixed model as a continuous variable to elucidate whether electrical parameters changed over the whole period of follow-up. The type of procedure concomitant to the lead implantation was added to the mixed