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Original research article

Middle-term stability of epicardial left ventricular electrodes for cardiac resynchronization therapy

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ABSTRACT

Introduction: Cardiac resynchronization therapy (CRT) is currently considered an effective and safe way to treat patients with severe heart failure. Unsuccessful attempts at endovascular insertion of the left ventricular (LV) electrode should prompt a consideration of having the electrode implanted by a cardiac surgeon.

Aims: The aims of our work were to evaluate the electric parameters of CS-implanted LV electrodes and to compare them with transvenous implanted electrodes, identify the causes of endovascular implantation failure, compare the clinical and echocardiographic resynchronization effects, and compare the safety of both approaches.

Methods and results: Patients indicated for CRT had the LV electrode implanted either endovascularly (“endo” group) or epicardially (“epi” group; in cases of endovascular approach failure or as a part of another CS procedure). The trial was planned as a case–control study. Each group comprised 92 patients (26 females, 66 males) with an average age of 69 (epi) and 68 (endo) years, respectively. LV stimulation was effective at the 3-year follow-up in 98.1% of patients in the epi group and in 96.6% of patients in the endo group (p = NS). The groups were comparable with respect to the stimulation threshold both before discharge and at the 3-year follow-up. At the 1-month follow-up, this threshold was significantly higher in the epi group (1.62 V vs. 1.06 V, $p < 0.001$) and the same was true for the 1-year and 2-year follow-ups (1.57 V vs. 1.09 V and 1.54 V vs. 1.21 V, respectively; $p < 0.001$). Energetic output during LV stimulation was significantly higher in the epi group at all time points. The overall procedural effectiveness of endovascular implantation was 94.6%. Clinical response to CRT was noted in 71.4% of epi group patients and in 68.1% of endo group patients (p = NS). The average absolute increase in LV ejection fraction was comparable in both groups (6.0% vs. 7.2%, p = NS). Significantly higher 1- and 3-year mortality was noted in the epi group (19.0% vs. 5.5% and 21.7% vs. 6.5%, respectively; $p < 0.001$).

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Conclusion: Epicardial electrodes are capable of effective LV stimulation, as shown during middle-term follow-up. Epicardial LV stimulation is more demanding energetically. Resynchronization effects are similar in patients with epicardial and endocardial LV electrodes; however, the mortality of patients with epicardial LV electrodes seems to be significantly higher.

Introduction

Currently, cardiac resynchronization therapy (CRT) is considered an effective and safe method for treatment of patients with moderate to severe forms of heart failure (NYHA II–IV) involving exhausted, or as the case may be, optimized pharmacotherapy, signs of ventricular dyssynchrony, and persistent depression of left ventricular (LV) function [1–7]. Meta-analyses and trials concerning CRT show significant lowering of both morbidity and mortality [8,9]. The standard approach to LV electrode insertion consists of a transvenous endocardial implantation during which the electrode is implanted endovascularly via the coronary sinus (CS) into the target branch above the most delayed LV segment. Despite the improvements of insertion instruments and LV electrodes, this approach to LV electrode implantation fails in about 5–10% of patients [10,11].

Epicardial implantation of the LV electrode is the method of choice in cases when the standard transvenous approach has failed. The ability of epicardial electrodes to provide adequate long-term LV stimulation is comparable to that of transvenous electrodes [12,13]. Available data comparing the clinical and echocardiographic benefit of CRT depending on the type of LV electrode implantation are incongruent; most authors describe the same level of improvement [12,14,15]. However, studies demonstrating worse functional and echocardiographic effects of CRT with epicardial LV electrodes also exist [16]. Mortality data can also be conflicting: some authors declare comparable survival in both groups [17,18] while others document higher mortality in patients with epicardial LV electrodes, especially in the early post-implantation period [19]. Published studies lack a comparison of electric parameters and energetic demands of LV impulses with respect to durability of the battery supplying the device. The major aim of our study was to evaluate the middle-term electric parameters of epicardial LV electrodes, compare them to those of electrodes implanted endovascularly, and to find out whether stimulation parameters can be influenced by clinical and demographic factors. We also wanted to compare the resynchronization effects of endocardial and epicardial LV electrodes with respect to clinical and echocardiographic outcomes and to compare the safety of CRT devices with endovascularly and epicardially implanted electrodes.

Methods

Our project was planned as a prospective, non-randomized, bicentric, longitudinal case–control study. It was performed at two centers: The Department of Internal Medicine I – Cardiology of the University Hospital Olomouc (in collaboration with the Cardiac Surgery Department of the same hospital) and the Heart Center, České Budějovice Hospital, Inc. Consecutive patients undergoing implantation of a biventricular cardiac pacemaker or biventricular cardioverter-defibrillator, according to the current guidelines of the European Society of Cardiology, were enrolled. The group of **cases** labeled as ''epicardial'' comprised patients in whom endovascular attempts at LV electrode implantation failed and whose LV electrodes were implanted epicardially by a cardiac surgeon either alone or in conjunction with another cardiac surgery (e.g. revascularization procedure or valve repair); the implantation of the device *per se* and of other electrodes was completed endovascularly later. The **Control** group, labeled as ''endocardial,'' comprised patients with completely endovascular implantation of the CRT system performed at the above centers according to current guidelines. Patients were paired and placed in the control group during the study such that they shared the following basic clinical characteristics: sex (100% agreement), age (±3 years), etiology of heart failure (ischemic vs. non-ischemic – 100% agreement), heart rhythm (sinus rhythm vs. atrial fibrillation – 100% agreement), and at least two thirds of the evaluated comorbidities (hyperlipoproteinemia, arterial hypertension, diabetes mellitus, and history of stroke or transient ischemic attack).

Twelve months following implantation of the CRT system, the clinical and echocardiographic effects of treatment were evaluated. Electric parameters of endocardial and epicardial electrodes were compared yearly. An interval of at least 3 years from implantation was considered adequate for evaluation of middle-term stability of electric characteristics of the implanted electrodes.

Endovascular implantation of left ventricular electrode

Endovascular implantation was performed by surgeons with varying degrees of experience. Atrial electrodes and right ventricular (RV) electrodes were implanted in standard positions (right atrial auricle, apex or septum). LV electrodes were inserted transvenously via the coronary sinus (CS). In all patients, the CS was targeted using an *electrophysiological approach*, i.e. it was cannulated with a dedicated non-steerable decapolar catheter. CS anatomy was visualized in at least two different projections using a contrast agent. Adequate lateral, posterolateral or anterolateral branches of the CS were sought for implantation, with the final choice of the target position of the LV electrode being left to the surgeon. The goal was to reach the mid-ventricular LV segment in the given location, depending on the target branch of the CS. The choice of LV electrode type was also left to the surgeon's discretion. In cases of failure, the implantation protocol included information

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