Prophylactic Epicardial Left Ventricular Lead Implantation for Biventricular Pacing During Operations

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Background. **Surgical epicardial left ventricular (LV) lead implantation for biventricular pacing has advantages over the transvenous approach in cardiac surgical patients. We investigated the benefit of concomitant prophylactic LV lead implantation during open heart operations and subsequent lead performance after patients with impaired LV function receive a biventricular device.**

Methods. **Retrospective data of 4,844 patients undergoing cardiac operations through a sternotomy between January 2001 and December 2011 were analyzed. Of these, 380 patients (7.8%) had severe impairment of LV function (contrast left ventriculogram showing grade 4 estimated ejection fraction or echocardiogram showing LV ejection fraction < 0.30). LV lead implantation was performed in patients in whom recovery of LV function was unlikely. Lead performance data were collected at follow-up.**

Results. **LV lead implantation occurred in 95 patients (25%), and 29 (30.5%) subsequently received a biventricular device. Of patients with impaired LV function, more patients with prophylactic LV leads underwent biventricular implant than those without LV leads (30.5% vs 1.1%, $p < 0.0001$). The median interval from LV lead implantation to connection to a biventricular device was 30 days (interquartile range, 5.5 to 145 days). At a median follow-up of 437.5 days (interquartile range, 13.8 to 1198 days), the mean pacing threshold (1.25 ± 0.46 vs 1.58 ± 0.66 volts, $p = 0.069$) and impedance (383.81 ± 70.33 vs 448.6 ± 200.1 Ohms, $p = 0.168$) remained stable compared with time of biventricular device connection.**

Conclusions. **A significant proportion of patients with poor LV function undergoing cardiac operations may benefit from concomitant LV lead implantation. Subsequent lead performance appears satisfactory. Epicardial LV lead placement is easily accomplished during open heart operations and should be considered before the operation.**

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Heart failure is a major public health problem, with an estimated prevalence of 2.1%, accounting for a total mortality of 41.8% in men and 58.2% in women [1]. Patients with advanced heart failure benefit from biventricular pacing, with a 30% decrease in hospitalizations and a 51% relative reduction in the mortality rate [2]. Updated guidelines state that biventricular pacing is indicated for patients on maximal medical therapy who have a left ventricular (LV) ejection fraction of 0.35 or less, sinus rhythm, left bundle branch block with QRS of 150 ms or more, and New York Heart Association (NYHA) class II, III, or IV symptoms [3].

The aim of biventricular pacing is resynchronization of ventricular contraction resulting in more efficient cardiac output. Effective placement of left ventricular leads is required for an optimal outcome [3]. Transvenous LV lead implantation through the coronary sinus is currently considered the first-line approach [4, 5]. However, transvenous LV lead placement is not possible in 8% to 10% of patients for a variety of reasons [4]. Surgical LV lead placement is the next option for these patients, often with a video-assisted thoracoscopic approach.

A small subset of patients with heart failure undergoing cardiac operations qualifies for cardiac resynchronization therapy [6]. A significantly larger population has impaired LV function and is likely to require biventricular pacing soon after their operation, even if not fully meeting criteria for biventricular pacing at the time of the operation. Prophylactic epicardial lead implantation during a concurrent operation is now emerging as a cost-effective and simple method of LV lead implantation [7]. Preliminary studies have shown positive results [6–8], but data are scarce and the number of patients is small.

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We investigated the benefit of concurrent prophylactic LV lead implantation during cardiac operations and subsequent lead performance in a large patient cohort.

Patients and Methods

The Institutional Ethics Committee approved publication of this study and the use of LV leads and patient data within the database.

The study included all patients undergoing cardiac operations between January 2001 and December 2011 in our institution. Data were retrieved retrospectively from the Australian and New Zealand Society of Cardiac and Thoracic Surgeons database and from patient medical records. A detailed description of data collection and validation has been previously described [9].

In the current study, 13 preoperative patient characteristics and three operative types were compared among various subgroups (Table 1). Definitions of patient characteristics have been previously described [9].

We screened all patients preoperatively to identify those with impaired LV function who would likely require biventricular pacing within 1 month postoperatively. Patients were defined as having impaired LV function if they had a grade 4 estimated ejection fraction (EF) or left ventricular EF (LVEF) of less than 0.30 on echocardiogram. According to the Australian and New Zealand Society of Cardiac and Thoracic Surgeons database definitions, estimated EF was defined as normal (LVEF >60%), mild impairment (LVEF 46% to 60%), moderate impairment (LVEF 30% to 45%), or severe impairment (LVEF <30%) estimated on contrast left ventriculogram. An echocardiographic LVEF of less than 0.30 was chosen to correspond to severe impairment on the estimated EF. Cardiac resynchronization therapy remained indicated postoperatively in up to 76% patients with preoperative indications for cardiac resynchronization therapy [6].

Each surgeon made a decision about using LV leads in patients. The rationale for this decision was patients in whom recovery of LV function was unlikely or uncertain after their operation. The likelihood of needing biventricular pacing in the early postoperative period, or more remotely from the operation, was also considered preoperatively and intraoperatively. Consent was obtained from all patients before their operation.

A sutureless bipolar nonsteroid-eluting Myopore epicardial lead (Model 511212, Enpath Medical Inc, St. Paul, MN; now Greatbatch Medical, Alden, NY) was implanted on the lateral or posterolateral portion of the LV concomitantly during the operation (Figs 1, 2). Care was taken to ensure electrode implantation into viable muscle and not into scarred tissue. The lead was capped and tunnelled to the left subclavicular area. All electrodes were implanted, and there were no direct lead-related complications. Lead performance was checked at the time of implant.

Ongoing lead performance was assessed by sensing and pacing threshold as well as by impedance. Data were collected by device interrogation after connection of a biventricular device. The last recorded data was at final follow-up in the outpatient clinic. Patients without LV lead data were excluded from the lead performance analyses.

The statistical analysis was performed using SPSS 21.0 software (SPSS Inc, Chicago, IL). Categoric data are expressed as percentages and continuous data as mean ± standard deviation or median with interquartile range. The χ^2 test was used for categoric variables and the independent samples t test for continuous variables. A two-sided p value of less than 0.05 was considered significant.

Results

Between June 2001 and December 2011, 4,844 consecutive patients underwent cardiac operations with a median sternotomy. Full results are provided in Table 1.

Clinical symptoms of heart failure were evident in 3,308 patients (68.3%) with NYHA class II, III, or IV symptoms. According to our criteria, 380 patients (7.8%), with a mean age of 66.5 ± 11.0 years, had impaired LV function, and 338 (88.9%) were in NYHA class II, III, or IV. There were statistically significant differences in most preoperative and operative patient characteristics between patients with or without impaired LV function (Table 1). In particular, the proportion of patients with arrhythmia (32.4% vs 16.8%, $p < 0.001$) and congestive heart failure (74.2% vs 31.3%, $p < 0.001$) was greater and NYHA status (2.95 ± 1.02 vs 2.23 ± 1.08, $p < 0.001$) was worse in patients with impaired LV function. There were also a smaller proportion of elective operations performed in patients with impaired LV function (41.6% vs 61.7%, $p < 0.001$).

Ninety-five patients (25%) with impaired LV function according to our criteria received a prophylactic LV lead compared with 47 patients (1.1%) in those without impaired LV function ($p < 0.0001$). There was a greater incidence of men (87.4% vs 77.9%, $p = 0.045$), congestive heart failure (89.5% vs 69.5% $p < 0.001$), coronary artery bypass grafting (92.6% vs 83.9%, $p = 0.033$), and elective operations (65.3% vs 33.7%, $p < 0.001$) in patients who received LV leads than in those who did not (Table 1). All other preoperative variables, including NYHA status ($p = 0.289$), were similar. More coronary artery bypass grafting patients received LV leads than patients with aortic valve replacement (92.6% vs 18.9%, $p < 0.001$). Cross-clamp time ($p < 0.001$) and bypass time ($p < 0.001$) were longer, and use of red blood cell units ($p = 0.042$) was more common, in patients who received LV leads. Reoperation for bleeding ($p = 0.734$), septicemia ($p = 0.556$), and 30-day mortality ($p = 0.617$) were not different (Table 3).

Twenty-nine patients (30.5%) with impaired LV function who received LV leads progressed to connection of a biventricular device compared with 3 patients (1.1%) with impaired LV function who did not receive an LV lead ($p < 0.001$). Only 9 patients (0.2%) without impaired LV function ultimately required biventricular pacing. The median interval from LV lead placement to biventricular