The Heart Surgery Forum #2006-1171
10 (2), 2007 [Epub February 2007]
doi: 10.1532/HSF98.20061171

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Long-term Results of Surgical Lead Implantation for Biventricular Pacemakers in Cardiomyopathy Patients

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ABSTRACT

Patients with congestive heart failure commonly display dysynchronous contraction patterns and weakened cardiac performance. Cardiac resynchronization therapy from biventricular pacing has been proven effective using coronary sinus cannulation or a less common surgical approach. In this study, the beneficial effects of implanting biventricular leads using the surgical approach for New York Heart Association functional class 3 or 4 patients (mean, 3.4 ± 0.5) were evaluated in 19 patients (17 male, 2 female). Pacing thresholds after 2 years were deemed favorable (left ventricle, 2.1 ± 0.8 V; right ventricle, 1.1 ± 0.4 V). Dobutamine therapy was no longer needed in 2 patients after they underwent biventricular pacing. No mortality or morbidity resulted from the procedure, and 2 patients were readmitted to the hospital, once each after the procedure over the 2-year follow-up period. The data show that the surgical approach for cardiac resynchronization therapy has durable long-term results.

INTRODUCTION

In an observational study we reported in October 2002, surgical lead implantation of a left ventricular (LV) epicardial lead had several advantages over the endovascular technique. There were no failures of implantation, no lead dislodgments or need for reimplantation, and no mortalities. There were no nonresponders. Surgically implanting the leads greatly decreased fluoroscopy times (less than 5 minutes), allowed for a 100% implantation rate, and caused no coronary sinus complications or cases of diaphragmatic pacing [Harostock 2002]. The endovascular method commonly has a fluoroscopy time of 26 to 28 minutes, an 8% to 30% failure rate, and a 25% necessary reimplantation rate [Cazeau 1996; Daubert 1998; Reuter 2002; Yu 2002]. Another nearly identical study with a larger sample size published in 2005 from the Cleveland Clinic showed comparable results. The authors of that article concluded that surgical LV lead implantation can be considered a primary option for resynchronization therapy [Navia 2005]. The aim of this study was to assess the long-term durability of the surgically implanted leads and to measure the long-term effect on cardiac performance.

Received October 17, 2006; received in revised form January 10, 2007; accepted January 19, 2007.

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METHODS

Patient Population

The study group included 19 patients, 17 men and 2 women, whose ages ranged from 41 to 83 years. All patients underwent biventricular pacemaker implantation using the minithoracotomy approach described above. The mean age was 68.7 ± 11.9. Drug therapy using a combination of angiotensin receptor blockers, beta blockers, diuretics, and ACE inhibitors had proven ineffective in sufficiently decreasing congestive heart failure symptoms. All patients had been receiving drug treatment prior to referral for 4.2 ± 2.2 years. Four patients were on outpatient dobutamine therapy. To be considered for inclusion in the study, patients must have displayed a QRS interval >130 ms and left ventricular ejection fraction (LVEF)<30%. The mean QRS interval was 162.2 ± 18.6 ms; the mean LVEF was 16.8 ± 4.4%. Patients who underwent the procedure commonly suffered from pulmonary edema (n = 3), tachycardia or bradycardia (n = 6), atrial fibrillation (n = 8), or mitral regurgitation (n = 8). Extended clinical patient data are displayed in Table 1.

Postoperatively, the study group was followed for 24 months. Electrocardiographic data, pacemaker data obtained by generator interrogation, instances of mortality, and implanted lead data were analyzed and compared to equivalent values incurred when the endovascular approach was used to determine the long-term efficacy of the surgical approach. Baseline, postoperative and 2-year clinical data of the study population are shown in Table 2.

Implantation Procedure

St. Jude Medical Integrity ADx-XL DDDR pacemakers (St. Paul, MN, USA), connected to biventricular adapters, were used in all patients. The patient was placed in the supine position with a roll placed under the left thorax and the left

Table 1. Clinical Characteristics of the Patient Population (N = 19)*

Age, *y*	68.7 ± 11.9
Sex	
Male	17 (89.5)
Female	2 (10.5)
New York Heart Association functional class	3.4 ± 0.5
Ejection fraction, %	16.8 ± 4.4
QRS duration, ms	162.2 ± 18.6
PR interval, ms	201.6 ± 29.3
Etiology of cardiomyopathy	
Ischemic	13 (68.4)
Nonischemic	6 (31.6)
Left bundle branch block	7 (36.8)
Atrial fibrillation	8 (42.1)
Mitral regurgitation	8 (42.1)
Cardiac arrhythmias	6 (31.6)
Baseline medications	
Outpatient dobutamine	4 (21.0)
Antiarrhythmic agents	7 (36.8)
Beta blockers	11 (57.9)
ACE inhibitors	13 (68.4)

*Data are presented as mean ± standard deviation or number (percentage) unless otherwise noted.

arm positioned at the side. A double lumen endotracheal tube and a pulmonary artery catheter were inserted. Fluoroscopy and a transesophageal echocardiography probe were positioned. The right atrial and right ventricular leads were positioned following the standard endovascular implantation technique and the leads' positions manipulated until thresholds were determined to be satisfactory. The LV leads were then implanted surgically. An 8- to 10-centimeter left lateral thoracotomy incision was fashioned, and the inframammary fold adhesions from prior surgeries were lysed. The phrenic nerve was identified, and the lateral and posterior left ventricular epicardial surfaces were exposed. An active fixating epicardial lead was then affixed to the posterolateral LV wall and its thresholds were measured. Areas identified for site interrogation were devoid of epicardial fat or significant cicatrix. In cases in which the post-lateral LV wall was covered with adipose tissue, superficial layers were removed to allow better access to the myocardium. The implantation sites were on the posterolateral LV wall. At least 3 sites were identified and the most favorable one chosen by measuring threshold data. After adequate thresholds were identified, the epicardial lead was affixed to the LV wall and a silk suture was used to secure the lead to the pericardium at its exit site. The leads were then tunneled to the generator, which, for most patients, was placed in the left infraclavicular fossa. In patients having left subclavian vein cannulation and in patients with prior left subclavian vein access issues, the lead was passed through the pericardium and thoracoscopically manipulated to the right infraclavicular fossa. A standard chest tube was placed and all incisions were closed with absorbable suture material. One patient had adhesions preventing pericardial passage of the LV lead; the lead was consequently passed by a subxyphoid route into the right hemithorax and into the right infraclavicular generator pocket. LV function was assessed by transesophageal echocardiography, and cardiac index was obtained using the pulmonary artery catheter.

Electrocardiography and Pacemaker Data

Patients were extubated within 2 hours of completion of the procedure and had a multigated angiogram scan performed within 1 week postoperatively. Ejection fraction was also assessed at 24 months by either echocardiograph or multigated angiogram. Each patient was seen by his or her cardiologist for a follow-up on approximately the seventh, fourteenth, and thirtieth days after surgery. Pacemaker thresholds were determined electronically by interrogating the generator approximately 1 week, 3 months, 6 months, 1 year, and 2 years after surgery.

Statistical Analysis

Wilcoxon signed rank tests were used to evaluate nonparametric data, and chi-square tests were used to evaluate dichotomous variables. All data are presented as mean ± standard deviation with corresponding percentages in parentheses. A *P* value of .05 or less was considered statistically significant. Statistical analysis was aided by XLSTAT v7.5.2 software (Addinsoft, New York, NY, USA).

RESULTS

No mortalities were observed postoperatively before the patients were discharged [Harostock 2002]. Two patients died before 2-year data could be recorded. There were no lead dislodgements in any patients who underwent surgical biventricular pacemaker implantation over the 24-month period.

Two patients (10.5%) were readmitted to the hospital 2 times for cardiac-related problems; 3 other patients (15.8%) were readmitted to the hospital one time, although the hospital readmissions were not related to congestive heart failure. The other 14 patients did not need to be readmitted at all within the 2-year study period. Of the 4 patients (21.1%) receiving dobutamine therapy preoperatively, one was stopped prior to discharge (5.3%) and 2 (10.5%) were still receiving the therapy at the 2-year follow-up mark. Extended clinical 2-year follow-up data are shown in Table 2.

24-Month Device Outcomes: Implanted Lead Durability and Pacemaker Function

Since no lead dislodgements resulted, postoperative follow-up pacemaker data for all 19 patients was collected. Two-year data for 17 patients were available. The mean right ventricle threshold immediately following the procedure was 0.46 ± 0.2 V with a pulse width of 0.7 ± 0.3 ms and impedance of 358.6 ± 156.5 Ω. Over 2 years, that mean increased to 1.1 ± 0.4 V with a pulse width of 0.6 ± 0.1 ms and impedance of 240.0 ± 59.4 Ω.

Table 2. Baseline, Postoperative, and 2-Year Data for Patients Who Underwent Biventricular Pacing*

	Baseline	Postoperative	2-Year
New York Heart Association functional class	3.4 ± 0.5	2.5 ± 0.6	2.2 ± 0.5†
Ejection fraction, %	16.8 ± 4.4	26.1 ± 5.8	37.1 ± 9.3‡
Left bundle branch block	7 (36.8)	6 (31.5)	5 (26.3)
Pacemaker thresholds, volts			
Right ventricular	—	0.5 ± 0.2	1.1 ± 0.4‡
Left ventricular	—	0.8 ± 0.1	0.7 ± 0.1†
Pulse width, ms			
Right ventricular	—	0.8 ± 0.3	0.6 ± 0.1†
Left ventricular	—	0.7 ± 0.3	0.6 ± 0.1†
Lead impedance, ohms			
Right ventricular	—	358.6 ± 156.5	240.0 ± 59.4§
Left ventricular	—	368.1 ± 153.0	236.0 ± 47.1‡
Estimated battery life, y	—	—	2.5 ± 0.9
Total hospital readmission	—	—	7
Morbidity			
Reimplantation	—	0	0
Infection	—	0	0
Bleeding/reoperation	—	0	0

*Data are presented as mean ± standard deviation or number (percentage) unless otherwise noted.
†$P < .0001$.
‡$P = .001$.
§$P = .002$.

The mean LV threshold was 0.8 ± 0.1 V with a pulse width of 0.6 ± 0.2 ms and impedance of 368.1 ± 153.0 Ω. Over 2 years, it increased to 2.1 ± 0.8 V with a pulse width of 0.6 ± 0.1 ms and impedance of 236.0 ± 47.0 Ω. The remaining battery longevity at the 2-year mark was measured to be 2.5 ± 0.9 years.

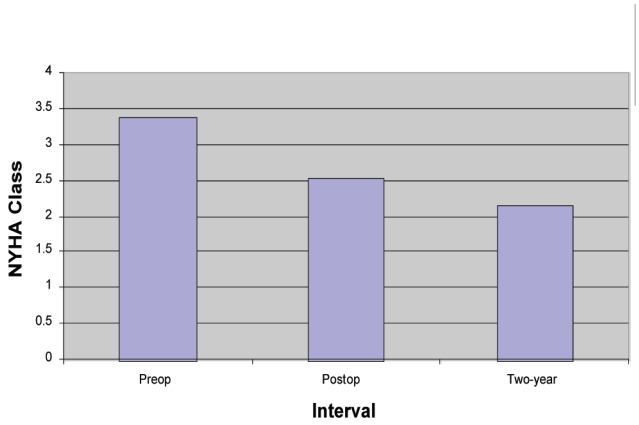
Cardiac performance improved in all 19 cases. The mean ejection fraction was 16.8% ± 4.4% before implantation, 26.1% ± 5.8% immediately after implantation, and 37.1% ± 9.3% at the 2-year mark. This indicates a 117.6% increase in ejection fraction after 2 years. The mean NYHA class decreased from 3.4 ± 0.5 prior to implantation to 2.5 ± 0.6 after implantation and 2.2 ± 0.5 after 2 years (Figure).

DISCUSSION

The benefits of biventricular pacing have been established [Walker 2000; Abraham 2002; Cazeau 2002; Yu 2002]. Ongoing studies have corroborated these benefits. We introduce data that represent a follow-up analysis from a previously presented patient cohort described in our study from 2002. Our current study represents an ongoing analysis of the surgical approach to biventricular pacemaker implantation.

Our data continue to demonstrate the benefits of biventricular pacing in general and the surgical approach in particular. There continues to be no failures of lead implantation, we have not yet had to reimplant a lead, and the current mortality rate is 0. No patients have yet been returned to the operating room for bleeding.

As presented in 2002, we have been able to establish adequate thresholds at the initial procedure. Our current data as presented confirm the maintenance of these thresholds over a 2-year period of follow-up. These lead thresholds are without drug-eluting tipped screw-in leads. Notably, the threshold data presented by Alonso et al using steroid-eluting



New York Heart Association (NYHA) class changes.

endovascularly placed leads showed comparable thresholds at 3 months and 24 months [Alonso 2001].

The surgical lead implantation thresholds later demonstrate the durability of our chosen technique. Its utility is certainly validated when the implantation techniques have been shown to be more successful than the endovascular approach and the results proven durable over a 2-year period.

As echocardiographically guided AV optimization was cumbersome and its value undemonstrated during the beginning of our gathering of the patient population in 2001, the AV delay on dual-chamber biventricular devices was set at 100 ms to prevent intrinsic AV conduction. There is little long-term ejection fraction data after CRT. The lack of any nonresponders in our study may be attributed to the accessibility of the LV anatomy surgically, whereas endovascular placement of the LV lead is limited to the course of the cardiac veins. The surgical approach to CRT will allow for a multiplicity of pacing sites to be evaluated. It has been shown to have durable results along with implantation advantages. We strongly consider surgical implantation as a primary technique for resynchronization therapy.

Study Limitations

Although this study reports the data we acquired 2 years postoperatively, we have no 2-year data from studies using the endovascular approach, making it difficult to provide direct, statistically sound comparisons of the 2 sets of results. Our institution does not have an electrophysiology lab from which we can guarantee comprehensive data; therefore, we must use data reported in the literature. The costs associated with pulmonary artery lines, thoracotomy techniques, and transesophageal echocardiography were unavailable to us. Our sample size was relatively small and contained a disproportionate number of men (89.5%).

Conclusion

Cardiac resynchronization therapy is a well-established treatment for a subset of patients with congestive heart failure. The surgical approach has received recognition in the literature for its safety and success. Our study indicates the results of surgical implantation are durable at 24 months.

ACKNOWLEDGMENT

A great debt of gratitude is owed to Thomas McGrath, a representative of St. Jude Medical, who has provided countless hours in retrieving data.

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