

Biventricular Pacing for Congestive Heart Failure: Early Experience in Surgical Epicardial versus Coronary Sinus Lead Placement

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ABSTRACT

Objective: Biventricular pacing (BVP) has recently been introduced for the treatment of refractory congestive heart failure. Coronary sinus lead placement for left ventricular pacing is technically difficult, has a risk of lead dislodgement, and has long procedure times. Surgical epicardial lead placement has the potential advantage of the visual selection of an optimal pacing site, does not need exposure to ionic radiation, and allows lead multiplicity, but it does require a thoracotomy and general anesthesia. We report our early experience of BVP with both modalities.

Methods: BVP was performed in 12 patients with New York Heart Association (NYHA) class IV congestive heart failure (10 men, 2 women). Mean patient age was 68.7 years (range, 41-83 years). Surgical epicardial leads were placed through a 2- to 3-inch incision via a left fourth or fifth intercostal thoracotomy in 4 patients with single lung ventilation under general anesthesia. The other 8 patients underwent transvenous coronary sinus lead placement under conscious sedation.

Results: Postoperative NYHA class status improved from class IV to class II in 8 patients and to class III in 3 patients. In 5 of the 8 patients who had undergone follow-up echocardiography with mitral regurgitation, the severity of the mitral regurgitation improved. The mean left ventricular ejection fractions before and after BVP were $18.3 \pm 8.3\%$ and $20.5 \pm 8.0\%$, respectively ($P = .16$). Mean fluoroscopy and total procedure times for transvenous lead placement were 77 ± 19 minutes and 266 ± 117 minutes, respectively. The mean surgery time for epicardial lead placement was

122 ± 13 minutes. There were no differences between the 2 methods in pacing threshold or in lead dislodgement. There were no complications related to the surgery or the laboratory procedure.

Conclusion: In patients with NYHA class IV congestive heart failure, epicardial lead placement through a minithoracotomy for BVP was performed safely with benefits equivalent to those of coronary sinus lead placement and with a shorter procedure time.

INTRODUCTION

Congestive heart failure (CHF) afflicts 2 to 4 million people in the United States. There are currently 400,000 to 700,000 new cases per year, and approximately 200,000 deaths are attributable to CHF [Dresing 2001, Cohen 2002]. Despite recent pharmacologic therapeutic advances, the overall long-term prognosis and quality of life are still limited in patients with severe CHF; therefore, device-based surgical therapies have been considered to improve the patient's hemodynamics, functional status, and survival probability. These strategies include cardiac pacing, implantation of left ventricular assist devices, partial left ventriculectomy, and cardiac transplantation. Cardiac pacing may be an inexpensive and less invasive alternative for certain CHF patients than those surgical approaches. Conventional dual-chamber (right atrial and right ventricular) pacing with a short atrioventricular delay was initially introduced as therapy for patients with advanced CHF to improve the patient's New York Heart Association (NYHA) class and left ventricular ejection fraction (LVEF) [Hochleitner 1990, Nishimura 1995]. The acute beneficial hemodynamic effects observed in early, uncontrolled studies were not confirmed in subsequent randomized, controlled studies with longer follow-up times. Recently, the importance of synchronized ventricular contraction has been recognized, and synchronization of the cardiac cycle through pacing has been hypothesized to improve both cardiac function and the symptoms of CHF. Cardiac resynchronization therapy by means of biventricular pacing (BVP) has been studied, and a number of large, multicenter double-blinded trials are ongoing [Abraham 2001, Cazeau 2001, Kuhlkamp 2002, Leclercq 2002]. These trials have consistently shown encouraging data. The present study reports our experience of BVP for patients with NYHA

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Table 1. Clinical Summary of the Patients*

Patient No.	Age, y	Sex	Diagnosis	ECG	Previous Procedures	LVEF, %, Pre-BVP	LVEF, %, Post-BVP	MR, Pre-BVP	MR, Post-BVP	NYHA Class, Post-BVP
Coronary Sinus Lead Placement										
1	72	F	ICM	Af bradycardia	CABG, PMI	30	30	Severe	Unchanged	II
2	64	M	ICM	SSS	CABG, PMI	30	NA	NA	NA	II
3	77	M	DCM	Af bradycardia	PMI	20	35	Moderate	Improved	II
4	60	M	DCM	SSS		10	10	Severe	Unchanged	IV
5	80	M	DCM	Sinus bradycardia, LBBB		25	25	None	None	II
6	73	M	ICM	SSS	CABG	20	20	Moderate	Unchanged	III
7	55	M	DCM	Af bradycardia	PMI	10	10	None	None	II
8	71	M	DCM	SSS, LBBB	MVR, PMI	20	20	Moderate	Improved	II
Epicardial Lead Placement										
9	80	M	DCM	Af bradycardia	PMI	5	20	Moderate	Improved	II
10	41	M	DCM	SSS	PMI	25	15	Severe	Improved	III
11	83	M	DCM	SSS	PMI	15	20	Moderate	Improved	II
12	71	F	DCM	LBBB	PMI	10	NA	Moderate	NA	III

*ECG indicates electrocardiogram; LVEF, left ventricular ejection fraction; BVP, biventricular pacing; MR, mitral regurgitation; NYHA, New York Heart Association; F, female; ICM, ischemic cardiomyopathy; Af, atrial fibrillation; CABG, coronary artery bypass graft; PMI, permanent pacemaker implantation; M, male; SSS, sick sinus syndrome; NA, not available; DCM, dilated cardiomyopathy; LBBB, left bundle branch block; MVR, mitral valve replacement.

class IV congestive heart failure and compares transvenous coronary sinus lead placement with surgical epicardial lead placement.

MATERIALS AND METHODS

Patient Population

Between June 2001 and February 2002, 12 patients with NYHA Class IV congestive heart failure (10 men, 2 women) underwent BVP treatment. The mean patient age was 68.7 ± 13 years (range, 41-83 years). Eight of the 12 patients underwent coronary sinus lead placement, and 4 underwent epicardial lead placement. The profiles of the patients prior to the procedures are summarized in Table 1. The patients were evaluated before and after BVP by NYHA functional class, 12-lead electrocardiogram, and transthoracic echocardiogram. QRS duration, LVEF, and the severity of mitral regurgitation were measured.

Coronary Sinus Lead Placement

Preprocedural assessment was performed by ultrasound or venogram to detect subclavian vein thrombosis. Coronary sinus lead placement was performed with the patient under conscious sedation in the catheterization laboratory. A transvenous left ventricular pacing lead was advanced via the subclavian vein into 1 of the coronary veins (anterior interventricular vein, left marginal vein, or left posterior vein) through the coronary sinus. The lead was positioned with fluoroscopy and coronary sinus venogram. The left ventricular lead was connected with a defibrillator-capable pacemaker generator. For BVP, a previously or a newly placed right ven-

tricular lead and a right atrial lead were used in synchrony with the left ventricular lead.

Epicardial Lead Placement

Epicardial lead placement for this study was performed only for patients who had a contraindication for coronary sinus lead placement. Two patients had left subclavian vein thrombosis. Two patients failed coronary sinus lead placement because of a small left subclavian vein, and in 1 patient the procedure was abandoned because of unstable hemodynamics.

A left fourth or fifth intercostal lateral thoracotomy is performed through a 5- to 7-cm skin incision with the patient under general anesthesia and with right-side single lung ventilation using a double-lumen endotracheal tube. The pericardium on the anterolateral left ventricular wall is opened, and the left atrial appendage is identified. Two epicardial pacing leads, either screw-in type (CapSure Epi #5071; Medtronic Inc, Minneapolis, MN, USA) or steroid-eluting (CapSure Epi #4965; Medtronic Inc) are placed on the lateral ventricular wall close to the base. The connecting ends of the leads are advanced in the left chest cavity to the pacemaker pocket, where 1 lead is connected to the previously implanted pacemaker generator. The other lead is left in the pocket and capped.

Statistical Analysis

Data are presented as the mean $\pm$ SD. The standard Student *t* test was used to compare preprocedural and postprocedural mean values of the same variable within the group and to compare mean values of the same variable between the 2 study groups. *P* values less than .05 were considered statistically significant.

RESULTS

Lead Threshold

The mean pacing lead threshold was 1.0 ± 0.84 V (range, 0.2-2.7 V) in the coronary sinus lead placement and 1.4 ± 0.86 V (range, 0.6-2.4 V) in the epicardial lead placement at the time of left ventricular lead placement. There was no difference in pacing thresholds in either procedure ($P = .4$). Three months after the procedure the mean pacing lead thresholds increased in the coronary sinus lead placement ($P = .08$) and in the epicardial lead placement ($P = .05$) to 2.1 V and 3.0 V, respectively ($P = .17$).

Procedure Time

The mean fluoroscopic time for coronary sinus lead placement was 77 ± 19 minutes. The mean total procedure time for coronary sinus lead placement and the mean surgery time for epicardial lead placement were 266 ± 117 minutes and 122 ± 13 minutes, respectively ($P = .004$). All patients who had had epicardial lead placement were extubated within 24 hours after surgery.

NYHA Class

BVP after coronary sinus lead placement improved NYHA class status from class IV to class II for 6 patients and to class III for 1 patient. One patient remained in status class IV after BVP. NYHA class status also improved after epicardial lead placement to class II for 2 patients and to class III for 2 patients (Table 1).

QRS Duration

BVP after coronary sinus lead placement significantly shortened QRS duration from 202 ± 41 milliseconds to 157 ± 21 milliseconds ($P = .01$). QRS duration also was shortened significantly from 172 ± 5.7 milliseconds to 142 ± 2.8 milliseconds after epicardial lead placement ($P = .02$) (Table 2).

Left Ventricular Ejection Fraction

The mean LVEF of BVP patients after coronary sinus lead placement improved from $20.6\% \pm 7.8\%$ to $21.4\% \pm 9.4\%$ ($P = .18$). The mean LVEF after epicardial lead placement improved from $13.8\% \pm 8.5\%$ to $18.3\% \pm 2.9\%$ ($P = .34$) (Table 2).

Mitral Regurgitation

Follow-up echocardiography of 5 patients with mitral regurgitation before BVP showed that for 2 of the 5 patients the severity of the mitral regurgitation improved from severe to moderate post-BVP after coronary sinus lead placement. The severity of the mitral regurgitation also improved from severe to moderate in 1 patient and from moderate to mild in 2 patients post-BVP after epicardial lead placement (Table 1).

Length of Hospital Stay

There were no complications related to either procedure. The mean time from procedure to discharge was 2.6 ± 1.4 days (range, 1-4 days) for coronary sinus lead placement and 8.3 ± 6.8 days (range, 3-18 days) for epicardial lead placement

($P = .001$). The mean length of hospital stay was 4.8 ± 2.8 days (range, 2-9 days) for coronary sinus lead placement and 32 ± 24 days (range, 11-67 days) for epicardial lead placement ($P < .001$). One patient had a tracheostomy for ventilator dependence prior to surgical epicardial lead placement and was weaned off the ventilator after BVP. Mean follow-up time was 9.1 ± 2.2 months (range, 5-11 months) in coronary sinus lead placement and 4.3 ± 2.8 months (range, 1-7 months) in epicardial lead placement. There was no mortality in either group.

DISCUSSION

BVP for CHF is a new procedure that has been approved by the US Food and Drug Administration. Studies have been published that suggest BVP improves patient quality of life, increases distance walked in 6 minutes, improves oxygen uptake, lowers NYHA class, decreases QRS duration, increases LVEF, and increases peak oxygen consumption [Abraham 2001, Cazeau 2001, Kuhlkamp 2002]. The mechanism by which BVP improves mechanical LV function and clinical status in patients with CHF is not well understood. BVP has been proposed to restore the homogeneity of LV contraction and the mechanical synchrony between LV and right ventricular (RV) systole. This restoration is associated with a short-term improvement in systolic myocardial function and a long-term improvement in clinical status in patients with severe CHF and left bundle branch block (LBBB) [Yu 2002].

Conduction abnormalities such as LBBB or intraventricular conduction delay are frequently seen in patients with severe CHF. These conduction abnormalities cause interventricular dyssynchrony and adversely affect left ventricular function [Grines 1989]. The 1986 animal study by Burkhoff and colleagues noted that left ventricular pressure decreased linearly as the QRS duration increased [Burkhoff 1986]. The hemodynamic effects of LBBB in CHF are the same as those of isolated LBBB, with a decrease in contraction performance. The magnitude of the interventricular asynchrony is proportional to the QRS duration [Kerwin 2000]. Patients with a very prolonged QRS duration, which implies a very dyssynchronous ventricular contraction, and patients with advanced CHF symptoms are most likely to benefit clinically from BVP [Auricchio 1999, Kass 1999]. Although BVP reduces the intraventricular dyssynchrony within the LV that is associated with LBBB, QRS duration narrowing with BVP does not predict a mechanical improvement of the left ventricle [Ellenbogen 1990, Leclercq 1998, Kass 1999]. In a current study, BVP after both coronary sinus lead placement and epicardial lead placement significantly shortened QRS duration, but the LVEF did not improve significantly. The severity of mitral regurgitation improved in 5 of 8 patients. The presence of intraventricular conduction delay in CHF is associated with a more severe mitral regurgitation and a worsened LV systolic and diastolic function and is an independent risk factor for an increased probability of mortality [Wong 2001]. BVP reduces the severity of mitral regurgitation in CHF and LBBB [Etienne 2001]. Although the mechanism is unclear, BVP may

decrease mitral regurgitation via the restoration of synchronous ventricular contraction [Oguz 2002].

Two routes are currently used to place the permanent LV pacing lead. In coronary sinus lead placement, the pacing lead is advanced through a guiding sheath for selective cannulation of the coronary sinus from the subclavian vein to a coronary vein. This route is used in most patients because of its less invasive nature, but it cannot be used for patients with poor venous access. In all 4 patients who had epicardial lead placement, coronary sinus lead placement was contraindicated because of deep vein thrombosis or occlusion detected by ultrasound or venogram in the preprocedural assessment. It is also technically difficult to place a ventricular pacing lead in the target vein of certain patients with anatomic problems or with severely dilated hearts [Daubert 1998]. Reportedly, pacing leads can be placed successfully by this approach in 80% of patients [Blanc 1998, Daubert 1998]. Another issue is the long procedure and fluoroscopy time. Gras and colleagues reported the results of the Medtronic Inc InSync study in which the procedure time exceeded 2 hours with more than 30 minutes of fluoroscopic exposure [Gras 1998]. In the current cases, the procedure time was 266 ± 117 minutes, and the fluoroscopy time was 77 ± 19 minutes. Early lead dislodgement requiring repositioning is reported to occur at an incidence of 5% [Daubert 1998]. However, early or late complications, such as pericardial effusion, evidence of coronary sinus occlusion, and lead fracture, are rarely observed.

Surgical epicardial lead placement allows easy access to the heart, has the potential advantage of the visual selection of the optimal pacing site, and allows for lead multiplicity. The procedure time is shorter and does not entail exposure to fluoroscopy or intravenous contrast medium. To allow access to the target epicardium, however, the procedure requires general anesthesia and a small thoracotomy with single lung ventilation and potentially has the complications associated with surgery, ie, infection, incision pain, lung atelectasis, and bleeding. The surgical risk increases according to the severity of CHF, the patient's age, and other medical conditions, but minimally invasive approaches such as a thoracoscopic or a robotically assisted endoscopic approach would further help the surgeon to reduce the trauma of surgery [Kleine 2002].

The limitations of our study are its retrospective design, a small sample size, and a short follow-up period. In the current study, epicardial lead placement was performed safely, but the indication for this approach was limited to patients who had contraindications for coronary sinus lead placement. A prospective randomized study is warranted for evaluation of the efficacy and safety of these 2 modalities.

CONCLUSION

BVP was performed in 12 patients with NYHA class IV congestive heart failure by means of transvenous coronary sinus or surgical epicardial lead placement. Epicardial lead placement through a minithoracotomy for BVP was performed safely in these patients with benefits that were equivalent to coronary sinus lead placement but with significantly decreased procedure time.

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REVIEW AND COMMENTARY

1. Editorial Board Member KT22 writes:

Biventricular pacing (BVP) as opposed to other alternatives for current treatment of chronic heart failure offers a less invasive approach than assist devices and cardiac transplantation, although its position in our daily therapeutic armamentarium is still to be defined by the ongoing research framework.

(a) The present paper adequately offers an insight into the 2 current approaches for BVP; however, the results presented may not be as informative as one would desire because of the small number of patients for that kind of study design. For instance, in comparing the preprocedural data one should employ at least a chi-square test to avoid implications of the study originating from a preprocedural cause of group selection rather than from the 2 respective procedures. In the present demographics, data are presented rather as cases.

(b) Second, are the data compatible with *t* test hypothesis testing? Moreover, the conclusions drawn from this study are based on predominantly nonsignificant differences. Higher numbers of enrolled patients would beneficially correct the observed deviation.

(c) Given that the epicardial lead placement may give rise to different responses to stimulation, what is the exact preferential site for epicardial lead placement and why?

(d) Considering indications and contraindications for/against epicardial versus transvenous lead placement, are there any data available on the potential deleterious effects of general anesthesia in maintaining hemodynamic stability in the targeted population?

Authors' Response by Hironori Izutani, MD:

(a) No preprocedural data were available to compare the 2 study groups by chi-square or Fisher exact test. In the present demographics, data are presented as cases because of small study numbers.

(b) The standard Student *t* test was used to compare preprocedural and postprocedural mean values of the same variable within the group and to compare mean values of the same variable between the 2 study groups. The Mann-Whitney

U test may be employed for this study instead of the *t* test because the study number is small, but this does not affect the statistical difference or the conclusion drawn from the results.

(c) The question of the exact preferential site for epicardial lead placement remains incompletely resolved, and the site is likely to vary somewhat from patient to patient. Butter et al reported in 2000 that short-term systolic response depended on the LV pacing site, with the mid part of the LV lateral wall generally providing the greatest improvement in the most patients. One potential explanation is that preexcitation of the lateral wall optimally offsets the region with the greatest basal delay in activation and may also help ameliorate mitral regurgitation by prestimulating the papillary muscle. Moreover, Pappone et al reported in 2000 that multiple LV sites might be even better than a single site.

(d) Preoperatively, surgical candidates were evaluated and cleared by the anesthesiologist for general anesthesia and thoracotomy with single lung ventilation.

2. Editorial Board Member DB515 writes:

This is an important paper because it demonstrates that surgeons still may have a role in pacing and maybe should focus more energy in this area. I came from an institution where pacers were still being done by surgeons but were gradually being taken over by cardiologists. The surgeons will, in my opinion, be able to stay in pacing only if they start to focus on the technology and the transvenous, as well as the surgical, approaches to lead placements.

The article also shows us how important management of CHF through a multimodality approach has become. In this article, it seems as if surgery was only a bailout modality for a failed catheter placement.

(a) In these reported cases, the other endocardial leads could obviously be placed by the venous approach, so it may be just a question of technique and technology before either all or none of the leads may be placed transvenously. How should that situation be handled, or what if the patient needs heart surgery (such as a Dor procedure or a mitral valve replacement) for heart failure?

(b) Should an LV lead be placed at that time, prophylactically?

(c) Certainly, I think the article shows that BVP can be accomplished through a surgical approach when the transvenous method cannot be successfully used. With some revisions, it should be accepted. I do not think that this approach will be or should be tested by randomized studies, and this suggestion should be removed.

(d) Were all procedures done by surgeons, or were they "bailouts" from cardiologists?

Authors' Response by Hironori Izutani, MD:

(a) The patients selected in this study were indicated for sole biventricular pacing. Epicardial lead placement under full sternotomy can be combined if needed in other procedures.

(b) In a patient who needs open heart surgery and has an indication for biventricular pacing, epicardial lead placement should be done during surgery, and the lead should be capped.

(c) If we consider the disadvantages of sinus lead placement, randomized studies are worth being done.

(d) All surgical procedures were done by a surgeon, but the management of the pacing leads, such as threshold measurement, device handling, and setting, were done with the cardiologist during surgery.

3. Editorial Board Member TY12 writes:

(a) All of the patients in the surgical group had RA and RV leads placed under fluoroscopy, yet their fluoroscopy times are not mentioned in the paper. Was the RA and RV lead placement performed during the same hospital stay? How did it influence the total length of the procedure (if you add both procedures)? How did it influence the length of stay?

(b) None of the surgical group patients had a previous cardiac operation, whereas 4 of 8 (50%) of the nonsurgical group had previous surgery. Do the authors think a redo procedure is not feasible? Do they think there are contraindications to the procedure?

Authors' Response by Hironori Izutani, MD:

(a) All the patients in the surgical group had RA and RV lead placements during previous hospital stays; however, coronary sinus lead placement and surgical epicardial lead placement were performed during the same hospital stay. Five of 8 patients who underwent coronary sinus lead placement also had previous right-side pacemaker implantation.

(b) Fortunately, none of our surgical group patients were redo patients, but a redo procedure is feasible.

4. Editorial Board Member AX44 writes:

Technique drawings, ie, port placement and pericardial incision and exact LV implant sites would add to the paper.

Authors' Response by Hironori Izutani, MD:

The pericardium was opened to identify the anatomy for lead placement. The leads were placed on the lateral ventricular wall close to the base, although the optimal pacing site is not well understood and may vary in each case.

5. Editorial Board Member LO23 writes:

This was not a randomized study, and there were many fewer patients in the "surgical group." Unfortunately, the comparison of "total procedure time" for the "surgical group" appears to have not taken into account the time

required to insert the pacemaker—presumably transvenously before the thoracotomy.

It would appear that the thoracotomy was used only for placement of the LV electrode, and the RA and RV electrodes were previously placed. Is this correct? If not, the methodology should be rewritten.

Authors' Response by Hironori Izutani, MD:

All the patients in the surgical group had RA and RV lead placements during previous hospital stays; therefore, "total procedure time" for the surgical group was only for the procedure of thoracotomy and LV lead placement.

6. Editorial Board Member SG14 writes:

(a) The study is underpowered. I wonder if a statistical analysis is possible by that low number.

(b) Two hours to pass 2 needles through the epicardium—it is much too long, and you definitely do not need single lung ventilation for that. This gives no right to the authors to report about a decrease of procedure time.

(c) A hospitalization of 8 days for a procedure that normally is performed ambulatory is much too long.

(d) The authors mentioned an increase of LVEF from 20.6% to 21.40%. Is this correct?

Authors' Response by Hironori Izutani, MD:

(a) The purpose of this study is to assess the feasibility and safety of the surgical approach to biventricular pacing. As mentioned in the discussion, the numbers are small and not enough to give a significant statistical difference.

(b) Surgery time includes lead threshold measurement, handling, and reimplantation of the pacemaker generator. Single lung ventilation may not be needed for this procedure, but it helps the surgeon to perform the surgery safely and quickly, especially in these patients with very dilated and irritable hearts.

(c) All patients who underwent epicardial lead placement were congestive heart failure and NYHA class IV patients in the hospital for a number of days before biventricular pacing. The length of hospital stay is reasonable for this group of patients. No surgeon performs these procedures as an ambulatory procedure.

(d) The increase of LVEF from 20.6% to 21.40% is not significant ($P = .18$).