Development of a Technique for Left Ventricular Endocardial Pacing via Puncture of the Interventricular Septum

Tim R. Betts, MD, FRCP; James H.P. Gamble, BMBCh, MRCP; Raj Khiani, MBBS, MRCP; Yaver Bashir, DM, FRCP; Kim Rajappan, MD, MRCP

Background—Left ventricular (LV) pacing through the coronary sinus is the standard approach for cardiac resynchronization therapy. When this route is unavailable, the alternatives have major limitations. LV endocardial pacing through the interventricular septum may offer a simpler solution. We describe an initial case series to demonstrate technical feasibility and to describe our refinement of the puncture technique.

Methods and Results—Ten patients with previous failed coronary sinus lead implant or with nonresponse to cardiac resynchronization therapy and a suboptimal LV lead position were selected. All patients were anticoagulated. Left ventriculography and coronary angiography were performed to identify LV borders and septal vessels. Subclavian vein access was used for a superior approach ventricular transseptal puncture under fluoroscopic guidance, using a steerable sheath and a standard transseptal needle, radiofrequency needle, or radiofrequency energy delivered through a guidewire. An active-fixation pacing lead was successfully delivered to the endocardial wall of the lateral LV in all patients (9 men; age, 62±10 years). LV lead implant procedure time shortened with experience. The use of radiofrequency energy delivered through a guidewire was the most effective technique. Mean threshold and R wave at implant were 0.8±0.3 V and 10.8±3.9 mV. At follow-up (mean, 8.7 months; minimum, 0; and maximum 19), thresholds were stable, and there were no thromboembolic events. Of 9 patients, 8 were classed as clinical responders (1 had inadequate follow-up to assess response).

Conclusions—LV endocardial pacing through a ventricular septal puncture is a feasible approach for cardiac resynchronization therapy. (Circ Arrhythm Electrophysiol. 2014;7:17-22.)

Key Words: cardiac resynchronization therapy • endocardium • heart ventricles • septal

Clinical Perspective on p 22

When the standard epicardial route via the CS is unavailable, surgical epicardial implantation is an alternative; however, this approach has associated morbidity, and an effective pacing site is not guaranteed.8 Several variations of a percutaneous atrial transseptal route for LV endocardial pacing have also been described, but all are complex, expose a significant length of the lead to the systemic circulation, and may potentially interfere with mitral valve function.9–13

Access to the LV endocardium through the interventricular septum may offer a simpler and more direct route for CRT. We have previously described LV endocardial pacing via the transinterventricular septal route in 1 patient.14 This report includes 9 additional patients, reports procedural feasibility, and details our refinement of the ventricular septal puncture technique.

Methods

Patients with indications for CRT, no contraindications to oral anticoagulation, and previous failed attempts at LV lead implantation or re-implantation via the CS, or with nonresponse to CRT and a poor lead position, were offered the procedure as an alternative to surgical lead placement. All patients gave written informed consent to undertake an investigatory procedure. The implant procedure was initially offered on compassionate grounds after institutional multidisciplinary team assessment and was subsequently approved by the Local Ethics Committee. The procedure was performed on therapeutic anticoagulation with warfarin at an international normalized ratio of 2 to 3. Transthoracic echocardiography was undertaken before the procedure to exclude the presence of LV thrombus.

The operations were performed under general anesthesia or conscious sedation. A 6F sheath was placed in the femoral artery for continuous arterial pressure monitoring and angiography. An incision was made over the existing generator. An extrathoracic subclavian...
vein puncture was used to gain venous access, or where indicated, extraction of an existing transvenous lead was performed to gain venous access and remove redundant leads. A 91-cm deflectable 8.5F inner lumen catheter sheath with a tapered dilator (Agilis; St Jude Medical Inc, St Paul, MN) was passed over a guidewire into the right ventricle. Left ventriculography was performed in a right anterior oblique view to identify the LV borders. The sheath and dilator were deflected and rotated in a counterclockwise direction to position the tip of the dilator as close to the midseptum as possible, with reference to the ventriculogram. An angiogram of the left coronary arteries was undertaken to ensure the puncture site was not adjacent to a major septal perforator vessel. The ventricular septum was then punctured using one of the following techniques.

1. Brockenbrough needle (case 1): a 98-cm Brockenbrough needle (St Jude Medical Inc) was inserted via the steerable sheath and dilator with a pressure line attached to the proximal end. An additional curve was added by manually bending the needle. Firm pressure was applied to advance the needle through the interventricular septum while alternating between left anterior oblique and right anterior oblique fluoroscopic views (Figure 1). Once a LV pressure trace was seen, a hand injection of contrast media was used to confirm that the needle was in the LV cavity. The dilator and sheath were then advanced 10 to 20 mm into the chamber over the needle. The needle was withdrawn and a 0.032-inch stiff 260-cm J guidewire was advanced through the sheath and dilator and curled in the LV cavity. The sheath and dilator were then advanced through the septum until the sheath tip was 1 to 2 cm inside the LV. The sheath and dilator were withdrawn and exchanged over the stiff guidewire for a slit-able, deflectable lead delivery catheter and dilator (Medtronic Attain or Select Secure; Medtronic, Minneapolis, MN).

2. Radiofrequency needle (cases 2 and 3): the procedure was performed using a stiff 98-cm radiofrequency transseptal needle (NRG; Bayliss Medical, Montreal, Canada). When opposed against the septum the needle was advanced while delivering power at 10 W for 1-s duration repeated bursts until the LV cavity was entered. The needle position was checked using pressure monitoring and contrast injections before advancing the deflectable sheath and dilator and then exchanging over the guidewire for the deflectable lead delivery catheter.

3. Guidewire and diathermy pen radiofrequency energy (cases 4, 6–10): the stiff, straight proximal end of a 0.032 guidewire was passed through the sheath and dilator to rest against the septum. If required for a basal puncture site, the dilator was withdrawn until the tip was proximal to the distal curve, allowing a more acute angle. A diathermy pen was used to deliver 30 W of energy in 1-s intervals to the proximal end of the wire, while gently probing through the septum. When the wire was felt to give and moved freely into the LV cavity, the dilator and sheath were advanced forward by 1.5 to 2 cm. The guidewire was withdrawn to assess flow through the septum. The wire was advanced through the sheath and dilator into the LV cavity. The sheath was then fully advanced across the septum into the LV and exchanged for the deflectable lead delivery catheter (Movie I in the Data Supplement).

4. Radiofrequency wire (case 5): a soft-tipped radiofrequency wire (Nykanen; Bayliss Medical) was advanced through the dilator and sheath into the LV cavity using 10 W power for 1-s duration intervals. When the wire was felt to give and moved freely into the LV cavity, the procedure was continued as described above.

The deflectable lead delivery sheath was steered toward the lateral LV wall. A 58-, 65-, or 69-cm active fixation bipolar pacing lead was delivered through the sheath and secured to the endocardial surface.

Figure 1. ECG leads showing biventricular pacing before (left) and after (right) procedure for a patient with a poorly positioned left ventricular lead.

Lead parameters were assessed, and high output pacing was performed to assess for phrenic nerve stimulation. The delivery catheter was slitted and withdrawn before the lead was secured and attached to the generator.

Patients underwent lead sensing and threshold checks and chest radiography the following day. At follow-up, transthoracic echocardiography was performed to assess LV dimensions and systolic function and to assess for evidence of flow across the septal puncture site.

### Results

The characteristics of the 10 patients who underwent the procedure between 2011 and 2013 are summarized in the Table. In 6 of the patients, previous attempts to implant or reimplant a LV lead had failed. In the other 4, a LV lead had been

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result (N=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>62±10 y</td>
</tr>
<tr>
<td>Male sex</td>
<td>9 (90%)</td>
</tr>
<tr>
<td>Ischemic cause</td>
<td>7 (70%)</td>
</tr>
<tr>
<td>QRS duration</td>
<td>160±29 ms</td>
</tr>
<tr>
<td>NYHA class</td>
<td>3.2±0.4</td>
</tr>
<tr>
<td>LVEF</td>
<td>27±9%</td>
</tr>
<tr>
<td>LVEDV</td>
<td>237±87 mL</td>
</tr>
</tbody>
</table>

Continuous variables expressed as mean±SD, others as number of patients (%). LVEDV indicates left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; and NYHA, New York Heart Association.

The deflectable lead delivery sheath was steered toward the lateral LV wall. A 58-, 65-, or 69-cm active fixation bipolar pacing lead was delivered through the sheath and secured to the endocardial surface.
implanted in a nonoptimal position because of anatomic limitations of the CS, and the patient had not responded to CRT. In 2 patients, a transatrial septal approach had been attempted but had failed. All patients underwent an acutely successful implant of a LV endocardial lead through a ventricular septal puncture. The median time taken to implant the LV lead was 62 minutes, minimum 20, maximum 82, with a trend of shortening times with experience. Eight procedures were undertaken using general anesthesia.

A consistent finding from the first 3 cases was that the use of a standard Brockenbrough or radiofrequency needle straightened out the curve of the deflectable sheath and dilator, advancing the puncture site apically. In the first 2 patients, contrast injections after the initial puncture showed subendocardial staining of the lateral apical LW wall, and it was not possible to advance the guidewire. In both cases, a second puncture attempt was required to allow easy passage of the wire and then sheath and dilator into the LV cavity. The use of a radiofrequency wire or guidewire allowed for a greater degree of sheath and dilator flexion to get to a more midbasal puncture site because passage of the wire to the dilator tip did not alter the shape and position. Withdrawing the dilator to a position proximal to the curve in the sheath allowed an even more acute angle and basal puncture site. The use of the guidewire and diathermy pen radiofrequency energy technique resulted in the quickest positioning, puncture, and advancement of the sheath and dilator assembly.

In 1 patient, the use of radiofrequency energy resulted in the induction of sustained monomorphic ventricular tachycardia that was treated with a 200J synchronized external shock. In another patient, prolonged failure to achieve a septal puncture was caused by a guidewire microfracture.

Mean threshold and R wave at implant were 0.8±0.3 V at 0.4 to 0.5 s pulse width and 10.8±3.9 mV. No sites examined had scar properties (small R wave or high threshold) that prohibited lead fixation. At follow-up (mean, 8.7 months; minimum, 3 weeks; and maximum, 19 months) mean threshold was 1.0±0.3 V.

Eight of 9 patients were classed as functional responders with improvement of ≥1 New York Heart Association class. One patient did not have adequate follow-up to assess response fully. Five patients had full echocardiographic data to assess response. End-systolic volume decreased by 21±28% and EF increased by 14±8%. Four of these had >5% increase in EF and 2 had a >15% decrease in end-systolic volume in the follow-up time included. No increase was seen in mitral regurgitation or flow across the septal puncture site. Figure 2 shows the typical appearance of ECG leads from 1 of the patients.

No thromboembolic or bleeding complications were observed during follow-up. One LV lead ceased to capture at high output 3 months after implant. Chest radiography was unchanged, suggesting microdisplacement or lead tip exit block. One patient continued to have frequent ventricular tachycardia storms, despite asymptomatic improvement to New York Heart Association class II although without an echocardiographic response. After unsuccessful attempts at catheter ablation, he underwent emergency cardiac transplantation. One patient died from severe sepsis arising from septic arthritis in his knee, 3 weeks after the implant procedure. No evidence of endocarditis or lead infection was seen on acute echocardiography. A post mortem examination was not performed.

Figure 2. Images of procedure. From top left, all in right anterior oblique (RAO) view: left ventriculogram; flexible sheath opposed to the interventricular septum, same view; wire is moved forward onto septum; middle left in RAO view: wire is pushed across the septum into the left ventricular (LV); wire curved in LV; sheath passed into LV, contrast injection shows LV endocardium. Bottom left, final lead position, RAO view; final lead position, anteroposterior view.
Discussion

Adverse CS and LV venous anatomy is a common obstacle to successful or optimal epicardial LV lead delivery. In 4% to 8% of patients, the LV lead cannot be implanted because of anatomic challenges, including obstructing valves, tortuositves in the venous branches, CS dissection, phrenic nerve stimulation, and areas of LV scar. Even if a lead is left in an LV vein, it may be in a suboptimal anatomic position because of difficulties at the ideal site; this may contribute to nonresponse, present in 20% to 40% of CRT recipients. As the population of patients with CRT devices continues to expand and survival increases there will be a greater need for LV lead replacement; however, this is not feasible in 20% to 50% of cases.

When a lead cannot be successfully delivered through the CS, there are alternative routes. Surgical placement of an epicardial lead can be performed but involves a longer recovery period and has a higher early morbidity and mortality. There are some concerns about the long-term durability of epicardial leads. The atrial transseptal approach to LV endocardial pacing was initially described by Jaïs et al. Modifications of the technique have been developed for the past decade, but it remains complex, with a combined inferior and superior approach used to puncture the atrial septum and deliver a lead from the subclavian vein. Balloon dilatation of the septum and the use of snares to feed guidewires or pacing leads across into the left atrium is a common feature. In the present study, all patients had a successful procedure using only the upper chest venous access site, reducing complexity. Although femoral arterial access was used for left ventriculography and coronary angiography, this could potentially be performed through radial arterial access, or avoided completely as experience grows, or other imaging techniques such as intracardiac or transesophageal echocardiography are used.

Direct puncture of the interventricular septum avoids the need for additional lead manipulation across the mitral valve and directs the lead immediately toward the lateral LV wall. The LV is a much larger cavity than the left atrium and has thicker muscle walls, potentially reducing the chance of inadvertent perforation and pericardial effusion. The structure of the septal muscle seems to facilitate rapid tissue contraction around a defect, and other groups have shown closure of largeiatrogenic defects. The ventricular septal approach avoids lead interaction with the mitral valve, potentially preventing worsening of mitral regurgitation and reducing the risk of mitral valve endocarditis.

Providing oral anticoagulation is continued lifelong, there seems to be a relatively low risk of systemic thromboembolism with LV endocardial pacing. Embolic events in atrial transseptal lead patients have been ascribed to subtherapeutic anticoagulation. The lack of residual flow across the ventricular septum, combined with the absence of lead in the low-pressure left atrial chamber, where lead thrombi are more likely to form, may make lead thrombosis or paradoxical emboli less likely than with the atrial transseptal route. Despite this all LV endocardial pacing is limited by the presence of a lead in the systemic circulation and the resultant need for lifelong anticoagulation, unless new technologies can safely eliminate the risk of thrombus formation. The risk–benefit ratio of anticoagulation in patients with heart failure is finely balanced and may make this approach inappropriate in some patients.

LV endocardial pacing may be superior to epicardial pacing at improving hemodynamic response to CRT. In part, this could result from better targeting of lead position because an endocardial approach is not constrained by venous anatomy or phrenic nerve stimulation. The lead tip can be steered to the site of latest electric or mechanical activation or site of maximum acute hemodynamic improvement, provided there is no endocardial scarring. Endocardial pacing has also been shown to result in more rapid ventricular depolarization, shorter global LV activation times, more synchronous LV activation and better acute hemodynamic parameters than epicardial pacing, and may be less arrhythmogenic. Consistent with the above observations, response to CRT with endocardial pacing in patients who had not responded to epicardial CRT has been reported, and response rates in previous reports of LV endocardial pacing have been high at >90%.

During the development of the ventricular transseptal puncture technique, it was found that use of a guidewire combined with radiofrequency energy facilitated a quicker procedure with a more basal or midseptal puncture site. The use of diathermy energy from an electrocautery pen delivered through a Brockenbrough needle has previously been described to facilitate atrial transseptal puncture. This is the first series of patients in whom radiofrequency energy has been used to puncture the interventricular septum and has demonstrated feasibility, and albeit in small numbers, safety. Another group have recently described ventricular septal puncture using a Brockenbarg needle and a Mullins transseptal sheath, to access the LV for endocardial ablation.

It is not known how challenging it would be to extract a chronic ventricular transseptal lead if required, or whether this could be done percutaneously or necessitate surgical intervention. There may be concerns over whether patients with an endocardial LV lead could safely be treated with a LV assist device.

Study Limitations

We describe a novel technique in a small number of patients only, with relatively limited follow-up. This article is primarily intended to describe the evolution of a technique that is now being assessed in a more formal manner as part of a trial (Clinicaltrials.gov NCT01818765; http://clinicaltrials.gov/ct2/show/NCT01818765).

Conclusions

LV endocardial pacing through a ventricular septal puncture is a feasible and safe approach for CRT in patients with previously failed implants. Radiofrequency energy delivered through a guidewire is the preferred technique.

Sources of Funding

Part of this work was supported by a grant from the United Kingdom National Institute for Health Research Oxford Biomedical Research Centre Program.
Disclosures

None.

References

Clinical Perspective

Cardiac resynchronisation therapy is an effective treatment, but it is not possible to place a left ventricular lead via the coronary sinus in ≈4% of cases. In this situation, the current alternatives are open surgery, which has significant risks, or endocardial left ventricular lead placement via puncture of the interatrial septum. The latter procedure is technically challenging because it leaves the lead in the left atrium and across the mitral valve. Despite these difficulties, preclinical and clinical data suggest that endocardial left ventricular pacing may have physiological benefits over pacing epicardially via the coronary venous system. We report the development of a technique for an alternative route to the left ventricular endocardium across the interventricular septum. The procedure was successful in all 10 patients reported with refinement of the puncture procedure during the study period. We report clinical follow-up to a mean of 9 months after procedure in these patients, who had expected response rates and no thromboembolic complications. We think that this procedure is an advance in the treatment of this challenging patient group because it achieves left ventricular pacing without many of the disadvantages of the alternatives. This procedure may be useful in those in whom a lead cannot be placed or replaced in the coronary venous system or in those in whom only a nonoptimal lead position is achievable.
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_Circ Arrhythm Electrophysiol_. 2014;7:17-22; originally published online January 14, 2014; doi: 10.1161/CIRCEP.113.001110

_Circulation: Arrhythmia and Electrophysiology_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-3149. Online ISSN: 1941-3084

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SUPPLEMENTAL MATERIAL

**Video 1**: Radiographic recordings and video to demonstrate the procedural technique in a patient with an existing CRT pacemaker device. A chronic RV and coronary sinus LV lead are seen, as well as a temporary RV pacing wire.

RAO right anterior oblique, LAO left anterior oblique, AP antero-posterior, PA postero-anterior, RF radio-frequency.