Targeted left ventricular endocardial pacing using a steerable introducing guide catheter and active fixation pacing lead

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Aims
Cardiac resynchronization therapy via the coronary sinus (CS) is not always possible. Left ventricular (LV) endocardial lead placement is a potential alternative. The purpose of this study was to assess the feasibility of endocardial LV pacing using a steerable lead introducer and active fixation polyurethane lead.

Methods and results
Endocardial LV lead placement was attempted in nine patients (seven males, age 48–77 years) in whom transvenous CS lead placement had failed. Trans-septal puncture and septal dilatation were performed via the femoral route. A steerable introducer catheter was advanced across the septal puncture site from the right or left subclavian vein into the LV. An active fixation polyurethane lead was then implanted into the high postero-lateral aspect of the LV endocardial wall. All patients were anticoagulated following implant. Successful LV lead placement was achieved in eight patients. There were no acute complications and no embolic events during follow-up (1–32 months). All implanted patients responded well with either improvement in New York Heart Association class or maintenance of symptomatic improvement that had previously been conferred by LV epicardial pacing.

Conclusion
Targeted LV endocardial pacing is a potential alternative to CS pacing and warrants a trial to characterize long-term benefits and risks.

Keywords
Left ventricular endocardial pacing • Cardiac resynchronization • Heart failure

Introduction

Left ventricular (LV) pacing [in the context of biventricular pacing for the purpose of cardiac resynchronization therapy (CRT)] is a well-established treatment for patients with heart failure.1 The conventional approach to LV pacing is to use tributaries of the coronary venous sinus for access to the LV epicardial surface or to place an epicardial pacing lead using a direct surgical approach.2,3 We report an experience of LV endocardial pacing using a steerable guide catheter for directional lead placement with an active fixation lead placed on the LV endocardial surface, at a location expected to achieve effective ventricular resynchronization.

Patients and methods

Seven males and two females aged 48–77 years underwent attempted LV endocardial pacing. Patients were currently, or had recently been, in New York Heart Association (NYHA) functional classes III–IV and all had failed conventional transvenous pacing approaches (Table 1). Surgical epicardial LV lead placement had been unsuccessful and abandoned due to infection in two patients, failed in one, and in the remainder surgery was not considered because of unacceptably high operative risk. All patients were deteriorating with respect to clinical status and were submitted to this procedure on the basis of previous reports in the literature of the efficacy of this approach and not as part of a controlled study.

Implant procedure

All patients were prepared in the standard manner for CRT pacemaker or CRT defibrillator implantation in either a left or right-sided (two patients) pre-pectoral or sub-pectoral device pocket. Venous access was gained using the Seldinger technique to either the left or right subclavian vein. Thereafter, right atrial and right ventricular pacing and/or defibrillation leads were implanted in a conventional manner (leads already in place in four patients and in these the existing device was...
Trans-septal puncture

During the same procedure, to gain access to the left heart, a trans-septal puncture was performed from a right femoral venous approach having gained access to the right femoral vein using the Seldinger technique. A radiofrequency needle (Baylis Medical, Montreal, Canada) was used to traverse the inter-atrial septum. Thereafter using an exchange technique, a 9 Fr Channel sheath (Bard Inc., Tewkesbury, MA, USA) was used to enlarge the trans-septal puncture hole. This was performed by an operator working from the right groin independently of the device/lead implanter to avoid infection contamination from the groin at the device implant site. Following trans-septal puncture, patients were anticoagulated with an intravenous heparin infusion maintaining an activated clotting time >300 s. In three patients, transoesophageal echocardiography was used to aid accurate trans-septal puncture.

Left ventricular pacing lead placement

All patients received an LV pacing lead (Select Secure, 3830–69 cm, Medtronic, Minneapolis, MN, USA) delivered via a steerable introducing catheter, which allowed precise and directed LV pacing site choice. The implanter manoeuvred the steerable introducer catheter sheath (Select Site C304–69 cm, Medtronic, Minneapolis, MN, USA) to inter-atrial septum. Under fluoroscopic control, the steerable introducer catheter was used to negotiate the trans-septal puncture site using a 0.035” angiographic guide wire as a vehicle for catheter support and passage of the steerable introducing catheter into the left atrium from this superior approach. Having gained access to the left atrium in this manner, the steerable introducer was advanced from left atrium and across mitral valve orifice into LV. The steerable introducer was orientated towards a pacing location on the postero mediastinal area at a high lateral aspect of the LV endocardial wall in all cases (see Figure 1 for illustrative radiograph). When the steerable introducing catheter was appropriately orientated, the pacing lead was introduced to the left ventricle via the steerable introducer. Fixation of the pacing lead was achieved by rotation of the lead body according to the manufacturer’s instructions. When deployed, the sensing and pacing characteristics of the lead were determined and a clinical assessment of their acceptability taken. When an acceptable pacing site/lead position (according to clinical judgement) was achieved, the active implanted device (CRT pacemaker of CRT defibrillator) was connected to the implanted leads and the implant site closed in the conventional manner. The different steps in the implant procedure are demonstrated in Figure 2.

After successful system implantation, all patients were anticoagulated using warfarin with a target international normalized ratio (INR) of 2–3. Heparin was continued until a therapeutic INR was achieved. All patients underwent routine clinical follow-up at 3 monthly intervals. Transesophageal echocardiography was performed routinely at 3–6 months, and at 1–2 months in patients with a short follow-up.

Results

Successful LV lead placement was achieved in eight of nine patients. In one, it was not possible to achieve access of the steerable introducer catheter into left atrium, despite a successful trans-septal puncture from the inferior approach and the procedure was abandoned. Subsequently, a technique was evolved using the Channel sheath (Bard Inc.) to stabilize the inter-atrial septum which facilitated access to left atrium by the steerable introducer catheter. In the three patients who underwent transoesophageal echocardiography, advantage was taken of this technique to assess the acute effect of the pacing lead on mitral valve function, and in these there was no discernible change in valve competency.

Procedure times, fluoroscopy times, and the implant electrical parameters for sensing and pacing at the LV endocardial site are summarized in Table 2.

Follow-up data are summarized in Table 3. There were no acute procedural complications and no patients have experienced embolic events during 1–32 months follow-up. All patients have responded well to the therapy with improvement in NYHA class in those patients receiving CRT for the first time, and with maintenance of previous clinical response in two patients converted from surgically placed LV epicardial to LV endocardial pacing because of infection. None report any serious adverse events. All are on optimized medical therapy. All have been maintained
Discussion

Cardiac resynchronization therapy is well established as a treatment for heart failure in patients with severely impaired LV systolic function and evidence of ventricular dyssynchrony. Guidelines have been developed for its optimal application in specific patient groups. The conventional access route for LV pacing has been via the coronary venous system, through tributaries of which it is possible to achieve LV endocardial pacing. This approach is limited by technical considerations (phrenic nerve stimulation and poor pacing characteristics) and the anatomy of the coronary venous system. These factors do not pertain to LV endocardial pacing.

Even when conventional implantation is successful, it is recognized that improvement in ventricular function and exercise capacity occurs in only a proportion of cases, with a significant number of non-responders. In some cases, this may be related to an inability to target pacing at a site optimal for resynchronization; however, additional theories have also been advanced. These

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**Figure 1** Chest X-ray (postero-anterior and lateral) demonstrating the final position of the left ventricular endocardial lead in a patient with a cardiac resynchronization therapy-defibrillator device.

**Figure 2** Fluoroscopic images (postero-anterior) demonstrating the different steps in the implant procedure. The image on the left demonstrates the Channel sheath in the right atrium via the femoral vein, and a guidewire exiting the sheath and traversing the inter-atrial septum into the left atrium (white arrows). The Channel sheath has been used to enlarge the trans-septal puncture hole and following this has been withdrawn back into the right atrium to allow access of the steerable introducing catheter into the left atrium. The steerable introducing catheter (black arrows) is entering the right atrium from the superior vena cava and traversing the inter-atrial septum through the puncture site made by the Channel sheath. The left ventricular lead is seen entering the left heart through the steerable introducing catheter (black arrows). The image on the right demonstrates the final position of the left ventricular lead (black arrow) and right ventricular lead (white arrow).
include the observation that LV activation via the coronary sinus (CS), and effectively epicardial pacing, results in reversal of the physiological gradient of LV contractility from the epicardium (which implicitly is also the case for LV epicardial pacing achieved via a direct surgical approach). This compares the improved activation in terms of the co-ordination of ventricular contraction achieved via a direct endocardial pacing approach.4,5 Both Garrigue and Jais reported improved cardiac haemodynamics with endocardial compared with epicardial LV pacing in patients undergoing CRT.4,5

Direct LV endocardial pacing has been reported previously. This has been achieved either inadvertently or by employing a specific directed LV endocardial pacing approach.4,5 There is also an experience of direct transaortic pacing in an animal model using polyurethane-constructed pacing leads, which has been associated with no embolic complications.8 To date, we find some 54 reported clinical cases in the literature.7,15 Authors have described the difficulties of the procedure both in terms of access to the LV endocardium and the limitations of the technology available for endocardial pacing. Most importantly, there has been great concern with respect to thrombus development, the risk of thrombus embolization, and consequent cerebrovascular accident or other end organ damage.7,15

Our experience is distinct from these reports. The use of the steerable guide catheter and the ability to precisely orientate pacing lead placement offers a controlled and targeted approach to LV endocardial pacing. In addition, the technology selected for pacing comprises a polyurethane-constructed pacing lead. To date, we have experienced no thrombo-embolic complications and this may be attributed to the lead construction which has been shown to be associated with very low fibrous encroachment and thrombo-embolism risks.8,16 Furthermore, the thrombo-embolic risk associated with endocardial pacing is likely to be less than that associated with a metallic mitral valve prosthesis, which has become a standard practice in valve surgery. All our patients have responded well to this version of LV endocardial pacing that may be related to the improved haemodynamics offered by endocardial compared with epicardial LV pacing as described above.4,5

There are other considerations. Conventional CRT, using either a CS tributary or surgical lead placement, results in non-physiological epicardial LV pacing. Reversal of the LV activation sequence has been shown to prolong the QT interval and increase repolarization heterogeneity, and these changes may be pro-arrhythmic in some patients with CRT.17,18 Experimental observations, however, have suggested that stimulation of the LV endocardium may avoid this potentially arrhythmogenic substrate.17

A potential drawback associated with LV endocardial pacing is the difficulty in managing infection of an endocardial system. Adherent vegetations may embolize systemically and any extraction would need to be surgical because of the high risk associated with a transvenous procedure. To date, there have been no reported cases of endocardial device infection. A further concern is the theoretical risk of mitral valve damage with long-term passage of the LV lead across the valve. However, this has not been borne out by clinical data. Pasquie et al.10 reported no significant change in the severity of mitral regurgitation in six patients with endocardial LV lead placement over a mean follow-up of 85 months. There is also as yet unpublished data that show the absence of mitral valve trauma with long-term

### Table 2: Implant procedure and fluoroscopy times, and left ventricular lead electrical parameters at implant

<table>
<thead>
<tr>
<th>Patient</th>
<th>Procedure time (min)</th>
<th>Fluoroscopy time (min)</th>
<th>LV intra-cardiac electrogram amplitude (mV)</th>
<th>LV lead threshold at 0.4 ms pulse width (V)</th>
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<td>22</td>
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<td>11</td>
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<tr>
<td>8</td>
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<td>28</td>
<td>12</td>
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</table>

LV, left ventricular.

### Table 3: Follow-up data and complications of nine patients who underwent attempted endocardial left ventricular lead placement

<table>
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<th>Patient</th>
<th>Follow-up duration (months)</th>
<th>Complications</th>
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<td>7</td>
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<tr>
<td>9</td>
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<td>None</td>
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endocardial LV pacing using small body leads (Personal communication, Medtronic).

In our series, we chose to achieve trans-septal access from an inferior approach as most available tools for trans-septal puncture have been designed for this. Others have reported experience of direct trans-septal puncture from a superior approach. Re-design of currently available tools for a superior approach is feasible and will reduce the complexity and procedural risk.

**Limitations**

The follow-up times reported in this study are relatively short, and it is possible that embolic complications may develop at a later stage in the history of the lead and the patients. We report only a small number of patients. We have not performed a randomized comparison of LV endocardial pacing with conventional LV pacing via CS in patients receiving CRT devices. We report only a clinical experience and not a prospective study, with limited echocardiographic data of impact on mitral valve function of the LV pacing lead.

**Conclusion**

We report an experience of LV endocardial pacing with steerable lead placement. Our experience supports the view that LV endocardial pacing is associated with acceptable lead stability, acceptable pacing parameters, and effective improvement of LV function through resynchronization of LV contraction. This experience is sufficient to justify a larger controlled study to demonstrate the efficacy and safety of targeted LV endocardial pacing, which could prove to be the optimal means of achieving cardiac resynchronization in patients with systolic heart failure and ventricular dyssynchrony, including patients who have not responded to conventional CRT.

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**References**


