Comparison of results with different left ventricular pacing leads

Eyal Nof*, Osnat Gurevitz, Shemy Carraso, David Bar-Lev, David Luria, Sharona Bachar, Michael Eldar, and Michael Glikson*

Heart Institute, Sheba Medical Center and Sackler Faculty of Medicine, Tel Aviv University, 52621 Tel Hashomer, Tel Aviv, Israel

Received 19 May 2006; accepted after revision 12 October 2007; online publish-ahead-of-print 13 November 2007

Introduction

Cardiac resynchronization therapy (CRT) is now an established form of therapy for patients with severe symptomatic systolic heart failure with a wide QRS (>120 ms) on ECG. Left ventricular (LV) pacing may be attained in a variety of ways, including direct access to the LV epicardial surface or via the transvenous approach using the coronary sinus (CS).

The literature suggests that, in the majority of cases, lateral or posterolateral aspects of the left ventricle should be paced to gain maximal haemodynamic benefit.1–3

Although the technique of transvenous CS lead implantation carries a lower risk than surgical epicardial lead implantation for the frail patient with heart failure, it nevertheless has several shortcomings and disadvantages. Despite increasing experience, the failure rate of CS lead implantation still averages up to 10% in most large studies.4–7 Failures may result from the inability to cannulate the CS, coronary veins with small diameters or takeoff at acute angles, unacceptable pacing thresholds, and unstable positions with recurrent dislodgement or intractable diaphragmatic pacing, due either to phrenic nerve or direct diaphragmatic stimulation.6–11 Even when apparently successful, a considerable number of implantations terminate with the lead in an anterior position in the great cardiac or anterior coronary vein, which is haemodynamically less beneficial than lateral or posterolateral positions.1,12,13 Moreover, following an initially successful implantation, some patients with a CS lead lose their LV pacing due to late dislodgment, intractable diaphragmatic stimulation, or late threshold increase due to micro- or macro-dislodgment.6,9,14 When taken together, acute and chronic failures result in a significant proportion of CRT recipients ending up with non-functional or ineffective LV pacing.

To overcome these technical problems, several manufacturers have developed various CS leads with different structures, designs, and delivery systems (DSs). The two main types of CS LV leads are over-the-wire (OTW) leads, which have central lumen and stylet-driven leads. The lead is advanced via a DS on the basis of long sheaths that are introduced into the CS through which the lead is advanced. Following positioning of the lead, some DSs are pulled back

KEYWORDS
Left ventricular leads; Cardiac resynchronization therapy; Delivery systems

Aims To compare different coronary sinus (CS) leads and delivery systems (DSs) for left ventricular pacing.

Methods and results Delivery systems-related (including CS dissection and dislocations during sheath/stylet removal) and lead-related (including failure to accomplish implantations and long-term malfunctions resulting in abandonment or repositioning/replacing of the lead) complications between systems and leads were compared. We used Medtronic (MDT) attainDS (n = 123) with over-the-wire (OTW) (4193, 4194) and stylet-driven (2187) leads, and Guidant (GDT)DS (n = 126) with Easytrak OTW leads (4513, 4518, and 4525). Coronary sinus dissection occurred in 6/123 (5%) cases using the MDT DS vs. 7/126 (6%) with GDT DS (P = NS). Dislocations during sheath/stylet removal occurred in 8/123 cases (6%) with MDT DS, and in 8/126 (6%) with GDT DS (P = NS). Failure to achieve successful implantation occurred in 6/32 (19%) of the 2187 leads, in 11/87 (13%) of the 4193/4194 leads, in 7/94 (7%) of the 4513/4518 leads, and in 4/29 (14%) of the 4525 leads (P = NS). Long-term lead-related complications occurred in 5/32 (15%) of the 2187 leads, 19/80 (23%) of the 4193/4194 leads, 19/93 (20%) of the 4513/4518 leads, and 2/28 (7%) of the 4525 leads (P = NS).

Conclusion No significant differences in complication rates between systems and leads were observed.

Publication information

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2007. For permissions please email: journals.permissions@oxfordjournals.org.

Published online in advance of print (EUROPA) 10.1093/europace/eum241
around the lead to be removed, whereas others have to be split by cutting in order to facilitate the removal.

In the current study, we sought to compare some of the different types of leads and DSs available with regard to short- and long-term performance and complications.

Methods

Patients

This study composed of 249 consecutive patients who underwent transvenous CRT system implantation according to current guidelines at time of implantation, between January 2001 and January 2007.

Leads

Leads implanted in this study included: pre-shaped OTW leads (Medtronic 4193 + 4194), pre-shaped stylet-driven cardiac vein leads with a hook-shaped distal configuration (Medtronic 2187) and OTW leads of straight unipolar, straight bipolar and pre-shaped curled bipolar design (Guidant Easytrak® models 4513, 4518, and 4525, respectively).

Medtronic attain® DSs were used for all Medtronic leads and Guidant DSs for all Guidant lead implantations. For analysis of DS-related complications, all Medtronic and all Guidant leads were grouped together. For analysis of lead performance, Easytrak 1 and 2 leads (4513 and 4518, respectively) were grouped together due to similarity of design, and Guidant Easytrak® OTW type 3 leads (4525) were analysed separately in the LV lead performance analysis, due to their distinctive design.

Implantations were performed in the pacemaker unit, using either local anaesthesia with conscious sedation or general anaesthesia, as required. All implantations were performed by one of three experienced operators (M.G., D.L., and O.G.). All three operators used all leads included in this specific study. The choice of system and lead was made according to availability at the day of implantation, rather than by the operator.

Venous access was achieved by puncture of the axillary or subclavian vein. The right ventricular lead was positioned first, followed by the LV lead. Right atrial leads, when indicated, were implanted last, prior to removal of the LV DS.

Complications at implantations and during 12-month follow-up were prospectively collected and retrospectively analysed in all patients using our CRT patient database. All patients were examined on the day following implantation, 2 weeks later and every 3 months thereafter. Our analysis included only complications that could be associated with either the DSs or the LV leads. Delivery system-related complications during implantation included CS dissection and/or failure to cannulate the CS and dislocations during sheath or stylet removal. Left ventricular lead-related complications during implantation included failure to accomplish successful LV lead implantation, associated with the need to switch to a different lead or to epicardial implantation, or to abort the LV lead implantation (excluding failures listed under DS-related complications). Complications during follow-up included LV lead dislocations proven by fluoroscopy, loss of LV capture or diaphragmatic pacing.

Statistical analysis

Continuous variables are expressed as mean ± SD. Distributions of nominal data were compared using χ² test. A value of P < 0.05 was considered as significant.

Results

There were no significant differences between the groups regarding baseline clinical characteristics (Table 1). The LV implantation site achieved with each lead was similar in all groups (Table 2).

Peri-operative DS-related complications

There were no significant differences between the two DSs regarding the occurrence of CS dissections (Table 3). Failure of CS cannulation occurred in six patients. In four of them, failure of cannulation was related to CS dissection. All CS dissections occurred with no haemodynamic compromise. Left ventricular lead dislocations during sheath or finishing wire removal occurred with similar frequency in both systems (Table 3). Of note, in one patient (with a Guidant DS®) we had to abandon LV pacing due to such recurrent dislocations. In another patient (with a Medtronic Attain® DS)
the LV lead (4193) was replaced by a lead from a different manufacture not included in this study.

**Failure to accomplish LV lead implantation**

Overall, failure to accomplish successful LV lead implantation despite successful CS cannulation (excluding cases of lead dislodgement during guiding/sheath removal), occurred in 6/32 (19%) of the 2187 leads, 11/87(13%) of the 4193 + 4194 leads, 7/94 (7%) of the Easytrak leads (4513 + 4518), and 4/29 (14%) of the Easytrak lead 4525 (Table 4) \( P = 0.3 \). Of these, four cases of failure to implant a 2187 lead were managed by switching to a 4193 lead; four cases of failure to implant a 4193 lead were managed by switching to a 2187 lead, and three by switching to an Easytrak 4518 lead. In one patient with a 4193 lead, it was necessary to re-operate with repositioning during the same session in the operating room. Three cases with failure to implant an Easytrak 4518 lead were switched to 4525 leads and one to a 2187 lead. Three patients with failed implantation were referred for epicardial LV lead implantation via thoracotomy, and in five patients LV pacing was abandoned. The main reasons for failure were: inability to stabilize the lead in the CS tributary without recurrent dislocation, intractable phrenic stimulation, and the inability to reach a vein with acceptable thresholds (Table 4).

Our final implant success rate (including the need to switch to a different lead) was 94% for the total study population of 249 patients.

**Long-term complications**

Follow-up was from 1 to 12 months with an average of 10 ± 2 months.

Long-term complications included diaphragmatic stimulation and late lead dislocations. The rate of dislocations proven by fluoroscopy and/or by loss of capture was not significantly different between lead types (Table 5). Left

<table>
<thead>
<tr>
<th>Table 3 Peri-operative complications related to the delivery system</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coronary sinus dissections</strong></td>
</tr>
<tr>
<td>Medtronic\textsuperscript{w} delivery system ( N = 123 )</td>
</tr>
<tr>
<td>6(5%)</td>
</tr>
<tr>
<td>4(3%)</td>
</tr>
<tr>
<td>8(6%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 4 Lead-related reasons for failure to accomplish successful LV lead implantation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Failure to accomplish successful left ventricular lead implantation</strong></td>
</tr>
<tr>
<td>Diaphragmatic pacing</td>
</tr>
<tr>
<td>Medtronic\textsuperscript{w} 2187 ( N = 32 )</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

\textsuperscript{a}See text for details.

<table>
<thead>
<tr>
<th>Table 5 Long-term left ventricular lead-related complications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left ventricular lead dislocations</strong></td>
</tr>
<tr>
<td>Medtronic\textsuperscript{w} (2187) ( N = 32 )</td>
</tr>
<tr>
<td>4 (12%) 2—LVP Stopped</td>
</tr>
<tr>
<td>1 (3%) 1—LVP Stopped</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Overall</td>
</tr>
</tbody>
</table>

LVP, left ventricular pacing.
ventricular pacing was abandoned in four patients due to lead dislocation, and in one patient due to diaphragmatic stimulation. There were no significant changes in the number of patients suffering from diaphragmatic stimulation (Table 5). In most cases (24/30, 80%) diaphragmatic stimulation was prevented by reprogramming pacemaker output and/or the polarities.

Re-operation (either repositioning or replacement of the lead) was performed in seven patients with Easytrak\(^{4513 + 4518}\) leads (four due to dislocation of the lead and three due to diaphragmatic stimulation), and in six patients with \(4193 + 4194\) leads (four due to dislocation of the lead and two due to diaphragmatic stimulation (Table 5).

At 1 year follow-up re-operation was required in 5% and LV lead pacing was abandoned in a further 2% of patients. These results did not differ between different lead types.

**Discussion**

Despite considerable progress in lead design and technology over the last several years, lead technology for transvenous LV pacing is still far from being optimal.

In this study of 249 patients, overall lead results were comparable to previous large series\(^{4,6,8–10}\) and demonstrated the current limitations of LV pacing via CS leads.

At the start of a CRT implantation procedure, the physician is faced with a variety of different DSs and leads, which are not always interchangeable during the implantation process due to their specific sheath and connector sizes. The choice of lead at the beginning of an implantation is therefore more crucial than in traditional pacing, and comparison between the different systems may help in making this choice.

We are not aware of any such previous comparative evaluation in the literature, and we therefore sought to compare four different leads, using two different DSs. CS cannulation and dissection failures occurred infrequently with all systems, and all CS dissections were benign, as previously reported\(^{5,6,9}\) with the exception of a 2% reported CS perforation in one study\(^4\) leading to haemodynamic compromise in a minority of these patients.

Guiding sheath removal by the cutting of Attain systems is perceived by many operators as a problematic step predisposing to acute lead dislodgement. However, the rate of acute dislodgements during sheath/stylet/finishing wire removal at the conclusion of the procedure did not differ between the two DSs.

Although it is conceivable that leads using the OTW technique and leads with smaller diameters may reach locations that are not accessible to larger, stiffer leads, we did not find significant failure rates or implant-related complications between leads using different techniques.

Diaphragmatic pacing is a very troublesome phenomenon with LV pacing using CS leads, which may result from direct diaphragmatic stimulation or from capture of the phrenic nerve. In our study group, 3% of patients did not tolerate diaphragmatic pacing even after LV pacing thresholds were lowered, resulting in re-operation in 5, and cessation of LV pacing in another 1. These numbers are comparable with previous series.\(^6\) Despite the relatively high level of diaphragmatic pacing, this problem was usually solved by programming at a lower output. Although numbers in this series are insufficient to demonstrate it, we have recently shown that bipolar leads (such as some of the Easytrak leads) may offer more flexibility in prevention of diaphragmatic stimulation by changing pacing location between the ring and the tip when this feature is available in the implanted device.\(^15\) Re-operation, or the need to abandon LV pacing over time, occurred in 7% of patients in the current study, which is relatively low compared to previous reports,\(^4,6\) and did not differ significantly among the different leads. It is important to emphasize that in some previous studies some of the leads used were older, which might account for the relative higher incidence of re-operation in one study\(^6\) and CS dissection in another.\(^4\) Furthermore, many older systems do not provide the ability of reprogramming polarity and therefore in cases of diaphragmatic stimulation or high thresholds the physician may have no choice but to re-operate. Another possibility is that implanters from different centres might have had different levels of experience with a procedure, which was relatively new during the early stages of the old studies.

**Limitations**

This is a retrospective analysis that carries all the weaknesses of a retrospective uncontrolled study, including lack of randomization between leads and lack of strict criteria for the decision to switch between leads and DSs. However, it is important to note that there was no selection bias between the systems, and the initial choice of the implanted system was based on the availability at the time of implantation, rather than on patient specific or procedure specific variables. Once a procedure was initiated with a certain system, the operator was often committed to leads of the same manufacturer (due to sheath and connector size and availability of products), thereby preventing efficient crossover between different designs that could have improved success rates. It is conceivable that different venous anatomies are better fitted to one particular lead than another. Operators should therefore encourage manufacturers to produce leads compatible with all systems, in order to provide optimal choice based on anatomy and problems encountered during the implantation procedure.

The numbers in this series might not have been large enough to detect minor differences between leads and/or DSs, and therefore further larger trials are warranted. All the procedures were performed by three highly trained experienced operators, with the types of leads and DSs, as well as the rates of DSs and lead-related problems being equally distributed among all three operators.

Additional parameters, such as procedure and fluoroscopy time, which could also have an impact on the choice of lead, were not available in some earlier implants in our database and therefore were not included in the current evaluation.

**Conclusions**

We have demonstrated that DSs and LV lead selection do not significantly affect overall short- and long-term results. The best results, however, can only be obtained when a complete variety of choice, without limitations of sheath sizes and connectors, is available for the individual implantor.
Acknowledgements
The authors thank Miss. Vivienne York for her technical support.

Conflict of interest: none declared.

References