Initial clinical experience with implantation of left ventricular lead guided by Overlay Ref for the treatment of congestive heart failure

Évaluation clinique initiale d’une technique d’implantation d’une sonde de stimulation en position ventriculaire gauche

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Summary

Background. — Cardiac resynchronization therapy (CRT) improves clinical outcome in selected patients with advanced congestive heart failure. The Overlay Ref technique may facilitate the procedure for implanting left ventricular (LV) pacing leads to deliver CRT.

Aim. — To assess the feasibility of deploying a LV pacing lead into a coronary sinus side branch guided by Overlay Ref.

Methods. — Data from 88 consecutive patients who met the CRT implantation criteria in our hospital between 28 November 2007 and 30 December 2009 were randomly assigned to two groups. Forty-four patients underwent CRT device implantation using Overlay Ref to guide target vein selection and advance a specifically designed pacing lead into the target vein (Overlay Ref group); 44 patients were conventionally implanted (control group).

Results. — LV lead implantation was successful in all patients. Mean CRT total procedure times (skin-to-skin) were: Overlay Ref group, 80.7 ± 18.0 min; control group, 98.5 ± 32.2 min; p = 0.029. Mean placement of LV pacing lead into target vein times were: Overlay Ref group, 16.2 ± 7.7 min; control group, 36.4 ± 23.4 min; p = 0.004. Mean total fluoroscopy times were: Overlay Ref group, 13.6 ± 4.3 min; control group, 23.8 ± 15.7 min; p = 0.007. Mean LV lead fluoroscopy times were: Overlay Ref group, 5.7 ± 2.9 min; control group, 14.4 ± 4.6 min; p = 0.003. No major complications occurred.

Abbreviations: CRT, cardiac resynchronization therapy; CS, coronary sinus; DSA, digital subtraction angiography; LV, left ventricular.

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Conclusions. — Overlay Ref facilitates location of and entry into the coronary sinus, and shortens the duration of LV pacing lead implantation into the target vein.

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Background

Multiple randomized clinical studies have suggested that patients in heart failure with left bundle branch block may benefit from cardiac resynchronization therapy (CRT) [1—3]. One of the greatest challenges to this therapy is the technical difficulty encountered with implantation of the left ventricular (LV) lead. Implantation of LV pacing leads to deliver CRT typically involves locating and entering the coronary sinus (CS), performing coronary venous angiography, selecting a target vein and advancing a specifically designed pacing lead into the target vein. To overcome this problem, a new technique named Overlay Ref has been introduced into clinical electrophysiology; this technique can overlap the reference images on the real-time fluorescence monitor, to facilitate implantation of LV pacing leads. This article reports our initial experiences with implantation of LV pacing leads guided by Overlay Ref.

Methods

Patient selection

Between 28 November 2007 and 30 December 2009, biventricular pacemaker implantation was performed in 88 consecutive candidates for CRT, who were randomized in a 1:1 ratio based on a permuted blocked randomization list, to provide an approximate balance between treatment groups. The randomization list was stratified by site. Randomization was done by opening sealed allocation envelopes (indicating ‘Overlay Ref’ or ‘conventional’ treatment).

Forty-four randomized patients underwent LV lead placement using the Overlay Ref technique to control the tip of a 0.014-inch guidewire (Medtronic Inc., Minneapolis, MN, USA). The control group was made up of 44 randomized patients scheduled for CRT during the same time period. The Overlay Ref technique was not used in the control group.
Standard 0.014-inch guidewires were used in the control group, as well as CS venography. The right ventricular and right atrial leads were initially placed in a standard fashion. The CS leads were commercially available over-the-wire leads (Medtronic Inc.).

The institutional review board of our institution approved the study protocol. Each patient signed a written consent form before treatment.

Inclusion criteria were as follows: symptomatic heart failure with idiopathic dilated or ischaemic cardiomyopathy; New York Heart Association functional class III or IV; LV end-diastolic diameter greater or equal to 60 mm; QRS width greater or equal to 120 ms (measured on surface electrocardiogram leads); and obvious mitral regurgitation by echocardiography.

Device

Impulse generators: Insync 8040, Insync III 8042 (Medtronic Inc.). LV leads: 2188, 2187, 4189, 4191, 4193 (Medtronic Inc.); Attain® OTW 6215 (Medtronic Inc.).

Implantation procedure: Overlay Ref group

After informed consent was obtained, implantation was performed for the patient under local anaesthesia and conscious sedation. After puncturing the left subclavian vein, two steerable hydrophilic guides were inserted. The short guide was used to introduce the atrial and right ventricular leads, and the long guide to introduce the LV lead delivery system.

Location of the coronary sinus ostium

One of the key steps in the implantation procedure for CRT is access to the CS. We used an electrophysiological guided approach to locate the CS ostium. The standard diagnostic CS electrophysiology catheter was used to cannulate the CS. When the catheter was put into the CS, the delivery sheath was then slipped over the catheter inside the CS as deeply as possible and the catheter was exchanged for a balloon catheter to perform an occlusive CS venogram; it then remained in the ostium to secure access (Fig. 1) [4].

Left ventricular lead implantation

The LV lead was selected on the basis of the anatomy of the CS branches. For large veins with few tortuositities, a large bore lead (2187) was used. For medium-sized or small veins with significant tortuositities, over-the-wire leads (mostly 4193) were selected. The lead was placed preferentially into the lateral or posterolateral vein using percutaneous transluminal coronary angioplasty (Fig. 2) [5,6]. Sensing and pacing thresholds were determined, along with the pacing threshold for phrenic nerve stimulation. After lead measurement, the sheath was removed and the right ventricular and right atrial leads were implanted. The right ventricular lead was generally placed at a site anatomically remote from the LV lead, with good electrical separation and, preferably, early in the QRS complex.

The digital subtraction angiography (DSA) system (AXIOM Artis dFC equipped with VB31E software package including Overlay Ref technique; Siemens, Erlangen, Germany) was used to perform selective CS angiography in both the right anterior oblique 30° view and the left anterior oblique 45° view. Meanwhile, the images were recorded in order to direct lead placement. The main branches of the CS are the great vein and the lateral, posterolateral, posterior and middle veins (Figs. 3a and 4a). The snapshot that showed the clearest contour of CS was drawn from the venography movie and transferred to the reference monitor; this served as the reference image. When the ‘Automap’ button was pressed, the DSA machine automatically restored the same zoom stage, matrix size and patient position as the reference image. The ‘Overlay’ button was then pressed, and the (inverted) reference image was faded into the live fluoroscopic image, so that the position of the LV lead could be located directly over the inverted and faded reference image. Hence, Overlay Ref was able to render the position of the LV lead during the implantation procedure. CS landmarks were chosen from the CS ostia region (Figs. 3b and 4b).

Implantation procedure: control group

The 44 control patients underwent routine CRT device implantation during the same period of time, as previously described [7]. Selective CS angiography at both the right anterior oblique 30° view and the left anterior oblique 45° view were performed. No reference images were recorded.
Figure 2. Typical lead placement in the anterior vein in (a) left anterior oblique view and (b) posterior-anterior view. In the same patient, the lead was positioned in the lateral vein by the over-the-wire technique, depicted in (c) left anterior oblique view and (d) posterior-anterior view. Photo reference from Sack et al [5].

Figure 3. A percutaneous transluminal coronary angioplasty wire was placed into the target vein, guided by the Overlay Ref technique, in left anterior oblique view. (a) Reference image. (b) Fluoroscopic image.

Figure 4. An over-the-wire left ventricular lead was placed into the target vein, guided by the Overlay Ref technique, in left anterior oblique view. (a) Reference image. (b) Fluoroscopic image.
and LV pacing leads were guided by the use of conventional fluoroscopy.

**Statistical analysis**

Statistical analyses were performed using SPSS13.0 for Windows (Apache Software Foundation, SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as means ± standard deviations and compared using Student’s t-test. Absolute numbers and percentages were compared using the chi-square test or Fisher’s exact test. A $p$ value less than 0.05 was considered statistically significant.

**Results**

**Left ventricular lead placement**

CS access and LV lead placement were successfully performed in all Overlay Ref and control group patients. There were two coronary venous anatomical difficulties in the Overlay Ref group: one patient had an atypically located CS ostium; another patient had undergone previous valve surgery that distorted the atrial anatomy. In 53 patients, the target CS side branch was located in the posterolateral wall of the left ventricle; in 32 patients the ideal CS side branch was considered to be in the lateral LV wall; in three patients the anterior LV wall was used due to the lack of acceptable pacing thresholds in other locations.

**Comparison between Overlay Ref and control groups**

Patient clinical characteristics were similar in the two groups (Table 1). Implantation procedural data are shown in Table 2. Using the Overlay Ref technique, placement of the LV pacing lead into the target vein took 16.2 ± 7.7 min. Total CRT procedure duration (skin-to-skin) was 80.7 ± 18.0 min, total fluoroscopy time was 13.6 ± 4.3 min and LV lead fluoroscopy time was 5.7 ± 2.9 min. Compared with the control group, Overlay Ref was associated with significantly shorter times for LV lead placement.

There were no implantation procedure-related deaths, CS dissections or LV lead dislodgements.

**Discussion**

CRT, by simultaneous pacing of the right and left ventricles, can improve symptoms and reduce mortality. With the publication of the CARE-HF trial, CRT gained further acceptance as an effective intervention for patients with advanced heart failure and LV systolic dysfunction [1]. The major problem with this therapy has been the implantation of LV pacing leads. Placing the LV lead at the target site involves cannulating the CS, performing coronary venous angiography and placing the LV lead to achieve adequate resynchronization.

The procedure is complicated. Firstly, some patients with advanced heart failure symptoms and depressed cardiac

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<th>Table 1</th>
<th>Baseline clinical characteristics.</th>
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<td></td>
<td>Overlay Ref group</td>
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<td></td>
<td>($n = 44$)</td>
</tr>
<tr>
<td>Age (years) $a$</td>
<td>62 ± 9</td>
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<td>Men/women ($n/n$)</td>
<td>30/14</td>
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<td>Ischaemic/non-ischaemic aetiology ($n/n$)</td>
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<td>Ejection fraction (%) $a$</td>
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<td>QRS duration (s) $a$</td>
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<td>Medical therapy</td>
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<tr>
<td>Beta-blockers (%)</td>
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<tr>
<td>ACE inhibitors (%)</td>
<td>100</td>
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<tr>
<td>Diuretics (%)</td>
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ACE: angiotensin-converting enzyme; NS: not significant.

$a$ Data are means ± standard deviations.

<table>
<thead>
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<th>Table 2</th>
<th>Left ventricular lead procedure data.</th>
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<td></td>
<td>Overlay Ref group</td>
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<tr>
<td></td>
<td>($n = 44$)</td>
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<tr>
<td>LV lead placement into target vein time (min)</td>
<td>16.2 ± 7.7</td>
</tr>
<tr>
<td>CRT total procedure time (min)</td>
<td>80.7 ± 18.0</td>
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<tr>
<td>Total fluoroscopy time (min)</td>
<td>13.6 ± 4.3</td>
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<tr>
<td>LV lead fluoroscopy time (min)</td>
<td>5.7 ± 2.9</td>
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LV: left ventricular; CRT: cardiac resynchronization therapy.

Data are means ± standard deviations.
function cannot withstand this time-consuming procedure because they need to lie still during the implantation. Secondly, previous studies have suggested that for the majority of patients, the optimal LV pacing site is considered to be a lateral or posterior lateral CS tributary [8,9]. However, as far as the tributaries of the CS are concerned, there are all kinds of variation. Moreover, the varied anatomy of the coronary venous system may be further complicated by distortion of the anatomy of heart failure patients [10]. As a result, it is difficult to advance the LV lead to the desired position inside the vein. Thirdly, the available LV leads are still not ideal. For example, the model 2187 Attain LV 7F (Medtronic, Inc.) is a stylet-driven lead with a preshaped stylet used to catheterize the CS without the use of a left heart delivery system; it is not only hard but also has a large curvature, and is therefore not appropriate for the thin branch. Finally, CRT is usually used for patients with severe heart failure. In such cases, the heart is significantly enlarged, which makes CS identification or cannulation more difficult.

This study demonstrates the feasibility of the Overlay Ref technique for guiding implantation of LV pacing leads for the treatment of heart failure. Our previous study showed that the Overlay Ref technique can facilitate the catheter ablation of paroxysmal atrial fibrillation and can help to standardize the landmarks selection procedure [11]. Using the Overlay Ref technique, the total duration of the procedure in the present study was shortened to 80.7 ± 18.0 minutes and we rarely saw intermittent contrast injection through the guide catheter. This suggests that the Overlay Ref technique might improve the accuracy of LV pacing lead implantation and shorten the duration of the total procedure.

The coronary venous anatomy may limit placement of the LV lead and the ability to pace a defined region of the LV for CRT in some cases. The use of the Overlay Ref technique might help to overcome some of the technical difficulties, such as cannulation of small veins, or track the lead to a more distal portion of the coronary vein. In addition, there was no learning curve associated with this technique.

The accuracy of Overlay Ref depends on the image quality of the venography of the CS. Only when the reference image outlines the contours of the CS clearly can Overlay Ref locate the catheter exactly. It should also be noted that respiratory motion and cardiac beat motion can change the catheter position, thus affecting the precision of Overlay Ref.

One reason for the precision of Overlay Ref could be that it is a flat, two-dimensional technique, rather than a three-dimensional mapping system. In fact, when Overlay Ref is started, the DSA machine automatically restores to the same zoom stage, matrix size and patient position as the reference image, ensuring precise location of the catheter guided by the flat fluorescence.

The limitation of this technique is that the Overlay Ref image cannot be stored and reviewed after implantation procedure due to technical reasons.

Study limitation

A limitation of this study was the small number of patients included. Although the study showed that the Overlay Ref procedure is safe and feasible, a larger, randomized trial is warranted.

Conclusion

The Overlay Ref technique is a safe, feasible and efficient tool for assisting LV lead placement during CRT, with the advantage of timesavings.

Conflicts of interest statement

None.

References