Europace (2008) 10, 1042–1047
doi:10.1093/europace/eun173

CLINICAL INVESTIGATION

Magnetically guided left ventricular lead implantation based on a virtual three-dimensional reconstructed image of the coronary sinus

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Received 24 February 2008; accepted after revision 2 June 2008; online publish-ahead-of-print 27 June 2008

KEYWORDS
Magnetic navigation;
Cardiac resynchronization therapy;
Three-dimensional reconstruction;
Left ventricular lead;
Implantation

Aims Left ventricular (LV) lead implantation is feasible using remote magnetic navigation of a guidewire (Stereotaxis, St Louis, MO, USA). A novel software that performs a three-dimensional (3D) reconstruction of vessels based on two or more angiographic views has been developed recently (CardiOp-B system™, Paeion Inc., Haifa, Israel). The objective of this paper is to evaluate: (i) the performance of the 3D reconstruction software which reproduce the anatomy of the coronary sinus (CS) and (ii) the efficacy of remotely navigating a magnetic guidewire within the CS based on this reconstruction.
Methods and results In patients undergoing cardiac resynchronization therapy implantation, a 3D reconstruction of the CS was performed using the CardiOp-B™ system. Accuracy of the reconstruction was evaluated by comparing with the CS angiogram. This reconstruction was imported into the Stereotaxis system. On the basis of the reconstruction, magnetic vectors were automatically selected to navigate within the CS and manually adjusted if required. Feasibility of deploying the guidewire and LV lead into the selected side branch (SB), fluoroscopy time (FT) required for cannulation of the target SB, and total FT were also evaluated. Sixteen patients were included. In one case, the software could not reconstruct the CS. The quality of the reconstruction was graded as good in 13 and poor in 2. In 10 cases, manual adjustments to the traced edges of the CS were required to perform the 3D reconstruction, and in 5, no adjustments were required. In 13 patients, the target SB was engaged on the basis of the automatically selected vectors. In two cases, manual modification of the vector was required. Mean total FT was 23 $\pm$ 14 min and the FT required to cannulate the target SB was 1.7 $\pm$ 1.3 min.
Conclusion A 3D reconstruction of the CS can be accurately performed using two angiographic views. This reconstruction allows precise magnetic navigation of a guidewire within the CS.

Introduction

Despite the technological progress aimed at improving success and reducing complication rates during cardiac resynchronization therapy (CRT) device implantation, in a proportion of cases, the delivery of a left ventricular (LV) pacing lead through the coronary sinus (CS) still fails. As recently demonstrated, transvenous implantation of a LV pacing lead is safe and feasible using remote magnetic navigation of a guidewire.[1,2] However, we encountered certain limitations in order to reach the ultimate goal of reproducibly implanting the LV lead remotely. Among these limitations, one of them was the lack of having a real-time three-dimensional (3D) CS model to facilitate more accurate navigation of the guidewire. A novel imaging system (CardiOp-B system, Paeion Inc., Haifa, Israel) is becoming

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an established technique for the 3D reconstruction of vessels using data obtained from standard vascular angiography.[3] The reconstructed vessel can be subsequently imported into the Niobe™ (Stereotaxis, St Louis, MO, USA) magnetic navigation system, and magnetic vectors can be selected based on the virtual model of the vessel.

Our purpose was to test the feasibility of reconstructing the anatomy of the CS using this software and evaluate the accuracy of navigating within the CS based on this 3D model.

Methods

Patient population

Sixteen consecutive patients who underwent CRT device implantation were included in this study. These patients met the standard criteria for CRT comprising advanced heart failure refractory to medical therapy, low ejection fraction (<35%), and a broad QRS (≥120 ms) on the electrocardiogram (ECG) with a left bundle branch block (LBBB)-like morphology. All patients gave informed consent.

Implantation procedure

All procedures were performed in the room equipped with magnetic navigation (Niobe™ II, Stereotaxis). In all patients, the left cephalic vein was dissected. A right ventricular (RV) shock lead (model 1580 Riata, St Jude Medical, Sylman, CA, USA or model 6947 Sprint Quattro Secure, Medtronic Inc., Minneapolis, MN, USA) was introduced and actively fixed to the RV apical wall. After a double left subclavian venous puncture, a right atrial active fixation lead (model 5076, Medtronic, Inc.) was introduced and positioned in the right atrial appendage. Pacing and sensing properties of these leads were assessed.

Coronary sinus angiography and three-dimensional reconstruction

A 9 Fr long guiding sheath (model Attain 6216, Medtronic, Inc.) was introduced in order to cannulate the CS. Angiograms of the CS were performed using 30° left anterior oblique (LAO), antero-posterior (AP), and 30° right anterior oblique (RAO) projections (projections allowed when the magnets are in the navigate position). These angiograms were imported into the CardiOp-B System™ (Paeion Inc.). An automatic algorithm detects the vessel edges in each of the projections used for the reconstruction. In case edge, detection was inaccurate (not exactly superimposed onto the angiographic edge), and manual adjustments could be made so as to obtain the best reconstruction possible. On the basis of the traced edges and using a minimum of two complementary angiographic views, a 3D reconstruction of the vessel was performed. The system allows reconstructing the body of the vessel and one bifurcation or side branch (SB) at a time. The reconstructed 3D model of the CS and its SB can then be imported into Niobe™ (Stereotaxis), where, after alignment to the real-time fluoroscopic views, flythrough images of the model can be used to navigate (*Figure 1*). The quality of the reconstruction was assessed by two operators performing the procedure and graded as (i) not possible to be reconstructed, (ii) poor, or (iii) good, after superimposing and aligning it to the real-time angiography in the LAO, AP, and RAO projections (*Figure 2*). The need of manual adjustment of the traced edges in order to improve the quality of the reconstruction was also evaluated.

Magnetic navigation based on the virtual three-dimensional image of the coronary sinus

Magnetic navigation is performed by positioning two external magnets (Stereotaxis) at each side of the table in order to generate a 0.08 T magnetic field within patients. The orientation of the

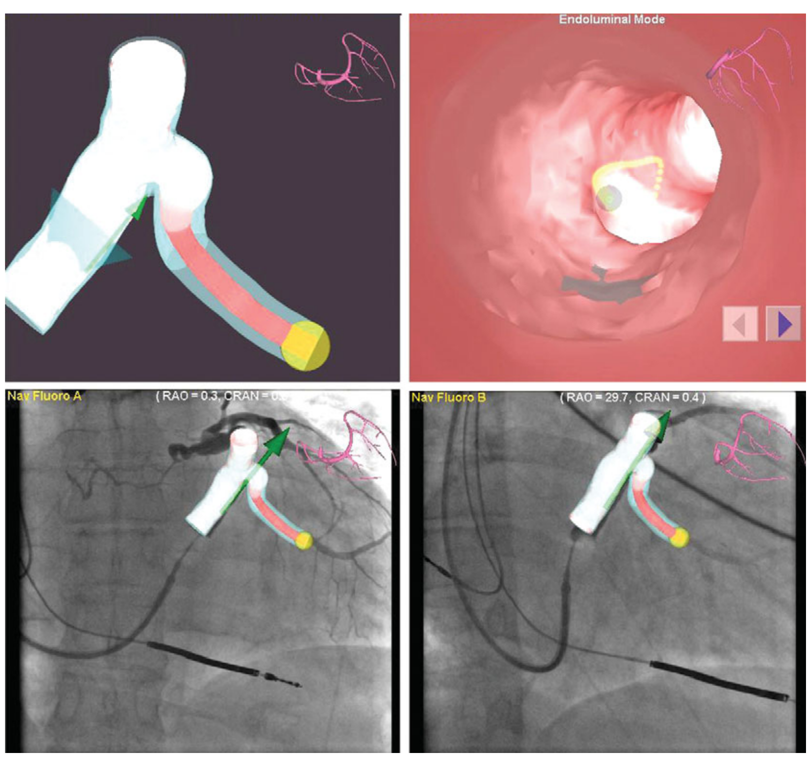

Figure 1 (Top) At the left, three-dimensional reconstruction of the coronary sinus with one side branch in an antero-posterior view. Note the marked angulation of the lateral side branch. At the right, a flythrough image of the reconstruction. (Bottom) Reconstructed model aligned to the fluoroscopic view in left anterior oblique projection (left panel) and antero-posterior projection (right panel). The automatically selected vector is shown in green.

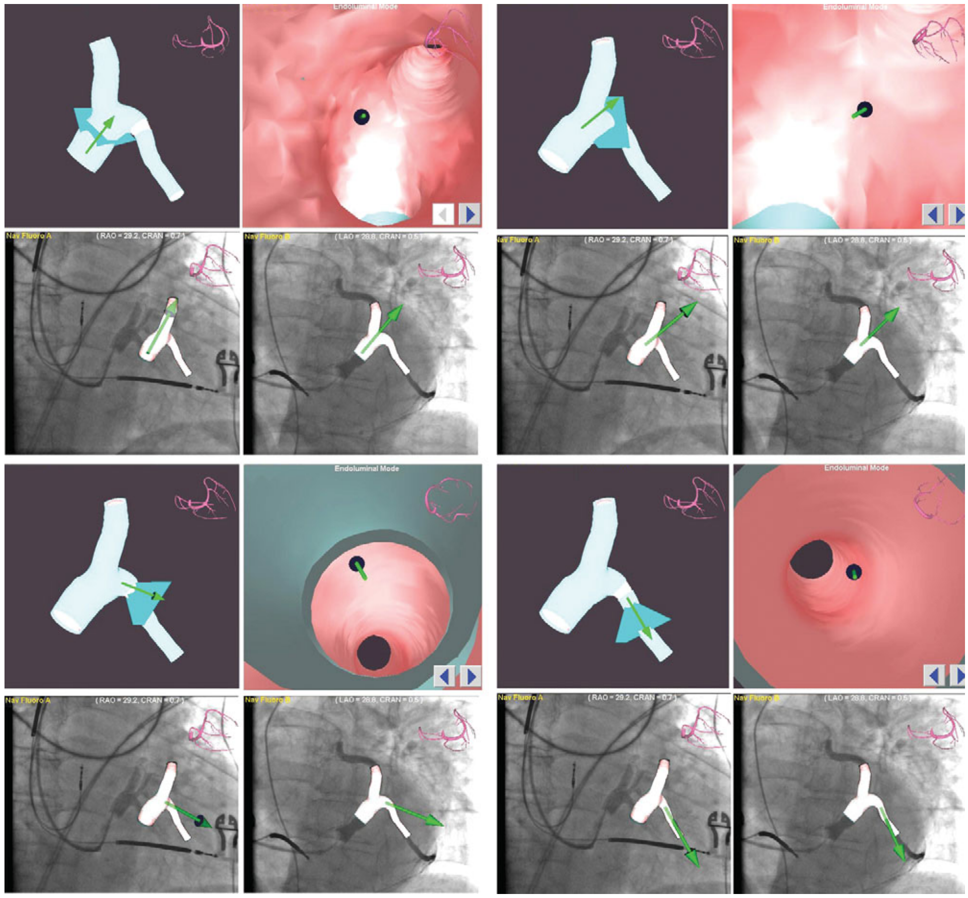

Figure 2 Four panels, as seen in real-time, showing the different automatically selected vectors (green arrows) chosen to navigate within the reconstructed coronary sinus model. In each panel, at the top left: three-dimensional reconstruction of the coronary sinus; top right: endovascular view; bottom left: right anterior oblique projection and not aligned three-dimensional model to facilitate the visualization of the side branch; bottom right: left anterior oblique projection with aligned three-dimensional model. Note how the vector changes according to the portion of the vessel it is aiming at.

magnetic field is established by the interaction of the two external magnets with each other and can be automatically determined or specified by an operator working remotely in the viewing room. A single 2 mm neodymium iron boron magnet attached at the tip of a 0.014 guidewire (Cronus™ Soft support Endovascular Guide wire, Stereotaxis), aligns itself to the direction of the magnetic vector. In this way, by changing the orientation of the magnets, the resultant magnetic vector changes and the tip of the guidewire aligns itself in the direction of the newly applied vector. A dedicated software package, the Navigant™ (Stereotaxis) allows the full integration of the Niobe™ system and the imported CardioOp® 3D reconstruction (Paeion). In this way, the vectors required to navigate within the reconstructed vessels and to access the desired portion of the vessel can be automatically determined using the system (*Figure 2*). If the vectors suggested by the system are not accurate enough to allow access to the desired SB, manual adjustments can be made. In this study, the guidewire was manually advanced after each modification of the magnetic field (every 3–5 mm steps), in order to access the ideal SB (as previously defined by the operators). Once the target SB was engaged, an over-the-wire LV pacing lead (Medtronic Attain, Medtronic, Inc. or QuickSite, St Jude Medical, Sylmar, CA, USA) was introduced and lodged in the vessel.

Feasibility of (i) deploying the guidewire and LV lead into the selected SB using the automatically determined vectors, (ii) need for manual adjustments of these vectors, (iii) fluoroscopy time (FT) required for cannulation of the target SB, (iv) total FT, and (v) procedure time were assessed.

Results

The procedural outcome of the 16 consecutive patients included in the study is detailed in *Table 1*. All had an LBBB-like broad QRS complex on the ECG, a severely depressed left ventricular ejection fraction, and advanced symptoms of heart failure (New York Heart Association functional class 3 ± 1). The mean procedure time was 99 ± 26 min, the mean FT 23 ± 14 min, and the mean FT required to position the LV lead into the target CS SB was 1.7 ± 1.3 min.

Three-dimensional reconstruction of the coronary sinus

In 15 patients (93%), the 3D reconstruction of the CS was successfully performed. In case 4, the software was unable to reconstruct the CS and consequently, the LV lead implantation was conventionally performed. In 10 cases, minor manual adjustments to the traced edges of the CS was required in order to obtain a 3D reconstruction of good (in 8 cases) or poor (2 cases) quality. In the remaining five patients, no manual adjustments were made in order to obtain a good reconstruction (*Figure 1*). Overall, the quality of the reconstruction was considered to be good in 13 cases (81%) and poor in 2 (12%) (*Table 2*).

Table 1 Procedure characteristics and left ventricular lead position

Patient number	Procedure time (min)	Fluoroscopy time (min)	LVL fluoroscopy (min)	Target SB accessed w/guidewire	Final LVL location	Pacing threshold (mV)
1	150	18.4	0.2	Yes	PL	1
2	85	36.7	3	Yes	AL	0.4
3	75	23.3	2.36	Yes	PL	0.5
4	–	–	–	Yes	PL	1.1
5	95	23.2	1.64	Yes	PL	0.7
6	140	46	0.13	Yes	Ant	1.6
7	96	14.48	4.5	Yes	L	1
8	101	19.2	0.33	Yes	L	1.2
9	75	18.4	0.26	Yes	PL	0.7
10	70	7.5	2.26	Yes	L	0.8
11	85	27.35	1.05	Yes	L	0.9
12	110	9.41	0.18	Yes	Ant	4.8
13	98	16.21	2	Yes	PL	2
14	60	8.7	3.05	Yes	L	1.5
15	110	21.42	2.4	Yes	PL	1.1
16	130	58	2.2	Yes	L	0.4
Mean (SD)	98.6 (25)	23.2 (14)	1.7 (1.3)			1.2 (1)

AL, antero-lateral; Ant, anterior; LVL, left ventricular lead; L, lateral; PL, postero-lateral side; SB, coronary sinus side branch; SD, standard deviation.

Left ventricular lead implantation

In all 15 patients, in whom magnetic navigation based on the reconstructed CS was performed, the target SB was successfully engaged with the magnetically steered guidewire. In 13 patients (87%), this was possible based only on the automatically selected vectors; in 2 cases (13%), manual modification of the automatically selected vectors was required in order to navigate distally in the target vessel.

In one case, the lead had to be definitively deployed in an anterior SB due to the lack of acceptable pacing thresholds in other locations. However, navigation through the CS was feasible in this patient using the automatically selected vectors. In two other cases, the LV lead had to be deployed in a different SB than that initially targeted because they could not be engaged with the selected leads. It is interesting to note that in patient 1, after CS angiography, no further fluoroscopy was required to engage the target SB and the position of the lead.

One patient suffered from diaphragmatic stimulation at high pacing output (10 V) but the lead required no repositioning because of the lack of diaphragmatic capture with lower output (7.5 V). No other complications were observed during or after the procedure.

Table 2 Quality of reconstruction and navigation

Patient number	Quality of 3D reconstruction	Edge adjustment needed	Type of navigation
1	Good	Yes	Automatic
2	Good	Yes	Automatic
3	Good	Yes	Automatic
4	Not obtained	–	–
5	Good	Yes	Automatic
6	Good	Yes	Automatic
7	Good	Yes	Automatic
8	Good	No	Automatic
9	Good	Yes	Automatic + manual
10	Good	No	Automatic
11	Poor	Yes	Automatic
12	Good	No	Automatic
13	Poor	Yes	Automatic + manual
14	Good	No	Automatic
15	Good	Yes	Automatic
16	Good	No	Automatic

Discussion

To the best of our knowledge, this is the first reported use of 3D reconstruction software to create an accurate real-time virtual map of the CS. We demonstrate that this virtual 3D model can be integrated in the magnetic navigation system in order to allow reliable navigation within the CS. On the basis of the reconstructed image, the system allows automatic vector selection to guide a magnetically enabled wire to its desired position within the CS in order to later advance the LV pacing lead.

Three-dimensional reconstruction of the coronary sinus

Transvenous LV lead implantation is sometimes time-consuming; it may require prolonged FTs and can eventually fail. Local complications generated by the delivery system and the occlusive angiogram of the CS (dissection of the vessel, spasm, or even rupture) may lead to implantation failure. However, the main reason for implantation failure remains sometimes challenging anatomical properties of the CS. Valvular structures, stenosis, lack of SBs, highly angulated SBs, and tortuous vessels are common findings during CRT implantation. Despite continuous innovations and technological improvement of the delivery systems, guidewires, and LV leads, ~10% of the implantation attempts still fail.[4]

Implantation procedures are conventionally guided by the use of fluoroscopy, which offer a two-dimensional view of the vessel of interest. In this way, tortuous SBs can appear foreshortened or overlapped,[5] resulting in inaccurate interpretations of the anatomy and making decisions regarding the selection of the appropriate material and manoeuvres required to reach certain vessels more difficult. Magnetic navigation of guidewires was meant to help overcome these difficulties and allows access to places in which the use of conventional technology is very challenging.[6,7] The possibility of performing an accurate 3D reconstruction of a vessel that is integrated into the magnetic navigation system allows more reliable and effective navigation when compared with that guided only by fluoroscopy. The advantage of this reconstruction is that it is performed with the patient in the same position and under the same circumstances (heart rate, rhythm, haemodynamic status, etc.) than that during the implantation. This should allow more precise navigation than using imported pre-operative 3D images obtained under different circumstances than during implantation.

In our experience, it was not possible to obtain a 3D model of the CS, in only one case, probably due to the fact that the diameter of this particular vessel was larger than conventionally encountered. This software was developed to reproduce the anatomy of coronary arteries, which are narrower and less tortuous than the CS, and its side-branches. In two other cases, the final result was a poor reconstruction. Here, the sizes of the vessels were no different than those that were more accurately reconstructed. Probably, the particular anatomy of these vessels required other fluoroscopic projections than the ones used (LAO 30°, AP, and RAO 30°) to create the model. Nevertheless, these reconstructions were good enough to allow navigation and deployment of the guidewire into the desired SB. In the remaining 13 cases, a good quality reconstruction was obtained. In 10 cases, the automatically traced contour of the vessel had to be manually modified in order to correct for inaccuracies in the interpretation of the vessel's edge. However, in most of them, the end result of the reconstruction was satisfactory.

Performing the 3D reconstruction, importing it to the magnetic navigation system, and aligning it to the fluoroscopic views required only a few minutes and did not delay the procedure significantly. The reconstruction of the CS was performed while the implanting physician was selecting the appropriate lead, preparing it, and introducing it into the guiding sheath.

This software, and its integration into the magnetic navigation system, offers a reliable 3D view of the CS and its SBs allowing precise navigation within the vessel. In all patients, reconstruction of the CS was feasible and the target SB was successfully engaged by the guidewire. In 87% of these cases, this was achieved only using the automatically selected vectors and, in two cases, manual modifications were required. Using the 3D reconstruction as a model for navigation provides much more information than the fluoroscopic views and allows the system (and the operator) to more precisely interpret the SB location, direction, angulation, and length. It is the model that is used to guide the implant, consequently, potentially reducing the use of fluoroscopy and limiting the amount of projections (and contrast injections) required to interpret the angiograms. In all patients, in whom the CS was successfully reconstructed, navigation within the CS was only based on the reconstruction irrespective of whether vectors were automatically selected or manually adjusted.

Limitations of the study

One limitation of this technique is that the 3D model of the vessel is obtained from static images of a beating heart. Although the fluoroscopic images used to perform the reconstruction were ECG-gated, it remains a static model that is being used to guide an implantation performed in a beating heart. Also, respirator movements are not compensated by this system. Consequently, inaccuracies of magnetic navigation based on this 3D reconstructed model may also be due to a lack of compensation for respiratory movements and cardiac cycle. Whether developments as rotational angiography will serve as better models for magnetic navigation is another step to investigate.[8] Nonetheless, these limitations would be applicable also for this technique. However, nowadays, it is not possible to integrate rotational angiography into the magnetic navigation system.

Another limitation of the present version of the software is that it allows reconstruction of the body of the vessel and only one SB or bifurcation. In this way, in order to navigate to a different SB than the initially selected, a new reconstruction using the second SB was required.

In our view, once the guiding sheath and the guidewire can be remotely advanced using an advancer system similar to the one used for radiofrequency ablation catheters,[9–12] this software will allow remote LV lead implantations with minimal fluoroscopic exposure. One example is the patient in whom navigation using the reconstructed CS image was enough to engage the desired SB without the use of fluoroscopy.

Conclusion

A reliable 3D reconstruction of the CS can be performed using at least two complementary angiographic views. This reconstruction, when integrated into the magnetic navigation system, allows accurate navigation within the vessel of a magnetically steered guidewire to perform LV lead implantations.

Conflict of interest: none declared.

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