Cardiac Resynchronization Therapy Device Implantation Using a New Sensor-Based Navigation System

Results From the First Human Use Study

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Background—Cardiac resynchronization therapy (CRT) device implantation can be challenging, time consuming, and fluoroscopy intense. To facilitate left ventricular lead placement, a novel sensor-based electromagnetic tracking system (MediGuide Technology [MGT], St. Jude Medical) has been developed. We report the results of the First Human Use study evaluating the feasibility, safety, and performance of a novel CRT implantation approach using electromagnetic trackable operation equipment.

Methods and Results—Fifteen consecutive patients (66±8 years, 53% male) with an established indication for CRT were implanted using the new tracking technology. Demographics, anatomical information, detailed fluoroscopy need, procedure time, and adverse events were collected. Patients were followed up for 4 weeks after implantation. The CRT system was successfully implanted with a lateral or posterolateral left ventricular lead position in all patients. The total procedure time was 116±43 minutes, the median total fluoroscopy time (skin to skin) was 5.2 (Q1–Q3, 3.0–8.4) minutes, and the median fluoroscopy time for left ventricular lead deployment (coronary sinus [CS] cannulation to withdrawal of CS sheath) measured 2.6 (Q1–Q3, 1.6–5.6) minutes. There were no severe complications that required an acute intervention or reoperation during the perioperative and postoperative periods.

Conclusions—Use of the MGT tracking technology allows for safe and successful CRT implantation with the potential for reduced fluoroscopy time. Future randomized studies are needed to validate these data.

Clinical Trial Registration—URL http://www.clinicaltrials.gov. Unique identifier: NCT01519739.

(*Circ Arrhythm Electrophysiol*. 2013;6:917-923.)

Key Words: cardiac resynchronization therapy ■ electromagnetic navigation ■ implantation technique ■ radiation exposure ■ tracking

Cardiac resynchronization therapy (CRT) is a well-established treatment option for patients with congestive heart failure[1] with a rapidly increasing number of implantations worldwide.[2] Conventional fluoroscopy is used to guide the implantation procedure, and radiation exposure remains a major concern even for experienced operators using an up-to-date fluoroscopy scanner.[3] Recently published data of a large registry show a mean total fluoroscopy time for CRT implantation of 22±18 minutes.[4] Most recently, a novel sensor-based electromagnetic tracking system (EMTS; MediGuide Technology, St. Jude Medical Inc., St. Paul, MN] has been introduced for coronary interventions and catheter ablation procedures. As a unique feature, the system is coregistered with fluoroscopy imaging, allowing for 3-dimensional tracking of sensor-equipped catheter tools within cardiac chamber models compensated for primary cardiac movement attributable to the heartbeats and secondary organ motion through respiration and patient movement.[5,6]

Clinical Perspective on p 923

We report the first clinical experience using such tracking technology for implantation of CRT devices (First Human Use study; ClinicalTrials.gov Identifier: NCT01519739). The objectives of this study were to investigate the safety and feasibility of CRT implantation, using nonfluoroscopic device tracking of sensor-embedded left ventricular (LV) delivery tools within prerecorded cine-loops, and to assess the impact of this implantation approach on procedural data such as fluoroscopy time and radiation exposure.

Methods

A prospective observational feasibility study was performed at our institution between January and February 2012. Implantation

Received February 22, 2013; accepted July 15, 2013.

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The online-only Data Supplement is available at http://circep.ahajournals.org/lookup/suppl/doi:10.1161/CIRCEP.113.000066/-/DC1.

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procedures were performed in fasting state by 3 experienced operators (S.R., M.D., and C.P.). The local ethics committee and the German Federal Institute for Drugs and Medical Devices (BfArM) approved the study, and all patients provided written and verbal informed consent to participate in the study.

Patient Selection

We included 15 patients scheduled for implantation of a CRT device according to the current European Society of Cardiology/American Heart Association guidelines.[7,8] Patients had to be ≥18 years old and in sinus rhythm or continuously paced to ensure stable cycle lengths during fluoroscopic image acquisition.

Technology Description

The new electromagnetic tracking system has been described previously.[9,10] Briefly, the system consists of miniaturized submillimeter single-coil sensors embedded in various tools that generate electrical currents once placed within an alternating electromagnetic field and can be tracked in real time. Information about the spatial relationship between the patient and the electromagnetic tracking field is obtained through a reference sensor attached to the patient's chest. The field generator is installed within the fluoroscopy detector of a conventional flat panel X-ray imaging system (Siemens Artis Zee 20×20, Erlangen, Germany). Using this hardware setup, fluoroscopic imaging and electromagnetic sensor tracking are prealigned and autoregistered. That way the three-dimensional (3D) real-time localization of sensor-equipped implantation tools can be projected onto preacquired live X-ray loops or cine-loops for visualization within a moving organ. Built-in algorithms compensate catheter tracking and image display with respect to primary cardiac motion or respiration and patient movement.

Implantation Procedure

Participants underwent an upgrade of a dual-chamber device or a de novo implantation of a CRT device. During the operation, patients were in conscious sedation and were monitored with invasive blood pressure, electrocardiogram (ECG), and oxygen saturation. The right atrial and right ventricular leads were implanted in the right atrial appendage and midventricular RV septum or septal RV outflow tract, respectively, using conventional fluoroscopy. Use of the new electromagnetic tracking technology was specifically dedicated to the implantation of the LV lead. Particular fluoroscopy times for implantation of the right-sided leads, coronary sinus (CS) intubation, and positioning of the LV lead were collected as well as the need of intravenous radiopaque material.

Application of the Electromagnetic Tracking System

In the present study, 4 distinct sensor-equipped devices were used: (1) a nonsteerable 8 F outer sheath (CPS Direct, Mediguide Enabled, St. Jude Medical Inc., St. Paul, MN), available in 3 different shapes (135°, 115°, and wide curve), for CS cannulation and delivery of the LV lead, (2) a nonsteerable 5.9 F inner sheath with a 90° or 135° curve (CPS Aim, Mediguide Enabled, St. Jude Medical Inc., St. Paul, MN) for selective intubation of a target vein side branch and delivery of a 4 F LV lead, (3) a steerable decapolar catheter (Livewire Catheter, Mediguide Enabled, St. Jude Medical Inc., St. Paul, MN) for CS intubation, and (4) a sensor-embedded 0.36 mm guidewire (Guidewire, Mediguide Enabled, St. Jude Medical Inc., St. Paul, MN), available in soft, medium, and stiff, for target vein access and over-the-wire lead deployment. All these devices can be cable connected to the patient interface unit of the EMTS. The sensors mounted on the tip of the different tools were displayed within the electromagnetic tracking system using different icons showing the position and spatial orientation of the sensor. The LV lead was not equipped with a sensor.

Nonfluoroscopic Intubation of the Coronary Sinus

After implantation of the right-sided leads, 2 ECG-gated X-ray cine-loops were recorded in a left anterior oblique (LAO 40±10°) and in a right anterior oblique (RAO 10±10°) view with a rate of 15 frames/second, which afterwards served as initial surrounding images for real-time catheter navigation. After insertion of the sensor-equipped outer sheath, the superior caval vein was landmarked. Subsequently, the system was able to compute and virtually display the device shaft between the sensor-equipped device tip and the superior caval vein landmark (Figure 1). Nonfluoroscopic CS intubation was performed using the outer sheath alone or together with the sensor-equipped steerable catheter (Figure 1; Movie I in the online-only Data Supplement). As safeguard, the operator was advised to use confirmatory live fluoroscopy in case of any uncertainty of the in vivo situation of the electromagnetically tracked tools.

Delivery of the Left Ventricular Lead

After successful intubation of the CS, an occlusive venogram using iodine contrast was performed in the 2 abovementioned projections and recorded within the system. These ECG-gated cine-loops displaying cardiac and CS anatomy served as further models for subsequent catheter/guidewire tracking and positioning of the LV lead (Figure 2; Movie II in the online-only Data Supplement). To get target vein access, 2 different approaches were used: (1) direct advancement of a sensor-equipped guidewire into the target vein and deployment of the electrode over the wire, or (2) subselective intubation of the target vein with a sensor-equipped inner sheath and deployment of a 4-french electrode (Quickflex μ or Quartet™, St. Jude Medical Inc., St. Paul, MN; Figure 3A; Movie III in the online-only Data Supplement). Final lead deployment required live fluoroscopy to judge the actual lead position because the LV lead was not equipped with a sensor and, hence, could not be displayed within the system. However, LV lead deployment was facilitated by a motion compensated superimposed angiographic CS anatomy, comparable with a moving road map (Figure 3B; Movie IV in the online-only Data Supplement).

Electrodes were preferably positioned to the midventricular posterolateral LV wall, and electric measurements were collected on pacing threshold and phrenic nerve capture. After removal of the slittable inner and outer sheaths, all electrodes were connected to a biventricular pacemaker or implantable cardioverter-defibrillator.

Postprocedural Care and Follow-Up

All patients underwent chest radiographs, transthoracic echocardiography, device interrogation, and taking of blood samples the day after the implantation procedure. Complications related to the CRT implantation procedure were recorded. A follow-up visit was scheduled after 4 weeks including clinical examination and device interrogation.

Data Analysis

The data were tested for normal (gaussian) distribution using the Kolmogoroff–Smirnov test. Normally distributed continuous variables are presented as mean±SD. In case of a nongaussian distribution, median and quartiles are given. Categorical variables are expressed as number and percentage of patients. All analyses were performed using SPSS for Windows, Release 17.0 (SPSS Inc., Chicago, IL).

Results

Study Population

The study population consisted of 15 consecutive patients (8 male, 53%) with a mean age of 66±8 years (range 52–77). Thirteen patients (87%) underwent a de novo implantation of a CRT device; the remaining 2 patients (13%) were upgraded from a dual-chamber device to CRT. Of the 15 study patients, 10 (67%) were implanted with a CRT–implantable cardioverter-defibrillator, and 5 (33%) patients were implanted with a CRT-pacemaker. The Table summarizes the clinical characteristics of

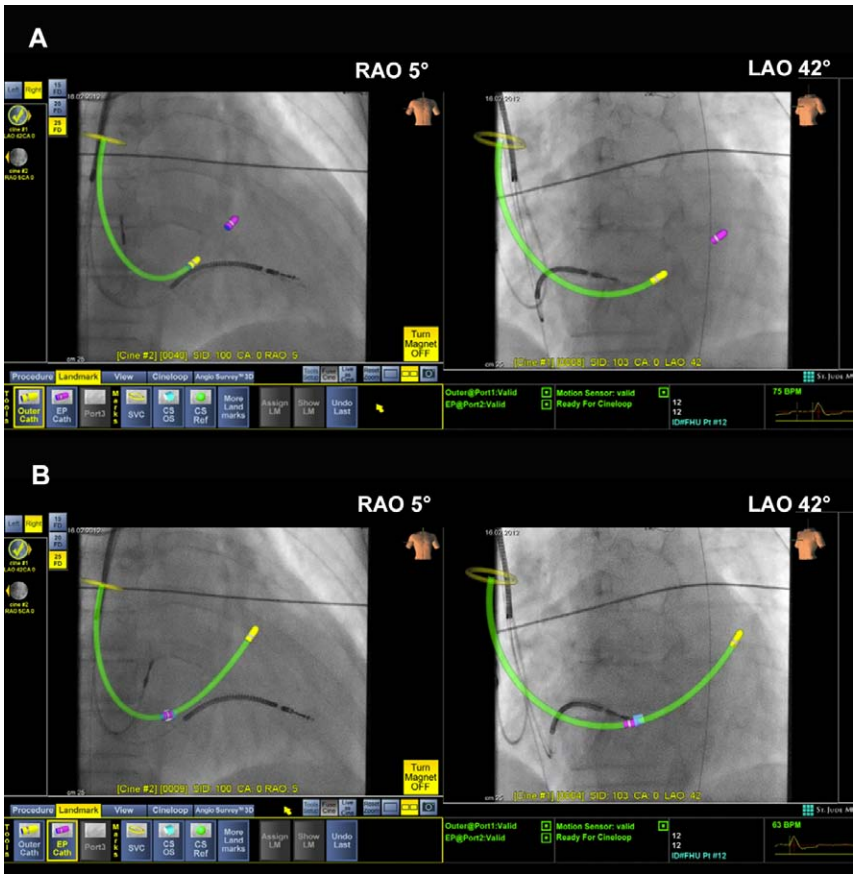

Figure 1. Nonfluoroscopic intubation of the coronary sinus (CS) on prerecorded cine-loops in right anterior oblique 5° (RAO 5°; **left**) and left anterior oblique 42° (LAO 42°; **right**) projection using an electromagnetic tracking system–enabled CS guiding catheter and steerable decapolar catheter (Lifewire™; see Movie I in the online-only Data Supplement). **A**, CS intubation with the Lifewire™ catheter (purple icon) and CS guiding catheter (yellow icon). **B**, Advancement of the CS guiding catheter and creation of a CS ostium landmark (blue icon) at the tip of the withdrawn Lifewire™ catheter. The entrance of the superior caval vein (SVC) into the right atrium has been tagged with a yellow ring icon. The shaft of the CS guiding catheter (displayed in green) is rendered between the SVC landmark and the tip of the catheter.

the study population. The mean LV ejection fraction measured 27±8%. Most of the patients were in NYHA functional class III, had left bundle–branch block, and were in sinus rhythm at enrolment. The mean intrinsic QRS duration of the 13 patients with left bundle–branch block measured 159±17 milliseconds. Two patients had persistent atrial fibrillation with complete atrioventricular block and need for permanent right ventricular pacing.

Procedural Data

The LV lead was successfully implanted in the target vein in all 15 patients without severe adverse events. Lead deployment using the electromagnetic tracking system was possible in 13 of the 15 patients (87%); in the remaining 2 patients, a tortuous venous anatomy forced the operator to abandon the system for safety reasons. The LV lead was finally placed in a posterolateral position in 10 patients (67%), in a posterior position in 2 patients (13%), and in a lateral position in 3 (20%) patients. The LV lead was successfully implanted within the first attempt of deployment in 9 of the 15 patients (60%). The remaining 6 patients (40%) needed a mean of 2.3±0.5 attempts for successful final lead positioning, predominantly because of lead dislocation while slitting the delivery sheaths. Table I in the online-only Data Supplement depicts the anatomical information collected during the CRT implantation procedures. Intraoperative measurements of the pacing parameters are given in Table II in the online-only Data Supplement.

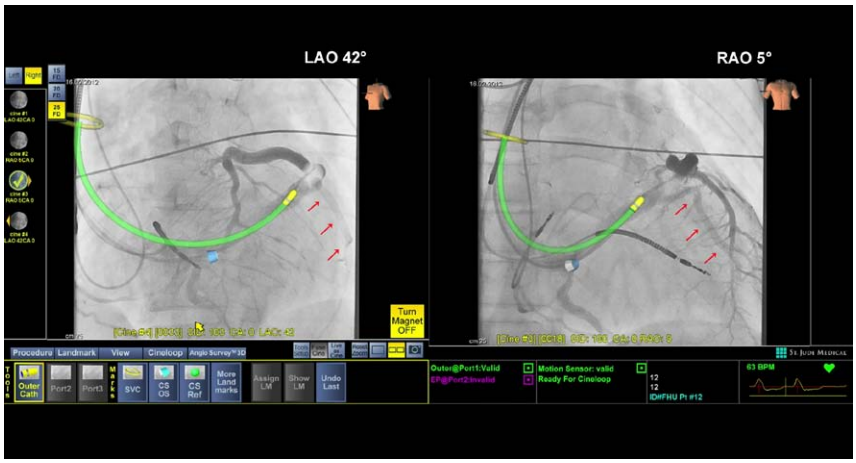

Figure 2. Cine-loops recorded during occlusive coronary sinus (CS) venography in right anterior oblique 5° (RAO 5°; **right**) and left anterior oblique 42° (LAO 42°; **left**) projection show a suitable posterolateral target vein (red arrows; see Movie II in the online-only Data Supplement). The CS ostium has been tagged with a blue icon. The entrance of the superior caval vein (SVC) into the right atrium has been tagged with a yellow ring icon. The shaft of the CS guiding catheter (displayed in green) is rendered between the SVC landmark and the tip of the catheter (yellow icon).

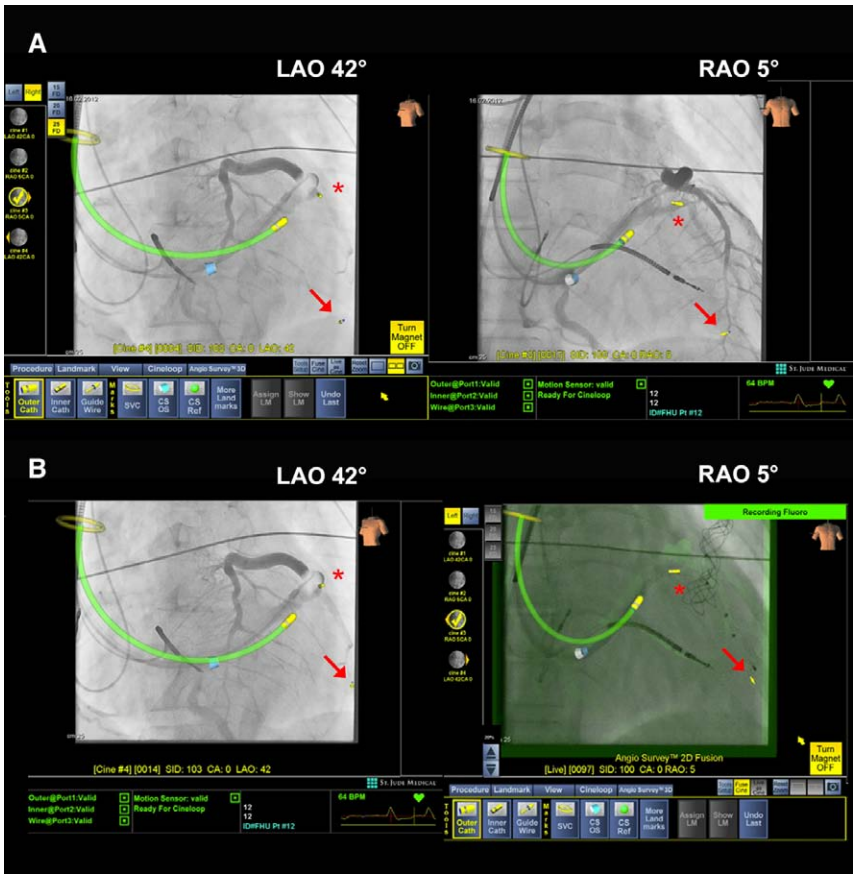

Figure 3. Nonfluoroscopic subselection of the coronary sinus (CS) target vein on prerecorded cine-loops (see Movie II in the online-only Data Supplement) in right anterior oblique 5° (RAO 5°; **right**) and left anterior oblique 42° (LAO 42°; **left**) projection using an electromagnetic tracking system (EMTS)–enabled subselector and guidewire (see Movie III in the online-only Data Supplement). **A**, A guidewire (yellow arrow-like icon; arrows) has been introduced into the posterolateral target vein through a subselector (yellow icon; asterisks) positioned at the ostium of the vein. **B**, Advancement of the quadripolar CS electrode (Quartet, St. Jude Medical) by use of fluoroscopy and integrated display of the EMTS-enabled delivery tools in RAO projection (**right**).

Procedure Duration

The total procedure time measured 116±43 minutes. The median LV lead delivery times assessed from (1) outer sheath insertion to successful CS cannulation and (2) CS cannulation to final LV lead deployment were 6 minutes (Q1–Q3, 4–12) and 33 minutes (Q1–Q3, 24–51), respectively. A mean of 61±31 ml of contrast dye was needed during the procedure.

Use of Fluoroscopy

The median total fluoroscopy time (skin to skin) was 5.2 minutes (Q1–Q3, 3.0–8.4), and the median fluoroscopy time for LV lead implantation (CS cannulation to final LV lead placement) was 2.6 minutes (Q1–Q3, 1.6–5.6; Figure 4). Of particular interest, no fluoroscopy was needed for CS cannulation in 12 of 15 cases (80%). The upmost fluoroscopy time needed for sole CS intubation was 2.0 minutes in a patient with a pronounced Thebesian valve and a vertical CS. The median total radiation exposure given as dose area product was 10.7 Gy·cm^2 (Q1–Q3, 6.9–17.4), and the median radiation exposure for LV lead implantation (CS cannulation to final LV lead placement) was 9.2 Gy·cm^2 (Q1–Q3, 6.1–16.2; Figure 5).

Complications

None of the study patients experienced a major adverse event necessitating any acute intervention. However, 5 patients (33%) experienced minor intraprocedural complications. In 4 patients, LV lead dislodgement occurred while slitting the subselector, which required lead repositioning. In another patient, guidewire perforation without relevant pericardial effusion occurred while advancing a conventional guidewire over a severely tortuous target vein takeoff.

In 2 out of these 5 patients, severe target vein kinking was the reason for the operator to switch to conventional fluoroscopy. In the first patient, LV lead deployment using the EMTS had been successfully completed with a fluoroscopy time of 10.5 minutes. However, lead dislocation occurred during subselector slitting. Using a conventional fluoroscopic approach, another 62.2 minutes of radiation exposure was needed to regain the initial lead position. In the second patient with tortuous target vein takeoff, the conventional guidewire perforated, as described above. The patient remained hemodynamically stable, did not need a pericardial puncture, and could eventually be implanted successfully with 18.4 minutes of total fluoroscopy time.

Predischarge and Follow-Up Visit

There were no major adverse events at the time of predischarge and 1-month follow-up. Two patients had intermittent phrenic nerve stimulation, which could be abolished by reprogramming of the LV lead pacing parameters in both cases. The pacing parameters remained stable and within normal limits at 1-month follow-up.

Discussion

Main Findings of the Study

The novel sensor-based electromagnetic tracking system is a safe and feasible technology to guide LV lead deployment. In all patients, the LV lead was successfully implanted without

Table. Clinical Characteristics of the 15 Study Patients

Characteristics	
Age, y	66±8
Male sex, n (%)	8 (53)
Ischemic heart disease, n (%)	5 (33)
Nonischemic heart disease, n (%)	10 (67)
NYHA functional class, n (%)	
NYHA II	1 (7)
NYHA III	14 (93)
Cardiac risk factors	
Hypertension, n (%)	14 (93)
Diabetes mellitus, n (%)	4 (27)
Atrial fibrillation, n (%)	3 (20)
GFR, ml/min	68±19
Electrocardiographic parameters	
Sinus rhythm, n (%)	12 (80)
Intrinsic QRS duration, ms	159±17
Left bundle–branch block, n (%)	13 (87)
Permanent RV pacing, n (%)	2 (13)
Echocardiographic parameters	
LVEF, %	27±6
LVEDD, mm	64±12
Medications, n (%)	
β-Blocker	15 (100)
ACE-inhibitor/ARB	14 (93)
Aldosterone antagonist	12 (80)
Diuretic	15 (100)
Digitalis	3 (20)
Implanted cardiac device, n (%)	
ICD	10 (67)
Pacemaker	5 (33)

Plus or minus values are mean±SD. ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; GFR, glomerular filtration rate; ICD, implantable cardioverter-defibrillator; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; and RV, right ventricular.

any major adverse event related to the system. In comparison with published data, we observed a substantial reduction in fluoroscopy time and radiation exposure.

Need for Improved Intracardiac Orientation

Conventional fluoroscopy is taking the center stage in tracking of intracardiac delivery tools and electrodes during CRT implantation. With this approach, LV lead implantation is feasible in the majority of patients, but can be time consuming, and associated with extensive use of radiation.[11] In addition to the radiation risks for patients and medical staff,[12–14] conventional fluoroscopy can only provide 2-dimensional (2D) intracardiac orientation. In times, however, when individually guided LV lead deployment or multisite pacing is discussed to overcome CRT nonresponse, better intracardiac orientation alone or in combination with fused imaging modalities may become relevant beyond the aspect of pure radiation reduction.[15]

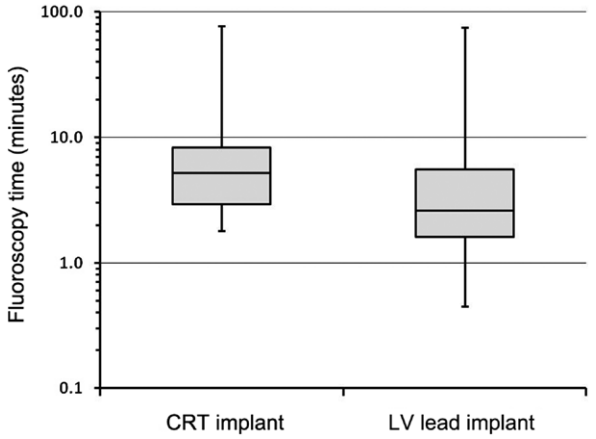

Figure 4. Fluoroscopy time for cardiac resynchronization therapy (CRT) implantation procedure (skin to skin) and left ventricular (LV) lead implantation (coronary sinus [CS] cannulation to final LV lead placement). The median total fluoroscopy time was 5.2 (Q1–Q3, 3.0–8.4) minutes, and the median fluoroscopy time for LV lead implantation was 2.6 (Q1–Q3, 1.6–5.6) minutes.

Methods to Improve Intracardiac Orientation

Different approaches have been suggested to improve intracardiac orientation during CRT implantation. Duckett and coworkers[16] reported the use of preinterventionally acquired cardiac magnetic resonance or computerized tomographic images to guide LV lead implantation. Preprocedural cardiac magnetic resonance or computerized tomographic imaging data were integrated into live fluoroscopy with respiratory motion compensation. Although this fused imaging modality resulted in an improved intracardiac orientation, total radiation exposure could not be reduced significantly. More recently, magnetic navigation using a dedicated guidewire (Cronus™, Stereotaxis Inc., St. Louis, MS) has been shown to be a safe and feasible alternative for LV lead placement during CRT

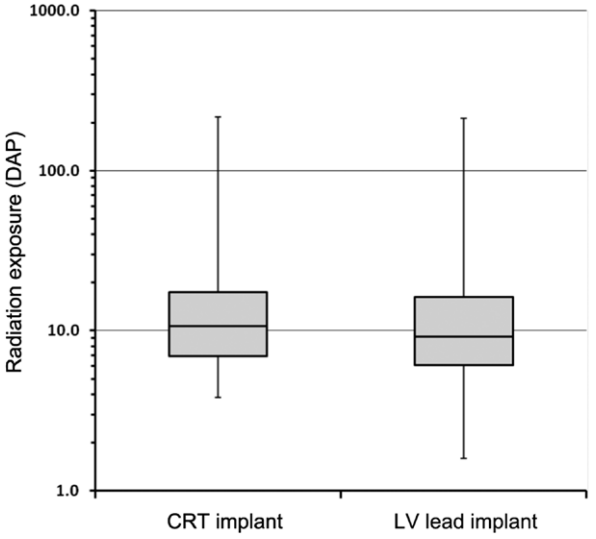

Figure 5. Radiation exposure for cardiac resynchronization therapy (CRT) implantation procedure (skin to skin) and left ventricular (LV) lead implantation (coronary sinus [CS] cannulation to final LV lead placement). The median total radiation exposure was 10.7 (Q1–Q3, 6.9–17.4) Gy·cm^2, and the median radiation exposure for LV lead implantation was 9.2 (Q1–Q3, 6.1–16.2) Gy·cm^2. DAP indicates dose area product.

implantation.[17,18] Compared with the conventional approach, Gallagher and associates[17] observed a trend towards reduced procedure and fluoroscopy times using magnetic navigation. Although primary results are promising, the Stereotaxis™ system seems to be inexpedient for this purpose.

In contrast to these technologies, for the first time the novel electromagnetic tracking system incorporates various aspects of organ mobility into technical solutions of catheter-tip localization. It is the only technology allowing for 3D catheter tracking in real time, without influence from primary or secondary organ motion. Therefore, after appropriate image acquisition, catheter tracking can be performed in dynamic images of the cardiac target anatomy. According to the hardware setup, the tracking capabilities are provided within the usual working environment and workflow of a conventional CRT implantation.

First Implementation During CRT Implantation

We implemented the system at several steps into our workflow during CRT implantation. First, nonfluoroscopic CS intubation within prerecorded cine-loops was successfully performed in the majority (80%) of patients (Figure 1; Movie I in the online-only Data Supplement). In 3 patients, the CS could not be engaged nonfluoroscopically, which was primarily caused by a difficult venous anatomy rather than problems with catheter tracking. The second more relevant step was the implementation during positioning of the LV lead. In contrast to conventional 2D monoplane fluoroscopy, the system enabled us to navigate various delivery tools in 3D space and to simultaneously display them in 2 different projections (pseudobiplane mode; Figure 3A; Movie III in the online-only Data Supplement). That way it was possible to work partially nonfluoroscopic and to overall improve the operators' orientation. As a result, radiation time and exposure could be minimized. Eventually, although live fluoroscopy was needed, motion compensated overlay of the prerecorded venous tree over the live X-ray image (road map) still generated additional benefit for intracardiac orientation (Figure 3B; Movie IV in the online-only Data Supplement).

The procedures performed in this study using the new EMTS tended to be slightly longer than reported from conventional implantations. However, reasons for extra time needed may be (1) a learning curve in applying the technology and its features and (2) the clinical study setup with time needed for documentation and data acquisition.

Adverse Events and Safety

The LV lead was successfully implanted without any major adverse event related to the system in all study patients. However, minor intraprocedural complications occurred in 5 patients, which were basically related to a learning curve about device handling (ie, slitting of the EMTS-enabled subselector). In 2 patients, severe target vein kinking forced the operator to switch to conventional fluoroscopy. In one of them, CS perforation occurred while advancing a conventional guidewire over a severely tortuous vein takeoff. The perforation did not result in a relevant pericardial effusion, and the procedure could be safely completed. There was no major complication that required any acute intraprocedural intervention or early reoperation during follow-up. Overall, the new nonfluoroscopic navigation system turned out to be a safe and effective technology for LV lead placement.

Future Developments

The data collected during this initial clinical study certainly need confirmation in an adequately powered and randomized trial. Application of the new EMTS technology in CRT patients, however, contains further fields of potential clinical use rather than just making procedures easier and less fluoroscopy intense. The capability of the technology of real-time sensor tracking offers the possibility to record/map actual wall motion data from the LV endocardium and epicardium. Such information may become relevant for tailored LV lead use to optimize CRT response and clinical outcome in patients with heart failure.

Study Limitations

At present, only the tip of the different sensor-equipped tools is tracked, and the shaft of the outer sheath is computed and virtually displayed. No information, however, is provided on the behavior of the shaft of the guiding catheters or guidewires. Therefore, the present system application has its limitations in cases with a difficult CS anatomy. Furthermore, current versions of the LV lead (as a permanent implantation) are not equipped with a sensor. As a consequence, final LV lead positioning required fluoroscopy in each case (Movie IV in the online-only Data Supplement). The problem of lead dislodgement during subselector slitting is partially conditioned by the different handling of the sensor-equipped sheaths with a greater outer diameter and resolved after the operators got used to the new tools and passed through a rapid learning curve. According to the study protocol, we had to perform occlusive CS venograms in 2 different angulations (LAO + RAO) in each patient. For cine-loop recording, the system requires a longer dye injection period than usually needed to get a valuable image of the CS anatomy. Moreover, in some cases, injection-induced premature beats occurred, which required reinjection attributable to invalid ECG-triggering. This explains the relatively high amount of contrast agent given in our study. Finally, our data are limited by the small sample size and the lack of a control group.

Conclusions

Implementation of this new EMTS during CRT implantation is safe and feasible. The concept of sensor-based tracking of lead delivery tools within moving cardiac chamber models has the potential to reduce radiation exposure with similar procedural outcome. Future randomized studies are needed to confirm our findings.

Sources of Funding

The study was supported by a research grant from St. Jude Medical.

Disclosures

M. Döring and S. John have received modest lecture honoraria from St. Jude Medical and Biotronik. S. Richter, T. Gaspar, S. Rolf, and P. Sommer have received modest lecture honoraria and congress sponsoring from St. Jude Medical, Biotronik, and Biosense Webster.

G. Hindricks has received modest lecture honoraria from St. Jude Medical, Biotronik, Medtronic, and Biosense Webster and is a member of the St. Jude Medical and Biosense Webster Advisory Board. C. Piorkowski has received modest lecture honoraria from St. Jude Medical and Biotronik and is a member of the St. Jude Medical Advisory Board.

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CLINICAL PERSPECTIVE

Radiation exposure, with its potential risks and harm to patients and operators, remains a major concern during cardiovascular interventions. Electroanatomical mapping systems are widely used today to guide complex catheter ablation procedures. Most recently, a new electromagnetic tracking system (MediGuide Technology) has been introduced into interventional practice. While displaying sensor-equipped catheters and guidewires in prerecorded, ECG-gated cine-loops with compensation for primary organ motion and patient movement, the system has been demonstrated to substantially reduce radiation exposure during catheter-based ablation procedures. We evaluated the feasibility and safety of this new electromagnetic tracking system during cardiac resynchronization therapy device implantations using different sensor-equipped left ventricular lead delivery tools. By working in a pseudobiplane mode on 2 prerecorded cine-loops obtained in distinct angulations, the system provides better spatial orientation. Nonfluoroscopic intubation of the coronary sinus and subselection of the target veins were feasible in the majority of patients, and no major complications occurred during the implantation procedures and follow-up period. The median total fluoroscopy time was as low as 5.2 minutes, whereas the median procedure time measured 116 minutes. Compared with conventional fluoroscopy-based implantation techniques, this new electromagnetic tracking system holds great promise to substantially reduce fluoroscopy time while allowing for safe and successful transvenous left ventricular lead implantation with increased spatial orientation.

Cardiac Resynchronization Therapy Device Implantation Using a New Sensor-Based Navigation System: Results From the First Human Use Study

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Circ Arrhythm Electrophysiol. 2013;6:917-923; originally published online September 3, 2013;
doi: 10.1161/CIRCEP.113.000066
Circulation: Arrhythmia and Electrophysiology is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 1941-3149. Online ISSN: 1941-3084

SUPPLEMENTAL MATERIAL

Supplemental Table 1.

Anatomical information

Anatomical information	**Parameters**	**n (%)**
CS anatomy*	Normal	10 (67)
	Small CS	1 (7)
	Tortuous CS	3 (20)
	Low CS ostium	0 (0)
	Thebesian valve present	3 (20)
	Double-os CS	0 (0)
	High CS ostium	1 (7)
	CS stenosis or occlusion	0 (0)
	Valve of Vieussens (mid-CS valve) present	0 (0)
CS side branches present*	Anterior	2 (13)
	Antero-lateral	6 (40)
	Lateral	7 (47)
	Middle cardiac vein	15 (100)
	Posterior	5 (33)
	Postero-lateral	11 (73)
CS target vein size	Small	0 (0)
	Average	7 (47)
	Large	8 (53)
CS target vein tortuosity	Minimal	6 (40)
	Moderate	6 (40)
	Severe	3 (20)
CS target vein take-off angle	$< 90^{o}$ (acute)	7 (47)
	90^{o}	3 (20)
	$> 90^{o}$ (obtuse)	5 (33)
Right atrial size	Normal	8 (53)
	Enlarged	7 (47)

CS, coronary sinus; *some patients revealed >1 anatomical feature.

Supplemental Table 2.

Intraoperative measurements

Device measurements	**n (%)**	
LV pacing configuration	LV (15/15)	LV tip – LV ring: 7 (47) LV ring – RV coil: 4 (27) E1 – E4: 2 (13) E3 – E2: 1 (7) E4 – RV coil: 1 (7)
Pacing threshold	RA (13/15) RV (15/15) LV (15/15)	0.6 ± 0.2 V / 0.5 ± 0.2 ms 0.7 ± 0.1 V / 0.5 ± 0.1 ms 1.0 ± 0.4 V / 1.0 ± 0.5 ms
Signal amplitude	RA (12/15) RV (13/15)	2.8 ± 1.4 mV 11.4 ± 1.6 mV
Pacing impedance	RA (13/15) RV (15/15) LV (15/15)	548 ± 132 Ω 583 ± 115 Ω 778 ± 225 Ω

RA, right atrium; RV, right ventricle; LV, left ventricle. E1-4 refers to the 4 electrodes (E) of the St. Jude Medical Quartet™ quadripolar CS lead (1, distal; 4 proximal).

Movie 1:

CS cannulation using outer sheath and steerable CS catheter (Livewire™)

Non-fluoroscopic intubation of the coronary sinus (CS) on pre-recorded cine-loops in RAO 5° (left) and LAO 42° (right) projection using an EMTS-enabled CS guiding catheter and steerable decapolar catheter (Lifewire™). After positioning of the tip of the CS guiding catheter at the CS ostium (yellow icon), the Lifewire™ catheter (purple icon) is being introduced and advanced into the CS. Thereupon the CS guiding catheter is being advanced over the Lifewire™ catheter into the CS. Finally, the Lifewire™ catheter is being withdrawn and positioned at the CS ostium to create a CS ostium landmark (not shown; blue icon in the subsequent movies). Note that the entrance of the SVC into the right atrium has been tagged with a yellow ring icon. The shaft of the CS guiding catheter (displayed in green) is rendered between the SVC landmark and the tip of the catheter.

Movie 2:

Acquisition of CS venogram cine-loops

Occlusive CS venogram cine-loops are being recorded consecutively in RAO 5° and LAO 42° projection (left panel). Conventional fluoroscopy is indicated in green as “recording fluoro“, fluoroscopic cine-loop recording in yellow (pre-recording) and green (recording) as “recording cine“. Finally, the recorded CS venogram cine-loops are displayed simultaneously and motion-compensated with the LAO projection on the left and RAO projection on the right. These ECG-gated CS venogram cine-loops serve as underlying model for subsequent catheter and guidewire tracking and positioning of the LV lead. The CS ostium has been tagged with a blue icon, the entrance of the SVC into the right atrium with a yellow ring icon. The shaft of the CS guiding catheter (displayed in green) is rendered between the SVC landmark and the tip of the catheter (yellow icon).

Movie 3.

Target vein access using sub-selector and guidewire

Non-fluoroscopic sub-selection of the CS target vein on pre-recorded CS venogram cine-loops (see Movie 2) in RAO 5° (left) and LAO 42° (right) projection using an EMTS-enabled sub-selector and guidewire. At first, the sub-selector (yellow icon) is being introduced and positioned at the ostium of the target vein. Thereupon, a guidewire (yellow arrow-like icon) is being introduced and advanced deeply into the posterolateral target vein through the subselector. The CS ostium has been tagged with a blue icon, the entrance of the SVC into the right atrium with a yellow ring icon. The shaft of the CS guiding catheter (displayed in green) is rendered between the SVC landmark and the tip of the catheter (yellow major icon).

Movie 4.

LV lead deployment with motion-compensated 2D overlay

Advancement of a quadripolar CS electrode (Quartet™, St. Jude Medical) into the target vein by use of fluoroscopy (“recording fluoro”) and motion-compensated 2D overlay of the CS venogram and integrated EMTS-enabled delivery tools in RAO projection (left panel). The corresponding non-fluoroscopic LAO view is displayed simultaneously on the right. Note that the LV lead is not equipped with an EMTS-enabled sensor making conventional fluoroscopy

necessary for final lead deployment. Icons are the same as described in the previous movies.