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Non-Fluoroscopic Transseptal Catheterization During Electrophysiology Procedures using a Remote Magnetic Navigation System

Bich Lien Nguyen, MD, PhD, Jose L Merino, MD, Yehoshua Shachar, BS, Alejandro Estrada, MD, David Doiny, MD, Sergio Castrejon, MD, Bruce Marx, BSME, David Johnson, BSEE, Wanda Marfori, MD, Eli S Gang, MD

Electrophysiology Section, Division of Cardiology, Department of Medicine, Cedars-Sinai Medical Center Los Angeles, California (B.L.N., E.S.G.). Electrophysiology Section, Heart and Great Vessels Department, Umberto I Hospital, Sapienza University of Rome, Italy (B.L.N.). Arrhythmia and Cardiac Electrophysiology Robotic Unit, La Paz University Hospital, Madrid, Spain (J.L.M., A.E., D.D., S.C.). Magnetecs, Corp., Inglewood, California (Y.S., B.M., D.J.). Department of Radiological Sciences, David Geffen School of Medicine at UCLA (W.M.)

Abstract

Transseptal punctures are commonly performed, and left atrial (LA) access is frequently lost during lengthy, complex electrophysiology (EP) procedures. We describe a new technique for non-fluoroscopic re-crossing the fossa ovalis using a new multielectrode transseptal sheath (TS) and a new remote magnetic catheter navigation system (RMNS) (CGCI System, Magnetecs) that uses 8 rapid external electromagnets for real-time navigation of a magnet-tipped electrode catheter across the initial transseptal puncture site in 5 patients undergoing left-sided ablation procedures. The three-dimensional (3D) position of a 8.5 Fr steerable TS with 5-ring 5-15-15-5-mm spaced distal electrodes (Agilis ES©, St Jude Medical), and site of fossal ovalis crossing were "shadowed landmarks" on a 3D electroanatomic mapping (EAM) system (EnSite/NavXTM, St Jude Medical). The TS-magnetic ablation catheter assembly was pulled-back to the inferior vena cava. EAM landmarks were used with RMNS-guided "manual" and "automated" catheter navigation modalities, until septal crossing was obtained. Transseptal re-crossing was successfully performed in all patients in 6.2±8.1 sec using the "automated" RMNS-guided technique and in 30.4±28.4 sec using the "manual" RMNS-guided technique (p=0.01) without complications. This new RMNS was safely and effectively used to perform non-fluoroscopic transseptal catheterization.

Introduction

Gaining catheter access to the left-sided cardiac chambers, particularly the left atrium (LA), has become commonplace in active electrophysiology laboratories that perform ablation procedures.[1-3] Originally described in 1959[4] as a means for measuring left-sided cardiac pressures, the technique has been resurrected in recent years by clinical electrophysiologists, most frequently for performing radiofrequency catheter ablative procedures in the LA.[5] Modifications and enhancements of the original technique have included delivery of radiofrequency current to the transseptal needle to facilitate septal puncture,[6] as well as the use of laser energy to achieve the same purpose.[7] Also, enhanced visualization of the transseptal puncture using intracardiac echocardiography (ICE),[8] real-time computed tomography imaging,[9] three-dimensional (3D) electroanatomic mapping (EAM) devices,[10,11] and most recently, robotic remote navigation systems,[12] have all been introduced to clinical practice in an attempt to enhance safety, lessen the duration of the procedure, and minimize exposure to fluoroscopic radiation. In clinical practice, it is not uncommon that during the performance of a complex ablation procedure in the LA, the transseptal sheath slips back into the right atrium (RA) and access to the LA is lost. Attempts to regain the LA access can be time consuming and frustrating. Invariably, the patient had already been treated with large doses of heparin and the performance of a needle-based repeat transseptal puncture is fraught with danger. With this clinical challenge in mind, we devised a simple, rapid and safe method for repeatedly crossing the fossa ovalis during a LA procedure. The techniques described

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Transseptal Catheterization, Fluoroscopy, Catheter Ablation, Left Atrium Access, Remote Navigation.

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Corresponding Author:
Eli S Gang, MD
Cardiovascular Research Foundation
414 North Camden Drive
Beverly Hills, CA 90210

in this report do not necessitate the use of fluoroscopy. Rather, we describe a new multielectrode transseptal sheath (TS) that can be readily visualized by a 3D EAM system integrated with a new remote magnetic navigation system (RMNS, catheter guidance, control and imaging -CGCI- Magnetecs Inc, Inglewood, CA) that creates a lobed magnetic field around the subject's torso for guiding a magnet-tipped ablation catheter across the initial transseptal puncture site. By tracking the stored and displayed "shadow" of the TS when it is initially correctly positioned across the interatrial septum, its rapid re-crossing can be repeatedly achieved. When deploying the RMNS, the magnet-tipped electrode catheter can be navigated across the septum in either "manual" or "automated" magnetic modes; in the latter, the catheter is automatically guided across the septum based on stored memory of septal and left atrial anatomy. To our knowledge, this is the first report of such transseptal crossing techniques.

Material and Methods

Techniques and Technology Description

This study was part of a larger clinical study[13] in which 5 patients underwent left-sided ablation procedures (left-sided accessory pathway ablation,[1] and left sided atrial flutter ablation,[4]) using CGCI RMNS-guided mapping. The study was approved by the Institutional Review Board at La Paz Hospital, Madrid, Spain. Informed consent was obtained from all patients.

Initial Transseptal Puncture

The initial transseptal puncture and crossing of the fossa ovalis was performed using standard techniques. A decapolar coronary sinus catheter (LivewireTM, St Jude Medical, Minnetonka, MN) was positioned in the coronary sinus via the right femoral vein. A standard Brockenborough needle (BRKTM, St Jude Medical) delivered via the braided 8 Fr SL-1 sheath (St Jude Medical) using the right femoral vein and was advanced to the fossa ovalis under fluoroscopic and ICE (AcuNav, Siemens, Mountainview, CA) guidance. The thin portion of the septum was visualized by ICE and crossing at that site was achieved using the BRK needle, followed by the TS. The position of the TS within the LA was confirmed by ICE imaging and injection of contrast material. Thereafter, a 110-125 U/kg bolus of unfractionated heparin was administered and the activated clotting time was maintained > 300 sec with intermittent bolus doses of heparin. The TS was then replaced over the wire by a custom-made a 8.5 Fr Agilis ES© steerable TS with 5-ring 5-15-15-5-mm spaced distal electrodes and a distal radius approximating the SL-0 curvature (St Jude Medical) was placed in the LA. A 3D

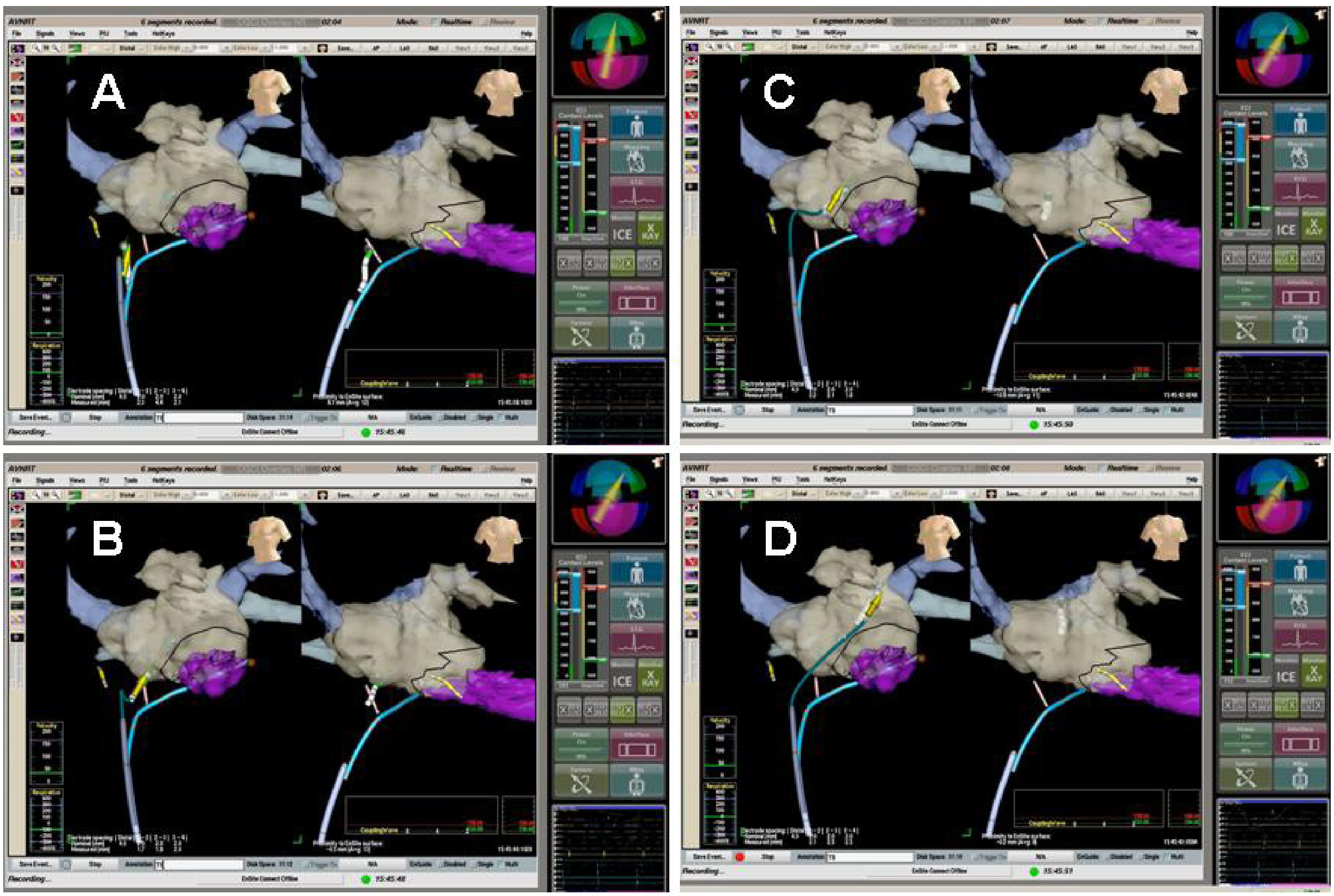

Figure 1: EnSite images of RMNS-guided catheter septal crossings. Panels A through D show the transseptal progression of the magnetic-tipped catheter from the inferior vena cava to the LA. LAO and RAO projections of the EAM are seen in each panel. The magnetic tipped ablation catheter is pointed towards a transseptal pathway "shadow" using a "manual" joystick-driven RMNS. The "shadow" is best seen in the LAO projections. The red arrow in panels B and C identifies the magnetic tipped catheter at the transseptal "shadow." A coronary sinus (CS) catheter is also seen in each image. The yellow arrow depicts the direction in which the RMNS is pointing the ablation catheter magnetic tip.

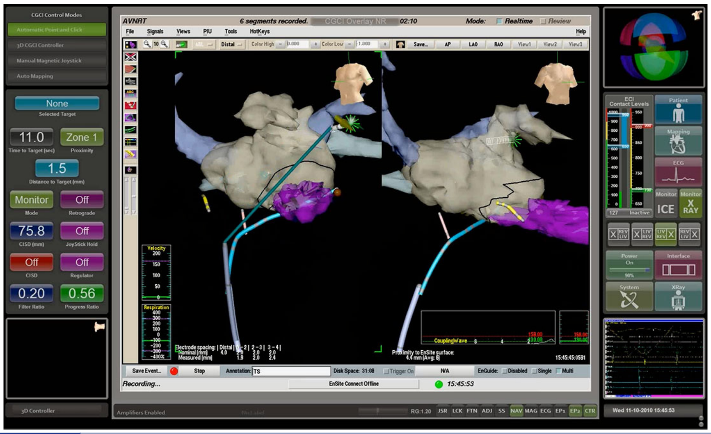

Figure 2: RMNS-guided catheter septal crossing. After withdrawal of the transseptal sheath and the magnetic-tipped catheter into the RA, automated remote navigation via the CGCI system was used for guiding the catheter across the septum. The operator first tagged a spot on the left atrial side of the septum (seen on LAO view as a light blue dot labeled "1"); upon automated crossing of the septum, the operator assumed control of magnetic navigation of the catheter via the joystick and navigated the catheter to the left and right superior veins, respectively.

electroanatomic "shell" map of the LA and its adjoining pulmonary veins was created using a 4-mm conventional ablation catheter (SafireTM, St Jude Medical) and conventional variable 15-25 mm 20-electrode circular mapping catheter (SpiralTM, St Jude Medical) and a computerized EAM system (EnSite/NavXTM/VerismoTM, St Jude Medical). The 3D transseptal position and orientation of the custom-made TS was recorded by the EAM system; a "shadowed landmark" of this anatomically correct position of the TS was superimposed onto the 3D electroanatomic "shell" map of the LA. The site of the interatrial septum crossing, i.e., the fossal ovalis, was also depicted on the 3D EAM map.

Remote Magnetic Navigation

The CGCI system has been described in detail elsewhere.[14] Briefly, an array of 8 electromagnets surrounding the torso of the subject provides real-time navigation of a magnet-tipped electrode catheter within the cardiac chambers. The magnetic field generated by this system is user-controlled, with a maximal field strength of 0.15T. The catheter can be guided in a "manual magnetic" mode, i.e., a joystick-driven navigation of the catheter with or without fluoroscopic guidance, as well as in an "automated magnetic" mode, in which points are designated on the 3D EAM map and the RMNS system controller then guides the catheter tip directly to the designated target sites.

Repeat Transseptal Catheterization

After completion of the EAM map, catheterization of the interatrial septum was tested using 2 RMNS-guided catheter septal crossing techniques in 5 patients: (a) after withdrawal of the TS sheath and the magnetic-tipped catheter into the inferior vena cava, remote navigation via the CGCI system in a "manual magnetic" mode (joystick-driven) under EnSite-guidance, was used for allowing the catheter cross to the fossa ovalis and to be repositioned in the LA using "shadowed" landmarks on the 3D shell as a "roadmap"; the catheter-sheath assembly was advanced to the "shadowed" fossa ovalis representation and crossing of the septum was achieved when the catheter was remotely moved parallel to or directly over the landmark; when necessary, the ablation catheter was further advanced and used for steering the sheath transseptally (Figure 1); (b) in the "automated magnetic" mode, an anatomic site on the left atrial 3-D map near the left atrial aspect of the interatrial septum was tagged. The RMNS then guided the catheter across the septum in an automated fashion, without the use of fluoroscopy, under EnSite-guidance (Figure 2). Time-to-crossing was recorded in each instance.

Results

A total of 5 patients (3 men, mean age 47±12 years) underwent repeat transseptal crossing during left-sided ablation procedures. In each patient, repeat septal crossing was performed 2.2±0.4 times using the "automated magnetic" CGCI maneuver, and 3.0±0.1 times using the "manual magnetic" CGCI maneuver. A total of 11 repeat crossings were performed with the RMNS "automated magnetic" technique, while 15 re-crossings were performed using the "manual magnetic" technique. The mean time required for successful interatrial septum re-crossing was significantly shorter using the RMNS "automated magnetic" technique compared to the "manual magnetic" technique (6.2±8.1 vs. 30.4±28.4 sec, n=11 and n=15, respectively, p=0.01). No complications occurred.

Discussion

The novel aspects of this report is our description of safe, rapid, reproducible and non-fluoroscopic techniques for re-crossing the interatrial septum using a new steerable magnetic ablation catheter-electrode TS assembly, an EnSite depiction of the proper TS location, and a new RMNS system for remotely guiding a catheter across the interatrial septum in an intuitive and time-saving manner. Transseptal crossing has become a mainstay of the active clinical electrophysiology laboratory. Initially used mostly for gaining access to the atrial insertion site of left-sided accessory pathways,[5] this technique is now also widely used for the ablation of atrial fibrillation and other arrhythmias arising from the LA, such as atrial flutter and ectopic atrial tachycardia.[1,2] When, during the course of such an ablation procedure, the sheath and ablation catheter dislodge back into the RA, re-crossing of the interatrial septum can add significant procedure time, and fluoroscopic exposure to the patient and the operator as well as the risks associated with performing a new transseptal puncture. The use of a novel real-time RMNS in conjunction with a clearly defined 3D landmark, or "shadow", of the multielectrode TS described in this report, placed upon the EnSite depiction of the fossa ovalis, provided a clear target and pathway for expedited crossing of the septum. Crossing of the septum using the RMNS was efficiently and safely achieved using the both "manual" and "automated" maneuvers. Importantly, all of the techniques described in this study eliminated the need for re-puncturing the septum, and the use of fluoroscopy. While the risk for performing the initial transseptal puncture has been estimated as being < 1%, [2] no studies have quantified the risk of repeated crossing of the fossa ovalis during an ablation procedure in the anticoagulated patient whose activated clotting time is frequently > 300 sec. While the feasibility of gaining initial transeptal access via 3D EAM systems [10,11] and via a robotic navigation system[12] have been described before, to our knowledge, this is the first description of repeated crossing of the interatrial septum using EAM system-guided "manual magnetic" and "automated magnetic" RMNS maneuvers on a 3D shell reconstruction in patients.

Conclusions:

We describe effective non-fluoroscopic techniques for regaining access to the LA during the performance of complex ablation procedures where repeat crossing of the interatrial septum may be difficult. A new multielectrode TS-magnetic ablation catheter assembly is maneuvered by a new RMNS, and its position and orientation can be tracked and "shadowed" by a 3D EAM system without the aid of fluoroscopy. An automated "robotic" mode is also shown to be capable of rapidly returning the catheter to the left atrium, using a previously acquired pathway across the septum. We expect that these techniques will be quickly adapted in electrophysiology laboratories when the CGCI RMNS and the multielectrode TS become more readily available.

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