EP LAB DIGEST

A New Option for Catheter Guidance Control and Imaging: Interview with Jose L. Merino, MD, PhD, FESC

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In this interview we speak with Dr. Jose Merino about Magnetecs Corporation's Catheter Guidance Control and Imaging (CGCI) system. Dr. Merino is the Director of the Arrhythmia & Electrophysiology Research Unit of Hospital General Universitario La Paz in Madrid, Spain.

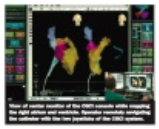

Dr. Jose Merino.

Tell us about Magnetecs Corporation's Catheter Guidance Control and Imaging (CGCI) system for patients with arrhythmia. What are the components of this system?

The system is composed of a magnetic chamber, a catheter insertion and retraction device, and a remote console from which the operator controls a magnetic catheter. The magnetic chamber is based in 8 electromagnets (coils) placed around the patient's torso. These magnets remain in a fixed position (they do not move as in other magnetic navigation systems), and do not generate a magnetic field unless electrical current flows through them. In addition, the magnetic field can be swiftly modified by changing the amount of electrical current which flows through each particular electromagnet. This highly dynamic magnetic field interacts with the magnetic tip of the catheter. The amount of catheter slack is controlled by the external device. The whole system is controlled from a remote control which also has integrated and operates all the other EP systems regularly used in the third millennium lab: EP recording system, 3D electroanatomical system, electrical stimulator, fluoroscopy system, and intracardiac echocardiography. This, in fact, is very convenient, because a single operator is in charge of everything and can determine the arrhythmia mechanism and control the ablation process, without losing time required to give instructions to different people managing the EP systems.

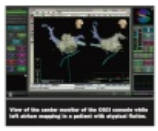
What are procedure times like using this system compared to other magnetic remote navigation systems?

The magnetic field can be changed almost instantaneously. This virtually eliminates any delay while remotely navigating the catheter, which makes the use of the system very intuitive and friendly. This is not the case for another magnetic remote navigation system which is based on the position change of heavy permanent magnets and, therefore, needs a relatively long time to change the magnetic field. Because catheter navigation to a desired intracardiac site is a composite of several individual movements and attempts, any delay between the operator's orders and the catheter response is very cumbersome and accumulates to prolong the whole process. Finally, the fast response of the CGCI system allows it to keep the catheter in a stable intracardiac position by rapidly correcting any drift due to breathing or cardiac cycle movements. This can be especially useful for radiofrequency current delivery at difficult ablation sites such as the ridge between the left superior pulmonary vein and the left atrial appendage.



What types of arrhythmia can be treated using this system? Does this include atrial fibrillation?

The system is designed to map and ablate any kind of cardiac arrhythmia from all four chambers of the heart and the great thoracic vessels. Nevertheless, atrial fibrillation ablation is the main target of the system, since this is a very prevalent and difficult arrhythmia substrate to ablate.



Describe the two human studies taking place in 2010 and 2011. What are the primary differences between these two trials? In addition, how many patients are expected to be studied during this time?

The first trial aims to demonstrate the accuracy and safety of the system in mapping the four human

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  Wed, 12/8/10 - 9:27am
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CLASSIFIED/RECRUITMENT OPPORTUNITIES

- Registered Nurse Lead - EP Lab - FT -Varied - Scripps Green Hospital - 12/20/10
  01/03/2011 - 10:40
- Cardiac Cath Lab RN and Radiologic Technologist - Tucson Medical Center - 12/15/10
  01/03/2011 - 10:39
- Electrophysiology Field Clinical Trainer - Boston Scientific - 12/14/10
  01/03/2011 - 10:35

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cardiac chambers. This has already been proven in the animal model. The trial is evaluating both operator remote navigation mapping and automatic remote navigation mapping in order to bring the catheter back to previously mapped intracardiac sites without operator intervention. The catheter being evaluated is a 4-mm electrode tip catheter. This trial is expected to enroll 40 patients and to be completed by the end of 2010 or the first quarter of 2011. The second trial is an ablation trial and will evaluate an irrigated tip ablation catheter in a sample of at least 40 patients with atrial fibrillation. This study is expected to start during the second quarter of 2011.

What interim results and/or success rates have been found thus far in the first human studies of the CGCI system?

The interim results found after 19 patients enrolled in the mapping trial are very promising. The operator was able to place the catheter on all per protocol-predefined sites (9 sites in each atria, 6 sites in the right ventricle and 5 sites in the left ventricle). During the automatic mode, the system succeeded to navigate the catheter twice to a distance shorter than 3 mm (average 2.1 mm) from the previous manually-acquired sites in 95% of the attempts. There were no significant adverse events during the procedure or at 7-day follow-up.

Tell us about the upcoming installations of the system in the US. How many locations have been selected?

Mount Sinai Medical Center in New York will be the first US center to have the system installed as an associated partner of the research program of the company, along with 2 other centers in Europe. In addition, many other centers within the US and around the world have shown their interest in the system, and agreements are under way to have the system installed shortly thereafter.

How soon could we see the CGCI system receive certification and commercialization?

The plans are to apply for CE mark certification, and the company expects to receive it shortly after the first trial completion. The amount of data gathered during the animal phase and the performance of the system during the human phase make us very optimistic about having the system very soon in the market outside the US.

What benefits are available using the CGCI system?

The most obvious are having the physician away from radiation and in a less physically demanding place of operation. However, the most important benefits are for the patient: easy and swift magnetic catheter navigation to difficult-to-reach sites for conventional catheters, having them there in contact with the tissue and stable, and, last but not least, being able to control all EP systems from a single console by a single operator, will all eventually result in shorter, safer and more efficacious procedures. Of course, all these potentials benefits remain to be proven, but the preliminary results found in the ongoing trial make us very positive about this.

Is there anything else you'd like to add?

Several renowned institutes and foundations, such the ECRI institute in the US, have placed remote navigation and robotics as one of the leading areas of development in future medicine. This system represents the second generation of these systems in EP, and I am fully convinced that it will change the paradigm from craftsman manual catheter manipulation of twentieth century medicine to reproducible and accurate remote catheter technology aided navigation of third millennium medicine.

Disclosure: Dr. Merino discloses he is a member of Magnetecs' Scientific Advisory Board, and that travel expenses were covered by Magnetecs to present preliminary results in a technology congress.

EP 101: A Surprise Visitor at the End of an Ablation

CLINICAL EVENTS CALENDAR

» **16th Annual Boston AF Symposium**
Thu, 01/13/2011 - Sat, 01/15/2011

» **Parent Heart Watch's 6th Annual National Conference**
Fri, 01/14/2011 - Sun, 01/16/2011
San Diego, CA, United States

» **International Stroke Conference 2011**
Wed, 02/09/2011 - Fri, 02/11/2011

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POLL

As a physician, do you use email to communicate with your patients?
Yes, I have communicated medical information with my patients via email when necessary.
44%
No, I do not communicate with my patients via email.
56%
Total votes: 9
33 reads Older polls

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