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Featured Review
Journal of Atrial Fibrillation

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The Unique Mediguide Technology For CRT Lead Placement And Catheter Ablation

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Abstract

Electrophysiologic procedures such as catheter ablation and/or cardiac resynchronization therapy (CRT) are usually performed under fluoroscopic guidance alone. Currently, we are witnessing the birth of a new era in which many patients can be safely and effectively treated without the use of fluoroscopy. Using MediGuide technology continuous fluoroscopy is no longer required to ascertain the position of the device/catheter, which minimizes the radiation exposure for both the physician and patient, with a further benefit by minimal need for contrast agent. This novel system provides real time tracking of devices projected into live fluoroscopy or pre-recorded cine-angiography. MediGuide technology is an important step forward facilitating complex ablation procedures such as AF ablation and CRT implantation.

Introduction

Electrophysiologic procedures such as catheter ablation and/or cardiac resynchronization therapy have been traditionally performed only with fluoroscopic guidance. Fluoroscopy provides direct visual feedback of images, taken in real time, of the position of the cardiac devices. Unfortunately, many procedures using fluoroscopic feedback expose both the patient and physician to high levels of radiation. There are several early or late side-effects of radiation exposure. An increasing number of case reports of skin changes on the hands and injuries to the lens of the eye in operators and assistants have been reported. Although cancer is uncommon, cancers associated with radiation exposure in adults may include leukemia and breast cancer. (A recent document of the American College of Cardiology recommends that all catheterization laboratories adopt the principles of 'ALARA' (radiation doses 'As Low As Reasonably Achievable'),[1] making radiation reduction an ethical issue. Many further technologies have tried to overcome these limitations, providing 3D positions of these devices. The unique Medical Position System (MPS) from MediGuide technology MG (St. Jude Medical Inc, St. Paul, MN)[2-8] uses fluoroless principles enabling localization, tracking and navigation of intracardiac devices. As a result, we are now witnessing the birth of a new era where patients can be safely and effectively treated without fluoroscopy. In our experience, the fluoroless technique is feasible, poses no additional safety concerns, and should be readily implementable in most electrophysiology laboratories worldwide without replacing careful interpretation of data and clinical experience.

The Unique MediGuide Technology

MediGuide technology has applied 3D visualization and navigation by Ensite Velocity System to a pre-recorded 2D X-ray image to create a real time navigation and ablation without use of fluoroscopy. The system consists of a transmitter unit generating a dynamic electromagnetic field and miniaturized single-coil sensors which can be tracked within that field. The sensors are mounted on intra-cardiac devices (electrophysiology catheters). A reference sensor, which is attached to the patient's chest, provides information about the spatial relationship between the patient and the tracking field. The transmitter unit is integrated in a conventional flat-panel X-ray imaging system (Siemens Artis, Erlangen, Germany). Owing to this hardware setup, fluoroscopy imaging and electromagnetic sensor tracking can be pre-aligned and auto-registered (Figure 1). With 3D localization of sensors, a real-time visualization and navigation on pre-acquired X- ray cine loops can be provided. Built in algorithms compensate catheter tracking and image display for respiration and cardiac motion. Therefore, continuous fluoroscopy is not necessary to establish the position of the catheter, thus minimizing X-ray exposure for both the physician and patient.

Safety And Effectiveness Of MediGuide

Before catheter introduction, usually a background fluoroscopy imaging is conducted, with two cine loops with a length of three cardiac cycles recorded. Three catheters can be introduced using MPS for navigation and the correct catheter positioning is confirmed with live fluoroscopy. To test the ability of the MPS to compensate for cardiac and respiration movement, coronary sinus pacing is applied, followed by a sudden displacement (20 cm) of the patient position relative to the fluoroscopy detector. The system compensated and adjusted catheter visualization during both maneuvers. Fluoroscopy is only used to obtain initial cine loops and then to confirm catheter

Disclosures:
Carlo Pappone had a consultant agreement with St. Jude. The other Authors report no conflict.

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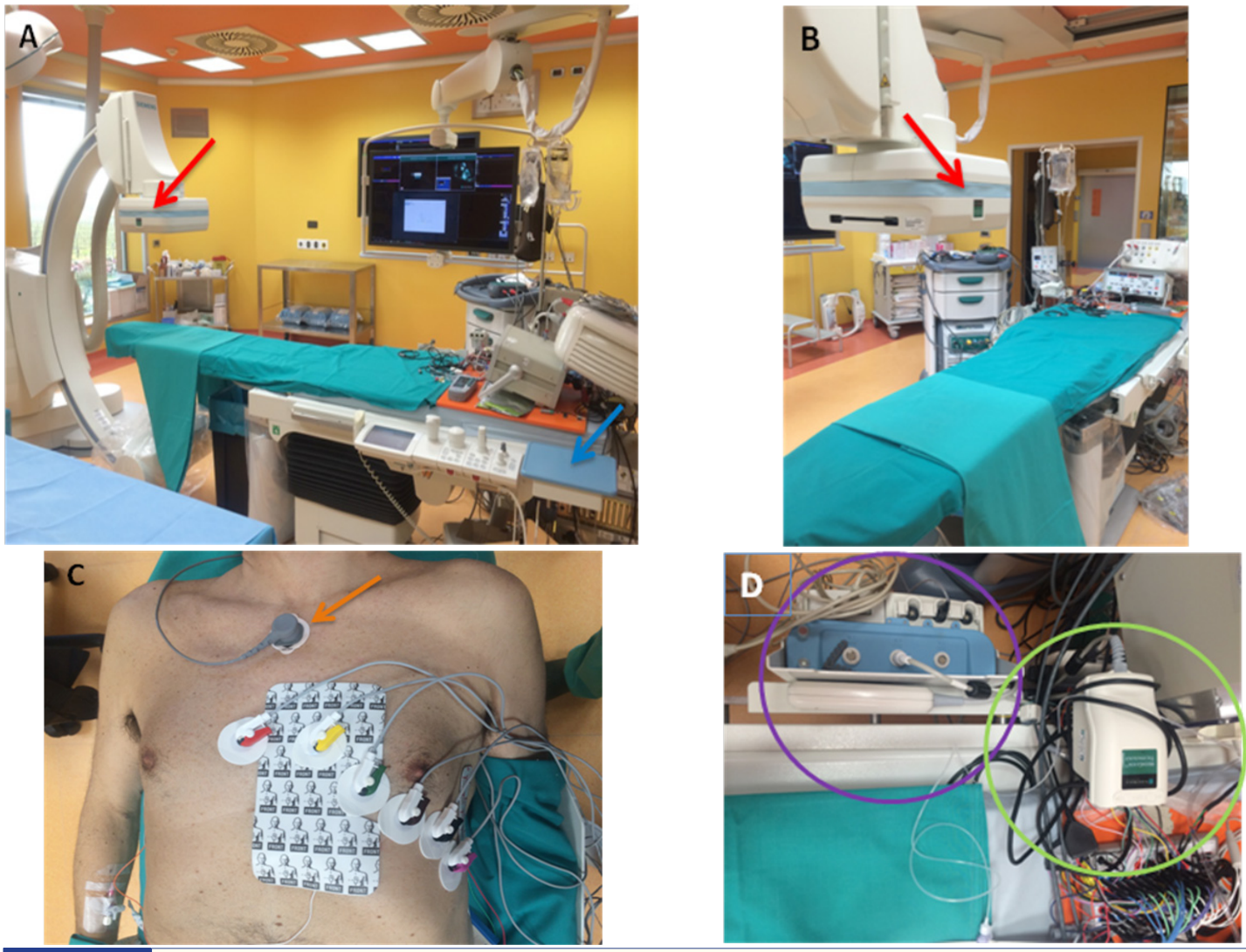

Figure 1: **MediGuide™ Technology System (A-D).**

MG™ Transmitters are installed in a X-ray system detector (Siemens) (Panels A and B, red arrows), and integrated into the electrophysiology laboratory. To the patient table rails is attached the Table Side Unit™ (TSU): a standard mouse and slide surface through which the user control the system (Panel A, blue arrow).
The Panel C shows the Patient Reference Sensor™ (PRS) (orange arrow), which compensates the calculated positioning of the MG during the patient's motion while sensing the respiration motion. The proximal end (PRS connector) is connected to the MG Connect™, while PRS distal end (the sensor) is externally attached to the patient chest at a predefined position.
Panel D. The MediGuide Connecting system (violet circle) allows connection of ECG, PRS on pa-tient chest and MG catheter (Panel D, green circle).

positioning. Potential limitations when using the MPS include: patient reference sensor movement may occur in obese patients or those with "loose" skin and the non-fluoroscopic MPS may miss deformation of cardiac structures caused by mechanical catheter forces. The MPS may be used to target a steerable catheter equipped with a MPS sensor to the coronary sinus (CS), the right ventricular apex (RVA) and the His bundle without the use of live fluoroscopy, using pre-recorded cine images. Although patient and respiratory movement are successfully compensated in almost all patients, intermittent loss of compensation and incomplete compensation may occur in some cases. The MPS may be used in conjunction with an electro-anatomic mapping system (EAMS) to reconstruct the anatomy of the left atrium, and to place steerable diagnostic EP catheters, equipped with MPS sensors, into the CS and RVA. Circumferential pulmonary vein isolation can be performed with a conventional irrigated tip catheter using conventional EAMS. The catheters can be easily tracked and visualized non-fluoroscopically by MPS and complete pulmonary vein isolation can be achieved safely and effectively with fluoroscopy time significantly shortened.

A small study described the use of MPS in 10 patients compared with conventional fluoroscopy (10 patients) who required ablation of cavo-tricuspid isthmus dependent flutter.[6] Two steerable diagnostic EP catheters equipped with MPS sensors were used for CS cannulation and for anatomical cavo-tricuspid isthmus reconstruction. Both patient groups (MPS' and conventional fluoroscopy's group) underwent cavo-tricuspid isthmus (CTI) ablation. In all 10 patients in the MPS group, the MPS enabled catheters could be visualized and tracked non-fluoroscopically. Successful anatomical CTI reconstruction was performed and after ablation, isthmus block was reported in all patients with no adverse events. Total procedure time did not differ between the two groups, however fluoroscopy time was significantly reduced in the MPS group (2.4 ± 2 minutes) compared to the control group (10.5 ± 6 minutes).[6]

MediGuide And CRT

Cardiac Resynchronization Therapy (CRT) represents one of the most important therapeutic options for patients with heart failure

Figure 2: **Cardiac Resynchronization Therapy implantation with MediGuide System (A-D).**

Real-time fluoroscopy (LAO, Panel A) and a simultaneous MG pre-recorded cine loop (LAO, Panel B) show a non-steerable CS sheath at the superior vena cava (yellow tip, green shaft). Superior vena cava is marked with a yellow ring (Panel B, yellow arrow).
The MG Technology is able to reconstruct a 3D model of coronary sinus from two cines recorded at different projections after contrast agent administration: a non-steerable CS sheath (yellow tip, green shaft) is advanced in the coronary sinus over a diagnostic catheter (Panel C).
Panel D: In RAO projection, the target vein is selectively intubated and a MG guidewire is advanced to the distal part of that vein (yellow small tip, blue arrow). The LV electrode is advanced to the final best position "over-the-wire" using an image-based overlay of prerecorded venogram fluoroscopy.

over the past 10 years. MG technology represents an important step forward to minimize fluoroscopy time with the option to visualize the device in the best Rx projection (left anterior oblique projection) with the C-arm in a more comfortable projection (anterior-posterior or right anterior oblique) avoiding scattered radiation. Traditional implantation of CRT requires a comparatively higher radiation exposure due to challenging implantation of the left ventricular (LV) lead into coronary sinus. Traditionally, sheaths, guide wires, and the catheters themselves are tracked under continuous fluoroscopy but using MPS the position of the device is projected in real-time to pre-recorded cine loops (fig 2).

Radiation exposure could be reduced significantly. The average fluoroscopy time used for LV lead positioning was less than three minutes and that for the entire implantation was less than six minutes, without any increase in the rate of complications.[5,6] It is likely that in the future in every EP laboratory, fluoroscopy will be used only at the beginning and at the end of a procedure, and very few electrophysiologists would need a lead apron.

MediGuide And Ablation

Daily exposure to x-ray to heath care workers in a high volume center of electrophysiology represent a big challenge. The fact that sensors can be integrated to catheters for 3D positioning projected on 2D fluoroscopy, or that communication links can be established between nonfluoroscopic and radiation systems represents the latest revolutionary realization. MG technology has applied 3D visualization and navigation by Ensite Velocity System to a pre-recorded 2D X-ray image to create a real time navigation and ablation without use of fluoroscopy. In the last few months we have applied this technology to 70 patients with paroxysmal or persistent atrial fibrillation undergoing catheter ablation. During the procedure, a small sensor inside the catheter tip can be located by receiving electromagnetic positioning signals from the MG

transmitters (which are incorporated into the detector housing of Artis Siemens System). The MG Technology then calculates the respective position and orientation of the catheter and displays it in real-time on 2D fluoroscopic images of the patient that were recorded at the beginning of the procedure. To display the catheter's position precisely, the technology also compensates for respiration and cardiac motion of the patient. Beside a reduction in fluoro time, there is an improved spatial resolution of the 3D mapping system resulting in higher quality maps. Because of additional localization information, 3D electroanatomical maps are much closer to reality and real time catheter tip visualization improves quality of 3D reconstruction of maps.

The Arrhythmology Department in Cotignola, Italy, is one of the first centers in the world to use MG Technology and we have performed about 100 MG procedures.

Limitations

MediGuide technology may be of limited use in obese patients. Accurate catheter tracking without use of fluoroscopy essentially depends on a stable position of the external PRS and in obese patients the PRS movement may affect tracking accuracy. Another limitation is that deformation of cardiac structures may be missed when using only nonfluoroscopic gMPS catheter tracking. Finally, larger clinical trials comparing usefulness of fluoroscopic and nonfluoroscopic procedures are required.

Conclusion:

There is increasing peer-reviewed evidence available to establish effectiveness of the MediGuide medical positioning system. Early clinical studies suggest that the gMPS could be used safety and effectively to localize, track and navigate cardiac catheters during different electrophysiological and/or ablation procedures, including CRT implantation. Our experience also suggests that as electrophysiologists become more familiar with this technology, less and less fluoroscopy can be used until it will be completely eliminated with long-term benefits to the community and catheter laboratory staff beginning a new electrophysiology era.

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