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Utility of High-Resolution Electroanatomic Mapping of the Left Ventricle Using a Multispline Basket Catheter in a Swine Model of Chronic Myocardial Infarction

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Introduction

With standard electroanatomic mapping systems, electrophysiologists (EPs) use a single catheter to perform left ventricular (LV) substrate mapping. With a new system, the Rhythmia™ Mapping System from Boston Scientific, EPs instead create maps with a 64-electrode mini-basket catheter. The aim of this study was to compare the accuracy of electroanatomic mapping using the Rhythmia system with that of mapping using a standard linear catheter in a swine model of chronic myocardial infarction (MI).

Methods

The Rhythmia Mapping System uses an 8F deflectable catheter with a mini-basket (1.8 cm diameter) of 8 splines of 8 electrodes (total 64 electrodes, 2.5 mm spacing). The system automatically generates chamber geometry and a high-resolution activation map using electrograms (EGMs) recorded within 5 mm of the chamber surface. It automatically acquires EGM and location information based on EGM stability and respiration phase.

Ten swine underwent left anterior descending coronary artery occlusion to create an anteroseptal MI. To assess the MI size, the researchers obtained delayed-enhancement magnetic resonance imaging (MRI) scans. They then created detailed LV voltage maps with both the basket and linear catheters. They compared map characteristics and scar area between the MRI, linear catheter, and Orion basket catheter. Lastly, they mapped induced ventricular tachycardia (VT) with the basket catheter.

Results

More points were acquired with the basket catheter than with the standard linear catheter (Table 1). And the correlation between MRI and catheter scar area measurement was best for the basket catheter (Figure 1). In three animals, sustained poorly tolerated VT was initiated and the circuit mapped successfully with the Orion basket catheter in < 5 minutes.

Table 1. Mapping Results in 10 swine

Map Type	EGM Points Acquired	Total Scar Area
Orion mini-basket catheter	8,762 (±3164)	17.8 cm2 (±8.7)
Standard linear catheter	1,712 (±551)	20.9 cm2 (±10.5)
MRI	N/A	17.5 cm2 (±7.4)
* Using a 1.5 mV bipolar voltage cutoff		

Conclusion

Rapid substrate and activation mapping using the Rhythmia Mapping System allows detailed voltage and activation mapping in postinfarction cardiomyopathy. This system may be useful for substrate and VT mapping in human postinfarction cardiomyopathy.

TO READ THE FULL ARTICLE, CLICK HERE http://www.sciencedirect.com/science/article/pii/S1547527114009254

The limitations of this study include the following that the basket catheter was not used with other commercially available mapping systems, that the healthy LV was not mapped due to cost limitations. Low voltage points required review to determine if adequate contact was achieved. Some of the mapping time was not included since the mapping was done by fellows who were at various stages of their training. Finally, the author was unable to perform entrainment mapping due to the fact that the swine became hemodynamically unstable.

RHYTHMIA™ MAPPING SYSTEM INTENDED USE/INDICATIONS FOR USE
The Rhythmia™ Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

CONTRAINDICATIONS There are no known contraindications.

WARNINGS AND PRECAUTIONS The use of the Rhythmia Mapping System in conjunction with radio frequency ablation and other medical devices, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose a risk of adverse events, such as cardiac perforation and arrhythmias (new and/or exacerbation of existing arrhythmias) that may require additional intervention. Do not operate the Rhythmia Mapping System near flammable anesthetics. System operation near flammable anesthetics may cause an explosion that could cause injury or death to the patient or user. All devices that are connected to the Rhythmia Mapping System must meet IEC 60601-1 requirements and any other relevant safety standards. When connected to other devices, the combined systems' configuration must meet the IEC 60601-1-1 safety standards. The use of the Rhythmia Mapping System with accessories and devices that do not comply with relevant standards may reduce the safety of the system, cause equipment damage or system malfunction, or harm to the patient or user. Only stimulators that are certified for IEC 60601 should be used with the Rhythmia Mapping System. Do not connect life-sustaining pacing through the Rhythmia Mapping System. The system is not intended to provide life-sustaining therapy and should not be used as such. In case of need for emergency pacing, or any failure of stimulator routing, directly connect the desired paced channel to the stimulator. The Rhythmia Mapping System is only designed to route the stimulation signal to the desired channel. To start or stop stimulation, always use the controls on the external stimulator. Use the Rhythmia Mapping System only with one of the following RF ablation generators: Maestro 3000™, Stockert™, or IBI™. Do not use the system with other RF ablation generators. Compatibility with other RF ablation generators has not been demonstrated. Do not apply RF energy larger than 150W to ablation catheters that are connected to the Maestro 3000 RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 70W to ablation catheters that are connected to the Stockert RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 50W to ablation catheters that are connected to the IBI RF generator and the Rhythmia Mapping System. To reduce the risk of electric shock or equipment damage, do not clean the Rhythmia Mapping System when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to a power source may cause an electrical shock that could cause injury or death to the patient or user. To reduce the risk of electric shock, assure that any ECG cables and electrodes are not in contact with any other conductive parts, including ground. To reduce the risk of electric shock during defibrillation, assure that the exposed connector tips on the ECG output box are covered at all times with the protective, non-conductive material provided with the ECG output boxes. Do not use the ECG output box if the protective cover is damaged (see ECG Output Box). The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system's normal operation and reduce the quality of catheter localization, and signals. Magnetic Localization System Do not operate the Localization Generator within 200 mm of installed cardiac implantable electronic devices (CIEDs). Doing so may affect pacing, temporarily suspend tachycardia therapy delivery, or lead to patient discomfort. Signal Station To minimize the risk of electric shock, connect the Signal Station only to supply mains with a protective ground (earth) connection. Use only a functioning, properly tested supply main with protective ground (earth) to power the Rhythmia Mapping System. The use of a faulty, ungrounded supply main increases the risk of electrical shock and system malfunction. To minimize the risk of electric shock, prior to using the Rhythmia Mapping System, connect the equipotential socket (located on the Signal Station rear panel) to a common ground. This connection grounds the Rhythmia Mapping System and must remain connected at all times (see Signal Station Setup in the DFU). The Signal Station requires a dedicated, 24V DC power supply, which is provided by Boston Scientific with the Signal Station. To reduce the risk of Signal Station damage, use only the power supply provided by Boston Scientific for use with the Signal Station. To reduce the risk of Signal Station damage, do not connect or disconnect the Signal Station to its power supply while the Signal Station is turned on. To minimize potential exposure to water or liquid, prevent fluids from entering air vents. Do not place beverages or containers of water or liquid directly on or near the Signal Station or other system components. Do not block the air vent on the Signal Station during Signal Station use. Blocking the air vent during Signal Station use can cause the Signal Station to overheat, which may affect system operation. Use only a flat stable surface to hold the Signal Station and Signal Station-related accessories. Workstation To minimize potential exposure to water or liquid, do not place beverages or containers of water or liquid directly on or near the Workstation or other system components. Use only a flat stable surface to hold or transport the Workstation and Workstation-related accessories. To prevent loss of data, frequently back up the data by archiving cases no longer needed for immediate access. Cables Use only the ECG cables supplied by Rhythmia™ Medical for use with the Rhythmia Mapping System. ECG cables provided by Rhythmia Medical are designed and tested to protect the Signal Station from defibrillation energy. Using other ECG cables may cause serious damage to the system hardware. Prior to using the Rhythmia Mapping System, inspect all external connections and cable connectors. Make sure all connections are secure. Tighten any loose connections prior to using the system. Do not use excessive force when connecting or disconnecting cable connectors. Excessive force can damage the connectors, which may cause system malfunction. Do not kink or sharply bend cables. Kinks and sharp bends can damage the cables, which may cause system malfunction. To minimize the risk of damage, store unused system cables in a clean, dry, and secure location, consistent with storage guidelines (see Equipment Storage & Transporting in the DFU). Electrical Never use ungrounded electrical outlets to power any system components. Do not use extension cords or adapters for ungrounded outlets. Using ungrounded outlets, extension cords, or adapters may cause equipment damage, system failure or malfunction. Body Surface Electrodes Use care when attaching the body surface electrodes to lead connectors. To minimize the risk of electric shock, make sure that electrodes and lead connectors do not contact one another or contact ground. To prevent low quality signals from body surface electrodes, properly prepare the skin prior to attaching the electrodes. Do not use excessive gel as this may lead to shorts between different electrodes. Environmental Do not immerse any cable connectors in water or liquid. Immersion in water or liquid may damage connectors, which may cause system malfunction. Magnetic Localization System Manually disabling the Localization Generator disables all catheter visualization and localization capabilities, including impedance tracking. Do not place the Localization Unit (SCU) or Sensor Interface Unit (SIU) within 1m of the Localization Generator. Doing so may lead to inaccurate tracking. Do not place cables used with the Rhythmia Mapping System within 30mm of the Localization Generator cable. If these cables are within 30mm or less, particularly if they are parallel to each other, inaccurate tracking or "noisy" signals may occur. Do not coil the Localization Generator cable. Doing so can disturb the magnetic field of the Localization Generator, which may lead to inaccurate tracking. Do not use the Magnetic Localization System in the presence of other magnetic fields or large metal objects. Doing so may lead to inaccurate tracking. Localization Generator Manually disabling the Localization Generator disables all catheter visualization and localization capabilities, including impedance tracking. During the Procedure To reduce catheter configuration mistakes, when connecting catheters to the system, always verify the signals by reviewing the signal display and recording system to ensure correct configuration of catheter electrodes to displayed channels. To ensure correct clinical decisions, use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify mapping results and catheter position. Always compare the anatomical map to the patient's expected anatomy. When a catheter localization error is encountered, use fluoroscopy or other visualization techniques to verify catheter location. Imported geometrical shells should only be used as a reference, for example to identify anatomical features in advance of mapping. Use other visualization tools, such as fluoroscopy or echocardiography to verify catheter location. During the mapping procedure, do not disconnect the Localization Unit from the Signal Station and/or the Localization Generator from the Localization Unit. Ensure caps are installed on Localization Unit SIU connection ports that are not in use. (Rev A)

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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