Pulmonary Vein Isolation Using Rhythmia™ Mapping System: Verification of Intracardiac Signals Using the Orion Mini-Basket Catheter

Elad Anter, MD; Cory M. Tschabrunn, CEPS; Fernando M. Contreras-Valdes, MD; Jianqing Li, MD; Mark E. Josephson, MD.

Published September 2015 in Heart Rhythm

Introduction

During pulmonary vein isolation (PVI), a circular lasso catheter is positioned at the junction between the left atrium (LA) and the pulmonary vein (PV) to confirm PVI. In this study, researchers compared signals between the RHYTHMIA™ Mapping System’s mini-basket catheter (from Boston Scientific) and the lasso catheter at the LA-PV junction.

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 HR 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.

Results

At baseline, recordings of LA and PV potentials were concordant in all PVs. However, after PVI, concordance between the catheters was poor — at only 68%. Discordance in all cases resulted from loss of PV potentials on the lasso catheter that were captured with the mini-basket catheter. In 9 of 13 PVs (69%), these potentials represented true PV potentials that were exclusively recorded with the Rhythmia system. In the other 4 PVs (31%), the potentials originated from neighboring structures and resulted in underestimation of PVI.

Conclusion

The use of the RHYTHMIA mini-basket catheter alone was sufficient to determine PVI. The RHYTHMIA catheter improved recording of PV potentials after incomplete ablation. It was also associated with frequent recording of “PV-like” potentials lost by the lasso catheter — most of which were related to incomplete PVI but some of which represented far-field signals originating from neighboring structures. In these cases, pacing maneuvers are helpful to determine PVI and avoid excessive ablation.

This is a single-center study with a limited number of patients. Nonetheless, the objective was to characterize the electrogram differences between the lasso and the mini basket catheter. A total of 48 PVs were assessed with consistent findings among all subjects. In addition, operators experienced with Rhythmia and the mini-basket catheter performed the ablation procedures.

TO READ THE FULL ARTICLE, CLICK HERE http://dx.doi.org/10.1016/j.hrthm.2015.05.019
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 60601-1-1 safety standards 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 safely 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, directory place the ablation catheter in 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 IBT®. 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 IBT RF generator and the Rhythmia Mapping System. To reduce the risk of electric shock or equipment damage, use only the power supply provided by Boston Scientific for use with the Rhythmia Mapping System. 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. 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 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 to minimize the risk of electric shock 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 dry, clean, and secure location, consistent with storage guidelines (see Equipment Storage & Transporting in the DFU). 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, temporary and permanent cardiac pacing, the performance of medical procedures, or the operation of magnetic localization system. 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, 24/7 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. 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 to minimize the risk of electric shock 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 dry, clean, and secure location, consistent with storage guidelines (see Equipment Storage & Transporting in the DFU). To prevent low voltage 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. Do not place cables used with the Rhythmia Mapping System within 20mm 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 cables. 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 localization and localization capabilities, including impedance tracking. 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)

1Cardiovascular Division, Department of Medicine, Harvard-Thorndike Electrophysiology Institute, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts.

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