Patient Introduction and History

A 54 year-old man is referred following recurrent palpitations and electrocardiogram (ECG) documentation of both narrow and broad complex tachycardias. Termination of tachycardia required both intravenous amiodarone and DC cardioversion. His medical history includes a Ross procedure for bicuspid aortic valve at 40 years, perioperative myocardial infarction, and an uncorrected right coronary artery fistula to the right atrium (RA). After obtaining informed consent, antiarrhythmic medication was stopped and he was brought to the EP lab for electrophysiology study and possible ablation. Using the RHYTHMIA™ 3D electroanatomic mapping solution, the left ventricle (LV) was mapped in sinus rhythm and during broad complex tachycardia, followed by mapping of the RA in sinus rhythm and during narrow complex tachycardia.

Details of the procedure

Both groins were prepped and draped in a sterile manner. Anaesthetist-administered sedation and local anaesthetic were used, after which femoral venous and arterial access was obtained via the Seldinger technique to place the necessary catheters.

Access and catheters used. Two 6 and one 7 French short sheaths were initially inserted in the left femoral vein to facilitate placement of a deflectable decapolar catheter into the coronary sinus (to act as the location and timing reference for the RHYTHMIA system), and two quadripolar catheters into the high RA and right ventricular apex (for pacing maneuvers). Next, access to the LV was obtained via both the retrograde approach (through the pulmonic autograft at the aortic position) as well as transseptal approach (via a 9 French nondeflectable Mullen’s sheath). The INTELLAMAP ORION™ high-resolution mapping catheter was used (an 8.5 French mini-basket multielectrode catheter specifically designed for use with the RHYTHMIA system). Another separate 9 French short sheath was also placed in the right femoral vein to facilitate access and mapping of the RA. Systemic heparin was given to achieve an activated clotting time of 300 to 350 seconds throughout the procedure.

Mapping of the LV. A substrate map of the LV was initially acquired in sinus rhythm (Figure 1a). The RHYTHMIA system acquired and automatically annotated 12,800 EGMs over 36 Minutes. Consistent with the location of regional wall motion abnormalities noted during echocardiography, a large area of low voltage in the basal and mid-inferior LV segments was found, including a potential isthmus site of highly fractionated potentials. Atrial burst pacing then led to induction of the clinical narrow complex tachycardia, which spontaneously degenerated into ventricular tachycardia (VT) with a surface ECG morphology identical to the clinical broad complex tachycardia. This VT was haemodynamically tolerated and therefore mapped; the map required 3,949 EGMs over 3 Minutes (Figure 1b). The map demonstrates a dual-loop reentry circuit as the basis of VT. There were two lines of conduction block, on either side of the previously identified potential isthmus. During VT, a roving virtual probe placed at the location of the isthmus showed almost continuous, low-voltage diastolic conduction (Figure 1c). Ablation to transect the isthmus and connect the lines of block led to termination of VT. Following further ablation of late potentials in this area, VT was rendered non-inducible (Figure 2).
Figure 1. (a) Voltage map during sinus rhythm. (b) Activation map during VT. (c) Diastolic potentials recorded in region of the roving virtual probe (straight white arrow), placed in region of the isthmus of the VT circuit. Activation wavefront shows dual-loop reentry.

Figure 2. Ablation of narrow isthmus and late potentials in the LV.

Mapping of the RA. Next, the RA was mapped in following induction of the clinical narrow complex tachycardia by right atrial burst pacing. The map during tachycardia required 6½ minutes to acquire and consisted of 14,545 EGMs, demonstrating a CTI-dependent circuit revolving counterclockwise around the tricuspid annulus (Figure 3a) and a second clockwise rotating circuit pivoting at the scar area located on the lateral wall of the RA (Figure 3b). Concealed entrainment was demonstrated from the CTI with the INTELLAMAP ORION™. Ablation of the CTI was therefore carried out. Upon completion of the CTI ablation, the tachycardia cycle length prolonged slightly with complete alteration of p-wave morphology on ECG (Figures 3c and 3d). The tachycardia was therefore remapped.

Figure 2. (a) RA activation map during narrow complex tachycardia, prior to CTI ablation. Counterclockwise CTI-dependent atrial flutter. (b) Concealed entrainment was demonstrated from the CTI with the INTELLAMAP ORION™. (c) Flutter wave morphology prior to CTI ablation. (d) Flutter wave morphology following ablation of the CTI.
This case illustrates the utility of pairing the novel RHYTHMIA™ 3D mapping system with the INTELLAMAP ORION™ high-resolution mapping catheter — a multipolar, basket catheter with small and closely spaced electrodes. Together, they represent a next-generation electroanatomic mapping solution engineered to address the problems in conventional systems through a combination of hardware and software enhancements.

Hardware enhancements. RHYTHMIA is optimized for use with a specially-designed mini-basket multi-electrode catheter, the INTELLAMAP ORION catheter. The ‘ORION’ is a bidirectional catheter with a maximum shaft diameter of 8.5 French. It has 64 imprinted electrodes with 2.5mm inter-electrode spacing on 8 nitinol splines arranged as a mini-basket whose diameter can be varied from 3mm (fully closed) to 22mm (fully deployed). Localization of INTELLAMAP ORION is both magnet-based for catheter positioning (resolution ≤ 1mm) and impedance-based for the deployment of the spines (resolution ≤ 2mm). The close electrode spacing together with the imprinted electrodes on one surface of each spline is designed to permit high-resolution point collection and the catheter has excellent signal:noise performance characteristics; typical noise floor at the signal station is less than 0.01mV.

Remapping required 11½ minutes to acquire 9,539 EGMs, and revealed a clockwise rotating lateral wall macroreentrant circuit, with the activation wavefront revolving around a line of conduction block in the posterolateral RA (Figures 4a and 4b). Comparison with the RA substrate map showed the line of block corresponded with an area of low voltage and highly fractionated potentials, presumably due to an atriotomy scar from prior cardiac surgery. Further ablation to connect the atriotomy scar to the inferior vena cava was then performed. (Figure 5) This led to termination of the narrow complex tachycardia. Neither the narrow complex tachycardia nor the broad complex tachycardia were subsequently inducible.

Case discussion

3D electroanatomic mapping solutions have revolutionized the practice of interventional electrophysiology. Through accurate, 3D localization of catheters, such systems permit real-time acquisition of local electrograms in 3D space. This permits the creation of substrate maps and local activation maps, and enables us to understand complex arrhythmias and formulate rational ablation strategies. However, conventional 3D electroanatomic systems are complex, have a considerable learning curve, and can easily mislead. In particular, maps usually contain a few hundred points at most, so map resolution may be limited, and points often require extensive manual reannotation to unravel the arrhythmia circuit. Not only is this latter step time-consuming, but considerable experience is needed. This case illustrates the utility of pairing the novel RHYTHMIA™ 3D mapping system with the INTELLAMAP ORION™ high-resolution mapping catheter — a multipolar, basket catheter with small and closely spaced electrodes. Together, they represent a next-generation electroanatomic mapping solution engineered to address the problems in conventional systems through a combination of hardware and software enhancements.

Figure 4. (a) Local activation map showing a circuit revolving around a posterolateral atriotomy scar. (b) Substrate map showing a posterolateral area of low voltage indicating site of an atriotomy scar and matching the line of conduction block identified in the local activation map.

Figure 5. Ablation line between atriotomy scar and inferior vena cava.
RHYTHMIA SCIENCE

Software enhancements. The software algorithms underlying RHYTHMIA are as important as the INTELLAMAP ORION catheter innovation. RHYTHMIA system allows continuous mapping from all 64 electrodes with automated analysis and annotation of accepted electrograms for both voltage information as well as activation timing:

a. Beat acceptance criteria. Electrograms must pass through a user-defined set of beat acceptance criteria before annotation; these criteria consist of the cycle length, electrogram stability, ECG morphology reference, respiration, mapping catheter movement, tracking quality, propagation reference and ventricular EGM overlap. In this way, only valid electrograms are entered into the mapping dataset. In addition, a beat template can be set up to facilitate continuous mapping of ectopic beats, and the propagation reference can be used to reject ectopic beats, as the clinical situation requires.

b. Automated annotation. In other electroanatomic mapping systems, manual annotation is almost always necessary for complex arrhythmias. In contrast, using RHYTHMIA, manual annotation is very rarely necessary due to a combination of automatic rejection of invalid electrograms (described above), and improved software algorithms that take into account not only the local electrogram but also the electrograms of surrounding points to determine the most likely activation sequence ('regional analysis'). Because annotation is automated, RHYTHMIA also permits retrospective changes of the mapping window; this may be particularly useful in cases such as ventricular tachycardia, to identify critical isthmus sites.

Limitations. RHYTHMIA received CE mark and FDA approval in mid-2013 and the number of centers worldwide with this mapping system is still relatively small, hence the relative strengths and weaknesses of RHYTHMIA system compared to other electroanatomic mapping systems is still an area of active study (see e.g. (4)). A frequent concern among new users of the RHYTHMIA system is the navigability of the relatively stiff INTELLAMAP ORION™ catheter, which possesses a long ‘nose’. In this case example, we have shown it is possible to easily map using INTELLAMAP ORION in the right atrium and the left ventricle via both transseptal and retrograde aortic routes. It is possible that certain LV arrhythmias may not be easily mapped using INTELLAMAP ORION (e.g. VT from the papillary muscles), but RHYTHMIA is designed using an open architecture so non-ORION catheters can be substituted as required. We have also successfully used INTELLAMAP ORION to map the left atrium, epicardial space, all four pulmonary veins, coronary sinus, superior vena cava, right ventricle and right ventricular outflow tract without complication in other cases.

REFERENCES:

RHYTHM™ Mapping System INDICATIONS FOR USE

The Rhythm™ Mapping System and accessories are indicated for catheter-based anial 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. WARINGS AND PRECAUTIONS

The use of the Rhythm 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 Rhythm Mapping System near flammable anesthetics. System operation near flammable anesthetics may cause an explosion that can cause death to the patient or user. All devices that are connected to the Rhythm 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 safety standards. The use of the Rhythm 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 Rhythm Mapping System. Do not connect life-sustaining pacing through the Rhythm 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 Rhythm 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.

The Rhythm Mapping System only with one of the following RF ablation generators: Maestro 3000™, Stockert™, or BiM™. 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 Rhythm Mapping System. Do not apply RF energy larger than 70W to ablation catheters that are connected to the Stockert RF generator and the Rhythm Mapping System. Do not apply RF energy larger than 50W to ablation catheters that are connected to the BiM RF generator and the Rhythm Mapping System. To reduce the risk of electric shock or equipment damage, do not clean the Rhythm Mapping System when it is plugged in, turned on, or 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 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 (ICIEs). 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 Rhythm Mapping System. The use of a faulty, unsupplied ground main increases the risk of electrical shock and system malfunction. To minimize the risk of electric shock, prior to using the Rhythm Mapping System, connect the equipotential socket (located on the Signal Station rear panel) to a common ground. This connection grounds the Rhythm 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 Rhythm Mapping System. 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 Rhythm Medical for use with the Rhythm Mapping System. ECG cables provided by Rhythm Medical are designed and tested to protect the Signal Station from defibrillation energy. Using other ECG cables may cause serious damage to the hardware system. Prior to using the Rhythm 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). Never use ungeared electrical outlets to power any system components. Do not use extension cords or adapters for ungeared outlets. Using ungeared outlets, extension cords, or adapters may cause equipment malfunction, damage, or over-heating. 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. 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 enter the Signal Station Unit (SIU) or Sensor Interface Unit (SIU) within 1m of the Localization Generator. Do not place all cables used with the Rhythm 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. Do 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. Do so may lead to inaccurate tracking. Localization Generator Manually disabling the Localization Generator disables all catheter visualization and location, which may result in impedance tracking failure. During the Procedure To reduce catheter configuration mistakes, when connecting catheters to the system, always verify the signals by reviewing the display screen and recording system to ensure correct configuration of catheter electrodes to display channels. To ensure correct clinical decisions, use fluoroscopy, ultrasound, x-ray, 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 connector ports that are not in use.

INTELLAMAP ORION™ High Resolution Mapping Catheter INDICATIONS FOR USE

The IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. The IntellaMap Orion Catheter should not be used in Patients who are not candidates for transvascular catheter procedures. Patients with a hypercoaguluable state or who have a history of uncontrolled anticoagulation therapy. Patients with prosthetic or stent valves, in the chamber where the prosthetic or stent valve resides. Patients with a history of, or current, pacemaker dependence or defibrillator dependence. The IntellaMap Orion Catheter should not be used for radio frequency (RF) ablation. The IntellaMap Orion Catheter should not be used inside an MRI machine. WARNINGS Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid. Do not use the catheter to deliver ablation therapy. Do not expose the catheter to alcohol or other cleaning solvents. Do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or un-deployment, stop and evaluate device location under fluoroscopy. Do not advance or retract the catheter through a sheath when deployed or articulated. In order to reduce the risk of clot formation: Maintain an activated clotting time (ACT) of greater than 300 sec. at all times during use of the catheter, and continuously flush the electrode array with saline via the irrigation port at the proximal end. Only use guiding sheaths with curves that allow passage of the catheter without using excessive force. When used with a steerable guiding introducer sheath: Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath. Do not articulate the sheath while the catheter array is inside the articulating section. Do not deploy or articulate the catheter while the distal end is inside the sheath. Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter. To prevent entanglement, use care when using the catheter in the proximity of other catheters. When pacing, verify desired waveform is observed. Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressurized saline bag to flush saline through the catheter shaft and electrode array. POTENTIAL ADVERSE EVENTS Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism, and death. Complications reported included also in (alphabetical order): air embolism, arrhythmia, AV fistula, hematoma, hemorrhage, pneumothorax, pneumoencephalus, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions.

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.