Local impedance characteristics of pulmonary vein reconnections during repeated AF ablation procedures: insight from an Italian multicenter registry


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BACKGROUND

AF recurrence is highly associated with pulmonary vein (PV) reconnection. Limited data exist on PV gaps characterized by Local Impedance (LI).

OBJECTIVE

To characterize PV gaps and ablated tissue with a novel LI algorithm after repeated AF ablation procedures according to previous ablation strategy.

METHODS

Consecutive patients (pts) undergoing redo AF ablation from the CHARISMA registry at 6 Italian centers were included. Rhythmia mapping system was used to map the left atrium and PVs before and after ablation. LI characteristics were collected through a RF ablation catheter equipped with a dedicated LI algorithm (DirectSense). Each gap was characterized in terms of LI and its variations during the procedure. Ablation endpoint was PVI as assessed by entrance and exit block.

RESULTS

A total of 41 PV gaps (mean number of gaps per pt = 2.3±1.1) from 18 cases were detected: 20 gaps from 9 cases after RF ablation and 21 gaps from 9 cases after cryoablation. In 14 cases (34.1%) the difference between LI at healthy tissue and LI at gap was lower than 5 Ω, suggesting that this spot was not treated by RF or Cryo delivery in the previous ablation (13 out 21 after Cryo ablation vs 1 out 20 after RF ablation, p<0.0001). No complications during the procedures were reported. All PVs were successfully isolated in all study pts.

CONCLUSION

LI characteristics at PV gaps significantly differ from both scar and healthy tissue. No significant difference was recorded between prior ablation approaches in terms of lesion extension.
RHYTHMIA HDx™ Mapping System

INTENDED USE
The RHYTHMIA HDx™ Mapping System (the system) is a 3D mapping and navigation system used in EP procedures. The SiS and related accessories provide data connection pathways for external input/output devices (e.g. catheters and recording systems) and serve as the data conduit to the system work station and software.

INDICATIONS FOR USE
The RHYTHMIA HDx 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
• Diagnosis and treatment of cardiac arrhythmias using the system in conjunction with radio frequency (RF) ablation and other medical devices may pose a risk of adverse events. Adverse events (e.g. cardiac perforation, new arrhythmias, exacerbation of existing arrhythmias) may require additional intervention.
• Do not use the system to route life-sustaining pacing signals. Only diagnostic stimulation signals (e.g. induction) may be routed through the system.
• All devices that are connected to system hardware must independently meet IEC 60601-1 requirements as well as any other relevant safety standards. The combined hardware configuration must also meet IEC 60601-1 safety standards. The use of system hardware 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.
• System hardware must be connected solely to a functional, properly-tested supply main with protective ground (earth). Do not use extension cords or adapters for ungrounded outlets. The use of a faulty or ungrounded supply main increases the risk of electrical shock and system malfunction.
• Do not connect more than one ablation catheter simultaneously to the Ablation System when used with Rhythmia HDx Mapping System.
• 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.
• Do not operate the localization generator within 200 mm of an implanted CIED (cardiac implantable electronic device.) Doing so may affect CIED pacing, temporarily suspend tachycardia therapy delivery, or lead to patient discomfort

CAUTIONS
• 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.
• Properly prepare the skin prior to attaching the electrodes to prevent receiving low quality signals from body surface electrodes. Do not use excessive gel as this may lead to signal crossover between electrodes.
• To minimize signal interference, route the surface ECG cables across the torso instead of alongside it.
• 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. Incorrect catheter localization may lead to incorrect clinical conclusion or patient injury.
• The localization generator may interfere with implanted cardiac implantable electronic devices (CIEDs). When mapping a patient with such a device, consider interrogating the device pre – and post-procedure. This will identify any changes in programmed parameters which could then be corrected before transferring the patient from the procedure room. Consult the CIED manufacturer instructions for additional information.
• If it becomes necessary to interrogate or program an implanted CIED while using the system, temporarily turn off the localization generator by using the on-screen button located on the annotating and editing maps toolbar.

POTENTIAL ADVERSE EVENTS
Any potential clinical complications are in large part expected to be related to the accessory diagnostic and/or ablation catheters that are used with the system, rather than the system itself. In order to identify potential adverse events, the user is instructed to read pertinent directions for use documents associated with the catheters and ablation generators that will be employed during a mapping session. As with other mapping systems, the RHYTHMIA HDx™ Mapping System can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the system include, but are not limited to, the following:

Arrhythmia
Due to the programmed electrical stimulation performed during EP diagnostic procedures and catheter manipulations, patients undergoing EP procedures are at potential risk of arrhythmia. The patient may experience discomfort from the rapid pacing and/or the initiation of an arrhythmia. While the system has no active role in RF ablation, a risk does exist that the effectiveness of an RF ablation procedure could be suboptimal and cause the targeted arrhythmia to recur.

Misinterpretation of data
Poor catheter localization may lead to clinical data misinterpretation and the potential of resultant patient injury. To ensure correct clinical decisions, the physician must use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify 3-D mapping results and catheter position.

Electrical hazards
With any electrical system there is a potential risk of electrical shock to the user, patient, and service representative.

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.
**IntellaMap Orion High Resolution Mapping Catheter**

**INTENDED USE/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.

**CONTRAINDICATIONS**

The IntellaMap Orion Catheter should not be used in:

- Patients who are not candidates for transvascular catheter procedures.
- Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy.
- Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside.
- Patients with active systemic infection.
- Pediatric patients.
- Pregnant and/or nursing patients.
- Patients with any other condition where catheter manipulation may not be safe.
- 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 seconds at all times during use of the catheter, and
  - Continuously flush the electrode array with saline via the irrigation port at the proximal end.
- Do not use the catheter with equipment (such as stimulators or recording systems) that is not isolated.

**PRECAUTIONS**

- To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue.
- Always deploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify deployment.
- Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient.
- 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 a 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.

**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, hemotherax, pneumotherax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions.

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**Brief Summaries**

**IntellaNav MiFi™ OI Ablation Catheter**

**INTENDED USE/INDICATIONS FOR USE**

The IntellaNav MiFi™ OI Catheter, when used with a compatible Radiofrequency Controller and Irrigation Pump, is indicated for:

- Cardiac electrophysiological mapping
- Delivering diagnostic pacing stimuli
- RF ablation of sustained or recurrent type 1 Atrial Flutter in patients age 18 years or older
- Treatment of drug refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system.

**CONTRAINDICATIONS**

The IntellaNav MiFi™ OI Catheter is contraindicated for use in patients:

- with active systemic infection;
- with a mechanical/prosthetic heart valve through which the catheter must pass;
- unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
- who have vent cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- who are hemodynamically unstable;
- who have myxoma or an intracardiac thrombus;
- who have had a ventriculotomy or atriotomy within the preceding eight weeks;
- who have had a Patent Foramen Ovale (PFO) occlusion device.

**WARNINGS**

**Note:** The IntellaNav MiFi™ OI Catheter is not designed to be compatible with the Maestro 3000® RF Cardiac Ablation System.

- When using the IntellaNav MiFi™ OI Catheter at lower than prescribed flow rate may increase the potential for thrombus, coagulum, and char that may result in embolism.
- Cardiac entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for cardiac entrapment may increase when the catheter is overtipped and/or positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.

**PRECAUTIONS**

- In the event of a suspected failure of the integrity of fluid flow through the IntellaNav MiFi™ OI Catheter or if there is a rapid temperature rise of greater than 15 °C noted on the RF Controller, the procedure should be stopped, and the IntellaNav MiFi™ OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the IntellaNav MiFi™ OI Catheter and the Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of air embolism.

- Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid overload; Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.

- Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.

**IntellaNav MiFi™ OI Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death.**

- The long-term risks effects of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown.

- If there is uncertainty regarding the patient's antiocoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage.

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