Highlights from:
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Salam et al., Journal of Innovations in Cardiac Rhythm Management, Volume 26, Issue 5, April 2020
DOI: 10.19102/icrm.2020.110405

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A Large Case Series Demonstrating Safety and Effectiveness of a Novel Fluoroless Transseptal Puncture Technique for Lead-Free Catheter Ablation

INTRODUCTION

- This large series of 382 consecutive cases demonstrates the safety and effectiveness of fluoroless transseptal puncture (TSP) and radiofrequency (RF) ablation using 3D electroanatomic mapping (EAM).

METHODS

Visualization setup

- **NRG™** Transseptal Needle (Baylis Medical*) was visualized on the CARTO® 3 System (Biosense Webster) using the **DuoMode™** Extension Cable† (Baylis Medical*) (Figure 1).
- An esophageal temperature probe was sutured to a quadripolar catheter to track on EAM.
- Devices were visualized using preset catheter definitions (20B 4F quad 2-5-2 mm fixed) and by enabling "extended features raw data" on the CARTO® 3 System.

Transseptal puncture and catheter ablation

- Femoral access was used to introduce the ThermCool SmartTouch® Catheter (Biosense Webster) for mapping the superior vena cava (SVC) and right atrium, marking the His bundle, coronary sinus, and fossa ovalis.
- The transseptal sheath was then re-positioned in the SVC to introduce the **NRG™** Needle.
- The sheath and dilator were pulled back to expose the round **NRG™** Needle tip for positional tracking on the CARTO® 3 System during dropdown onto the septum (**DuoMode™** Cable set to "mapping mode").
- Intracardiac echocardiography (ICE) was used to confirm needle position on the fossa ovalis before RF puncture (**DuoMode™** Cable set to "generator mode").
- Left atrial mapping and RF catheter ablation were performed as per usual protocol.

RESULTS

- Double or single TSP was achieved 100% successfully and without fluoroscopy within 28±15 min.
- Total procedure time was 135±34 min without significant complications.
- Recurrence rate was 27% at 3±1 month follow-up.

DISCUSSION AND CONCLUSIONS

- This study demonstrates the safety and effectiveness of non-fluoroscopic TSP using the **NRG™** RF Transseptal Needle, 3D-EAM, and ICE.
- The atraumatic electrode tip of the RF needle allowed exposure during drop-down for positional tracking from the SVC to the fossa ovalis, unlike the sharp tip of a mechanical needle.
- Dedicated RF transseptal needles improve safety, efficiency, precision, and TSP success in diverse septal anatomies, offsetting the material costs.
- Use of electrified mechanical needles is not characterized and presents risks of injury.

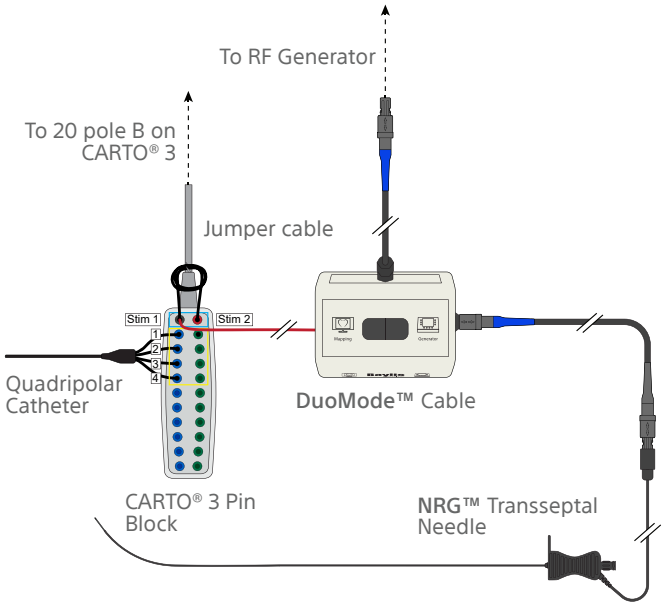

Figure 1. Graphical adaptation of the equipment setup used by Salam et al for device visualization on EAM.

* A wholly-owned subsidiary of Boston Scientific Corporation.
† Consult your mapping system's user manual for connectivity and configuration instructions prior to **DuoMode™** Cable use.

NRG™ Transseptal Needle

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. • Do not alter this device in any way. • The NRG Transseptal Needle is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • For RFP-100: Do not attempt to puncture with an initial power setting of greater than 10 Watts. The initial attempt should be made with a setting of 10 Watts. In subsequent punctures, the power setting can be increased, if necessary. • The pressure transducer system used with the NRG Transseptal Needle must comply with the electrical safety requirements of IEC 60601. Failure to use compliant pressure transducers may result in patient or operator injury.

PRECAUTIONS: • Do not attempt to use the NRG Transseptal Needle or ancillary equipment before thoroughly reading the accompanying Instructions for Use. • Radiofrequency puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised. • Visually inspect the needle prior to use. Do not use the needle if there is any damage or visibly exposed metal on the shaft where it connects to the handle. • Do not use the NRG Transseptal Needle after the "Use By" date indicated on the label. • The NRG Transseptal Needle is intended for use with only those devices listed in section VII "Equipment Required" • Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.• Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • Do not attempt to puncture until firm position of the active tip has been achieved against the atrial septum. • It is not recommended to exceed five (5) radiofrequency power applications per NRG Transseptal Needle. • Do not bend the NRG Transseptal Needle. Excessive bending or kinking of the needle shaft may damage the integrity of the needle and may cause patient injury. Care must be taken when handling the needle. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the needle and DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the tip of the needle against the atrial septum. Only increase the power if low power output persists. • Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the Baylis Medical Radiofrequency Puncture System. • Ensure the distal tip is protruding the dilator/sheath assembly when visualizing on electroanatomic mapping systems. Visualization of the distal tip of the NRG Transseptal Needle may be lost when retracted within the dilator/sheath assembly.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

97185932 (Rev. A.1)

DuoMode™ Cable

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The DuoMode Cable is intended to serve as an extension cable that is used with the Baylis Medical radiofrequency puncture devices, the Baylis Medical Company Radiofrequency Puncture Generator and diagnostic equipment. .

CONTRAINDICATIONS: The DuoMode Cable is not recommended for use with any other RF generator.

WARNINGS: • The DuoMode Cable is a reusable device. Failure to properly clean the device can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • The DuoMode Cable must only be used with Baylis RF Puncture Generators and RF puncture devices. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.

PRECAUTIONS: • Do not bend the cable. Excessive bending or kinking of the cable may damage the integrity of the cable and may cause patient injury. Care must be taken when handling the cable. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application.

ADVERSE EVENTS: The RFP-100A Generator Instructions for Use should be consulted for any adverse events.

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