Highlights from:
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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.

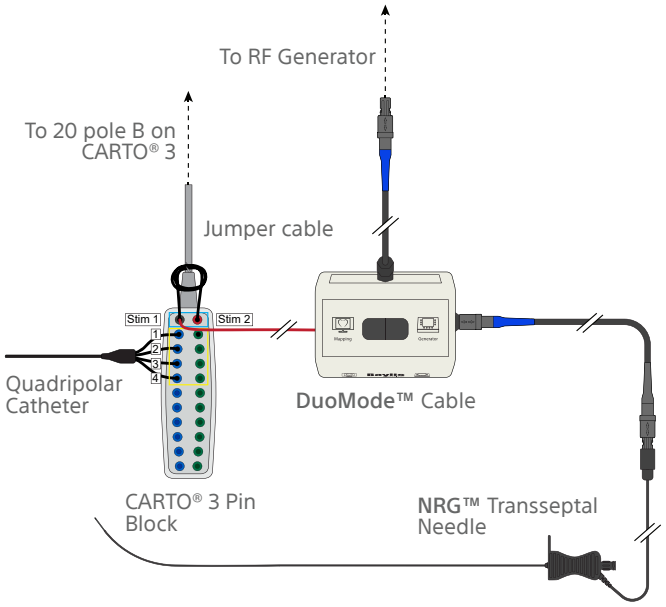

Figure 1. Graphical adaptation of the equipment setup used by Salam et al for device visualization on EAM.

* 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.

Brief Summary | **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: • 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.

PRECAUTIONS: • 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. • 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. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

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

EP-1506305-AA

Brief Summary | **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: Adverse events associated with the use of this device are similar to those indicated for the Baylis Medical Radiofrequency Puncture System.

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