Highlights from:
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Guarguagli et al., Cardiology Research and Practice, June 2020 DOI: 10.1155/2020/5420909

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Initial Experience Using the Radiofrequency Needle Visualization on the Electroanatomical Mapping System for Transseptal Puncture

INTRODUCTION

- This series of 42 retrospective consecutive cases evaluates the safety and effectiveness of transseptal puncture (TSP) using a radiofrequency (RF) needle in left-sided ablations with low or no fluoroscopy.

METHODS

Visualization setup

- Pre-procedural contrast enhanced computed tomography or cardiac magnetic resonance were used to create 3D reconstructions of cardiac chambers and vessels.
- Electroanatomical Mapping (EAM) was performed using CARTO®3 (Biosense Webster) or Rhythmia™ (Boston Scientific) systems and merged with 3D reconstructions using the POLARIS software (Biosense Webster).
- Transesophageal echocardiography and/or remote magnetic navigation (Stereotaxis Inc) were used in challenging and congenital heart disease (CHD) cases.
- 3D map of the right atrium (RA) and coronary sinus were acquired using fast anatomical mapping using NaviStar® ThermoCool® Catheter (Bioscience Webster).
- **NRG™** Transseptal Needle (Baylis Medical*) was visualized on the EAM map using the **DuoMode™** Extension Cable† (Baylis Medical*) using the following configuration:
  - A jumper cable (stackable, 2 mm pin) is plugged into ports 1 and 2 on the pin block
  - **DuoMode™** Cable is plugged into the jumper cable in port 1
  - The RF needle was defined as a 2F bipolar catheter, with 2 mm spacing centre-to-centre and 1 mm electrode width/length on the EAM

Transseptal puncture (TSP)

- Single or double TSP was performed and 1 or 2 sheaths (**TorFlex™** Transseptal Guiding Sheath, Baylis Medical* or SL1™ sheath, Abbott) were placed in the left atrium.
  - n=37 cases; first attempt to TSP was made with the **NRG™** Needle
  - n=5 cases; **NRG™** Needle was used after initial attempt with Brockenbrough needle (BN) failed

RESULTS

- TSP was achieved 100% successfully with no immediate procedural complications (See Figure 1).

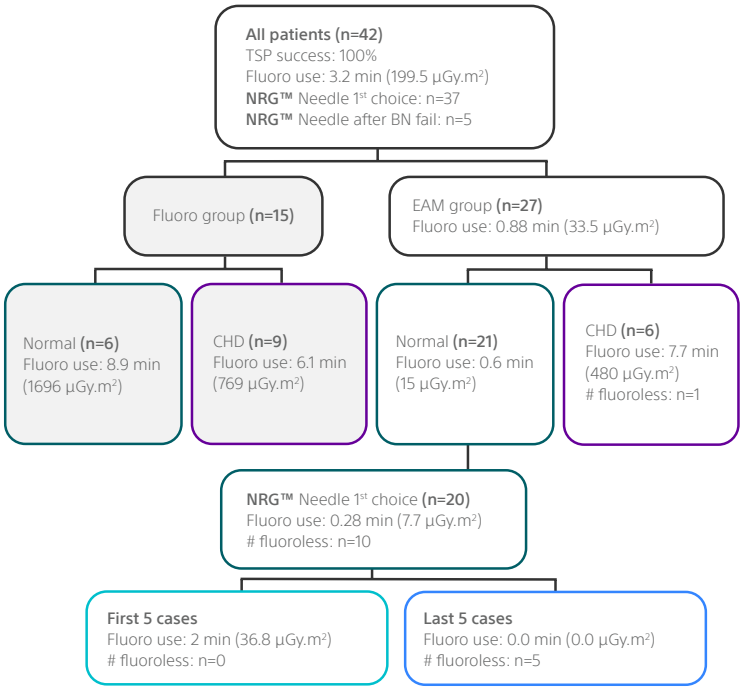

Figure 1. The **NRG™** Needle enabled successful TSP with low or no fluoroscopy use in both normal and complex cases with CHD. Number of fluoroless cases increased with physician experience in **NRG™** Needle visualization on EAM. (Adapted from Guarguagli et al.).

DISCUSSION AND CONCLUSIONS

- The prevalence of redo ablations (i.e. fibrotic septa) and adult patients with CHD presents an increasing challenge in TSP.
- This study demonstrates successful TSP using the **NRG™** Needle in patients with complex and normal interatrial septum anatomies.
- **NRG™** Needle can be visualized in real time using 3D EAM to reduce/eliminate the need for fluoroscopy.
- Time saving from more effective TSP using the RF needle offsets the additional time required to map the RA.

* 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 | **TorFlex™** Transseptal Guiding Sheath

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 TorFlex™ Transseptal Guiding Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: Laboratory staff and patients can undergo significant x-ray exposure during interventional 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 use of echocardiography is recommended. • The TorFlex™ Transseptal Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.

ADVERSE EVENTS: Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment.

EP-1515406-AA

EP-1562208-AA