Highlights from:
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The use of a radiofrequency needle improves the safety and efficacy of transseptal puncture for atrial fibrillation ablation

INTRODUCTION

- This large case series compares the safety and efficacy of transseptal puncture (TSP) using the purpose-built radiofrequency (RF) **NRG™** Transseptal Needle (Baylis Medical*) to a sharp mechanical needle (BRK-1™ or BRK-1™ ES, Abbott) for atrial septal puncture.

METHODS

- 1550 consecutive atrial fibrillation (AF) ablations were retrospectively analyzed.
- Fluoroscopy, intracardiac ultrasound, pressure measurement, and/or contrast injection were used to guide the transseptal puncture.

Transseptal puncture

- Mechanical needle (975 ablations).
  - Forward force was applied for TSP and to advance the transseptal apparatus across the septum.
- **NRG™** RF Needle (575 ablations).
  - RF energy was applied using a dedicated generator (RFP-100-115, Baylis Medical*) to perforate the septum with no significant forward motion of the needle.
  - The transseptal apparatus was then advanced into the left atrium (LA) over the needle.
- After a successful transseptal puncture, all patients underwent standard AF ablation.

Data analysis

- Instrumentation time was recorded from lidocaine injection to heparin injection upon LA access.
- Complications during TSP were assessed, including failure of LA access, pericardial tamponade, inadvertent aortic puncture, death, stroke, or transient ischemia.
- Operator experience over time was assessed by quartile using Cochran-Armitage trend analysis.

RESULTS

- Failure of TSP was lower with RF needle than mechanical needle (0.17% vs. 1.23%; p=0.039).
- No cardiac tamponade occurred with RF needle compared to mechanical needle (0.00% vs. 0.92%; p<0.04).
- With mechanical needle, septal crossing rates (p=0.79) and rate of tamponade (p=0.46) did not improve with operator experience.
- Instrumentation time was shorter with the RF needle than mechanical needle (27.1 ± 10.9 min vs. 36.4 ± 17.7 min; p<0.0001).

DISCUSSION AND CONCLUSIONS

- RF needles reduce the rate of atrial perforation by requiring minimum forward movement to cross the septum compared to sharp mechanical needles.
- RF needles improve the rate of crossing, even in septa that are thick or scarred from prior punctures.
  - Atraumatic tip of RF needle allows verification of needle tip position without tissue penetration.
  - Sharp mechanical needles can create micro-punctures upon tissue contact that may lead to procedure termination to prevent risks from procedural anticoagulation.
- Clean tissue perforation requires a dedicated RF needle and purpose-built generator.
  - Connecting an ablation generator to a mechanical or RF needle may lead to tissue heating, necrosis, and septal damage.
- This study showed that purpose-built RF needles reduce instrumentation times, increase TSP efficacy, and reduce the incidence of pericardial tamponade during AF ablation.

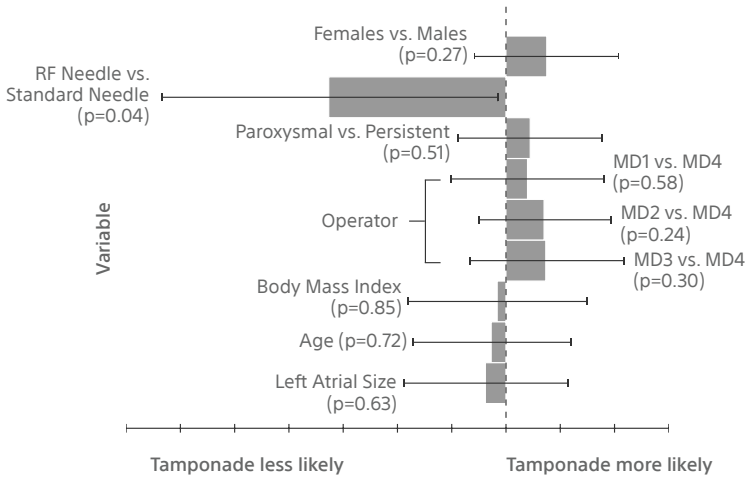

Figure 1. Multivariate analysis of pericardial tamponade indicated that the RF needle is the only variable associated with lower tamponade (95% confidence interval).

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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

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