



The use of a radiofrequency needle improves the safety and efficacy of transeptal puncture for atrial fibrillation ablation

INTRODUCTION

- ▶ This large case series compares the safety and efficacy of transeptal puncture (TSP) using the purpose-built radiofrequency (RF) **NRG™** Transeptal 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 transeptal puncture.

Transeptal puncture

- ▶ Mechanical needle (975 ablations).
 - Forward force was applied for TSP and to advance the transeptal 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 transeptal apparatus was then advanced into the left atrium (LA) over the needle.
- ▶ After a successful transeptal 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.

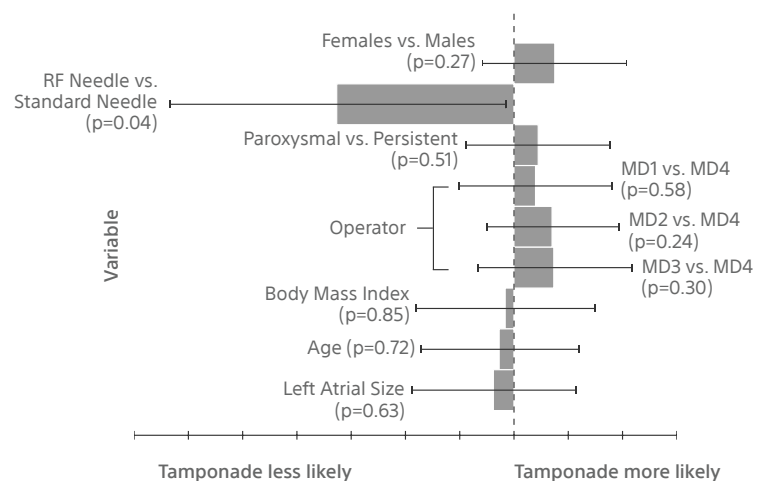


Figure 1. Multivariate analysis of pericardial tamponade indicated that the RF needle is the only variable associated with lower tamponade (95% confidence interval).

* A wholly-owned subsidiary of Boston Scientific Corporation.

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

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