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Radiofrequency needle for transseptal puncture is associated with lower incidence of thromboembolism during catheter ablation of atrial fibrillation: propensity score-matched analysis

INTRODUCTION

- Catheter ablation of atrial fibrillation (AF) is a well-established but not risk-free procedure. Silent ischemic lesions and neuropsychological decline have been observed following these procedures.
- The impact of different approaches to accessing the heart has recently been considered as a risk factor for silent acute cerebral embolism (ACE). This study aimed to compare the incidence of ACE following AF ablation procedures performed with a radiofrequency (RF) needle versus mechanical needle for transseptal puncture.

METHODS

- This retrospective, propensity score-matched analysis of 232 patients who underwent a catheter ablation procedure for AF compared those with transseptal puncture performed with a RF transseptal needle* (n=116) to those with a non-RF (mechanical) transseptal needle (n=116). Cerebral magnetic resonance images were collected following all procedures to assess for ACE.

RESULTS

- Incidence of ACE was significantly lower in the RF needle group than in the mechanical needle group (19% vs. 32%, p=0.02). This represents an approximately 40% lower incidence (see Figure 1).
- Total procedure time was significantly shorter in the RF needle group than in the mechanical needle group (167±50 min. vs. 181±52 min., p=0.01). This represents a 14 min. lower mean procedure time, which suggests economic benefits through improved electrophysiology (EP) lab efficiencies may be achieved.

DISCUSSION AND CONCLUSIONS

- It is speculated that the basis for lower incidence of ACE with RF needles may be associated with reduced skiving† and/or a more predictable transseptal process with the RF needle involving reduced time and interaction with the septum.
- It is widely accepted in the AF ablation and EP community that efforts to help lower the incidence of silent ACE are desirable, despite an incomplete understanding of the clinical consequence of these events.‡
- The results of this study suggest that physicians may consider an RF transseptal needle to help lower incidence of ACE.

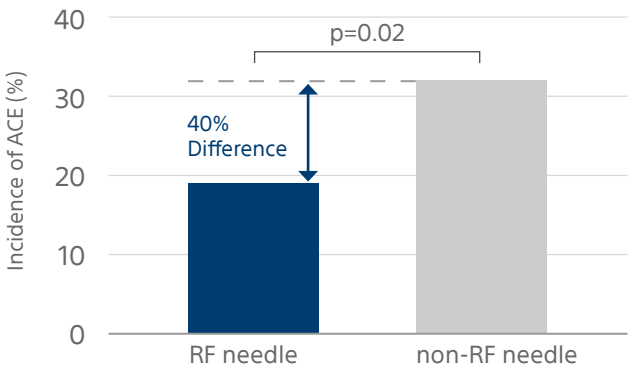

Figure 1. Incidence of acute cerebral embolism (ACE) was lower in patients who had transseptal puncture performed with a radiofrequency (RF) needle than those using a non-RF needle.

* Marketed in US, Canada and EU as **NRG™** Transseptal Needle (Baylis Medical Company, a fully-owned subsidiary of Boston Scientific Corporation).
† As generated by mechanical needles during the catheterization process
‡ Calkins et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2017 Oct;14(10):e275-e444.

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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