



## Highlights from:

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# Persistence of an iatrogenic atrial septal defect after a second-generation cryoballoon ablation of atrial fibrillation

## INTRODUCTION

- ▶ Iatrogenic atrial septal defects (iASDs) following left heart catheterization procedures typically close within three months of a radiofrequency (RF) ablation<sup>1,2</sup>, but have a greater persistence in patients undergoing first-generation cryoballoon (CB) ablations<sup>3</sup> (Table 1). This is believed to be because CB ablation procedures require larger sheaths for left atrial (LA) access than RF ablations.
- ▶ This study investigated the incidence of persistent iASDs and the predictive factors in patients undergoing second-generation CB ablation for paroxysmal atrial fibrillation.

## METHODS

- ▶ Transseptal puncture was performed in 83 patients using a radiofrequency (RF) needle (Baylis Medical\*) and standard 8F sheath. A 15F steerable sheath was used for the ablation.
- ▶ Patients underwent pre-procedural computed tomography (CT) as well as transthoracic echocardiography (TTE) before and after the procedure.
- ▶ An atrial septal defect was evidenced by a patent opening in the interatrial septum and/or color Doppler flow using a Valsalva maneuver.

## RESULTS

- ▶ **Incidence:** 8.4% of patients had persistent iASD at a median of 15.5 (6.8–17.3) months, with a median size of 3.4 (2.6–4.0) mm.
- ▶ **Symptoms:** No iASD-related adverse events or symptoms (e.g. paradoxical emboli, heart failure, or migraine headaches) occurred during a median of 17.7 (14.4–23.3) months of follow-up.
- ▶ **Predicting factors:** Multivariate analysis of CT images indicated that atrial septal angle was the only significant factor predicting a persistent iASD (odds ratio 0.764) with a minimum optimal atrial septal angle of 57.5°.

## DISCUSSION AND CONCLUSIONS

- ▶ **Persistence:** Persistent iASDs were detected in 8.4% of patients at a median of 15.5 months after second-generation CB ablation using a 15F steerable sheath. This is consistent with findings from the PROTECT AF study<sup>2</sup> using a similar-sized sheath for LA appendage closure.
- ▶ **Atrial septal angle:** The atrial septal angle may be a predictor of persistent iASDs possibly due to the high forces on the puncture hole while maneuvering a large stiff sheath to reach and isolate the pulmonary veins.

	Rillig et al., 2008 <sup>1</sup>	Singh et al., 2011 <sup>2</sup>	Cronin et al., 2013 <sup>3</sup>		Watanabe et al., 2018
Procedure type	RF ablation	WATCHMAN™ Device	RF ablation	CB ablation (1 <sup>st</sup> gen)	CB ablation (2 <sup>nd</sup> gen)
Sheath size	8F	14F	8F	15F	15F
Follow-up time	12 months	12 months	4 months	4 months	15.5 months
Incidence of iASD	3.7%	7%	2.4%	16.7%	8.4%

Table 1. Summary of studies describing persistent iASDs in Watanabe et al., 2018.

\* 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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<sup>1</sup>Rillig et al. J Interventional Cardiology Electrophysiology. Sept 2008;22:177-181.

<sup>2</sup>Singh et al. Circulation: Arrhythmia and Electrophysiology. Apr 2011;4:166-171.

<sup>3</sup>Cronin et al. J American College of Cardiology. Oct 2013;62:1491-1492.

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