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# Achieving Contrast-Free Ultra-Low Radiation Exposure Without Compromising Safety and Acute Efficacy Through Evolving AF Cryoballoon Ablation Procedure Techniques

# INTRODUCTION

- Due to the detrimental effects of radiation during catheterbased procedures, it should be assumed that a safe level of radiation exposure does not exist.
- This study demonstrates the safety and acute effectiveness of ultra-low fluoroscopy use during cryoballoon ablation for atrial fibrillation.

### **METHODS**

A retrospective observational analysis was performed on 307 cryoballoon ablation procedures for pulmonary vein isolation (PVI) using ultra-low fluoroscopy.

#### Imaging

- Pre-procedural planning included cardiac computed tomography or magnetic resonance imaging.
- ▶ Transesophageal echocardiography to rule out thrombus.
- Intracardiac echocardiography (ICE; Zonare Ultrasound System, St. Jude Medical) was used for transseptal puncture and catheter guidance.
- SD electroanatomic mapping (EAM) was used to recreate cardiac geometries and for catheter guidance (Achieve™ Mapping Catheter, Medtronic, Inc.; EnSite™ NavX™ Mapping System, St. Jude Medical).
- "Single-shot" fluoroscopy (3.75 frames/s) was used if resistance was felt during device exchange.

#### Transseptal access

- ► Transseptal puncture was performed using the **NRG**<sup>™</sup> Transseptal Needle (Baylis Medical\*).
- Catheter exchange in the left atrium was initially done using a STORQ<sup>®</sup> Steerable Guidewire (Cordis) during the first 18 months of the study before switching to the ProTrack<sup>™</sup> Pigtail Wire (Baylis Medical<sup>\*</sup>) for the remaining 28 months.

#### Cryoballoon ablation

- Ablations were performed using the Arctic Front Advance™ Cryoballoon (Medtronic, Inc.).
- Direct pressure monitoring and Doppler flow were used to confirm pulmonary vein occlusion in place of radiopaque contrast.

## RESULTS

- Radiation dose decreased from 6.7 mGy to 2.0 mGy over the study period (p<0.01).</li>
- ► Fluoroscopy time decreased from 0.75 min to 0.2 min over the study period (p<0.0001).
- Use of a 28-mm cryoballoon required significantly lower fluoroscopy use than both the 23-mm cryoballoon and combination of 23-mm and 28-mm cryoballoons.
- Acute procedural success was achieved in 99% of patients with a 2.0% complication rate, consistent with other cryoballoon studies.
- One incidence of left atrial appendage perforation leading to cardiac tamponade was attributed to the STORQ<sup>®</sup> Steerable Guidewire, and prompted the switch to the **ProTrack™** Pigtail Wire.

### DISCUSSION AND CONCLUSIONS

- This study describes a method for ultra-low fluoroscopy cryoballoon ablation compared to other large sponsored studies, and demonstrates safety and effectiveness.
- The best practices for fluoroscopy reduction include:
  - ICE to visualize the NRG<sup>™</sup> Transseptal Needle for transseptal puncture and ProTrack<sup>™</sup> Pigtail Wire for wiring across the left atrium
  - 3D EAM, ICE, pressure waveform, and Doppler imaging for catheter navigation
  - Cryoballoon dosing algorithm to minimize freezing beyond acute PVI
  - Slow fluoroscopy frame rate when needed
- These tools and techniques are common within electrophysiology labs and require minimal additional operator training.

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