



A Large Case Series Demonstrating Safety and Effectiveness of a Novel Fluoroless Transseptal Puncture Technique for Lead-Free Catheter Ablation

INTRODUCTION

This large series of 382 consecutive cases demonstrates the safety and effectiveness of fluoroless transseptal puncture (TSP) and radiofrequency (RF) ablation using 3D electroanatomic mapping (EAM).

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METHODS

Visualization setup

- NRG[™] Transseptal Needle (Baylis Medical^{*}) was visualized on the CARTO[®] 3 System (Biosense Webster) using the DuoMode[™] Extension Cable[†] (Baylis Medical^{*}) (Figure 1).
- An esophageal temperature probe was sutured to a quadripolar catheter to track on EAM.
- Devices were visualized using preset catheter definitions (20B 4F quad 2-5-2 mm fixed) and by enabling "extended features raw data" on the CARTO® 3 System.

Transseptal puncture and catheter ablation

- Femoral access was used to introduce the ThermCool SmartTouch® Catheter (Biosense Webster) for mapping the superior vena cava (SVC) and right atrium, marking the His bundle, coronary sinus, and fossa ovalis.
- The transseptal sheath was then re-positioned in the SVC to introduce the NRG[™] Needle.
- The sheath and dilator were pulled back to expose the round NRG[™] Needle tip for positional tracking on the CARTO[®] 3 System during dropdown onto the septum (DuoMode[™] Cable set to "mapping mode").
- Intracardiac echocardiography (ICE) was used to confirm needle position on the fossa ovalis before RF puncture (DuoMode[™] Cable set to "generator mode").
- Left atrial mapping and RF catheter ablation were performed as per usual protocol.

RESULTS

- Double or single TSP was achieved 100% successfully and without fluoroscopy within 28±15 min.
- Total procedure time was 135±34 min without significant complications.
- Recurrence rate was 27% at 3±1 month follow-up.

DISCUSSION AND CONCLUSIONS

- This study demonstrates the safety and effectiveness of non-fluoroscopic TSP using the NRG[™] RF Transseptal Needle, 3D-EAM, and ICE.
- The atraumatic electrode tip of the RF needle allowed exposure during drop-down for positional tracking from the SVC to the fossa ovalis, unlike the sharp tip of a mechanical needle.
- Dedicated RF transseptal needles improve safety, efficiency, precision, and TSP success in diverse septal anatomies, offsetting the material costs.
- Use of electrified mechanical needles is not characterized and presents risks of injury.



Figure 1. Graphical adaptation of the equipment setup used by Salam et al for device visualization on EAM.

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[†] Consult your mapping system's user manual for connectivity and configuration instructions prior to DuoMode™ Cable use.

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