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Fluoroless Left Atrial Access for Radiofrequency and Cryoballoon Ablations using a Novel Radiofrequency Transseptal Wire

HIGHLIGHTS

- The VersaCross™ RF Transseptal Solution can enable fluoroless transseptal puncture in ablation procedures.
- Efficient procedure with average transseptal puncture time under 20 minutes.
- Zero exchanges required for transseptal puncture.

INTRODUCTION

- Procedure efficiency and transseptal puncture (TSP) remain a barrier to the full adoption of fluoroless procedures to reduce radiation exposure and associated health risks.
- This study reports the first clinical experience using the VersaCross™ RF Transseptal Solution (Baylis Medical*) for more efficient left atrial (LA) access through reduced device exchanges to facilitate fluoroless radiofrequency ablation (RFA) and cryoballoon ablation (CBA).

METHODS

- Fluoroless RFA and CBA procedures at two centers were retrospectively evaluated for procedural efficiency and safety.
- The VersaCross™ RF Transseptal Solution, consisting of a transseptal sheath, shapeable dilator, and RF wire (J-tip or pigtail), was used to cannulate the superior vena cava (SVC), perform RF TSP, and deliver RF ablation or the FlexCath Advance™ Steerable Sheath (Medtronic) in CBA.
- The VersaCross™ RF Transseptal Solution was visualized without fluoroscopy using:
 - Electroanatomic mapping (EAM) using the **DuoMode™ Cable** (Baylis Medical) and EnSite Precision™ Cardiac Mapping System (Abbott), and intracardiac echocardiography (ICE).
 - B. ICE only.
- RFA or CBA procedures were then performed as per usual protocol.

RESULTS

- 126 patients underwent RFA (n=72) or CBA (n=54) for leftsided cardiac arrhythmias.
- Fluoroless TSP was successful in 100% of cases regardless of septal anatomy. Device exchanges were not required for TSP or repositioning on the septum.
- All procedures were 100% successful without any intraprocedural complications.
- Average procedure time was 104.4 ± 38.0 min for RFA and 91.1 ± 22.1 min for CBA.

- Transseptal Puncture Time (Figure 1)
 - 2.8 ± 1.0 min for RFA and 3.5 ± 1.6 min for CBA from VersaCross™ RF Wire insertion into femoral introducer.
 - 14.5 ± 6.6 min for RFA and 19.2 ± 11.7 min for CBA from initial vascular access.

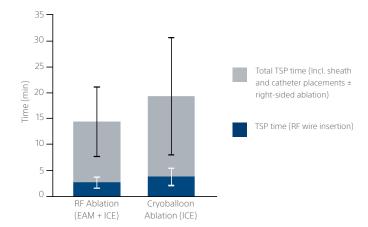


Figure 1. Transseptal puncture time during RF ablation (EAM + ICE) and cryoballoon ablation (ICE) using the VersaCross™ RF Transseptal Solution (Baylis Medical).

DISCUSSION & CONCLUSIONS

- RFA and CBA can be performed safely using the VersaCross™ RF Transseptal Solution without the use of fluoroscopy or lead.
- The VersaCross™ RF Transseptal Solution enabled more efficient and faster catheter ablation procedures compared to conventional techniques by:
 - Effective fluoroless visualization using EAM and/or ICE.
 - Reducing the number of device exchanges for LA access.
- TSP time with fluoroless visualization of the VersaCross™ RF Wire are comparable to fluoroscopy-guided TSP using RF wire, suggesting fluoroless visualization does not compromise TSP efficiency.1

¹Sayah N., et al. Initial clinical experience with VersaCross transseptal system for transcatheter mitral valve repair. Catheter Cardiovasc Interv. 2021;97(6): 1230-4. https://doi.org/10.1002/ccd.29365.

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