



## Highlights from:

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# Initial Clinical Experience with VersaCross Transseptal System for Transcatheter Mitral Valve Repair

## HIGHLIGHTS

The novel **VersaCross™** Radiofrequency (RF) Transseptal Solution enabled MitraClip™ Guide delivery in under 7.5 minutes.\* The initial experience shows using the **VersaCross™** RF Transseptal Solution is:

- ▶ Efficient: Achieved TSP and MitraClip™ Guide delivery under 7.5 mins.
- ▶ Exchangeless: Reduced number of wire exchanges.
- ▶ Effortless: Repositioned on the fossa without rewiring.

## INTRODUCTION

- ▶ Transseptal puncture (TSP) location is critical for transcatheter mitral valve repair success.
- ▶ Brockenbrough needles can cause excessive tenting of the septum, leading to unpredictable TSP location and complications.
- ▶ Purpose-built RF devices avoid excessive septal tenting or slippage to allow crossing at the desired location and have increased in use during MitraClip™ procedures (Abbott).
- ▶ The **VersaCross™** RF Transseptal Solution (Baylis Medical†) utilizes an RF wire and shapeable dilator for targeted TSP while reducing wire exchanges to improve procedural efficiency.
- ▶ This study describes the initial clinical experience using the **VersaCross™** RF Transseptal Solution in 25 prospective consecutive MitraClip™ procedures.

## METHODS

- ▶ Right femoral vein access was obtained using standard techniques.
- ▶ The **VersaCross™** RF Wire (pigtail configuration) was used to introduce the transseptal sheath and dilator, perform RF TSP, and introduce the MitraClip™ Guide into the LA with no wire exchanges.
- ▶ Procedural efficiency was evaluated in terms of time from **VersaCross™** RF Wire insertion to (A) TSP and (B) MitraClip™ Guide in the left atrium (LA).
- ▶ Major adverse events were assessed at hospital discharge.

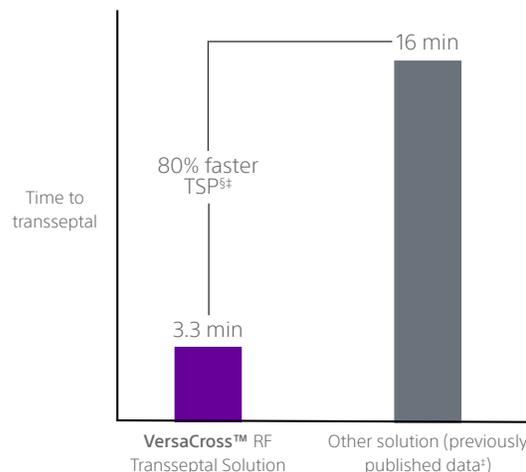
## RESULTS

- ▶ TSP using the **VersaCross™** RF Transseptal Solution was 100% successful with no major adverse procedural events.
- ▶ TSP was achieved within  $3.3 \pm 1.6$  min (Figure 1) or  $1.2 \pm 0.5$  attempts.
- ▶ MitraClip™ guide catheter was placed in the LA within  $3.8 \pm 3.0$  min.

## DISCUSSION & CONCLUSIONS

- ▶ The **VersaCross™** RF Transseptal Solution combines several tools to minimize exchanges that are typically required to insert the MitraClip™ Guide into the LA, including:
  - Shapeable dilator to optimize position on the fossa ovalis
  - Soft pigtail wire for easy repositioning
  - RF puncture device for targeted TSP
  - Long supportive wire to advance the MitraClip™ sheath
- ▶ Case series demonstrates the safety and feasibility of targeted TSP using the **VersaCross™** RF Transseptal Solution in under 5 min.
- ▶ Outcomes suggest a potential improvement in procedural efficiency using the **VersaCross™** RF Transseptal Solution.

### Transseptal Time for MitraClip™ Procedures



**Figure 1.** TSP time for MitraClip™ procedures reported by Sayah et al using the **VersaCross™** RF Transseptal Solution is 80% faster, as compared to previously published data.‡§

\* From femoral access; based on 3.3 min for TSP and 3.8 min for subsequent MitraClip™ guide exchange.

† A wholly-owned subsidiary of Boston Scientific Corporation.

‡ Results from different clinical investigations are not directly comparable. Information provided for educational purposes only. Sayah et al compared the time to transseptal puncture in their case series to data previously published by Maisano et al.⁵

§ Maisano, et al. Transseptal access for MitraClip™ procedures using surgical diathermy under echocardiographic guidance. EuroIntervention. 2012;8(5):579-86.

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