

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

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Sayah et al. Catheter Cardiovasc Interv. 2020; in press (DOI: 10.1002/ccd.29365)

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® Solution in 25 prospective consecutive MitraClip™ procedures.

METHODS

- ▶ Right femoral vein access was obtained using standard techniques.
- ▶ The VersaCross® RF Pigtail Wire 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® 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® Solution was 100% successful no major adverse procedural events.
- ▶ TSP was achieved within 3.3 ± 1.6 min (Figure 1) or 1.2 ± 0.5 attempts.
- ▶ MitraClip™ guide catheter was placed in the LA within 3.8 ± 3.0 min.

DISCUSSION & CONCLUSIONS

- ▶ The VersaCross® 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® Solution in under 5 min.
- ▶ Outcomes suggest a potential improvement in procedural efficiency using the VersaCross® Solution.

Transseptal Time for MitraClip™ Procedures

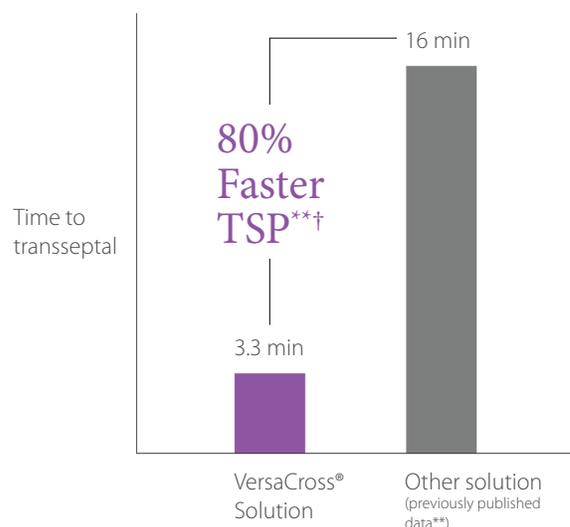


Figure 1 TSP time for MitraClip™ procedures reported by Sayah et al using VersaCross® Solution is 80% faster, as compared to previously published data.**†

* From femoral access; based on 3.3 min for TSP and 3.8 min for subsequent MitraClip™ guide exchange.
** Not based on head-to-head comparison. Sayah et al compared the time to transseptal puncture in their case series to data previously published by Maisano et al.
† Maisano, et al. Transseptal access for MitraClip™ procedures using surgical diathermy under echocardiographic guidance. EuroIntervention. 2012;8(5):579-86.