



Transseptal Device Comparison for Improved Puncture and Streamlined Mitral Edge-to-Edge Repair

HIGHLIGHTS

- ▶ In a single-center retrospective analysis of consecutive MitraClip™ mitral transcatheter edge-to-edge repair (M-TEER) cases, the VersaCross™ Large Access Solution (VLA) was associated with shorter time to transseptal puncture (TSP), optimized steerable guide catheter (SGC) delivery, and streamlined overall procedure time compared with needle-based workflows (mechanical needle, MN; radiofrequency needle, RFN).
- ▶ TSP time was significantly more consistent with VLA compared to MN.
- ▶ Compared with needle-based workflows, the VLA RF wire and 12.5F dilator design streamlined the procedural workflow by reducing exchanges and enabling *de novo* septal dilation for large-bore sheath delivery.

INTRODUCTION

- ▶ TSP is a key step for left atrial (LA) access during M-TEER and other left-heart transcatheter interventions.
- ▶ Needle-based techniques may require greater septal tenting force and additional exchanges, while purpose-built RF-wire based approaches aim to improve efficiency and reduce steps.
- ▶ This study aimed to assess the differences between needle and wire-based TSP devices (Table 1).

METHODS

- ▶ **Design:** Single-center, retrospective chart review of consecutive M-TEER cases using:
 - Mechanical BRK™ Transseptal Needle (MN, Abbott); n = 28
 - Radiofrequency NRG™ Transseptal Needle (RFN, Boston Scientific); n = 55
 - VersaCross Large Access Solution with RF wire (VLA, Boston Scientific); n = 109

Endpoints	Description
Primary	TSP success; time to TSP (femoral access to LA access)
Secondary	M-TEER success; SGC delivery time; clip deployment time; number of clips; overall procedure time; acute intraprocedural adverse events

Table 1. Defined endpoints for TSP and M-TEER procedural assessment.

RESULTS

Success and safety signals:

- ▶ TSP was successful in 100% of cases with TSP times being significantly more consistent with VLA than MN.
- ▶ No adverse events were reported.

Workflow efficiency:

- ▶ VLA significantly reduced time to TSP (15.8 ± 10.0 min) compared to both RFN (21.3 ± 11.9 min) and MN (26.6 ± 18.5 min) (Figure 1A).
- ▶ VLA significantly reduced time to SGC (5.4 ± 4.6 min) compared to both RFN (9.7 ± 5.1 min) and MN (18.4 ± 12.8 min) (Figure 1B).
- ▶ **Total procedure time:** VLA 96.0 ± 51.0 min, MN 138.0 ± 64.0, and RFN 123.0 ± 63.0 min (Figure 1C).
- ▶ Regression models estimated median overall procedure time for VLA was 26% less vs RFN, and 44% less vs MN after adjustment (age, sex, prior TSP, number of clips deployed).

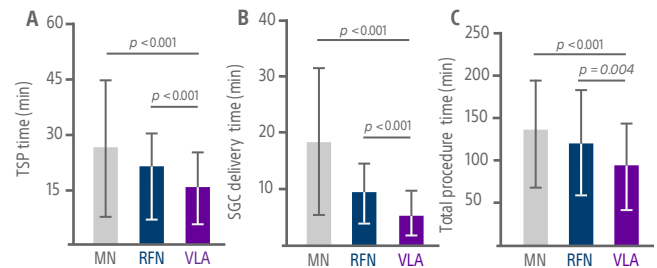


Figure 1. Comparison of procedure time across transseptal puncture (TSP) techniques. (A) Time to TSP was shorter with VersaCross Large Access (VLA; 15.8 ± 10.0 min) vs mechanical needle (MN; 26.6 ± 18.5 min) and radiofrequency needle (RFN; 21.3 ± 11.9 min). (B) Post-TSP SGC delivery was faster with VLA (5.4 ± 4.6 min) vs MN (18.4 ± 12.8 min) and RFN (9.7 ± 5.1 min). (C) Total procedure time was shorter with VLA (96.0 ± 51.0 min) vs MN (138.0 ± 64.0 min) and RFN (123.0 ± 63.0 min). Kruskal-Wallis and F-tests were used; p ≤ 0.05 considered significant.

DISCUSSION AND CONCLUSIONS

- ▶ Needle-based workflows require a starter wire to position the sheath/dilator in the SVC and additional exchanges post-crossing; the VLA RF wire can function as a starter wire, puncture device, and post-TSP guidewire, reducing exchanges.
- ▶ VLA facilitates procedural efficiency by using (1) a 12.5F large access dilator that aids septal dilation, and (2) an RF wire that can support advancement of the SGC, both of which reduce the need for exchanges and may lower related risks such as air entry.
- ▶ The VersaCross Large Access Solution was associated with shorter TSP time and more efficient SGC delivery.
- ▶ The transseptal workflow of choice can impact overall procedure time, cath lab efficiency, and predictability.



[Indications, safety and warnings for VersaCross™ Large Access Solution](#)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse events, and Operator's instructions.

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