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Randomized comparison of a radiofrequency wire versus a radiofrequency needle system for transseptal puncture

HIGHLIGHTS

- ▶ RF wire-based transseptal technique resulted in a faster time to transseptal puncture, with fewer equipment exchanges, compared to an RF-needle-based workflow.

INTRODUCTION

- ▶ The overall efficiency and safety of many electrophysiology and structural interventions are dependent on the success of the transseptal puncture (TSP), which can be improved using radiofrequency (RF) energy.
- ▶ The **VersaCross™** RF solution (Baylis Medical®) system uses a single RF wire to position the TSP assembly into the superior vena cava (SVC), perform RF TSP, and then lead the TSP assembly into the left atrium (LA), eliminating the need for a transseptal needle and wire/needle exchange.
- ▶ The WIRE-IT (**W**ire **I**nstrumentation with **R**F **E**nergy to **I**mpact **T**SP) is a randomized controlled trial comparing the use of a standard needle-based workflow to the **VersaCross™** wire based-workflow in patients undergoing left atrial catheter ablation.

METHODS

- ▶ Single-center single-blinded randomized trial comparing efficacy and safety of two TSP workflows:
 - **NRG™** needle-based workflow: TSP was performed using an **NRG™** transseptal needle (Baylis Medical®) with an Agilis™ NXT (Abbott) or Vizigo™ (Biosense Webster) steerable sheath. In some cases, a second TSP was performed using a separate **NRG™** transseptal needle with an SL1™ sheath (Abbott).
 - **VersaCross™** wire-based workflow: TSP performed using a **VersaCross™** pigtail RF transseptal wire with a **VersaCross™** Steerable Sheath. A second TSP was performed using the same RF wire and an 8.5F fixed curve **VersaCross™** Transseptal Sheath.
- ▶ **Primary outcome:** Time to first TSP from wire insertion to removal of the dilator and transseptal needle or wire after LA access.
- ▶ **Secondary outcome:** Times to second and combined TSP, TSP fluoroscopy time, number of equipment exchanges, and complications.

RESULTS

- ▶ 75 patients underwent TSP using either the **NRG™** needle-based workflow ($n=36$) or the **VersaCross™** wire-based workflow ($n=39$).
- ▶ Double TSP was performed in 83% of participants in the needle workflow group vs. 90% in the wire workflow group ($p=0.41$). Device exchanges were not required for TSP or repositioning on the septum.

- ▶ The wire-based workflow resulted in 25% shorter time to first TSP compared to the needle-based workflow ($p=0.03$, Figure 1A).
- ▶ 29% shorter time to second TSP (median 6.0 [IQR: 4.9-7.8] min vs. 8.4 [IQR: 5.5-13.4] min, $p=0.04$) and 32% shorter combined TSP time ($p=0.007$) in the wire-based workflow compared to needle-based workflow (Figure 1B).
- ▶ Lower trend (30%, $p=0.06$) for overall TSP fluoroscopy time for the wire-based workflow vs. the needle-based workflow (Figure 1C).
- ▶ More equipment exchanges in the needle-based workflow (one) compared to the wire-based workflow (none) for first TSP; 28% of needle-based workflow patients required two or more exchanges on the first TSP.
- ▶ No complications in the wire-based workflow compared to one transient ventricular asystole due to atrioventricular (AV) block in the needle-based workflow (mechanical injury to the AV node caused by the steerable sheath).

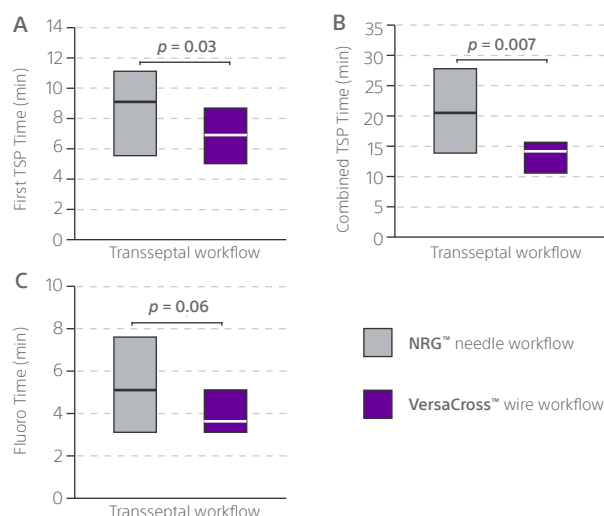


Figure 1. Outcomes following randomization to **NRG™** needle-based workflow or **VersaCross™** wire-based workflow in patients undergoing double TSP for left atrial catheter ablation. A) First TSP time, B) Combined TSP time, C) Overall fluoroscopy time. Values are the median $\pm$ interquartile range (IQR).

DISCUSSION & CONCLUSIONS

- ▶ **VersaCross™** wire-based workflow resulted in shorter time to TSP and fewer device exchanges, eliminating guidewire removal, sheath flushing, and needle insertion after positioning in SVC.
- ▶ **VersaCross™** wire-based workflow allowed easy repositioning for TSP assembly without rewiring to optimize TSP location.
- ▶ TSP procedural variability was limited with **VersaCross™** wire-based workflow (smaller IQRs) resulting in a more consistent experience and an overall positive procedural efficiency.

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