The Office of Scientific Affairs Presents Highlights from:

A new transseptal solution for enabling left atrial access of large delivery sheaths

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INTRODUCTION

- Obtaining transseptal access for delivery sheaths may be hindered by tissue resistance against the sheath-dilator stepped interface, which necessitates additional force that can:
  - Increase the risk of injury
  - Reduce procedural efficiency
  - Lead to procedural termination
- ExpanSure® Large Access Transseptal Dilator is a 12.5F single introducer and dilation device with a smooth sheath-dilator transition that can be used to advance transseptal needles and dilate the septum for left heart access of large sheaths.

METHODS

In Vitro Force Comparison:

- A pre-punctured 0.03" thick silicone membrane was used to model the interatrial septum.
- Crossing force was measured using an Instron® Testing System (Instron) as the ExpanSure® transseptal dilator or 8.5F Swartz™ SL1™ sheath and dilator (Abbott) were advanced through the silicone to model 'transeptal access.'
- The transseptal systems were exchanged for a WATCHMAN™ delivery sheath (Boston Scientific), and force was measured for both cases.

Case Series:

- ExpanSure® transseptal dilator was evaluated in its first clinical experience in a series (n=19) of left atrial appendage closure (LAAC) procedures.
- ExpanSure® transseptal dilator was used to introduce the NRG® Transseptal Needle (Baylis Medical) for transseptal puncture.
- ProTrack™ Pigtail Wire (Baylis Medical) was used to exchange the ExpanSure® transseptal dilator for WATCHMAN™ or Amulet™ (Abbott) implant delivery systems.
- Procedure time, success, fluoroscopy use, and complications were assessed in this series.
- Operator experience was surveyed for ease of septal crossing and integration into typical LAAC workflows.

RESULTS

- While advancing through the silicone model, 38% less work was required with the ExpanSure® transseptal dilator than the SL1™ dilator ($p<0.001$; Fig. 1-A).
- While advancing the WATCHMAN™ sheath through the silicone model, 20% less work was required when the silicone had been pre-dilated with ExpanSure® transseptal dilator than the SL1™ dilator ($p<0.001$; Fig. 1-B).
- Clinical experience showed smooth crossing of the ExpanSure® transseptal dilator regardless of the septal anatomy (e.g., fibrotic and aneurysmal) in addition to well integration with LAAC workflows.
  - Procedures were 100% successful, with no complications
  - Procedure time for delivery sheath access into the left heart was 16.8±11.4min

DISCUSSION & CONCLUSIONS

- Smooth sheath-dilator transition of the ExpanSure® transseptal dilator and reduced crossing force provides a potential solution to reduce septal tearing and tissue injury.
- Large (12.5F) diameter allowed tissue dilation to facilitate advancement of a large delivery sheath.
- Easy advancement of the delivery sheaths was achieved using the NRG® needle, ProTrack™ wire and ExpanSure® transseptal dilator which enabled the puncture, exchange, and effective dilation of the septum.
- The ExpanSure® transseptal dilator may be a key tool for improving efficiency of left atrial access for procedures requiring large sheaths.

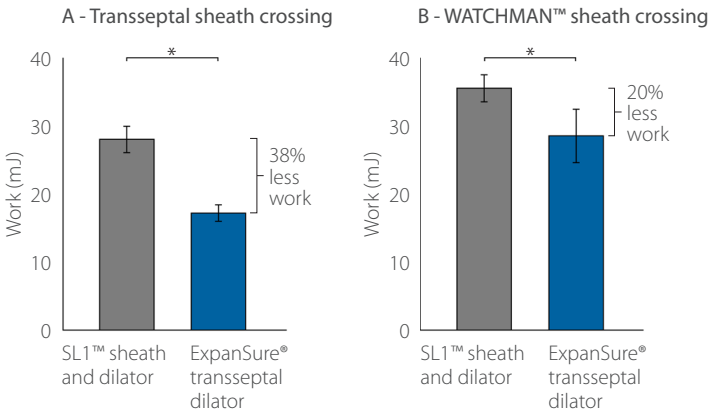

Figure 1: (A) Bench study showed 38% less work required to cross using the ExpanSure® transseptal dilator than a standard SL™ sheath. (B) 20% less work was required to advance the WATCHMAN™ sheath after pre-dilating with the ExpanSure® transseptal dilator than a SL™ sheath (n = 12; * p <0.001).

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