Highlights from:
Jacqueline Saw, MD, Thomas Gilhofer, MD, Darwin Yeung, MD, and Michael Tsang, MD
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First experience with the ExpanSure Dilation System to streamline transseptal puncture for left atrial appendage closure

INTRODUCTION

- Tissue resistance against the sheath-dilator interface may be experienced while obtaining transseptal access for delivery sheaths.
- This could reduce procedural efficiency and might require tissue dilation or re-puncture at a thinner part of the septum.
- This study describes the use of the **ExpanSure™** Large Access Transseptal Dilator (Baylis Medical*) to facilitate access for large left atrial appendage closure (LAAC) implant delivery sheaths.
  - The **ExpanSure™** Large Access Transseptal Dilator is a 12.5F single unit system with no sheath-dilator interface that can be used to both advance a transseptal needle and dilate the septum to obtain left atrial access

METHODS

- Prospective evaluation of initial clinical experience using the **ExpanSure™** Dilator in patients undergoing LAAC procedures using WATCHMAN™ (Boston Scientific) or Amulet™ (Abbott) implants.
- Transesophageal echocardiography was used for transseptal puncture and catheter guidance.
- The **ExpanSure™** Dilator was introduced though the right femoral vein towards the septum and used to position a radiofrequency transseptal needle infero-posteriorly at the fossa ovalis for transseptal puncture.
- The **ProTrack™** Pigtail Wire (Baylis Medical*) was used through the **ExpanSure™** Dilator for delivery sheath exchange into the left atrium.
- Time taken for procedural steps (i.e. transseptal access, advancement of device delivery sheath into the left atria, release of LAAC device, overall procedure, and fluoroscopy use) and subjective experience for left atrial access was assessed.

RESULTS

- 19 LAAC cases, including three with aneurysmal and one with lipomatous septum, were performed using the **ExpanSure™** Dilator with 100% success.
  - Eight cases using the WATCHMAN™ Implant (mean implant size: 28.7±2.9 mm; 14F delivery sheath)
  - Eleven cases using the Amulet™ Implant (mean implant size 25.5±3.5 mm; 6 cases with 12F delivery sheath, 5 cases with 14F delivery sheath)

Time taken for each step from femoral access (minutes)	ExpanSure™ Dilator
Transseptal access time	10.1±7.5
Delivery sheath access to left atrium time	16.8±11.4
Time to occluder release time	36.5±13.6
Overall procedure time	37.6±13.5
Fluoroscopy use time	13.0±6.9

Table 1. Procedural time points

- Both the **ExpanSure™** Dilator and delivery sheath were advanced into the left atrium easily without excessive tenting of the septum.
- No access site and in-hospital complications occurred for any of the cases.

DISCUSSION AND CONCLUSIONS

- The **ExpanSure™** Large Access Transseptal Dilator has a seamless design with no dilator-sheath step-up, and a large diameter that facilitates easy and efficient interatrial crossing of large delivery sheaths.
- This design may be more beneficial compared to standard sheath-dilator systems.

* A wholly-owned subsidiary of Boston Scientific Corporation.

Brief Summary | **ProTrack™** Pigtail Wire

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.

INDICATIONS FOR USE: The ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.

ADVERSE EVENTS: Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

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