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Inohara et al., Journal of Cardiovascular Electrophysiology, Mar 2021 DOI: 10.1111/jce.14903

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

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 transseptal 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 ($p<0.001$; Figure 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 ($p<0.001$; Figure 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 integrating well with LAAC workflows.
  - Procedures were 100% successful, with no complications
  - Procedure time for delivery sheath access into the left heart was 16.8±11.4 min

DISCUSSION AND 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.

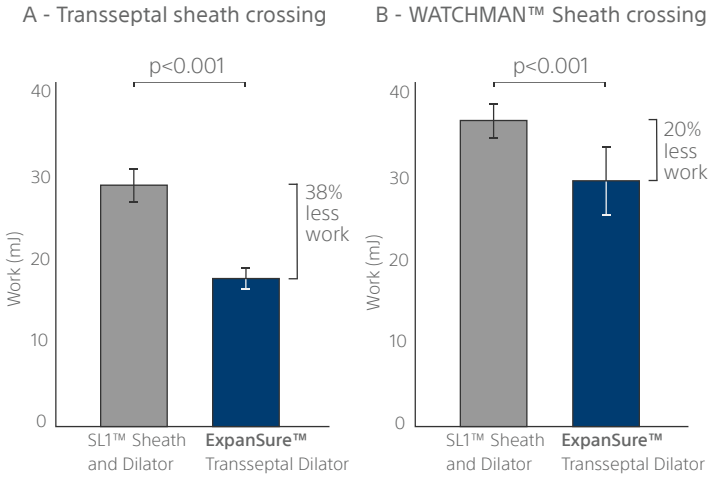

Figure 1. (A) Bench study showed 38% less work required to cross using the **ExpanSure™** Transseptal Dilator than a standard SL™ Sheath. (B) 20% less work was required to advance the WATCHMAN™ Sheath after pre-dilating with the **ExpanSure™** Transseptal Dilator than a SL™ Sheath (n=12).

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Brief Summary | **NRG™** Transseptal Needle

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 NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This 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. • The NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

PRECAUTIONS: • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

EP-1506305-AA

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

EP-1515204-AA

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