

A Simple Improvement on Existing Technology to Enhance Transseptal Puncture and Left Atrial Access Using Large Diameter Sheaths for Mapping, Ablation and LAA Occlusion Procedures

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Since the earliest description of transseptal catheterization techniques by Ross, et.al. in the late 1950's, to the modern era of cardiac electrophysiology which relies heavily on the same technique, the evolution of technology has been critical to transseptal catheterization improvement, including ease of performance and safety¹⁻³. In this issue of the Journal of Cardiac Electrophysiology⁴, Inohara, et.al. report their benchtop research and first in human experience with a new transseptal dilator (ExpanSure Large Access Transseptal Dilator®, Baylis Medical, Montreal, Canada) used to aid left atrial (LA) access for large sheaths commonly employed in procedures such as the Watchman™ LA appendage occluder deployment.

The authors employed a standard test system (Instron Testing System, Norwood, MA) to measure force and displacement in-vitro while advancing the new ExpanSure® dilator compared to a standard 8.5F Swartz™ SL1 sheath and dilator (Abbott Medical, St. Paul, MN) through a model silicone septum. In addition, during in-vivo studies in man, they determined time to positioning of a Watchman™ delivery sheath (Boston Scientific, St. Paul, MN) in the LA during a standard LA appendage occlusion procedure and administered a survey to the operators to subjectively assess crossing force and tissue resistance observed after predilating with the Expansure® dilator.

The authors found during their in-vitro studies that use of the Expansure® dilator reduced peak crossing force and total work by 20% and 38%, respectively, compared to a standard SL1 sheath when advanced through the silicone septum, and a 12% reduction in peak crossing force and 20% reduction in total work for the Watchman™ sheath when advanced through the silicone septum after pre-dilatation with the Expansure® dilator compared to the SL1 sheath. They also found during their in-vivo studies in patients that prior to deployment of the Watchman™ device in the LA appendage, delivery of the initial large guiding sheath to the LA

was accomplished in a short time, and subjectively with a low crossing force and tissue resistance in most cases. However, there was no statistical comparison of these objective or subjective variables during the Watchman™ procedures performed following pre-dilation with the Expansure® dilator to those following pre-dilation with a standard SL1 sheath or without pre-dilation.

While the use of a large dilator to transition from a standard transseptal crossing tool (e.g. 8.5 French SL1 sheath) to one of several large diameter transseptal sheaths commonly in use today (e.g. Watchman™ guide sheath 14 French OD, Flexcath Medtronic guide sheaths 13 or 15 French OD, Acutus guide sheath 16 French OD) is obviously logical to allow for greater ease in crossing the inter-atrial septum, until now this technology has not been commercially available⁵⁻⁷. Theoretical approaches for septal dilatation after initial puncture have been proposed using balloons, stents, and expanding sheaths, but these approaches would involve use of additional complex equipment and be time consuming. A simple approach such as that described in this paper using the Expansure® dilator alone with a transseptal needle (i.e. without the need for another standard 8.5 French sheath system first followed by a dilator exchange) is technically appealing, potentially cost saving, and if the results are reproducible, may enhance delivery of a large diameter sheath into the LA. Transseptal catheterization can be difficult in contemporary practice (particularly in a repeat procedure where the septum may be stiff due to fibrosis from previous healing of the access point) when transitioning from a standard size sheath such as an 8.5 French transseptal sheath to a large diameter 13-16 French sheath for mapping, ablation, or LAA occluder device delivery. Perhaps the only potential concern if using the Expansure® dilator alone versus a standard 8.5 French SL1 sheath would be the larger profile of the system when performing initial transseptal catheterization, and the maneuverability of this larger system

in achieving the desired transseptal access site. However, this did not appear to be a concern from subjective operator responses during this study.

In summary, while randomized clinical trials comparing the Expansure® dilator to a standard transseptal sheath for inter-atrial septal crossing prior to upsizing to a large diameter sheath for ease and safety would provide definitive evidence supporting its use, the data presented in this paper, in addition to the logic behind this approach and low probability of any increased risk, make it reasonable to adopt in clinical practice without mandating further investigation.

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