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.
- Trans-esophageal echocardiography was used for transseptal puncture (TSP) and catheter guidance.
- ExpanSure dilator was introduced though the right femoral vein towards the septum and used to position a radiofrequency (RF) transseptal needle infero-posteriorly at the fossa ovalis for transseptal puncture.
- 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 3 with aneurysmal and 1 with lipomatous septum, were performed using the ExpanSure® dilator with 100% success.
  - 8 cases using WATCHMAN™ implant (mean implant size: 28.7 ± 2.9 mm; 14F delivery sheath).
  - 11 cases using Amulet™ implant (mean implant size 25.5 ± 3.5 mm; 6 cases with 12F delivery sheath, 5 cases with 14F delivery sheath).

Table 1: Procedural time points

<table>
<thead>
<tr>
<th>Procedure</th>
<th>ExpanSure</th>
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<tbody>
<tr>
<td>Transeptal access time</td>
<td>10.1±7.5</td>
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<tr>
<td>Delivery sheath access to LA time</td>
<td>16.8±11.4</td>
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<tr>
<td>Time to occluder release time</td>
<td>36.5±13.6</td>
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<tr>
<td>Overall procedure time</td>
<td>37.6±13.5</td>
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<tr>
<td>Fluoroscopy use time</td>
<td>13.0±6.9</td>
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DISCUSSION & CONCLUSIONS

- The ExpanSure® Large Access Transseptal Dilator has a seamless design with no dilator-sheath step-up and 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.