SAFETY AND COMPLICATIONS RESULTS

- The primary safety assessment met the pre-defined acceptance criterion.
- Access-related major complication rates at 48 hours (1.3%) and 30 days were low (1.9%).
- Most complications occurred within 48 hours.

Freedom From Major Femoral Vein Access-Related Complications* Through 30 Days

Femoral Vein Access-Related Complication Rates

Note: Primary analysis population used and included only each subject’s first occurrence of each event. Purple dotted lines represent 95% confidence intervals.

Note: Major complications were reported in 3 subjects and events included deep vein thrombosis in target limb (1), significant bleeding requiring transfusion or surgical intervention (1), hematoma not requiring transfusion or surgical intervention (1), access site re-bleeding requiring treatment or re-hospitalization (1), and pseudoaneurysm (1).

CAUTION: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.
PERCLOSE PROGLIDE COHORT IN THE REALISM CLINICAL TRIAL

A prospective analysis was performed to evaluate the safety and effectiveness of Perclose ProGlide (Perclose) in closing large-sized venous access sites through a retrospective data collection. The prospective analysis included subjects in whom Perclose was used as the primary method for large-bore venous access site closure during the MitraClip index procedure with a 24F vascular sheath.

SITE SELECTION FLOW FOR STUDY

MATERIALS AND METHODS

- 5 sites with high VCD usage and using Perclose for venous closure were included
- Primary analysis cohort (Perclose group); subjects who received at least one Perclose as the intended femoral vein access site closure device
- Predefined subgroup analyses included:
  - Perclose Alone (without any adjunctive methods other than brief ≤10 minutes manual compression vs. Perclose plus secondary vessel closure method)
  - One Perclose vs. Two Percloses

PRIMARY ANALYSIS POPULATION

- Predefined subgroup analyses included:
  - Perclose Alone (without any adjunctive methods other than brief ≤10 minutes manual compression vs. Perclose plus secondary vessel closure method)
  - One Perclose vs. Two Percloses

BASELINE CHARACTERISTICS

<table>
<thead>
<tr>
<th>PERCLOSE (N=159)</th>
<th>PERCLOSE Alone (%/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at procedure, years (range)</td>
<td>76 (28/98)</td>
</tr>
<tr>
<td>Male</td>
<td>52.8% (84/159)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>89.2% (141/158)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>84.8% (143/158)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>64.7% (99/153)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>67.7% (107/158)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>26.4% (42/159)</td>
</tr>
<tr>
<td>Moderate to severe renal disease</td>
<td>24.3% (39/159)</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>23.3% (37/159)</td>
</tr>
<tr>
<td>NYHA Functional Classification</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>59.7% (95/159)</td>
</tr>
<tr>
<td>IV</td>
<td>24.8% (39/159)</td>
</tr>
</tbody>
</table>

NYHA = New York Heart Association

Perclose ProGlide
Suture-Mediated Closure System

DON'T JUST CLOSE. REPAIR.

RESULTS

KEY STUDY FINDINGS

- Major complication was low at 1.9%
- Freedom from major femoral vein access site-related complications was 98.1% at 30 days
- Perclose is safe and effective in the closure of venous access site with up to 24F sheath

98.1%
Freedom from major femoral vein access site-related complications

1.9%
Low major complication

Low major complications at 30 days

SUBJECT RESULTS

- Patients treated with two Percloses 90.6% [144/159] vs. one Perclose 9.4% [15/159]
- Majority of subjects 69.2% [110/159] were treated with Perclose alone
- “Perclose Alone” group mean time to achieve hemostasis was 5.15 ± 6.05 minutes

Achievement of Hemostasis With Perclose Alone vs. Perclose Plus Adjunctive Methods

Mean Time to Achieve Hemostasis

Data shows mean ± standard deviation.

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