Clinical Outcomes Among Vascular Procedure Patients Receiving Suture-mediated vs Surgical Cutdown for Closure of Large-bore Arterial Access

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Perclose ProGlide vs. Surgical Closure Outcomes – Real world Evidence

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☒ Consulting: Abbott Vascular
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Acknowledgement

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1. New York Presbyterian Hospital / Weill Cornell Medical Center, Weill Cornell Medicine
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3. Abbott Laboratories: Santa Clara, CA
4. St. Luke’s Episcopal Hospital – Texas Heart Institute, The University of Texas Medical School, Baylor College of Medicine, University of Zagreb Medical School
Background

- Patients undergoing procedures requiring large bore arterial access require arterial closure
- Closure is typically achieved using either a surgical cutdown and manual closure (cutdown) or a closure device such as the Perclose ProGlide Suture-Mediated Closure System (Perclose)
Perclose ProGlide Suture-Mediated Closure Device

- Percutaneous “surgical repair” with USP Class I monofilament polypropylene suture
- Pre-close with heat-formed pre-tied knot
- Sheath upsize / downsize for complex cases
- Indicated for 5F to 21F
Objective

• Compare clinical outcomes and complication rates among patients undergoing closure of large bore arterial access using the Perclose ProGlide Suture-Mediated Closure System (Perclose) vs surgical cutdown (Cutdown) in a real-world setting
Database and Patient Population

• Retrospective study utilizing IBM® Explorys data from IBM Watson Health™
  – Longitudinal data for ~55 mil US pts since 2012
• Patients undergoing the following procedures:
  – Transcatheter Aortic Valve Replacement (TAVR)
  – Endo Abdominal Aortic Aneurysm Repair (AAA)
  – Thoracic Endovascular Aortic Repair (TAA)
  – Balloon Aortic Valvuloplasty (BAV)
Patient Selection and Methodology

Record \textit{w/} model number for Perclose

Pts receiving procedures 1/1/13 – 4/24/17

Record \textit{w/out} model number for Perclose*

Perclose Cohort

Cutdown Cohort

Match cohorts:
- Age
- Sex
- Index proc
- Index yr
- Baseline blood transfusion
- Peripheral vasc disease

Multivariate regression controlled for baseline:
- Anticoagulant use
- Atherosclerosis
- Cancer
- Chronic respiratory disease
- MI
- Stroke
- Blood transfusion

*Patients treated by the same physicians that did not have record of Perclose or any other vessel closure system
## Baseline Characteristics

*From matched cohort, 6 months pre-index  
**p<0.05

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Cutdown N=757</th>
<th>Perclose N=757</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age</td>
<td>76.8</td>
<td>77.0</td>
</tr>
<tr>
<td>Male</td>
<td>67.6%</td>
<td>67.6%</td>
</tr>
<tr>
<td><strong>Clinical Comorbidities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>81.4%</td>
<td>80.1%</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>23.1%</td>
<td>23.1%</td>
</tr>
<tr>
<td>Chronic respiratory disease</td>
<td>29.3%</td>
<td>29.5%</td>
</tr>
<tr>
<td>MI</td>
<td>7.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Stroke**</td>
<td>7.7%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Cancer</td>
<td>11.8%</td>
<td>14.5%</td>
</tr>
<tr>
<td>Renal dysfunction</td>
<td>26.7%</td>
<td>27.5%</td>
</tr>
</tbody>
</table>
Baseline Characteristics*, cont.

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Cutdown N=757</th>
<th>Perclose N=757</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Comorbidities, cont.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atherosclerosis</td>
<td>64.1%</td>
<td>64.5%</td>
</tr>
<tr>
<td>Coronary</td>
<td>59.6%</td>
<td>60.2%</td>
</tr>
<tr>
<td>Lower extremity specified</td>
<td>4.5%</td>
<td>4.5%</td>
</tr>
<tr>
<td><strong>Clinical Complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion procedure</td>
<td>2.5%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Hemorrhage complicating a procedure</td>
<td>0.4%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Any infection</td>
<td>26.7%</td>
<td>28.5%</td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulants**</td>
<td>17.8%</td>
<td>44.9%</td>
</tr>
<tr>
<td>Antiplatelets</td>
<td>0.8%</td>
<td>0.4%</td>
</tr>
<tr>
<td>MRSA antibiotics**</td>
<td>27.3%</td>
<td>11.0%</td>
</tr>
</tbody>
</table>

*From matched cohort, 6 months pre-index
**p<0.05
Patients may have had multiple procedures during index admission.
Results – Matched Cohorts

Index Hospitalization

- Blood transfusion: 35.7% (Cutdown) vs. 9.5% (Perclose), p<0.001
- Hemorrhage: 3.0% (Cutdown) vs. 1.8% (Perclose), p=0.134
- Infection: 22.2% (Cutdown) vs. 15.6% (Perclose), p=0.001

30 Days

- Blood transfusion: 35.0% (Cutdown) vs. 10.7% (Perclose), p<0.001
- Hemorrhage: 3.7% (Cutdown) vs. 1.7% (Perclose), p=0.026
- Infection: 31.2% (Cutdown) vs. 21.6% (Perclose), p<0.001
### Multivariate Results: Index Procedure

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Time Point</th>
<th>Odds Ratio</th>
<th>p-value</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Cutdown</strong></td>
<td><strong>Perclose</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=757</td>
<td>N=757</td>
<td></td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>Index Proc Stay</td>
<td>1</td>
<td>0.20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>Index Proc Stay</td>
<td>1</td>
<td>0.67</td>
<td>0.283</td>
</tr>
<tr>
<td>Infection</td>
<td>Index Proc Stay</td>
<td>1</td>
<td>0.59</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

- At index admission, Perclose patients 80% less likely to require a blood transfusion and 61% less likely to have an infection.
### Multivariate Results: 30 Days

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Time Point</th>
<th>Odds Ratio</th>
<th>p-value</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cutdown N=757</td>
<td>ProGlide N=757</td>
<td></td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>30 days</td>
<td>1</td>
<td>0.21</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>30 days</td>
<td>1</td>
<td>0.45</td>
<td>0.034</td>
</tr>
<tr>
<td>Infection</td>
<td>30 days</td>
<td>1</td>
<td>0.57</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

- At 30-days, Perclose patients 79% less likely to require a blood transfusion, 63% less likely to have an infection, and 55% less likely to have a hemorrhage
Mortality and Length of Stay

- At 30 days, Perclose patients 70% less likely to die

*Logistical regression model performed for mortality.
**Poisson regression model performed for hospital length of stay.
COST ANALYSIS

▪ The MarketScan sample used for cost analyses was comprised of patients undergoing any of the 4 procedures of interest in the year 2016.

▪ A majority of patients underwent TAVR at index date

Explorys Sample for Main Analyses:
- Transcatheter aortic valve replacement/repair (TAVR): 44.9%
- Abdominal aortic aneurysm repair (AAA): 38.6%
- Thoracic endovascular aortic repair/TEVAR (TAA): 21.3%
- Balloon aortic valvuloplasty (BAV): 3.4%

MarketScan Sample for Cost Analyses:
- Transcatheter aortic valve replacement/repair (TAVR): 68.5%
- Abdominal aortic aneurysm repair (AAA): 25.9%
- Thoracic endovascular aortic repair/TEVAR (TAA): 4.7%
- Balloon aortic valvuloplasty (BAV): 2.8%
While controlling for index procedure, age, and gender, length of stay was a significant predictor of costs, with each day associated with a 4% increase in total cost for the hospitalization ($p<0.05$).

To quantify the predicted cost difference between cohorts, we compared mean and median length of stay results obtained from the main analysis:

- **Mean LOS**
  - ProGlide: 5.1 days
  - Cutdown: 9.0 days
  - Predicted difference: $14,687

- **Median LOS**
  - ProGlide: 3.0 days
  - Cutdown: 7.0 days
  - Predicted difference: $20,599
Limitations

• Study is retrospective and not randomized
• Clinical characteristics that are unavailable in the database (ie, arterial anatomy) may impact the outcomes
• Medical record information may be incomplete / inconsistent, leading to misclassification of patients
• Direct causality can not be ascertained
Conclusions

- The use of Perclose for closure of large bore arterial access is associated with significantly lower blood transfusions, infections, mortality, and length of stay compared to Cutdown
  - Perclose patients 80% less likely to require a blood transfusion and 61% less likely to have an infection
  - Hospital length of stay significantly shorter for Perclose patients (5 days vs 10 days)
- Perclose should be considered preferred to Cutdown to minimize access site complications and resource use
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