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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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 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

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

Record w/ model number for Perclose

Record w/out model number for Perclose*

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*

| Cohort               | Cutdown  
|----------------------|---------|
|                      | N=757   | Perclose  
|                      | N=757   |
| **Patient Characteristics** |         |         |
| Mean age             | 76.8    | 77.0    |
| Male                 | 67.6%   | 67.6%   |
| **Clinical Comorbidities** |         |         |
| Hypertension         | 81.4%   | 80.1%   |
| Type 2 diabetes      | 23.1%   | 23.1%   |
| Chronic respiratory disease | 29.3% | 29.5% |
| MI                   | 7.0%    | 5.0%    |
| Stroke**             | 7.7%    | 5.0%    |
| Cancer               | 11.8%   | 14.5%   |
| Renal dysfunction    | 26.7%   | 27.5%   |

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

- Transcatheter aortic valve replacement / repair (TAVR) - 44.9%
- Thoracic Endovascular Aortic Repair (TAA) - 38.6%
- Endovascular Abdominal Aortic Aneurysm Repair (AAA) - 21.3%
- Balloon Aortic Valvuloplasty (BAV) - 3.4%

Patients may have had multiple procedures during index admission.
Results – Matched Cohorts

Index Hospitalization

- Blood transfusion: 35.70% (p<0.001)
- Hemorrhage: 9.50% (p=0.134)
- Infection: 22.20% (p=0.001)

30 Days

- Blood transfusion: 35.00% (p<0.001)
- Hemorrhage: 10.70% (p=0.026)
- Infection: 21.60% (p<0.001)

The graphs compare the outcomes of Cutdown and Perclose methods for blood transfusion, hemorrhage, and infection rates.
## 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>Cutdown</td>
<td>Perclose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=757</td>
<td>N=757</td>
<td></td>
</tr>
<tr>
<td><strong>Blood Transfusion</strong></td>
<td>Index Proc Stay</td>
<td>1</td>
<td>0.20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Hemorrhage</strong></td>
<td>Index Proc Stay</td>
<td>1</td>
<td>0.67</td>
<td>0.283</td>
</tr>
<tr>
<td><strong>Infection</strong></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></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood Transfusion</strong></td>
<td>30 days</td>
<td>1</td>
<td>0.21</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Hemorrhage</strong></td>
<td>30 days</td>
<td>1</td>
<td>0.45</td>
<td>0.034</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.22</td>
</tr>
<tr>
<td><strong>Infection</strong></td>
<td>30 days</td>
<td>1</td>
<td>0.57</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.44</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

**Logistical regression model performed for mortality.**

**Poisson regression model performed for hospital length of stay.**

**Mortality**

- **30-days:**
  - Cutdown: 3.00%
  - Perclose®: 1.10%
  - **p = 0.006**

- **6-months:**
  - Cutdown: 6.90%
  - Perclose®: 4.90%
  - **p = 0.101**

**Hospitalization Length of Stay (LOS)**

- **Relative LOS**
  - Cutdown: 1.0
  - Perclose®: 0.57
  - **p < 0.001**

**Time Point**

- **30-days**
  - Cutdown: 0.13
  - Perclose®: 0.71

**Hospitalization Length of Stay (LOS)**

- **5.4 days**

**Mortality**

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

**Hospitalization Length of Stay (LOS)**

- Hospitalization 43% shorter for Perclose patients

*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): 21.3%
- Thoracic endovascular aortic repair/TEVAR (TAA): 38.6%
- 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%
COST-ANALYSIS: Length of Stay, Multivariate Model

- 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:

```
Predicted difference = $14,687
Predicted difference = $20,599
```

- Mean LOS (ProGlide=5.1 days; Cutdown=9.0 days)
- Median LOS (ProGlide=3.0 days; Cutdown=7.0 days)
Limitations

• Study is retrospective and not randomized
• Clinical characteristics that are unavailable in the database (i.e., 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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