Vascular Closure Device Type Impacts Bleeding and Vascular Complications After TAVR: Results from the BRAVO 3 Randomized Trial

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The BRAVO-3 Investigators
Study Objectives

• To investigate the impact of type of vascular closure device on clinical outcomes after transfemoral TAVR in the large randomized BRAVO-3 trial population

  • Major Bleeding (BARC criteria)
  • Major Vascular Complications
  • Minor Vascular Complications

  • Acute Kidney Injury (AKI)
  • Major Adverse Cardiac and Cerebral Events (MACCE)
  • Death
BRAVO 3 Trial Population
N = 802

56 patients not included in analysis
- Surgical Access or Alternate VCD (N = 52)
- No VCD data available (N = 4)

Received Vascular Closure Device
N = 746 (93%)

Non-randomized assignment

Prostar
N = 352 (47%)

ProGlide
N = 394 (53%)
## Clinical Outcomes

<table>
<thead>
<tr>
<th>30 Day Clinical Outcomes</th>
<th>PS</th>
<th>PG</th>
<th>Unadjusted OR</th>
<th>p-value</th>
<th>Adjusted OR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major/Minor Vascular Complications</strong></td>
<td>86 (24%)</td>
<td>61 (15%)</td>
<td>0.57 (0.39 – 0.82)</td>
<td>0.02</td>
<td>0.54 (0.37 – 0.80)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Major Vascular Complications</td>
<td>41 (12%)</td>
<td>28 (7%)</td>
<td>0.68 (0.35 – 0.96)</td>
<td>0.03</td>
<td>0.62 (0.37 – 1.04)</td>
<td>0.07</td>
</tr>
<tr>
<td>Minor Vascular Complications</td>
<td>47 (13%)</td>
<td>33 (8%)</td>
<td>0.59 (0.37 – 0.95)</td>
<td>0.03</td>
<td>0.55 (0.34 – 0.90)</td>
<td>0.02</td>
</tr>
<tr>
<td>Major Bleeding (BARC ≥3b)</td>
<td>39 (11%)</td>
<td>33 (8%)</td>
<td>0.73 (0.45 – 1.19)</td>
<td>0.21</td>
<td>0.74 (0.45 – 1.22)</td>
<td>0.23</td>
</tr>
<tr>
<td>Any BARC Bleeding</td>
<td>167 (47%)</td>
<td>194 (49%)</td>
<td>1.07 (0.80 – 1.43)</td>
<td>0.49</td>
<td>1.10 (0.82 – 1.49)</td>
<td>0.52</td>
</tr>
<tr>
<td><strong>Acute Kidney Injury</strong></td>
<td>70 (25%)</td>
<td>57 (17%)</td>
<td>0.68 (0.46 – 1.00)</td>
<td>0.05</td>
<td>0.61 (0.40 – 0.90)</td>
<td>0.01</td>
</tr>
<tr>
<td>MACCE</td>
<td>28 (8%)</td>
<td>32 (8%)</td>
<td>1.02 (0.60 – 1.74)</td>
<td>0.93</td>
<td>1.09 (0.64 – 1.88)</td>
<td>0.74</td>
</tr>
<tr>
<td>Death</td>
<td>21 (6%)</td>
<td>16 (4%)</td>
<td>0.67 (0.34 – 1.30)</td>
<td>0.23</td>
<td>0.80 (0.41 – 1.59)</td>
<td>0.53</td>
</tr>
</tbody>
</table>
Conclusions

• Access-site related **vascular complications occurred in 24%** of all patients following transfemoral TAVR

• ProGlide was associated with significantly **lower rates of 30-day major or minor vascular complications**

• ProGlide was associated with **lower risk of acute kidney injury**

• ProGlide may be associated with **shorter length of hospital stay** and **shorter procedural duration**
Thank you for your attention

Questions and Comments to:
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