First clinical experience with GORE® TAG® Conformable stent graft with ACTIVE CONTROL system

G. Torsello, Münster
Disclosure

Speaker name:

......................G.Torsello...........................................................

I have the following potential conflicts of interest to report:

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

Research grant by Gore

☐
# Meta-analysis of perioperative results

<table>
<thead>
<tr>
<th></th>
<th>TEVAR</th>
<th>Open</th>
<th>Pooled OR</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periop. mortality</td>
<td>5.57%</td>
<td>16.5%</td>
<td>0.36 (95% CI 0.228-0.578)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Major neurologic injury</td>
<td>5.4%</td>
<td>14.0%</td>
<td>0.39 (95% CI 0.25-0.62)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Major reintervention</td>
<td>7.0%</td>
<td>8.4%</td>
<td>0.91 (95% CI 0.610-1.619)</td>
<td>NS</td>
</tr>
<tr>
<td>Length of ITU stay</td>
<td>NA</td>
<td>NA</td>
<td>–1.26 days (95% CI –1.77 to –0.76)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>NA</td>
<td>NA</td>
<td>–1.00 days (95% CI –1.58 to –0.45)</td>
<td>0.0004</td>
</tr>
</tbody>
</table>

«bird-beak» after graft deployment in the aortic arch
The new „Active Control System“

Controlled two deployment stages

Optional angulation control in the aortic arch
Delivery system similar to Matryoshka stacking dolls

( of decreasing size placed one inside another)

1. Deployment at intermediate diameter
2. Optimize angulation (optional)
3. Deployment at full diameter
4. Optimize angulation (optional)
5+6. Withdraw lock-wire and angulation control fibers
Deployment Optimization Techniques

• Advance device past target location and bring back
  – Last movement always distal
• Position device on outer curve
  – Stabilize device on the outer curve by maintaining forward pressure on the wire
• Two-person deployment
  – Stabilize sheath to body
  – Stabilize catheter to sheath
• Slower deployment while maintaining a steady motion
  – An aggressive pull on the deployment line may result in sub-optimal deployment accuracy
## Active Control System - preliminary results -

<table>
<thead>
<tr>
<th></th>
<th>TAA N = 14</th>
<th>Dissection N = 2</th>
<th>Trauma N = 0</th>
<th>Total N = 16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Technical success (%)</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
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<tr>
<td>Secondary procedure</td>
<td>1</td>
<td>0</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Endo/ Open</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
SURPASS Registry: Design

• Observational
• Prospective
• Single-arm
• Post-market registry
• 125 patients
• Up to 20 European sites in 7 countries
Summary

The Active Control System of the well known CTAG-device is a unique system to achieve an ideal positioning of the graft.

No need for aggressive blood pressure reduction during the deployment.

Graft angulation can be adjusted in the arch but be aware because it is not reversible.
Thank you!

homepage: www.gefaesschirurgie-muenster.de

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