Where is FEVAR Going: Custom-Made By Industry vs Off-The-Shelf (OTS) Devices vs. Surgeon Modified

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Background

Our center is currently performing a physician-sponsored investigational device exemption trial (IDE #G130210) to evaluate FEVAR using physician-modified endografts (PMEG) and company manufactured devices (CMD).

Disclosures

- A. Schanzer: Case proctor, Cook Medical

Physician-Modified Endografts (PMEG)

PMEG: commercially available aortic endografts, modified on back table by surgeon

Advantage: devices available immediately for modification
Disadvantage: limited design options

Company Manufactured Devices (CMD)

CMD: company-manufactured to specifications provided by surgeon, based on preoperative measurements

Advantages: rigorous quality control; range of options for customization
Disadvantages: 8-12 weeks for graft manufacturing; limited availability
Primary Aim

To evaluate differences in perioperative and 1-year outcomes between PMEG and CMD using a matched cohort analysis.

Methods

• Primary endpoint
  – Perioperative complications at 30 days
    • Myocardial infarction, paraplegia, paralysis, stroke, renal function, acute onset dialysis, target artery patency, access vessel complications, presence of a type I or type III endoleak, and mortality
  
• Secondary endpoint
  – Postoperative outcomes at 1 year, Kaplan-Meier method
    • Type I or III endoleak, target artery patency, reintervention, and overall survival
  
• Analyses stratified by device type (PMEG or CMD)

Results: Cohort Characteristics

<table>
<thead>
<tr>
<th></th>
<th>PMEG (n=41)</th>
<th>CMD (n=41)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>66.1±13.4</td>
<td>65.6±12.5</td>
<td>0.70</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>28.4±5.9</td>
<td>28.3±5.7</td>
<td>0.86</td>
</tr>
<tr>
<td>Hypertension</td>
<td>36 (88%)</td>
<td>39 (95%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Diabetes</td>
<td>13 (32%)</td>
<td>15 (37%)</td>
<td>0.46</td>
</tr>
<tr>
<td>Smoking</td>
<td>13 (32%)</td>
<td>12 (29%)</td>
<td>0.59</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>7 (17%)</td>
<td>7 (17%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Prior aneurysm repair</td>
<td>18 (44%)</td>
<td>21 (51%)</td>
<td>0.47</td>
</tr>
<tr>
<td>Type I endoleak</td>
<td>2 (5%)</td>
<td>2 (5%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Type III endoleak</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Target artery patency</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Access vessel complications</td>
<td>2 (5%)</td>
<td>1 (2%)</td>
<td>0.69</td>
</tr>
</tbody>
</table>

Results: Operative Characteristics

<table>
<thead>
<tr>
<th></th>
<th>PMEG (n=41)</th>
<th>CMD (n=41)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose to procedure (min)</td>
<td>86.8 (58.7, 115.3)</td>
<td>73.9 (44.9, 110.2)</td>
<td>0.22</td>
</tr>
<tr>
<td>Dose dose (mg)</td>
<td>5.97 (4.40, 9.25)</td>
<td>4.77 (2.97, 6.81)</td>
<td>0.19</td>
</tr>
<tr>
<td>Operator’s time (min)</td>
<td>88 (42)</td>
<td>90 (44)</td>
<td>0.52</td>
</tr>
<tr>
<td>Time to incision (min)</td>
<td>91 (33)</td>
<td>76 (23)</td>
<td>0.02</td>
</tr>
<tr>
<td>Time to incision (min)</td>
<td>279 (64)</td>
<td>319 (79)</td>
<td>0.00</td>
</tr>
<tr>
<td>Operating room time (min)</td>
<td>12.850 (10.904, 19.834)</td>
<td>14.407 (11.878, 17.034)</td>
<td>0.58</td>
</tr>
<tr>
<td>Hospital length of stay (median)</td>
<td>5 (3, 7)</td>
<td>2 (2, 7)</td>
<td>0.82</td>
</tr>
</tbody>
</table>

1-Year Survival

PMEG=83%, CMD=92%

log-rank p=0.33
1-Year Type I or III Endoleak

PMEG = 91%, CMD = 97%
log-rank p = .46

1-Year Target Artery Patency

PMEG = 93%, CMD = 100%
log-rank p = .08

1-Year Reintervention Rate

PMEG = 37%, CMD = 13%
log-rank p = .04

In Summary
CMD had a significantly reduced rate of 1-year reinterventions over PMEG.

Modest differences favor CMD in operative technique and efficiency, e.g. volume of contrast used, radiation exposure, and operative times.

Off The Shelf Devices

- Option A: 64%
- Option B: 55%
- Combined: 76%
“…. applicable in 88% of cases of TAAA that would otherwise have been treated using customized stent-grafts…”

Conclusion

Within the context of an IDE clinical trial, CMD and PMEG both appear to function equally well, aside from advantage in 1-year reinterventions.

Further studies and long-term durability data are imperative to evaluate whether this relative equivalence persists over the long term.

OTS devices are attractive and can be used without manufacturing delay but do always require some compromise compared to a patient specific design.

Thank You.