Update on BEVAR trial for bridging stents

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Disclosure
Speaker name:

I have the following potential conflicts of interest to report:

☒ Receipt of grants/research support
☐ Receipt of honoraria and travel support
☐ Participation in a company-sponsored speaker bureau
☐ Employment in industry
☐ Shareholder in a healthcare company
☐ Owner of a healthcare company
☐ I do not have any potential conflict of interest
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CMD- FEVAR/BEVAR:

Well-established for about 20 years.

Dedicated bridging stentgrafts are still missing!
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- Advanta V12™ Getinge
  - Durability
  - ePTFE outside
  - Stainless steel (encapsulated)
  - ePTFE inside

- BeGraft™ Bentley
  - Flexibility
  - ePTFE outside
  - Kobaldchrom inside

- BeGraft+™ Bentley
  - Radial force
  - Kink-resistance
  - ePTFE outside
  - Kobaldchrom in between

- VBX™ Gore
  - Flexibility
  - Additional length
  - Thin layer ePTFE outside
  - Stainless steel (independent struts)
  - Heparin surface

Could all these Stentgrafts be used as Bridging stentgraft in FEVAR or BEVAR?
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BeGraft Peripheral Plus

BeGraft Evolution

1. Generation BeGraft peripheral
2. Generation BeGraft peripheral
BeGraft peripheral Plus
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Feature: Kink resistance

90° bending

BeGraft peripheral Plus
Ø8 x 57mm
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Feature: Shear strength

Analysis of the shear strength:

Are the different BSG able to keep the fenestration in front of the target-vessel orifice?

Bench test of different BSG in a flat fenestrated model
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Feature: Shear strength

Graph showing shear strength for different stent types:
- Advanta 6x39
- BeGraft 6x38
- BeGraft+ 6x38
- VBX 6x39

- Max force
- Force at 6 mm Displacement

N/mm 100-150%
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Fatigue-Test:

<table>
<thead>
<tr>
<th>Material</th>
<th>Pre</th>
<th>After 10 Mio</th>
<th>After 50 Mio</th>
<th>After 100 Mio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanta V12 6x38</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>BeGraft 6x38</td>
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</tr>
<tr>
<td>BeGraft+ 6x38</td>
<td></td>
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<tr>
<td>VBX 6x39</td>
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</tbody>
</table>
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Product Portfolio

<table>
<thead>
<tr>
<th>Expanded Stent Graft Diameter</th>
<th>Nominal Stent Graft Length (mm)</th>
<th>Introducer Sheath Compatibility</th>
<th>Catheter Lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>5mm</td>
<td>28, 38, 58</td>
<td>7F</td>
<td>120cm</td>
</tr>
<tr>
<td>6mm</td>
<td>28, 38, 58</td>
<td>7F</td>
<td>120cm</td>
</tr>
<tr>
<td>7mm</td>
<td>27, 37, 57</td>
<td>7F</td>
<td>120cm</td>
</tr>
<tr>
<td>8mm</td>
<td>27, 37, 57</td>
<td>7F</td>
<td>120cm</td>
</tr>
<tr>
<td>9mm</td>
<td>27, 37, 57</td>
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</tr>
<tr>
<td>10mm</td>
<td>27, 37, 57</td>
<td>8F</td>
<td>120cm</td>
</tr>
</tbody>
</table>
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BeGraft peripheral Plus - BEVAR Study

Branched Endocascular Aortic Repair (BEVAR)

Study Set-up:

Prospective, single arm, multi-center, clinical trial investigating the BeGraft Peripheral Plus Stent Graft System as bridging stent in BEVAR for complex aortic aneurysms

Primary Endpoints

Technical success

- successfully introduction and deployment of the BeGraft Plus (Bentley InnoMed) as bridging stent in BEVAR
- Bridging stent patency at 12 months, (24 month planned)

Safety

- Absence of procedure related complications and bridging stent related endoleaks at 12 months.
Secondary endpoints:
1. Bridging stent **patency** post-op and at 6-months
2. Freedom from bridging stent related **endoleaks** post-op and at 6 months
3. Freedom from bridging stent related **secondary intervention**
4. Freedom from type I & III endoleaks post procedure and at 6 and 12 months 30-day **mortality**
6. Freedom from stent graft **migration**, freedom of **fracture or dislocation** of bridging stent.
7. Freedom from **AA diameter increase** at 6 and 12 months as compared to post-op implantation
8. Freedom from aneurysm related secondary endovascular procedures
9. Freedom from **conversion to open surgical repair** post procedure and at 6 and 12 months
10. Freedom from aneurysm related mortality post procedure and at 6 and 12 months
11. Freedom from **aneurysm rupture** within 12 months post-implantation
12. Freedom from any **major adverse events** post procedural and at 6 and 12 months
13. Health Related **Quality of Life** scores at 12 months post implantation
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Procedure:

The branched endograft should be positioned so that all target vessels can be reached using only 1 bridging stentgraft.

The BGP+ should cover at least the entire branch/cuff.

The balloon of the BGP+ should be inflated to reach at least the size of the target vessel.

Investigator should aim for a landing zone of 15mm (at least 10mm).

Renal arteries with \(<100^0\) cranial orientation should be excluded.
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Study Status: BEVAR and BeGraft plus™: BEVAR Study

Inclusion completed: 118 pt, 393 target vessels

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of Inclusions</th>
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</thead>
<tbody>
<tr>
<td>St. Franziskus Hospital Münster</td>
<td>28</td>
</tr>
<tr>
<td>LMU München</td>
<td>18</td>
</tr>
<tr>
<td>UK Regensburg</td>
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<tr>
<td>Klinikum Nürnberg Süd</td>
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<tr>
<td>UK Leipzig</td>
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<td>UKE Hamburg</td>
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<tr>
<td>UK RWTH Aachen</td>
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<tr>
<td>Klinikum Stuttgart</td>
<td>2</td>
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<tr>
<td>UK Heidelberg</td>
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<tr>
<td>UK Schleswig-Holstein</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>92 (89%)</td>
</tr>
</tbody>
</table>

Included patients: 118 393 TV per Protocol
Per Protocol: 93
ITT: 25
M:F 65 : 28
Mean age 71Y

Technical success: 98.8%
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Case: male, 80 Y. Huge, growing pararenal AAA due to a type 1a EL
Case: male, 80 Y. Huge, growing pararenal AAA due to a type 1a EL

Case Planning

80 ys old male patient

- Fast growing Aneurysm after EVAR many years ago due to a proximal degeneration of the neck and huge Type Ia Endoleak (80 mm diameter)
- X-over bypass after occlusion of the right iliac also many years ago.
- Comorbidities: AH, Hypercholesterolemia, NYHA II, H.I.
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Case: male, 80 Y. Huge, growing pararenal AAA due to a type 1a EL
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Case: male, 80 Y. Huge, growing pararenal AAA due to a type 1a EL
Take-home message:

Unique study to understand how the stentgraft BeGraft plus performs as a bridging stentgraft in BEVAR.

Technical success is promising.

Chance to have an approved and dedicated bridging stentgraft in the future.

Hope that some more companies take care of this special indication for covered stentgrafts.
SAVE THE DATE

13.–14. Mai 2024 | Münster