Comparison of Four Balloon Expandable Covered Stents for the Treatment of Aorto-iliac Occlusive Lesions: Which, Where and When?

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Auckland Hospital, Auckland, New Zealand

VEITH Symposium, New York Wednesday 14th November

Current Treatment Algorithm for AIOD

• In 2018, most TASC types of AIOD are treated with an endovascular first approach1,2,3
• There are still some TASC D lesions where open surgery may be considered but even those are being challenged with endovascular approaches

Relevant Disclosures

• Dr Holden is a Clinical Investigator and Medical Advisory Board Member for Gore Medical
• Dr Holden is a Clinical Investigator for Bard
• No other relevant disclosures

Current Treatment Algorithm for AIOD

• There is also little direct evidence comparing BE and SE stents in AIOD
• Several industry sponsored trials showed a mixed use of BE and SE stents was often necessary in complex AIOD1,2

Current Treatment Algorithm for AIOD

• BE stents are usually used to manage arterial occlusive disease at the aortic bifurcation and CIAs
• The high radial resistive force, accurate deployment and ability to post-dilate are important as disease is often resistant and calcified

Current Treatment Algorithm for AIOD

• Covered balloon expandable endoprostheses offer advantages over bare metal stents in complex AIOD
  - Prevent plaque protrusion through stent
  - Prevent in-stent neointimal hyperplasia
  - Decrease risk of complications stemming from distal embolization, perforation, rupture, or dissection
Current Treatment Algorithm for AIOD

- Studies such as the Cobest Trial have shown a clinical benefit with balloon-expandable stent-grafts in complex TASC II C & D lesions

Comparison of Balloon Expandable Covered Stents

- Until recently, only one BE covered endoprosthesis has been available

Comparison of Balloon Expandable Covered Stents

- Suddenly the space has become more crowded!!!

- BARD Lifestream
- Bentley BeGraft
- Gore VBX

Comparison of BE Covered Stents in AIOD

- No "head to head" device trials to date
- Three of 4 device trials had a similar primary composite endpoint – composite of 30 day death +/- MI as well as 9 month CD-TLR (+/- patency)
- Trials reported primary patency at ~ 9 months*
- This allows some comparison between devices

* BeGraft primary patency reported @ 12 months

Getinge ADVANTA Atrium V12

- Available for many years with a known track record of performance
- ePTFE fully encapsulated stainless steel stent
- Performance studied in iCAST Atrium Registry Ultrasound Study (iCARUS)

- 152 patients in 25 centres
- All patients had claudication or rest pain (RC 2-4)
- Primary 9 month patency 95.1%

- Courtesy J Laird, VEITH 2016
Freedom from TLR through 3 years (KM), N= 152


• Dual layer ePTFE fully encapsulated stainless steel stent
• Evaluated in BOLSTER multicentre clinical trial

155 patients in 17 centres
• All patients had claudication or rest pain (RC 2-4)
• Primary 9 month patency 89.1%

Bentley BeGraft

• ePTFE covered chromium cobalt stent
• Folded at edges only to reduce crimp profile, increase stent retention and flexibility

18. Courtesy K Deloose, LINC 2018

• Performance assessed in European multicentre clinical trial
• Patency and TLR @ 12 rather than 9 months
• 12 month composite primary endpoint

• 70 patient multicentre trial
• All patients had claudication or rest pain (RC 2-4)
• Mean lesion length 34.3mm
• Primary 12 month patency 94.0%
• Freedom from CD-TLR @ 12 months 96.7%
Bentley BeGraft
- Performance assessed in European multicentre clinical trial
- Patency and TLR @ 12 rather than 9 months
- 12 month composite primary endpoint
  - 70 patient multicentre trial
  - All patients had claudication or rest pain (RC 2-4)
  - Mean lesion length 34.3mm
  - Primary 12 month patency 94.0%
  - Freedom from CD-TLR @ 12 months 96.7%

Bentley BeGraft Plus
- Newest generation of BeGraft
- Sandwich design consisting of 2 layers of ePTFE and internal and external stents
- Higher radial force at a small cost in profile and flexibility

Gore Viabahn BX (VBX)
- Discrete fluoropolymer connected stainless steel rings
- Provides excellent conformability, flexibility and radial strength
- Fully encapsulated ePTFE with CBAS Heparin coating for thromboresistance

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- Fully encapsulated ePTFE with CBAS Heparin coating for thromboresistance
  - 134 patient multicentre VBX FLEX IDE Trial
  - All patients had claudication or rest pain (RC 2-4)
  - Mean lesion length 42.1mm
  - Primary 9 month patency 96.7%

Gore VBX-- FLEX IDE Case
- Performed as a Live case at VIVA 2014

Gore VBX-- FLEX IDE Case
- 24 month results now available
- Freedom from CD-TLR 97.7%

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Primary Procedure</th>
<th>6m</th>
<th>12m</th>
<th>24m</th>
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### Device Comparisons

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- **Nominal diameters:**
  - 5,6,7,8,9,10 mm

- **Profile:**
  - 6,7,8,9,10 mm

- **Available:**
  - 12-24 mm
  - Can be post-dilated to 30 mm

- **Graft System:**
  - Double cobalt chromium stent between stents and on outer with fluoropolymer tubing

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<td>1st Composite Endpoint</td>
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<td>Patency</td>
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<td>Freedom from TLR</td>
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*1st Composite Endpoint: Death at 30 days, Freedom from CD-TLR @ 9 months, Primary Patency @ 9 months*

### Device Comparisons – 24 Months

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<td>24 month CD-TLR</td>
<td>88.3</td>
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### My Approach to BE Endoprostheses

- It is likely that all devices will perform well in relatively simple disease (TASC A, B and even C iliac occlusive disease)
- Other issues such as clinical support and price may be relevant in deciding devices for these cases
- In complex occlusive disease (e.g., TASC D aorto-iliac lesions), the additional conformability of VBX may offer improved patency
- The additional flexibility of VBX and BeGraft may offer advantages in parallel graft and other applications