Latest techniques for Aortoiliac Reconstruction of TASC C&D lesions: Are covered stents the solution?

Koen Deloose, MD

Aortoiliac lesions TASC II C - D

Type C lesions: open revascularization procedures have superior long-term results & endovascular methods should only be used when high risk is associated with open repair.

Type D lesions: Endovascular methods do not yield good enough results to justify them as primary treatment

Endovascular meta-analysis TASC C - D

Early and late outcomes of percutaneous treatment of TransAtlantic Inter-Society Consensus class C and D aorto-iliac lesions

Wei Ye, Chang-Wei Liu, Jean-Baptiste Ricco, Kevin Mani, Rong Zeng, Jingmei Jiang


• Technical Success Rate (=successful endo revascularization with < 30% residual stenosis)

749 patients

958 patients
Endovascular meta-analysis TASC C - D

- Overall 1 yr Primary Patency Rate
  - 787 patients

<table>
<thead>
<tr>
<th>Institution</th>
<th>Primary patency rate (%)</th>
<th>Heterogeneity</th>
<th>Test (Z)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subramanian (21)</td>
<td>75.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batra (19)</td>
<td>80.0</td>
<td></td>
<td></td>
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<tr>
<td>Bozbas et al. (10)</td>
<td>80.0</td>
<td></td>
<td></td>
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<tr>
<td>Verheye et al. (3)</td>
<td>80.0</td>
<td></td>
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<tr>
<td>Hassan (25)</td>
<td>75.0</td>
<td></td>
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<tr>
<td>Jackiw et al. (2)</td>
<td>85.0</td>
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<tr>
<td>Kelle (16)</td>
<td>85.0</td>
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<tr>
<td>Leuscher et al. (15)</td>
<td>85.0</td>
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<tr>
<td>Kolon et al. (14)</td>
<td>75.0</td>
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<tr>
<td>Kuhar et al. (26)</td>
<td>75.0</td>
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<tr>
<td>May (18)</td>
<td>75.0</td>
<td></td>
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<tr>
<td>Pulkki et al. (3)</td>
<td>85.0</td>
<td></td>
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<tr>
<td>Poveda et al. (21)</td>
<td>75.0</td>
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</tbody>
</table>

Total: 100% 787 patients

- Long term Primary & Secondary Patency Rate
  - 443 patients

<table>
<thead>
<tr>
<th>Time period</th>
<th>Primary Patency Rate (%)</th>
<th>Secondary Patency Rate (%)</th>
<th>Heterogeneity</th>
<th>Test (Z)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12m</td>
<td>C: 91.9%</td>
<td>D: 85.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24m</td>
<td>C: 91.9%</td>
<td>D: 84.8%</td>
<td></td>
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</tbody>
</table>

P = 0.516

- 1 yr Primary Patency Rate subanalysis: primary stenting (433) vs bail-out stenting (354)
  - 787 patients

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Stenosis (%)</th>
<th>Primary stenting</th>
<th>Bail-out stenting</th>
<th>Heterogeneity</th>
<th>Test (Z)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary stenting</td>
<td>0</td>
<td>432</td>
<td>351</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective stenting</td>
<td>5</td>
<td>354</td>
<td>18</td>
<td></td>
<td></td>
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</tbody>
</table>

- Bravissimo trial

<table>
<thead>
<tr>
<th>TASC</th>
<th>Baseline</th>
<th>12MFU</th>
<th>24MFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>40%</td>
<td>24%</td>
<td>24%</td>
</tr>
<tr>
<td>B</td>
<td>18%</td>
<td>18%</td>
<td>18%</td>
</tr>
<tr>
<td>C</td>
<td>17%</td>
<td>17%</td>
<td>17%</td>
</tr>
<tr>
<td>D</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
</tr>
</tbody>
</table>

- Some complications in TASC C and D group
  - Distal embolization
  - Perforation
Are there better endovascular solutions...?


- 171 patients, 193 lesions, 100% TASC C – D
- 100% associated with CFA-EA
- Mixed device-use

<table>
<thead>
<tr>
<th>Device</th>
<th>Percentage of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>SX stents</td>
<td>55%</td>
</tr>
<tr>
<td>BX stents</td>
<td>5%</td>
</tr>
<tr>
<td>SX covered stent</td>
<td>32%</td>
</tr>
<tr>
<td>BX covered stent</td>
<td>3%</td>
</tr>
</tbody>
</table>

Are there better endovascular solutions...?


- Subanalysis primary patency Stent vs Covered Stent

<table>
<thead>
<tr>
<th>Primary Patency</th>
<th>Secondary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>87%</td>
</tr>
<tr>
<td>12 months</td>
<td>70%</td>
</tr>
</tbody>
</table>

Are there better endovascular solutions...?

Conclusions from various studies:

- The Advanta V12 PTFE covered stent shows to be safe & feasible with excellent clinical results @ 1yr.
- The iCARUS data support the safety & efficacy of the iCast covered stent when used for revascularization of iliac lesions.
- Subanalysis primary patency Stent vs Covered Stent:
  - Stent: 82.1%
  - Covered Stent: 53.0%

THE COBEST TRIAL

- Prospective, single blind RCT comparing long-term BMS (different) vs. Covered Stents (Advanta V12) for complex Aorto-Iliac lesion treatment
- Primary Endpoint: patency rates at 6 – 12 – 18 – 60 month, based on Duplex UltraSound.
- 168 limbs, 125 patients randomized:
  - 83 Advanta V12
  - 85 BMS
**The COBEST Trial**

**Freedom from restenosis for the type of stent used adjusted for TASC C/D Group**

**The COBEST Trial : Primary Patency**

- **77.5%**
- **37.5%**

**The COBEST Trial : Cox regression analysis**

<table>
<thead>
<tr>
<th>Variables</th>
<th>P-Value</th>
<th>Hazard Ratio</th>
<th>95.0% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent</td>
<td>0.003</td>
<td>2.477</td>
<td>1.350</td>
</tr>
</tbody>
</table>

**Conclusion**

For Extensive TASC C&D lesions, covered stents perform better than BMS. These results appears to be durable until 5 years FU.

**Are there better endovascular solutions...?**

**Radial mismatch : in vitro-testing**

- **SX Kissing**
- **BX CS kissing**
- **CERAB**

- Color photograph
- Rontgen images
- Endoscopy
- Computer tomography

**Are there better endovascular solutions...?**

**Radial mismatch : in vitro-testing**

- **SX Kissing**
- **BX CS kissing**
- **CERAB**

- **Coverage capacity**
  - Moderate
  - Full
  - Low

**COX REGRESSION FOR PRIMARY PATENCY**

**Variables**

**P-Value**

**Hazard Ratio**

**95.0% CI**

**Stent**

0.003

2.477

1.350

4.545

**Are there better endovascular solutions...?**

- **What can be the problem with the aortic bifurcation?**
- **Kissing?**
- **Radial mismatch** (=discrepancy between stented lumen and aortic lumen)

**Bloodflow-decrease**

**Stasis of blood column**

**Thrombus formation**

**Immature mesenchymal formation**

**Intimal hyperplasia**

*S: Histopathological findings

**Are there better endovascular solutions...?**

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**Groot Jebbink E et al.**


**SX Kissing**

**CERAB**

**BX CS Kissing**

**Intima hyperplasia**

*S: Histopathological findings

**Are there better endovascular solutions...?**

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**Groot Jebbink E et al.**


**SX Kissing**

**CERAB**

**BX CS Kissing**

**Radial mismatch**

- Moderate
- High
- Low

**Covering capacity**

- Full
- Full
- Full
Are there better endovascular solutions...?

**BX CS Kissing**
Sabri S et al.; J Vasc Interv Radiol. 2010;21(7):995-1003

- 54 patients: 26 pts in Covered Stent-group (CS)
- 28 pts in BMS-group (BMS)
- 100% Kissing Procedure for aortic bifurcation lesions

<table>
<thead>
<tr>
<th></th>
<th>BMS</th>
<th>Covered Stent</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Major complications</td>
<td>7%</td>
<td>11%</td>
<td>0.66</td>
</tr>
<tr>
<td>Clinical improvement</td>
<td>54%</td>
<td>85%</td>
<td>0.02</td>
</tr>
<tr>
<td>Primary patency 12m</td>
<td>78%</td>
<td>92%</td>
<td>0.023</td>
</tr>
<tr>
<td>Primary patency 24m</td>
<td>62%</td>
<td>92%</td>
<td></td>
</tr>
</tbody>
</table>

Are there better endovascular solutions...?

**CERAB**
Grimme FA et al.; Eur J Vasc Endovasc Surg 2015 Sep (3)

- 103 CERAB patients, 95% TASC C – D lesions (88% D)
- 95% Technical Success rate
- 30d Major complication rate: 2% (renal failure – pneumonia)

<table>
<thead>
<tr>
<th></th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency</td>
<td>87.3%</td>
<td>82.3%</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>95%</td>
<td>85%</td>
</tr>
<tr>
<td>Freedom TLR</td>
<td>88.2%</td>
<td>85.6%</td>
</tr>
<tr>
<td>Limb Salvage</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Endovascular aorto-iliac disease treatment TASC C&D

- TASC C&D
- Aortic involvement?
  - Y
  - N

- Kissing position?
  - N
  - Y

- (Ch) CERAB
  - CIA
  - EIA
  - BECS

- Small (female) vessels?
  - Y
  - N

- Extreme (circumferentially) calcification?
  - Y
  - N

- Heterogenous (thrombus containing) lesions / occlusions?
  - Y
  - N

- BECS
- SES
- SECS
+ CAVE OUTFLOW!!!