What Is The Best Endovascular Device For Aorto-Iliac Occlusive Lesions: When Self-Expanding Stent; When Balloon Expandable Stent; Which Covered Stent And For Which Lesion

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Editor’s Choice — 2017 SCC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (EVAR)
recommendation level: A = strong, B = moderate

Introduction
- Open aortic surgery has been the gold standard for extensive AOID, given the good long-term outcome
- Endovascular treatment is progressively being accepted, also in complex lesions of the iliac artery

Meta-analysis of 958 patients

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<thead>
<tr>
<th></th>
<th>SBC C</th>
<th>SBC D</th>
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<tbody>
<tr>
<td>Technical success</td>
<td>92.7%</td>
<td>90.1%</td>
</tr>
<tr>
<td>1-year primary patency</td>
<td>89.6%</td>
<td>87.3%</td>
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<tr>
<th></th>
<th>Primary</th>
<th>Selection</th>
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<tbody>
<tr>
<td>Technical success</td>
<td>94.2%</td>
<td>88.0%</td>
</tr>
<tr>
<td>1-year primary patency</td>
<td>92.2%</td>
<td>82.0%</td>
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</table>

Meta-analysis of 958 patients
TASC C TASC D
Technical success 93.7% 90.1%
1-year primary patency 89.6% 87.3%

Primary Selective
Technical success 94.2% 88.0%
1-year primary patency 92.1% 82.9%

Recommendations on endovascular stent grafting for iliac occlusive lesions

- In patients fit for surgery, while Bilateral plugs should be considered in selected cases.
- An aortic endograft may be considered in long and/or infrarenal lesions in patients with a high surgical risk or aorto-iliac involvement of both iliac arteries.
- Open surgery should be considered in selected cases, even in the presence of dissection, etc.
- Secondary and symptomatic stenosis after primary endografting should be considered.
- In the case of femoral occlusion lesions, the only treatment option is the iliac extension and femoral endarterectomy; the lesion should be extended up to the common iliac artery.

Consultation may be advised for patients with no other alternative for endovascular interventions.

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660 patients with stenotic lesions in the iliac artery Randomized between BE and SE stent

325 patients with aorto-iliac lesions
- TASC A/B n=190
- TASC C/D n=135

24-month primary patency
- Overall 87.9%
- self-expanding stent 92.1%
- balloon-expandable stent 85.2%

Kissing stent configuration independent predictor of failure

Advantages of covered stents
- Reduces the incidence of in-stent re-stenosis
- Focal edge stenosis:
  - incidence independent of lesion length
  - Easier to treat compared to diffuse ISR
- May reduce the risk on embolization
- May reduce the risk on rupture (or the consequences of rupture)

Balloon-Expandable Stents for Iliac Artery Oclusive Disease
Randomized ICT Trial

Self-expanding stents outperform balloon-expandable stents at 1-year follow-up

RCT comparing treatment of isolated iliac artery oclusive lesions with a bare metal stent with covered stent

125 patients with 168 iliac artery lesions were prospectively enrolled
Cobest trial
longterm outcome

- BE covered stent group had a significantly higher patency and lower TLR rate than the BMS up to 5-year follow-up
- No difference in amputation rate
- Highest benefit observed in TASC C and D lesions
- Multivariate analysis, the type of stent used and the Rutherford classification significantly affected primary patency

Advanta V12 BX Covered Stent

- First BX covered stent with close to 15 years of history and over half million sold units and over 260 publications.
- Designed to maintain deployed diameter and an open pathway with radial strength three times greater than physiologic need
- Ability to post-dilate, allowing a customized solution to varying anatomy

Unique Thermo-conformable covering technology
Completely encapsulated in PTFE (1 piece)

BE Covered Stent Market
Comparison of Properties

<table>
<thead>
<tr>
<th></th>
<th>BeOlfit</th>
<th>Advanta V12</th>
<th>Electroline</th>
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<tbody>
<tr>
<td>Graft Material</td>
<td>ePTFE sleeve</td>
<td>ePTFE film</td>
<td>ePTFE</td>
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<tr>
<td>Stent Material (Composition)</td>
<td>CoCr (L605)</td>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Stent Graft Design</td>
<td>Single Stent</td>
<td>Film-Cast Encapsulation</td>
<td>Film-Cast Encapsulation</td>
</tr>
<tr>
<td>Sheath Compatibility</td>
<td>6F up to 8x57mm</td>
<td>7F for remaining sizes</td>
<td>6F for Ø5/6x16mm and Ø5/6x22mm all other sizes 7F</td>
</tr>
<tr>
<td>Guide Wire</td>
<td>0.035”</td>
<td>0.035”</td>
<td>0.035”</td>
</tr>
<tr>
<td>Shaft Size / Shaft Lengths</td>
<td>5F / 75 + 120cm</td>
<td>5F / 80 + 120cm</td>
<td>6.5F (10mm + 12mm) 80 + 135cm n/a</td>
</tr>
<tr>
<td>Nominal Pressure</td>
<td>9 bar (Ø5 - 7 mm)</td>
<td>8 bar (Ø8 - 10mm)</td>
<td>8 atm 8atm n/a</td>
</tr>
<tr>
<td>Rated Burst Pressure</td>
<td>13 bar (Ø5 - 7 mm)</td>
<td>12 bar (Ø8 - 10mm)</td>
<td>12 atm 12 atm 15 atm for Ø5-7 13 atm for Ø8-10</td>
</tr>
<tr>
<td>Crimped Profile</td>
<td>2.0 – 2.4mm</td>
<td>2.1 – 2.5mm</td>
<td>n/a</td>
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Configuration of stents

The kissing stents technique is most frequently used to treat AOID involving the aortic bifurcation

Meta-analysis of Individual Patient Data After Kissing Stent Treatment for Aortoiliac Occlusive Disease

- Median follow up; 24 months
- Primary patency
  - 24 months 81%
  - 60 months 73%
- Secondary patency
  - 24 months 93%
  - 60 months 89%

Stent configuration

Patency of kissing stents is affected by geometrical factors:

- Radial mismatch; aortic lumen dead space around the protruding segment of the stents
- Differences in stent conformation
- The overlap of the free proximal stent ends
  - Re-circulation, turbulence and stasis
  - Mesenchymal tissue, thrombus and intimal hyperplasia

Covered Endovascular Reconstruction of the Aortic Bifurcation - CERAB

Goal: to provide a more anatomical and physiological endovascular reconstruction of the aortic bifurcation

CERAB versus KS

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<thead>
<tr>
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<th>KS meta-analysis</th>
<th>CERAB series</th>
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<tbody>
<tr>
<td>Number of patients</td>
<td>605</td>
<td>130</td>
</tr>
<tr>
<td>Previous interventions</td>
<td>27%</td>
<td>41%</td>
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<tr>
<td>Critical limb ischemia</td>
<td>16%</td>
<td>33%</td>
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<tr>
<td>TASC C and D</td>
<td>47%</td>
<td>94%</td>
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<tr>
<td>Primary patency 24 months</td>
<td>81%</td>
<td>89%</td>
</tr>
<tr>
<td>Secondary patency at 24 months</td>
<td>93%</td>
<td>97%</td>
</tr>
</tbody>
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Summary

- An endovascular-first strategy is well accepted for iliac artery occlusive disease, with primary stenting being better than selective stenting
- Choice of stents;
  - TASC A/B; SE outperform BE bare metal stents
  - TASC C/D; BE Covered stents outperform bare metal stents
  - Involvement of the aortic bifurcation; CERAB seems to outperform the KS configuration
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