When not to use a bare metal – when not to use a covered stent for iliac stenotic lesions

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Disclosure

Speaker name:
MMPJ Reijnen

I have the following potential conflicts of interest to report:

☒ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Endovascular treatment of the iliac artery

Dilemma:
• Angioplasty or stenting
• Self-expanding or balloon-expandable stents
• Covered stents or bare metal stents
• Common iliac artery versus the external iliac artery
DIST trial

"There were no substantial differences in technical results and clinical outcome of the two treatment strategies both at short-term and long-term follow-up"

"Selective stenting should be the treatment of choice"

Stenosis in 92% of patients
Randomized clinical trial of stents versus angioplasty for the treatment of iliac artery occlusions (STAG trial)

S. D. Goode, T. J. Cleveland and P. A. Gaines on behalf of the STAG trial collaborators*

Results: There were 118 patients recruited to the study; six were excluded from the analysis owing to major protocol violations, leaving a total of 112 patients for analysis. Some 55 patients had PTA and 57 had a primary iliac stent. Technical success was achieved in 46 patients (84 per cent) in the PTA group and 56 (98 per cent) in the stent group ($P=0.007$). There were 11 (20 per cent) major procedural complications after PTA compared with three (5 per cent) after primary stenting ($P=0.010$). There were no significant differences in primary or secondary patency between the groups after 1 and 2 years.

Conclusion: Primary stent placement for iliac artery occlusion increased technical success and reduced major procedural complications (predominantly distal embolization) compared with balloon angioplasty.

Registration number: ISRCTN 48145465 (http://www.controlled-trials.com).

*The STAG trial collaborators are co-authors of this study and can be found under the heading Collaborators
TASC C and D lesions

- Meta analysis including 958 patients:
  
<table>
<thead>
<tr>
<th></th>
<th>TASC C</th>
<th>TASC D</th>
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</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>93.7%</td>
<td>90.1%</td>
</tr>
<tr>
<td>1-yr primary patency</td>
<td>89.6%</td>
<td>87.3%</td>
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<tr>
<td></td>
<td>Primary</td>
<td>Selective</td>
</tr>
<tr>
<td>Technical success</td>
<td>94.2%</td>
<td>88.0%</td>
</tr>
<tr>
<td>1-yr primary patency</td>
<td>92.1%</td>
<td>82.9%</td>
</tr>
</tbody>
</table>
  
- Long-term patency rates better for primary stenting

Endovascular approach of iliac artery occlusive disease

- 5-years patency of iliac stenting: 69-83%
- Overall complication rate: 2-24%
  - Major complication rate: 3-4%
  - Emboli: 0-9%
- Lesions with increased risk:
  - Heavily calcified
  - Excentric
  - Ulcerative plaque
When to use a covered stent?; theoretical advantages

- Likely to reduce 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 of an eventual rupture
Why using Advanta V12 covered stents?

Due to specific characteristics:

- low profile
- double ePTFE layer
- easy and accurate deployment
- radial force
- dog-bone type inflation of balloon
- diameter adaptiveness
Cobest trial: covered versus BMS in iliac artery occlusive disease

- Prospective, multi-center, randomized, controlled trial
- Covered stents versus bare-metal stents in iliac artery occlusive disease
- Included patients: 125
- Included limbs: 168
- Follow-up at 1, 6, 12 and 18 months

Cobest trial: covered versus BMS in iliac artery occlusive disease

Primary endpoints

• Rate of binary restenosis
• Freedom from stent occlusion at 18 months

Secondary endpoints

• Stent patency TASC B, C and D
• Amputations above the ankle
• ABI changes from baseline

Cobest trial: covered versus BMS in iliac artery occlusive disease

- TASC B: Similar patency
- TASC C and D:
  - Less binary re-stenosis
  - Less occlusions
- Less re-interventions in the covered stent group
  \( p = 0.006 \) at 12 months

DISCOVER: Dutch Iliac Stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents in the common iliac artery: study protocol for a randomized controlled trial

Joost A Bekken, Jan Albert Vos, Ruud A Aarts, Jean-Paul PM de Vries and Bram Fioole

Patients with symptomatic CIA stenosis or occlusion → Angiography

CIA Stenosis > 3cm CIA Occlusion

Randomisation

Covered BE stent N=87

Bare metal BE stent N=87

CIA Stenosis ≤ 3cm

Exclusion

Primary endpoint: absence of binary restenosis after 2 years.
Discover trial

• 68/174 patients randomised

<table>
<thead>
<tr>
<th>Lesion</th>
<th>Count/Total</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Occlusion</td>
<td>53/68</td>
<td>78%</td>
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<tr>
<td>Stenosis &gt; 3cm</td>
<td>15/68</td>
<td>22%</td>
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<table>
<thead>
<tr>
<th>Gender</th>
<th>Count/Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>35/68</td>
<td>51%</td>
</tr>
<tr>
<td>Female</td>
<td>33/68</td>
<td>49%</td>
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</table>

<table>
<thead>
<tr>
<th>Rutherford classification</th>
<th>Count/Total</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Rutherford 1</td>
<td>21/68</td>
<td>31%</td>
</tr>
<tr>
<td>Rutherford 2</td>
<td>12/68</td>
<td>18%</td>
</tr>
<tr>
<td>Rutherford 3</td>
<td>20/68</td>
<td>29%</td>
</tr>
<tr>
<td>Rutherford 4</td>
<td>13/68</td>
<td>19%</td>
</tr>
<tr>
<td>Rutherford 5</td>
<td>2/68</td>
<td>3%</td>
</tr>
<tr>
<td>Rutherford 6</td>
<td>0/68</td>
<td>0%</td>
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</tbody>
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• Completion of enrollment is scheduled for July 2016

Property of Bram Fioole, Maasstad Hospital, The Netherlands
Covered stents in iliac artery occlusive disease: mid-term outcome

- 115 Advanta V12 stents in 87 patients
- Primary procedures (n=69)
  - 1-year patency 89%
  - 4-years patency 72%
- Secondary procedures (n=46)
  - 1-year patency 78%
  - 4-years patency 53%

- Primary patency significantly higher in the primary treatment group (p<0.05)

The kissing stent configuration

- Review of 951 patients
- Intermittent claudication 72.8 %
- TASC C or D 50 %
- Technical success rate 98.2 %
- Complication rate 11 %
- Primary patency
  - 12 months 88.8 %
  - 24 months 78.9 %
  - 36 months 68.5 %

Kissing covered stents

Non-randomized comparison of 26 patients with kissing covered stents and 28 patients with kissing bare stents

<table>
<thead>
<tr>
<th>Demographics</th>
<th>V12</th>
<th>Bare-stents</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Subjects</td>
<td>n=26</td>
<td>n=28</td>
<td></td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>17/9</td>
<td>15/13</td>
<td>0.42</td>
</tr>
<tr>
<td>Mean Age</td>
<td>61</td>
<td>61</td>
<td>0.89</td>
</tr>
<tr>
<td>HTN</td>
<td>25 (96%)</td>
<td>25 (89%)</td>
<td>0.61</td>
</tr>
<tr>
<td>DM</td>
<td>13 (50%)</td>
<td>13 (46%)</td>
<td>0.58</td>
</tr>
<tr>
<td>CAD</td>
<td>13 (50%)</td>
<td>13 (46%)</td>
<td>1.00</td>
</tr>
<tr>
<td>S. Crt &gt;2.0mg/dl</td>
<td>3 (12%)</td>
<td>1 (4%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Smoking Hx</td>
<td>20 (77%)</td>
<td>23 (82%)</td>
<td>0.74</td>
</tr>
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<table>
<thead>
<tr>
<th>Technical</th>
<th>V12</th>
<th>Bare-stents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>T. Success</td>
<td>26/26 (100%)</td>
<td>28/28 (100%)</td>
<td></td>
</tr>
<tr>
<td>Major Compl.</td>
<td>3/26 (11%)</td>
<td>2/28 (7%)</td>
<td></td>
</tr>
<tr>
<td>6-7mm Diam.</td>
<td>12/26 (46%)</td>
<td>11/28 (40%)</td>
<td></td>
</tr>
<tr>
<td>8-10mm Diam.</td>
<td>14/26 (54%)</td>
<td>17/28 (60%)</td>
<td></td>
</tr>
<tr>
<td>Aortic Ext.</td>
<td>5/26 (19%)</td>
<td>8/28 (28%)</td>
<td></td>
</tr>
<tr>
<td>Ext Iliac</td>
<td>14/26 (54%)</td>
<td>12/28 (43%)</td>
<td></td>
</tr>
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Kissing covered stents

- Advanta V12 covered stents:
  - Increased clinical improvement ($p<.05$)
  - Superior patency at 24 months (92% vs. 62%, $p<.05$)

<table>
<thead>
<tr>
<th>C/P response</th>
<th>V12</th>
<th>Bare-stents</th>
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<tbody>
<tr>
<td>Improved</td>
<td>22/26 (85%)</td>
<td>15/28 (54%)</td>
</tr>
<tr>
<td>Stable</td>
<td>2/26 (8%)</td>
<td>0/28 (0%)</td>
</tr>
<tr>
<td>Worse</td>
<td>2/26 (8%)</td>
<td>13/28 (54%)</td>
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Kissing covered stents
Midterm outcome

• Retrospective analysis
• 73 consecutive kissing stent procedures
• TASC-2
  • A n= 22 including 10 patients after previous stenting
  • B n=24 including 15 patients after previous stenting
  • C n=3
  • D n-24

1 year 4 years

• Primary patency 87.2% 69.1%
• Secondary patency 87.2% 72.7%
• The freedom from re-intervention at four years: 76.5%

Conclusions

• Endovascular treatment seem to be justified for all TASC categories
• Angioplasty and bare metal stenting are treatment of choice in less complex lesions and covered stents in more extensive disease
• As re-do procedures perform worse the initial treatment strategy is crucial
• Critical issues include cost-efficacy and the development of techniques for extensive aorto-iliac occlusive disease
CERAB for extensive aorto-iliac occlusive disease
CERAB for extensive aorto-iliac occlusive disease

- Median follow-up 12 months
- Primary patency
  - 6 months  92%
  - 12 months  87%
  - 18 months  87%
- Secondary patency
  - 6 months  98%
  - 12 months  95%
  - 18 months  95%
- Limb salvage  100%
When not to use a bare metal – when not to use a covered stent for iliac stenotic lesions

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