Outcome of femoropopliteal procedures in diabetic patients

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- [x] 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
Unique aspects and challenges for endovascular work in the diabetic patient

Medial calcinosis, large calcium burden.

Potential problems:

- Difficulty to cross
- Embolic potential
- Less drug effectiveness for DCB / DES
  - ABI not accurate
- Poor visibility in duplex scans
Epidemiology

• 1/3 of patients with PAD have diabetes
• In patients with CLI >50% have diabetes

Illustration from: Diehm et al Eur J Vasc Endovasc Surg (2006)
Selected studies: Nitinol Stents

- 65 patients
- SMART Stents & Dynalink Stents
- Lesions > 10cm (mean lesion length 16 cm)

Sabeti et al, JEVT 2005
Selected studies: Nitinol Stents: FAST Trial

- 168 patients, RCT
- LUMINEXX Stents vs PTA
- Lesions < 10cm (mean lesion length 4.5 cm)

Krankenberg et al, Circulation 2007
Selected studies: Drug eluting stents

The Zilver PTX Single-Arm Clinical Study
Selected studies: Drug eluting stents

The Zilver PTX Single-Arm Clinical Study

Zilver PTX results are similar in diabetic and non-diabetic patients

M. Dake, presentation at ICI meeting 2015
## Selected studies: Drug eluting balloons

**FIGURE 1** Subgroup Analysis of Primary Patency at 24 Months

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>IN.PACT DCB %</th>
<th>Control PTA %</th>
<th>Hazard Ratio [95% CI]</th>
<th>p-value for interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall ITT</td>
<td>78.9%</td>
<td>50.1%</td>
<td>3.25 [2.17, 4.87]</td>
<td>NA</td>
</tr>
<tr>
<td>Rutherford Classification</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 2</td>
<td>78.9%</td>
<td>40.1%</td>
<td>4.51 [2.40, 8.48]</td>
<td>0.292</td>
</tr>
<tr>
<td>Category 3</td>
<td>78.6%</td>
<td>58.0%</td>
<td>2.48 [1.42, 4.34]</td>
<td></td>
</tr>
<tr>
<td>Category 4</td>
<td>81.8%</td>
<td>33.3%</td>
<td>4.12 [0.75, 22.69]</td>
<td></td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>73.3%</td>
<td>45.8%</td>
<td>2.82 [1.61, 4.96]</td>
<td>0.673</td>
</tr>
<tr>
<td>No</td>
<td>82.5%</td>
<td>54.5%</td>
<td>3.49 [1.95, 6.24]</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥75</td>
<td>85.7%</td>
<td>42.1%</td>
<td>5.47 [2.24, 13.33]</td>
<td>0.175</td>
</tr>
<tr>
<td>&lt;75</td>
<td>76.8%</td>
<td>52.7%</td>
<td>2.78 [1.75, 4.40]</td>
<td></td>
</tr>
<tr>
<td>Lesion Length</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5 cm</td>
<td>89.0%</td>
<td>66.7%</td>
<td>3.85 [1.26, 11.78]</td>
<td>0.551</td>
</tr>
<tr>
<td>≥5 cm and &lt;10 cm</td>
<td>79.1%</td>
<td>57.8%</td>
<td>2.65 [1.34, 5.21]</td>
<td></td>
</tr>
<tr>
<td>≥10 cm and &lt;18 cm</td>
<td>72.6%</td>
<td>35.4%</td>
<td>3.63 [1.97, 6.69]</td>
<td></td>
</tr>
<tr>
<td>Total Occlusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>78.9%</td>
<td>40.9%</td>
<td>3.97 [1.77, 8.88]</td>
<td>0.571</td>
</tr>
<tr>
<td>No</td>
<td>78.9%</td>
<td>52.6%</td>
<td>3.06 [1.92, 4.89]</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Sex</td>
<td>76.7%</td>
<td>42.3%</td>
<td>3.35 [1.75, 6.41]</td>
<td>0.911</td>
</tr>
<tr>
<td>Male Sex</td>
<td>80.2%</td>
<td>53.7%</td>
<td>3.22 [1.92, 5.40]</td>
<td></td>
</tr>
</tbody>
</table>

Laird et al. 24-Month Results From the IN.PACT SFA Trial, JACC 2015
Selected studies: Drug eluting balloons

Low-dose Paclitaxel-coated Versus Uncoated Percutaneous Transluminal Angioplasty for Symptomatic Femoropopliteal Disease: 1-year Results of a European Randomized Controlled Trial

Stellarex® DCB (Spectranetics) vs. PTA

Illummenenate EU study, submitted for publication
Outcome of femoropopliteal procedures in diabetic patients

No studies have specifically addressed this question.

Subgroup analyses from selected studies have not suggested ineffectiveness of standard treatment modalities (DES, BMS, DCB) in the fem-pop segment in diabetic patients.

Mainly claudicants were treated in these studies, it is not clear if e.g. DCBs are safe or effective in diabetics with foot ulcerations.
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