Supera Stent in popliteal aneurysms

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Disclosure

Speaker name:
.....Jörg Tessarek MD........................................................

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
Clinical pathology of popliteal aneurysms determined

- Low risk of rupture or bleeding (0.9-4.6%)
- Main risk: chronic embolisation (symptomatic chronic debris shower in >40% ) progressive rarefication of outflow vessels
- PAD of various degree Therapy resistant occlusive disease with high risk of limb loss
- Acute on chronic PAA thrombosis
- Worst case scenario: angiographical "blind popliteal" or "empty calf" with up to 70% risk of limb loss and 36% mortality

Kassem MM et al Aneurysm, Popliteal Artery Stat Pearls Last Update: October 9, (2017)
Clinical endpoints for PAA

1. Limb salvage
2. Prevention of embolisation related PAD
3. Rupture
4. PP, assisted PP, SP...
## Therapeutic options for PAA treatment

<table>
<thead>
<tr>
<th>surgery</th>
<th>covered stent</th>
<th>multilayer (MFM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Invasive</td>
<td>• Minimal invasive</td>
<td>• Minimal invasive</td>
</tr>
<tr>
<td>• vein/graft dependent outcome</td>
<td>• Adjunctive thrombolysis</td>
<td>• Adjunctive thrombolysis ?</td>
</tr>
<tr>
<td>• Results run off dependent</td>
<td>• Implant costs</td>
<td>• Implant costs</td>
</tr>
<tr>
<td>• No adjunctive thrombolysis</td>
<td>• Device dependent complications</td>
<td>• Device dependent complications (dislocation,...)</td>
</tr>
</tbody>
</table>

Surgery comparable to Endo

>50% thrombosis during 12 mo FU
Challenges for any femoropopliteal endo-implant as often reported

- Dislocation and migration → landing zone/ fixation
- Diameter mismatch with crimping → thrombogenicity
- Resistance to component separation → thrombosis/ no endo repair
- Crushing and stent fractures → thrombosis/ no endo repair
- Reliable thrombus fixation → run off preservation
- dedicated device → mophological challenges

References:

Therapeutic options for PAA exclusion: dedicated nitinol intervowen stent

Double layer Nitinol Intervowen Stent with adaptable mesh design dedicated for the femoropopliteal segment

(CE marked for use in arterial segments)
dual layer modification of Supera stent: Higher density of mesh without loss of flexibility

Technical aspects of the procedure: Bilateral PAA with left limb claudication
Technical aspects of the procedure: telescope technique for mesh density
- Monolayer
- Double layer
- Monolayer
Technical aspects of the procedure: time
Technical aspects of the procedure: preservation of collateral run off
Baseline FU examination: DUS / ABI/ 0-3-9-15...
Lingen experience with Supera for elective PAA

January 2011 - January 2018 (FU 3-55 Mon)

- 28 (132) elective PAA (19 pat.) : 1.9-5.1cm
- Single/ two stent : 1/ 20
- Fusiform PAA → more stents : 7
- Re-Interventions : 8 (4 PAA)
- conversions : 4
- Minor/ major amputation : 0
- PAA growth /shrinkage : 0 / 11 (0/ 39.2%)
- detected embolisation/ trash : 0
Lingen experience with Supera for elective PAA

January 2011 - January 2018 (FU 31.7mo (3-55))

<table>
<thead>
<tr>
<th></th>
<th>Supera</th>
<th>CS</th>
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<tbody>
<tr>
<td>30 d mortality</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Lost to FU</td>
<td>3.6 %</td>
<td></td>
</tr>
<tr>
<td>12 Mo PP</td>
<td>85.7%</td>
<td>50-91.2%</td>
</tr>
<tr>
<td>&gt; 12 mo PP</td>
<td>82.1%</td>
<td>73.6-85.5%</td>
</tr>
<tr>
<td>TLR</td>
<td>15.7%</td>
<td></td>
</tr>
<tr>
<td>Conversion</td>
<td>15.7%</td>
<td></td>
</tr>
<tr>
<td>Limb salvage</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Device failure</td>
<td>0% (#, migration)</td>
<td>-4%</td>
</tr>
</tbody>
</table>

Sacciforme PAA (1/2 stents) did better than fusiform PAA

Costs benefits for Supera
Meaning of run off and initial clinical appearance: acute TASC IIB or Rutherford 4-6

<table>
<thead>
<tr>
<th></th>
<th>TASC II</th>
<th>Rutherford</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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<tbody>
<tr>
<td>IIA</td>
<td>IIB</td>
<td>IIA</td>
<td>IIA</td>
<td>IIB</td>
<td>IIB</td>
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<td>VI</td>
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<td></td>
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<td>IV</td>
</tr>
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Procedure time: puncture to closure 44-71 min. followed by local thrombolysis

<table>
<thead>
<tr>
<th>Patency</th>
<th>0,5</th>
<th>0</th>
<th>0,5</th>
<th>0,5</th>
<th>0,5</th>
<th>0,5</th>
<th>0,5</th>
<th>1</th>
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<tbody>
<tr>
<td>BTK</td>
<td>0,5</td>
<td>0</td>
<td>0,5</td>
<td>0,5</td>
<td>0,5</td>
<td>0,5</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patency po</td>
<td>1,5</td>
<td>1</td>
<td>2</td>
<td>1,5</td>
<td>1,5</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1,5</td>
</tr>
</tbody>
</table>

Secondary procedures

| 0 | Reocclusion after 8 Mon. Successful Lysis | 0 | US Amp. 6 Mo. | 0 | Aspiration of emboli BTK and Stenting during index procedure | 0 | 0 |

Complications

| Fasciotomie | Local hematoma | Local hematoma |   |   |   |   |   |   |   |

Aspiration thrombectomy with stenting and thrombolysis: Bolus 5-10mg +1,5mg/h = Bolus +10,5-36mg rTPA
In conclusion: Supera in PAA is a safe and effective therapeutic approach

• Primary endpoint: limb salvage
  – 100% limb salvage up to 55 mo

• Secondary endpoint: rupture, embolisation, run off preservation
  - 100% freedom form rupture, growth and embolisation

• Technically: stable solution without device related complications

• Economically: cheaper and “affordable“ bridging device for thrombus fixation under thrombolysis (index procedure) in acute settings

• Limitations: maximum vessel diameter at landing zones: 7mm

• Starting flow lab in vitro testings for further proof of concept and standardisation in the “femoro-popliteal“ setting
Thank you for your attention

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