Recanalization of Long Superficial Femoral Artery Occlusions by a Transpopliteal Approach: Acute and 12-Month Results

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Objective: Although crossover recanalization of chronic superficial femoral artery (CSFA) has shown higher technical success rates than antegrade recanalization, in chronic CSFA occlusions there is still a considerable technical failure rate due to inability to cross the occlusion.

Methods: We analyzed the acute and 12 month results of 103 patients who underwent transpopliteal recanalization of long CSFA occlusions (mean length 14.8 cm). In 82 patients the popliteal approach was used as a salvage technique after failure to pass the occlusion using an antegrade technique due to subintimal passage. In the remaining 21 cases the transpopliteal approach was used as the primary approach to cross 90 and 180 days. After crossing the SFA without patent proximal stump of the vessel. Puncture of the popliteal artery was performed using fluoroscopic control and road mapping after contrast injection through an ipsilateral or contralateral F4 femoral access. In all cases the distal third of the SFA as well as the popliteal artery were patent allowing placement of a 6 French introducer sheath. Retrograde recanalization of the SFA occlusion was performed using hydrophilic guide wires and Excimer laser assistance followed by adjunctive balloon angioplasty (diameter 5-6 mm).

Results: An acute successful recanalization could be achieved in 89 of 103 cases (86.4%). There were no major procedure related adverse events. Puncture site complications occurred in 11 cases (10.7%). There were 3 false aneurysms (2.9%), 6 hematomas (5.8%) and 2 cases of thrombotic occlusion of the popliteal artery / bihoprenal trunk (1.9%). In both cases we were mechanically able to全长alize the thrombotic occlusion. Primary and secondary patency rates after 12 months as assessed by color-coded ultrasound were 54.4% and 73.8%, respectively.

Conclusion: The transpopliteal approach is an alternative effective technique to recanalize long SFA occlusions, which could not be crossed by standard techniques.

Dose Response of Sirolimus-Eluting SMARTSTM Stents in Porcine Iliac Arteries and Relationship to Arterial Tissue SIrolimus Levels


Background: The dose-response of peripheral arteries to sirolimus delivered from sirolimus-eluting stents has not been established. This study was performed to evaluate several doses of sirolimus-eluting SMART stents and to correlate the vascular response to tissue sirolimus levels.

Methods: To assess efficacy, 8x40 mm SMART stents coated with 50, 150, 500 & 1500µg/sirolimus or control metal or polymer-coated SMART stents were implanted in the iliac arteries of 36 Yucatan miniswine. After a 30, 90 or 180 day recovery period, the iliac arteries were removed and prepared for histomorphometric analysis. All doses were studied at 30 days but only the 500µg and 1500µg/stent doses were studied at 90 and 180 days. Arterial sirolimus was determined by implanting the same four doses of drug eluting stents in the iliac arteries of an additional 45 miniswine and removing the arteries after either 1, 3, 8 and 30 days; the 500 & 1500µg/stent doses were continued for 90 days. Results: At 30 days, significant (p<0.05) reductions in neointimal area were noted in the 150µg, 500µg and 1500µg/stent groups but not in the 50µg/stent group (see Table). Peak tissue levels ranged from 0.6 to 68 ng/ml. However reductions in necrotic area was not observed with peak tissue levels below 1 ng/ml. Conclusion: This dose-response revealed safety at all sirolimus doses and maximum benefit at the 500µg dose. The lack of efficacy at 50µg establishes for the first time apparent minimal tissue levels needed for pharmacological activity.

Dose Response Efficacy at Day 30 and Arterial Tissue SIrolimus Levels

<table>
<thead>
<tr>
<th>Stent/ Dose</th>
<th>Intimal Area (mm²)</th>
<th>Intimal Media Ratio</th>
<th>% Area Occlusion</th>
<th>Intimal Thickness (µm)</th>
<th>Tissue Level Day 1 (ng/ mg)</th>
<th>Tissue Level Day 3 (ng/ mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bare Metal</td>
<td>7.11±2.91</td>
<td>2.00±0.99</td>
<td>21.16±8.60</td>
<td>417.3±123.5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>50µg</td>
<td>7.60±4.46</td>
<td>3.36±2.67</td>
<td>22.15±18.1</td>
<td>447.3±290.4</td>
<td>0.57±0.164</td>
<td>0.33±0.117</td>
</tr>
<tr>
<td>150µg</td>
<td>9.13±5.18</td>
<td>2.99±1.28</td>
<td>36.03±21.8</td>
<td>526.6±128.3</td>
<td>2.32±1.12</td>
<td>1.48±1.54</td>
</tr>
<tr>
<td>500µg</td>
<td>5.44±2.02*</td>
<td>2.06±0.71</td>
<td>16.7±5.65</td>
<td>336.1±176.2</td>
<td>3.65±12.31</td>
<td>7.64±31.37</td>
</tr>
</tbody>
</table>

* P < 0.05; ANOVA/ Dunnett Test

Vascular Brachtherapy With 192Iridium After Femoropopliteal Stenting in High-Risk Patients: Results From the Vienna-5 Trial

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Background: To evaluate the efficacy of endovascular brachtherapy (EBT) for the prevention of restenosis after femoropopliteal stenting in high-risk patients.

Materials and Methods: A total of 88 patients with femoropopliteal lesions (mean treatment length 16.8 ± 7.3 cm) were included into the trial. Patients underwent PTA and stent implantation and were randomized in a double blinded fashion to receive either gamma-EBT with an 192Iridium source or treatment with non-radioactive seeds. A dose of 14 Gy was prescribed to 2mm into the arterial wall (target depth = vessel radius + 2mm). The primary endpoint was angiographic binary restenosis >50% at 6 months.

Results: Recanalization and EBT were successfully accomplished in all patients. The overall 6-month recurrence rate was 34.8% in the Stent- vs. 33.3% in the Stent plus EBT group. (p=0.89). Nine (10.2%) patients developed early re-occlusion of the stented segment (2 patients [4.3%] in the Stent- and 7 [16.7%] in the Stent + EBT group), among them 3 patients in the Stent plus EBT group within the first 24 hours after intervention. Late thrombotic occlusion (LTO >30 days) was observed in 3 patients (7.1%) in the Stent plus EBT group.

Conclusion: EBT does not improve 6-months patency after femoropopliteal stenting in high risk patients, due to a high incidence of early and late thrombotic occlusion.