**Drug Eluting Stents in Tibial Arteries for Critical Limb Ischemia:**
4 year results show favorable outcomes

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**Disclosures**
- No financial disclosures
- I do discuss off label use of devices. It is approved by our hospital legal department and our hospital IRB

**Introduction**
- Critical Limb Ischemia (CLI) represents a severe degree of Peripheral Arterial Disease (PAD) that is defined by rest pain and ischemic tissue loss
- Within a year of diagnosis, CLI is associated with a 25% mortality and 30% major amputation
- Highest incidence of CLI is seen in diabetics and is associated with infrapopliteal atherosclerotic disease
- Revascularization is the optimal treatment, but surgery may be limited by medical comorbidities, poor distal targets, and limited conduit options

**Tibial Stenting**
- Angioplasty alone with bare metal stent for bail out is a commonly utilized endovascular therapy
- The last decade has seen success in using Drug Eluting Stents (DES) in coronary arteries
- Drug Eluting Stents (DES) in SFA and infrapopliteal disease has also been used with good early results
- We evaluated the role of DES in below-the-knee revascularization in patients with CLI who were deemed high-risk candidates for open revascularization

**Methods**
- Retrospective review of 38 high risk patients who underwent drug eluting stent placement over a period of 39 months between April 2010 and July 2013
- Stent systems
  - Xience (Abbott) Everolimus Eluting Stent
  - Promus (Boston Scientific) Everolimus Eluting Stent
- Standard percutaneous technique
- Pharmacologic Intervention
  - All patients were given initial Plavix dose 150 mg
  - Treated indefinitely with dual therapy ASA/Plavix 75mg
- Follow up
  - Initial 2 week clinical follow up
  - 6 week duplex, then every 3-6 months

**Patient Demographics**

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>38</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>79.5 ± 9.2 yrs.</td>
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<tr>
<td>Gender</td>
<td>29 males/9 females</td>
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<tr>
<td>ASA</td>
<td>3.5 ± 0.7</td>
</tr>
<tr>
<td>Rutherford</td>
<td>4.9 ± 0.8</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>HTN (90%); Diabetes (65%); CAD (60%); Smoking (50%); Hyperlipidemia (75%); Chronic Renal Insufficiency (50%)</td>
</tr>
</tbody>
</table>
# of lesions/limbs | 49 Lesions/45 Limbs
---|---
Lesion locations | 4 BK Pop; 11 TPT; 7 AT; 7 Peroneal; 9 PT; 11 Distal Bypass anastomoses
Proximal Intervention | 13 of 38 (34%) with simultaneous SFA intervention
Average stent diameter (mm) | 2.96 ± 0.5 mm
Average lesion length (mm) | 26.4 ± 0.4 mm

## Target Lesion Characteristics

### Posterior tibial lesion pre-intervention

### Post DES deployment

### Tibioperoneal trunk lesion

**pre-intervention**

**Post intervention**

## Follow up

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Mean follow up: 1425 days (3.9 years)</th>
<th>Median follow up: 1575 days (4.3 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>41/49 lesions (84%)</td>
<td></td>
</tr>
<tr>
<td>Wound healing</td>
<td>31/38 (82%)</td>
<td></td>
</tr>
<tr>
<td>Amputation free survival</td>
<td>32/38 (84%)</td>
<td></td>
</tr>
<tr>
<td>Pain Relief</td>
<td>31/38 (82%)</td>
<td></td>
</tr>
<tr>
<td>Complications</td>
<td>3/38 (8%)</td>
<td>2 hematomas; 1 puncture site pseudoaneurysm</td>
</tr>
<tr>
<td>Death</td>
<td>5/38 (13%)</td>
<td>3 CAD; 1 CVA; 1 Malignancy</td>
</tr>
</tbody>
</table>

## Conclusions

- PTA is the current standard for endovascular therapy in infrapopliteal disease based on the BASIL trial
- Stenting is traditionally reserved for bailout situations where PTA failed to achieve results or is complicated by flow-limiting dissection or elastic recoil
- <50% of balloon dilated tibial lesions remain open after 1 year
Conclusions

• This study shows that the use of DES in infrageniculate positions is safe and can be an effective method for treatment of critical limb ischemia.

• We demonstrate significant improvement at 3.9 years in stent patency, pain relief, along with amputation free survival.

• Moreover, for certain patients, these results suggest that DES could rival surgical bypass as a primary treatment option.

• Further studies to determine longer term follow up are warranted.

Critical Limb Ischemia and poor surgical candidate

Yes
Bypass
PTA w selective stenting

No
Optimistic
intervention

Long lesion >3.5 cm length

Primary stenting w DES

Atherectomy w selective stenting

Thank You