Not so fast:
Atherectomy is not only useful but a necessity

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Medicare data

• All comers
• Prior amputation not clear
• Recall definition of atherectomy includes true devices and non-atherectomy devices
• Granularity of the patients is unknown

Medicare amputation data

Clinical Limitations & Unmet Needs

Calcium as a Barrier

Calcium Limits Vessel Expansion

Calcium May Limit Drug Effect

Longer Lesion Length

Increased lesion length is an independent predictor of decreased patency.
**Tibial calcification**

- Association with PAD and abnormal ABI independent of serum calcium, other biochemical levels (CRP etc)
- Association with renal failure and independent to age, gender, diabetes and tobacco

- Calcification is a marker for amputation and poor wound healing

**SCAFFOLDS STILL NEEDED, LIKELY AT RATES PROPORTIONAL TO LESION COMPLEXITY**

**DEFINITIVE LE**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>CLI (n=279)</th>
<th>Patency (PSVR &lt; 2.4)</th>
<th>Lesion Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (n=522)</td>
<td>75%</td>
<td>7.5</td>
<td>75%</td>
</tr>
<tr>
<td>Lesion type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stenoses (n=361)</td>
<td>64%</td>
<td>11.0</td>
<td>64%</td>
</tr>
<tr>
<td>Occlusions (n=161)</td>
<td>58%</td>
<td>9.8</td>
<td>67%</td>
</tr>
<tr>
<td>Femoral (n=252)</td>
<td>77%</td>
<td>8.1</td>
<td>64%</td>
</tr>
<tr>
<td>Popliteal (n=251)</td>
<td>77%</td>
<td>8.6</td>
<td>44%</td>
</tr>
<tr>
<td>Tibial (n=49)</td>
<td>90%</td>
<td>5.5</td>
<td>78%</td>
</tr>
</tbody>
</table>

**DEFINITIVE LE**

**WOUND-HEALING IN CLI**

(RCC 5 & 6 at Baseline)

- 12 Months: 72%
- 6 Months: 61%
- 3 Months: 52%
LIBERTY Enrollment and 1-Year Follow-up

- 1,204 Subjects Enrolled at 51 Sites
- All Comers - All Treatments

Completed 1-Year Follow-up

- Rutherford 2-3: 389 Subjects
- 389 Lesions
- ATK Only

- Rutherford 4-5: 462 Subjects
- 758 Lesions
- BTK Only

- Rutherford 6: 168 Subjects
- 14th Lesions
- ATK & BTK

LIBERTY Target Lesion Locations

- Proximal lesion location is lower in the leg (BTK) as severity of Rutherford Classification increases.

LIBERTY Device Usage by Lesion

- Balloon and/or atherectomy were preferred devices with orbital atherectomy (OAS) the most frequently used atherectomy device. Bailout stenting was significantly less frequent in RC6 compared to either RC2-3 or RC4-5.

12 Month Freedom from MAEs

- Freedom from MAEs: Death to 30 days, Major amputation, TVR

Conclusions

- Medicare data are compelling
  - Placed in context
  - Science is distinct
- Arterial calcification and plaque burden is an issue for many if not all endovascular procedures
- Arterial outcomes appear (registry data) improved (primary patency, MALE) with upfront atherectomy for tibial circulation and core lab adjudicated above knee trials
- Arterial compliance remains an issue
  - Costs remain a question
- There is no doubt financial incentives have swayed use/overuse of atherectomy in OBL’s