Current Treatment For SFA/Pop Occlusive Lesions: What Technology Is Best And When

(The Data that Gets Us There)

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What Should Drive an Algorithm?

• Randomized Data if possible
• Matching technology to Lesion Characteristics
• Procedural Cost
• Longer term Costs
• Patency
• Need for Repeat Procedures
• Safety
• Physician reimbursement
• Hospital profit margin

What to Do when No Randomized Data

• Use sparingly
• Use where it makes clinical sense ie specific technology characteristics
• Push for randomized data

Variables That Effect Patency and Clinical Outcome

<table>
<thead>
<tr>
<th>Length</th>
<th>15-20 cm breaking point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter/Location</td>
<td>Normal</td>
</tr>
<tr>
<td></td>
<td>Less than 5 mm vessel</td>
</tr>
<tr>
<td>Calcification</td>
<td>Intimal and “Dense”</td>
</tr>
<tr>
<td>Technical</td>
<td>Stent/graft</td>
</tr>
<tr>
<td>Restenosis</td>
<td>Drug vs no drug</td>
</tr>
</tbody>
</table>

What Does Randomized Fempop Data Tell Us?

• Supervised Walking programs work
• Medical Therapy with Cilostazol can double walking distance in 40% of patients (85% tolerate max dose and 1/2 have clinical benefit)
• Cilostazol decreases restenosis in SBS and DES in Japanese Population
• Technologies with Improved clinical efficacy vs POBA
  - BMS
  - DES
  - Stent graft
• Not all Nitinol Tubular Stents are created equally (Veryan vs Lifestent)
• Improved efficacy vs BMS
  - Drug vs no drug
  - DES
  - Stent graft equivalent to fempop prosthetic bypass at 4 years
• Prosthetic fempop bypass inferior to DES
• Short term DES Eluvia has improved patency/TLR at 1 year vs Zilver PTX which has good patency and TLR data to 5 years
  - Present but not published
**What Randomized Data Do We Need?**
- DCB vs DES
- Atherectomy and DCB vs DCB or DES
- Stent graft vs DCB or DES
- DCB vs DCB (Surmodics doing this, Need to make sense of why noncore lab controlled DCB data for Lutonix in long lesions appears better than its use in short lesions compared to Impact and illuminate which is consistent in most groups)
- Longer term DES vs DES data
- DES vs DCB and spot or shorter length BMS
- DCB and Helical Stent vs DCB and straight stent
- Woven nitinol stent after DCB vs DCB
- All of these data sets in really long lesions (> 20 cm)

**What Do We Do with Atherectomy**
- Does appear to lead to less stent use
- Good patency in nonrandomized non-adjudicated trials
- Animal only data for increased drug uptake
- Continue to ask for randomized data
- Use sparingly until then due to most expensive treatment
- Severely Calcified vessels
- Small Diameter vessels
- No Stent Zones
- Long Lesions

**Evidence: Published Studies of Atherectomy + DCB**

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Patients</th>
<th>Atherectomy</th>
<th>Patency 1 year</th>
<th>Patency 2 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITIVE AR</td>
<td>DA + DB</td>
<td>92 (DA + DB)</td>
<td>80% (DB)</td>
<td>84.6%</td>
<td>81.3%</td>
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<tr>
<td>STAVROULAKIS</td>
<td>DA + DB</td>
<td>41 (DA + DB)</td>
<td>85% (DB)</td>
<td>NR</td>
<td>84.7%</td>
</tr>
<tr>
<td>CIOPPA</td>
<td>DA + DB</td>
<td>30 (DA + DB)</td>
<td>NR</td>
<td>NR</td>
<td>84.7%</td>
</tr>
<tr>
<td>SIXT</td>
<td>DA + DB</td>
<td>29 (DA + DB)</td>
<td>43.8%</td>
<td>NR</td>
<td>84.7%</td>
</tr>
<tr>
<td>GANDINI</td>
<td>Laser + DB</td>
<td>24 (Laser + DB)</td>
<td>0%</td>
<td>66.7%</td>
<td>37.5%</td>
</tr>
<tr>
<td>Kokkinidis</td>
<td>Laser + DB</td>
<td>62 (Laser + DB)</td>
<td>NR</td>
<td>NR</td>
<td>86.7%</td>
</tr>
</tbody>
</table>
Other Interesting Core Lab Controlled Data Sets

- Woven Nitinol Stents appear to have a flat restenosis rate after initial restenosis from angioplasty
- Helical tubular stents appear to have a flat restenosis rate after initial restenosis from angioplasty
- BMS to treat complex DCB treated lesions does not appear to decrease patency
- DES associated with a simpler pattern of restenosis

What Does Randomized Fempop Data Tell Us? (Summary)

- Medical Therapy with Cilostazol can double walking distance in 40% of patients
- Exercise Therapy is poorly tolerated but effective
- For Intervention it is becoming a Drug Based World and everything else has to prove it is worth it
- Newer stent designs appear to be more favorable long term