DEBATE: An Endovascular First Approach To All CLI Patients Results In Better Limb Salvage: Based On Long-Term Follow-Up Of A Single Vascular Surgical Center

Ramon Varcoe
Sydney, Australia

Disclosure
Speaker name: Ramon Varcoe
Consulting: Abbott, Boston, Gore, Covidien, Medtronic
Advisory Board: Abbott

MODERN-DAY ENDOVASCULAR SURGERY

Is it reasonable to take an endo-first approach to ALL patients with CLI?

Our Own Experience

- Critical limb ischaemia
- 8 year single-centre experience at POWH (2004-2012)
- 344 limbs; 279 patients; 546 hospital admissions

Endovascular-first vs. Open Repair

- Major amputation reduced by 62%
  (7.7 vs. 20%; p<.001)
- Reduced theatre time
  (158 vs. 317min; p<.0001)
- Reduced LOS
  (15 vs. 32d; p<.001)
- Reduced ICU stay
  (2.3 vs. 23.7h; p=.033)
Factual Advantages of an Endovascular approach to CLI...

- Reduced 30d mortality
- Reduced procedural morbidity
- Fewer Wound Related Issues
  - Fewer wound complications
  - Less pain
  - Faster recovery
  - Less leg swelling
- Shorter hospital stay
- No requirement for good quality autogenous conduit

RCTs: 30-Day Mortality

<table>
<thead>
<tr>
<th>Bypass Trial</th>
<th>Year</th>
<th>N</th>
<th>Mortality</th>
<th>Endov Trial</th>
<th>Year</th>
<th>N</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wolf et al</td>
<td>1993</td>
<td>126</td>
<td>3.1%</td>
<td>Wolf</td>
<td>1993</td>
<td>129</td>
<td>0%</td>
</tr>
<tr>
<td>Abufahama et al</td>
<td>1999</td>
<td>43</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Johnson et al</td>
<td>2000</td>
<td>752</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Klinkert et al</td>
<td>2003</td>
<td>151</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PREVENT III</td>
<td>2006</td>
<td>1061</td>
<td>2.7%</td>
<td>Higgin</td>
<td>2005</td>
<td>104</td>
<td>0%</td>
</tr>
<tr>
<td>BASIL</td>
<td>2010</td>
<td>753</td>
<td>2.4%</td>
<td>Zilver PTX</td>
<td>2011</td>
<td>872</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>VIASTAR</td>
<td>2013</td>
<td>101</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>In.Pact SFA</td>
<td>2015</td>
<td>383</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Levant 2</td>
<td>2015</td>
<td>476</td>
<td>0%</td>
</tr>
</tbody>
</table>

Sample Weighted Mean

|                      | Total | 2704 | 2.2%    | Total | 1879 | 0.36%   |

6.1x Mortality Risk

Factual Advantages of an Endovascular approach to CLI...

- Reduced 30d mortality
- Reduced procedural morbidity
- Fewer Wound Related Issues
  - Fewer wound complications
  - Less pain
  - Faster recovery
  - Less leg swelling
- Shorter hospital stay
- No requirement for good quality autogenous conduit

Factual Advantages of an Endovascular approach to CLI...

- Reduced 30d mortality
- Reduced procedural morbidity
- Fewer Wound Related Issues
  - Fewer wound complications
  - Less pain
  - Faster recovery
  - Less leg swelling
- Shorter hospital stay
- No requirement for good quality autogenous conduit

Factual Advantages of an Endovascular approach to CLI...

- Reduced 30d mortality
- Reduced procedural morbidity
- Fewer Wound Related Issues
  - Fewer wound complications
  - Less pain
  - Faster recovery
  - Less leg swelling
- Shorter hospital stay
- No requirement for good quality autogenous conduit

Factual Advantages of an Endovascular approach to CLI...

- Reduced 30d mortality
- Reduced procedural morbidity
- Fewer Wound Related Issues
  - Fewer wound complications
  - Less pain
  - Faster recovery
  - Less leg swelling
- Shorter hospital stay
- No requirement for good quality autogenous conduit
BASIL: Amputation Free Survival

- 452 CLI patients
- Recruitment 1999–2004
- 20% immediate PTA failure
- 9 stents used!
- Prosthetic grafts used

“So Why Would You Use Bypass-First?”

“Open-Bypass Has Better Durability in Long (TASC C&D) Disease”
<table>
<thead>
<tr>
<th>Study Device</th>
<th>Year</th>
<th>Device</th>
<th>Patients</th>
<th>Mean Lesion Length</th>
<th>12-Month Primary Patency</th>
<th>Definition of Patency Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>DURABILITY-200</td>
<td>2011</td>
<td>Protege Everflex</td>
<td>100</td>
<td>242mm</td>
<td>64.8%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>STELLA Registry</td>
<td>2012</td>
<td>Lifestent</td>
<td>58</td>
<td>220mm</td>
<td>66.0%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>Zilver PTX Global Registry</td>
<td>2013</td>
<td>Zilver PTX</td>
<td>134</td>
<td>228mm</td>
<td>77.6%</td>
<td>&gt;50%; PSVR &gt;2.0</td>
</tr>
<tr>
<td>Valabah TASC CAO</td>
<td>2014</td>
<td>Valabah</td>
<td>71</td>
<td>223mm</td>
<td>67.0%</td>
<td>&gt;50%; PSVR &gt;2.5</td>
</tr>
<tr>
<td>SUPERA 500</td>
<td>2014</td>
<td>Supera</td>
<td>172</td>
<td>223mm</td>
<td>80.5%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>STELLA PTX</td>
<td>2015</td>
<td>Zilver PTX</td>
<td>45</td>
<td>252mm</td>
<td>52.5%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>Brescia et al</td>
<td>2015</td>
<td>Supera</td>
<td>87</td>
<td>279mm</td>
<td>80.1%</td>
<td>&gt;50%; PSVR &gt;2.5</td>
</tr>
</tbody>
</table>

Mean 622 (total) 232mm 69.8% >50%; PSVR >2.0-2.5

**Definition of Loss of Primary Patency**

1. >70%
2. >50% with rec Sx
3. ABI<0.4
4. PSVR >3.0
5. PSV>300cm/sec

**Compared with Endo Studies**

1. >50%
2. PSVR >2.0-2.5

**61%**

**Primary Patency**

- Published 2006
- 1404 patients
- RCT: edifoligide vs placebo
- Ex vivo vein bypass grafts
- They systematically measured patency
### Study Device Table

<table>
<thead>
<tr>
<th>Study Device</th>
<th>Year</th>
<th>Device</th>
<th>Patients</th>
<th>Mean Lesion Length</th>
<th>12-Month Primary Patency</th>
<th>Definition of Patenty Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>DURABILITY-200</td>
<td>2011</td>
<td>Protege Everflex</td>
<td>100</td>
<td>242mm</td>
<td>64.8%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>STELLA Registry</td>
<td>2012</td>
<td>Lifetent</td>
<td>58</td>
<td>220mm</td>
<td>66.0%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>Zilver PTX Global Registry</td>
<td>2013</td>
<td>Zilver PTX</td>
<td>134</td>
<td>216mm</td>
<td>77.6%</td>
<td>&gt;50%; PSVR &gt;1.0</td>
</tr>
<tr>
<td>Valaschi TASC CAD</td>
<td>2014</td>
<td>Valaschi</td>
<td>71</td>
<td>223mm</td>
<td>67.0%</td>
<td>&gt;50%; PSVR &gt;2.5</td>
</tr>
<tr>
<td>SUPERA 500</td>
<td>2014</td>
<td>Supera</td>
<td>172</td>
<td>275mm</td>
<td>80.5%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>STELLA PTX</td>
<td>2015</td>
<td>Zilver PTX</td>
<td>45</td>
<td>212mm</td>
<td>52.3%</td>
<td>&gt;50%; PSVR &gt;2.4</td>
</tr>
<tr>
<td>Brescia et al.</td>
<td>2015</td>
<td>Supera</td>
<td>47</td>
<td>279mm</td>
<td>80.1%</td>
<td>&gt;50%; PSVR &gt;2.5</td>
</tr>
<tr>
<td>Mean</td>
<td>2016</td>
<td></td>
<td>622 (total)</td>
<td>232mm</td>
<td>69.8%</td>
<td>&gt;50%; PSVR &gt;2.0-2.5</td>
</tr>
</tbody>
</table>

### PREVENT III

- **Vein graft bypass:** 6404
- **<61%**
- **>50%; PSVR <2.0-2.5**
- **70%: >50% with
cr: X: 400x; 300x; PSVR <3.0; PSV >300cm/sec**

### So Why Would You Use Bypass-First?

**“Endo-First May Make Subsequent Bypass Less Successful”**

### Why?

- **Strong selection bias** – The patients are selected out as a group who will do badly due to impaired in- or out-flow ± hypercoaguability
- Endo may jeopardise the anastomotic zones or run-off

### Summary

- **Bypass surgery is DANGEROUS (c/w Endo)**
- **Its uses more healthcare resources**
- The potential benefits of bypass are **Questionable and Marginal at best**

### Conclusion

1. **Bypass-First surgery has a diminishing place**
2. It requires careful justification