Use of DCB in BTK

Con
At Least Not Yet!

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Disclosure

Speaker name: Gary Ansel, MD

I have the following potential conflicts of interest to report:

- **Consulting** Medtronic, BSC, Cook Med, WL Gore, Abbott Vasc, CR Bard, Phillips
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- **Other(s)**
  - Royalties: Cook Medical,

I do not have any potential conflict of interest
When Not to Adopt a Technology

- Not enough data on efficacy
- Cant afford unproven technology
- Possible Safety Concerns
Big Data Deficit

- There are several single center data sets but come on these are biased! Can you say Renal Denervation! “Randomized core lab controlled”

- Why was true CLI excluded from all SFA IDE trials and no one reports incidence of toe amputations?

- What Happened in the 1 multicenter randomized, core lab controlled CLI trial?
## TABLE 4  12-Month Efficacy Endpoints

<table>
<thead>
<tr>
<th></th>
<th>IA-DEB</th>
<th>PTA</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late lumen loss,* mm</td>
<td>0.605 ± 0.775</td>
<td>0.616 ± 0.781</td>
<td>0.950</td>
</tr>
<tr>
<td>Binary restenosis*</td>
<td>41.0 (25/61)</td>
<td>35.5 (11/31)</td>
<td>0.609</td>
</tr>
<tr>
<td>Occlusion rate</td>
<td>11.5 (7/61)</td>
<td>16.1 (5/31)</td>
<td>0.531</td>
</tr>
<tr>
<td>Longitudinal restenosis†</td>
<td>62.7 ± 56.2</td>
<td>93.2 ± 60.8</td>
<td>0.167</td>
</tr>
<tr>
<td>Clinically driven TLR (AFS subjects)</td>
<td>9.2 (18/196)</td>
<td>13.1 (14/107)</td>
<td>0.291</td>
</tr>
<tr>
<td>Clinically driven TLR (all ITT subjects)</td>
<td>11.9 (27/226)</td>
<td>13.5 (15/111)</td>
<td>0.682</td>
</tr>
</tbody>
</table>

Values are mean ± SD or % (n/N). *Angiographic cohort (core lab analyzed). †Mean % of stenosis length versus treated lesion length (angiographic cohort).

AFS = amputation-free survival; TLR = target lesion revascularization; other abbreviations as in Table 1.
Cant Afford Unproven Technology

- If Surgery could not beat POBA in CLI
- Then How can any technology beat POBA?
- Say Basil Very Slowly

- Wasting money here takes it from there
Health Expenditures Per Capita

Source: OECD Health Statistics 2015 (2013 data or nearest year), Bernstein analysis
Possible Safety Concerns?

Zeller et al JACC 2014:1568-76
Possible Safety Concerns?

Not much room for debri in these collaterals

Current Generation DCBs Debri
Case Report of Panicilitus after DCB

Ibrahim et al. JACC 2016:69;e179
Summary
Why We Should Not Adopt DCB in CLI Yet

• We don’t have enough data on efficacy!

• We can’t afford unproven technology!

• There are possible Safety Concerns!
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