MAKE COMBINATION THERAPY GREAT AGAIN
DCBS AND AND SPOT STENTS IN FEMPOP LESIONS

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Disclosure

Speaker name:
Gunnar Tepe

I have the following potential conflicts of interest to report:
Study support and Advisory Board BBraun
Consequent Study - Design

- 153 patients randomized 1:1
  - 78 patients DCB
  - 75 patients POBA

- 6-month angiographic follow-up* (range 6-8 mo)
  - DCB
  - POBA

- 12-month clinical follow-up*
  - DCB
  - POBA

- 24-month clinical follow-up*
  - DCB
  - POBA

- including walking test, ABI and Duplex
## Lesion details – target lesions

<table>
<thead>
<tr>
<th></th>
<th>All patients</th>
<th>Drug Coated Balloon</th>
<th>Uncoated Balloon</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target lesions</td>
<td>153</td>
<td>78</td>
<td>75</td>
<td>-</td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>122 (79.7%)</td>
<td>63 (80.8%)</td>
<td>59 (78.7%)</td>
<td>0.912</td>
</tr>
<tr>
<td>P1/P2</td>
<td>9 (5.9%)</td>
<td>4 (5.1%)</td>
<td>5 (6.7%)</td>
<td></td>
</tr>
<tr>
<td>SFA + P1/P2</td>
<td>22 (14.4%)</td>
<td>11 (14.1%)</td>
<td>11 (14.7%)</td>
<td></td>
</tr>
<tr>
<td>TASC A</td>
<td>54 (35.3%)</td>
<td>28 (38.9%)</td>
<td>26 (34.7%)</td>
<td>0.934</td>
</tr>
<tr>
<td>TASC B</td>
<td>63 (41.2%)</td>
<td>31 (39.7%)</td>
<td>32 (42.7%)</td>
<td></td>
</tr>
<tr>
<td>TASC C</td>
<td>26 (17.0%)</td>
<td>13 (16.7%)</td>
<td>13 (17.3%)</td>
<td></td>
</tr>
<tr>
<td>TASC D</td>
<td>10 (6.5%)</td>
<td>6 (7.7%)</td>
<td>4 (5.3%)</td>
<td></td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>76.6 ± 18.1</td>
<td>76.0 ± 17.7</td>
<td>77.1 ± 18.5</td>
<td>0.703</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>40 (26.1%)</td>
<td>18 (23.1%)</td>
<td>22 (29.3%)</td>
<td>0.462</td>
</tr>
<tr>
<td>Lesion length, cm</td>
<td>13.2 ± 10.4</td>
<td>13.7 ± 12.2</td>
<td>12.6 ± 8.2</td>
<td>0.540</td>
</tr>
<tr>
<td>Reference diameter, mm</td>
<td>5.22 ± 0.87</td>
<td>5.06 ± 0.77</td>
<td>5.38 ± 0.94</td>
<td>0.050</td>
</tr>
<tr>
<td>2nd non-target lesion</td>
<td>18 (11.8%)</td>
<td>9 (11.5%)</td>
<td>9 (12.0%)</td>
<td>0.929</td>
</tr>
</tbody>
</table>
24-month Kaplan-Meier Curve

No additional TLR between 14 and 24 months
24-month patency

CONSEQUENT trial:
24 month Patency

Patency defined as binary restenosis with diameter stenosis >50% (angiographic) or PSVR>2.4 (sonographic), definition by Diehm et al. [8]
Stents + DCBs

- Longer mean lesion length correlates with higher provisional stenting rate

*Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design*

*Results from different trials are not directly comparable. Information provided for educational purposes.*
Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Rx Only.
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CASE 2
<table>
<thead>
<tr>
<th>Safety outcome*</th>
<th>CTO Imaging Cohort N=115 subjects†</th>
<th>Non-Stented N=63 subjects</th>
<th>Stented N=52 subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically-driven TLR, n (%)</td>
<td>13 (11.3)</td>
<td>9 (14.3)</td>
<td>4 (7.7)</td>
</tr>
<tr>
<td>Thrombosis, n (%)</td>
<td>5 (4.3)</td>
<td>5 (7.9)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

CTOs: Data from In.Pact Global
Conclusion

- DCB only = good solution, if possible
- DCB = no weapon which solves everything
- Especially in CTOs do not leave relevant rest stenosis and hope that the DCB does the rest
- DCB + (Spot)Stent = very good option
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