IN-STENT RESTENOSIS

Jeffrey Wang MD
Horizon Vascular Specialists
In-Stent Restenosis

• Vascular Intervention is Paliative not Curative
• If the patient lives long enough you will have to re-intervene
• If you use stents….you will get In-stent restenosis
• Instent Restenosis
  • Crossing
  • Intervention
Crossing

- Technically more challenging “ReDo”
- Stay within the previous stent
- Make a loop with the wire
- Crossing devices
- IVUS
- Balloon anchoring
Re-intervention

• What to do?.....
• Balloon?
• Bare Metal Stent?
• “Doing the same thing over and over again and expecting a different result”
• Atherectomy?
• Drugs?
• Covered Stent?
Iliac Occlusion

- 58 yo male right leg rest pain
- Fairly Healthy
- 84 pack year smoking history
- Prior appendectomy as a child
HPI

- 55 yo male with diabetes had ulcer which has healed
- Now with recurrent rest pain
- Prior Sfa intervention with bare metal stents placed
Randomized, Multi-Center, Prospective Clinical Trials for Treatment of ISR

- RELINE Clinical Trial (GORE® VIABAHN® Endoprosthesis/PTA vs PTA)
- EXCITE ISR Trial (Excimer Laser Atherectomy/PTA vs PTA)
- FAIR Trial (IN.PACT DCB vs PTA)
Comparing Multi-Center, Randomized ISR Trials: *Lesion Characteristics*

<table>
<thead>
<tr>
<th></th>
<th>FAIR Trial</th>
<th>EXCITE ISR Trial</th>
<th>RELINE Trial</th>
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</thead>
<tbody>
<tr>
<td><strong>Mean Lesion Length (mm)</strong></td>
<td>82</td>
<td>82</td>
<td>196</td>
</tr>
<tr>
<td><strong>% CTOs</strong></td>
<td>24%</td>
<td>33%</td>
<td>31%</td>
</tr>
<tr>
<td><strong>Moderate-Severe Calcification</strong></td>
<td>10%*</td>
<td>9%*</td>
<td>27%</td>
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</tbody>
</table>

*RELINE Trial and EXCITE ISR Trial report Moderate-Severe Calcification, while FAIR Trial reports only “Heavy Calcium”.

Dippel, EJ: TCT 2014; Krankenberg H; LINC 2015; Bosiers M: JEVT 2015
Comparing Multi-Center, Randomized ISR Trials: 12-month Outcomes

<table>
<thead>
<tr>
<th></th>
<th>FAIR Trial</th>
<th>EXCITE ISR</th>
<th>RELINE Trial</th>
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<tbody>
<tr>
<td><strong>IN.PACT DCB</strong></td>
<td>70.5%</td>
<td>~40%</td>
<td>75%</td>
</tr>
<tr>
<td><strong>PTA</strong></td>
<td>37.5%</td>
<td>~20%</td>
<td>28%</td>
</tr>
<tr>
<td><strong>Excimer Laser Atherectomy</strong></td>
<td></td>
<td>~47%</td>
<td>~28%</td>
</tr>
<tr>
<td><strong>PTA</strong></td>
<td></td>
<td>~28%</td>
<td>40%</td>
</tr>
<tr>
<td><strong>GORE® VIABAHN® Endoprosthesis</strong></td>
<td></td>
<td>80%</td>
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<tr>
<td><strong>PTA</strong></td>
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</tbody>
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- **Primary Patency at 12-months**: 70.5%, 37.5%, ~40%, ~20%, 75%, 28%
- **Freedom from TLR at 12-months**: 91%, 53%, ~47%, ~28%, 80%, 40%

*RELINE Trial and EXCITE ISR Trial report Moderate-Severe Calcification, while FAIR Trial reports only “Heavy Calcium”.

Dippel, EJ: TCT 2014; Krankenberg H; LINC 2015; Bosiers M: JEVT 2015
Conclusion

- No head to head direct comparison
- When looking at lesion length and patency duration
- Trend to favor Viabahn for complex ISR
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