What is the best treatment for ISR? DCBs delay restenosis but there is a catch-up. What is the solution?

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Disclosures
Study support by BART, Bayer, BBraun, Biotronic, Gore, Phillips, Medtronic, Shockwave, Verian

FAIR and PACUBA (DCB)
- FAIR 6 mo RS rate: Length: 8.1 cm
- PACUBA 6 and 12 mo: Length: 17.9 cm
  Good results after 6 months but nothing beyond!

RELINE (Viabahn)
- 12 mo Results
  Good results after 12 months

DES (Zilver PTX)
- Good results? after 12 months, no control group

Study flow chart
- 88 Patients
  Rutherford 2-5
- DCB: m=47
- POBA: m=41

Follow-up
Clinical/Functional: 1, 6, 12, 24 months
DSA: 6 and 24 months with core lab
OSA: any TLR with core lab
DUS: 6, 12, 24 months
Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>POBA</th>
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<tbody>
<tr>
<td>Calcification</td>
<td></td>
<td></td>
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<tr>
<td>within stent</td>
<td></td>
<td></td>
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<tr>
<td>None/Mild</td>
<td>70.2%</td>
<td>72.3%</td>
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<tr>
<td>Moderate/Severe</td>
<td>29.8%</td>
<td>24.4%</td>
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<tr>
<td>missing</td>
<td>2.4%</td>
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<td>Total occlusion of the stent</td>
<td>25.5%</td>
<td>36.6%</td>
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<tr>
<td>% maximal stenosis</td>
<td>91.4 ± 9.0</td>
<td>92.0 ± 9.1</td>
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<tr>
<td>Former revascularization</td>
<td>38.3%</td>
<td>19.5%</td>
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<td>Stent fracture</td>
<td>N=4</td>
<td>N=0</td>
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<tr>
<td>Target lesion length [mm]</td>
<td>119.6 ± 99.5</td>
<td>109.3 ± 78.1</td>
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Continuous data: mean ± SD (n); Categorical data: % of n (n)

(n) = total number of patients in the group for whom the information is available (results of the intention-to-treat set (ITT))

Number of patients in the ITT: DCB: 38, POBA: 28

Results, LLL

Results, TLR 6 mo

Results, TLR 2y

DCB vs. POBA with longer f/u

46 patients with In.Pact DCB vs. 42 patients with POBA (historic control)

Limitations: mono-center, no core lab, historic control

Debate ISR 3 Y

Grotti et al., JEVT, 2016; 23: 52-57

The same results!
Baseline DD vs. Other Groups

Conclusions

• Follow-up less than 2 y in in-stent RS has no value
• First prospective randomized DCB study which shows a catch-up of the DCB group after a certain time
• A delayed TLR after DCB might be driven
  • By the underlying disease (ISR, calcium burden)
  • By the DCB product (different drug content over time in the vessel wall)
• First DCB study which shows a dose effect of DCB therapy
  • Higher dose might be needed especially in complex SFA lesions with higher chance of restenosis