Drug – coated balloons: Impact of the balloon structure on drug transfer

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Disclosure

Speaker name:
Ulrich Speck

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☒ Stockholder of a tiny healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
DCB: Impact on efficacy

- Drug
- Drug formulation
- Coating method
- Vessel preparation
  - Stenting
- Balloon structure
Coated balloons in the porcine model
Which drugs work on balloons?

- **Paclitaxel, crystalline** yes
- **Rapamycin** (yes?)
- **Zotarolimus** (yes?)
- **Epothilon (Fantolon)** no
- **Methotrexate** (yes?)
- **Proteasome inhibitor** no
- **Flavone(s)** no
- **Thalidomide** no
- **As$_2$O$_3$** no
- **Docetaxel** ?
- **Protaxel** ?
- **Paclitaxel, amorph** no

grey: no clinical experience
Which formulations work on balloons?

Clinical Results: TLR 6/12 Months

![Graph showing clinical results for various balloon formulations.](image-url)
Tested balloon structures

Paccocath
coating of conventional balloons 2003 2014

AngioSculpt X
only PTCA available
uncoated coated

Chocolate Touch
currently limited availability
uncoated coated

Nipro NSE, non slip
pilot coating
uncoated coated

Gore composite ePTFE surface
clinical trial ongoing
no drug drug-coated
Impact of the balloon structure on drug transfer

Results

<table>
<thead>
<tr>
<th>DCB</th>
<th>Loss on the (simulated) way to the lesion [% of dose]</th>
<th>Drug transfer to the vessel wall [% of dose]</th>
<th>Residual drug on balloon after use [% of dose]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paccocath</td>
<td>6 ± 10</td>
<td>8.7 ± 4.9</td>
<td>7.9 ± 2.6</td>
</tr>
<tr>
<td>AngioSculpt</td>
<td>17 ± 8</td>
<td>8.6 ± 3.8</td>
<td>27 ± 9</td>
</tr>
<tr>
<td>Chocolate Touch</td>
<td>6 ± 12</td>
<td>14 ± 4</td>
<td>17 ± 3</td>
</tr>
<tr>
<td>Nipro NSE</td>
<td>10 ± 6</td>
<td>7.8 ± 3.3</td>
<td>42 ± 2</td>
</tr>
<tr>
<td>Gore DCB</td>
<td>12 ± 4</td>
<td>28 ± 4</td>
<td>36 ± 4</td>
</tr>
</tbody>
</table>

Conclusions

• Combining scoring, modified pressure distribution, non-slip, surface modification with drug delivery is feasible

• Equal or improved drug delivery, reduced systemic drug exposure
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