Drug transfer to the vessel wall by drug-coated hyper-compliant balloon catheters (DCHCB)

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

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

☐ I do not have any potential conflict of interest
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• Background

DES and DEB:
Significant reduction of restenosis after percutaneous vascular therapy by local drug delivery but
- often associated with modification of the vascular anatomy
- rarely uniform cylindrical lumen after atherectomy and stenting or of diseased long vessel segments

• Aim

Exploration of technical feasibility of drug delivery by DCHCB for local treatment

• Methods

In vitro and in vivo testing of hyper-compliant balloon catheters with varying balloon lengths
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- **Results**

**Physical characteristics**

<table>
<thead>
<tr>
<th>Property</th>
<th>Standard PTA balloon catheter</th>
<th>Hyper-compliant balloon catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon type</td>
<td>Non- or semi-compliant</td>
<td>Hyper-compliant</td>
</tr>
<tr>
<td>Before inflation</td>
<td>Folded</td>
<td>Contracted</td>
</tr>
<tr>
<td>After deflation</td>
<td>Irregular shape of folds</td>
<td>Contracted to its original state</td>
</tr>
<tr>
<td>Inflation</td>
<td>High pressure (6-16 atm)</td>
<td>Low pressure (&lt; 0.5 atm)</td>
</tr>
<tr>
<td>Surface area upon inflation</td>
<td>Almost unchanged</td>
<td>Significantly increased</td>
</tr>
<tr>
<td>Shape and diameter</td>
<td>Cylindrical, defined diameter</td>
<td>Conformable to the shape of the vessel lumen, diameter: 3-12 mm</td>
</tr>
</tbody>
</table>
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Conformability to the structure of various types of vessels in swine

### Coronary arteries
- Left anterior descending
  - Native
  - Hyper-compliant balloon

### Renal arteries
- Native
- Hyper-compliant balloon

### Iliac-femoral arteries
- Native
- Hyper-compliant balloon
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Hyper-compliant balloon coated with paclitaxel

- Drug content: $\sim 12 \text{ mg on 20 cm balloon} = \sim 60 \text{ µg drug / mm of the balloon length}$
- Drug loss during passage through introducer sheath: $18.0 \pm 3.9 \%$ of dose
- Drug in the vessel wall ca. 10-20 min after balloon inflation: $6.8 \pm 3.9 \%$ of dose
- Residual drug on balloon after inflation and retraction: $27 \pm 14 \%$ of dose

**Efficacy:** Treatment of the vessel segment with a hyper-compliant balloon catheter after stent implantation in swine

Optical coherence tomography (OCT) of the internal iliac arteries at 4-weeks follow-up
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**Conclusion**

- A novel atraumatic balloon catheter adapts its shape to the existing vascular anatomy
- Coating with a sufficient dose of drug is feasible despite the low and unprotected balloon surface of non-inflated balloons
- High drug transfer to the vessel wall

⇒ Drug-coated hyper-compliant balloon catheters may allow homogenous treatment of irregularly shaped vessel segments
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