SELUTION SLR™ in Clinical Practice: Angio Case Examples

Ulrich Beschorner
Disclosure

Speaker name:
Ulrich Beschorner

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
# Vascular Remodeling after PTA

<table>
<thead>
<tr>
<th></th>
<th>POBA</th>
<th>AHERECTOMY</th>
<th>PACLITAXEL COATED BALLOON</th>
<th>LIMUS COATED BALLOON</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RESTENOSIS</strong></td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>??</td>
</tr>
<tr>
<td><strong>LATE LUMEN LOSS</strong></td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>??</td>
</tr>
<tr>
<td><strong>PATTERN OF RESTENOSIS</strong></td>
<td>focal and diffuse</td>
<td>diffuse</td>
<td>focal</td>
<td>??</td>
</tr>
<tr>
<td><strong>DILATATION / ANEURYSMS</strong></td>
<td>-</td>
<td>+/-</td>
<td>+</td>
<td>??</td>
</tr>
</tbody>
</table>
Vascular Remodeling after PTA

<table>
<thead>
<tr>
<th></th>
<th>POBA</th>
<th>AHERECTOMY</th>
<th>PACLITAXEL COATED BALLOON</th>
<th>LIMUS COATED BALLOON</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESTENOSIS</td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>+/--</td>
</tr>
<tr>
<td>LATE LUMEN LOSS</td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>+/--</td>
</tr>
<tr>
<td>PATTERN OF RESTENOSIS</td>
<td>diffuse</td>
<td>diffuse</td>
<td>focal</td>
<td>focal</td>
</tr>
<tr>
<td>DILATATION / ANEURYSMS</td>
<td>-</td>
<td>+/-</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>
Why do we expect a morphological difference to Paclitaxel-PTA after Sirolimus-PTA?
Why do we expect a morphological difference to Paclitaxel-PTA after Sirolimus-PTA?

<table>
<thead>
<tr>
<th>ATTRIBUTE</th>
<th>SIROLIMUS (OR ANALOGS)</th>
<th>PACLITAXEL (PTX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODE OF ACTION</td>
<td>CYTOSTATIC</td>
<td>CYTOTOXIC</td>
</tr>
<tr>
<td>MARGIN OF SAFETY</td>
<td>10’000 FOLD</td>
<td>100 FOLD</td>
</tr>
<tr>
<td>THERAPEUTIC RANGE</td>
<td>WIDE</td>
<td>NARROW</td>
</tr>
<tr>
<td>ANTI-RESTENOTIC</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Lower Late Lumen Loss</td>
<td></td>
</tr>
<tr>
<td>ANTI-INFLAMMATORY</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>TISSUE ABSORPTION</td>
<td>SLOW</td>
<td>FAST</td>
</tr>
<tr>
<td>TISSUE RETENTION</td>
<td>SHORT</td>
<td>LONG</td>
</tr>
</tbody>
</table>
Typical Example of Vascular Remodeling after PTX-DCB

SFA-CTO recanalization with PTX-DCB (Impact) 2011
still patent 2016

Focal dilatation
SELUTION SFA Primary Endpoint

LLL at 6M (N=34)

Calcified Target Lesion (CoreLab assessed by 360 score)

*Late Lumen Loss presented as median value
Positive Remodeling
Positive Remodeling
Positive Remodeling

POST 6 MO
SELUTION SFA Primary Endpoint

LLL at 6M (N=34)

- Calcified Target Lesion (CoreLab assessed by 360 score)

*Late Lumen Loss presented as median value

No aneurysmatic degeneration!
SELUTION SFA Primary Endpoint

LLL at 6M (N=34)

- Calcified Target Lesion (CoreLab assessed by 360 score)

*Late Lumen Loss presented as median value
Restenosis

PRE

POST
BAILOUT STENT

6 MO, focal ISR
SELECTION SFA Primary Endpoint

LLL at 6M (N=34)

*Late Lumen Loss presented as median value

- Calcified Target Lesion (CoreLab assessed by 360 score)

No diffuse neointima hyperplasia!
SELUTION SFA Primary Endpoint

LLL at 6M (N=34)

• Calcified Target Lesion (CoreLab assessed by 360 score)

*Late Lumen Loss presented as median value
Good result

PRE

POST

6 MO
Case Review SELUTION SLR™

Conclusion

• No evidence of toxic vessel wall damage
• No aneurysmatic vessel degeneration
• No diffuse neointima hyperplasia
• Restenosis as expected in severely dissected segments
• Some cases of ISR
• Overall promising patency, also in rather challenging lesions
SELUTION SLR™ in Clinical Practice: Angio Case Examples

Ulrich Beschorner