Effectivity of a Synthethic Intimal-Coating in the prevention of intimal hyperplasia after vascular wall damage

A pilot animal study

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Disclosure

Speaker name:
Steven van Haelst

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
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- I do not have any potential conflict of interest
Background

- European consortium “The GRAIL Project”:
  - SIC as “gel” on a balloon: **Time for in vivo testing**
Animal model: arterial intimal damage

Theory:
  I. Stent
  II. Non-compliant balloon overdistention
  III. Compliant balloon overdistention & traction
  IV. Human serum xenoreaction

Not effective:
  III. Fogarty compliant balloon alone
  IV. Human serum xenoreaction

Alternative?
  • Cutting balloon & Fogarty balloon
Study objectives

1. To validate whether vascular wall damage with the use of Cutting balloon angioplasty is an effective model to induce intimal hyperplasia

2. To study whether the SIC is an effective technique to prevent the formation of intimal hyperplasia after vascular wall damage
Methods

• Vascular damage iliac artery bilateral
  ➢ Both Cutting balloon
  ➢ And Fogarty balloon

• SIC placement on 1 side

• n= 4 feasibility

• n=12 pilot
Results

Minimal damage per artery:

- $0 = 0\%$
- $1 = 8,3\%$
- $2 = 12,5\%$
- $3 = 79,2\%$
Results

Size does matter
Results

Only deposition of SIC in damaged segments
Results

• Intimal hyperplasia
## Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Estimate</th>
<th>Std. Error</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIC (yes)</td>
<td>154.21</td>
<td>67.35</td>
<td>0.024 *</td>
</tr>
<tr>
<td>Damage (1)</td>
<td>-43.48</td>
<td>121.82</td>
<td>0.722</td>
</tr>
<tr>
<td>Damage (2)</td>
<td>106.66</td>
<td>110.89</td>
<td>0.338</td>
</tr>
<tr>
<td>Damage (3)</td>
<td>781.86</td>
<td>85.00</td>
<td>&lt;0.001 *</td>
</tr>
</tbody>
</table>
Conclusion

1. Reliable model to induce intimal hyperplasia

2. SIC does not reduce the amount of intimal hyperplasia
   - Placement?
   - Adhesion?
   - Model?
   - Effectivity?
Thank you for your attention

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Dr. Vink
Dr. Petri
Dr. Hazenberg
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