Non invasive 24/7 Flow Augmentation in deep venous Pathology

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Flow augmentation after venous stenting for a venous obstruction potentially improves outcome

Disclosures

• None

Important characteristics of noninvasive compression device, after venous stenting.

• To improve blood flow inside the newly stented veins
• To use stimulation of the calf muscle pump
• To be a synergistic tool along anticoagulation
• To decrease the risk of re-occlusion in venous stent, crucial in first 48 hour post treatment.

Flow Augmentation Devices.

Intermittent pneumatic calf compression device (IPC)
Covidien

Neuromuscular stimulation devices
FlowAid
Geko

Physiologic effects of intermittent pneumatic compression

• Decrease venous stasis and venous pressure
• Increase the flow velocity in deep veins, decrease interstitial edema
• Increase of fibrinolysis
• Increase the blood volume flow and venous emptying
• Increase endothelial shear stress
• Increase the A-V pressure gradient.
• Decrease the incidence of thrombosis.
Neurostimulation devices: FlowAid

- The FlowAid is a battery powered, neuromuscular electro-stimulation device designed to increase blood flow in the veins of the leg.
- The FlowAid device uses a sequential pattern of neuromuscular electrical stimulation to increase blood flow, activating the calf muscle pump and increasing venous, arterial and microcirculatory blood flow.
- They show good results in healthy volunteers.

Neurostimulation devices: Geko

- The geko™ is a battery powered, disposable, neuromuscular electro-stimulation device designed to increase blood flow in the veins of the leg.
- The geko™ device stimulates the common peroneal nerve activating the calf and foot muscle pumps and increasing venous, arterial and microcirculatory blood flow.
- They show good results in healthy volunteers.

But how do these devices perform in PTS patients before and after treatment?

Pilot study in 7 patients?

We measured the flow velocity and volume before and after stenting the iliac tract, to see for it increases flow in the common femoral vein in those PTS patients.

Results population demographics

<table>
<thead>
<tr>
<th>Patients, N</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical characteristics</td>
<td></td>
</tr>
<tr>
<td>Male gender</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Female gender</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>Mean age ± SD</td>
<td>39.3 ± 12.3</td>
</tr>
</tbody>
</table>

VQSM score:
- Left leg | 8.45 ± 5.14 |
- Right leg | 0.08 ± 2.17 |

VHb score:
- Left leg | 51.29 ± 9.53 |
- Right leg | 6.71 ± 6.22 |

Adverse effects:
- 0 |

Serious adverse effects | 3 |

Results in the common femoral vein

<table>
<thead>
<tr>
<th>Study phase</th>
<th>VQSM (cm/s) before treatment</th>
<th>VQSM (cm/s) 1 week after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left leg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Depth</td>
<td>6.64 ± 4.63</td>
<td>6.75 ± 5.12</td>
</tr>
<tr>
<td>Percent change to baseline</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Right leg | | |
| N | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 |
| Depth | 5.05 ± 7.61 | 6.14 ± 6.07 | 5.13 ± 5.93 | 5.42 ± 6.65 | 5.35 ± 5.96 | 6.02 ± 5.65 | 5.35 ± 5.96 | 6.02 ± 5.65 |
| Percent change to baseline | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
Conclusion literature and pilot?

- Neurostimulation devices have a proven good augmented blood-flow in healthy subject even better then IPC devices
- But no experiences in PTS patients
- This small pilot study shows that the results obtained in healthy subject cannot be extrapolated to
  - PTS patients
  - Post stent situations
- Therefore we are conducting two studies to compare FlowAid to IPC and Geko to IPC in PTS patients before and after stenting.

Conclusion

- Because of the potential benefits of neurostimulation over IPC
  - Mobile
  - 24/7
    - E.g. 2 weeks postoperative after stenting
    - Replace AV fistulae
    - Preventing early re-occlusions
- It need to be studied more extensively in PTS patients
  - Compare FlowAid to IPC
  - Compare Geko to IPC