Roadsaver – the paradigm shift in carotid artery treatment

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Disclosure

Speaker name:

...............G. Torsello.................................................................

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Research grant

☐ I do not have any potential conflict of interest
Frequency of carotid procedures

- **Germany**
  - CEA ~27’500
  - CAS ~7’000
- **France**
  - CEA ~17’000
  - CAS ~1’500
- **Italy**
  - CEA ~16’500
  - CAS ~4’800

Source: BIBA Medtech Insights Estimates; Population estimates taken from each country’s respective statistics office websites (Sep. 2013)
What should make CAS attractive for physicians and patients

• Minimal invasive, can be done in local anesthesia, ambulatory settings might be possible
• Short convalescence
• Offers therapy options in high risk patients
  – Post cervical radiation
  – Post coronary DES
  – in patients with orthopedic anomalies (e.g. M. Bechterev)
• No surgically related complications
  – no cranial nerve damage
  – short or no clamping time
Demanding access to the lesion
Optimal Therapy?

- CEA → Removal of embolic material → low embolisation risk
Problem of plaque protrusion in uncovered areas with resulting delayed stroke

Courtesy by Makaroun, Pittsburg and Balzer Mülheim
Known facts in CAS

- 66% of strokes occur after removal of cerebral protection
- This occurs despite of optimal medical therapy
- Reason:
  - plaque prolapse through stent struts
  - Suggestive data of apparent superiority of closed cell over open cell design stents
“Stent design” based analysis

<table>
<thead>
<tr>
<th>ALL EVENTS</th>
<th>Total population</th>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>n/N</td>
</tr>
<tr>
<td>Closed</td>
<td>51/2242</td>
<td>21/934</td>
<td>30/1308</td>
</tr>
<tr>
<td>Open</td>
<td>39/937</td>
<td>27/383</td>
<td>12/554</td>
</tr>
<tr>
<td>TOTAL</td>
<td>90/3179</td>
<td>48/1317</td>
<td>42/1862</td>
</tr>
</tbody>
</table>

Bosiers, Setacci, Castriota, 2007
SPACE Results: Closed cell superior to open Cell
Kinking of distal ICA after CAS

Fig. 7A. - 90% left internal carotid artery stenosis within the vessel kink.

Fig. 7B. - Wallstent 10x20.

Fig. 7C. - Post CAS. Moderate kink distally to the stent.

Technique of carotid angioplasty with stenting, Vitek J.J., New York Heart and Vascular Institute at Lenox Hill Hospital
## The Dilemma

<table>
<thead>
<tr>
<th>Open cell design</th>
<th>Closed cell design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suboptimal plaque coverage</td>
<td>Good plaque coverage</td>
</tr>
<tr>
<td>Conforms to vessel anatomy</td>
<td>Suboptimally conforms to vessel anatomy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Double layer micromesh design</th>
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<tbody>
<tr>
<td>Optimal plaque coverage</td>
</tr>
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<td>Conforms to vessel anatomy</td>
</tr>
</tbody>
</table>
Dual layer micromesh stent

- Sustained Embolic Protection
- Lesion specific scaffolding
  - Tight plaque coverage
  - High in-vessel flexibility
  - Maximal wall apposition
- Deliverability due to the flexibility of distal tip
  - 5Fr stent delivery system
- Re-sheathable/ re-positionable
73yo male, symptomatic right carotid stenosis
Angiography after Roadsaver
First clinical cases
84 Patients with high grade carotid lesions
Details of procedure

- 32 symptomatic, 52 asymptomatic
- 58 Men, 26 Women
- Sedation: none
- Femoral Approach: All
- Protection: All – Filter: 61, MOMA: 23
- Atropine before inflation: All
- Direct Stenting: 25
- Post-Dilatation: All
Details of procedure

Morphology of access vessels:
- 43% Type I Arch
- 14% Type II Arch
- 36% Type III Arch

Morphology of lesions:
all mild to moderate calcified 70 – 98%
Extreme flexibility of distal tip

- Trackability through complex aortic arches
- Reduced dislodgement risk of access sheath or catheter

- 68yo female, high grade lesion right ICA, Type III Arch
Stroke. A device implanted on even a few people can restore blood flow after a stenosis and avoid a rare complication and feared embolism. An occluded Carotid, only one stent, two functions. To inactivate the plaque and prevent stroke, carotid stent has already proved equal to surgical endarterectomy. But today you can avoid the risk of embolism after implantation, using an innovative device (…)
Roadsaver – the paradigm shift in carotid artery treatment?
Conclusion

• The dual layer micromesh stent has proven good deliverability and wall adaptation
• Access to the supra-aortic vessels appears not to be an exclusion criteria anymore
• Evaluation in larger registries or trials is needed to examine the safety, efficacy and durability of CAS performed with the Roadsaver stent
home page: www.gefaesschirurgie-muenster.de

Thank you!

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