Dual Layer Micromesh Stents Decrease New Ischemic Brain Lesions After CAS: What Is The Functional Significance and Will These Micromesh Stents Have Downsides

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Disclosure Statement of Financial Interest

I, Maria Antonella Ruffino, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

The clinical importance of white matter hyperintensities on brain magnetic resonance imaging: systematic review and meta-analysis

BMJ

IMPLICATIONS

- FOR CLINICIANS:
  - Clinical importance of WM lesions, even when found as incidental finding

- FOR RESEARCHERS:
  - WMH can be quantified reliably and non invasively on large samples, be measured as a continuous trait, providing increased statistical power to detect an association
  - Be a potentially useful intermediate marker for identification of new risk factors for stroke and dementia
  - Have a role as a surrogate marker to assess treatment efficacy in research setting (treatment trial)

23 protected (distal filter) CAS

PATIENTS
- 60.9% pts. symptomatic
- 60% pts. NIHSS score ≥1
- 78.2% pts. CHA2DS2-VAS ≥3

Patients were scheduled to undergo clinical, duplex ultrasound and DWF-MR evaluations of their status at baseline, 24 h and at 30 days after the stenting
INCIDENCE, NUMBER, SITE AND VOLUME OF NEW ISCHEMIC BRAIN LESIONS AT 24 HOURS DWI-MR

<table>
<thead>
<tr>
<th>Lesion of interest</th>
<th>PROCEDURE</th>
<th>Lesion median volume</th>
<th>IQR TOTAL AMOUNT [VR]</th>
<th>Maximum lesion volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>VASCULAR RADIOSURGERY</td>
<td>CAS ROADSAVE R (low flow)</td>
<td>0.016</td>
<td>0.005 – 0.166</td>
<td>0.027 – 0.389</td>
</tr>
<tr>
<td>VASCULAR RADIOSURGERY</td>
<td>CAS RAIDSHIAN (low flow)</td>
<td>0.28</td>
<td>0.038</td>
<td>0.089</td>
</tr>
<tr>
<td>PROJECT</td>
<td>CAS (dual filter)</td>
<td>0.0</td>
<td>0.0 – 0.58</td>
<td>-</td>
</tr>
<tr>
<td>PROJECT</td>
<td>CAS (dual filter)</td>
<td>0.47</td>
<td>-</td>
<td>0 – 2.4</td>
</tr>
<tr>
<td>CARENET</td>
<td>CAS (dual filter &amp; stent)</td>
<td>0.039</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* Procedures with NO lesions EXCLUDED from the calculation
** Procedures with NO lesions INCLUDED in the calculation
° study reports volumes as normal variables, i.e. as mean± standard deviation

INCIDENCE OF NEW LESIONS

| STUDY | PROCEDURE | EMBOLIC PROTECTION | PATIENT N | Incidence of new lesions (%)
<table>
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</thead>
<tbody>
<tr>
<td>VASCULAR RADIOSURGERY</td>
<td>CAS ROADSAVE R (dual filter, microspheres)</td>
<td>7/26</td>
<td>26.9</td>
<td></td>
</tr>
<tr>
<td>ICAS</td>
<td>CAS (dual filter, balloon)</td>
<td>62/124</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>LEAS</td>
<td>CAS (dual filter, balloon)</td>
<td>10/167</td>
<td>6.1</td>
<td></td>
</tr>
<tr>
<td>ARER</td>
<td>CAS (dual filter, balloon)</td>
<td>27/31</td>
<td>87.1</td>
<td></td>
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<tr>
<td>PMER</td>
<td>CAS (dual filter, balloon)</td>
<td>14/31</td>
<td>45.1</td>
<td></td>
</tr>
<tr>
<td>LEN</td>
<td>CAS (dual filter, balloon)</td>
<td>11/33</td>
<td>33.3</td>
<td></td>
</tr>
<tr>
<td>LEG</td>
<td>CAS (dual filter, balloon)</td>
<td>4/91</td>
<td>4.4</td>
<td></td>
</tr>
<tr>
<td>CARENET</td>
<td>CAS CGUARD (dual filter, 2 Months)</td>
<td>10/27</td>
<td>37.0</td>
<td></td>
</tr>
</tbody>
</table>

WHAT IS THE FUNCTIONAL SIGNIFICANCE

Even if few data are available about the actual relationship between number and volume of ischemic brain lesions and their effects on cognitive function, a stenting procedure that involves a low number of lesions per procedure, with small volumes and complete recovery at 30 days without new lesions as reported for Roadsafer stents, would be a valuable asset for patients with carotid artery stenosis not suitable for CEA

DOWNSIDES? Actually no, but...

- New device structures [nitinol/PET, double nitinol layer]
- Stenosis
- Thrombosis
- ICA patency
- Stent patency

CAS with dual layer micromesh stents seems to be a safe procedure with a lower incidence of new ischemic cerebral lesions than those reported in studies with conventional carotid stents

CONCLUSIONS

This finding indicates that these new double-layer micromesh stents may exert intrinsic embolic protection and impact positively on CAS outcomes

Low number of lesions per procedure, with small volumes and complete recovery at 30 days without new lesions as for Roadsafer stent or few lesions as for CGuard stent, could potentially reduced the occurrence of recurrent TIA or stroke in the follow up

Actually no downsides (stenosis, stent thrombosis, or ECA occlusion), but just larger studies and longer follow up could confirm these preliminary promising data and finally lead to a revision of CAS