WHAT IS THE CURRENT GOLD STANDARD OF CEREBRAL PROTECTION WITH CAS

Giancarlo Biamino

Disclosure

- Speaker name:
- ................................................................................
- 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

PAST OF CAROTID STENTING

Instable and confusing because of inconsistent data, particularly in randomized studies:

CEA vs. CAS

Cerebral Protection Strategies

- Distal Flow Blockage
- Distal Filters
- Proximal Protection with Flow Reversal
- Proximal Protection with Flow Blockage

NO PROTECTION NO CAS

Filter Wire - Animation

Soft Guide Wire
Montevergine Registry on PEC protected CAS

- From July 2004 to March 2009, 1300 patients underwent CAS using PEC
- All patients had a >80%, if asymptomatic, and >60%, if symptomatic, diameter stenosis of the internal carotid artery, measured according to the NASCET criteria
- The only exclusion criteria were the presence of critical stenosis of the ipsilateral common carotid artery and/or the occlusion of the ipsilateral external carotid artery
- Patients received a detailed clinical assessment one hour, twenty four hours and 30 days

Stabile et al. JACC 2010

Results

Cumulative results at 30 days (MACCE = 1.3 %)
No AMI!

Stabile et al. JACC 2010

Results 1° Endpoint

ARMOUR
proximAl pRotection with the MO.ma device during caRotid stenting

Principal Investigators:
Gary Ansel - Columbus (OH)
L. Nelson Hopkins – Buffalo (NY)

Clinica Montevergine-VME-VMC Registry

<table>
<thead>
<tr>
<th>Death and Stroke</th>
<th>Frequency (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>PP</td>
<td>2.02% (4)</td>
</tr>
</tbody>
</table>

30 Day 0.5% (1)

Total 2.52% (5)

Creatinine clearance >30 < 60 ml-min (%) (n)
68.8 (82)

Presence of significant CAD (%) (n)
58.8 (70)

Symptomatic Patients (%) (n)
55.8 (47)

Proximal Protection meta-analysis

A Meta-Analysis of Proximal Occlusion Device Outcomes in Carotid Artery Stenting

The incidence of stroke was 1.71%
THE PRESENT OF CAS

- The CREST study demonstrated the validity of CAS.
- Nowadays CAS and CEA are to be considered equivalent, independently from:
  - Arch type
  - Tortuosity of the lesion
  - Severity of the lesion
  - Age of the patient

DESERVE STUDY

Diffusion Weighted-MRI based evaluation of the effectiveness of endovascular clamping during Carotid Artery Stenting with the Mo.Ma device

- Prospective, multicenter, single arm, European Study.
- Principal Investigator: Prof Giancarlo Biamino.
- 127 subjects included between February 2008 and October 2010.
- 6 sites (Italy, Germany, Poland):
  - Dr. A. Cremonesi, Cottignola (Italy).
  - Prof. D. Dudek, Krakow (Poland).
  - Dr. B. Reimers, Mirano (Italy).
  - Prof. P. Rubino, Mercogliano (Italy).
  - Prof. D. Scheinert, Leipzig (Germany).
  - Prof. H. Sievert, Frankfurt (Germany).


Results 1° Endpoint DESERVE

<table>
<thead>
<tr>
<th>TARGET SIDE</th>
<th>%</th>
<th>(N =127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pts with new &quot;lesions&quot;</td>
<td>26%</td>
<td>(33)</td>
</tr>
<tr>
<td>Single &quot;lesion&quot;</td>
<td>46%</td>
<td>(15)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTRALATERAL SIDE</th>
<th>%</th>
<th>(N =127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pts with new &quot;lesions&quot;</td>
<td>3.9%</td>
<td>(5)</td>
</tr>
<tr>
<td>Single &quot;lesion&quot;</td>
<td>0.9 %</td>
<td>(1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OVERALL</th>
<th>%</th>
<th>(N =127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pts with new &quot;lesions&quot;</td>
<td>29.9%</td>
<td>(38)</td>
</tr>
<tr>
<td>Single &quot;lesion&quot;</td>
<td>43%</td>
<td>(16)</td>
</tr>
</tbody>
</table>

Conclusions DESERVE

The DESERVE Study confirmed the safety and effectiveness of Mo.Ma proximal protection for CAS, showing a cumulative event rate of 2.4% at 30 days.

The rate of new DW-MRI lesions post-procedure corresponds to the frequency of lesions documented in the literature after supraortic diagnostic procedures.

Incidence of new Cerebral Ischemic Lesions (Primary Endpoint)

Conclusions

The Mo.Ma.
PROXIMAL PROTECTION DEVICE:

1. EASY TO USE
2. SAFE (Arch I-III)
3. EFFECTIVE
4. AT THE MOMENT THE PROTECTION SYSTEM OF CHOOSE
THE FUTURE OF CAS IS BRIGHT !?!?

No, they don’t ...!!!

Post-procedural phase

ENDOVASCULAR → Plaque protrusion!

THE GREAT SOLUTION ??

RoadSaver® All Comers
Italian Registry
- First results on 150 Patients -

Alberto Cremonesi, MD, FESC
Roberto Nerla, MD
Interventional CV Unit
Maria Cecilia Hospital - Cotignola (RA) 82 Patients
Vascular & Endovascular Surgery
Policlinico Univeristario - Siena (SI) 52 Patients
Interventional Radiology Unit
AOU San Giovanni Battista - Torino (TO) 16 Patients

Clinical results of a multidisciplinary approach

Terumo® Carotid Stent

RoadSaver Stent Platform
- Design: Double layer, micromesh
- Construction: Braided mesh
- Material: Nitinol®
- Stent Delivery System
  - Guide wire compatibility: 0.014” (0.36mm)
  - Introducer sheath compatibility: 5Fr. (I.D. > 0.074”)
  - Delivery system construction: Rapid Exchange (RX)

Clinical events

<table>
<thead>
<tr>
<th>30 days (n=150)</th>
<th>MACCE (MI, stroke, death)</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

RoadSaver Terumo® Carotid Stent

OCT

Changing paradigms in CAS

Micromesh stents and sustained anti-embolic action to reduce cerebral embolization may contribute to solve the remaining limitations of carotid stenting.
• NO data considering the ability of the interventionalist to produce a complication-free result.