The future of carotid stenting – Proximal protection and mesh-covered stents are the answer?

TECHNICAL FORUM
Management of carotid artery disease: Remaining controversies and challenges ahead

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Krakow, Poland
Disclosure

Speaker name:

......Staislaw Bartus........................................................

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
Limitations of CAS development: CAS complications

Major complications come from:
• Puncture site bleeding – increase mortality
• Embolization – stroke, death
• Embolization after the procedure (plaque prolapse) – stroke, death

- Complications at the site of the vascular access
- Major embolic stroke
- Minor embolic neurological events (TIAs)
- Intracranial hemorrhage
- Hyperperfusion syndrome
- Carotid perforation (very rare)
- Acute stent thrombosis (very rare)
- Carotid artery spasm
- Sustained hypotension / bradycardia
- Carotid artery dissection
- Contrast encephalopathy (very rare)
Limitations of CAS development: CAS complications

Intuitively, potential solutions:
Major complications come from:
• Puncture site - radial access
• Embolization during procedure - EPD
• Embolization after the procedure (plaque prolapse) - mesh (DL)-stents

• Complications at the site of the vascular access
• Major embolic stroke
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A. Cremonesi EuroPCR 2012
Influence of Arterial Access Site Selection on Outcomes in Primary Percutaneous Coronary Intervention

Are the Results of Randomized Trials Achievable in Clinical Practice?

Local complications

The influence of access site selection was studied in 46,128 PPCI patients; TFA was used in 28,091 patients and TRA in 18,037.

This analysis of a large number of PPCI procedures demonstrates that utilization of TRA is independently associated with major reductions in mortality, MACCE, major bleeding, and vascular complication rates.

Periprocedural stroke

Brain protection systems
Proximal protection  MO.MA

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

- 127 pts
- CAS + MO.MA
- New lesions in MRI-DWI 3-12 h
  - 26% new lesions in DW-MRI

- 30 days FU
  - 2.4% stroke (major -0, minor 2.4%)
  - 0.8% TIA
  - 0% death
  - 0% MI

Stabile E, Biamino G. Int J Cardiol. 2014 Jun 15;174(2):382-
Proximal Balloon Occlusion versus Distal Filter Protection in Carotid Artery Stenting: A Meta-Analysis and Review of the Literature

Pooled analysis comparing P-EPD to D-EPD

Cochrane Central Register of Controlled Trials: January 1998 - May 2015. 12,281 patients were included from 18 studies (13 prospective and 5 retrospective) comparing (D-EPD) and (P-EPD) in the setting of CAS.

The primary endpoint: 30-day mortality and stroke. Secondary endpoint: included new cerebral lesions on diffusion-weighted magnetic resonance imaging (DWMRI) and contralateral lesions on DW-MRI.

in terms of stroke incidence, no significant difference

in terms of mortality, no significant difference

Proximal Balloon Occlusion versus Distal Filter Protection in Carotid Artery Stenting: A Meta-Analysis and Review of the Literature

**Pooled analysis comparing P-EPD to D-EPD**


12,281 patients were included from 18 studies (13 prospective and 5 retrospective) comparing (D-EPD) and (P-EPD) in the setting of CAS.

The primary endpoint: 30-day mortality and stroke.

Secondary endpoint: included new cerebral lesions on diffusion-weighted magnetic resonance imaging (DWMRI) and contralateral lesions on DW-MRI.

new cerebral lesions of DWMRI, contralateral lesions on DW-MRI, no statistical or numerical differences.
New stent design for CAS

mesh covered stent/dual layer stents

Late stroke

Periprocedural stroke

Selfexpandible nitinol
closed-cell Notinol mesh

A. Cremonesi EuroPCR 2012
Technical summary of the new stents

<table>
<thead>
<tr>
<th></th>
<th>Roadsaver</th>
<th>CGuard™</th>
<th>Gore Carotid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company</strong></td>
<td>Microvention / Terumo</td>
<td>Inspire MD</td>
<td>WL Gore</td>
</tr>
<tr>
<td><strong>Material</strong> (Stent/Micromesh)</td>
<td>Nitinol / Nitinol</td>
<td>Nitinol/PET</td>
<td>Nitinol/PTFE/CBAS Coating</td>
</tr>
<tr>
<td><strong>Size of delivery</strong></td>
<td>5F</td>
<td>6F</td>
<td>6F</td>
</tr>
<tr>
<td><strong>Size of Pores μ</strong></td>
<td>375-500</td>
<td>150-180</td>
<td>500</td>
</tr>
<tr>
<td>Flared tips</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retrievable/Repositionable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Conformability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Crossability</strong></td>
<td>+++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td><strong>ECA preservation</strong></td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>EPD compatibility</strong></td>
<td>All</td>
<td>All</td>
<td>All</td>
</tr>
</tbody>
</table>

Max Amor, MEET
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent The C-guard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

Late stroke
Periprocedural stroke

The 30-day major adverse cardiac or cerebrovascular events rate was 0%.

New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm(3).

The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm(3)) lesion in relation to the 48-h scan.

DW-MRI analysis @ 48 hours

<table>
<thead>
<tr>
<th></th>
<th>CARENET (n=27)</th>
<th>PROFI (all) (n=62)</th>
<th>ICSS† (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of new ipsilateral lesions</td>
<td>37.0%</td>
<td>66.2%</td>
<td>68.0%</td>
</tr>
<tr>
<td>Average lesion volume (cm³)</td>
<td>0.039</td>
<td>0.375</td>
<td>-</td>
</tr>
<tr>
<td>Maximum lesion volume (cm³)</td>
<td>0.445</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Schofer J. et al JACC Cardiovasc Interv. 2015; 17; 8(9):1229-34
The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period.

Schofer J. et al. JACC Cardiovasc Interv. 2015; 17; 8(9):1229-34
The future of carotid stenting

Late stroke
Periprocedural stroke

Proximal protection
+
mesh-covered stents

?
Double layered stents for carotid angioplasty: A meta-analysis of available clinical data

**Meta-regression analysis.**

*Impact of proximal EPDs use on 30-day mortality and stroke*

10 studies, 635 patients,

- composite endpoint of 30-day stroke and death
- and the occurrence of procedural unsuccess after CAS
- use of two different DL-stent for CAS

significant inverse relationship between the use of proximal EPDs and the incidence 30-day mortality and stroke  p<0.003,

Is the use of DL-stent + Proximal-EPD the best solution ???

MOMA Ø 2.12mm vs Roadsaver Ø 1.88mm

MODEL SPECIFICATIONS

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<tr>
<th>Reference Number</th>
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<td>MUS0130069X6</td>
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<td>0.083&quot;/2.12mm</td>
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MOMA Ø 2.12mm vs Roadsafer Ø 1.88mm

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Pore size in Filter wire Ez is 110 µm
Near future of CAS:
Distal protection devices
Mesh-covered stents (First generation...)

Startrek
Picture from www.strtrek.com
Our case:
CAS from radial approach with d-EPD (Roadsaver 7x30&Filterwire)

Late stroke
Periprocedural stroke
Local complications

Performed by
Zoltan Ruzsa Hungary
Stanislaw Bartus Poland
In the far future:
CAS
Proximal protection devices +
Mesh-covered stents
(\textit{generation next - 4F})
The future of carotid stenting – Proximal protection and mesh-covered stents are the answer?

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Remaining controversies and challenges ahead

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