A Pioneer’s View of the Carotid World:

What are the Remaining Questions?

Prof. Dr. Dr. h.c. Klaus Mathias
Department of Clinical and Interventional Angiology
Aklepios Klinik St. Georg
Hamburg / Germany
I, Klaus Mathias, 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.
A Pioneer’s View of the Carotid World

... first publication 36 years ago...

... no enthusiastic reaction!
Carotid Artery Disease

We still have to answer many open questions!

- Do we already have the ideal stent for each lesion?
- What is the optimal cerebral protection?
- Should we treat acute ICA occlusions?
- Should we treat carotid dissections?
- Should we treat carotid aneurysms?
- Do we need stents in FMD?
- Should we treat asymptomatic ICA stenosis?
- How much experience do you need for a good outcome of CAS?

...............?
Stents

We have many differing properties of stents

- Cell size - scaffolding
- Radial force
- Tapering
- Plaque protrusion
- Late events - day 1-30
Stents

Plaque protrusion may lead to late events.

Debris

Arterial Wall

Stent Struts
Hybrid Stent
= combination of nitinol stent and fine meshwork
= should prevent plaque prolaps
= should prevent late embolic events
plaque prolapses through stent meshes

fine meshwork prevents plaque prolaps
Cerebral Protection

Filters & Proximal Balloon Protection

- We should always use CP
- Proximal balloon protection is more effective than filters
- Lesions with little plaque burden in asymptomatic patients are well suited for filters
- Proper use of devices required
  - Filters must be well apposed to arterial wall
  - Aspiration before injection always necessary
Cerebral Protection

Flow Blockage

Proximal Balloon Protection is more efficient than filters

Flow Reversal
## Cerebral Protection

### European Trial Flow Reversal

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled pts.</td>
<td>122</td>
<td>100%</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>1</td>
<td>0.8%</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1</td>
<td>0.8%</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Total subjects with MAE</td>
<td>2</td>
<td>1.6%</td>
</tr>
</tbody>
</table>
Cerebral Protection

**European MO.MA Trial**

<table>
<thead>
<tr>
<th>Enrolled pts.</th>
<th>157</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor stroke</td>
<td>3</td>
<td>1.8%</td>
</tr>
<tr>
<td>Major stroke @ 30 days</td>
<td>1</td>
<td>0.6%</td>
</tr>
<tr>
<td>Death</td>
<td>1</td>
<td>0.6%</td>
</tr>
<tr>
<td>Total subjects with MAE</td>
<td>4</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

A. Cremonesi, Charing Cross 2004
Cerebral Protection

EMPIRE (Embolic Protection with Reverse Flow)

- Death/Major Stroke: 0.8%
- Minor Stroke: 2.0%
- Death/Any Stroke: 2.9%
- Death/Stroke/MI: 3.7%
- Primary Endpoint MAE*: 4.5%

MAE 2.9%

% of Subjects (N=245)
Cerebral Protection

*Improvements of CP have made CAS a safe procedure!*

MAE today 1 - 3%
Acute ICA Occlusion

Bad results of IVT and CEA!

- Thrombolysis too slow
- CEA inefficient in carotid T occlusions
- Organization essential for acute stroke management
Acute ICA Occlusion

D.E. f-62  Hemiplegic for 4 hours
CTA right ICA & MCA occluded
Acute ICA Occlusion

Bifurcational disease or carotid-T occlusion?

D.E. f-62  Hemiplegic for 4 hours
Acute ICA Occlusion

Some thrombus also in MCA - stent retriever cleaned it.
Acute ICA Occlusion

Solitaire® 6 mm
Carotid Artery Aneurysm

Endovascular Tx best choice!

- Effective independent of the cause of aneurysm
  - atherosclerosis
  - chronic dissection
  - injury
  - tumor erosion
  
....
Self-expandable Covered Stents

Aneurysms of CCA and ICA can be treated - also surgically inaccessible lesion close to the skull base.
AM 44 J. (m)
spontaneous dissection
exclusion of both
aneurysms
with Wallgraft 6 mm

for 5 years free of
symptoms
Silent Infarctions? - Stroke Risk Increased!

Positive CT increases the stroke risk of asymptomatic patients 400%!

Asymptomatic Stenosis

Significant difference already after 1 year
Experience of Interventionalists

4/5 of the trials allowed minimal expertise of 10 CAS and tutoring

<table>
<thead>
<tr>
<th>Study</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAVATAS(^a)</td>
<td>Training in neuroradiology and angioplasty (but not necessarily in the carotid artery) required. Tutor-assisted procedures allowed.</td>
</tr>
<tr>
<td>SAPPHIRE(^a)</td>
<td>Procedures submitted to an executive review committee; CAS periprocedural death or stroke rate had to be &lt; 6%. No tutor-assisted procedures allowed.</td>
</tr>
<tr>
<td>SPACE(^a)</td>
<td>At 25 successful CAS or assistance of a tutor for interventionalists having performed at least 10 CAS.</td>
</tr>
<tr>
<td>EVA-3S(^a)</td>
<td>( \geq 12 ) CAS cases or ( \geq 5 ) CAS and ( \geq 30 ) cases of endovascular treatment of supra-aortic trunks. Tutor-assisted CAS allowed for centers not fulfilling minimal requirements.</td>
</tr>
<tr>
<td>ICSS(^a)</td>
<td>A minimum of 50 total stenting procedures, of which at least 10 should be in the carotid artery. Tutor-assisted procedures allowed for interventionalists with insufficient experience.</td>
</tr>
</tbody>
</table>
Experience of Interventionalist

That is nonsense!
It is unethical to conduct a trial on that basis!

Probationary Centres

The trial protocol recognises that many centres may lack the necessary experience of carotid stenting. Centres fulfilling the other requirements for entry but where interventionalists (or surgeons) have insufficient experience of carotid stenting (or endarterectomy) may join the ICSSS for a probationary period.
Experience of Interventionalist

- European trials with poor outcome due to unexperienced interventionalists
  - EVA-3S → CAS not reimbursed in France & Belgium
  - SPACE
  - ICSS
- Better results of CREST in the last 2 years of the study - no stroke at all!
Experience of Interventionalist

5,341 CAS at 25 hospitals

Pro-CAS Registry

<table>
<thead>
<tr>
<th>Numbers of CAS/hospital</th>
<th>death / stroke (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;51</td>
<td>5.9</td>
</tr>
<tr>
<td>51-150</td>
<td>4.5</td>
</tr>
<tr>
<td>&gt;150</td>
<td>3</td>
</tr>
</tbody>
</table>

Theiss et al., Stroke 2009, 39: 2325-30
### Experience of Interventionalist

#### Multivariate Analysis of Predictors of CAS Events*

<table>
<thead>
<tr>
<th>Experience</th>
<th>OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 50 vs. &gt;150/J.</td>
<td>1.77 (1.1-2.8)</td>
<td>0.017</td>
</tr>
<tr>
<td>50-61 vs &gt;150/J.</td>
<td>1.48 (1.0-2.1)</td>
<td>0.034</td>
</tr>
</tbody>
</table>

*Data from the ProCAS Registry*
Experience of Interventionalist

- Better results of CREST in the last 2 years of the study
- No strokes at all!
Experience of Interventionalist

MAE in high risk carotid stent IDE trials: 2002-2009 (n>4000)

Improving Results over Time

% MAE

SAPPHIRE 2002
ARCHER 2003
SECURITY 2003
BEACH 2004
MAVeRIC 2004
CABERNET 2004
CREATE 2005
EMPIRE (2008)
EPIC (2008)
PROTECT (2008)
ARMOUR (2009)
CAS - Mature for General Use?

Yes, when the own CAS results are independently controlled and meet the AHA criterions!

There is no certification for operators performing CAS, but regulated training for CEA!

**Bad trials damage good methods!!!**