Carotid Stenting
With Proximal Protection in Consecutive CAS Patients

Horst Sievert, Markus Hornung,
Ilona Hofmann, Laura Vaskelyte, Stefan Bertog,
Sameer Gafoor, Predrag Matić, Markus Reinartz, Iris Grunwald
CardioVascular Center Frankfurt - CVC,
Frankfurt, Germany
Background

• Many studies have shown that proximal protection may be more effective than distal filters

• However, proximal protection
  - is often considered to be more complex than distal filters
  - has several limitations and contraindications
    • Contralateral occlusion, intolerance, ....

• Therefore, proximal protection is often considered for "complex lesions" only
Purpose

• To assess the use of proximal protection devices in consecutive patients as the preferred means of cerebral embolic protection for carotid stenting
Methods

- Neurological examination (NIH stroke scale)
- Duplex ultrasound or MR angio
- Angiography including intracranial vessels
- Carotid stenting with proximal protection
  - GORE Flow Reversal System or the Mo.Ma with flow reversal
  - Angiographic verification of complete protection
  - Extensive aspiration before device removal
- Day 1 and/or discharge:
  - Neurological examination (NIH stroke scale)
- At 30 days:
  - Carotid duplex
  - Neurological examination (NIH stroke scale) and MRI or CT scan if any symptoms had occurred
Inclusion criteria

- Age > 18 years
- Symptomatic ICA stenosis ≥ 50% and/or asymptomatic ICA stenosis ≥ 70%, as defined by duplex ultrasound, angiography or MR angiography
- Symptomatic is defined as a carotid artery stenosis associated with ipsilateral TIA, amaurosis fugax, ischemic stroke or retinal infarction within 6 months prior to enrolment
- Stenosis location within 5cm of the carotid bifurcation
Exclusion criteria

• Prior stenting in the target vessel, if the stent covers the ECA
• Myocardial infarction within the past day
• Stroke, intracranial hemorrhage or hemorrhagic stroke within 1 day prior to the procedure
• Peripheral vascular disease, supra-aortic tortuosity or other anatomical limitations precluding the use of catheter-based technics
• Total occlusion of the target carotid artery treatment site
Medication

- Aspirin: 100 mg/day
- Clopidogrel: 75 mg/d (at least 1 day prior to the procedure and for 1 month after the intervention)
- Heparin: 5,000 – 7,500 IU during procedure
- Atropin: 1 mg prior to balloon inflation
Proximal protection

- GORE Flow Reversal System
- Mo.Ma
  - Used as flow reversal system by leaving the stop cock of the working channel open
Primary Endpoint

• Neurological complications during or after the intervention (until 30 day FU)

Secondary Endpoint

• Technical success:
  – Protection device delivered, placed, reverse or blocked flow established and device retrieved

• Clinical success:
  – Procedure successful without adverse event
Patients

- 124 consecutive patients
- Age 72 ± 9 years
- Male n = 93 (75%)
- Symptomatic stenosis n = 26 (21%)
- Anatomic lesion characteristics
  - Diameter of stenosis 80.1 ± 6.7 %
  - Lesion length 13.3 ± 10.3 mm
  - Contralateral ICA occlusion n = 5 (6.7%)
  - Aortic arch type II n = 12 (9.7%)
  - Aortic arch type III n = 9 (7.3%)
  - Bovine arch n = 1 (0.8%)
EPDs used

74% Flow Reversal System
26% Mo.Ma Ultra
Stents used

- Protégé: 23%
- Precise: 9%
- Xact: 8%
- Zilver: 3%
- Wallstent: 2%
- No stent: 55%
Results

- Procedure time: 61.2 min
- Flow reversal time: 11.4 min
- Radiation time: 13.9 min
- Predilatation: 41 33.1%
- 2nd stent: 4 3.2%
- No stent: 3 2.4%
Results

- Temporary intolerance: 10  8.1%
  - limited to the balloon inflation

- Secondary endpoint

  - Technical success  122  98.4%
    - persistent antegrade flow  2
      - additional protection with a distal filter

  - Clinical success  124  100%

- Primary endpoint  1  0.8%
  - due to acute stent thrombosis @ day 10
# Primary endpoint

<table>
<thead>
<tr>
<th></th>
<th>@ discharge</th>
<th>@ 30 day FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>TIA</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Conclusion

• The use of proximal protection as the first choice for embolic protection in carotid stenting is feasible and very safe
  - Periprocedural stroke/TIA rate zero
  - 30 day stroke rate 0.8%

• Proximal protection was used successfully even in patients with classic contraindications like contralateral occlusion

• After finishing this trial, additional 83 consecutive patients have been treated with proximal protection without stroke/TIA
Thank you!