Differentiating Between Embolic Protection Choices in CAS

Max Amor, MD
Clinic Louis Pasteur
Essey les Nancy, France
max-amor@wanadoo.fr
I, Max Amor M.D  **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.
Preparation of the patient for CAS & Prevention of Complications

• Before:
  - Antiplatelet therapy
  - Statins
  - Blood pressure control (interruption of hypotensive drugs)
  - Renal function & Hydratation

• Meticulous & careful technique during all steps of the procedure
11 Systems of protection

- 7 Filters:
  - Angioguard (J&J)
  - Accunet (Abbott)
  - Easy Filterwire (BSC)
  - Emboshield (Abbott)
  - Interceptor (Medtronic)
  - Spider Rx (EV3)
  - Fibernet (Lumen-Invatec)

- 2 Flow Reversal
  - Moma Device (Invatec)
  - Gore Neuro-protecting system (Gore)

- 2 Occlusive Balloon
  - Percusurge (Medtronic)
  - Mini-invasys Theron double balloon (Mini-Invasys)
EMBOLIC P.D : Improvement of results over time

11 US FDA approval trials with improving outcomes
(all approved as safe and effective) / Registries

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

- SAPPHIRE 2002
- ARChER 2003
- SECURITY 2003
- BEACH 2004
- MAVeRIC 2004
- CABERNET 2004
- CREATE 2005
- EMPIRE (2008)
- EPIC (2008)
- PROTECT (2008)
- ARMOUR (2009)

% MAE

- From W. Gray

Reported 30 day stroke rates. Study parameters and definition of stroke rate may vary per clinical trial.
Main filters in 2010

- Angioguard: Fixed
- Filterwire EZ: Fixed
- Accunet: Bare
- SpiderX: Fixed
- Nav6: Bare
- Medtronic Interceptor: Bare
- Fibernet: Fixed
Advantages & Disadvantages of filters

- **Advantages**
  - Plethora of devices
  - Easiest to use: Fast & Simple
  - Cheapest EPD
  - Preservation of flow
  - Visualization all along the procedure
  - Usable if ipsilateral external carotid or contralateral internal carotid occluded

- **Disadvantages**
  - Incomplete & unsatisfactory protection
  - Stop flow complication difficult to understand and manage
  - Local complications: spasm, dissection
<table>
<thead>
<tr>
<th>DEVICE</th>
<th>Vessel Size (mm)</th>
<th>Crossing Profile (Inches/French)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FiberNet</td>
<td>3.5 mm – 7.0 mm</td>
<td>2.4 – 2.9 F</td>
</tr>
<tr>
<td>Angioguard XP</td>
<td>4.5 – 7.5 mm</td>
<td>3.2 - 3.9 F</td>
</tr>
<tr>
<td>FilterWire EZ</td>
<td>3.5 – 5.5 mm</td>
<td>3.2 F</td>
</tr>
<tr>
<td>Emboshield Pro</td>
<td>2.5 – 7.0 mm</td>
<td>2.8 – 3.2 F</td>
</tr>
<tr>
<td>RX AccuNet</td>
<td>3.25 – 5.0 mm</td>
<td>3.5 – 3.7 F</td>
</tr>
<tr>
<td>SpiderFX</td>
<td>3.0 – 7.0 mm</td>
<td>3.2 F</td>
</tr>
<tr>
<td>GuardWire</td>
<td>3.0 – 5.5 mm</td>
<td>2.8 F</td>
</tr>
<tr>
<td>Emboshield Nav 6</td>
<td>2.5 – 7.0 mm</td>
<td>3.2F</td>
</tr>
</tbody>
</table>

Determine the Landing zone
## Product Attribute Differences

<table>
<thead>
<tr>
<th>Features</th>
<th>Emboshield NAV&lt;sup&gt;6&lt;/sup&gt;</th>
<th>FilterWire EZ</th>
<th>Accunet 3:1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crossing Profile</td>
<td>2.8/3.2 F</td>
<td>3.2 F</td>
<td>3.5-3.7F</td>
</tr>
<tr>
<td>Radiopacity</td>
<td>Circumferential</td>
<td>Circumferential</td>
<td>4 Radiopaque Markers</td>
</tr>
<tr>
<td>Pore Size</td>
<td>120 µM</td>
<td>110 µM</td>
<td>115 µM average</td>
</tr>
<tr>
<td>Filter length</td>
<td>19/22.5 mm</td>
<td>34 mm</td>
<td>44 mm</td>
</tr>
<tr>
<td>Vessel Size Range</td>
<td>2.5-4.8 mm/4.0-7.0 mm</td>
<td>3.5-5.5 mm</td>
<td>3.25-7.0mm</td>
</tr>
<tr>
<td>Filter Sizes Offered</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Filtration membrane design &amp; materials</td>
<td>Nylon</td>
<td>Polyurethane</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Non-thrombogenic Coating</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Capture Efficiency</td>
<td>Equivalent</td>
<td>Equivalent</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Wire type</td>
<td>3 BareWires to choose anatomy specific</td>
<td>Coronary Wire?</td>
<td>Balanced Heavy Weight</td>
</tr>
<tr>
<td>BareWire or Fixed Wire</td>
<td>BareWire</td>
<td>Fixed Wire</td>
<td>Fixed Wire</td>
</tr>
</tbody>
</table>
Filters: main differentiating points

- Crossing profile & length of the landing zone
- **Bare or Fixed** wires ➤ maneuverability
- One or multiple size ➤ vessel size range
- Capture efficiency in straight and curved segments
- Retrieval catheter (size, aspiration, shapeable…)
- Stent Snagging
## Geometric Factors for selecting filters

<table>
<thead>
<tr>
<th></th>
<th>EZ</th>
<th>Accunet</th>
<th>Nav 6</th>
<th>SPIDER</th>
<th>Fibernet</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \geq ) 6mm</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Tight stenosis</td>
<td>++</td>
<td>++</td>
<td>+++</td>
<td>+++±</td>
<td>+</td>
</tr>
<tr>
<td>Small landing zone</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Angulations</td>
<td>++</td>
<td>++</td>
<td>+++±</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Curved landing</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Complex crossing</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>+</td>
</tr>
</tbody>
</table>
Complications of filters
Stop Flow after post dilatation
Export™ catheter for aspiration
Successful retrieval of EPD
Uneventful 30 day period
Access selection for CAS

Femoral access

Possible

Common Femoral
- Normal
  - Guiding 8 or 7 F if filter
- Pathologic
  - 6F Shuttle

Impossible

Direct Puncture

Radial Art.
- 6F Shuttle

Brachial Art.
- 6F Shuttle Guiding 7F

9F Introducer if flow reversal

Manual Compression

Closing
- Angioseal 8F
- Perclose

Starclose For Closing

8F Introducer if flow Reversal

Selection according to the presence of symptoms or high risk factors for CAS (Hypo-echogenic, Ulceration)

Asymptomatic
Low Risk

Symptomatic
High Risk
Octogenarians?

Filter

• Distal IC
  • ≤5mm: Easy Boston, Spider Rx EV3
  • >5mm: Emboshield, Accunet, Angioguard

• Crossing
  • Easy: Easy Boston
  • Difficult: Emboshield Abbot
  • Very Difficult: Spider RX

• Failure: Surgery or ▶

Flow Reversal

Filter Fibernet Invatec
TORTUOSITIES: 2 exemples of impossible filter placement
Systems of protection

• **Numerous Filters:**
  - Angioguard (J&J)
  - Accunet (Abbott)
  - Easy Filterwire (BSC)
  - Emboshield (Abbott)
  - Spider Rx (EV3)
  - Fibernet (Lumen-Invatec)

• **Flow Reversal**
  - Moma Device (Invatec)
  - Gore Neuro-protecting system (Gore)

• **Occlusive Balloon**
  - Percusurge (Medtronic)
  - Mini-invasys Theron double balloon (Mini-Invasys)
GORE Neuro-Protection System
Advantages & Disadvantages of Flow reversal

• Advantages
  - Protection before crossing
  - Any Coronary Wire to cross the lesion
  - No parking space required
  - No local complication: spasm, dissection
  - Angiography possible during occlusion
  - All particles are stopped

• Disadvantages
  - Unusable if ipsilateral external carotid or contralateral internal carotid occluded
  - Unusable if diseased or difficult aortic arch
When do we **NOT** use proximal balloon protection?

- arteries arising at the bifurcation
- reversed flow in the superior thyroid artery
- orthograde flow in the ICA

From Klaus Mathias (Meet 2010)
## ARMOUR (MO.MA) results (225 Pts)

### 30d Results (ITT & Full Population)

<table>
<thead>
<tr>
<th></th>
<th>ARMO Under 75</th>
<th>ITT (220)</th>
<th>ITT + Roll-in (257)</th>
<th>1° Endpoint cumulative MACCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major Stroke</strong></td>
<td>0,9%</td>
<td>0,8%</td>
<td>0,8%</td>
<td>0,9%</td>
</tr>
<tr>
<td><strong>Minor Stroke</strong></td>
<td>1,4%</td>
<td>1,2%</td>
<td>0,9%</td>
<td>1,2%</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>0,9%</td>
<td>0,8%</td>
<td>0,0%</td>
<td>0,9%</td>
</tr>
<tr>
<td><strong>MI</strong></td>
<td>0,0%</td>
<td>0,0%</td>
<td>0,0%</td>
<td>0,0%</td>
</tr>
<tr>
<td><strong>TIA</strong></td>
<td>0,9%</td>
<td>1,2%</td>
<td>0,9%</td>
<td>1,2%</td>
</tr>
</tbody>
</table>

### 30d Results by Symptoms and Age (ITT)

<table>
<thead>
<tr>
<th></th>
<th>ALL (0%)</th>
<th>Asymptomatics (3%)</th>
<th>Symptomatics (6%)</th>
<th>Age &gt;75 (2%)</th>
<th>Symptomatics &amp; Age &gt;75 (6%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>30d Strokes</strong></td>
<td>2,3%</td>
<td>2,7%</td>
<td>3,2%</td>
<td>2,3%</td>
<td>2,3%</td>
</tr>
<tr>
<td><strong>30d MACCE</strong></td>
<td>0,0%</td>
<td>0,0%</td>
<td>0,0%</td>
<td>0,0%</td>
<td>0,0%</td>
</tr>
</tbody>
</table>

---

*From W. Gray MEET 2010*
Carotid artery stenting in octogenarians using a proximal endovascular occlusion cerebral protection device: a multicenter registry

From July 2005 to May 2009, a total of 198 octogenarians patients, in three different institutions, were included in this registry. All patients underwent CAS using proximal endovascular occlusion device (MoMa. device Invatec, Roncadelle, Italy).

198 octogenarians (135 men; mean age: 83.2 years) were included in the registry. 39.4% of the patients were symptomatic.

Procedural success was 100%. In-hospital complications: Two minor and two major strokes (2.02%) occurred. No device-related complications and no serious access site complication were noted. Between discharge and 30-day follow-up, one patient died due to a cardiac arrest.

The overall 30-day combined stroke/death rate was 2.52%, resulting in 1.61% event incidence in asymptomatic and 3.9% in symptomatic patients (P = ns). Logistic regression did not identify independent predictor of neurological events, except in the female gender.

RICA restenosis before & after MOMA placement
Intra-cerebral circulation
Right & Left injection
Post Balloon 3 x20mm

Careful contrast medium injection
After placement of BSC ADAPT Stent L 21mm ø 4-9mm

IVUS before & after placement
Complications of proximal occlusion

- Due to flow reversal
  - Cerebral consciousness
  - Seizures
- Due to common carotid balloon
  - Dissection, flap
- Due to external carotid balloon
  - Occlusion, dissection

5 to 15%
4 chapters to consider for each individual.

- **Age**
- **General conditions**
- **Patient Preference**

**Lesion**
- Bifurcation
- Calcification
- Irregular, Ulceration
- Length ...

**Feasibility**
- Access
- Protection
- Stenting

**Asymptomatic**
- Symptomatic
- Time & Delay
Extreme tortuosities: Protection impossible

Surgery CEA is in many difficult CAS a good option!
Conclusion

- Carotid protection is indispensable in all patients and is possible in more than 97% of CAS procedures.
- Filter are the easiest device: have a favorite fixed wire and a favorite bare wire.
- Reversal of flow with proximal balloons is complex but could become prevalent in high risk patients or lesions.
Save the date
MEET 2011
Crowne Plaza St Peter’s Hotel
Rome, Italy
October 27-29
5 Steps to consider for feasibility

Symptoms
Embolic Risks

Access Femoral
Access Radial or Brachial
Common Carotid

Stenting
Post stenting dilatation
Retrieval of protection

Step 1
Step 2
Step 3
Step 4
Step 5

Protection
Reversal of flow
Filter type

Crossing the lesion
Pré-Dilatation

From Step 2 to Step 5 Feasibility depends on Anatomy
CAPTURE 2 risk-adjusted stroke outcome benchmarks for carotid artery stenting with distal embolic protection.


- The second phase of carotid ACCULINK/ACCUNET post approval trial to uncover rare events (CAPTURE 2) is an ongoing prospective, multicenter, clinical trial conducted to assess CAS outcomes in the general practice setting after device approval for high surgical risk patients (symptomatic with >50% stenosis or asymptomatic with >80% stenosis).

- Five thousand two hundred ninety-seven consecutive patients (5297) had CAS performed by 459 physicians at 186 sites before the data cutoff of January 10, 2009.

- The 30-day rate of stroke was 2.7% (95% confidence interval [CI], 2.3-3.2). Multivariable predictors of periprocedural stroke included age, symptomatic status, and dwell time of embolic protection device.

- A parsimonious model $P(i) = \frac{1}{1+e^{(-3.83 + 0.51 \times \text{symptomatic} + 0.31 \times (age \geq 80) + 0.62 \times (age \geq 80 \times \text{symptomatic})})}$, including symptomatic and octogenarian status and the term of the interaction of the two, was established based on consideration of clinical predictors, clinical interaction, and practicability.
Safety and effectiveness of the INVATEC MO.MA proximal cerebral protection device during carotid artery stenting: results from the ARMOUR pivotal trial.

This prospective registry enrolled 262 subjects, 37 roll-in and 225 pivotal subjects evaluated with intention to treat (ITT) from September 2007 to February 2009. Subjects underwent CAS using the MO.MA device.

The primary endpoint, myocardial infarction, stroke, or death through 30 days (30-day major adverse cardiac and cerebrovascular events [MACCE]) was compared to a performance goal of 13% derived from trials utilizing distal EPD.

Symptomatic patients comprised 15.1% and 28.9% were octogenarians. Device success was 98.2% and procedural success was 93.2%. The 30-day MACCE rate was 2.7% [95% CI (1.0-5.8%)] with a 30-day major stroke rate of 0.9%. No symptomatic patient suffered a stroke during this trial.

The absence of stroke in symptomatic patients is the lowest rate reported in any independently adjudicated prospective multicenter registry trial to date.
STENTING

Embolic Risk
Durability
Antiplatelet Therapy
Bleeding
Local complication
Hypotension

SURGERY

Cardiac Risk
General Anesthesia
Cranial Nerves Injury
Scar&wound compli.
Hypertension

Natural History
under Medical therapy
Improvement of results over time

11 US FDA approval trials with improving outcomes (all approved as safe and effective) /Registries

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

% MAE

From W. GRAY

Reported 30 day stroke rates. Study parameters and definition of stroke rate may vary per clinical trial.
Right intra-cerebral circulation