Carotid Artery Stenting

Is it a standard therapy for carotid stenosis?
Natural history of the carotid stenosis

- Asymptomatic 80% carotid stenosis
  - 6% risk of stroke / year
- Symptomatic carotid stenosis have
  10% risk of CVA at one year and
  40% at 5 years
Why should we open?

Carotid end-arterectomy
Vs.
Medical therapy
## CEA vs. Medical

### Symptomatic Patients

<table>
<thead>
<tr>
<th>Study</th>
<th>Death or Stroke (%)</th>
<th>CEA</th>
<th>Medical Rx</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECST</td>
<td>12.3</td>
<td>21.9</td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>VA</td>
<td>7.7</td>
<td>19.4</td>
<td></td>
<td>0.011</td>
</tr>
<tr>
<td>NASCET</td>
<td>9</td>
<td>26</td>
<td></td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
CEA vs. Medical
Asymptomatic Stenotic Patients

Death or Stroke (%)

<table>
<thead>
<tr>
<th></th>
<th>CEA</th>
<th>Medical Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASANOVA</td>
<td>10.7</td>
<td>11.3</td>
</tr>
<tr>
<td>VA</td>
<td>8.0</td>
<td>20.6</td>
</tr>
<tr>
<td>ACAS</td>
<td>5.1</td>
<td>11.0</td>
</tr>
</tbody>
</table>

P=NS
P<0.01
P<0.01
Limitations of CEA

- Average risk of perioperative stroke for low risk patient is ~6%
- Anatomic considerations
- Cranial nerve palsies (7~27%)
- Restenosis ~15%
- > 50% have severe coronary artery disease
Death or Stroke after CEA

- NASCET: 5.8%
- ECST: 7.1%
- ACAS: 2.3%
- Real World: 11.4%

Chaturverdi, Neurology 2001 Sep
Carotid Stenting
Carotid Stenting

Potential Benefits

• Reduced complication rates
• Less invasive
• Can reach essentially all blockages
• Very low restenosis rate
• Rapid return to daily life
Current Contraindication of Carotid Stenting

- Severely tortuous, calcified and atheromatous aortic arch vessels
- Pedunculated thrombus at the lesion site
- Severe renal impairment
- Recent stroke (3 weeks); should be placed on anticoagulants and antiplatelets for 1 month
- Unable to tolerate antiplatelet agents
Carotid Stenting *Without* Protection
## Success & Complications Rates

### Carotid Stenting

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>N</th>
<th>Success</th>
<th>Stroke &amp; TIA*</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roubin (1996)</td>
<td>High risk</td>
<td>146</td>
<td>99%</td>
<td>6.2%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Shawl (2000)</td>
<td>High risk</td>
<td>170</td>
<td>99%</td>
<td>2.9%</td>
<td>0%</td>
</tr>
<tr>
<td>Wholey (2000)</td>
<td>registry</td>
<td>5129</td>
<td>98.4%</td>
<td>4.2%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Roubin (2001)</td>
<td>High risk</td>
<td>428</td>
<td>99%</td>
<td>4.6%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

*Major stroke < 1%
Complications Rates in Multicenter Carotid Stenting

*N*=4757 pts, 36 major carotid centers, 1988-1997

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIAs</td>
<td>2.82%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2.72%</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1.49%</td>
</tr>
<tr>
<td>Deaths</td>
<td>0.86%</td>
</tr>
<tr>
<td>Total stroke &amp; death</td>
<td>6.29%</td>
</tr>
<tr>
<td>6-mo ISR</td>
<td>1.99%</td>
</tr>
<tr>
<td>12-mo ISR</td>
<td>3.46%</td>
</tr>
</tbody>
</table>

Carotid Stenting

*With* Protection
# Embolization during CAS

<table>
<thead>
<tr>
<th></th>
<th>Cerebral Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>(n=102)</td>
</tr>
<tr>
<td><strong>TCD-HITS</strong></td>
<td>100%</td>
</tr>
<tr>
<td><strong>DW-MRI</strong></td>
<td>29%</td>
</tr>
<tr>
<td><strong>TIA</strong></td>
<td>8%</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>3%</td>
</tr>
<tr>
<td><strong>TIA + Stroke</strong></td>
<td>11%</td>
</tr>
</tbody>
</table>

*Protection devices: Angioguard, PercuSurge & EPI*

K. Mathias et al, AJNR 2001
Cerebral Embolization

**High Risk Lesions**

- Unstable plaque
  - break down of fibrous cap
- Soft plaque
- Long stenosis string sign
  - contains thrombus
## Embolic Complications of Stenting

### Periprocedural
- **Angiography** → Rare
- **Access** → Rare
- **Wire Crossing** → Rare if coronary wire
- **Balloon Dilatation** → Rare
- **Stent Placement** → Potential and unpredictable
- **Post Dilatation** → Potential and unpredictable

### Postprocedural
- **Postprocedural** → Rare
Protection of Distal Embolization

- Use cerebral protection device
- No pre-dilatation with a peripheral balloon
- No oversizing of balloon
- Never use high pressures
- Never try to dilate the stent to obliterate contrast filled ulcerated area external to the stent
## Distal Protection Devices

<table>
<thead>
<tr>
<th>Type</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal occlusion</td>
<td>Theron balloon, PercuSurge Guardwire</td>
</tr>
<tr>
<td>Filter</td>
<td>MedNova NeuroShield, EPI filter, Angioguard filter, Medtronic filter,</td>
</tr>
<tr>
<td></td>
<td>BSC Captura, Bate’s Floating Filter, Accu-Filter, E-Trap, Microvena Trap</td>
</tr>
<tr>
<td>Proximal occlusion</td>
<td>Kachel balloon, ArteriA Parodi Catheter</td>
</tr>
</tbody>
</table>
Distal Protection Devices - Concepts

- Distal Occlusion Device
- Filter Device
The Ideal Protection System

• Does not cause harm
  - Complete protection
  - Capture efficiency
• Protection at all time for all particles
• Wide applicability
• User friendly
<table>
<thead>
<tr>
<th>GuardWire™</th>
<th>PERCUSURGE, Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td>System</td>
<td>0.014</td>
</tr>
<tr>
<td>Crossing Profile</td>
<td>0.036”(3-6mm), 0.028”(2-5mm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The Export® Aspiration Catheter</th>
<th>PERCUSURGE, Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Length</td>
<td>137 cm</td>
</tr>
<tr>
<td>RX shaft design</td>
<td>3.5 x 4.5F distal OD</td>
</tr>
<tr>
<td>Aspiration system</td>
<td>20cc locking syringe</td>
</tr>
</tbody>
</table>
Mean embolic count

Control

GuardWire

P < 0.001

P < 0.004

P < 0.002

Al-Mubarak et al, Circulation, 2001
Protection with Percusurge GuardWire system

- 242 patients with PercuSurge (179, 74% high risk)
- 99.3% Technical Success
- Overall mean balloon protection time = 410 ± 220 sec
- 30 days outcome (2.3%)
  - 3 TIA, 1 retinal embolism 1.5 % (4)
  - Major Stroke 0.4 % (1)
  - Death(cardiac) 0.4 % (1)
  - Total events 2.3 % (6)

- 36-month event-free survival (stroke, death) : 97%
  4 death( 2 AMI, 1 contralateral stroke, 1 cancer)

*Catheter Cardiovasc interv 2004;61:293-305*
Distal Occlusion balloon

**Strength**

- Mimics standard guidewire more than any filters
- Ability to cross lesion
- Particles of all sizes can be blocked (ICA)
Distal Occlusion balloon

Weakeness

- Unprotected
  1) During passage,
  2) ECA
  3) Incomplete suction
- Does not preserve ICA flow (can’t be angiogram)
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot move wire during exchange, several added steps, aspiration)
Distal Protection Devices

Filter
Guidant - ACCUNET

BSC - EPI

MedNova - Emboshield

MedNova – Gen III
Filter Device

Strength

• Intuitive

• Preserves ICA flow
**Filter Device**

**Weakness**

- Not same as standard guidewire
- Larger profile, less flexible
- Frequent need to predilate (recross PTA site)
- Unprotected
  1) during passage
  2) small particles
  3) flow around filter
  4) during filter retrieval
- May thrombose
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot move wire during exchange, several added steps)
Periprocedural Outcomes with Protection Device

- **Minor stroke**
  - Unprotected: 2.86%
  - Protected: 1.10%
  - P<0.05

- **Major stroke**
  - Unprotected: 1.61%
  - Protected: 0.72%

- **Procedure death**
  - Unprotected: 0.82%
  - Protected: 0.45%

- **All events**
  - Unprotected: 5.29%
  - Protected: 2.27%

- **Unprotected (n=6683)**
- **Protected (n=4005)**

AET 2003
30-Day Outcomes with Protection Device

Without protection, n=2537
With protection, n=896

Minor stroke
- Without protection: 3.7%
- With protection: 0.5%
  \[ P < 0.001 \]

Major stroke
- Without protection: 1.1%
- With protection: 0.3%
  \[ P < 0.05 \]

Death
- Without protection: 0.8%
- With protection: 0.8%
  \[ P = \text{NS} \]

Combined stroke and death
- Without protection: 5.5%
- With protection: 1.8%
  \[ P < 0.001 \]

*Stroke 2003;34:813-819*
Periprocedural Outcomes

Symptomatic & Asymptomatic

All events: minor, major stroke, & all cause death

<table>
<thead>
<tr>
<th></th>
<th>Unprotected symptomatic (n=4223)</th>
<th>Protected symptomatic (n=1949)</th>
<th>Unprotected asymptomatic (n=2465)</th>
<th>Protected asymptomatic (n=2056)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>6.97 (% P&lt;0.05)</td>
<td>3.25 (%)</td>
<td>2.53 (%)</td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>4.78 (%)</td>
<td>4.78 (%)</td>
<td>4.78 (%)</td>
<td>2.53 (%)</td>
</tr>
</tbody>
</table>

AET 2003
## Predictors of stroke

### Multivariate analysis

<table>
<thead>
<tr>
<th>30 days outcomes</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor stroke</td>
<td></td>
</tr>
<tr>
<td>Protection(-)</td>
<td>0.0182</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.0216</td>
</tr>
<tr>
<td>Major stroke</td>
<td></td>
</tr>
<tr>
<td>Protection(-)</td>
<td>0.0892</td>
</tr>
<tr>
<td>Age&gt;80 yrs</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Fatal stroke</td>
<td></td>
</tr>
<tr>
<td>Protection(-)</td>
<td>0.0892</td>
</tr>
<tr>
<td>Prior TIA</td>
<td>0.0320</td>
</tr>
<tr>
<td>All stroke</td>
<td></td>
</tr>
<tr>
<td>Protection(-)</td>
<td>0.0009</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.0102</td>
</tr>
<tr>
<td>Age&gt;80 yrs</td>
<td>0.0081</td>
</tr>
<tr>
<td>Prior CEA</td>
<td>0.0822</td>
</tr>
</tbody>
</table>

_AET 2003_
Comparison of Devices Efficiency
Capture Efficiency of Protection Devices

<table>
<thead>
<tr>
<th>Protection Device</th>
<th>Pore Size</th>
<th>Capture Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>AG&lt;sup&gt;T.M&lt;/sup&gt;</td>
<td>100µ</td>
<td>91.5%</td>
</tr>
<tr>
<td>FwEX&lt;sup&gt;T.M&lt;/sup&gt;</td>
<td>80µ</td>
<td>91.7%</td>
</tr>
<tr>
<td>EmboShield&lt;sup&gt;T.M&lt;/sup&gt;</td>
<td>140µ</td>
<td>95.9%</td>
</tr>
<tr>
<td>Trap&lt;sup&gt;T.M&lt;/sup&gt;</td>
<td>65-200µ</td>
<td>91.3%</td>
</tr>
<tr>
<td>PS&lt;sup&gt;T.M&lt;/sup&gt;</td>
<td>N/A</td>
<td>85.4%</td>
</tr>
</tbody>
</table>

JVIR 2003;14:613-620
## CAS with protection
### Complication at 30 days

<table>
<thead>
<tr>
<th>Complication</th>
<th>Al-Mubarak 2002 (Neuroshield)</th>
<th>Tubler, 2001 (Percusurge)</th>
<th>ARCHeR (Acculink, Accunet)</th>
<th>SAPPHIRE (Angioguard, Precise)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>N=162</td>
<td>N=58</td>
<td>N=437</td>
<td>N=408</td>
</tr>
<tr>
<td>Death</td>
<td>1.0%</td>
<td>0%</td>
<td>2.3%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.0%</td>
<td>4%</td>
<td>5.3%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Major</td>
<td>0%</td>
<td>2.0%</td>
<td>1.6%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Minor</td>
<td>1.0%</td>
<td>2.0%</td>
<td>3.7%</td>
<td>2.7%</td>
</tr>
<tr>
<td>MI</td>
<td>0.5%</td>
<td>0%</td>
<td>2.1%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Total MAE</td>
<td>2.0%</td>
<td>4%</td>
<td>7.8%</td>
<td>7.8%</td>
</tr>
</tbody>
</table>


*Complications: Death, Stroke, Major, Minor, MI.*

*AET 2003*
## Comparisons Between Filter Devices
### 30 days Outcomes

<table>
<thead>
<tr>
<th>Major Endpoints</th>
<th>N=56 Angioguard filter</th>
<th>N=55 Neuroshield filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor stroke</td>
<td>1 (1.78%)</td>
<td>0</td>
</tr>
<tr>
<td>Major stroke</td>
<td>0</td>
<td>1 (1.8%)</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>death</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**No difference !!!**
Endarterectomy Vs. Stenting
## CAVATAS

### Multicenter Randomized Trial: CEA vs. Angioplasty

<table>
<thead>
<tr>
<th></th>
<th>Angioplasty (N=251)</th>
<th>CEA (N=253)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day death &amp; stroke</td>
<td>6.4%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Cranial neuropathy</td>
<td>0%</td>
<td>8.7%</td>
</tr>
<tr>
<td>1-year restenosis *</td>
<td>14%</td>
<td>4%</td>
</tr>
</tbody>
</table>

*Stenting = only in 26%*  

*Lancet 2001;357:1729-37*
The SAPPHIRE Study

Senting with filter device
vs. Endarterectomy
in high risk patients
30-Day Events

SAPPHIRE

Death/MI/Stroke

- CAS + Filter: 5.8%
- CEA: 12.6%

P = 0.047

Cranial n. palsy

- CAS + Filter: 0%
- CEA: 5.3%

P < 0.001
Patient selection of carotid stenting

Only high surgical risk patients

Vs.

All patients
High Risk Surgical Criteria

**Should be the stenting!**

**Anatomic high risk**
- High(C2) carotid bifurcation
- Prior neck irradiation or radical neck dissection
- Restenosis following prior CEA
- Contralateral occlusion
- Ostial common carotid lesion
- Spine immobility

**Surgical high risk**
- Severe CAD
  - Not revascularized or awaiting CABG
- Class III or IV CHF
- Severe COPD
- Age > 80
30 days Outcomes of CAS with protection

Symptomatic vs. Asymptomatic

P = 0.96

Time to Event (days)

ACC 2004
### 30 days outcomes of CAS with protection

**High vs. low risk**

<table>
<thead>
<tr>
<th></th>
<th>High risk</th>
<th>Low risk</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=326</td>
<td>N=262</td>
<td></td>
</tr>
<tr>
<td>Minor stroke</td>
<td>4(1.2%)</td>
<td>3(1.1%)</td>
<td>ns</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1(0.3%)</td>
<td>1(0.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Fatal stroke</td>
<td>2(0.6%)</td>
<td>0</td>
<td>ns</td>
</tr>
<tr>
<td>All stroke</td>
<td>7(2.1%)</td>
<td>4(1.5%)</td>
<td>ns</td>
</tr>
<tr>
<td>All death</td>
<td>4(1.2%)</td>
<td>1(0.4%)</td>
<td>ns</td>
</tr>
<tr>
<td>Death+Stroke</td>
<td>9(2.8%)</td>
<td>5(1.9%)</td>
<td>ns</td>
</tr>
</tbody>
</table>

High risk: age > 80, prior ipsilateral CEA, prior neck surgery or radiation, contralateral occlusion, anatomic low or high lesion, unstable/severe heart disease

*ACC 2004*
Now. Carotid Stenting

- With the use of the protection device, carotid stenting may be a more preferred therapy to carotid endarterectomy in carotid stenosis.

- The efficacy of carotid stenting may be extended to all patients subsets, such as symptomatic, asymptomatic, high risk, and low risk subgroups.