Percutaneous Intervention for Carotid Artery Stenosis
Natural Incidence of CVA In Carotid Stenosis

• Asymptomatic 80% carotid stenosis
  - 6% / year

• Symptomatic carotid stenosis
  - 10% / year
  - 40% / 5 years
Annual incidence of major stroke according to stenosis severity

(%) % diameter stenosis

0-19% 20-29% 30-39% 40-49% 50-59% 60-69% 70-79% 80-89% 90-95%

TCT 2005
Why should we open?

Carotid End-Arterectomy vs. Medical Therapy
NASCET

Benefit of CEA by Stenosis Severity

Absolute % Risk Reduction Of CVA

Stenosis Severity

- 50-69%
- 70-79%
- 80-89%
- 90-99%

CEA=carotid end arterectomy
# Carotid End-Arterectomy

3,061 CEA during a 10-year period

<table>
<thead>
<tr>
<th></th>
<th>Stroke</th>
<th>Death</th>
<th>Stroke, MI, Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk Patients</td>
<td>3.5%</td>
<td>4.4%</td>
<td>7.4%</td>
</tr>
<tr>
<td>Low Risk Patients</td>
<td>1.7%</td>
<td>0.3%</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

*High risk patients:* severe coronary disease, COPD, renal insufficiency

CEA vs. Medical Rx
Symptomatic Patients

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

Death or Stroke (%)

- CASANOVA
  - CEA: 10.7
  - Medical therapy: 11.3
  - P=NS

- VA
  - CEA: 8
  - Medical therapy: 20.6
  - P<0.01

- ACAS
  - CEA: 5.1
  - Medical therapy: 11
  - P<0.001

- ASCT
  - CEA: 6.4
  - Medical therapy: 11.7
  - P<0.001
Limitations of CEA

- Perioperative stroke for low risk patients: ~6%
- Anatomic considerations
- Cranial nerve palsies: 7~27%
- Restenosis: ~15%
- > 50% have severe coronary artery disease
Death or Stroke after CEA

Chaturverdi, Neurology 2001 Sep
MRC ACST Collaborative group, Lancet 2004

Real World?

5.8% 7.1% 2.3% 2.8% 11.4%
NASCET ECST ACAS ACST

Neurologist Audit

CardioVascular Research Foundation
Asan Medical Center
Carotid Stenting
Carotid Stenting

- Reduced complication rates
- Less invasive
- Can reach essentially all blockages
- Very low restenosis rate
- Rapid return to daily life
High Risk Features of Surgery vs. Stenting for Carotid Stenosis

Surgery
- Restenosis
- Prior radiation
- Cranial nerve palsies
- Previous OHS
- High and low lesion
- Contralateral occlusion
- Cardiovascular disease
- Pulmonary disease

Intervention
- Elderly
- String sign
- Thrombus
- Acute stroke
- Tortuosity
- Poor access
- Severe calcification
- Previous OHS
- Arch anatomy
- Intolerance to antiplatelet
Carotid Stenting
Current Indications

• Symptomatic stenosis $\geq 50\%$ DS

• Asymptomatic stenosis $\geq 70\%$ DS

Consider patients’ clinical status, Doppler hemodynamics, and operator’s experience …
Carotid Stenting
Current Contraindications

• Severely tortuous, calcified and atheromatous aortic arch
• Pedunculated thrombus at the lesion site
• Recent stroke $\leq$ 3 weeks $\rightarrow$
  anticoagulants and antiplatelets for 1 month
• Unable to tolerate antiplatelet agents
Carotid Stenting

Without Protection
## CAS without Protection

### Success & Complications Rates

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>No</th>
<th>Success Rate</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

**CAS without Protection**

4,757 pts, 36 major carotid centers, 1988-1997

<table>
<thead>
<tr>
<th>Condition</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>
</tbody>
</table>

* 6-mo ISR = 1.99%
* 12-mo ISR = 3.46%

Long-term Outcomes

Enrollment: 1994-99, 528 patients with CAS

- 30-day stroke: 5.8% (major: 1%, minor 4.8%)
- 30-day stroke and death: 7.4%
- Most of patients: high risk group
- Fatal and nonfatal stroke between 31 days-3 yrs: 3.2%
- The 3-year freedom from stroke: 92 ± 1%

Most of all strokes occurred in periprocedural period.

Roubin GS et al. Circulation 2001;103:532-537
## Long-term Outcomes Compared to CEA

<table>
<thead>
<tr>
<th></th>
<th>CAS (n=42)</th>
<th>NASCET Med (n=331)</th>
<th>NASCET CEA (n=328)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any ipsilateral stroke</td>
<td>9.5%</td>
<td>26%</td>
<td>9%</td>
</tr>
<tr>
<td>Any stroke</td>
<td>14.3%</td>
<td>27.6%</td>
<td>12.6%</td>
</tr>
<tr>
<td>Any stroke or death</td>
<td>19%</td>
<td>32.3%</td>
<td>15.8%</td>
</tr>
</tbody>
</table>

Mean follow-up: 1.7 yrs, range (1-62 months)

CAS = carotid artery stenting
CEA = carotid endarterectomy

Fox DJ et al. Stroke 2002;33:2877-2880
Why distal protection?

Carotid Stenting

With Protection
CAS with Embolic Protection for High Risk Patients

- Randomized Trial
  - SAPPIRE Trial
- Non-randomized Trials
  - ARCHER
  - SHELTER / BEACH
  - MAVERICK
  - CABERNET
  - SECURITY
Lesions at High Risk of Embolization

- Unstable plaque: break down of fibrous cap
- Soft plaque
- Long stenosis string sign: contain thrombus
Embolic Complications in Stenting

**Periprocedural**
- Angiography → Rare
- Access → Rare
- Wire Crossing → Rare if coronary wire
- Predilation → Rare
- Stent Placement → Potential and unpredictable
- Postdilation → Potential and unpredictable

**Postprocedural** → Rare
Methods for Prevention of Distal Embolization

- **Use embolic protection device (EPD)**
- No pre-dilatation with a peripheral balloon
- No oversizing of balloon
- Never use high pressures
- Never try to dilate the stent to in ulcerated area external to the stent
## Independent Predictors of Embolic Stroke

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

<table>
<thead>
<tr>
<th>Cerebral Protection</th>
<th>No (n=102)</th>
<th>Yes (n=142)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCD-HITS*</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Diffusion weighted-MRI</td>
<td>29%</td>
<td>7.1%</td>
</tr>
<tr>
<td>TIA</td>
<td>8%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Stroke</td>
<td>3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>TIA + Stroke</td>
<td>11%</td>
<td>4%</td>
</tr>
</tbody>
</table>

*Transcranial doppler-high intensity transient signals
Protection devices: Angioguard®, PercuSurge® & EPI

K. Mathias et al, AJNR 2001
Ideal Protection System

• Does not cause harm
  - Complete protection
  - Capture efficiency

• Protection at all time for all particles

• Wide applicability

• User friendly
# Embolic Protection Devices

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

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

**Filter Device**
- User-friendly
- Preserves ICA flow
**Weakness of Each System**

**Occlusion Device**

- Unprotected
  1) During passage
  2) ECA
  3) Incomplete suction
- Does not preserve ICA flow
- Cumbersome procedure (cannot move wire during exchange, several added steps, aspiration)

**Filter Device**

- Not same as standard guidewire
- Larger profile, less flexible
- Occasional need to predilate (recross PTA site)
- Unprotected
  1) during passage
  2) small particles
  3) flow around filter
  4) during filter retrieval
- May thrombose
# Different Protection Devices

## Advantages and Disadvantages

<table>
<thead>
<tr>
<th></th>
<th>Easy to use</th>
<th>Emboli during lesion crossing</th>
<th>Flow decrease</th>
<th>ICA protect</th>
<th>Angio during protection</th>
<th>Emboli through ECA</th>
<th>Spasm/damage to ICA</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filters</td>
<td>+++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+++</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Occlusion</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Flow reversal</td>
<td>+</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>
Embolic Protection Devices

Distal Occlusion Device

Filter Device
Benefit of Distal Protection
Periprocedural Outcomes

% 10

- Minor stroke
- Major stroke
- Procedure death
- All events

P<0.05

Unprotected (n=6683):
- Minor stroke: 2.86%
- Major stroke: 1.61%
- Procedure death: 0.82%
- All events: 5.29%

Protected (n=4005):
- Minor stroke: 1.1%
- Major stroke: 0.72%
- Procedure death: 0.45%
- All events: 2.27%

AET 2003
Benefit of Distal Protection
Periprocedural Outcomes

All cause death, major & minor stroke

%  

<table>
<thead>
<tr>
<th>Group</th>
<th>Event Rate</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unprotected symptomatic</td>
<td>6.97</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Protected symptomatic</td>
<td>3.25</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Unprotected asymptomatic</td>
<td>4.78</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Protected asymptomatic</td>
<td>2.53</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AET 2003, CVRF, Asan Medical Center
Benefit of Distal Protection
30-Day Outcomes

Percentage

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

Minor stroke: 3.7% (P<0.001)
Major stroke: 0.5% (P<0.05)
Death: 0.8% (P=NS)
Combined stroke and death: 1.8% (P<0.001)

Stroke 2003;34:813-819
Embolic Protection Device
Distal Occlusion

PercuSurge GUARDWIRE™
**Distal Occlusion Device**

**PercuSurge GuardWire™**

Mean embolic count

- **Control**
- **GuardWire**

- **P < 0.001**
- **P < 0.002**
- **P < 0.004**

*Al-Mubarak et al, Circulation, 2001*
246 patients with 272 lesions

Complete intolerance to balloon: 0.8%
Partial transient intolerance to balloon: 3.7%
## Distal Occlusion Device

**PercuSurge GuardWire™**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>179</td>
</tr>
<tr>
<td><strong>Technical success</strong></td>
<td>99.3%</td>
</tr>
<tr>
<td>Overall mean balloon time (sec)</td>
<td>410 ± 220</td>
</tr>
<tr>
<td><strong>30-day stroke rate</strong></td>
<td></td>
</tr>
<tr>
<td>Minor stroke (TIA, retinal embolism)</td>
<td>4 (1.5%)</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Death (cardiac)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td><strong>36-month event (stroke &amp; death )-free survival</strong></td>
<td>97%</td>
</tr>
<tr>
<td>Death (AMI, stroke, cancer)</td>
<td>4 (1.5%)</td>
</tr>
</tbody>
</table>

*Catheter Cardiovasc interv 2004;61:293-305*
Embolic Protection Devices

Filter

Guidant - ACCUNET

BSC - FilterWire

ABBOTT - Emboshield

Cordis - Angioguard

EV3 - Spider
Features of Filter

- Delivery profile
- Steerability
- Vessel wall apposition
- Pore size
- Capture efficiency
- Ease of retrieval
- Clinical event rates
Wall Apposition in Curves

AngioGuard

Accunet

FilterWire EZ
Accunet Filter

ARChER Trial

30-Day Event

513 high risk patients

Mednova Filter
SECuRITY Trial
30-Day Event

305 high risk patients

- Death/Stroke/MI: 7.2%
- Stroke: 6.9%
- Death: 1.0%
- MI: 0.3%

ACC 2003
Filter Wire

BEACH Trial

30-Day Event

747 high risk patients

Death/Stroke/MI: 6.5%
Stroke: 4.2%
Death: 1.5%
MI: 0.8%

30 Day Stroke/Death/MI in High Risk Registry 2002-2004

TCT 2005
Practical Use of Distal Protection
CAPTURE 2500 Registry

• Stent; RX ACCULINK
• Protection device; RX ACCUNET™ filter system
• N=2,500 at 137 hospitals
  (less than maximal 40 patients per a hospital)
• More than 1/3 patients were enrolled at hospitals with a high level of experience.
• 1º Endpoint; composite of 1-month death / MI / stroke

ACC 2006
### Practical Use of Distal Protection

**CAPTURE 2500 Registry vs ARCHeR Trial**

Primary Events < 30 days

<table>
<thead>
<tr>
<th>Event</th>
<th>CAPTURE (N=2,500)</th>
<th>ARCHeR (N=581)</th>
<th>DIFFERENCE 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death, Stroke, MI</strong>*</td>
<td>5.7%</td>
<td>8.3%</td>
<td><strong>-2.54% [-4.96, -0.13]</strong></td>
</tr>
<tr>
<td>Death</td>
<td>1.6%</td>
<td>2.1%</td>
<td><strong>-0.47% [-1.72, 0.79]</strong></td>
</tr>
<tr>
<td>Stroke-related death</td>
<td>0.8%</td>
<td>0.5%</td>
<td>0.24% [-0.43, 0.92]</td>
</tr>
<tr>
<td>All stroke</td>
<td>4.2%</td>
<td>5.5%</td>
<td><strong>-1.27% [-3.28, 0.75]</strong></td>
</tr>
<tr>
<td>Major stroke</td>
<td>1.7%</td>
<td>1.5%</td>
<td>0.13% [-0.99, 1.25]</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>2.6%</td>
<td>4.0%</td>
<td><strong>-1.32% [-3.02, 0.39]</strong></td>
</tr>
<tr>
<td><strong>MI</strong>*</td>
<td>0.9%</td>
<td>2.4%</td>
<td><strong>-1.49% [-2.79, -0.19]</strong></td>
</tr>
<tr>
<td>All stroke and death</td>
<td>5.1%</td>
<td>6.9%</td>
<td><strong>-1.80% [-4.04, -0.43]</strong></td>
</tr>
<tr>
<td>Major stroke and death</td>
<td>2.5%</td>
<td>2.9%</td>
<td><strong>-0.41% [-1.91, 1.10]</strong></td>
</tr>
</tbody>
</table>

* P<0.05

**ACC 2006**

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CardioVascular Research Foundation

Asan Medical Center
## Practical Use of Distal Protection

### CAPTURE 2500 Registry vs ARCHeR Trial

**Asymptomatic Patient Events < 30 days**

<table>
<thead>
<tr>
<th>Event</th>
<th>CAPTURE (N=2,267)</th>
<th>ARCHeR (N=443)</th>
<th>DIFFERENCE 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, Stroke, MI*</td>
<td>4.9%</td>
<td>6.8%</td>
<td>-1.92% [-4.42, -0.58]</td>
</tr>
<tr>
<td>Death</td>
<td>1.3%</td>
<td>2.0%</td>
<td>-0.71% [-2.10, 0.69]</td>
</tr>
<tr>
<td>Stroke-related death</td>
<td>0.5%</td>
<td>0.2%</td>
<td>0.26% [-0.27, 0.79]</td>
</tr>
<tr>
<td>All stroke</td>
<td>3.5%</td>
<td>3.8%</td>
<td>-0.31% [-2.25, 1.63]</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1.3%</td>
<td>0.7%</td>
<td>0.65% [-0.25, 1.54]</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>2.2%</td>
<td>3.2%</td>
<td>-0.91% [-2.65, 0.83]</td>
</tr>
<tr>
<td>MI*</td>
<td>0.7%</td>
<td>2.5%</td>
<td>-1.73% [-3.23, -0.24]</td>
</tr>
<tr>
<td>All stroke and death</td>
<td>4.4%</td>
<td>5.4%</td>
<td>-1.05% [-3.32, 1.22]</td>
</tr>
<tr>
<td>Major stroke and death</td>
<td>2.2%</td>
<td>2.3%</td>
<td>-0.41% [-1.60, 1.41]</td>
</tr>
</tbody>
</table>

* P<0.05  

**ACC 2006**
# Practical Use of Distal Protection

## CAPTURE 2500 Registry vs ARCHeR Trial

**Symptomatic** Patient Events < 30 days

<table>
<thead>
<tr>
<th>Event</th>
<th>CAPTURE (N=233)</th>
<th>ARCHeR (N=138)</th>
<th>DIFFERENCE 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, Stroke, MI*</td>
<td>14.2%</td>
<td>13.0%</td>
<td>-1.12% [-6.06, 8.30]</td>
</tr>
<tr>
<td>Death</td>
<td>4.3%</td>
<td>2.2%</td>
<td>2.12% [-1.44, 5.68]</td>
</tr>
<tr>
<td>Stroke-related death</td>
<td>3.4%</td>
<td>1.4%</td>
<td>1.98% [-1.09, 5.06]</td>
</tr>
<tr>
<td>All stroke</td>
<td>11.2%</td>
<td>10.9%</td>
<td>0.29% [-6.29, 6.87]</td>
</tr>
<tr>
<td>Major stroke</td>
<td>5.2%</td>
<td>4.3%</td>
<td>0.80% [-3.63, 5.23]</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>6.4%</td>
<td>6.5%</td>
<td>-0.08% [-5.27, 5.10]</td>
</tr>
<tr>
<td>MI</td>
<td>2.6%</td>
<td>2.2%</td>
<td>0.40% [-2.77, 3.57]</td>
</tr>
<tr>
<td>All stroke and death</td>
<td>12.0%</td>
<td>11.6%</td>
<td>0.42% [-6.36, 7.20]</td>
</tr>
<tr>
<td>Major stroke and death</td>
<td>6.0%</td>
<td>5.1%</td>
<td>0.94% [-3.83, 5.70]</td>
</tr>
</tbody>
</table>

* P<0.05

**ACC 2006**

---

CVRF CardioVascular Research Foundation

Asan Medical Center
### Practical Use of Distal Protection

**CAPTURE 2500 Registry**

Events < 30 days by Physician Experience

<table>
<thead>
<tr>
<th>CAPTURE (N=2,500)</th>
<th>High (N=226)</th>
<th>Medium (N=1770)</th>
<th>Low (N=504)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, Stroke, MI</td>
<td>6.2%</td>
<td>5.8%</td>
<td>5.4%</td>
</tr>
<tr>
<td>Death</td>
<td>0.0%</td>
<td>1.7%</td>
<td>2.0%</td>
</tr>
<tr>
<td>All stroke</td>
<td>5.8%</td>
<td>4.2%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1.3%</td>
<td>1.8%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>4.4%</td>
<td>2.5%</td>
<td>2.2%</td>
</tr>
<tr>
<td>MI</td>
<td>0.4%</td>
<td>0.9%</td>
<td>1.2%</td>
</tr>
<tr>
<td>All stroke and death</td>
<td>5.8%</td>
<td>5.1%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Major stroke and death</td>
<td>1.3%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

* P<0.05  

**ACC 2006**
Practical Use of Distal Protection
CAPTURE 2500 Registry: Conclusions

• Community based carotid stenting provides excellent results.

• Rollout of therapy to physicians with varying levels of experience achieved excellent results comparable to ARCHeR.

• Stroke/death rate (3.6%) for asymptomatic patients <80 years approaches ACAS/ACST outcomes in high risk patients.
Carotid Endarterectomy vs. Carotid Stenting
# CAVATAS

## CEA vs. Angioplasty without protection in Low and High Surgical Risk group

<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 (&gt;70% DS)*</td>
<td>14%</td>
<td>4%</td>
</tr>
<tr>
<td>3-year death or disabling stroke</td>
<td>14.3%</td>
<td>14.2%</td>
</tr>
</tbody>
</table>

* Stenting = only in 26%

*Lancet 2001;357:1729-37*
## CEA vs. CAS without protection

Prospective Randomized Trial in Low and High Surgical Risk group

<table>
<thead>
<tr>
<th></th>
<th>CAS (N=53)</th>
<th>CEA (N=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death/cerebral ischemia, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TIA</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Other, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial thrombosis/amputation</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hematoma</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Cranial/cervical n injury</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Hypotension</td>
<td>12</td>
<td>3</td>
</tr>
</tbody>
</table>

*Brooks et al. J Am Coll Cardiol 2001;38:1589-95*
CAROTID STENOSIS WITH HIGH RISK (n=334)

Randomization (1:1)

Carotid stenting with filter device (n=167)
Carotid endarterectomy (n=167)

Primary endpoint: composite of death, stroke, or MI within 30 days or death or ipsilateral stroke btw 31 days and 1 year

Yadav JS, et al. NEJM 2004;351:1493
CEA vs. CAS with Filter

30-Day Outcomes

Death /MI /Stroke

<table>
<thead>
<tr>
<th></th>
<th>CAS + Filter</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death /MI /Stroke</td>
<td>5.8%</td>
<td>12.6%</td>
</tr>
</tbody>
</table>

P = 0.047

Cranial nerve palsy

<table>
<thead>
<tr>
<th></th>
<th>CAS + Filter</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cranial nerve palsy</td>
<td>0%</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

P < 0.001

Yadav JS, et al. NEJM 2004;351:1493
1-Year Clinical Outcomes

Primary endpoint: composite of death, stroke, or MI within 30 days or death or ipsilateral stroke between 31 days and 1 year

P=0.053

Yadav JS, et al. NEJM 2004;351:1493
CEA vs. CAS with Filter

1-Year TLR

\[
P = 0.06
\]

0.6

4.0

CAS + Filter

CEA

Yadav JS, et al. NEJM 2004;351:1493
Conclusion

- Among patients with severe carotid-artery stenosis and coexisting conditions, CAS with the use of an emboli-protection device is not inferior to CEA.

Yadav JS, et al. NEJM 2004;351:1493
CEA vs. CAS

30 days outcomes from 5 RCT (n=1269) (CAVATAS, Kentucky A&B, Leicester, WALL STENT, SAPPHIRE)

Death / any stroke

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>8</td>
<td>6.2</td>
</tr>
</tbody>
</table>

OR, 1.33; CI, 0.86-2.04

Death / disabling stroke

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>5.3</td>
<td>4.2</td>
</tr>
</tbody>
</table>

OR, 1.22; CI, 0.61-2.41

CEA vs. CAS

Outcomes from 5 RCT (n=1269)
(CAVATAS, Kentucky A&B, Leicester, WALL STENT, SAPHIRE)

Death /any stroke at 1 year

- CAS: 13.5%
- CEA: 13.3%

OR, 1.01; CI, 0.71-1.44

Cranial nerve palsy

- CAS: 6.5%
- CEA: 0%

OR, 0.13; CI, 0.06-0.25

CES vs. CAS with Filter
From 2001 to 2004

Carotid a stenosis (n=602)

Concurrent-risk matched group

Carotid stenting with filter device (n=301)
Carotid endarterectomy (n=301)

Perioperative and midterm results of CAS vs. CEA

CEA vs. CAS with Filter

30-Day Outcomes

50% of CAS disabling strokes occurred during cannulation of epiaortic vessel

Death / disabling stroke

<table>
<thead>
<tr>
<th></th>
<th>CAS + Filter</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death / disabling stroke</td>
<td>2.6%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

\[P = 0.4\]

TIA

<table>
<thead>
<tr>
<th></th>
<th>CAS + Filter</th>
<th>CEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIA</td>
<td>6.3%</td>
<td>1%</td>
</tr>
</tbody>
</table>

\[P = 0.0004\]

CEA vs. CAS with Filter

30-Day Outcomes

A decreasing trend in 30-day stroke with expertise

Any stroke

All patients (n=301pts/arm)

- CAS + Filter: 7.9%
- CEA: 2.3%

P = 0.001

Last 201 pts/arm

- CAS + Filter: 5.4%
- CEA: 1.9%

P = 0.1

36-Month Restenosis

CAS + Filter: 6.4%
CEA: 7.9%
P = 0.6

## CEA vs. CAS with Filter

### Independent Risk Factors

<table>
<thead>
<tr>
<th>Predictors</th>
<th>Disabling stroke/death</th>
<th>Any stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS</td>
<td>HR 3.6 [0.93-13.9], p=0.06</td>
<td>HR 3.9 [1.6-9.4], p=0.002</td>
</tr>
<tr>
<td>Urgency</td>
<td>HR 8.9 [1.71-46.4], P=0.009</td>
<td>HR 4.6 [1.2-18.6], P=0.03</td>
</tr>
<tr>
<td>Diabetes</td>
<td>HR 2.2 [1.01, 4.83], P=0.045</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>HR 1.06 [1.01, 1.1], P=0.02</td>
<td></td>
</tr>
</tbody>
</table>

*Cao P, et al. Stroke 2006;37:1221-1226*
## Crotid Stenting vs. CEA before Open Heart Surgery for Combined Severe Carotid and Coronary Stenosis

<table>
<thead>
<tr>
<th>30-Day Event</th>
<th>CS + OHS N=56</th>
<th>CEA + OHS N=112</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>2 (3.3%)</td>
<td>14 (12.6%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (1.8%)</td>
<td>10 (9.0%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Death</td>
<td>3 (5.4%)</td>
<td>8 (7.2%)</td>
<td>0.65</td>
</tr>
<tr>
<td>Death/MI, or stroke</td>
<td>6 (10.7%)</td>
<td>24 (21.6%)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

* CEA+OHS group had higher baseline risk profile

*Am J Cardiol 2005;96:519-523*
Carotid Stenting

- Although there is insufficient evidence to support CS, CS may be a more preferred therapy to CEA with appropriate learning curve and the use of the protection device.

- Technical progress, advance in technical expertise and patients selection are important to reduce the risk of CS.

- CS may be extended to all patients subsets, such as symptomatic, asymptomatic, high risk, and low risk subgroups.