Carotid Intervention: *Who and How?*

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Conflicts / Disclosures

- Consultant/Advisory Board member/DSMB member/research support:
  - Abbott Vascular
  - Cordis
  - Medtronic
  - EV3
Stroke - Background

- Third leading cause of death in USA
- Leading cause of disability
- Afflicts 700,000 pts/yr and results in 170,000 deaths/yr
- Major disability among survivors costs $41 billion annually

- Extra cranial carotid disease responsible for 30% of strokes
  - Unfortunately, many of these patients first presentation is CVA
  - Progression of asymptomatic carotid disease is unpredictable
Risk of Stroke in Asymptomatic Patients

- Ulceration increases risk of stroke.
- 80% of pts with known carotid stenosis will not have warning TIA before stroke.

Norris Stroke. 22(12):1485-90, 1991
Mendelsohn & Yadav, Management of Atherosclerotic Carotid Disease, Remedica Publishing, 2000
Carotid Artery Stenosis

Am I providing the best stroke prevention for my patient?

Strategies for Stroke prevention

- Optimal medical therapy
  - Anti-platelet Rx, statins, ace inhibitors
- Revascularization
  - CEA - 200,000/ yr
  - CAS – 25,000/ yr
Evidence for Carotid Endarterectomy

  - 1212 patients with TIA or minor stroke within 120 days randomized to CEA or medical therapy (stratified by 30-69% stenosis and >70% stenosis)
  - Major ipsilateral stroke at 2 years 26% in medical pts vs. 9% in CEA pts (p<0.001)
- Asymptomatic Carotid Artery Surgery (ACAS) trial- JAMA 1995
  - 1659 pts >60% stenosis: medicine vs. CEA
  - At 2.7 years, 11% ipsilateral stroke in medical arm vs. 5.1% in surgical arm.
  - Benefit present if surgery can be performed with <3% peri-operative complication rate
ACE Inhibition Prevents Recurrent Stroke

The Progress Trial

6105 subjects with previous stroke randomly assigned to perindopril (n=3051) or placebo (n=3054)

PROGRESS Collaborative Group. Lancet 2001:358; 1033
SPARCL: High Dose Atorvastatin vs Placebo In Patients with Prior CVA/TIA

![Graph showing the comparison between Atorvastatin and Placebo in the SPARCL study. The graph displays the number of stroke or transient ischemic attack events over time. The hazard ratio (HR) is 0.77 (95% CI, 0.67–0.88); P<0.001.]

Asymptomatic Carotid Surgery Trial

Early vs. Deferred CEA in 3120 Asymptomatic Pts with ICA Stenosis

ACST benefit of intervention with Med Rx over Med Rx alone

Use of Medical Rx

At entry, by year of randomisation

[Graph showing event-free rates over time for immediate vs. deferred intervention]

Difference 5.35% (95% CI 2.96–7.75)
z=4.38, p<0.0001

At last clinic follow-up visit in 2002 or 2003, by treatment allocation

Lancet 2004;363
ACAS and ACST

- The benefit associated with surgery was realized within the first-year interval, and 89% of patients survived long enough to achieve that benefit with the mean age at entry of 67 years.

- Relative risk reduction for patients at or younger than the mean age of 67 was 60%; the comparable risk reduction for those older than 67 was 43%. This difference was not statistically significant.

- Using data from patients in the ACST trial, it was determined that the overall Kaplan-Meier estimate of stroke risk at 3 years was 2.1% in the distribution of the asymptomatic internal carotid artery. More striking was that patients in each decile up to 80% stenosis of the asymptomatic internal carotid artery had a very low risk of stroke (<2%).

- Stroke risk was 9.8% in the 80-89% internal carotid artery stenosis decile and increased to 14.4% in patients with 90-99% asymptomatic stenosis.
NASCET / ACAS Trials

• NASCET/ACAS anatomic high-risk exclusion criteria:
  • Previous CEA
  • Radiation treatment to neck (ACAS)
  • Status post radical neck dissection
  • Tandem lesions
  • Contralateral symptoms within 45 days or contralateral CEA within 4 months

• NASCET/ACAS anatomic exclusion criteria are essentially the high-surgical risk inclusion criteria for multiple Carotid stent registries
Carotid Stent Evolution
15 year history

- Initial results were discouraging – high morbidity and mortality
  - Technology evolution
  - Embolic protection
  - Better patient selection
  - Large clinical experience

Evolution of Clinical Outcomes continues
<table>
<thead>
<tr>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk</td>
<td>High-risk</td>
</tr>
<tr>
<td>Standard-risk</td>
<td>Standard-risk</td>
</tr>
</tbody>
</table>

**Carotid Artery Disease**

**CEA Patient subsets**
Carotid Stent Clinical Trials

- **High Risk Registries**
  - SHELTER (BSC/Percusurg)
  - ARCHER, CAPTURE, SECURITY, EXACT, CHOICE, PROTECT (Abbott)
  - MAVERICK (Medtronic)
  - CARESS (ISES)
  - BEACH (BSC,EPI)
  - CABERNET (BSC, Endotex)
  - VIVA (Bard)
  - CREATE (EV3, Spider)
  - CASES , SAPPHIRE WW(Cordis)

- **Randomized**
  - CREST (NIH), SAPPHIRE (Cordis), ACT 1 (Abbott)
  - SPACE and SPACE 2(OUS), EVA-3S (OUS)
Carotid stent with EPD

All Stroke - Stenting Trials for High Risk Surgical Patients

Factors: embolic protection, experience, case selection
EPDs/ Filters Dominate

Scion

MedNova

BSX/Rubicon

BSX/FilterWire Gen I

BSX/FilterWire Gen II

MDT/Interceptor

Kensey Nash

EPDs/ Filters Dominate

BSX/FilterWire Gen I

BSX/FilterWire Gen II

MDT/PercuSurge

Abbot/Rubicon - Guardian

MicroVena - Trap
FDA Approved CAS/EPD systems: 2009

- Abbott Acculink stent | Accunet filter
- Abbott EXACT stent | Emboshield filter
- Cordis Precise stent | Angioguard filter
- BSC Next stent | EPI Filterwire
- EV3 Protégé stent | Spider filter
CMS Coverage Decision – 3/17/05

Summary – CAS Covered For:

• High Risk Symptomatic ≥ 70%
• Only FDA Approved CAS/EPD Systems
• Only Covered Under IDE (B) or PMS
  - High Risk Symptomatic Patients 50 – 70%
  - High Risk Asymptomatic Patients ≥ 80%

Covers < 15% of US CEA population
SPACE

- Stent-protected angioplasty vs. CEA in symptomatic pts
- Non-inferiority design, expected rate 5%, delta 2.5%
- 1183 pts enrolled with stenosis > 70%
- Primary endpoint: 30 day ipsilateral CVA or Death
  - CEA 6.34% vs. CAS 6.84%
- Concerns
  - Any stent or filter could be used
  - Only 27% received an embolic protection device
  - Age >75 - CEA 7.53% vs. CAS 11.01%
  - Age ≤75 - CEA 5.94% vs. CAS 5.92%

SPACE failed to prove CAS was non-inferior to CEA, but caution raised in the elderly and over widespread adoption of CAS technology

Lancet Oct 06
Endarterectomy vs. Angioplasty in Patients with Symptomatic Severe Carotid Stenosis trial

**EVA-3S**

- Stent-protected angioplasty vs. CEA in symptomatic pts with stenosis >60%

- Non-inferiority design, 872 pts to assess with 80% power with expected 30 d D/MI rate 5.6% after CEA and 4% after CAS, delta 2%

- 527 pts enrolled, DSMB stopped trial for safety and futility reasons

- Primary endpoint: 30 day CVA or Death
  - CEA 3.9% vs. CAS 9.6%
  - 6 month CVA/D – CEA 6.1% vs. 11.7%

- Concerns
  - Variable experience - >25 CEA in prior year vs. 5 prior CAS procedures
  - No plavix prior to CAS 17%
  - 91% received an embolic protection device

- EVA-3S suggests pts with symptomatic carotid stenosis of >60% have lower rates of CVA and death at 1 and 6 mo than CAS.

Mas et al. NEJM 355: 1660, oct 06
Carotid Stent Issues

- **AHA guidelines for CEA:**
  - Symptomatic pts: 6% risk of death or major stroke
  - Asymptomatic pts: 3% risk of death/major stroke

- **High risk vs. low risk for CEA**
- Symptomatic vs asymptomatic pts

- **Initial strategy by multiple companies with various devices targeted CAS for the high risk CEA pt -**
  - **Clinical** – USA, CHF(EF <30%), AS, MR, sev COPD, CABG w/in 6 wks, age >80 yrs.
  - **Anatomic** – prior CEA, high ICA lesion, prior neck XRT, contralateral occlusion, contralateral laryngeal nerve palsy, severe tandem lesions.
Distal Protection Advances

- Lower profile- 7Fr-> 4Fr -> 2.5 Fr
- Improved centering
- Improved transitions
- Independent wire movement – EmboShield, Spider
- Independent wire use
Aortic Arch Types

Type I
Type II
Type III
Risk Factors for CAS

- Advanced age
- Recent symptoms < 2 weeks
- Poor access--arch and iliofemoral
- Tortuosity—unable to use EPD
- Severe calcification
- Free-floating thrombus
- String sign
- Experience level of interventionalist
Post CEA Restenosis - “favorable”
Higher Risk for CAS: Calcification and Ulceration

Heavy concentric calcification
EXACT/CAPTURE 2: Design, Conduct, Endpoints

- High risk post-approval/market trials
- Sponsor: Abbott Vascular
- Devices: RX Acculink® Carotid Stent System and RX Accunet® Embolic Protection System; RX Xact® Carotid Stent System and Emboshield ® Embolic Protection System

Overview:
- Pre-enrollment, 24-hour and 30-day neurologic exam performed by an independent neurologist
- Independent adjudication of neurological events by CEAC

Primary Endpoint:
- Composite of death, stroke and MI at 30 days
Carotid Stenting Post-Marketing Studies: Temporal relationships

**CAPTURE**
First Generation Post Approval Study
- Oct '04
- 144 sites (n=4383)
- Enrollment completed

**EXACT**
Second Generation Post Approval Study
- Nov '05
- 128 sites (n=2240)
- Follow-up Completed

**CAPTURE 2**
Temporal Second Generation Post Market Study
- Apr '07
- 90 sites (n=6181)
- Enrollment Ongoing

**CHOICE**
Temporal Second Generation Post Market Study
- Aug '06
- 200 sites (n=5436)
- Enrollment Ongoing
## Patient Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CAPTURE N=4225</th>
<th>EXACT N=2232</th>
<th>CAPTURE 2 N=4356</th>
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<tbody>
<tr>
<td>Mean Age</td>
<td>72.7</td>
<td>72.5</td>
<td>72.5</td>
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<tr>
<td>Age ≥ 80</td>
<td>23.4%</td>
<td>23.9%</td>
<td>22.5%</td>
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<tr>
<td>% Symptomatic</td>
<td>13.8%</td>
<td>10.3%</td>
<td>13.2%</td>
</tr>
<tr>
<td>% Male</td>
<td>60.8%</td>
<td>63.2%</td>
<td>61.7%</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>34.9%</td>
<td>34.7%</td>
<td>36.2%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>88.4%</td>
<td>89.5%</td>
<td>89.7%</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>78.0%</td>
<td>74.4%</td>
<td>88.6%</td>
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<tr>
<td>CHF</td>
<td>16.3%</td>
<td>18.3%</td>
<td>17.9%</td>
</tr>
<tr>
<td>Anatomic §</td>
<td>11.4%</td>
<td>10.6%</td>
<td>20.5%</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>21.0%</td>
<td>19.6%</td>
<td>23.3%</td>
</tr>
<tr>
<td>PVD</td>
<td>37.4%</td>
<td>44.8%</td>
<td>46.2%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>8.2%</td>
<td>7.2%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

§ Excluding co-morbidities
30 Day Composite Endpoint of Death and Stroke

Hierarchical- Includes only the most serious event for each patient and includes only each patient first occurrence of each event.

EXACT (N=2145)*
CAPTURE 2 (N=4175)
Combined (N=6320)

EXACT (N=213)
CAPTURE 2 (N=548)
Combined (N=761)

EXACT (N=1931)
CAPTURE 2 (N=3627)
Combined (N=5558)
Hierarchical- Includes only the most serious event for each patient and includes only each patient first occurrence of each event.
### 30 Day Composite Endpoint of < 80y/o and ≥ 80y/o: EXACT

<table>
<thead>
<tr>
<th>Hierarchical</th>
<th>&lt; 80 (N=1634)</th>
<th>≥ 80 (N=511)</th>
<th>Difference [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Death, Stroke and MI</td>
<td>3.7% (60/1634) [2.8%, 4.7%]</td>
<td>5.7% (29/511) [3.8%, 8.0%]</td>
<td>-2.00% [-4.46%, 0.45%]</td>
</tr>
<tr>
<td>Death</td>
<td>13</td>
<td>6</td>
<td></td>
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<tr>
<td>All Stroke</td>
<td>45</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Major Stroke</td>
<td>6</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>39</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>All Stroke, Death</td>
<td>3.5% (58/1634) [2.7%, 4.6%]</td>
<td>5.7% (29/511) [3.8%, 8.0%]</td>
<td>-2.13% [-4.57%, 0.32%]</td>
</tr>
<tr>
<td>[95% Conf. Interval]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Stroke, Death</td>
<td>1.2% (19/1634) [0.7%, 1.8%]</td>
<td>2.7% (14/511) [1.5%, 4.6%]</td>
<td>-1.58% [3.34%, 0.18%]</td>
</tr>
<tr>
<td>[95% Conf. Interval]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CAPTURE 3500: 30 Day Outcomes by Symptomatic Status

% of all patients

- All pts (N=3500)
  - All stroke & Death*
  - Major stroke & Death*
- Symp (N=482)
  - All stroke & Death*
  - Major stroke & Death*
  - §
- Asymp (N=3018)
  - All stroke & Death*
  - Major stroke & Death*
  - §

§ Denotes statistically significant difference at the 0.05 level
* Hierarchical Events – Includes only the most serious event for each patient and includes only each patient first occurrence of each event.
Combined EXACT/CAPTURE 2: 30-day Major Adverse Events in Symptomatic Patients (<80 y/o)

Symptomatic patients

Hierarchical - Includes only the most serious event for each patient and includes only each patient first occurrence of each event.

Clinical trial data presented may not be directly comparable and is presented for educational purposes.
Combined EXACT/CAPTURE 2: 30-day Major Adverse Events in Asymptomatic Patients (<80 y/o)

Asymptomatic patients

 Hierarchical- Includes only the most serious event for each patient and includes only each patient first occurrence of each event. Clinical trial data presented may not be directly comparable and is presented for educational purposes.
Combined EXACT/CAPTURE 2: 30-day Major Adverse Events in Anatomic High Risk Subset of Symptomatic Patients

Symptomatic patients – Anatomic High Risk Subset

Hierarchical- Includes only the most serious event for each patient and includes only each patient first occurrence of each event.

Clinical trial data presented may not be directly comparable and is presented for educational purposes.
Hierarchical - Includes only the most serious event for each patient and includes only each patient first occurrence of each event.

Clinical trial data presented may not be directly comparable and is presented for educational purposes.
CAS - who is selecting the cases?

The influence of experience on stroke & death

Asymptomatic patients <80 years

```
<table>
<thead>
<tr>
<th>Level</th>
<th>CAPTURE: n</th>
<th>EXACT: n</th>
<th>CAPTURE 2: n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>n = 210</td>
<td>n = 267</td>
<td>n = 83</td>
</tr>
<tr>
<td>Level 2</td>
<td>n = 1879</td>
<td>n = 776</td>
<td>n = 1026</td>
</tr>
<tr>
<td>Level 3</td>
<td>n = 735</td>
<td>n = 482</td>
<td>n = 318</td>
</tr>
</tbody>
</table>
```

Stroke Death rates:
- Level I: 2.5%
- Level 2: 3.4%
- Level 3: 3.8%
CAPTURE 2 and EXACT: Conclusions

- Two post market studies treating patients at high risk for CEA in the anatomic risk category have reached the AHA guidelines for death and stroke in the normal risk population.
- EXACT & CAPTURE 2 approaching AHA guidelines in both symptomatic/asymptomatic patient groups
CAPTURE 3500:
30 Day Outcomes by Octogenarian Status

% of all Patients

≥ 80 (N=829)

8.9%

5.2%

4.7%

< 80 (N=2671)

2.2%

§ Denotes statistically significant difference at the 0.05 level

* Hierarchical Events – Includes only the most serious event for each patient and includes only each patient’s first occurrence of each event
What is the problem with octogenarians?

- Poor cerebrovascular reserve?
  - Atrophy, small vessel disease, cerebral autoregulation
  - Microembolization?, “silent” emboli on MRI
- Higher incidence of risky stenting anatomy.
  - Carotid tortuosity, bad arch, diffuse calcification
- More hemodynamic instability.
Major Adverse Events at 30 Days: SAPPHIRE vs. CASES vs. SAPPHIRE WW

MAE defined as any death, MI or stroke
Note: Collection of cardiac enzymes differed among all three studies
Contralateral strokes were minimal compared to what has been previously reported demonstrating an improvement in technique.

Any Stroke: 3.2%
Major Ipsilateral: 1.0%
Major Non-Ipsilateral: 0.1%
Major Bilateral: 0.2%
Minor Ipsilateral: 1.9%
Minor Non-Ipsilateral: 0.1%
Minor Bilateral: 0.0%

SAPPHIRE WW (n=2,001)
# Anatomic vs. Physiological High-Risk Characteristics

<table>
<thead>
<tr>
<th>Anatomic N = 716</th>
<th>Physiological N = 918</th>
<th>Both Factors N = 327</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHF (class III/IV) &amp;/or known severe LV dysfunction LVEF &lt; 30%</td>
<td>--</td>
<td>20.2%</td>
</tr>
<tr>
<td>Open heart surgery within 6 weeks</td>
<td>--</td>
<td>2.3%</td>
</tr>
<tr>
<td>Recent MI (&gt; 24 hours and &lt; 4 weeks)</td>
<td>--</td>
<td>2.5%</td>
</tr>
<tr>
<td>Unstable angina (CCS class III/IV)</td>
<td>--</td>
<td>9.8%</td>
</tr>
<tr>
<td>Coexistent severe cardiac &amp; carotid disease requiring open heart surgery &amp; carotid revascularization</td>
<td>--</td>
<td>9.2%</td>
</tr>
<tr>
<td>Severe pulmonary disease</td>
<td>--</td>
<td>20.9%</td>
</tr>
<tr>
<td>Abnormal stress test</td>
<td>--</td>
<td>18.4%</td>
</tr>
<tr>
<td>Age ≥80 years as a single risk factor</td>
<td>--</td>
<td>37.4%</td>
</tr>
<tr>
<td>Contralateral carotid occlusion</td>
<td>23.7%</td>
<td>--</td>
</tr>
<tr>
<td>Contralateral laryngeal palsy</td>
<td>1.0%</td>
<td>--</td>
</tr>
<tr>
<td>Post radiation treatment</td>
<td>13.3%</td>
<td>--</td>
</tr>
<tr>
<td>Previous CEA recurrent stenosis</td>
<td>43.3%</td>
<td>--</td>
</tr>
<tr>
<td>High cervical ICA or CCA lesions below the clavicle</td>
<td>21.1%</td>
<td>--</td>
</tr>
<tr>
<td>Severe tandem lesions</td>
<td>3.9%</td>
<td>--</td>
</tr>
</tbody>
</table>
Major Adverse Events at 30 Days: Anatomic Risk vs. Physiologic Risk

MAE defined as any death, MI or stroke
p-values are based on comparison of anatomic risk vs. physiological risk
Filters: Newer Devices

Emboshield

Interceptor

FilterWire EZ

Rubicon

FiberNet
Recent Trial Results

<table>
<thead>
<tr>
<th></th>
<th>PROTECT</th>
<th>EPIC</th>
<th>EMPIRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke/Death</td>
<td>1.80%</td>
<td>2.10%</td>
<td>2.9%</td>
</tr>
<tr>
<td>s/d/mi</td>
<td>2.30%</td>
<td>3.00%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Octogenarians event rate</td>
<td></td>
<td>2.8%</td>
<td></td>
</tr>
<tr>
<td>Symptomatic event rate</td>
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<td>3.8%</td>
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<tr>
<td>N=</td>
<td>220</td>
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<td>245</td>
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<tr>
<td># of Sites</td>
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<tr>
<td>Age</td>
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<tr>
<td>%Oct</td>
<td>28.8</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>%sym</td>
<td>12.1</td>
<td>20</td>
<td>31</td>
</tr>
</tbody>
</table>

Data not directly comparable; different definitions and data collection.
Abbott (IDE) Trial 30-day Outcomes: ARChER, SECuRITY, and PROTECT

Hierarchical Events – Includes only the most serious event for each patient and includes only each patient’s first occurrence of each event.

- DSMI*: 6.1, 4.1, 4.4, 2.3
- Death/Stroke*: 5.5, 4.1, 4.2, 1.8
- Major Stroke/Death*: 2.6, 1.5, 1.4, 0.5

* Hierarchical Events – Includes only the most serious event for each patient and includes only each patient’s first occurrence of each event.
CREST

- NIH supported study with Acculink/Accunet includes normal risk patients
- Long lead-in phase
  - MAE for 191 symptomatic pts 5.7%
  - MAE for 395 asymptomatic pts 3.5%
- Added asymptomatic arm in 2005
- Randomized over 2000 patients
- Enrollment completed in July 08
- MAE = Death/CVA/MI
ACT 1-
Asymptomatic Carotid Trial

- Abbott Vascular supported RCT with EXACT stent/Emboshield filter includes standard risk patients for CEA
- Randomization 3:1 CAS/CEA
  - Max 1858 pts, lead-in enrollment up to 400 pts
  - 860 pts randomized to date
  - Excludes octogenarians
- Prospective, randomized, non-inferiority, multi-center trial
  - Prescribed contemporary medical therapy guidelines for all patients
  - Subjects followed at 1, 6, 12 mo post-procedure and annually for 5 years
- MAE = Death/CVA/MI
• Recommended: Before and after CAS & CEA
  • Aspirin daily indefinitely
  • Target systolic blood pressure: < 130 mm/hg
  • Target diastolic blood pressure: < 85 mm/hg
  • First recommended: Diuretics (except for diabetics)
  • Secondly recommended: ACE inhibitors
  • Target LDL: <70 mg/dl by Statins
  • Target HDL: >50 mg/dl
  • For diabetics: Target Hgb A1c: <7%
  • Lifestyle: Physical Activity, weight loss, smoking cessation
### ACT 1: Outcomes

#### Lead In Patients *(Adjudicated by CEC)*

<table>
<thead>
<tr>
<th>Event</th>
<th>30 days, N=145</th>
<th>31-365 days, N=106</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, Stroke and MI*</td>
<td>1.4%</td>
<td></td>
</tr>
<tr>
<td>All Stroke and Death*</td>
<td>1.4%</td>
<td></td>
</tr>
<tr>
<td>Major Stroke and Death*</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>All Stroke</td>
<td>1.4%</td>
<td></td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>1.4%</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>0.0%</td>
<td></td>
</tr>
</tbody>
</table>

*Hierarchical – Includes only the most serious event for each patient and includes only each patient’s first occurrence of each event*
ACST-2

- RCT comparing CEA and CAS
- Sites screened for track records of interventionalists and surgeons, with a blended stroke/death rate of $\leq 4\%$ for asymptomatic patients and $\leq 8\%$ for symptomatic patients.
- CEA and CAS techniques and equipment must be appropriate for routine clinical practice, and EP is optional.
- Subjects in whom CEA and CAS are anatomically practicable are randomized 1:1 to CEA or CAS.
- Main outcomes: 1-month stroke/MI/death and long term stroke ($\geq 5$ years).
- Randomization and 1-month evaluations are performed by the study doctor, and long term follow up is primarily though direct contact from the ACST office.
Asymptomatic (no ipsilateral symptoms within previous 180 days)
   Carotid artery stenosis $\geq$ 70% Ultrasound
   proven by certified study personal

Informed consent

Randomization

CEA
   n=1550
   Procedure within 30 days

CAS
   n=1550
   Procedure within 30 days

conservative
   n=540

Optimal medical treatment up to 5 years
Randomized trials help define best Rx for pts

ACT 1 will focus on evaluating CAS in asymptomatic patients with carotid stenosis
  - excludes high risk for CEA--protocol defined
  - excludes high risk for CAS--protocol defined
  - surgeon and interventionalist criteria are strict and verified
  - standardized protocol: routinely uses embolic protection
  - central core labs, independent audit
Conclusions

• Carotid stents - a less invasive alternative to CEA
• Hemodynamic perturbations are common in carotid stenting and should be anticipated in pre-procedural planning
• In the symptomatic population, outcomes of CEA vs. CAS pts have varied by trial
• In the much larger asymptomatic population, the large RCTs CREST and ACT 1 must be completed and analyzed before dissemination of CAS to the majority of our patients
Best Reference

ACCF/SCAI/SVMB/SIR/ASITN 2007 Clinical Expert Consensus Document on Carotid Stenting


Developed in Collaboration With the American Society of Interventional & Therapeutic Neuroradiology, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, and Society of Interventional Radiology

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History

- LM is a 67 y/o thin bm with prior CVA after 3 TIAs- 2005
  - Residual partial L facial paralysis and dysarthria
- Referred for asymptomatic L common carotid stenosis
- Past Med Hx:
  - HTN, CHol.
Physical Exam/ Labs

• thin bm – 5’5”, 155 lb, p 88, BP 151/56
• Poor dentition
• Bilateral carotid bruits and supraclavicular bruit
• Lungs – few rhonchi
• Cor – RRR, + S4, 2/6 aortic outflow murmur
• Ext - 1+ fem pulses
• paralysis of L face, with moderate dysarthria

• Cr 1.1, Hgb 11.9, nl electrolytes and coags
Aortic Arch

- Type II
- Severe ostial left common carotid lesion
- Minimal L ICA disease
- Tortuous innominate
Right ICA

- 90 degree right lateral projection
- 50% lesion by QA
- R ICA fills R MCA, R ACA and L ACA via anterior communicating artery
Ostial L CCA lesion

- Challenging to cannulate
- Significant calcium
- Failed with 5Fr Berenstein and vertebral catheters
Setup

• Given severe femoral and iliac disease, chose 6 Fr 65cm Destination sheath
• Telescoped 90 cm 6 Fr JR 4 guide into sheath with .035” Glide wire
• Very difficult to cannulate
Cannulation success

- Pt was enrolled in CAPTURE II high risk carotid stent registry due to lung CA, prior XRT and lesion location
- Switched Glide wire to MB 4.5 .014” wire with success
- Attempt to Buddy wire with 7.0 Accunet filter wire was not successful
Predilate

- Successful in crossing lesion with a 2.5 x 20mm Maverick balloon
- Dilated to 14 atm
- Removed 6 Fr guide but still unable to deliver Accunet filter wire due to angulation and calcium
What next?

- ??
What next?

- Buddy wire ??
- Spider filter wire ??
- Emboshield ??
- Balloon-expandable stent through 6 Fr guide without distal protection ??
Stent deployment

- Redilated the lesion with 2.5 Maverick balloon after reinserting the 6 Fr JR4 guide
- Advanced guide through lesion while retrieving balloon (renal technique)
- Deployed 6 x 24 Genesis stent at 14 atm (6.24 mm)
Post- stent result

- Stent appears well deployed distal to ostium and appropriate size to this common carotid vessel
- No neurologic changes
- Is the ostium dilated enough ??
Post dilation

• Post-dilate the proximal stent with a 7.0 x 15 mm Aviator balloon (fits in 6 Fr guide and 0.014” wire compatible)

• Trumpet the ostium at high pressure (14 atm) for a size of 7.24mm
Final images

- RAO view - note minimal disease in proximal L ICA
- LAO view ->
Final result

- Thoughts ??
- Discharged following morning without any neurologic or hemodynamic changes