Carotid Artery Angioplasty And Stenting: Current Indications

Michael T. Caps, MD MPH
Vascular Surgeon, HMPG

Third Annual Kaiser National Surgical Symposium
Napa, CA, July 13th, 2007
Topics TBD

- Data from recent randomized trials
  - SAPPHIRE, EVA-3S, SPACE
- Important sub-groups defined by:
  - Symptoms, gender, age, device, lesion, & access vessel characteristics
- Current CMS coverage
- CAS in the Kaiser system
- Kaiser Hawaii experience with CAS
AHA Guidelines

Peri-op stroke/death
<3% Asymptomatic
<6% Symptomatic

Registry Data

- Not designed to evaluate efficacy
- Multiple potential biases
  - Confounding
  - Selection
  - Outcome ascertainment
  - Non-reporting
- Stroke/death rates low w/ declining temporal trend
  - Generally lower than RCT data
- Strengths
  - Hypothesis generation, not hypothesis testing
  - Large N: power for sub-group analyses
SAPPHIRE

- Industry-sponsored RCT, 327 patients randomized
- Asymptomatic ≥80% and symptomatic ≥50% stenosis in “high risk” patients.
- 70% of patients were asymptomatic.
- 30 day rate of stroke and death for CAS was 3.7% and for endarterectomy was 5.3% (NS).
- CAS results same or better than CEA in all categories.
- Significant when MIs included.

NEJM 351;2004
EVA-3S

- Publicly funded, multi-center RCT conducted in France
- 527 symptomatic patients (≥60% stenosis) randomized
- 227/261 (87%) of stented patients had dist protection
- Variety of stents and CPDs used
- Trial stopped due to safety and futility
- 30-D stroke/death (P = .01):
  - CEA: 3.9%
  - CAS: 9.6%
Criticisms Of EVA-3S

- Low accrual
  - 5 patients/year/center
- Relative inexperience of interventionalists
  - 12 prior CAS procedures, or
  - 35 supraaortic trunks (≥5CAS)
- Trend toward better outcomes with CPD
  - 30 D stroke/death 18/227 (7.9%) with CPD
  - 5/20 (25%) without CPD
SPACE

- 1200 patients with symptomatic \( \geq 50\% \) stenosis randomized
- Germany, Austria, and Switzerland – private/public funding
- CPDs used in only 151/567 (27\%) of patients
- Trial stopped because CAS not proven to be non-inferior to CEA
- Ran out of funding

Ipsilateral stroke/death
Ipsilateral stroke
Death
Disabling stroke/death
Disabling stroke
Any stroke
Any stroke/death
Procedural failure

SPACE Sub-Groups

![Graph showing OR (CAS/CEA) for SPACE sub-groups based on age and gender.](image)

- **Ipsilateral stroke/death**

  - Age:
    - $\leq 75$
    - $>75$

  - Gender:
    - Male
    - Female

*SPACE Investigators, *Lancet*, 2006*
Equivalence And Non-Inferiority
Primary endpoint = procedural stroke/death (CEA – CAS)
Important Ongoing Trials

- CREST
- ACT 1
- TACIT
- ACST II

Have We Pushed It Too Far?
The hardest thing to manage in life is change.
CEA and CAS

- CAS and CEA are closer than we think.
  - Different complications.
- CEA is mature, CAS is developing.
  - CAS will get safer, CEA may not.
- You need to be able to do both!!
  - The role of CAS is likely to grow
  - Procedures are not mutually exclusive
Carotid Angioplasty and Stenting is based upon...

- Knowledge of anatomy
- Pattern recognition
- Patient selection
- Meticulous technique
- Vigilant clinical management

If the carotid artery was not attached to the brain, we would say it was ideal for endovascular treatment!
CAS
Next Developments

- Figure out who is at high risk for CAS
- Better understanding of CAS-related stroke
- Make devices/delivery systems smaller
- Better coverage of lesion
- Make particle capture more complete
Safer CAS Equipment

- **Access**
  - Smaller caliber, radial approach, reduced embologenic potential

- **Stents**
  - Open cell or closed cell, cell size, flexible, durable

- **Cerebral Protection**
  - Smaller caliber delivery, pore size
Closed- vs. Open-Cell Stents

Carotid stents are expected to trap dissected, crushed plaque and its contents

Exponent  Protégé  PRECISE®  Acculink  NexStent  Xact  Carotid Wallstent

Events after stenting are different than after endarterectomy: more frequent, more delayed, and less severe.
CAS or CEA?

**Medical Risk**
- **High:** Fails eyeball test
- **Low:** Patient looks better than the doctor

**Anatomical Risk**
- **Easy**
- **Complex**

**CAS**
**CEA**

**EITHER**
Most people could be treated with either CAS or CEA
CAS or CEA?
What Does High Surgical Risk Mean?

<table>
<thead>
<tr>
<th>Medical</th>
<th>Anatomical</th>
</tr>
</thead>
<tbody>
<tr>
<td>- CHF class III/IV</td>
<td>- Radical neck</td>
</tr>
<tr>
<td>- LV EF $\leq$30%</td>
<td>- Neck radiation</td>
</tr>
<tr>
<td>- Angina class III/IV</td>
<td>- Laryngeal palsy</td>
</tr>
<tr>
<td>- Recent MI &lt;30d</td>
<td>- Recurrent stenosis</td>
</tr>
<tr>
<td>- Need CABG</td>
<td>- Contralateral occlusion</td>
</tr>
<tr>
<td>- Pulm insuff-FEV1</td>
<td>- High lesion above C2</td>
</tr>
<tr>
<td>- Home O2</td>
<td>- Low lesion at clavicle</td>
</tr>
<tr>
<td>- Severe CAD</td>
<td>- Spinal immobility</td>
</tr>
<tr>
<td>- Severe valvular disease</td>
<td>- Tracheostomy</td>
</tr>
<tr>
<td>- Renal failure</td>
<td></td>
</tr>
<tr>
<td>- Age $&gt;80$</td>
<td></td>
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CAS Is Not….
A Simple Replacement Product

<table>
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<tr>
<th>CAS</th>
<th>CEA</th>
</tr>
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<tbody>
<tr>
<td><strong>I would rather stent:</strong></td>
<td><strong>I would rather operate:</strong></td>
</tr>
<tr>
<td>- Hostile neck</td>
<td>- Bad anatomy for CAS</td>
</tr>
<tr>
<td>- Stoma, radical neck, inaccessible lesion recurrence</td>
<td>- Tortuosity, calcification, no access</td>
</tr>
<tr>
<td>- High medical risk</td>
<td>- Renal insufficiency</td>
</tr>
<tr>
<td>- Heart, lung</td>
<td>- Life expectancy &gt;10 yrs</td>
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*Leave these folks alone: Very frail elderly, dementia, bed-bound*
High Risk For CAS
## CAS or CEA?

### What About High CAS Risk?

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<tbody>
<tr>
<td>▪ CHF class III/IV</td>
<td>▪ Tortuous arch</td>
</tr>
<tr>
<td>▪ LV EF ≤30%</td>
<td>▪ Calcified arch</td>
</tr>
<tr>
<td>▪ Angina class III/IV</td>
<td>▪ Diseased great vessels</td>
</tr>
<tr>
<td>▪ Recent MI &lt;30d</td>
<td>▪ Tortuous carotid artery</td>
</tr>
<tr>
<td>▪ Need CABG</td>
<td>▪ Pre-occlusive lesion</td>
</tr>
<tr>
<td>▪ Pulm insuff-FEV1</td>
<td>▪ Heavy plaque burden</td>
</tr>
<tr>
<td>▪ Home O2</td>
<td>▪ Circumferential calcification</td>
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<td>▪ Severe CAD</td>
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<td>▪ Age &gt;80</td>
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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.
What is the problem with octogenarians?

CREST lead in:
Significant stroke/death difference
<60: 1.7%, 60-69: 1.3%, 70-79: 5.3%, >80: 12.1%
Odds ratio adjusted for symptomatic status
<60 yoa: 1.0, 60-69: <1.0, 70-79: 3.1, >80: 7.8

*J Vasc Surg 40: 2004*

CAPTURE:
Stroke/death/ MI
<80 yoa: 4.8%, >80: 8.9%

*TCT, 2005*
CMS Coverage Of CAS

- Patients qualifying:
  - Outside trial: symptomatic, high-risk for CEA, ≥70% arteriographic stenosis, only with EPD’s
  - FDA-approved CAS trials or post-marketing studies
- CMS certification of facilities:
  - Written affidavit attesting minimum: high-quality imaging, physiologic monitoring, emergency management, privileging program, data collection; and/or
  - FDA-approved site for CAS trials/post-marketing studies
Unique Aspects Of CAS In KP

- Capitation
  - For the majority of our Medicare and commercial patients, a bill is not generated
  - CMS certification pursued more for compliance issues than for revenue generation

- Utilization management/resource stewardship is highly variable throughout Kaiser
  - Not aggressive in our region
Reimbursement Algorithm

Patient at high-risk for CEA
  Yes
  Suitable anatomy for CAS
    Yes
    Eligible for FDA trials (IDE or PMS)
      Yes
      Organization enrolled in IDE trial or PMS:
        No
        Symptomatic >70% stenosis
          No
          CMS reimbursed CAS
        Yes
        Enroll in low surg risk CAS v CEA trial
          No
          1) High-risk CEA
          2) Medical Rx

1) Self-pay for CAS procedure
2) 3rd party payer for CAS
3) High-risk CEA
4) Medical Rx
<table>
<thead>
<tr>
<th>Symptoms</th>
<th>High-Risk</th>
<th>Low-Risk</th>
<th>Low-Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>Self-Pay CAS</td>
<td>CMS-Reimbursed</td>
<td>PMS*</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>Self-Pay CAS</td>
<td>Medical Mngmnt</td>
<td>PMS*</td>
</tr>
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* SAPPHIRE Wordwide, Abbot
Kaiser Hawaii Experience With CAS

- CAS attempted in 143 patients over 5 years
  - Technical success in 141 (99%) of cases
- All done by 3 vascular surgeons in OR
  - Fixed imaging
  - Many assisted by an interventional radiologist
- Complications:
  - TIA 2, minor stroke 2, Major stroke 3, Death 0
  - Any 7/143 = 4.9%, stroke/death = 3.5%
KPH Experience - Strokes Following CAS

- Minor strokes
  - Expressive aphasia – resolved at 30 d
  - Retinal embolus – perm field cut

- Major strokes
  - Contralat stroke 3 d post-op, minor at 30 d
  - Hemiparesis 8 hrs post-op, minor at 30 d
  - Major hemiparesis, died shortly after 30 d