CAROTID ARTERY DISEASE IN 2017: TO STENT, TO OPERATE, TO MEDICATE: THAT IS THE QUESTION

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Stroke/CVA

• 5th leading cause of death, #1 cause serious long-term disability US
• 795,000 CVA/yr US (one CVA every 40 seconds)
  • 600K first-ever strokes/yr US
• 130,000 CVA related deaths/yr
• Cost of stroke care 2008 in US = $34M
• 85% CVA are ischemic
  • 80% carotid territory, 20% vertebrobasilar
  • Approx 50% % due to carotid bifurcation dz
• Transient ischemic attack (TIA)
  • 1/3 pts with TIA will have CVA in 12m if no Rx
  • 10-15% with TIA will have MAJOR CVA in 3m

Centers for Disease Control and Prevention
cdc.gov

American Heart Assoc/American Stroke Assoc
Carotid Artery Stenosis: Treatment

Goal: Stroke Risk Reduction

2 main considerations

Degree of stenosis (%)  Presence/absence of symptoms
Treatment of carotid artery stenosis

- symptomatic
- Revascularization
  - Surgery/Endarterectomy (CEA)
  - Stent/angioplasty (CAS)
Asymptomatic carotid stenosis

- Lack of consensus
- 85-90% CEA in US are for asymptomatic dz (120K interventions/yr)
  - (60% Germany, 15% Canada, Australia)
- ACAS/ACST
  - Small but significant benefit (any stroke) of CEA (12% v 6% @5y) compared to BMT
    - But no benefit of CEA age >75yo
    - Advocates of intervention state that until proof otherwise, things should not change
  - ACST 4.6% absolute risk reduction @ 10y vs BMT
    - (46 strokes prevented at 10 years/1000 operations – only 5%)
Next 100 strokes

- Ischemic: 85
- Hemorrhagic: 15

Ischemic strokes

- Carotid: 68 (80%)
- Vertebrobasilar: 17 (20%)

Carotid territory strokes

- Extracranial carotid: 34 (50%)
- Small vessel dz: 17 (25%)
- Cardioembolic: 14 (20%)
- Misc/rare: 3 (5%)

34% of all strokes will follow ICA embolic event

www.stroke.org
34 carotid territory CVA pts

20 will not have “surgical” >50% stenosis

14/next 100 strokes from prev asx ICA stenosis
(20% of these (3/next100) will have TIA prior to the CVA

11/next 100 pts with >50% stenosis

In US, 66,000 of the 600,000 first ever strokes
(0.02% US gen pop)
(0.07% US >50yo)
**Table 1 – What are the controversies that contribute towards the current lack of consensus in the management of asymptomatic carotid disease?**

| The 2011 AHA Guidelines are based upon Level I evidence from large randomised trials | ACAS and ACST are now too historical to be relevant in the modern era |
| 80% of strokes are not preceded by a TIA or minor stroke. Strokes due to a carotid stenosis harboured a treatable asymptomatic lesion prior to the event | Even if you could identify and operate on every patient with a significant asymptomatic stenosis, 95% of all strokes would still occur in the community |
| Selective screening could identify patients with significant asymptomatic stenoses, thereby enabling early intervention to prevent avoidable stroke | The US Preventive Services Task Force has concluded that there were no eligible studies providing direct evidence that screening reduced fatal or disabling stroke |
| The AHA already recognises that only ‘highly selected’ patients should undergo intervention | AHA did not define ‘highly selected’ and there is little evidence that this caveat influences case selection |
| The risks of CEA/CAS are now much lower and this will make interventions even more effective | Even if the procedural risk could be reduced to 0%, 93% of all interventions would still be ultimately unnecessary |
| The recent (apparent) decline in stroke on medical therapy is based upon flawed data | The decline in stroke appears real and is evident in both randomised and non-randomised studies |
Treatment of carotid artery stenosis

Asymptomatic

Any stenosis

BMT

Best Medical Therapy

Antiplatelet therapy (clopidogrel, ASA)

Statin therapy

≥80% stenosis

CEA + BMT

CAS + BMT
CREST
Carotid Revascularization
Endarterectomy versus Stenting
(sx ≥ 50% & asx ≥ 60%)

1° composite endpoint:
Stroke, MI, death periprocedural period +
any subsequent ipsilateral stroke out to 4 years

10-year followup
1° composite endpoint
Any ipsilateral stroke after 30d

2502 pts

Composite: 11.8% stent 9.9% CEA (NSS)
Any ipsilateral stroke: 6.9% stent 5.6% CEA (NSS)
Current FDA/CMS guidelines on CAS

- High-risk, >70% symptomatic carotid stenosis

The Centers for Medicare and Medicaid Services (CMS) has determined that the evidence is adequate to conclude that carotid artery stenting (CAS) with embolic protection is reasonable and necessary for the following:

1. Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis ≥ 70%. Coverage is limited to procedures performed using FDA approved carotid artery stenting systems and embolic protection devices;
2. Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7);
3. Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7).

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon. Significant comorbid conditions include but are not limited to:

- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) < 30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis;
- prior radiation treatment to the neck; and
- other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.
Embolic Protection Devices

0.014” guidewire with “basket”/ “filter”
- designed to capture any embolic debris during stenting procedure
Carotid stenting
74yo male with TIA symptoms

Abnormal carotid duplex scan

Severe, 90% carotid stenosis
Pre-dilate stenosis

Post angioplasty/stent
Severe, 95% Left carotid stenosis

Post 7mm PTA/stent
Which is best? CEA or CAS?

• Answer: it depends!
• Both effective in reducing future stroke risk
• In general CEA well-tolerated but…
• Risk less with CAS if:
  • Previous radiation therapy to neck
  • Previous CEA with restenosis
  • Anatomic factors (high bifurcation)
  • Severe COPD/cardiac issues (high risk of operative complications)
• ACT-1, CREST others show non-inferiority of CAS vs CEA
Hope for the future? CREST-2

• Two independent Multicenter, randomized controlled studies of carotid revascularization vs BMT
  • CAS v BMT
  • CEA v BMT
  • Primate outcome measure:
    • Stroke + death @44 dyas post-procedure
    • Ipsilateral stroke thereafter out to 4 years
My practice

• Symptomatic
  • High-risk: CAS
  • Average risk: CEA

• Asymptomatic
  • Considerations
    • PMD opinion
    • Patient opinion
      • Anxiety
      • Comfort level
      • Education about warning signs
    • Serial DUS
  • Lean towards BMT
    • Females
    • >75yo
    • Stable DUS
Conclusions

• Multiple options for treatment of sx carotid stenosis 2017

• CEA remains a very good, durable procedure

• CAS is noninferior to CEA in several studies
  • Currently only high-risk, sx >70% can be treated in US outside a clinical trial

• Spectrum of opinion on treatment of Asx carotid stenosis

• Evidence for BMT years away from head to head comparison
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