Asymptomatic Carotid Disease: Guidelines for Assessment and Management

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Disclosures

- Consultant/Research or Grant Support
  - Gore Medical
  - Abbott Vascular
  - Cordis Endovascular
  - IDEV Technologies
  - Atrium Medical
  - Bard Medical
  - Cook Medical
  - Medrad/Possis
My Carotid Stent Trials as PI

- CREST- leading NE site
- SAPPHIRE
- SAPPHIRE-WW
- CHOICE
- EXACT
- CARES
- CARES-PMS
- PROTECT
- SONOMA
- EMBOLDEN
- CREATE
- CREATE-PAS
- FREEDOM
- EPIC
Management of Patients With Atherosclerotic Disease of the Carotid Arteries

2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease

Circulation 2011;124:489-523
Stroke- Scope of the Problem

- ~700,000 strokes/yr = 1/min
- 3rd leading cause of death in the US
- ~150,000/yr.; #1 cause of disability
- ~20% strokes due to carotid disease
- Stroke cost = $58.8 billion/yr.
- 4.4 million stroke survivors
  - 20% require institutional care
  - up to 1/3 have permanent disability
Stroke Risk of Extracranial Carotid Disease- Who’s at Risk?

- Asymptomatic ≥80%
  - Annual risk of 1-4.3%
- TIA
  - 15% risk of stroke at 1 month
  - 30% risk of TIA/CVA/death within 3 months

*Stroke* 1991;22:1485
## Vascular Risk of Asymptomatic Carotid Stenosis - *mean F/U 43 months*

<table>
<thead>
<tr>
<th>Stenosis</th>
<th>TIA</th>
<th>CVA</th>
<th>Cardiac Event</th>
<th>Vascular Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50%</td>
<td>1.0</td>
<td>1.3</td>
<td>2.7</td>
<td>1.8</td>
</tr>
<tr>
<td>50-75%</td>
<td>3.0</td>
<td>1.3</td>
<td>6.6</td>
<td>3.3</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>7.2</td>
<td>3.3</td>
<td>8.3</td>
<td>6.5</td>
</tr>
</tbody>
</table>

Diagnosing Carotid Artery Disease

- Complete neurologic & medical history and physical exam
- Carotid Duplex Ultrasonography (CDUS)
- MRA
- CTA
- Digital Subtraction Angiography (DSA)
What Can the Physical Exam Tell You About the Etiology of Stroke?

<table>
<thead>
<tr>
<th>AFib/Flutter</th>
<th>Cardiogenic Embolus</th>
</tr>
</thead>
<tbody>
<tr>
<td>No distal pulses</td>
<td>Systemic embolization</td>
</tr>
<tr>
<td>Carotid bruit</td>
<td>Extracranial carotid disease</td>
</tr>
<tr>
<td>Fever and acute CVA</td>
<td>Endocarditis with cardiogenic embolus</td>
</tr>
</tbody>
</table>
Indications for Carotid Duplex (CDUS)

- Cervical bruit
- TIA/TMB
- CVA
- F/U of known stenosis
- F/U after CEA or CAS
- Intra-op assessment of CEA
- CVD assessment in patients with multiple CRFs

Radiology 2000;214:247-252
CDUS

Advantages

- rec as initial test - *Class I*
- excellent sensitivity/specificity
- inexpensive
- reproducible; can follow pre-post CEA/CAS
- no pain, radiation

Disadvantages

- difficult to assess calcified lesions; low/high neck segments
- may be difficult to tell subtotaled vs. occluded vessel
MRA

- Advantages
  - Assess arch, cervical and cerebral arteries
  - accurate, excellent sensitivity/specificity

- Disadvantages
  - overestimates stenosis severity
  - contraindicated in pts. with CRI, PPM/ICD
  - claustrophobia
  - cost
CTA

- Advantages
  - very good sensitivity/specificity
  - accurate, quick
  - can use in pts. with PPM/ICD

- Disadvantages
  - ionizing radiation
  - contrast in pts with CRI
  - difficult to assess calcified lesions
  - may overestimate stenosis
  - cost
Contrast Angiography - DSA

- **Advantages**
  - “gold standard” imaging modality; used during CAS
  - used when non-invasive angiography yields conflicting results, or when obesity, CRI, implantable devices renders CTA/MRA inadequate or impossible
  - able to distinguish true occlusion vs. string sign

- **Disadvantages**
  - risk or stroke, <1%
  - invasive; risks of contrast, radiation, access site complications
Stroke Risk Factors

- HLP
- Diabetes
- Smoking
- HBP
- Physical Inactivity
Hypertension

- Most potent risk factor for stroke
- ARIC, MESA, Cardiovasc Health Study, Framingham all found association between HBP and stroke
- For each 10mmHg drop in BP, risk for stroke decreases 33%
- Antihypertensive therapy reduces risk of recurrent stroke by 24%
- Type of drug therapy less important than the response
Effect of ACE-I Therapy vs. Placebo on CV Endpoints

Recommendations for Treatment of Hypertension

1. **Class I**
   Antihypertensive treatment is recommended for patients with hypertension and asymptomatic extracranial carotid or vertebral atherosclerosis to maintain blood pressure below 140/90 mm Hg.111,228–231 (Level of Evidence: A)

3. **Class IIa**
   - Except during the hyperacute period, antihypertensive treatment is probably indicated in patients with hypertension and symptomatic extracranial carotid or vertebral atherosclerosis, but the benefit of treatment to a specific target blood pressure (eg, below 140/90 mm Hg) has not been established in relation to the risk of exacerbating cerebral ischemia. (Level of Evidence: C)
Smoking and Stroke

Framingham Study

- Smoking increases relative risk of stroke 25-50%
- Stroke risk drops significantly in those who quit

JAMA 1988;259:1025-1029
Recommendations for Cessation of Tobacco Smoking

1. Class I  
2. Patients with extracranial carotid or vertebral atherosclerosis who smoke cigarettes should be advised to quit smoking and offered smoking cessation interventions to reduce the risks of atherosclerosis progression and stroke.246–250 (Level of Evidence: B)
Hyperlipidemia and Stroke

- Randomized 4731 pts. S/P TIA/CVA with no CAD and LDL 100-190, to 80 mg atorvastatin vs. placebo
- Primary endpoint: first nonfatal or fatal stroke

SPARCL Investigators, NEJM 2006;2006:355:549-559
Hyperlipidemia and Stroke

ARR of 2.2% @ 5-yrs.

RRR of ischemic stroke by 22%

SPARCL Investigators, NEJM 2006;2006:355:549-559
Statins Decrease the Risk of Stroke in High-Risk Patients: Heart Protection Study

SIMVASTATIN: MAJOR VASCULAR EVENTS

<table>
<thead>
<tr>
<th>Vascular event</th>
<th>STATIN (10269)</th>
<th>PLACEBO (10267)</th>
<th>Risk ratio and 95% CI</th>
<th>Risk</th>
<th>24% SE 2.6 reduction (2P&lt;0.00001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total CHD</td>
<td>914</td>
<td>1234</td>
<td>STATIN better</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total stroke</td>
<td>456</td>
<td>613</td>
<td>STATIN worse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revascularisation</td>
<td>926</td>
<td>1185</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANY OF ABOVE</td>
<td>2042 (19.9%)</td>
<td>2606 (25.4%)</td>
<td></td>
<td></td>
<td>50% reduction in CEA or angioplasty (simvastatin 42 [0.4%] vs placebo 82 [0.8%]; P=0.0003)</td>
</tr>
</tbody>
</table>

MRC/BHF HPS Investigators Lancet 2002; 360 (9326): 7
Recommendations for Control of Hyperlipidemia

1. **Class I**
2. Treatment with a statin medication is recommended for all patients with extracranial carotid or vertebral atherosclerosis to reduce low-density lipoprotein (LDL) cholesterol below 100 mg/dL.111,259,260 (Level of Evidence: B)

3. **Class IIa**
   - Treatment with a statin medication is reasonable for all patients with extracranial carotid or vertebral atherosclerosis who sustain ischemic stroke to reduce LDL cholesterol to a level near or below 70 mg/dL.259 (Level of Evidence: B)
   - If treatment with a statin (including trials of higher-dose statins and higher-potency statins) does not achieve the goal selected for a patient, intensifying LDL-lowering drug therapy with an additional drug from among those with evidence of improving outcomes (ie, bile acid sequestrants or niacin) can be effective.261–264 (Level of Evidence: B)
   - For patients who do not tolerate statins, LDL-lowering therapy with bile acid sequestrants and/or niacin is reasonable.261·263·265 (Level of Evidence: B)
Diabetes and Stroke

- Risk of ischemic stroke in pts. with DM increased 2-5 fold
- Progression of carotid IMT in pts. with DM
- UKPKD and ACCORD trials showed intensive Rx of DM did NOT reduce risk of stroke...
Intensive Diabetes Treatment and CV Disease in Patients with Type I Diabetes

The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group

Randomized to conventional vs. intensive glycemic control; mean F/U 6.5 years

Reduced risk of any CV event by 42%
Reduced risk of non-fatal MI, CVA, CVD death by 57%

CV Disease = non-fatal MI, CVA, death due to CVD, angina, need for CABG/PCI

NEJM 2005;353:2643-53
1. Class IIa

2. Diet, exercise, and glucose-lowering drugs can be useful for patients with diabetes mellitus and extracranial carotid or vertebral artery atherosclerosis. The stroke prevention benefit, however, of intensive glucose-lowering therapy to a glycosylated hemoglobin A1c level less than 7.0% has not been established.286,287 (Level of Evidence: A)

3. Administration of statin-type lipid-lowering medication at a dosage sufficient to reduce LDL cholesterol to a level near or below 70 mg/dL is reasonable in patients with diabetes mellitus and extracranial carotid or vertebral artery atherosclerosis for prevention of ischemic stroke and other ischemic cardiovascular events.288 (Level of Evidence: B)
Anti-thrombotic Therapy

- ASA recommended in pts. with ECVD
- WARSS- Warfarin-Aspirin Recurrent Stroke Study- ASA vs. warfarin- no benefit of warfarin over aspirin
- ASA/Dipyridamole superior to ASA alone in pts. with prior TIA/stroke in the 2nd European Stroke Prevention Study
- Clopidogrel: NO reduction in stroke risk w/combo Rx
  - MATCH- Management of Atherothrombosis With Clopidogrel in High-Risk Patients
  - CHARISMA- Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance
1. Class I

2. Antiplatelet therapy with aspirin, 75 to 325 mg daily, is recommended for patients with obstructive or nonobstructive atherosclerosis that involves the extracranial carotid and/or vertebral arteries for prevention of MI and other ischemic cardiovascular events, although the benefit has not been established for prevention of stroke in asymptomatic patients.33,260,305,338 (Level of Evidence: A)

3. In patients with obstructive or nonobstructive extracranial carotid or vertebral atherosclerosis who have sustained ischemic stroke or TIA, antiplatelet therapy with aspirin alone (75 to 325 mg daily), clopidogrel alone (75 mg daily), or the combination of aspirin plus extended-release dipyridamole (25 and 200 mg twice daily, respectively) is recommended (Level of Evidence: B) and preferred over the combination of aspirin with clopidogrel.260,305,339-342 (Level of Evidence: B) Selection of an antiplatelet regimen should be individualized on the basis of patient risk factor profiles, cost, tolerance, and other clinical characteristics, as well as guidance from regulatory agencies.

4. Antiplatelet agents are recommended rather than oral anticoagulation for patients with atherosclerosis of the extracranial carotid or vertebral arteries with343,344 (Level of Evidence: B) or without (Level of Evidence: C) ischemic symptoms. (For patients with allergy or other contraindications to aspirin, see Class IIa recommendation #2 below.)
Carotid Endarterectomy (CEA) in Asx Low-Risk Patients - ACAS

- MC, RCT of CEA vs. Med Rx with >60% stenosis
- N=1662; median F/U 2.7 years
- Primary outcome: ipsilateral stroke and periprocedural stroke or death

JAMA 1995;273:1421-8
ACAS CEA Caveats

- Elite surgeons, <3% stroke rate in prior year
- High-risk Patients Excluded:
  - age > 79
  - prior ipsilateral CEA
  - ACS or MI in past 6 mo
  - contralateral occlusion
  - prior CVA
  - cardiac valve or rhythm abnormality likely to cause emboli

No RCTs of Med Rx vs. CEA in high surgical risk patients
Early vs. Deferred CEA in Asymptomatic Patients with >70% ICA Stenosis - ACST

- MC, RCT of 3120 pts, with carotid stenosis >70% to immediate vs. deferred CEA
- 5-yr. F/U
- Similar exclusions to ACAS, i.e., low-risk for surgery
- 3.1% risk of Stroke/Death w/in 30 days of CEA
- No benefit of CEA age >80

ACST Investigators, Lancet 2004;363:1491-1502
CEA: Risk of Stroke/Death

- Depends who checking!
  - self-reported, 2.3%
  - neurologist oversight, 7.7%

- High surgical risk
  - age > 75: 7-10% symptomatic; asymptomatic ~ 3%
  - CHF: 8-9%
  - CAD requiring CABG: 6-10%
  - Contralateral carotid occlusion: 14.3% in NASCET
  - Prior CEA w/restenosis: 8-10%
  - CKD- Cr>1.5 (8.2%); Cr>2.9 (43%)
Non-Stroke Risks of CEA

- Wound Complications - higher if XRT, prior surgery, high/low location
  - hematoma 1-5%
  - cranial nerve dysfunction 5-8%, permanent 1-2%
- Higher risk if CKD, esp HD; pulmonary disease
- Hyperperfusion syndrome <1%
- MI 1-3%
- Restenosis 2-6%
What Constitutes High-Risk for CEA?

**Medical Co-morbidities**
- EF <30%, NYHA class ≥III
- FEV1 < 30%
- ESRD on dialysis
- Need for heart surgery w/in 30 days
- ACS, prior MI past 30 days
- 2 or more cor vessels with ≥70% stenosis
- Age > 80

**Unfavorable Anatomy**
- S/P radical neck surgery
- Inaccessible lesions
- Spinal immobility
- Tracheostomy
- Contralateral occlusion
- Contralateral laryngeal nerve palsy
- Restenosis after prior CEA
Carotid Artery Stenting (CAS)

Pre

Post

3 Different Systems of Cerebral Protection

Distal Balloon  Distal Filter  Proximal Balloon
Early CAS High Risk Registries

Incidence of stroke and death in high risk carotid stent IDE trials: 2002-2008

% MAE

SAPPHIRE 2002
ARCHER 2003
SECURITY 2003
BEACH 2004
MAYePIC 2004
CABERNET 2004
CREATE 2005
EMPIRE (2006)
EPC (2006)
PROTECT (2006)

Courtesy of W Gray
EXACT/CAPTURE Combined 30-day MAE: asymptomatic,< 80
Remarkable Results for Recent High Surgical Risk Patients

3% AHA/ASA Guideline

EPIC: 3%
EMPIRE: 2.9%
PROTECT: 1.8%
ARMOUR: 2.7%

30-day Death/Stroke/MI
High-Risk RCT of CAS vs. CEA: Sapphire

<table>
<thead>
<tr>
<th>Event</th>
<th>Intention-to-Treat Analysis</th>
<th>Actual-Treatment Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stenting (N=167)</td>
<td>Endarterectomy (N=167)</td>
</tr>
<tr>
<td>Death</td>
<td>12 (7.4)</td>
<td>21 (13.5)</td>
</tr>
<tr>
<td>Stroke</td>
<td>10 (6.2)</td>
<td>12 (7.9)</td>
</tr>
<tr>
<td>Major ipsilateral</td>
<td>1 (0.6)</td>
<td>5 (3.3)</td>
</tr>
<tr>
<td>Major nonipsilateral</td>
<td>1 (0.6)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Minor ipsilateral</td>
<td>6 (3.7)</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Minor nonipsilateral</td>
<td>3 (1.9)</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>5 (3.0)</td>
<td>12 (7.5)</td>
</tr>
<tr>
<td>Q-wave</td>
<td>0</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Non-Q-wave</td>
<td>5 (3.0)</td>
<td>10 (6.2)</td>
</tr>
<tr>
<td>Cranial-nerve palsy</td>
<td>0</td>
<td>8 (4.9)</td>
</tr>
<tr>
<td>Target-vessel revascularization</td>
<td>1 (0.6)</td>
<td>6 (4.3)</td>
</tr>
<tr>
<td>Conventional end point (stroke or death at 30 days plus ipsilateral stroke or death from neurologic causes within 31 days to 1 yr)</td>
<td>9 (5.5)</td>
<td>13 (8.4)</td>
</tr>
<tr>
<td>Primary end point (death, stroke, or myocardial infarction at 30 days plus ipsilateral stroke or death from neurologic causes within 31 days to 1 yr)</td>
<td>20 (12.2)</td>
<td>32 (20.1)</td>
</tr>
</tbody>
</table>

* Patients may have had more than one event. P values were determined by the log-rank test. Rates of adverse events were estimated with the use of the Kaplan–Meier method.

NEJM 2004;351:1493-501
Sapphire:
Death/Stroke/MI within 30 d, ipsilateral CVA between 31-365 days

CAS Superior

NEJM 2004;351:1493-501
Sapphire: Cumulative % of Stroke

No advantage of CEA over CAS in efficacy

LR p=0.945

<table>
<thead>
<tr>
<th>Time (Days)</th>
<th>Cumulative % of Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Days</td>
<td>Stent: 3.6%, CEA: 3.0%</td>
</tr>
<tr>
<td>360 Days</td>
<td>Stent: 4.9%, CEA: 5.8%</td>
</tr>
<tr>
<td>720 Days</td>
<td>Stent: 6.3%, CEA: 6.7%</td>
</tr>
<tr>
<td>1080 Days</td>
<td>Stent: 7.1%, CEA: 6.7%</td>
</tr>
</tbody>
</table>

NEJM 2005;112:416
Standard Risk US RCT of CAS vs. CEA: CREST

- Landmark NINDS/NIH sponsored, prospective, MC, RCT
- Independent angio, EKG, MI, US core labs; ind. neuro eval
- 53% symptomatic, 47% asymptomatic
- Only 52% CAS operators were accepted into trial
- Required surgeons to achieve stroke/death rate of <3% for asymptomatic, <6% symptomatic patients
- Began in 2000, completed enrollment in 2008
- 1st generation stent/EPD; early CAS experience

NEJM 2010;363:11-23
## CREST: Composite Primary Endpoint of Death/Stroke/MI Within 30 Days

<table>
<thead>
<tr>
<th>Per Protocol</th>
<th>CAS N=1,131</th>
<th>CEA N=1,176</th>
<th>Difference</th>
<th>p=value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Death, Stroke, or MI</td>
<td>5.8%</td>
<td>5.1%</td>
<td>0.7%</td>
<td>0.52</td>
</tr>
<tr>
<td>Death</td>
<td>0.53%</td>
<td>0.26%</td>
<td>0.27%</td>
<td>0.33</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>4.1%</td>
<td>1.9%</td>
<td>2.2%</td>
<td>0.0019</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.9%</td>
<td>0.4%</td>
<td>0.5%</td>
<td>0.20</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>3.2%</td>
<td>1.5%</td>
<td>1.7%</td>
<td>0.0088</td>
</tr>
<tr>
<td>MI</td>
<td>2.0%</td>
<td>3.4%</td>
<td>-1.5%</td>
<td>0.0387</td>
</tr>
</tbody>
</table>
Primary Composite Endpoint for Asymptomatic Status

Primary Endpoint = Death/Stroke/MI

- CAS: 5.3%
- CEA: 5.6%
Neurological Residual Deficits by mRS Associated With Minor Strokes: Similar at 6 Months
Lack of Association of Minor Stroke With Long Term Mortality

NEJM 2010;363:11-23
Peri-op MI carries significant mortality risk!
Similar Association of Any Stroke or MI on Long Term Mortality

![Graph showing freedom from all cause mortality over time for different groups including control, MI, and any stroke, with percentages at 365, 730, 1095, and 1460 days.]
CREST- Primary Outcome- 4 Years

CREST: 90% of subjects: no difference between therapies

$P_{interaction} = 0.020$

NEJM 2010;363:11-23
CREST 1° Endpoint at 4 Years

*Periprocedural Death, Stroke, MI PLUS Ipsilateral Stroke at 4 Years

p=ns

NEJM 2010;363:11-23
CREST Conclusions

- CAS non-inferior to CEA for the primary endpoint of death/stroke/MI
- CAS shows similar durability to CEA by freedom from primary endpoint, mortality, ipsilateral stroke and TLR to 4 years
- CAS less invasive, avoids CN injury
## ACT-1: RCT of CEA vs. CAS in Standard Surgical Risk Patients: CAS Lead-in Outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>30 days, N=118</th>
<th>31-365 days, N=77</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, Stroke, MI</td>
<td>1.7%</td>
<td></td>
</tr>
<tr>
<td>All Stroke and Death</td>
<td>1.7%</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>1.7%</td>
<td></td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>1.7%</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>0.0%</td>
<td></td>
</tr>
</tbody>
</table>

Contemporary, ongoing trial with modern devices, experienced operators.
Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences. (Level of Evidence: C)
Recommendations for Selection of Asymptomatic Patients for Carotid Revascularization

1. **Class IIa**
   2. It is reasonable to perform CEA in asymptomatic patients who have more than 70% stenosis of the internal carotid artery if the risk of perioperative stroke, MI, and death is low.74,76,359,361–363 (Level of Evidence: A)
   3. It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention.360,364–368 (Level of Evidence: B)
   4. It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery.369–373 § (Level of Evidence: B)
Conclusions

- You should screen for CVD- CDUS best initial test
- Aggressively treat risk factors with ASA, statins, ACE/ARB, diet, exercise, intensive glucose control, smoking cessation aids
- Asymptomatic patients with ≥80% ICA stenosis should be referred for revascularization; there is NO level 1 evidence that medical therapy is better than/equal to revascularization
- CAS ~ CEA for standard risk patients, preferred for high surgical risk patients, younger patients
Thanks for your attention!
Recommendations for Selection of Asymptomatic Patients for Carotid Revascularization

1. **Class IIb**
   
   2. Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established.360 (Level of Evidence: B)

   3. In symptomatic or asymptomatic patients at high risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established.35·361·362·366·369·372·375·376 (Level of Evidence: B)