GET YOUR FACTS FIRST
THEN YOU CAN DISTORT THEM AS YOU PLEASE

Mark Twain
Why Screen?

• “... If detected early, they stand a reasonable chance of being cured, whereas if not diagnosed until the patients come to the hospital with clear-cut symptoms they may be incurable. ... it would seem that the practice of screening for disease would be widespread. That it is not so to the extent that might be expected is due to a number of factors, among them the cost of screening, and the tendency of the medical profession to wait for patients rather than actively look for disease in the population. Another factor undoubtedly is inadequate knowledge of the principles and practice of screening for disease.”

Wilson, WHO Public Health Paper, 1968
Principles of screening

• The screening program should respond to a recognized need.
• The objectives should be defined at the outset
• There should be a defined target population.
• There should be scientific evidence of screening program effectiveness
• The natural history of the disease should be understood, and an agreed policy on who to treat.
• “The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole.”

WHO, Princ of Screen, 2008
Cost-effectiveness

• “Cost-effectiveness analysis is a method for assessing the gains in health relative to the costs of different health interventions. The basic calculation involves dividing the cost of an intervention in monetary units by the expected health gain measured in natural units, such as number of lives saved.”
Medicare Part B screening

- Abdominal aortic aneurysm
  - You have a family history of abdominal aortic aneurysms.
  - You're a man age 65 to 75 and have smoked at least 100 cigarettes in your lifetime.

- Mammography

- Prostate cancer

- Lung cancer
  - They're 55-77.
  - They're asymptomatic (they don't have signs or symptoms of lung cancer).
  - They're either a current smoker or have quit smoking within the last 15 years.
  - They have a tobacco smoking history of at least 30 “pack years” (an average of one pack a day for 30 years).

WHO, Princ of Screen, 2008
Why not screen for carotid artery disease?
Stroke Incidence

• 750,00 CVA/year: 20-30% associated with extracranial CAS
• 3rd most common cause of death.¹
• Leading cause of disability.¹
• 5 year survival 56% for men, and 64% for women.²

¹ Sacco, Ischemic Stroke 1994
² Sacco, Stroke 1982
Stroke Cost

- Stroke responsible for 500,000+ hospitalizations annually.
- Estimated 6,000,000+ stroke survivors in the U.S.
- Recurrent stroke risk 4 – 15% at 1 year, and 25% at 5 years.
- Annual health care cost estimated at $68 billion.
- Ancillary and emotional costs associated with lifelong disability cannot be calculated.
ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline

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


Developed in Collaboration With the American Academy of Neurology and Society of Cardiovascular Computed Tomography
Indications for Carotid Duplex

- Cervical bruit in an asymptomatic patient
- Follow-up of known stenosis (>50%) in asymptomatic individuals
- Vascular assessment in a patient with multiple risk factors for atherosclerosis
- Stroke risk assessment in a patient with CAD or PAD
- Amaurosis fugax
- Hemispheric TIA
- Stroke in a candidate for carotid revascularization
- Follow-up after a carotid revascularization procedure
- Intraoperative assessment during CEA or stenting
“FACTS ARE STUBBORN, BUT STATISTICS ARE MORE Pliable.”

MARK TWAIN

© Lifehack Quotes
Screening for Asymptomatic Carotid Artery Stenosis: U.S. Preventive Services Task Force Recommendation Statement

Michael L. LeFevre, MD, MSPH, on behalf of the U.S. Preventive Services Task Force*

Description: Update of the 2007 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for carotid artery stenosis.

Methods: The USPSTF commissioned a systematic review to synthesize the evidence on the accuracy of screening tests, externally validated risk-stratification tools, the benefits of treatment of asymptomatic carotid artery stenosis with carotid endarterectomy (CEA) or carotid angioplasty and stenting (CAAS), the benefits from medications added to current standard medical therapy, and the harms of screening and treatment with CEA or CAAS.

Population: This recommendation applies to adults without a history of transient ischemic attack, stroke, or other neurologic signs or symptoms.

Recommendation: The USPSTF recommends against screening for asymptomatic carotid artery stenosis in the general adult population. (D recommendation)


For author affiliation, see end of text.

* For a list of USPSTF members, see the Appendix (available at www.annals.org).

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GRADE D RECOMMENDATION!
USPSTF recommendations

• Methodology appears biased – “the benefits from medications added to current medical therapy, and the harms with screening or treatment with either CEA or CAAS.”

• “Asymptomatic CAS causes a relatively small number of strokes.”

• “Ultrasonography yields many false positive results in the general population.”

• Assume the incidence of disease in the general population is <1%, yet do not stratify for risk.

• None of the board members are physicians who care for patients with stroke.
• Population based screening study from Korea; 3030 patients over the age of 50.
• Incidence of moderate to severe CAS was 1.1%
• Risk factors; age >80 (OR 8.1), male sex (OR 2.1), HTN (OR 1.72), dyslipidemia (OR 1.84).
Who should be screened?

“I try to eat healthy. I never sprinkle salt on ice cream, I only eat decaffeinated pizza and my beer is 100% fat free.”
Carotid stenosis Incidence

- Framingham Study: >50% stenosis in pts older than 66; 7% in women and 9% in men.
- 1991 Swedish study showed a 3% incidence of stenosis greater than 50% in patients over the age of 60.
- University of Washington study from 1984 showed an 8% incidence of significant disease in pts referred to the vascular lab.
- Meta analyses estimates a 5% incidence in patients over the age of 60.
A model for predicting occult carotid artery stenosis: screening is justified in a selected population☆


Glenn R Jacobowitz, MD, Caron B Rockman, MD, Paul J Gagne, MD, Mark A Adelman, MD, Patrick J Lamparello, MD, Ronnie Landis, RN, Thomas S Riles, MD

- Prospective study analyzing patients > age 60, with a h/o smoking, heart disease, HTN, and dyslipidemia.
- Hemodynamically significant disease found in 9.6%.

<table>
<thead>
<tr>
<th>No. of risk factors</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>54</td>
<td>156</td>
<td>133</td>
<td>48</td>
<td>3</td>
</tr>
<tr>
<td>% carotid stenosis</td>
<td>1.8</td>
<td>5.8</td>
<td>13.5</td>
<td>16.7</td>
<td>66.7</td>
</tr>
</tbody>
</table>

JVS, 2003
Conventional Carotid duplex

- ‘Gold Standard’
- Cost – $3 -500/study
- Exam time 1 hour, and requires trained specialists to perform and interpret
- Readily available in most hospitals.
- Sensitivity and specificity of over 90%
Life Line Screening

• Commercial vascular screening:
  – Carotid ultrasound, AAA ultrasound, PAD ankle brachial index, ECG for AF
• Screened 8M people in USA, UK and Ireland
• USA
  – Started in 1993
  – Screen ~750,000 adults per year
• UK & Ireland
  – Started in 2007
  – Screen ~50,000 adults per year

http://www.lifelinescreening.co.uk/
• Testing takes less than 1 hour. Results usually available within 1 – 3 weeks.
• Small, non-randomized studies have shown correlation with conventional duplex US.
• ‘For profit company’
• No physician on site. Technologists are registered or ‘eligible’
• No established oversight, or standardized quality control measures.
• May give patients a false sense of security.
‘Limited’ carotid duplex

- Designed as a rapid, cost effective approach to assess the carotid bifurcation.
- Assess for PSV > 125 cm/s
- 1014 vessels studied
- Average exam time of 3.2 m
- Sensitivity 86%, Specificity 98%
- PPV 95%
- Limited screening studies recommended for high risk patients.

Carsten, et al AJS 1999
DVX

- Authors based their study/device on the presumption of a 5% incidence of CAS in the over 65 age group, a standard carotid duplex cost of $210, and a calculated cost of $4,200 to identify one significant lesion.
- They proposed a low cost screening device that would identify hemodynamically significant disease, that would subsequently be referred for a conventional CD (analogous to screening mammography).
- Device identifies velocities in the region of the carotid bifurcation that are greater than 140 cm/s.
- Can be done in the office. No specialized training necessary.
- 15 minute exam, with a cost of less than $15.
- Estimated cost of finding a greater than 50% stenosis was $1,530.
DVX

- 898 patients studied over an 18 month period.
- 23% referred for conventional duplex
- 16% were found to have >50% stenosis.
- Exam time 4.3 ± 1.8 minutes

Vilkomerson, Proc SPIE 2005
DVX probe

- 6 receivers around transmitter
- Transmitter
- 10 mm diam
DVX

- 1,000 screened patient’s at $15/study = $15,000.
- 23% referral rate – 230 x $210/CUS + $48,300.
- 29 patients who subsequently underwent CEA for >60% stenosis @ $5,300/surgery = $154,000.
- Total cost to screen and treat 1,000 patients = $219,000.
- Assuming stroke rate reduced by 7% = 2.1 strokes prevented.
- Assuming stroke cost of $190,000, savings of $392,000 (net $172K).
- Extrapolating data to the Medicare population, potential cost savings of $4.2 billion

Vilkomerson, AIUM 2010
Carotid screening

- ACAS data – 11% stroke incidence at 5 years in patients with >60% stenosis.
- AVA screening program of 18,446 senior found a 7.4% incidence of >60% stenosis.
- Assuming a stroke rate of <2% associated with CEA, estimated that 200,000 strokes may be prevented by screening.
- Stroke cost $145,000, compared to cost associated with evaluation and management of CAS of $82,000 (-$64,000).
- Overall cost saving potentially of $13 billion/year.

Levenson, JVS 2011
Asymptomatic carotid disease
What do we do with the results?
The Natural History of Carotid Arterial Disease in Asymptomatic Patients With Cervical Bruits


- 2% normal
- 62% less than 50% stenosis
- 32% were severe to critical/4% occluded.
- Mean annual rate of disease progression to moderate or greater was 8%.
- Risk factors associated with disease progression were active tobacco use, DM and age.
Progression of asymptomatic mild carotid artery stenosis: Implications for frequency of surveillance.

Hamilton RD¹, Shield CE¹, Laughrun D².

- Retrospective study over a 10 year period.
- Evaluated patients with 20 – 49% stenosis that were followed with serial DU at 3 and 5 year intervals.
- 440 vessels assessed; 5.45% progressed to moderate disease, 0.02% to severe.
- Decreased use of statin tx in group that progressed.
The value of a carotid duplex surveillance program for stroke prevention.

Cull DL, Cole T, Miller B, Johnson B, Rawlinson D, Walker E, Taylor SM.

- Retrospective review of 3,003 patients following CEA over a 9 year period.
- 11,531 studies, or 3.84 per patient.
- 225 CEA (7.5%), preventing 13 CVA.
- Duplex cost: $332 per study.
- Total cost: $3,830,000, or $290,000 per CVA.
- “… eliminating routine surveillance in the absence of contralateral disease, and limiting number of studies in asymptomatic patients…”
## Table 2. Event Rates in Patients With Carotid Artery Stenosis Managed Without Revascularization

<table>
<thead>
<tr>
<th>Study (Reference)</th>
<th>No. of Patients</th>
<th>Symptom Status</th>
<th>Stenosis, %</th>
<th>Follow-Up</th>
<th>Medication Therapy</th>
<th>Endpoint</th>
<th>Event Rate Over Study Period (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Observational studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hertzer et al.78</td>
<td>290</td>
<td>Asymptomatic</td>
<td>$\geq 50$</td>
<td>33–38 mo</td>
<td>Aspirin or dipyridamole (n=104); or anticoagulation with warfarin (n=9); or no medical treatment (n=82)</td>
<td>Death TIA Stroke</td>
<td>22.0, or 7.33 annualized 8.21, or 2.74 annualized 9.23, or 3.1 annualized</td>
</tr>
<tr>
<td>Spence et al.79</td>
<td>168</td>
<td>Asymptomatic</td>
<td>$\geq 60$</td>
<td>$\geq 12$ mo</td>
<td>Multiple, including antiplatelet, statins, exercise, Mediterranean diet, ACE inhibitors</td>
<td>Stroke</td>
<td>3.8, or 1.3 annualized</td>
</tr>
<tr>
<td>Marquardt et al.80</td>
<td>1153</td>
<td>Asymptomatic</td>
<td>$\geq 50$</td>
<td>Mean 3 y</td>
<td>Multiple, including antiplatelet, anticoagulation, statin, antihypertensive drugs</td>
<td>Ipsilateral stroke</td>
<td>0.34 (95% CI 0.01 to 1.87) average annual event rate</td>
</tr>
<tr>
<td>Abbott et al.81</td>
<td>202</td>
<td>Asymptomatic</td>
<td>60–90</td>
<td>Mean 34 mo</td>
<td>Multiple, including antiplatelet, warfarin, antihypertensive drugs, cholesterol-lowering therapy</td>
<td>Ipsilateral stroke or TIA; ipsilateral carotid hemispheric stroke</td>
<td>Ipsilateral stroke or TIA or retinal event: 3.1 (95% CI 0.7 to 5.5) average annual rate; ipsilateral carotid hemispheric stroke: 1.0 (95% CI 0.4 to 2.4) average annual rate</td>
</tr>
</tbody>
</table>
Conclusions

• Stroke is one of the leading causes of death and disability in industrialized nations.

• There are identifiable risk factors that predispose patients for carotid stenosis, which is responsible for up to 1/3 of all strokes.

• There is an accepted screening exam in place that is minimally invasive, and has a proven strong degree of sensitivity and specificity.

• Cost-effective alternatives to conventional carotid duplex already exist.

• Screening selected patients could result in potential health care savings costs in the billions.
Conclusions

• Mild, asymptomatic disease typically has a benign course with appropriate medical therapy.

• Moderate to severe disease should continue to be followed on at least a yearly basis.

• Current surveillance strategies are likely too conservative, though the frequency of follow-up care has yet to be determined.
Thank you