How Duplex Ultrasound Screening Can Lead to Overuse of Carotid Interventions

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No Disclosures

Low Prevalence of Disease
Low Virulence of Disease/Low Therapeutic Index of Intervention
Poor Specificity Screening Test

Prevalence ≥70% Asymptomatic ICA Stenosis*

*Stroke 2010;41:1294-1297
**Prophylactic Carotid Intervention**

- Background of better medical management of atherosclerosis.
- Increased use of Plavix, statin medications, beta blockers and ace inhibitors.
- Differences between surgical and medical management of ICA high-grade stenosis may therefore be even less pronounced than those suggested by the random trials.

**Statins and Ischemic Stroke**

- Meta analysis of 90,056 participants in 14 randomized trials of statin therapy.
- 22% reduction in first ischemic stroke per mmol/L reduction in LDL cholesterol.
- Independent of previous MI or CAD.

**Prophylactic Carotid Intervention**

- The estimated current risk of stroke in patients with asymptomatic carotid stenosis is 0.5% per year.
- Lower than the risk of CEA in CREST or stenting in CREST and the recently published ACT 1 trial.
- Unlike symptomatic disease, the severity of stenosis in patients with asymptomatic stenosis does not reliably predict stroke risk.

**Prophylactic Carotid Intervention**

- Following results of the randomized trials of carotid surgery use carotid endarterectomy increased.
- Carotid stenting initially also took off driven primarily by industry.
- Up to 92% of carotid interventions in the United States are now performed for asymptomatic disease.
Prophylactic Carotid Intervention

- There is at best only a small benefit of prophylactic carotid intervention in asymptomatic patients.

- Carotid intervention is often based only on duplex scanning without other preprocedure diagnostic modalities.

Threshold Levels vs Categories of Stenosis

• Categories of Stenosis: The degree of stenosis is identified as being between high and low values.

• Threshold Levels of Stenosis: The degree of stenosis is identified as being above or below a threshold value.

Threshold Level vs Categories of Stenosis

• The use of relatively broad categories of stenosis reflects the fact duplex cannot predict stenosis in fine increments.

• One can therefore develop categories of stenosis with acceptable sensitivities and specificities where changes between categories are potentially clinically meaningful and reproducible.

• Natural history of the disease.

Threshold Level vs Categories of Stenosis

• Threshold levels of stenosis can be used to determine whether a patient is an anatomic candidate for an intervention using duplex scanning as the sole imaging modality prior to the intervention.

  - Above the line: yes!
  - Below the line: no!

• Predictive values and the therapeutic index of the procedure are more important when using threshold levels.
SRU Carotid Duplex Consensus Conference
(Determination of Percent Stenosis)

“NASCET” Based Criteria for ICA Stenosis

Carotid Duplex Consensus Conference

- Society of Radiologists in Ultrasound
- 16 panelists: Radiology, Vascular surgery, Cardiology and Neurology
- Goals of conference:
  - Develop recommendations for performance of exam
  - Standardization of technical factors
  - Recommend defined diagnostic criteria for ICA stenosis

Carotid Duplex Consensus Conference
Participants
Moderator: Ed Grant*

Andrei Alexandrov
J. Dennis Baker
Carol Benson*
Ed Bluth
Barbara Carroll
Michael Eliasziw
John Gocke
Barbara Hertzberg
Sandra Katanick
Gregory Moneta*
Larry Needleman
John Pellerito
Joe Polak
Ken Rholl
Doug Wooster
Gene Zierler

* = Writing Committee
Carotid Duplex Consensus Conference

(SRU Suggested Criteria for Duplex Diagnosis of ICA Stenosis)

<table>
<thead>
<tr>
<th>Degree of Stenosis (%)</th>
<th>ICA PSV (cm/s)</th>
<th>Peak Systolic Velocity (cm/s)</th>
<th>EDV (cm/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>47.8</td>
<td>31.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Moderate</td>
<td>14.3</td>
<td>58.6</td>
<td>1.9</td>
</tr>
<tr>
<td>Severe</td>
<td>10.5</td>
<td>104.8</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Society Radiologists in Ultrasound (SRU) Consensus Conference

OHSU Criteria for >60 – 99% ICA Stenosis

(n = 352 angio/ duplex comparisons)

- ICA PSV ≥ 290cm/s and EDV ≥ 80cm/s

- Sensitivity: 78%
- Specificity: 96%
- PPV: 95%
- NPV: 92%
- Accuracy: 88%

* >70% ICA Stenosis

Radiology 2003; 229: 340-346
A PSV of 230 cm/sec maximizes sensitivity for detection of >70% ICA stenosis likely at the expense of higher numbers of false positives.

For symptomatic patients one can argue this is irrelevant as NASCET also indentified >50% to 69% symptomatic ICA as benefiting from CEA.

For asymptomatic patients this my be unacceptable as potentially many patients with less than 70% stenosis could be subject to a procedure of now marginal or even uncertain or no benefit!

Follow-up Asymptomatic Carotid Stenosis (OHSU Study)

- NIH sponsored trial of the effects of folate supplementation on PAD
- 562 subjects were entered and randomized
- 87 subjects met inclusion criteria with an ICA PSV between ≥230 and 300 cm/s
- Mean follow-up 27.4 months; range 4-102 months

Follow-up Asymptomatic Carotid Stenosis (OHSU Study)

- 44/87 (50.6%) subjects remained <290 cm/s during follow-up (Non-progression group) (Mean F/U = 34.8m)
- 43/87 (49.4%) subjects progressed beyond 290 cm/s during follow-up (Progression group) (Mean F/U = 32m)
- Mean time to progression: 19.9 months (range 6 – 60 months)

Follow-up Asymptomatic Carotid Stenosis (OHSU Study)

- Subjects were followed every 6 months with clinical history and physical exam screening for new neurologic symptoms
- Carotid artery duplex scanning every 6 months
- Subjects assessed for progression of ICA PSV to >300 cm/s
**Vascular Laboratory Endpoint and Operative Intervention**

- Progression Non-progression
- Operative
- Non-operative

**Clinical Endpoint Progression**

- Ipsilateral CVA, TIA, AF
- Asymptomatic
- 84/87 (96.6%)
- 3/87 (3.4%)

**Ipsilateral Stroke**

- 3/87 subjects had ipsilateral stroke
- 2 strokes occurred after progression of ICA PSV to >300 cm/s
  - One patient refused operative intervention
  - One patient was unfit for intervention

**Multivariate Logistic Regression Analysis**

for Progression to >300 cm/s

- Age
- Gender
- Diabetes (OR=.25)
- Tobacco
- Hypertension
- Statin
- Ipsilateral PSV
- Contralateral PSV (OR=.99)

- p = .72
- p = .29
- p = .03
- p = .70
- p = .53
- p = .39
- p = .21
- p = .04
Conclusions

- Diabetes and an elevated contralateral PSV are independent risk factors associated with vascular laboratory determined progression of ICA stenosis.

- In subjects with ICA PSV 230 to 300 cm/s the 2-year risk of ipsilateral stroke or TIA is <2%.

Conclusions

- Categories of stenosis as carotid criteria have proven useful in natural history studies of carotid atherosclerosis and in clinical monitoring of individual patient’s level of ICA stenosis.

- Use of threshold levels of stenosis as carotid stenosis criteria may facilitate clinical decision making for potential intervention.

Conclusions

- The therapeutic index for intervention is likely too low to justify PCI for an ICA PSV >230 cm/s as the minimum cut point.

- Use of the SRU Consensus Conference recommendation of ICA PSV >230 cm/s as diagnostic of ICA stenosis >70% in asymptomatic patients will result in overuse of prophylactic carotid intervention.

Questions?