Carotid Interventions Should Not be Based on Consensus Duplex Velocity Criteria:
More Stringent Criteria Can Reduce Unnecessary Procedures and Show the Value of Interventions in CREST 2

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Variation in Carotid Duplex Criteria

What is the natural history of these patients?

230 cm/sec
DHMC 430 cm/sec

Thanks to Co-authors on this work:

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Objectives

• To report the natural history of patients who may have undergone CEA or CAS at other institutions but were treated medically based on more conservative CDUS criteria.

• To determine the fraction of strokes in this population that are potentially preventable by prophylaxis with CEA or CAS (i.e., carotid-etiology strokes).

Methods

• All patients who underwent CDUS from January 1st to December 31st 2009 were reviewed.

  Inclusion:
  ICA PSV ≥230 cm/sec

  Exclusion:
  Symptomatic at presentation
  Prior ipsilateral intervention (CEA/CAS)
  ≥80% stenosis by DHMC criteria

  Endpoints:
  • Freedom from progression to TIA
  • Freedom from any stroke
  • Freedom from revascularization
  • Freedom from carotid-etiology stroke

Disclosures

• None related to this work
Patient Characteristics: n=327

<table>
<thead>
<tr>
<th>Variable</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean 73 (44 – 96)</td>
</tr>
<tr>
<td>Male</td>
<td>51%</td>
</tr>
<tr>
<td>HTN</td>
<td>96%</td>
</tr>
<tr>
<td>CAD</td>
<td>45%</td>
</tr>
<tr>
<td>CHF</td>
<td>14%</td>
</tr>
<tr>
<td>COPD</td>
<td>22%</td>
</tr>
<tr>
<td>CKD</td>
<td>37%</td>
</tr>
<tr>
<td>DM</td>
<td>33%</td>
</tr>
<tr>
<td>Smoking</td>
<td>85%</td>
</tr>
<tr>
<td>Antiplatelet Therapy</td>
<td>94%</td>
</tr>
<tr>
<td>Statin</td>
<td>80%</td>
</tr>
<tr>
<td>Contralateral &gt;80% Stenosis</td>
<td>9%</td>
</tr>
<tr>
<td>Contralateral Occlusion</td>
<td>6%</td>
</tr>
<tr>
<td>Contralateral Revascularization</td>
<td>16%</td>
</tr>
</tbody>
</table>

Patient Cohort and Results

ICA PSV ≥230 cm/sec n=426
Included Patients n=327
Symptomatic or ≥80% stenosis n=99

Stroke due to any cause: n=16 of 327 patients
- Non-carotid: n=12
  - Major: n=10
  - Minor: n=2
- Carotid: n=4
  - Management:
    - Medical: n=12

Freedom From TIA

TIA: n=17 of 327 patients
- Cortical: n=11
- Ocular: n=6
- No TIA progressed to stroke
- Management:
  - CEA: n=12
  - Medical: n=5

Freedom From Any-Cause Stroke

Stroke due to any cause: n=16 of 327 patients
- Non-carotid: n=12
  - Major: n=10
  - Minor: n=2
- Carotid: n=4
  - Management:
    - Medical: n=12

Freedom From Carotid-Etiology Stroke

Carotid-Etiology Stroke: n=4 of 327 patients
- Stroke severity
  - Major: n=2
  - Minor: n=2
- Management:
  - CEA: n=1
  - Medical: n=3

Freedom From Revascularization

Revascularization: n=59 of 327 patients
- CEA: n=56
- CAS: n=3
- Indication:
  - Asymptomatic Progression: n=46
  - TIA: n=12
  - Stroke: n=1
Cox Proportional Hazards Model

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard Ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Stroke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>4.4 (1.3 – 15)</td>
<td>0.02</td>
</tr>
<tr>
<td>Contralateral CEA</td>
<td>4.2 (1.4 – 13)</td>
<td>0.01</td>
</tr>
<tr>
<td>TIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAD</td>
<td>4.6 (1.5 – 14)</td>
<td>0.007</td>
</tr>
<tr>
<td>Progression to PSV &gt;430 cm/sec</td>
<td>3.8 (1.3 – 11)</td>
<td>0.02</td>
</tr>
<tr>
<td>Baseline PSV &gt;302 cm/sec</td>
<td>3 (1.04 – 8.5)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Note: There were not enough events to analyze predictors of carotid-etiologic stroke.

Summary

- Asymptomatic patients with intermediate carotid stenosis (ICA PSV 230 – 429 cm/sec) have a very low incidence of stroke attributable to the ipsilateral carotid artery.

- Even when accounting for TIA and asymptomatic progression of disease, less than 20% of patients in this cohort underwent carotid intervention.

Conclusions

- Patients with intermediate asymptomatic carotid stenosis (ICA PSV 230 – 429 cm/sec) do well with medical therapy when carefully monitored and intervened upon using conservative duplex criteria.

- Utilizing the Consensus Criteria correlating a PSV of 230 cm/sec with a stenosis of 70% would lead to a large number of surgical procedures in patients who could have safely undergone medical therapy with close surveillance.

Implications for CREST 2

- CREST 2 criteria:
  - PSV >230 cm/s AND EDV >100 cm/s OR ICA/CCA >4.

- Half of the patients in our study met CREST 2 criteria.

- Sub-analysis of the CREST 2 Cohort produced nearly identical results (p=NS). Carotid-etiologic stroke rate <2% at 5 years.

Implications for CREST 2

- If CREST 2 enrolls primarily patients with intermediate asymptomatic carotid stenosis (ICA PSV 230 – 429 cm/sec) the stroke rate in the medical therapy arm will not differ from the intervention arm – due to low stroke rate, and strokes that are not carotid-etiologic.

- CREST 2 must enroll patients with high velocities (PSV >430 cm/sec, EDV >150 cm/sec, and/or ICA/CCA ratio >7.5) in order to show the benefit of carotid interventions. Treatment of asymptomatic progression may also be a key issue.

Thank You