Carotid Artery Stenting
Cervical Approach

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Disclosure

Speaker name: Wael Tawfick

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☑️ I do not have any potential conflict of interest
New NICE guideline on acute stroke and TIA: need for major changes in delivery of stroke treatment

D J Werring and M M Brown

Heart 2009;95;841-843; originally published online 4 Mar 2009;
doi:10.1136/hrt.2009.167676

CONTROVERSIAL ASPECTS

Some of the NICE recommendations differ from the previous National Stroke Strategy (NSS), which may be because the NICE aspirational document is strictly evidence-based, whereas the NSS is an stroke services in the UK. In the NSS, carotid endarterectomy is recommended within 48 h, by contrast with the 2-week target in the NICE guideline. The latter represents the timescale for which there is good evidence that early intervention is beneficial. There are no data suggesting that the outcome is better for very early endarterectomy within 48 h, and indeed there is evidence that it can be harmful, especially in patients with unstable symptoms,
Recommendations

1. For patients with recent TIA or ischemic stroke within the past 6 months and ipsilateral severe (70% to 99%) carotid artery stenosis, CEA is recommended if the perioperative morbidity and mortality risk is estimated to be <6% (Class I; Level of Evidence A).

2. For patients with recent TIA or ischemic stroke and ipsilateral moderate (50% to 69%) carotid stenosis, CEA is recommended depending on patient-specific factors, such as age, sex, and comorbidities, if the perioperative morbidity and mortality risk is estimated to be <6% (Class I; Level of Evidence B).

3. When the degree of stenosis is <50%, there is no indication for carotid revascularization by either CEA or CAS (Class III; Level of Evidence A).

4. When CEA is indicated for patients with TIA or stroke, surgery within 2 weeks is reasonable rather than delaying surgery if there are no contraindications to early revascularization (Class IIa; Level of Evidence B).
Stroke and death after carotid endarterectomy and carotid artery stenting with and without high risk criteria

In the United States over a period of 4 years, CAS has a higher risk of stroke & death than CEA after adjustment for medical high risk criteria

stroke, transient ischemic attack (TIA), and/or amaurosis fugax. The primary outcome was postoperative death, stroke (complication code 997.02), and combined stroke or death, stratified by high risk vs non-high risk status and symptom status.

Results: Patient totals of 56,564 (10.5%) CAS and 482,394 (89.5%) CEA were identified. Half of the patients in each group were high risk. CABG/V was performed less commonly with CAS than CEA (2.8% vs 4.0%, P < .001). Patients undergoing CAS were more likely symptomatic than those undergoing CEA (13.1% vs 9.4%, P < .001). Mortality was higher after CAS than CEA for both high risk and non-high risk patients. Stroke was also higher after CAS for both high risk and non-high risk patients. Combined stroke or death was higher after CAS again for both high risk (asymptomatic 1.5% vs 1.2%, P < .05, symptomatic 14.4% vs 6.9%, P < .001) and non-high risk (asymptomatic 1.8% vs 0.6%, P < .001, symptomatic 11.8% vs 4.9%, P < .001). Combined stroke or death for patients undergoing CABG/V during the same admission was similar for CAS and CEA (4.8% vs 3.2%, P = .19). Multivariate predictors of combined stroke or death adjusted for age and gender included CAS vs CEA (odds ratio [OR] 2.4, P < .001), symptomatic status (OR 6.8, P < .001), high risk (OR 1.6, P < .001), and earlier year of procedure (OR 1.1, P < .01).

Conclusions: In the United States from 2004 to 2007, CAS has a higher risk of stroke and death than CEA after adjustment for medical high risk criteria. Further analysis with prospective assessment of risk factors is needed to guide appropriate patient selection for CEA and CAS in the general population. (J Vasc Surg 2010;)}
Outcomes of carotid stenting compared with endarterectomy are equivalent in asymptomatic patients and inferior in symptomatic patients

Jeannine K. Giacovelli, MD, MPH, a Natalia Egorova, PhD, MPH, a Rajeev Dayal, MD, b Annette Geligns, PhD, a James McKinsey, MD, b and K. Craig Kent, MD, c New York, NY; and Madison, Wisc

Background: Despite the current Centers for Medicare and Medicaid Services coverage criteria for carotid artery stenting (CAS), consensus regarding its appropriateness in patients with carotid artery stenosis has not been reached. This is one of the first population-based studies to use a dedicated administrative convention for the endovascular procedure to address whether there is a cohort of patients in whom CAS is more beneficial than carotid endarterectomy (CEA).

Methods: We analyzed in-hospital mortality, postoperative stroke, and combined postoperative stroke/mortality in 47,752 CAS or CEA hospitalizations, matched by propensity score, in discharge data sets obtained from the states of New York and California for the years 2005 to 2007. Other outcomes included postoperative complications, length of stay, and volume-outcome relationships.

Results: For symptomatic patients undergoing CAS, rates were significantly higher for in-hospital mortality (3.7% vs 1.3%) and combined stroke/mortality (8.3% vs 4.6%) compared with CEA. For asymptomatic patients, there was no statistical difference between mortality (0.6% vs 0.4%), stroke (2.0% vs 1.8%), or combined stroke/mortality (2.4% vs 1.9%) across the endovascular and open procedures, respectively. Postoperative respiratory and urinary complications as well as cranial neuropathy were more common after CEA, whereas postoperative complications, including device malfunction and hypotension, were more frequent after CAS. We did not find a volume-outcome relationship for CEA, but one did exist for CAS.

Conclusions: In symptomatic patients with carotid artery stenosis, the most appropriate procedure appears to be CEA, whereas CAS appears to be a suitable minimally invasive approach for asymptomatic patients. On the basis of these results and data from recent multicenter randomized trials, the use of CAS in symptomatic patients should be approached with caution. (J Vasc Surg 2010;52:906-13.)
Mechanisms to explain the poor results of carotid artery stenting (CAS) in symptomatic patients to artery stenosis and to determine the pathogenetic mechanism(s) associated with stroke following the treatment of such lesions. Based on this, we propose steps to improve the results of CAS for the treatment of symptomatic carotid stenosis. 

Methods: PubMed/Medline was searched up to March 25, 2010 for studies investigating the efficacy of CAS for the management of symptomatic carotid stenosis. Search terms used were “carotid artery stenting,” “symptomatic carotid artery stenosis,” “carotid endarterectomy,” “stroke,” “recurrent carotid stenosis,” and “long-term results” in various combinations.

Results: Current data suggest that CAS is not equivalent to CEA for the treatment of symptomatic carotid stenosis. Differences in carotid plaque morphology and a higher incidence of microemboli and cerebrovascular events during and after CAS compared with CEA may account for these inferior results.

Conclusions: Currently, most symptomatic patients are inappropriate candidates for CAS. Improved CAS technology referable to stent design and embolic protection strategies may alter this conclusion in the future. (J Vasc Surg 2010; 7158.)

All symptomatic patients are inappropriate candidates for CAST

Improved CAS technology is required
Tensile Strength of Symptomatic Carotid Atherosclerotic Plaque
Symptomatic Carotid Plaque
True Stress Vs True Strain

- Desired lumen after CAST = 30% lumen-gain
- True strain to open a Carotid stent = 86%
- Graph shows complete plaque rupture occurs at 49%
- Stenting was not an option with any symptomatic Carotid patient tested

CAST and Embolisation

<table>
<thead>
<tr>
<th>PERI-PROCEDURE</th>
<th>POST</th>
</tr>
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<tbody>
<tr>
<td>ACCESSING THE SITE</td>
<td>MAINTAINING THE SITE</td>
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<tr>
<td>INITIAL ANGIO, SHEATH/GUIDE ACCESS</td>
<td>POST-PROCEDURE PLAQUE STABILITY</td>
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<tr>
<td>PROTECTING THE SITE</td>
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<tr>
<td>EPD PLACEMENT AND DEPLOYMENT</td>
<td></td>
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<tr>
<td>TREATING THE SITE</td>
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<td>PRE-DIL, STENTING, POST-DIL</td>
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<td>EPD RECAPTURE OR REMOVAL</td>
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<tr>
<td>ACCESS DEVICES</td>
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<tr>
<td>EMBOLIC PROTECTION</td>
<td></td>
</tr>
<tr>
<td>IMPLANTS</td>
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</tbody>
</table>

- There are multiple stages in the procedure where emboli release occur.
- CAPTURE 3500: 18% of strokes were non-ipsilateral\(^1\)
- Could more than 30% of strokes be coming from access alone?

\(^1\) Gray, WA, et. Al. TCT’06, CAPTURE 3500, Predictors of Outcomes in Carotid Stenting
## Cast with or without CPD

<table>
<thead>
<tr>
<th></th>
<th>Leicester-1998</th>
<th>Pittsburgh-2008</th>
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<td>CPD</td>
<td>No Filter</td>
<td>Accunet</td>
</tr>
<tr>
<td>Dual Antiplatelet</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Learning Curve</td>
<td>8 cases-Positive</td>
<td>25 cases-Negative</td>
</tr>
<tr>
<td>Clinical stroke</td>
<td>5 out of 7</td>
<td>2 out 18 in CPD</td>
</tr>
<tr>
<td>New MRI Lesions</td>
<td>Abandoned</td>
<td>72% in CPD VS 44% in non CPD</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Need for CPD</td>
<td>No Need for CPD</td>
</tr>
</tbody>
</table>
CPD Meta-analysis

- Thirteen licensed embolic protection devices are currently marketed in Europe
- A Meta-analysis was conducted of each device focusing on features
  - Pore size
  - Guidewire size
  - Fabric of balloon or filter
  - Ability of device to cross tortuous lesions
  - Flow interruption
  - Trouble-shooting during device retrieval

## CPD Meta-analysis

<table>
<thead>
<tr>
<th>Device</th>
<th>Type</th>
<th>Patient</th>
<th>Men%</th>
<th>Age</th>
<th>Procedure</th>
<th>Position Acc.%</th>
<th>Major Stroke</th>
<th>Minor Stroke</th>
<th>Death</th>
<th>Success %</th>
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<tbody>
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<td>Bal. Occlus.(D)</td>
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<td>67</td>
<td>69</td>
<td>412</td>
<td>98</td>
<td>1</td>
<td>5</td>
<td>3</td>
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<td>Paes</td>
<td>Flow reversal</td>
<td>60</td>
<td>60</td>
<td>75</td>
<td>66</td>
<td>93</td>
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<td>93</td>
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<td>3</td>
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<tr>
<td>Filterwire</td>
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<td>75</td>
<td>72</td>
<td>192</td>
<td>95</td>
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<td>1</td>
<td>0</td>
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<td>90</td>
<td>74</td>
<td>34</td>
<td>100</td>
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<td>2</td>
<td>0</td>
<td>93.33</td>
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<td>79</td>
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<td>96</td>
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<td>3</td>
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<tr>
<td>MO.MA</td>
<td>Bal. Occlus.</td>
<td>158</td>
<td>82</td>
<td>71</td>
<td>158</td>
<td>100</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>96.20</td>
</tr>
<tr>
<td>Total</td>
<td>All prot. Devices</td>
<td>1878</td>
<td>74.3</td>
<td>72.6</td>
<td>1914</td>
<td>95.78</td>
<td>8</td>
<td>26</td>
<td>4</td>
<td>94.95</td>
</tr>
</tbody>
</table>
CPD Meta-analysis

• The maximum protection afforded by protection devices is 94% +/- 3%

• Some devices are favourable when crossing the lesion, but have issues when being retrieved

• We could not recommend any single device over another
  • Any positive feature eg. small pore size was accompanied with a negative element eg. difficulties with device retrieval

• All devices increased the brain hits as detected by TCD

Protection or Nonprotection in Carotid Stent Angioplasty: Interventional Techniques on Outcome Data From the 
OLav Jansen, Jens Fiehler, Marius Hartmann and Hartmut 
Stroke 2009;40:841-846; originally published online J 
DOI: 10.1161/STROKEAHA.108.532083 

An erratum has been published regarding this article. Please see 
http://stroke.ahajournals.org/cgi/content/full/strokeahaj 

The Influence of Interventional Techniques 

SPACE trial does not support the need for a PD in CAST 
Stent design seems to have an impact on MACE
Protection Devices did not seem to be effective in preventing cerebral ischemia during stenting.
Hostile Neck

• Previous neck surgery

• Previous radiation

• Uncalculated risk of stroke
  – Difficult dissection
  – Rough manipulation of Carotid
Trans-Femoral CAST
Trans-Cervical CAST
Aim of Study

• To compare CEA to Trans-femoral CAST (F-CAST) and Trans-Cervical CAST (C-CAST) in high-risk patients regarding clinical success, efficacy in decreasing morbidity & mortality

• Composite Primary Endpoints
  • Stroke
  • MI
  • Death

• Secondary endpoints
  • Patency rates
  • Re-intervention Rates
Materials & Methods

• From 2003 till 2015, 1847 patients were evaluated with carotid stenosis >60%

• Multiple Logistic Regression was used to control for co-morbidities & anatomical high-risk factors

• Propensity Scoring was used to adjust for baseline characteristics & selection bias, by matching co-variables, creating a pseudo-randomized control design
# Demographics

<table>
<thead>
<tr>
<th></th>
<th>CEA</th>
<th>F-CAST</th>
<th>C-CAST</th>
<th>P</th>
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<tbody>
<tr>
<td><strong>Number</strong></td>
<td>51</td>
<td>33</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td><strong>Mean Age (years)</strong></td>
<td>68.4+/ -8.0</td>
<td>69.1+/ -9.0</td>
<td>67.4+/ -8.5</td>
<td>0.756</td>
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<tr>
<td><strong>Male %</strong></td>
<td>67%</td>
<td>64%</td>
<td>74%</td>
<td>0.130</td>
</tr>
<tr>
<td><strong>Bilateral Intervention</strong></td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>0.664</td>
</tr>
<tr>
<td>(7.8%)</td>
<td>(6%)</td>
<td>(5.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Contra-lateral Occlusion</strong></td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>0.321</td>
</tr>
<tr>
<td>(5.9%)</td>
<td>(3%)</td>
<td>(5.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Echolucent Plaque</strong></td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>0.427</td>
</tr>
<tr>
<td>(11.8%)</td>
<td>(12%)</td>
<td>(5.2%)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>CEA</td>
<td>F-CAST</td>
<td>C-CAST</td>
<td>P Value</td>
</tr>
<tr>
<td>------------------</td>
<td>-------</td>
<td>--------</td>
<td>--------</td>
<td>---------</td>
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<tr>
<td>Number</td>
<td>51</td>
<td>33</td>
<td>19</td>
<td>NA</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0.037</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>(0%)</td>
<td>(12.1%)</td>
<td>(0%)</td>
<td>0.062</td>
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<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.533</td>
</tr>
<tr>
<td>MI</td>
<td>(1.9%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>0.361</td>
</tr>
<tr>
<td>Combined</td>
<td>(1.9%)</td>
<td>(12.1%)</td>
<td>(0%)</td>
<td>0.041</td>
</tr>
</tbody>
</table>
5-Year stroke free Survival

CEA: 93.3% +/- 8.05%
C-CAST: 92.9% +/- 11.07% (p=0.818, HR=2.25, 95%CI [0.68-2.48])
F-CAST: 87.9% +/- 3.53% (p=0.194, HR=0.88, 95%CI [0.31-2.55])
5-Year overall Survival

CEA: 96.1% +/- 2.13%
C-CAST: 86.4% +/- 4.45% (p=0.736, HR=0.93, 95%CI [0.48-3.79])
F-CAST: 78.8% +/- 6.92% (p=0.548, HR=1.96, 95%CI [0.31-6.82])
5-Year patency

CEA: 63%
C-CAST: 54%
F-CAST: 44%
5-Year re-intervention rates

- CEA: 65%
- C-CAST: 50%
- F-CAST: 45%
Conclusion

- RCTs have been unable to prove superiority / non-inferiority of CAST Vs CEA
- CPDs are being singled out as causes of increased morbidity and elevated risk of stroke
- C-CAST provides a safer option, with significantly less risk of peri-operative stroke and combined stroke/MI/death
Conclusion

• CAST technology is still lagging

• Further understanding of plaque stability and tensile strength is required, in order to achieve the optimum endovascular approach
Thank you
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