New Approach to Carotid Stenting
From high surgical risk patients to low stenting risk patients.

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Lydia Movšensonová – Vítková
18.dubna 1903
27.Prosince 1957
Why in randomized trials there is a low rate of complications in CEA?

1. CEA based on non-invasive studies.
   
   (US, CTA, MRA)

2. “High surgical risk” patients excluded.

3. Cranial nerve palsies are not “complications”
   
   considered “collateral damage”

4. General anesthesia.
   
   covers procedural events
June 03 – Oct. 07  1126 patients admitted for revascularization based on non-invasive studies.

All underwent cervico – cerebral angiography. 350 patients (31%) did not fulfill the criteria for revascularization ($\geq 50\%$ stenosis symptomatic; $\geq 75\%$ asymptomatic)

Eligible for revascularization:  P – 776

<table>
<thead>
<tr>
<th>Risk Level CAS</th>
<th>Risk Level CEA</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>High</td>
<td>49%</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
<td>44%</td>
</tr>
<tr>
<td>High</td>
<td>Low</td>
<td>4%</td>
</tr>
<tr>
<td>High</td>
<td>High</td>
<td>3%</td>
</tr>
</tbody>
</table>
High Surgical Risks

Group 1 (Anatomic)
- High Lesions, Low lesions, prior CEA, Contra Occlusion, prior neck radiation, cervical immobility etc

Group 2 (Co Morbidities)
- Cardiopulmonary (specific criteria), need for surgery etc. Risk of GA.

for CAS not high risk
Rt. Post. CAS. 10. months control.

C2

Rt. Post. CAS.

Rt. 10. months control.
95% LICA
100% RICA

Ankylosing spondylitis
Post radiation stenoses.

Post CAS.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death or Stroke</td>
<td>5.8%*</td>
</tr>
<tr>
<td>Cranial Nerve Palsy</td>
<td>7.6%</td>
</tr>
<tr>
<td>Wound Hematoma</td>
<td>5.5%</td>
</tr>
<tr>
<td>Wound Infection</td>
<td>3.4%</td>
</tr>
<tr>
<td>Cardiac</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

*Adjudication at 30 days.
Cranial Nerve Injury
(Randomized Arm Saphire - 2003)

- CEA = 4.6% (7/151)
- Stent = 0.0% (0/159)

P value = 0.006
Cranial nerve palsy ??

Minor stroke ?  NO
Major stroke ?  NO

= Collateral damage
Achilles heal of randomized trials

1. Length of the trial

2. Changing technology

3. Number and experience of operators
**SPACE** (Lancet 2006; 368:1239-1247)  
CAS – 599  
CEA – 584  
30 day complication/death  
CEA – 6.34%  
CAS – 6.84%  
73% without EPD  
ipsilateral stroke/death longer then 24h  
CEA/CAS = identical  
disabling stroke/death at 30 days  
CEA/CAS = identical

The use of protection devices, predilatation, and balloon size – to the “discretion” of interventionalist  
CRANIAL NERVE PALSIES ??  
Did not show any trends that CAS is safer then CEA

**EVA – 3S** (NEJM 2006; 355:1660-1671)  
CAS – 260  
CEA – 257  
30 day stroke/death  
CEA – 3.9%  
CAS – 9.6%  
(5% failed ??)  
6 months  
CEA 6.1% ??  
CAS 11.7% ??  
High surgical risk excluded from CEA  
17% CAS - predilatation

CRANIAL NERVE PALSIES – 7.7%  
10p – XII.n. 1p – IX.n. 7p – VII.n. 2p – RLn.  
30 days – 1 RLn. 1 XII. (severe)

CEA safer – trial prematurely stopped
Experience – surgeons minimum 25 CEA per year

endovascular in total 12 CAS or from
35 supra aortic 5 CAS

= experienced and supervised less experienced

Appearance of the lesion - no factor in selection

(high stenting risk lesions not excluded)
### ICSS - International Carotid Stenting Study

<table>
<thead>
<tr>
<th></th>
<th>CEA n-853</th>
<th>CAS n-857</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>30 day complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>stroke, MI, death</td>
<td>4% (33)</td>
<td>7.4% (61)</td>
</tr>
<tr>
<td>minor stroke</td>
<td>11</td>
<td>36</td>
</tr>
<tr>
<td><strong>Cranial N palsies</strong></td>
<td>5% (44)</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Significant hematoma</strong></td>
<td>3.2% (28)</td>
<td>0.9% (8)</td>
</tr>
</tbody>
</table>

**In CAS**

| Stent not deployed in | 7.5% (62) |
| EPD no used in        | 24.8% (209) | Experience ?? |
Carotid Revascularization
Endarterectomy vs Stenting Trial
Carotid Revascularization Endarterectomy vs Stenting Trial

427 interventionalists applied

73 (17%) exempt lead – in phase

116 (27%) rejected

238 (56%) selected to participate in lead – phase

14 (6%) rejected

224 (52%) selected to participate in CREST
**Primary Endpoint: peri-procedural components**
(any death, stroke, or MI within peri-procedural period)

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.2</strong> vs. <strong>4.5%</strong></td>
<td>HR = 1.18; 95% CI: 0.82-1.68</td>
<td>0.38</td>
</tr>
</tbody>
</table>
# Peri-procedural Stroke and MI

<table>
<thead>
<tr>
<th></th>
<th>CAS vs. CEA</th>
<th>Hazard Ratio 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stroke</strong></td>
<td>4.1 vs. 2.3%</td>
<td>HR = 1.79; 95% CI: 1.14-2.82</td>
<td>0.01*</td>
</tr>
<tr>
<td><strong>MI</strong></td>
<td>1.1 vs. 2.3%</td>
<td>HR = 0.50; 95% CI: 0.26-0.94</td>
<td>0.03</td>
</tr>
</tbody>
</table>

* Driven by Minor Stroke
Cranial Nerve Palsies
Peri-procedural

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3 vs. 4.7%</td>
<td>HR = 0.07; 95% CI: 0.02-0.18</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
## Ipsilateral Stroke after Peri-procedural Period ≤ 4 years

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.0</strong> vs. <strong>2.4%</strong></td>
<td>HR = 0.94; 95% CI: 0.50-1.76</td>
<td><strong>0.85</strong></td>
</tr>
</tbody>
</table>
## Primary Endpoint ≤ 4 years
(any stroke, MI, or death within peri-procedural period
plus ipsilateral stroke thereafter)

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2 vs. 6.8%</td>
<td>HR = 1.11; 95% CI: 0.81-1.51</td>
<td>0.51</td>
</tr>
</tbody>
</table>
Stent

Death /Stroke/MI

CREST

Primary Endpoint

p = ns.

CEA

Death /Stroke/MI
CREST

Stent

CEA

Death /Major Stroke

Death /Major Stroke

p = ns.
Stent

Delta = 1.8%
Predominantly Minor Strokes = 1.5%

Death /Major /Minor Stroke

CEA

CREST
Peri-procedural.

Death /Major/Minor Stroke

Ignoring MI’s and cranial nerve palsies.
Stent vs. CEA

Death / Major / Minor Stroke
Cranial N. Palsy

Delta = 2.4%
(4.5% minus 2.1%)
Stenting is looking like a less morbid revascularization alternative to CEA.
End Points that Matter.

• **Neurologists** care about **Strokes**
• **Cardiologists** care about **Myocardial Infarction.**
• **Patients** care about **Strokes, MI’s and Cranial Nerve Palsy.**
Peri-procedural Events.

- The difference between stroke and death in CREST (largely Non Disabling strokes) was 2.1%.

- The difference between the treatments by ITT for Cranial Nerve Palsy was 4.5%.
CREST conclusions

1. Carotid Revascularization is safe and effective in preventing stroke.

2. The primary outcome demonstrated these techniques equivalent with respect to major cardiovascular events.

3. The weight of the evidence demonstrates that CAS is a less morbid procedure.

4. CAS results continue to improve due to increased experience and better understanding of risk factors.
CREST messages

1. Carotid revascularization results in CREST are outstanding for both CEA and CAS. (younger/asymptomatic patients). (Overall Mortality - 0.6%, Major Stroke -0.85 %)

2. Overall CAS and CEA had equivalent results.
   - minor strokes more common with CAS
   - MI’s more common with CEA

3. Major stroke and death are not different.

4. Cranial nerve injuries more common with CEA.

5. CAS results continue to improve and in just 15 years, have reached equivalence with CEA.
## Overall-30 Day Outcomes

<table>
<thead>
<tr>
<th>n = pts / stent</th>
<th>n = 700/759</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor Stroke</strong></td>
<td>10 (1.3%)</td>
</tr>
<tr>
<td><strong>Major Stroke (+hemorrhage)</strong></td>
<td>9 (1.2%)</td>
</tr>
<tr>
<td><strong>All CVA</strong></td>
<td>19 (2.5%)</td>
</tr>
<tr>
<td><strong>All death</strong></td>
<td>3 (0.4%)</td>
</tr>
<tr>
<td><strong>All Strokes &amp; Deaths</strong></td>
<td>19 (2.5%)</td>
</tr>
</tbody>
</table>

No statistical difference in age, gender or symptomatic sts.

Lenox Hill Heart and Vascular Institute in New York
# AGE $\geq$ 80y (21%) - 30 Day Outcomes

<table>
<thead>
<tr>
<th></th>
<th>n = pts / stent</th>
<th>n = 150/157</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Stroke</td>
<td>2 (1.3%)</td>
<td></td>
</tr>
<tr>
<td>Major Stroke*</td>
<td>2 (1.3%)</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Death (IC hemorrhage)</td>
<td>1 (0.6%)</td>
<td></td>
</tr>
<tr>
<td><strong>All Strokes &amp; Deaths</strong></td>
<td>5 (3.2%)</td>
<td></td>
</tr>
</tbody>
</table>

* Failure EPD

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### Procedure Complications 2009

<table>
<thead>
<tr>
<th>n = pts / stent</th>
<th>n = 100/111</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confusion 15 minutes - resolved</td>
<td>1</td>
</tr>
<tr>
<td>Amaurosis fugax - resolved</td>
<td>1</td>
</tr>
<tr>
<td>IC embolus - asymptomatic</td>
<td>1</td>
</tr>
<tr>
<td>Dissection ICA - stented</td>
<td>1</td>
</tr>
<tr>
<td>TIA – 20 min.</td>
<td>1</td>
</tr>
</tbody>
</table>

Lenox Hill Heart and Vascular Institute in New York
### Overall-30 Day Outcomes 2009

<table>
<thead>
<tr>
<th>Event</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Stroke</td>
<td>0</td>
</tr>
<tr>
<td>Major Stroke (+hemorrhage)</td>
<td>0</td>
</tr>
<tr>
<td>All CVA</td>
<td>0</td>
</tr>
<tr>
<td>All death</td>
<td>0</td>
</tr>
<tr>
<td>All Strokes &amp; Deaths</td>
<td>0</td>
</tr>
</tbody>
</table>

*Lenox Hill Heart and Vascular Institute in New York*
Traditional Paradigm

Carotid Revascularization Indicated?

- Yes
  - High CEA Risk
    - Yes: Carotid Stenting
    - No: Medical Management Surveillance
- No
  - No: Surgery
Avoiding complications is vital….

Key to avoiding Complications = Recognizing Situations where complications can be expected
High Risk Patients
High Risk Lesions
for
CAROTID STENTING
Criteria of High Risk Carotid Stenting

• **Clinical**
  - Age >80y.
  - ▼ Cerebral Reserve
    - Dementia
    - Prior CVA
    - Microangiopathy
    - Multiple lacunar infarcts

• **Anatomic**
  - ▶ Excessive Tortuosity
    - ≥ 2 90° bend points, including take off from CCA→ICA, within 5cm of each other AFTER sheath placement
  - ▶ Heavy concentric calcification
    - ≥ 3mm and deemed by at least 2 orthogonal views to be circumferentially situated around lesion
Atheromatous Aortic Arch
No CAS examples.
Not suitable for CAS: 1. heavy calcifications
2. 90% angulated origin LICA
3. Tortuous distal LICA
Not recommended for stenting.
Any 2 of the following = High Risk for CAS

- AGE $\geq 80$
- Excessive Tortuosity
- ↓Cerebral Reserve
- Heavy concentric calcification
Assess Peri-procedural Risk Differently!

Not whether pt is high or low risk for CEA

Instead, is the patient high or low risk for Stenting?
Proposed New Paradigm

Carotid Revascularization Indicated?

Yes

High Stent Risk

Yes

CEA if low risk

No

Carotid Stent

No

Medical Management Surveillance

If high risk for both – MEDICAL THERAPY
Patient and Lesion Selection is Critical for CAS.
BE SELECTIVE

NOT ALL LESIONS ARE AMENABLE TO CAS especially when using protection devices.

It is proper to recommend surgery rather then to risk complication.
CONCLUSIONS

Experienced operators can perform carotid stenting with outcomes equivalent to, or superior to CEA

Selection of patient and lesion is CRITICAL + EXPERIENCE

(For patients CAS less invasive.)