QUESTIONS

- Is carotid artery stenting (CAS) FEASIBLE?
- Is it SAFE?
- What are the RESULTS and what are the INDICATIONS?
- Is carotid endarterectomy (CEA) DEAD?

Risk reduction / % stenosis

<table>
<thead>
<tr>
<th>Pooled Trials</th>
<th>% STENOS</th>
<th>N</th>
<th>ARR @ 5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>NASCET+ECST+VA</td>
<td>50-69% SYMPTO</td>
<td>6092</td>
<td>4.6%</td>
</tr>
<tr>
<td></td>
<td>70-99% SYMPTO</td>
<td></td>
<td>16%</td>
</tr>
<tr>
<td>ACAS + ACST</td>
<td>&gt;60% ASYMPTO</td>
<td>4072</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

CEA

Works Well!
Large Amounts of Data!
CEA
NASCET
ECST
ACAS
ACST
1950 1970-80 1994
C Angioplasty
2000
CAS

1 Stent Eradicates 10,000 Vascular Surgeons

LE TRONE DU STENT CAROTIDIEN

CAS
IS IT FEASABLE?
IS IT SAFE?

Literature Review
Literature Review

- Leicester
- Wall stent
- Kentucky
- CAVATAS
- Non-randomized case series

On-going trials

Leicester 1998, UK
- 29 patients, >70%
- F/U 1 mo
- Stroke/Death/HITs D30
- 6 excluded
- Endovascular 5/7 strokes
- Surgery

Wallstent 2001, USA
- 219 pts, >60%
- F/U 1,12 mo
- Endovascular 12.1% (1 yr)
- Surgery 3.6% (1 yr)
- No protection devices
- Ticlopidine

Wallstent 2001
- No protection devices used
- Lack of experience of interventionalists
- Stent primarily not dedicated to carotid artery
- Stroke and MI rates > CEA group
- Prematurely arrested
- Abandoned by commercial sponsors

Kentucky 2001, USA
- 104 patients, >70%
- F/U 1,3,6,12,24 mo
- Endovascular 1/53 TIA
- Surgery 1/53 MI
- Limited series

CAVATAS 2001
- Europe, Australia, Canada
- 504 patients, >70%
- F/U 1,6,12,67 mo
- Endovascular 251
- Surgery 253
- Not the best current clinical practice

JVS 1998

JACC 2001

Lancet 2001
STROKE & DEATH

<table>
<thead>
<tr>
<th>Number</th>
<th>% based on vessels treated</th>
<th>% based on patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIA</td>
<td>134</td>
<td>2.57%</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>129</td>
<td>2.49%</td>
</tr>
<tr>
<td>Major stroke</td>
<td>1</td>
<td>1.55%</td>
</tr>
<tr>
<td>Neurologic Deaths</td>
<td>41</td>
<td>0.79%</td>
</tr>
<tr>
<td>Nonneurologic Deaths</td>
<td>58</td>
<td>1.11%</td>
</tr>
<tr>
<td>Total stroke and procedure-related death rate</td>
<td>4.69%</td>
<td>5.07%</td>
</tr>
<tr>
<td>Total stroke and total death rate</td>
<td>5.74%</td>
<td>6.24%</td>
</tr>
</tbody>
</table>

Global Experience in Cervical Carotid Artery Stent Placement

What we need is a brand new idea that has been thoroughly tested.

Embolic Protection Device

TABLE 1. Carotid Angioplasty and Stent With Delivery Protection: Study Characteristics and 30-Day Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>No. of Patients</th>
<th>Mean Age</th>
<th>Sex %</th>
<th>No. of Lesions Treated</th>
<th>No. of Stents Inserted</th>
<th>Mean Stent Size</th>
<th>Mean Stroke Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kastrup</td>
<td>2000</td>
<td>50</td>
<td>68</td>
<td>55%</td>
<td>45</td>
<td>25</td>
<td>3.2</td>
<td>3%</td>
</tr>
<tr>
<td>Interv Cardiovasc Catheter</td>
<td>2000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TABLE 2. Carotid Angioplasty and Stent With Carotid Protection: Study Characteristics and 30-Day Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
TABLE 4. Comparison of Overall Minor, Major Stroke or Death Within 30 days of Carotid Angioplasty and Stenting With and Without Cerebral Protection

<table>
<thead>
<tr>
<th></th>
<th>Without Cerebral Protection</th>
<th>With Cerebral Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor stroke</td>
<td>94/2537 (9.6%)</td>
<td>5/896 (0.6%)</td>
</tr>
<tr>
<td>Major stroke</td>
<td>28/2537 (1.1%)</td>
<td>3/896 (0.3%)</td>
</tr>
<tr>
<td>Death</td>
<td>18/2537 (0.7%)</td>
<td>8/896 (0.9%)</td>
</tr>
<tr>
<td>Any stroke or death</td>
<td>140/2537 (5.5%)</td>
<td>16/896 (1.1%)</td>
</tr>
</tbody>
</table>

Kastrup, Stroke 2003

Embolic protection methods

Interv Cardiovasc Catheter 2006

Table 1 Features of different protection devices

<table>
<thead>
<tr>
<th>FilterWire</th>
<th>Cardot WallStent</th>
<th>FilterWire EX/EZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>0.042-0.048</td>
<td>0.842-0.847</td>
</tr>
<tr>
<td>120</td>
<td>0.053-0.056</td>
<td>0.864-0.867</td>
</tr>
<tr>
<td>140</td>
<td>0.056-0.064</td>
<td>0.884-0.887</td>
</tr>
<tr>
<td>80</td>
<td>0.057-0.064</td>
<td>0.909-0.912</td>
</tr>
<tr>
<td>100</td>
<td>0.059-0.066</td>
<td>0.939-0.942</td>
</tr>
<tr>
<td>120</td>
<td>NA</td>
<td>0.964-0.967</td>
</tr>
<tr>
<td>200</td>
<td>0.064-0.074</td>
<td>0.984-0.997</td>
</tr>
</tbody>
</table>

ALKK CAS registry hospitals

- 28 centres
- 1888 pts

Z Cardiol 2005
Short-Term Impact of EPDs

« Embolic protection should be considered the standard of care in carotid stenting. When use of an EPD is precluded by anatomic factors, alternative treatment strategies (CEA or medical therapy) must be strongly considered »

Roubin, Circulation 2006

CAROTID ARTERY STENTING

Results / indications
Distal protection
Simplicity
Feasibility

CAS vs CEA

WHAT ARE THE RESULTS ?

CAS VS CEA

WHAT ARE THE RESULTS ?

CAS vs CEA
**GUIDELINES for CEA**

<table>
<thead>
<tr>
<th>INDICATION LEVEL</th>
<th>SYMPTOMATIC</th>
<th>ASYMPTOMATIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROVEN</td>
<td>70-99% RISK &lt; 6%</td>
<td>&gt; 60% RISK &lt; 3% Life expectancy &gt; 5 y</td>
</tr>
<tr>
<td>ACCEPTABLE</td>
<td>50-69% RISK &lt; 3%</td>
<td>&gt; 60% RISK &lt; 3% Planned CABG</td>
</tr>
<tr>
<td>UNACCEPTABLE</td>
<td>&lt; 29% OR RISK &gt; 6%</td>
<td>&lt; 60% OR RISK &gt; 5% No CABG</td>
</tr>
</tbody>
</table>

**CAS vs CEA RESULTS IN SUBGROUPS**
- SYMPTOMATIC PATIENTS
- ASYMPTOMATIC PATIENTS
- MODERATE CAROTID STENOSIS
- SEVERE CAROTID STENOSIS
- HIGH SURGICAL RISK

**SAPPHIRE 2002, USA**
- 747 pts
- $\sum > 50\%$ stenosis,
- $a\sum > 80\%$ stenosis
- F/U 1,12 mo
- Stroke/Death/MI D30
- HIGH SURGICAL RISK

**Criteria for high risk**
- Age >80 yr
- Clinically significant cardiac disease
  -(CHF, abnormal stress test, or need for CABG)
- Severe COPD

**Criteria for high risk**
- Contralateral carotid occlusion
- Previous radical neck surgery or radiation therapy to the neck
- Recurrent stenosis after endarterectomy
- High lesions behind the mandible
- Low lesions requiring thoracic exposure

*NEJM 2004*
SAPPHIRE 2002, USA

- 747 pts
- 406 Excluded
- Not suitable for stenting
- High Surgical Risk
- 20/167 Endovascular
- 32/167 Surgery

CAS vs CEA
RESULTS IN SUBGROUPS

- SYMPTOMATIC PATIENTS
- ASYMPTOMATIC PATIENTS
- HIGH SURGICAL RISK
  - MODERATE CAROTID STENOSIS
  - SEVERE CAROTID STENOSIS

CREST 2004, USA

- 2500 patients, >50%
- F/U 1 mo
- Stroke/Death/MI D30
- Recruitment 2000
- 454 randomized pts
- Endovascular + Cerebral protection
- Surgery

EVA-3S 2004, France

- 1000 pts
- F/U 132 st
- Stroke/Death/Restenosis
- Recruitment 2000
- 452 randomized pts
- Endovascular
- Surgery

ARRETER POUR EXCES DE MORBIDITE!!! (Madame le Professeur MG Bousser)

Clopidogrel/Ticlopidine

Stroke 2004

NEJM 2004
ICSS 2004 (= CAVATAS-2), UK
1500 pts, ≥70%
F/U 1 mo
Stroke/Death/Mi D30
Recruitment 2001
> 600 so far
Endovascular ± CP
Surgery

SPACE 2001, Germany
1900 pts, ≥70%
F/U 1 mo
Stroke/Death D30
Restenosis 24 mo
Recruitment 2002
970 pts
Endovascular ± CP
Surgery

Literature Review
- Leicester
- Wall stent
- Kentucky
- CAVATAS
- Non-randomized case series

Before EPD
After EPD

CAS or CEA
1. Available data (one trial) show that CAS is superior to CEA in selected high risk patients.
2. In all other patient groups no data is currently available to answer this question

CAS
CEA
CEA vs CAS Trial
**Carotid Revascularization**

*Indicated*  
Yes  

**CEA Risk**

<table>
<thead>
<tr>
<th>High</th>
<th>Low</th>
</tr>
</thead>
</table>

**CAS**  
**CEA vs CAS Trial**

**CAS: Contradications**

- Intolerance to antiplatelet agents.
- Major surgery within 3 to 4 weeks that will require cessation of antiplatelet therapy
- Contrast nephropathy (<75 mL of contrast)
- Intracranial arterial stenoses
- Arteriovenous malformations
- Stable aneurysms

**Relative Roubin, Circulation 2006**

**Increased Procedural Risks After CAS**

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Advanced age Age &gt; 80 y</td>
</tr>
<tr>
<td></td>
<td>Decreased Cerebral reserve Dementia Prior (remote) stroke</td>
</tr>
<tr>
<td></td>
<td>Multiple lacunar infarcts Intracranial microangiopathy</td>
</tr>
<tr>
<td>Angiographic</td>
<td>Excessive tortuosity 2 90° bends within 5 cm of the lesion</td>
</tr>
<tr>
<td></td>
<td>Heavy calcification Concentric, circumferential, Width 3 mm</td>
</tr>
</tbody>
</table>

**Age & risk of Stroke / Death**

<table>
<thead>
<tr>
<th>Age strata</th>
<th>N</th>
<th>Events (%)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60</td>
<td>120</td>
<td>2 (1.7%)</td>
<td>1.0</td>
</tr>
<tr>
<td>60-69</td>
<td>229</td>
<td>3 (1.3%)</td>
<td>0.78 (0.13-4.75)</td>
</tr>
<tr>
<td>70-79</td>
<td>301</td>
<td>16 (5.3%)</td>
<td>3.31 (0.75-14.63)</td>
</tr>
<tr>
<td>80+</td>
<td>99</td>
<td>12 (12.1%)</td>
<td>8.14 (1.78-37.30)</td>
</tr>
</tbody>
</table>

**CREST lead-in phase, JVS 2006**

Impact of age on risk of stroke and death D30
Increased Procedural Risks After CAS

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Excessive tortuosity
- Difficulty of access
- Failure of device delivery
- Prevent EPD positioning
- Unsufficient “landing zone”
- Atheroembolism
- Air embolism
- Excessive contrast
- Bifurcation plaque disruption
- ICA dissection

Increased Procedural Risks After CAS

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</table>

Plaque Calcifications
- Difficulty in
  - Tracking devices
  - Lesion dilation
  - Stent positioning
  - Achieving adequate expansion

Carotid Revascularization
- CEA Risk
  - High
  - Consider CAS
  - Low
  - CEA vs CAS Trial
  - Low
- Risk for CAS
  - High
  - CAS
  - Low
- CEA or Medical Therapy
  - High
  - CAS
  - Low
Angiographic Restenosis

<table>
<thead>
<tr>
<th>Internal Carotid Plaque Size</th>
<th>38 d</th>
<th>6 mo</th>
<th>12 mo</th>
<th>24 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of treated arteries reaching internal</td>
<td>130</td>
<td>130</td>
<td>131</td>
<td>70</td>
</tr>
</tbody>
</table>

Clinical
- No. of treated arteries reaching internal
  - 203 (97%)
  - 203 (97%)
  - 119 (87%)
  - 17 (92%)
- Symptomatic event
  - 29 (77%)
  - 119 (87%)
  - 17 (92%)
  - 7 (86%)
- Restenosis rate
  - 11 (5.3%)
  - 11 (5.3%)
  - 1 (5.5%)
  - 1 (5.5%)

Restenosis rate
- 4% (5.3%)

Gray, STROKE 2002

Restenosis
- 2167 pts CAS (stenting rate 95%)
- 5-year follow-up
- 85% of pts alive & free from ipsilateral stroke
- Restenosis rate 4%

Bosier, J Cardiovasc Surg (Torino) 2005