Extracranial Carotid Artery Stenting With or Without Distal Protection Device

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Backgrounds

- Although **surgical endarterectomy** has been known to be the standard treatment modality of carotid artery stenosis, it had several limitations in high-risk patients, particularly with coronary artery disease.

- **Carotid angioplasty and stenting** has been suggested to be a safer and more cost-effective alternative to carotid endarterectomy in the management of symptomatic carotid artery disease.
30-Day Procedure Complications

- Global Experience in Cervical Carotid Artery Stent Placement

<table>
<thead>
<tr>
<th>Complication</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIAs</td>
<td>2.87%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2.72%</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>1.49%</td>
</tr>
<tr>
<td>Neurologic Death</td>
<td>0.86%</td>
</tr>
<tr>
<td>Nonneurologic Death</td>
<td>1.22%</td>
</tr>
</tbody>
</table>

\( n = 4,757 \) patients

Backgrounds

• Obstructive carotid artery lesions are known to contain friable thrombotic and atherosclerotic components that have the potential to embolize during intervention and may be responsible for the majority of the neurologic events during carotid artery stenting.

• A number of “distal protection” strategies, designed to capture embolic debris released during carotid intervention, are currently being evaluated for their efficacy in minimizing the risk of embolic neurologic events.

Angioplasty Summit 2004
Backgrounds - 30 day clinical event rates

(Kastrup A et al. Stroke 2003;34:813)

Without cerebral protection
With cerebral protection

P<0.001
P<0.05
P=0.6
P=0.6

Minor stroke: 94/2537, 3.71%
P<0.001
Minor stroke: 5/896, 0.56%

Major stroke: 28/2537, 1.10%
P<0.05
Major stroke: 3/896, 0.33%

Death: 18/2537, 0.71%

Any stroke or death: 140/2537, 5.52%
P<0.001
Any stroke or death: 16/896, 1.79%
The purpose of this study is to evaluate the feasibility, safety and short (30-day), mid-term (6-month) clinical follow up results of elective carotid artery stenting with or without distal protection device in patients with carotid artery stenosis.
Method

Jun 1997 ~ Sep 2003, 58 pts (62 lesions) were included

• Inclusion criteria
  - Symptomatic and asymptomatic pts with carotid artery stenosis (>60%)
  - Informed consent

• Exclusion criteria
  - Intracranial tumor or arteriovenous malformations
  - Severely disabled as a results of stroke or dementia
  - Intracranial stenosis that exceeded the severity of the extracranial stenosis
  - Peripheral vascular disease to prevent vascular access
  - Acute ischemic neurologic stroke or past 48hrs
  - Total occlusion of the target carotid artery
Method

Stenting Protocol

- Transvenous pacemaker (till 1999)
- Heparin 5,000U bolus IV after arterial sheath
- 9 Fr guiding catheter or 7Fr Tuohy Borst Introducer
- Cross the stenosis with extra-support wire
- Drug regimen: aspirin 300mg indefinitely, ticlopidine 250mg or clopidogrel 75mg for 4wks
- Protection device (from Sep 2001): 19 case (30.7%)
  - PercuSurge – 13 case
  - EPI filter – 6 case
PercuSurge GuardWire system

EPI FilterWire

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Protection Device (PercuSurge GuardWire)
F/79
Pre-→Post-
Protection Device (EPI filter device)
M/73
# Results - Clinical Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Men</strong></td>
<td>45(77.6%)</td>
</tr>
<tr>
<td><strong>Age (yr)</strong></td>
<td>67.4 ± 7.5</td>
</tr>
<tr>
<td><strong>Cardiovascular risk factor</strong></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>44(75.9%)</td>
</tr>
<tr>
<td>Smoking</td>
<td>36(62.1%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>18(31%)</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>14(24.1%)</td>
</tr>
<tr>
<td><strong>Past History</strong></td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>10(17.2%)</td>
</tr>
<tr>
<td>CVA</td>
<td>13(22.4%)</td>
</tr>
<tr>
<td>PTCA</td>
<td>28(48.3%)</td>
</tr>
<tr>
<td>High Risk Patients</td>
<td>31(53.4%)</td>
</tr>
</tbody>
</table>
### Results - Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right / Left</td>
<td>32(51.6%) / 30(48.4%)</td>
<td></td>
</tr>
<tr>
<td>Common CA</td>
<td>4 (6.4%)</td>
<td></td>
</tr>
<tr>
<td>Internal CA</td>
<td>58(93.6%)</td>
<td></td>
</tr>
<tr>
<td>Combined coronary stenosis</td>
<td>41(70.7%)</td>
<td></td>
</tr>
<tr>
<td>Bilateral CA</td>
<td>4 (6.9%)</td>
<td></td>
</tr>
</tbody>
</table>

CA; carotid artery
Results - Types of Stents

- Wall 42: 42
- Smart 7: 7
- PS 6: 6
- 3
- 4
- 1
- 1

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Results - Presenting Symptoms

Asymptomatic: 32 (55.2%)
Symptomatic: 26 (44.8%)

TIA: 13 (22.4%)
CVA: 13 (22.4%)
Total occlusion of LICA

Critical stenosis of RICA

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Stent placement
(Self expendable nitonal stent)

Post-Inflation

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Pre- vs. Post-stenting cerebral angiography

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Four Vessel Stenting

Pre - → Post -

M/75

RICA

Angioplasty Summit 2004
Four Vessel Stenting

Pre - → Post -

LICA

Angioplasty Summit 2004
Four Vessel Stenting

LVA

Pre -  →  Post -

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Results Procedural Success

- 100% (43/43) without DPD
- 94.7% (18/19) with DPD

p=NS

1 case: Incomplete distal protection due to spontaneous balloon deflation in patient with PercuSurge GuardWire

→ Successful stenting without distal protection
Major stroke: 2 hemorrhagic stroke due to hyperperfusion, No major embolic stroke
Results – 6 month clinical outcome

Without DPD

With DPD

Minor stroke: 4.7%, 2/43 vs. 5.3%, 1/19
Major stroke: 2.4%, 1/43 vs. 5.3%, 1/19
Non-neurologic death: 4.7%, 2/43 vs. 5.3%, 2/19
Neurologic death: 0% vs. 0%
Total event (2 cardiac death): 11.6%, 5/43 vs. 10.5%, 2/19

p=NS
## Results - Baseline QCA data

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVD(mm)</td>
<td>5.93 ± 1.45</td>
<td></td>
</tr>
<tr>
<td>MLD(mm)</td>
<td>1.46 ± 0.78</td>
<td>5.01 ± 1.28</td>
</tr>
<tr>
<td>%DS</td>
<td>77.4 ± 8.4</td>
<td>13.7 ± 12.9</td>
</tr>
<tr>
<td>Length(mm)</td>
<td>18.8 ± 10.1</td>
<td></td>
</tr>
</tbody>
</table>
Results

PercuSurge GuardWire Experience and Result

- Technical success rate: 12/13 (92.3%)
- Balloon inflation time: 6 min 27 sec ± 1 min 42 sec
- Aspirated material: 12/12 (100%)
- Direct stenting: 6/12 (50%)
- Clinical Results: 1 hemorrhagic stroke developed within 24 hrs after stenting due to hyperperfusion
Results

EPI Filter Wire Experience and Result

- Technical success rate: 6/6 (100%)
- Visible filtered material: 2/6 (33.3%)
- Clinical Results: 1 minor embolic stroke developed within 30 days after stenting
Hyperperfusion Syndrome

Sundt et al. first described in 1981
Recognized complication of CEA

- Triad: Unilateral headache, Focal seizure, ICH
- Symptoms: Usually developed 5 to 7 days after CEA
- Speculations: Elevated ipsilateral cerebral blood flow
- Incidence of ICH after CEA: From a recent review of the literature
  0.3 to 1.2%
  Associated with elevated BP at the time of presentation

- ICH after carotid stenting
  Gachon data (N=58): 2/58 (3.5%)
  Morrish et al (N=90): 4/90 (4.4%)
# Patient Profile of ICH post-stenting

<table>
<thead>
<tr>
<th></th>
<th>Patient 1</th>
<th>Patient 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age/Sex</td>
<td>74/M</td>
<td>76/M</td>
</tr>
<tr>
<td>Target lesion</td>
<td>RICA</td>
<td>LICA</td>
</tr>
<tr>
<td>% stenosis (%)</td>
<td>95</td>
<td>99</td>
</tr>
<tr>
<td>Presenting Sx</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Contralateral carotid artery stenosis</td>
<td>occluded</td>
<td>No significant stenosis</td>
</tr>
<tr>
<td>Residual stenosis after CAS (%)</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Time to onset of neurologic Sxs</td>
<td>7 days</td>
<td>1 hour</td>
</tr>
<tr>
<td>Clinical Outcome</td>
<td>fatal</td>
<td>fatal</td>
</tr>
</tbody>
</table>
Pre-  

Post-stenting cerebral angiography

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Left basal ganglia hemorrhage after stenting
Summary

- Clinical event rate during the 30 days (short term) and 6 month (mid-term) of follow-up was not significantly different in carotid artery stenting between protected and non-protected group.

- 2 hemorrhagic strokes developed in patients with subtotal carotid artery occlusion, and severe carotid stenosis combined with contralateral occlusion.
Conclusions

• Carotid stenting is a safe and feasible procedure with high immediate success rate and relatively low major clinical events during the follow up periods.

• However, intracerebral hemorrhage can occur after carotid stenting possibly due to cerebral hyperperfusion injury.

• Furthermore, the use of neuroprotection devices will contribute to the decline in embolic event rates.