Impact of Carotid Technique and Device Selection (Stents and Protection Systems) on Clinical Outcomes

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Hahnemann University Hospital
Drexel University College of Medicine
Outline

- Why Do Carotid Complications Occur?
- Does Embolic Protection Make A Difference And What Is The Best Configuration?
- Does Carotid Stent Design Make a Difference?
- What CAS Patients Should Be Avoided?
Percutaneous Transluminal Angioplasty in Arteriosclerotic Internal Carotid Artery Stenosis

Stephan A.M. Bokenheimer and Klaus Mathias

First Series of Case Reports
Carotid Angioplasty and Doppler Flow: Pre- and Post-PTA
Elective Stenting of the Extracranial Carotid Arteries

Jay S. Yadav, MD; Gary S. Roubin, MD, PhD; Sriram Iyer, MD; Jiri Vitek, MD; Peter King, MD; William D. Jordan, MD; Winfield S. Fisher, MD
Methods

- March 1994–Nov 1995
- 77% excluded from NASCET, ACAS
- Symptomatic Patients > 70% stenosis
- Asymptomatic Patients > 60% (after ACAS)
- Stents:
  - Palmaz medium biliary stents (J&J) 69%
  - Flex-Stents (Cook Inc) 20%
  - Wallstents (Schneider) 11%

Yadav, J.S., Circulation 1997;95:376–381.
Results at 30 Days

Why Use Embolic Protection in Carotid Artery Stenting?

The main cause of complications is . . .

Cerebral Embolization
Transcranial Doppler During CAS
Microembolic Profile During CAS and New (DW) MR Lesions After CAS

CAPTURE 3000 Vs. EXACT 900: Timing of Stroke

The Majority of Strokes Occur Post-Procedure and Before Discharge
Selection of EPD

- Filter devices
- Distal balloon occlusions
- Proximal protection
Therapeutic Options:
Current Embolic Protection Categories

- Distal Occlusive Devices
- Distal Filters
- Proximal Occlusion and Flow Reversal
Right ICA

- 59 YO with h/o CABG and St. Jude AVR
- RCEA 6 years ago
- Amaurosis fugax despite therapeutic INRs
GuardWire — PercuSurge EPD
### Embolic Protection Devices

#### Balloon Occlusion Devices

**Advantages**
- Easy to cross lesion
- Compatible with devices
- Aspirate large and small particles
- Reliably trap debris
- Easy device retrieval

**Disadvantages**
- No antegrade flow
- 5–8% are intolerant
- Balloon-induced injury
- Not as steerable as PTCA wires
- Difficult to image during the procedure
Proximal Protection

69 male
CAD
HTN
Dyslipidemia
CAS

McCormick, DJ TCTmd.com 2006
Merci® Balloon Guide Catheter

Proximal occlusion

PercuSurge Device or FilterWire

Merci® Balloon Guide Catheter 8F or 9F
Distal Embolic Protection Devices

Filter Devices

Advantages

• Preserve antegrade flow
• Contrast imaging is possible throughout the procedure

Disadvantages

• May not capture all debris
• Filters may clog, cause spasm
• Delivery catheters may cause embolization before filter deployment
• Retrieval sheath may snag on stents
Current DPDs in Use

- Accunet
- Guardwire
- SPIDER
- FilterWire EZ
- Angioguard
- Emboshield
Death and Stroke With and Without CPD

“A Systematic Review of the Literature”

Unprotected (n=2,537) Protected (n=896)

5.5 1.8

p < 0.001

Combined Stroke and Death Outcomes (One Month)

n=145

Without Protection

- Overall Stroke: 2.76%
- Overall Death: 1.4%
- Total: 4.16%

With Protection

- Overall Stroke: 1.25%
- Overall Death: 0%
- Total: 1.25%

McCormick, D.J., Catherization and Cardiovascular Interventions 2003;59:122.
EVA-3S

Symptomatic Carotid Stenosis > 60% (n=527)

Death/ CVA @ 30 days

- CEA: 3.9
- CAS: 9.6

- p=0.01

Death/ CVA @ 6 mon

- CEA: 6.1
- CAS: 11.7

- p=0.02

EVA-3S

Symptomatic Carotid Stenosis > 60% (n=527)

\[ p=0.03 \]

Death/ CVA without EPD: 25
Death/ CVA with EPD: 7.9
n=20
n=227

Mas, J.L., NEJM 2006;355:1660.
EVA-3S: Learning Curve
The Type of Embolic Protection Does Not Influence the Outcome in Carotid Artery Stenting

Vikram Iyer, MD, Gianmarco de Donato, MD, Koen Deloose, MD, Patrick Peeters, MD, Fausto Castriota, MD, Alberto Cremonesi, MD, Carlo Setacci, MD, and Marc Bosiers, MD
## 30-Day Events (TIA, Stroke, and Death)

<table>
<thead>
<tr>
<th>Comparison</th>
<th>RR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proximal occlusion vs. filter</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unadjusted</td>
<td>1.52</td>
<td>0.75–3.13</td>
<td>1.00</td>
</tr>
<tr>
<td>• Adjusted for RF, ST</td>
<td>1.59</td>
<td>0.71–3.10</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Distal occlusion vs. filter</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unadjusted</td>
<td>2.72</td>
<td>0.71–10.51</td>
<td>0.96</td>
</tr>
<tr>
<td>• Adjusted for RF, ST</td>
<td>3.38</td>
<td>0.55–10.87</td>
<td>0.54</td>
</tr>
<tr>
<td><strong>Distal vs. proximal occlusion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unadjusted</td>
<td>1.79</td>
<td>0.40–7.96</td>
<td>1.00</td>
</tr>
<tr>
<td>• Adjusted for RF, ST</td>
<td>1.79</td>
<td>0.40–7.96</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Eccentric vs. concentric filter</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unadjusted</td>
<td>0.59</td>
<td>0.38–0.92</td>
<td>0.04</td>
</tr>
<tr>
<td>• Adjusted for RF, ST</td>
<td>0.76</td>
<td>0.47–1.22</td>
<td>0.51</td>
</tr>
</tbody>
</table>
FiberNet®
A New 3-D Filter: (Lumen Biomedical)

- Ability to allow flow during the procedure (FILTER)
- Capability to capture emboli (FILTER)
- Captures all small particles (OCCLUSION BALLOON)
- Very deliverable as a standard coronary guidewire (0.014)
- Capture embolic particles in a “3-dimensional filter”
New Distal Embolic Protection Device

The FiberNet® 3 Dimensional Filter: First Carotid Human Study

Michel Henry, Antonios Polydorou, Isabelle Henry, Jerry Sedgewick, and George Ruth
Mean Surface Area of Particulate Caught via FiberNet® System

FiberNet System vs. other distal filter devices

Carotid Artery Stenting in the Elderly (Octogenarians)
Thirty-Day Outcomes in Patients <80 Versus >80 yrs of Age

![Bar chart showing outcomes for <80 and >80 years groups.](image)

- Minor Strokes: p=NS
- Major Strokes: P<0.01
- All strokes & Death: P<0.01

Roubin GS, Circulation 2001;103;532-537
Carotid artery stenting is associated with increased complications in octogenarians: 30-day stroke and death rates in the CREST lead-in phase

Robert W. Hobson II, MD; Virginia J. Howard, MSPH; Gary S. Roubin, MD, PhD; Thomas G. Brott, MD; Robert D. Ferguson, MD; Jeffrey J. Popma, MD; Darlene L. Graham; and George Howard, MD, PhD; the CREST Investigators
Death and Stroke Within 30 Days of Stent Procedure — CREST Lead-In Phase

Death, Stroke, and MI

Statistically Significant

Percentage of Patients

Symptomatic (482)

Asymptomatic (3,018)

Age < 80 yrs

Age > 80 yrs

DSMI by Physician Level by Symptomatic Status

All patients

Symptomatic

Asymptomatic

% of all patients

Level 1  Level 2  Level 3

## Markers of Increased Risk During Carotid Stenting

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical</strong></td>
<td></td>
</tr>
<tr>
<td>Advanced age</td>
<td>Age ≥ 80 years</td>
</tr>
<tr>
<td>Decreased cerebral reserve</td>
<td>• Prior large stroke</td>
</tr>
<tr>
<td></td>
<td>• Multiple lacunar infarcts</td>
</tr>
<tr>
<td></td>
<td>• Intracranial microangiopathy</td>
</tr>
<tr>
<td></td>
<td>• Dementia</td>
</tr>
<tr>
<td><strong>Angiographic</strong></td>
<td></td>
</tr>
<tr>
<td>Excessive tortuosity</td>
<td>≥ 2 90° bends within 5 cm of the lesion</td>
</tr>
<tr>
<td>Heavy calcification</td>
<td>Concentric calcification; width ≥ 3 mm</td>
</tr>
</tbody>
</table>

≥ 2 Risk Factors ~ High Risk for Complications

Thirty-Day Event Rates in Octogenarians

<table>
<thead>
<tr>
<th>Event Type</th>
<th>All (n= 153)</th>
<th>Symptomatic (n= 39)</th>
<th>Asymptomatic (n= 114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Strokes</td>
<td>1.3%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Major Strokes</td>
<td>1.3%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Death</td>
<td>0.7%</td>
<td>0%</td>
<td>0.9%</td>
</tr>
<tr>
<td>All Stroke or death</td>
<td>3.3%</td>
<td>2.6%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>
Trend for Complication Rates in Octogenarians

Hostile Aortic Arch
MRI Brain w/o contrast
Carotid Stent Design and Lesion Specific Stent Selection
Basic Principle of Open Versus Closed Cell
Free Cell Area of Available Stent Designs . . .
Scaffolding and Plaque Coverage

Plaque Coverage

- closed cell elgiloy stent – Wallstent

- open cell nitinol stent

- closed cell nitinol stent

- Debris

- Vessel Wall

Stent-struts
Difficult Access:
High Stent Deliverability Required!

Mesh Wire Stents Superior
Stent Design: Lesion Coverage and Scaffolding

Closed cell-mesh wire  Open cell-Nitinol
Comparison of Post-Procedural Event Rates by Cell Types

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Sympt. Patients</th>
<th>Asympt. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIA, Stroke and Death</td>
<td>1.3</td>
<td>3.4</td>
<td>6.3</td>
</tr>
<tr>
<td>% Postprocedural Events</td>
<td>1.3</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
<td>0.001</td>
<td>ns</td>
</tr>
</tbody>
</table>

30-Day Stroke (As Defined By the Authors) / Death Rates (no TIAs)

Difference: 0.3% (95% CI – 0.5% to 1.4%, p=0.495)

Adapted from Table 3 in Bosiers, M., et al, Eur J Vasc Endovasc Surg 2007;33:135e–141.
Does Carotid Stent Cell Design Matter?

European Registry

Martin Schillinger, MD; Manfred Gschwendtner, MD; Bernhard Reimers, MD; Johannes Trenkler, MD; Luc Stockx, MD; Johann Mair, MD; Sumaira Macdonald, MD; Franz Karnel, MD; Kurt Huber, MD; Erich Minar, MD

Addition of stent “mesh”

- Finest mesh stent

Courtesy of Dr. Mark Wholey
CAS Outcomes Tied To . . .

**ANATOMY**
- Difficult Arch
- CCA/ICA Tortuosity
- Lesion anatomy

**PATIENT**
- Symptoms
- Octogenarians
- Cerebral Reserve

**OPERATOR**
- Early learning curve
- Case selection
- Stubborn persistence

**DEVICE SELECTION TECHNIQUE**
- Embolic Protection
- Stent design
- Cerebral protection
Opportunity
Judgment