Recent Advances in Interventional Neuroradiology 2008
Van V. Halbach, M.D.
Christopher F. Dowd, M.D.
Randall T. Higashida, M.D.
The Neurovascular Medical Group
Interventional Neuroradiology Section,
UCSF Medical Center, San Francisco
415 353-1863

Neuroform Stent
(BSC/Target)
pre-loaded, self-expanding nitinol stent in flexible 3F microcatheter

Cordis Enterprise Second Generation Intracranial Stent
(Higashida RT, Halbach VV: AJNR: Sept 2005; 26)
• New Nitinol Self Expanding Stent
• Treatment Of Wide Neck Intracranial Aneurysms
• Placed Through Prowler Plus (.021") Micro-Catheter
• Retrievable, Closed Cell Design
• Each Cell Is 1.5 mm Diameter
• Allows Excellent Retention Of Coils
Enterprise Self-Expanding Stent System:
Diameter 4.5 mm x 22 mm (Ends Flare To 6 mm)

Large Wide Neck Supraclinoid Aneurysm: Enterprise Stent

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Fusiform Distal Vertebral Aneurysm

- 70 Year Old Male
- Symptoms Of Mass Effect From Fusiform Distal Intracranial Vertebral Aneurysm
- Upper 1/3 Of Aneurysm Incorporated The PICA Vessel
- Length: 10.5 mm
- Width: 8.5 mm
- Separate Inflow & Outflow

Fusiform Large Distal Vertebral Aneurysm With Enterprise Stent

Technique

- Deployed 4.5 x 22m Enterprise Stent Across Fusiform Aneurysm
- Placed Microcatheter Through Stent
- Placed 15 mm Balloon Across Stent
- Inflated Balloon To Protect Coils From Herniating Into Stent & Insure Coils Circumferentially Occluded Outside Of Stent
- 8 Coils Placed, While Not Occluding PICA Vessel
Fusiform Large Distal Vertebral Aneurysm With Enterprise Stent

• 48 Year Old Female
• Grade III Acute SAH
• Dysplastic Fusiform Distal Vertebral Artery Aneurysm
• Hypoplastic Contralateral Left Vertebral Artery
• Treated With Enterprise Stent & Coiling

Ruptured Fusiform Distal Vertebral Aneurysm
Ruptured Fusiform Distal Vertebral Aneurysm

Ruptured Fusiform Distal Vertebral Aneurysm
Warfarin vs. Aspirin for Symptomatic Intracranial Disease

- Prospective, Double-Blind, Randomized, Multi-center
- Rationale: Uncertainty About Optimal Anti-Thrombotic Therapy For Symptomatic Intracranial Stenosis
- Comparing Warfarin (INR 2-3) vs. Aspirin (1300 mg/d)
- Angiographically Verified Stenosis: >50%
- TIA or Non-Disabling Stroke W/in 90 Days
- End Point: Stroke, Hemorrhage, Death

Total Patients: 569
Mean Follow Up: 1.8 Yrs
Study Stopped Due To Concerns Of Patient Safety In Warfarin Arm
2 Year Stroke Rate:
- Aspirin: 19.7%
- Warfarin: 17.2%

Prognosis of Intracranial Atherosclerosis is Poor
(Warfarin Aspirin Symptomatic Intracranial Disease Study: Stroke 1998; 29: 1389-1392; EC-IC Bypass Study; Bougoulavsky et al; Chimowitz et al)

- Supraclinoid Carotid Stenosis 8% 13%-17% 21%-25%
- Middle Cerebral Artery Stenosis 8% 3% 11%
- Distal Vertebral Stenosis 3%-8% 4% 7%-12%
- Basilic Artery Stenosis 5%-11% 4%-9% 9%-20%

Current Treatment of Intracranial Atherosclerosis is Poor
(EC-IC Bypass Study: NEJM, 1985; 313: 1191-1200)

- Fatal/Non Fatal Stroke Medical Surgical
- Intracranial Carotid Stenosis >70% 36% 38%
- Middle Cerebral Artery >70% 24% 44%
Medical Treatment of Vertebral Basilar Insufficiency Is Poor
(Warfarin Aspirin Symptomatic Intracranial Disease Study: Stroke 1998; 29:1389)

- 68 Pts >50% Stenosis of Vertebral or Basilar Artery
- Follow Up: 14 months
- Aspirin: 20% /yr stroke or death rate
- Warfarin: 12% /yr stroke or death rate
- Concluded that “the high rate of stroke with either agent suggests other therapies (eg: intracranial angioplasty) may be needed”.

Surgical EC-IC Bypass
(Ausman et al: Journal of Neurosurgery: 1990; 72; 554-558)

- Surgery for Symptomatic Vertebral-Basilar Stenosis
- Total Patients with EC-IC Bypass: 83
- Surgical Morbidity: 13.3%
- Surgical Mortality: 8.4%
- Combined Morbidity/Mortality: 21.7%

Symptomatic Intracranial Atherosclerosis: Outcome of Patients Who Fail Antithrombotic Therapy

- Goal: To Determine Prognosis of Patients Who Failed Antithrombotic Therapy
- Total Patients Evaluated: 52
- Pts Failing Maximal Medical Therapy: 29 (55.8%)
  - Anti-Platelet Agents: 55%
  - Warfarin: 31%
  - Heparin: 14%
- Median Time of Failure (Stroke, TIs, Death): 36 Days
- This Group Represents Target Group For More Aggressive Therapy As Angioplasty/Stenting

INTRACRANIAL STENTING
64 Year Old Male with Multiple TIAs: Cavernous Carotid Artery Stenosis

MCA Stenosis

- 46 y.o. woman with elevated cholesterol and smoking who has transient episodes of right arm weakness and problems with word finding

Angioplasty (POBA)
Pre Treatment  |  Post Treatment

35 Yr Old S/P Radiation for Brain Tumor: Middle Cerebral Artery Severe Stenosis: TIA’s on Aspirin

Placement of 3.5 x 8 mm Stent in Middle Cerebral Artery Stenosis

Stenting Of Symptomatic Middle Cerebral Artery Stenosis
(Stroke 2004; 35:1375-1380; Jiang, et al)

- Symptomatic Middle Cerebral Stenosis, Failed Medical Therapy
- Total Cases: 42
- Success Rate: 97.6%
- Complications 10%
  - SAH: 7.5% (3/40)
  - Acute Occlusion/Death: 2.5% (1/40)
- Follow Up 10 Months: No Recurrent Stroke, TIAs, Death
Basilar Artery Stenting

72 y.o. retired policeman with repeated episodes of gait problems and weakness in arms and legs despite medical therapy.

Angioplasty and Stenting

67 Yr Old Male with Severe Posterior Fossa Ischemia: Failed Coumadin Therapy
Intracranial Stenting For Distal Vertebral-Basilar Artery Stenosis: Long Term Outcomes


- Mean Follow Up: 30 months
- Asymptomatic (mRS=0): 41 (56.2%)
- Mild Disability (mRS=1-2): 15 (20.5%)
- Moderate/Severe Disability (mRS=3-5): 5 (6.8%)
- Died (mRS=6): 8 (10.9%)
  - None Stroke Related
- Major Disability-Free Survival at 1 Year: 95.6%
- Major Disability-Free Survival at 3 Years: 79.0%

Stenting Of Symptomatic Atherosclerotic Lesions In The Vertebral or Intracranial Arteries

(Stroke 2004; 35:1388-1392. SYLVIA Trial)

- Prospective, Non-Randomized, Symptomatic >50% Stenosis
- Total Cases: 61
  - Intracranial: 43
  - Extracranial Vertebral: 18
- Success Rate: 95%
- 30 Day Stroke Rate: 6.6%
- Stenosis >50% at 6 Months:
  - Intracranial: 32.4% (12/37)
  - Extracranial Vertebral: 42.9% (6/14)
- Composite 1 Year Stroke Rate: 13.1%
Wingspan Intracranial Stent
(Data Submitted To FDA: 2005)

- Total Patients: 45
- Sites: All International: 12
- Pts With Stroke, Refractory To Medical Therapy & Stenosis >50%
- Mean Age: 66 Years
- Device Success: 44/45 (97.8%)
- Anterior Circulation Stenosis: 23 (51.1%)
  - Middle Cerebral Stenosis: 10 (22.2%)
- Posterior Circulation Stenosis: 22 (48.9%)
  - Basilar Artery Stenosis: 9 (20%)

Mean % Stenosis:
- Pre Tx: 74.9% (+/- 9.8%)
- Post PTA: 50.0% (+/- 16.2%)
- Post Stent: 31.9% (+/- 13.6%)
- 6 Months: 28.0% (+/- 23.2%)

Wingspan In Stent Restenosis

- In Stent Restenosis
  - 65 patients at 5 centers
    - Young patients (<55 yrs old) 45.2%
    - Older patients 24.2%
    - Anterior circulation 50%
      - Young Supraclinoid ICA 89.9%
      - Symptomatic 40%
    - Posterior circulation 20%
    - Symptomatic (non supraclinoid) 3.9%
    - Restenosis (non supraclinoid) 24.4%

CAROTID STENTING
Higashida RT: UCSF

76 yr old s/p Radiation to Neck
Underwent Endarterectomy now with Recurrent Stenosis

>85% Recurrent Stenosis
Stent Deployed

Post Stenting Angiogram
Follow Up Angiogram

Higashida RT: UCSF
Long Segmental Stenosis: 7 cm

Placement of 2 Overlapping 4 cm Stents to Cover Entire Lesion

Carotid Stenting Indications

- High Risk Surgical Patients
  - Severe Coronary or Pulmonary Disease
  - Recent MI, Stroke
- Surgically Difficult Access
  - Lesions arising off Aortic Arch
  - Lesions above the Mandible >C2
  - All Intracranial Lesions
- Traumatic or Spontaneous Spiral Dissections

Relative Carotid Stenting Indications

- Multiple Vessel Disease
  - Occlusion of Contralateral Carotid or Vertebral
  - Tandem Stenosis with Intracranial Lesion
- Recurrent Stenosis Post Endarterectomy
- History of Cervical Radiation
- Long Segmental Lesions >4 cm
- Traumatic Carotid Pseudoaneurysms
### Current International Status of Carotid Artery Stenting

(Catheterization & Cardiovascular Interventions: 2004)

- Total Number of Carotid Stent Cases: 11,243
- Total Number of Centers: 53
- % of Symptomatic Cases: 55%
- % of Asymptomatic Cases: 45%
- Total Number of Carotid Stents Placed: 12,392
- Technical Success Rate: 98.9%

### Restenosis (>50% at 36 months): 2.40%

### Minor Strokes (recovery w/in 30 d): 265 (2.14%)

### Major Stroke: 149 (1.20%)

### Procedure Related Death: 80 (.65%)

### Non Procedure Deaths: 95 (0.77%)

### 30 Day All Strokes and Death: 589 (4.76%)

### Stent Complications: Stroke/Death

(Catheterization & Cardiovascular Interventions)

- Symptomatic Cases (6392 Pts): 4.94%
- Asymptomatic Cases (4581 Pts): 2.95%
- Without Cerebral Protection (6688 Pts): 5.29%
- With Cerebral Protection (4005 Pts): 2.27%
- Ipsilateral Neurological Events at 36 Mos: 1.70%
- Ipsilateral Neurological Events at 48 Mos: 4.50%

### Sapphire Trial

(Stenting and Angioplasty with Protection in Patients with High Risk for Endarterectomy) (NEJM: 2004; 351:1493-720)

- Cordis/J&J Sponsored
- High Risk Surgical Patients
- Randomized between Surgery vs. Stenting
- Incorporates the AngioGuard Distal Protection Device with Cordis Precise SMART Stent
- Status: Stopped June 2002
- Total Centers: 29
- Enrollment: 716
- Total Randomized: 310
Sapphire Trial
(Stenting and Angioplasty with Protection in Patients with High Risk for Endarterectomy)
(NEJM: 2004; 351:1493-732)

- High Risk Cohort Either With Surgical or Medical Co-Morbidity
- Angiogram or Ultrasound Screening
- Symptomatic Stenosis >50% or
- Asymptomatic Stenosis >80%
- Primary Endpoint: 30 Day & 1 Year – Death, Stroke, MI

Sapphire Trial: 30 Day Results
(Stenting and Angioplasty with Protection in Patients with High Risk for Endarterectomy)
(NEJM: 2004; 351:1493-732)

- Surgery (151)   Stenting (159)
- Stroke: 5.3% 3.8%
- Death: 2.0% 0.6%
- Myocardial Infarct: 7.3% 2.6%
- Stroke/Death/MI: 12.6% 5.8%
- Technical Success Rate: 98%
- Debris Detected: 60%
- Cranial Nerve Injury: 4.6% 0%

Sapphire Trial: 1 Year Results
(Stenting and Angioplasty with Protection in Patients with High Risk for Endarterectomy)
(NEJM: 2004; 351:1493-732)

- Surgery (151)   Stenting (159)
- Stroke: 7.3% 5.7%
- Death: 12.6% 6.9%
- Myocardial Infarct: 7.9% 2.5%
- Stroke/Death/MI: 27.8% 15.1%
- Technical Success Rate: 95.6% 99.4%
- Target Lesion Revasc. 4% (6) 0.6% (1)

Meta-Analysis For Carotid Stenting vs. Surgery
(Neurosurgery 2005; 56:1171-1181; Quershi, et al)

- Evaluated 5 Published Randomized Trials
- Total Patients: 1154 (577 Randomized Equally)
- Composite Endpoint At 30 Days: Stroke/Death
- Concluded: “There were NO significant difference of composite rates of stroke or death among patients in the endovascular treatment group, compared with the surgical treatment group”.
- “The 1 month rates of Myocardial Infarction and Cranial Nerve Injury were significantly lower for carotid artery stenting”.
- “No significant differences were observed in 1 year rates of ipsilateral stroke.”
Significant Co-Morbidities

• Congestive Heart Failure (CHF) Class III/IV
• Left Ventricular Ejection Fraction <30%
• Unstable Angina
• Contralateral Carotid Occlusion
• Recent Myocardial Infarction
• Previous CEA With Recurrent Stenosis
• Prior Radiation Treatment To Neck

Symptomatic Carotid Stenosis

• Carotid Transient Ischemic Attack
• “Distinct Focal Neurological Dysfunction <24 Hrs
• Focal Cerebral Ischemia With Non-Disabling Stroke (modified Rankin <3)
• Transient Monocular Blindness (Amaurosis Fugax)
• Patients With A Disabling Stroke (modified Rankin >3) Are Excluded From Coverage
• Appropriate Documentation In The Medical Records Is Required Prior To Performing The Procedure
• The Degree Of Stenosis >70% Must Be Determined By Cerebral Angiography

Conclusions

• Carotid stenting can be performed in high risks patients with acceptable low morbidity and mortality.
• Advances in intracranial stent design allow improved treatment of aneurysms and intracranial atherosclerosis.
• Preliminary outcome of Wingspan suggests a high degree of symptomatic in stent restenosis in the younger patients with supraclinoid disease