Carotid Artery Disease

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Clinical Presentation Extracranial Carotid Disease

- Asymptomatic bruit
- Transient ischemic attack (TIA)
- Amaurosis fugax
- Reversible ischemic neurologic deficit
- Cerebrovascular accident (CVA)
- · Global cerebral ischemia

Incidence Of Stroke

- Ranks third as cause of death in USA

 √ 1 of 17 deaths
- 795,000 CVA's in 2005
- Rate decreased 29.7%
 - ✓ Between 1995 2005
- Females > Males
- Blacks 2x Whites

Circulation 2009; 119: 21

Physical Findings Extracranial Carotid Disease

- Cervical bruit
- Contralateral motor deficit
- · Contralateral sensory deficit
- Expressive aphasia/dysarthria
- · Ocular deficits
- Global deficit

Pathology

- Atherosclerosis
- Fibromuscular dysplasia
- Dissection



Differential Diagnosis

- Extracranial carotid artery disease
- · Cardiac embolic disease
- · Intracranial small vessel disease
- Vasospastic disease (migraine)

Pathophysiology

- Embolism
- Flow reduction

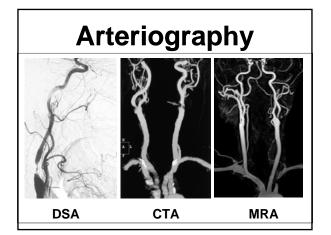


Cardiac Sources

- Paradoxical embolism
- · Atrial fibrillation
- · Atrial myxoma
- Valvular disease
- Mural thrombus
- Arch disease

Diagnostic Studies

- Duplex ultrasonography
- EKG / Rhythm strip
- Echocardiography
- CT Scan / MRI
- Arteriography



Arteriography

- · CT angiography
- MR angiography
- Contrast angiography

Attention to aortic arch, extracranial, and intracranial vessels

Anterior and posterior circulations

Medical Therapy

- · Risk factor management
 - √ Tobacco cessation
 - √ Hypertension control
 - ✓ Diabetes management
 - √ Hyperlipidemia treatment

Management of Concomitant Disease

- · Coronary artery disease
- Claudication
- · Renovascular disease
- · Mesenteric ischemia

Statin Therapy

- Zocor
- Lipitor
- Crestor

Target = LDL < 100 HDL > 50

TG < 150

Major anti-inflammatory effect

Antiplatelet Therapy

- Aspirin
 - 81 Mg QD
 - 325 Mg QD
- Clopidogrel (Plavix) 75 Mg QD
- Dypyridamole (Aggrenox)
- Ticlopidipine (TICLID) 250 Mg QD
 - ? Anticoagulation

Surgical Management

- Carotid endarterectomy
- Arch reconstruction
- Extranatomic bypasses
- Vertebral revascularization

Carotid Endarterectomy Asymptomatic Disease

- Acas study
- Randomization: ASA vs CEA
- Stenosis > 60%
 - Medical Rx = 11 % @ 5 yrs
 - CEA Rx = 5.1 % @ 5 yrs

.ΙΔΜΔ 1995: 273: 142:

Carotid Endarterectomy Symptomatic Disease 50 – 69% Stenosis

- Nascet study
- Randomization: ASA vs CEA
 - Medical Rx = 22.2% @ 5 yrs
 - CEA Rx = 15.7% @ 5 yrs

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Carotid Endarterectomy Symptomatic Disease 70 – 99% Stenosis

- Nascet study
- Randomization (659 pts): ASA vs CEA
 - Medical Rx = 28% @ 2 yrs
 - CEA Rx = 9% @ 2 yrs

NF.IM 1991: 325: 44

Surgery Morbidity & Mortality

Nascet Study

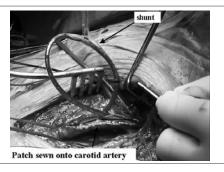
2.1% Death + CVA

Acas Study

1.5% Death + CVA

Highly selected surgeons Major medical centers Strict criteria

Carotid Endarterectomy



Carotid Artery Disease

20 to 30% of strokes are caused by atherosclerotic carotid artery disease

- Carotid artery disease increases the risk for stroke:
- By plaque or clot breaking off from the carotid arteries and blocking a smaller artery in the brain
- By narrowing of the carotid arteries due to plaque build-up
- By a blood clot becoming wedged in a carotid artery narrowed by plaque



Franchis Complex for the Assessment Complete Methods (State State State

Endovascular Treatment of Carotid Artery Disease

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Treatment Modalities

- Medical therapy
- Carotid endarterectomy
- Carotid artery stenting

Medical Treatment

- Advantages
 - ✓ Good option for those with short life expectancy (i.e. benefits of endovascular or surgical therapy does not outweigh the risks)
 - ✓ Does not require hospitalization
- Disadvantages
 - √ Risk of stroke may be higher
- √ Risk of hemorrhage
- √ Regular lab monitoring



Carotid Endarterectomy

- Disadvantages
 - √ Surgical therapy, longer recovery time
 - ✓ Risk of general anesthesia
 - √ Other risks
 - · Potential for emboli causing stroke
 - · Cranial nerve palsy
 - Infection

Carotid Endarterectomy

- Advantages
 - ✓ Proven history in low surgical risk patients
- ✓ Safe and effective (if surgeon and hospital are experienced)
- ✓ Decreases the risk of stroke

"High Risk" patients for surgery

- · Contralateral occlusion
- · Recurrent stenosis after surgery
- · History of neck dissection and/or radiation
- "High" lesion
- Medically unsuitable patients (class III/IV CHF, unstable angina, recent MI, CABG anticipated, severe COPD)

Carotid Artery Stenting

Treatment

- Stenotic artery is opened and plaque "wallpapered" to vessel wall
- Endovascular procedure, femoral access
- Local anesthesia
- Embolic protection device deployment
- Carotid artery stent placement



Carotid Artery Stenting

- Disadvantages
 - √ Limited safety/efficacy or long term data
 - √ Potential for embolization resulting in stroke
 - ✓ Currently there are limited experienced clinicians
 - ✓ Not all patients are suitable for carotid stenting
 - Severe aortic arch and supra-aortic vessel tortuosity and/or calcifications
 - Thrombus
 - · Very long severe lesions
 - String sign
 - · Heavy circumferential calcification

Carotid Artery Stenting

- Advantages
 - √ Treatment option for patients contraindicated for CEA
 - ✓ Stabilizes the plaque to minimize risk of embolization
 - √ Avoids the risk of cranial nerve damage
 - ✓ Does not require general anesthesia

Carotid Artery Stenting

- Goal of carotid stenting is to reduce the risk of future stroke
- Stenting the lesion:
- Stabilizes and "traps" the plaque
- Reduces the flow pressures on the plaque
- Improves blood flow
- Angiographic perfection is not the goal "The enemy of good is better"



Tapered



Percutaneous Femoral Arterial Access

 The procedure is completed via the femoral artery under local anesthesia with sedation. A guiding sheath is inserted. Heparin is administered.



Pre-dilatation of Diseased Area

A balloon catheter may be inserted into the stenotic area. The balloon may be temporarily inflated in order to pre-dilate the artery.



1. Carotid Artery Stenting - A Guide for Patients and Their Families. Guidant Corporation, August 2004. LT 2921888.

Embolic Protection Device Positioning

The filter is positioned into the distal carotid artery.
After crossing the diseased area of the artery, the filter will be opened. It will stay in place during the procedure to help capture any plaque or emboli.

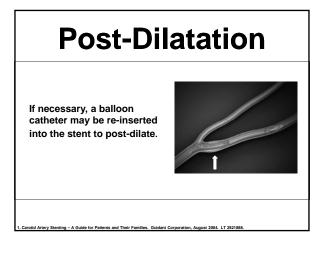


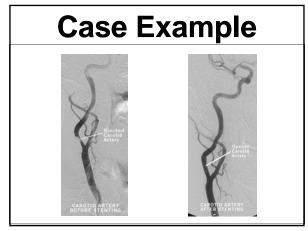
Stent Delivery and Deployment

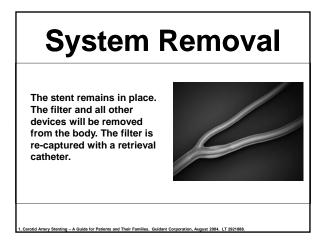
The stent is advanced to the area of the stenosis. After careful positioning, the stent will be opened to cover the plaque.

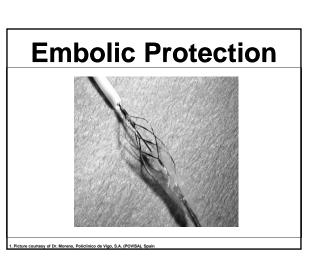


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Carotid Artery Stenting Clinical Studies

- Complication rates for CAS and CEA are low
- Large sample sizes are required to show a significant differences
- · 4 types of studies:
 - √ Prospective, randomized studies
 - √ Prospective registries
 - √ Retrospective registries
 - √ Meta-analyses

Prospective Registries

- · Used to gain FDA approval for most stents
- · Beach, ARCHeR
- Compared to comparable, historical high risk surgical populations

Prospective, Randomized CAS Studies

- · 3 multi-center, randomized studies:
 - ✓ SPACE: standard risk, symptomatic patients; 73% without EPD; higher event rates in both CEA and CAS groups; could not reach new enrollment goals
 - ✓ EVA-3S: standard risk, symptomatic patients; required subjects underestimated; underexperienced operators with excessive adverse events
 - √ SAPPHIRE: high risk, symptomatic and asymptomatic
 patients, non-inferiority of stenting was demonstrated

CREST Trial

- Only NIH sponsored, prospective, randomized, controlled, multi-center trial; normal risk patients
- Long enrollment period
- Rigorous operator training and credentialing
- Best medical therapy regimen used (although due to time period, this is probably now different)
- Independent neurologist evaluation
- · Crossovers discouraged
- New devices now
- Results available February 2010?

Post-approval studies

- Collect 30 day stroke, MI, and death information, for the most part
- Capture 2
- Sonoma/cabana
- · Sapphire ww
- Exact

Summary

- Patients with known vascular disease (esp. carotid distribution) increasing rapidly
- Number of qualified specialists remaining stable
- Improvement in endovascular techniques/devices
- Increasing number and types of patients that can be treated with less invasive means
- Next frontier: better medical optimization, drug eluting stents, bioabsorbable stents, preventing vascular disease?

Reimbursement

- · FDA-approved, CMS regulated
- Patients must have a >50% stenosis if symptomatic and >80% stenosis if asymptomatic
- Patient must enroll in post-approval study if asymptomatic for coverage
- All must be "high risk"