CAROTID INTERVENTIONS AND STENTING

Selections from the Vascular Surgery Symposium, presented April 2005 by the University of California, San Francisco, and Stanford University

Carotid Interventions: What Is the Future?—Christopher K. Zarins, MD, Chidester Professor of Surgery and Chief, Division of Vascular Surgery, Stanford University School of Medicine, Stanford, California

Review of prospective randomized trials

North American Symptomatic Carotid Endarterectomy Trial (NASCET): stroke/death rate within first 30 days 5.8% for carotid endarterectomy (CEA), 3.3% for medical treatment; trial halted due to high risk for stroke (26%) in medical treatment group; CEA associated with absolute risk reduction of 17%

Asymptomatic Carotid Atherosclerosis Study (ACAS): stroke/death rate for CEA 2.3% (0.4% for medical treatment within first 30 days); >50% of stroke risk attributable to preoperative arteriography; without arteriography, stroke risk ≈1%

Implications for surgical therapy: CEA effective, but need to reduce perioperative risk through elimination of carotid angiography, improved patient selection, improved techniques, and careful monitoring of outcomes and results

Implications for medical therapy: current therapies ineffective; high-risk patients with carotid disease outside of inclusion and exclusion criteria of trials should not be operated on; increased use of angiography indicated to ensure surgery limited to patients with sufficient degree of stenosis; new treatments required

CEA outcomes:

Massachusetts General Hospital—in 2000 patients undergoing CEA (two thirds asymptomatic), stroke/death rate 1.4%; low incidence of complications; contrast arteriography reduced from 88% to 13%; Stanford University—in >1000 patients, stroke/death rate 1%; population-based state registries—in 10,000 patients, stroke/death rate 2.6%; in 12,000 patients, stroke/death rate 3.7%; surgeon experience—increased stroke risk if few CEAs performed; single-center studies—in 5000 patients, stroke rate 1.7%; multicenter studies—in 50,000 patients, stroke/death rate 2.3%

High-risk patients: patients not candidates for CEA by NASCET criteria considered high risk; criteria—age >80 yr; stroke >6 mo ago; previous CEA on either side; intracranial disease; contralateral carotid occlusion; Yadav et al— patients not candidates by NASCET criteria for CEA; for symptomatic patients, stroke/death rate 10.8%; for asymptomatic patients, stroke/death rate 4%

Meta-analysis (2000): in 13 angioplasty and stent studies, stroke/death rate 7.8%; in CEA studies, stroke/death rate 4%

Embolization and carotid stenting: cerebroprotective devices (eg, balloons, filters, flow-reversal strategies) developed in response to problem of embolization, and have demonstrated efficacy in reducing complication rates of carotid stenting
Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial: patients randomized to CEA or carotid stenting with Cordis AngioGuard; no significant difference between stroke/death rate for stenting and CEA (4.5% and 6.6%, respectively); combined stroke, death, and myocardial infarction (MI) rate for CEA 12.5%, compared to 5.8% for stenting; 1-yr follow-up—no significant difference between risk for stroke, death, MI, or combined endpoint; no significant difference between stenting and CEA; Food and Drug Administration (FDA) advisory panel—Cordis’ Premarket Approval submission approved based on SAPPHIRE trial data, but device not currently approved by FDA for marketing

Acculink for Revascularization of Carotids in High-Risk Patients (ARCheR) trial: inclusion criteria included cardiac, comorbid, and anatomic conditions that made patients unsuitable for CEA; patients received Guidant’s Acculink carotid stent and Accunet embolic protection system; stroke/death rate for ARCheR 1, ARCheR 2, and ARCheR 3 trials 6.3%, 6.8%, and 7.6%, respectively; Acculink/Accunet system approved by FDA on basis of combined endpoint

Centers for Medicare and Medicaid Services decision summary: carotid stenting with embolic protection reasonable and necessary, but only for high-risk patients with symptomatic stenosis ≥70%, using FDA-approved carotid stent and embolic protection device; definition of high risk for CEA—significant comorbidities and/or anatomic risk factors, and poor candidate for CEA in opinion of surgeon

Carotid Revascularization with Endarterectomy or Stenting System (CaRESS) trial: nonrandomized prospective cohort study involving standard-risk patients; stroke/death rate 2% for CEA and stenting; only trial to involve large number of surgeons (most other trials administered by cardiologists); 45% of stenting procedures performed by vascular surgeons; conclusions—risk for stroke and death after stenting with cerebral protection equivalent to CEA in standard-risk patients, both symptomatic and asymptomatic; achievable risk (2%) within standard of care for carotid treatment

Catheter and Sheath Selection for Carotid Access and Intervention —George H. Meier, MD, Chief and Program Director, Vascular Surgery Fellowship, Eastern Virginia Medical School, Norfolk

Patients at high risk from CEA: age ≥80 yr; very sick (very few patients cannot tolerate carotid surgery with local anesthetic); redo surgery carries higher risk for complications; previous radiation treatment of neck

Elements of carotid stenting: nonselective arteriography to define anatomy and how best to catheterize; selective catheterization of carotid artery (CA); wire placement into external CA for sheath insertion (generally change to stiff Amplatz-type wire); sheath insertion into common CA; placement of embolic protection device across carotid lesion; predilation; placement of stent; postdilation; retrieval of embolic protection device

Carotid access: basic options femoral, brachial, and radial access; retrograde femoral access—commonly used; radial access—likely only used by cardiologists who routinely use radial access for carotid catheters; right brachial access—indicated in cases involving bovine arch; if bovine arch present, access to left CA may be possible only from right radial or brachial approach

Wire requirements: use basic relatively stiff wire with safe tip (to avoid artery dissection) to access aorta; for carotid cannulation, speaker uses stiff glide wire (good for tortuous anatomy, but more dangerous than standard wire, so not routinely used in aorta); use 0.35-mm wires for access and cannulation; when catheter in external CA, stiff wire (speaker uses Amplatz Super Stiff) used to drive sheath; use 0.14-mm wire to place embolic protection device

Issues with iliac arteries: cannot use femoral approach if unable to traverse iliac arteries; arteriography of abdominal aorta can help elucidate obstruction; do not attempt to traverse iliac arteries if aorta near occlusion; safer to access aortic arch with brachial approach

Aortic arch angiography: speaker recommends routine use, except in cases of significant dye issues, eg, renal dysfunction or allergies; speaker uses pigtail catheter (safer than Universal Flush) and standard wire

Aortic arch classification: with more counterclockwise rotation of arch vessels, cannulation increases in difficulty; origin of innominate artery determines difficulty; top of arch defines easy cannulation (type I), bottom of arch defines difficult cannulation (type III); the further down the arch the innominate originates, the more likely withdrawal catheter and retrograde approach necessary; amount of aortic disease also affects ease of cannulation, with more disease requiring more care and specificity; in type III arches, increasing distortion indicates more disease within associated vessels, ie, type III indicates difficult pathophysiology more than difficult anatomy; bovine arch—often cannot be seen on anteroposterior x-ray; defined by common trunk to common left CA and right innominate artery; complicates access

Carotid cannulation

Withdrawal catheter: catheter reformed into normal shape and pulled out, cannulating CA; speaker never reforms catheter in innominate artery; option 1—standard teaching for using Simmons catheter involves placing wire in subclavian, advancing catheter over arch to reform, then cannulating innominate (speaker uses this technique only if arch has no disease); option 2—more common to reform catheter off aortic valve; less traumatic approach; contraindicated in patients with aortic valve disease (check by listening for murmur)
Advancement catheter: angled deflection catheter, eg, Berenstein, Headhunter, vertebral; when advanced, catheter deflects wire using built-in angulation; catheter initially placed along curve of arch, then flipped over to use arch as fulcrum; most useful in type 1 arches; inner curve of arch used to drive catheter cephalad; generally safe and speaker’s favored approach for type 1 and many type II arches without much disease

Sheath placement: once wire and catheter advanced into external CA, stiff wire (eg, Amplatz) exchanged in external CA, but only when catheter fully protects path of wire; sheath placed over Amplatz into common CA; if no external CA, can telescope sheath up over catheter and stiff wire; with straight access, can place stent without sheath

Sheath selection: sheath needs to resist kinking and protect debris from being dislodged; Shuttle—used by speaker; 90 cm long; hydrophilic along most of length; Rabe—in speaker’s experience, kinks more often than Shuttle; sheath requirements—must handle tortuosity; must be woven; speaker believes metal wrapping/chain mail sheaths (eg, Arrowflex) have more resistance to movement; must track easily in difficult anatomy, ie, have hydrophilic coating

Alternative access options: open surgery fallback option; speaker aborts 10% of carotid stent procedures in favor of operative option or conservative management; if access not secure, think twice about placing stent, especially if inexperienced with procedure

The Impact of Drug-eluting Stents in Peripheral Vascular Disease: Outcomes vs Costs — Dr. Meier

Incidence of restenosis

Superficial femoral artery (SFA): most studies show stents do not convey patency advantages in SFA; stents make retreatment of SFA more difficult; stents increase treatment costs; issues—stents have demonstrated patency advantages in other beds (eg, coronary and renal circulation; conflicting data about iliac system); SFA difficult to treat surgically

Coronary arteries: most series involving bare-metal stents report restenosis rate of 20% to 30%; introduction of radiation-eluting stents conferred some improvements (β gave more benefit than γ); once developed, sirolimus-coated stents became treatment of choice

Carotid circulation: incidence of restenosis 5% (10% in some series)

Renal circulation: stents mostly balloon-expandable due to high radial-force requirement; incidence of restenosis 20%

Drugs currently used on stents: sirolimus; paclitaxel; actinomycin D—trial on coronary stents abandoned because of association with higher incidence of acute thrombosis; batimastat—similar to actinomycin D; when used in covered stent, thrombosis rate 20%

Cell cycle: most drugs on stents have effect on cell cycle; sirolimus inhibits progression from synthesis (S) stage to Gap 2 (G2); actinomycin D and radiation theoretically inhibit progression from S to G2; paclitaxel arrests cells at metaphase

Sirolimus-Coated Cordis (SIROCCO) stent trials 1 and 2 (Duda et al): patients randomized to sirolimus-eluting stent or uncoated stent for obstructive SFA disease (36 patients in SIROCCO I and 57 patients in SIROCCO II); patients had limited lesions; maximum number of stents 2 in SIROCCO II because dose of drug too high in SIROCCO I; results—6-mo angiography and 9-mo ultrasonography (US) showed no significant difference in any variables; at 18 mo, sirolimus dissipated, and US shows same degree of restenosis in sirolimus-eluting group as conventional-stent group; polished stents—SIROCCO I showed that highly polished stents required because surface of unpolished stents prone to corrosion; conclusions—sirolimus-eluting stents safe in SFA; trend toward superiority unsubstantiated; bare stent achieved excellent results (18-mo patency 17.9%)

Radiation-eluting stents: radioactive metal; tend to get large central component and “candy-wrapper stenosis” at ends of stent where radiation wanes; global effect not great enough to give real benefit

Resorbable stents: metal-alloy stents—Biotronik produces magnesium stent alloyed with elements to slow absorption and provide sufficient scaffolding and pliability; plastic biopolymer stents—completely resorbed; ideal drug-delivery stents; Biotronik data—ingrowth produces small amount of coverage on stent at 10 days; at 60 days, struts of stent completely dissolved; stents invisible (can completely resorbed; ideal drug-delivery stents)

Cost: conventional coronary stents in large volumes $600 each (older-generation stents =$400); drug-eluting stents $1500 to $3000 each; no demonstrated benefit of drug-eluting stents in SFA means cost not currently an issue; in United States, drug- eluting stents standard of care; in Europe, only high-risk patients receive drug-eluting stents, thereby significantly reducing cost

Conclusions: no role for drug-eluting stents in peripheral vascular disease at present time, but matter of time before right drug developed; resorbable stents may provide benefits not seen with drug-eluting stents; ultimate answer may be combination of resorbable stent with drug delivery

Educational Objectives
The goal of this program is to educate the listener on issues in carotid interventions and stenting. After hearing and assimilating this program, the clinician will be better able to:

1. Review the randomized trial data on carotid endarterectomy.
2. Identify patients at high risk for carotid endarterectomy.
3. Select the appropriate catheter and sheath for carotid access.
4. Discuss how aortic arch classification affects carotid access.
5. Review drug-eluting stents and their current applications.

**Discussed on This Program**

Batimastat (BB-94)
Dactinomycin (actinomycin D; ACT) [Cosmegen]
Sirolimus [Rapamune]
Paclitaxel [Onxol, Paxene, Taxol, Abraxane]

**Suggested Reading**


**Faculty Disclosure**

In adherence to ACCME guidelines, the Audio-Digest Foundation requests all lecturers to disclose any significant financial relationship with the manufacturer or provider of any commercial product or service discussed. For this issue, the speakers reported nothing to disclose.

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