J Am Coll Cardiol (2004);43:1596-601
Intracranial hemorrhage and hyperperfusion syndrome following carotid artery stenting: risk factors, prevention, and treatment
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OBJECTIVES: The study defined the incidence of cerebral hyperperfusion syndrome and intracranial hemorrhage (ICH) and the risk factors for their development following carotid artery stenting (CAS). BACKGROUND: Hyperperfusion syndrome and ICH can complicate carotid revascularization, be it endarterectomy or CAS. Although extensive effort has been devoted to reducing the incidence of ischemic stroke complicating CAS, little is known about the incidence, etiology, and prevention strategies for hyperperfusion and ICH following CAS. METHODS: We retrospectively reviewed the prospective database of 450 consecutive patients who were treated with CAS in our department to identify patients who developed hyperperfusion syndrome and/or ICH. RESULTS: The mean age of the patients was 72.7 +/- 10.9 years, and the mean diameter narrowing was 84 +/- 12.8%. Five (1.1% [95% confidence interval 0.4% to 2.6%]) patients developed hyperperfusion. Three (0.67%) of the five developed ICH. Two of these patients died (0.44%). Symptoms developed within a median of 10 h (range, 6 h to 4 days) following stenting. All five patients had correction of a severe internal carotid stenosis (mean 95.6 +/- 3.7%) with a concurrent contralateral stenosis >80% or contralateral occlusion and peri-procedural hypertension. These same risk factors are involved in cerebral hyperperfusion following carotid endarterectomy. The use of platelet glycoprotein IIb/IIIa receptor blockers did not appear to increase the risk ICH. CONCLUSIONS: The hyperperfusion syndrome occurs infrequently following CAS, and ICH occurs in 0.67% of patients. Patients with severe bilateral carotid stenoses may be predisposed to ICH, particularly if there is concurrent arterial hypertension. Patients with these factors may require more intensive hemodynamic monitoring after CAS, including prolongation of hospitalization in some cases.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15120817

Catheter Cardiovasc Interv (2004);63:364-70
Endovascular treatment of the subclavian artery: stent implantation with or without predilatation
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The endovascular treatment of subclavian artery (SA) lesions is less invasive than open surgical repair, with a low rate of complications. We report our experience in 89 subclavian obstructive lesions (n = 86) treated with stenting: 76 (85.3%) stenoses and 13 (14.6%) total occlusions. The left side was most frequently involved (83.1%), localized at the prevertebral segment in 91%. Technical success was obtained in 83 (93.3%) cases, 100% in stenotic lesions and 53.8% in total occlusions. There were nine global complications (10.1%): five (5.6%) at site of puncture, two distal embolization (2.2%), and two (2.3%) major events. The long-term follow-up was 3.51 +/- 1.98 years, during which time 13 (16.8%) restenoses and 2 (2.6%) reocclusions were noted.

Subgroup analysis of patients with stenting after predilatation versus direct stenting technique showed in-hospital complications only in the first group, with a restenosis rate of 28.5% vs. 4.7%, respectively (P = 0.003). We consider stenting for SA obstructive lesions the first therapeutic option.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15505851

Catheter Cardiovasc Interv (2004);61:1-4
Cutting balloon angioplasty of the popliteal and infrapopliteal vessels for symptomatic limb ischemia
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Options for lower limb percutaneous revascularization are limited especially for complex vessel obstruction. Cutting balloon angioplasty (CBA) has been described in the coronary literature as effective for complex disease. We analyzed our peripheral vascular database and report procedural outcomes along with the clinical success at a mean of 1-year follow-up in 73 patients with symptomatic lower limb ischemia undergoing CBA. CBA was successfully completed in all 73 patients (93 vessels; 100%) with predilation necessary in 4% of vessels. Severe intimal dissection or inadequate hemodynamic result necessitated in adjunctive stenting in 20%. There were no incidents of vessel perforation or surgical target vessel revascularization. One patient (1.5%) died during the periprocedural period due to renal failure. After mean follow-up of 1 year (6-21 months), 89.5% of threatened limbs were salvaged. CBA is a safe and feasible option for the treatment of popliteal and infrapopliteal vessels.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14696150

Catheter Cardiovasc Interv (2004);61:5-11
Subclavian artery stenting: factors influencing long-term outcome
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This study provides extended follow-up of a nonrandomized series of symptomatic patients who underwent subclavian stent-supported angioplasty (SSA) with emphasis on preprocedure factors that may have influenced outcome. The endpoints of mortality and restenosis were analyzed using backward stepwise logistic regression with the following clinical variables: coronary artery disease, hypertension, hyperlipidemia, smoking, diabetes mellitus, chronic obstructive pulmonary disease, chronic renal insufficiency/failure, and hypothyroidism. Restenosis is reported based on prospective serial noninvasive studies and/or angiography. Mortality was evaluated by retrospective database review and inquiry to the State Department of Health and Human Services' statistical registry in patients who were lost to follow-up. Over a 9-year period (mean follow-up, 36.1 +/- 30.4 months; maximum observation, 109.5 months), 101 stents were placed in 91 consecutive patients (37 male, 54 female). The mean age at intervention was 62.03 +/- 9.3. The procedure was technically successful in 89 patients 97% (mean pre- and postoperative stenosis and pressure gradients were 90.2% +/- 9.4% vs. 3.7%

+/- 6.6%, P < 0.001, and 59.9 +/- 35.2 vs. 0 mm Hg, P < 0.001, respectively), with 13 minor complications and no immediate major complications. One patient died of unrelated causes within 30 days. Per Kaplan-Meier method, for years 1 through 5, the rates of overall patency were 96%, 91%, 86%, 77%, and 72%; likewise, overall patient survival was 93%, 88%, 8%4, 81%, and 76%. No clear predictors for restenosis were discovered, although a trend toward higher recurrence was noted in women (18.5% in female vs. and 8.6% in male; P > 0.05), but the same were less likely to die during follow-up (P > 0.001). Also, the presence of hypothyroidism (P = 0.004) and increasing age (P = 0.068) were positively correlated with all-cause mortality. This study suggests that SSA is predictable, safe, and durable. The diagnosis of symptomatic subclavian disease is of prognostic importance, with age and male gender representing important predictors of all-cause long-term mortality. The strong association of increased mortality with hypothyroidism is difficult to discard and raises the question of a yet to be described thyroid steal phenomena.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14696151

Catheter Cardiovasc Interv (2004);63:7-12
Wireless laser-assisted angioplasty of the superficial femoral artery in patients with critical limb ischemia who have failed conventional percutaneous revascularization
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Percutaneous revascularization has become an effective treatment for patients suffering from chronic critical limb ischemia (CLI) due to chronic atherosclerotic obstructions, including total occlusions. Unlike other vascular beds, total chronic occlusions of the femoropopliteal arteries are frequently found in patients with severe claudication or CLI. As a consequence, patients with long chronic total occlusions of the femoropopliteal arteries are generally not considered optimal candidates for percutaneous revascularization and are frequently referred for surgical revascularization. In the present study, we sought to evaluate the feasibility, safety, and outcome of a modified wireless laser ablation technique to recanalize total occlusions in patients with CLI who had failed conventional percutaneous techniques for limb salvage. Procedural success, complications, actuarial freedom of limb loss, and surgical revascularization were evaluated in 25 patients after a mean follow-up ofczon ww9.2( )]Tcra( )pati25 patf 0 TD-5.5-0.05.3(=a

J Am Coll Cardiol (2004);44:941-57
ACC/ACP/SCAI/SVMB/SVS clinical competence statement on vascular medicine and catheter-based peripheral vascular interventions: a report of the American College of Cardiology/American Heart Association/American College of Physician Task Force on Clinical Competence (ACC/ACP/SCAI/SVMB/SVS Writing Committee to develop a clinical competence statement on peripheral vascular disease)
M. A. Creager*, et al.*
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15312891

Catheter Cardiovasc Interv (2004);63:21-30
Optimal therapeutic approaches to femoropopliteal artery intervention
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Superficial femoral artery disease presents a complex challenge for therapy. The extent of vascular involvement may vary from focal disease with symptoms of intermittent claudication to long total occlusions manifest as critical limb ischemia. Optimal therapy requires understanding the available options including exercise programs, pharmacologic medical therapy, surgery and interventional endovascular therapy. Rapidly advancing endovascular technology for enabling safe intervention in complex, long occlusive segments of the superficial femoral artery continues to emerge. New devices like the SafeCross wire, Excimer laser, Silverhawk Atherectomy catheter, Cryoplasty catheter and new generations of bare metal and drug-eluting nitinol stents are shifting the paradigm for therapy from surgical to more endovascular treatment even for the most complex disease presentation.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15343563

J Am Coll Cardiol (2004);44:2307-14
Primary stent-supported angioplasty for treatment of below-knee critical limb ischemia and severe claudication: early and one-year outcomes
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OBJECTIVES: The objective of this study was an investigation of the safety and efficacy of primary below-knee stent-supported angioplasty (BKSSA) for restoring straight inline arterial flow in patients with critical limb ischemia (CLI) or lifestyle-limiting claudication (LLC). BACKGROUND: Surgical tibial bypass for CLI and severe LLC is associated with significant morbidity, mortality, and graft failure, whereas percutaneous angioplasty is suboptimal. METHODS: Below-knee stent-supported angioplasty was attempted in 82 patients (92 limbs) with either CLI (68%) or severe LLC (32%). Patients received daily aspirin, thienopyridine, and glycoprotein IIb/IIIa agents during the procedure. One-month major adverse events (MAEs) were defined as death, myocardial infarction, major unplanned amputation, need for surgical revascularization, or major bleeding. Clinical success was defined as improved resting ankle brachial index by > or =0.10, relief of resting pain, healing of ulceration or amputation, and improvement of claudication. RESULTS: Mean age of patients was 74 +/- 17 years. In 86 limbs, straight

inline flow was restored to at least one tibial vessel. Technical success was 94% for de novo lesions and there were no MAEs. Ankle brachial indexes increased for all groups (CLI = 0.32 +/- 0.13 to 0.9 +/- 0.14 and LLC = 0.65 +/- 0.09 to 0.95 +/- 0.12; p < or = 0.0001, pre vs. post). Relief of rest pain and healing of ulcerations and amputations were seen in 96% (47 of 49) of patients with CLI who underwent successful intervention. CONCLUSIONS: Below-knee stent-supported angioplasty for CLI and LLC improves ankle brachial indexes comparable to tibial bypass, heals amputations and ulcerations, relieves rest pain, and improves ambulation. Because BKSSA is associated with minimal MAE, it may hold promise as an alternative therapy for patients with CLI and LLC.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15607391

Catheter Cardiovasc Interv (2004);61:293-305
Carotid angioplasty under cerebral protection with the PercuSurge GuardWire System
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The purpose of this study was to examine the possible beneficial effect of the PercuSurge GuardWire cerebral protection device based on balloon occlusion of the distal internal carotid artery and debris aspiration for patients undergoing carotid artery stenting (CAS). A total of 268 CAS procedures were attempted under cerebral protection using the PercuSurge GuardWire system in 242 patients (194 men; mean age, 71.2 +/- 9.4 years; range, 40-91). The lesions were mainly atherosclerotic; 64% were symptomatic. Technical success was 99.3%. All lesions were stented except three postangioplasty restenoses. Prophylactic occlusion during balloon dilatation and stenting was well tolerated in 255 patients (95.9%). Microscopic analysis of the aspirated blood showed different types of particles numbering between 7 and 145 per procedure, with a mean diameter of 250 microm (mean, 56-2,652 microm). The 30-day stroke and death rate was 2.3%, with four periprocedural complications at < 48 hr (one retinal embolism and three transient ischemic attacks), one intracerebral hemorrhage at

the chronic total occlusions with no clinical perforations or distal embolizations, and complications consisted of a single dissection greater than or equal to grade C.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15476633

Catheter Cardiovasc Interv (2005);64:12-7
Percutaneous transluminal angioplasty of infrapopliteal arteries in patients with intermittent claudication: Acute and one-year results
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In advanced stages of infrapopliteal peripheral arterial occlusive disease with critical ischemia of the lower limb, the efficacy of percutaneous transluminal angioplasty (PTA) is well established. In contrast, PTA is currently not the therapy of choice in intermittent claudication (IC). In this prospective study, patients with IC were treated percutaneously. Technical aspects and long-term results are presented. In 78 patients (61 males, or 78.2%; age, 71 +/- 11 years) with IC (Rutherford grade 2 or 3), 104 interventions were performed. At baseline, the initial/absolute walking distance (IWD/AWD) was 49 +/- 34/102 +/- 88 m; the ankle-brachial index (ABI) was 0.61 +/- 0.2 before and 0.49 +/- 0.2 after exercise. A crossover approach was used in 74% and an antegrade access in 26% of the cases. In 19 interventions (18.3%), the excimer laser technique was used, and in 26 interventions (25%) a total of 39 stents were implanted. Procedural success rate was 89.4%. IWD and AWD improved to 107 +/- 67 m and 167 +/- 74 m ($P < 0.0001$ vs. baseline each), respectively, and the ABI at rest and after exercise increased to 0.88 +/- 0.13 and 0.72 +/- 0.19 ($P < 0.0001$ vs. baseline each). Six complications occurred (5.8%). One embolic occlusion, two minor groin hematoma, one arteriovenous fistula, one compartment syndrome, and one perforation. All were treated conservatively. After 12 months, the primary patency rate was 66.3%, cumulative primary assisted patency rate was 81.9%, and secondary patency rate was 91.5%. Percutaneous revascularization of infrapopliteal arteries in patients with IC is feasible and associated with good acute clinical results and an encouraging long-term patency rate. The complication rate is low. Catheter Cardiovasc Interv 2005;64:12-17. (c) 2004 Wiley-Liss, Inc.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15619276

Circulation (2004);109:1476-81
Beneficial effects of clopidogrel combined with aspirin in reducing cerebral emboli in patients undergoing carotid endarterectomy
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BACKGROUND: Postoperative thromboembolic stroke affects 2% to 3% of patients undergoing carotid endarterectomy (CEA) and is preceded by 1 to 2 hours of increasing cerebral embolization. Previous work has demonstrated that high rates of postoperative embolization are associated with increased platelet reactivity to adenosine 5'-diphosphate (ADP). Our hypothesis was that preoperative administration of the platelet ADP antagonist clopidogrel could reduce postoperative embolization.
METHODS AND RESULTS: One hundred CEA patients on routine aspirin therapy (150

mg) were randomized to 75 mg clopidogrel (n=46) or placebo (n=54) the night before surgery. Platelet response to ADP was assessed by whole-blood flow cytometry. The number of emboli detected by transcranial Doppler within 3 hours of CEA was independently quantified. Time taken from flow restoration to skin closure was used as an indirect measure of the time to secure hemostasis. In comparison with placebo, clopidogrel produced a small (8.8%) but significant reduction in the platelet response to ADP (P<0.05) while conferring a 10-fold reduction in the relative risk of those patients having >20 emboli in the postoperative period (odds ratio, 10.23; 95% CI, 1.3 to 83.3; P=0.01, Fisher's exact test). However, in the clopidogrel-treated patients, the time from flow restoration to skin closure (an indirect marker of hemostasis) was significantly increased (P=0.04, Fisher's exact test), although there was no increase in bleeding complications or blood transfusions. CONCLUSIONS: This is the first study to show that a CEA patient's postoperative thromboembolic potential can be significantly reduced by targeted preoperative antiplatelet therapy without increasing the risk of bleeding complications.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15007001

J Am Coll Cardiol (2004);43:1358-62
Severe bilateral carotid stenosis: the impact of ipsilateral stenting on Doppler-defined contralateral stenosis
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OBJECTIVES: The study examined the effect of carotid stenting (CS) on contralateral carotid Doppler-defined degree of stenosis. BACKGROUND: Patients with carotid disease are frequently referred for carotid revascularization (carotid endarterectomy

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Catheter Cardiovasc Interv (2004);63:1-6
Carotid stenting with a new system for distal embolic protection and stenting in high-risk patients: the carotid revascularization with ev3 arterial technology evolution (CREATE) feasibility trial
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The purpose of this study was to evaluate the feasibility of carotid artery revascularization using a new system for carotid stenting and distal embolic protection in 30 patients with severe carotid stenosis and high risk for carotid endarterectomy (Carotid Revascularization With ev3 Arterial Technology Evolution, or CREATE). Previous studies suggest that patients with carotid stenosis and serious comorbid cardiopulmonary and anatomic conditions are at high risk for carotid endarterectomy. All patients underwent percutaneous revascularization using the Protege GPS self-expanding nitinol stent (ev3, Plymouth, MN) and the Spider distal embolic protection system (ev3). In-hospital and 30-day outcomes were analyzed. High-risk features included age > 75 years (63%), left ventricular ejection fraction < 35% (20%), and restenosis after prior carotid endarterectomy (53%). Procedural success was 100%. In-hospital complications included severe vasovagal reactions in six patients (20%) and a popliteal embolus in one patient (3.3%), treated by successful embolectomy. During 30 days of follow-up, two patients (6.6%) experienced minor neurological deficits, including transient expressive aphasia that resolved without therapy in one patient and homonymous hemianopsia due to contralateral posterior circulation stroke in one patient. This study supports the feasibility of percutaneous carotid artery revascularization with the Protege GPS self-expanding stent and Spider distal embolic protection system, which will be evaluated in a large multicenter pivotal trial (CREATE Pivotal Trial).
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15343559

J Am Coll Cardiol (2004);44:1966-9
Effect of two different neuroprotection systems on microembolization during carotid artery stenting
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OBJECTIVES: This study sought to compare the efficacy of two different cerebral protection systems for the prevention of embolization during carotid artery stenting (CAS) using a transcranial Doppler (TCD) monitoring with the detection of microembolic signals (MES). BACKGROUND: Despite the introduction of cerebral protection systems, neurologic complications during CAS cannot completely be prevented. Transcranial Doppler and detection of MES may aid in assessing the efficacy of different neuroprotection systems. METHODS: A total of 42 patients with internal carotid artery stenoses were treated by CAS using either a filter (E.P.I. FilterWire, Boston Scientific Corp., Santa Clara, California) (n = 21) or a proximal endovascular clamping device

(MO.MA system, Invatec s.r.l., Roncadelle, Italy) (n = 21). Microembolic signal counts were compared during five phases: placement of the protection device, passage of the stenosis, stent deployment, balloon dilation, and retrieval of the protection device. RESULTS: There were no significant differences in clinical or angiographic outcomes between the two groups. Compared to the filter device, the MO.MA system significantly reduced MES counts during the procedural phases of wire passage of the stenosis, stent deployment, balloon dilation, and in total (MES counts for the filter device were 25 +/- 22, 73 +/- 49, 70 +/- 31, and 196 +/- 84 during the three phases and in total, MES counts for the MO.MA system were 1.8 +/- 3.2, 11 +/- 19, 12 +/- 21, and 57 +/- 41, respectively; $p < 0.0001$). CONCLUSIONS: In comparison to a filter device the MO.MA system led to significantly lower MES counts during CAS. The detection of MES by TCD may facilitate the evaluation and comparison of different neuroprotection systems.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15542277

Catheter Cardiovasc Interv (2004);62:230-3
Percutaneous revascularization of the common femoral artery for limb ischemia
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We performed percutaneous transluminal intervention in 20 consecutive patients (21 limbs) with common femoral artery (CFA) lesions causing symptomatic limb ischemia. In 12 limbs, concurrent additional percutaneous intervention proximal or distal to the target CFA lesion was performed. Angiographic success was obtained in 100%, with procedural success (angiographic success without a major in-hospital complications) in 90% and clinical success (procedural success and in-hospital improvement by at least one Fontaine functional class) in 81% of the limbs. The in-hospital Fontaine class improved by at least one functional class in 17 of 19 patients (89%), and the overall in-hospital event-free survival was 90% (18 of 20 patients). At follow-up (11.4 +/- 6 months), the overall event-free survival was 90% (18 of 20 patients) and 17 of 19 patients (89%) continue to show improvement by at least one functional (Fontaine) class. Percutaneous intervention of the CFA can be performed with a rate of high technical success and a low complication rate. It provides excellent clinical results at mid-term follow-up and appears to be a reasonable alternative to surgical therapy in patients at high risk for surgery.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15170717

N Engl J Med (2004);351:1493-501
Protected carotid-artery stenting versus endarterectomy in high-risk patients
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BACKGROUND: Carotid endarterectomy is more effective than medical management in the prevention of stroke in patients with severe symptomatic or asymptomatic atherosclerotic carotid-artery stenosis. Stenting with the use of an emboli-protection device is a less invasive revascularization strategy than endarterectomy in carotid-artery

disease. METHODS: We conducted a randomized trial comparing carotid-artery stenting with the use of an emboli-protection device to endarterectomy in 334 patients with coexisting conditions that potentially increased the risk posed by endarterectomy and who had either a symptomatic carotid-artery stenosis of at least 50 percent of the luminal diameter or an asymptomatic stenosis of at least 80 percent. The primary end point of the study was the cumulative incidence of a major cardiovascular event at 1 year--a composite of death, stroke, or myocardial infarction within 30 days after the intervention or death or ipsilateral stroke between 31 days and 1 year. The study was designed to test the hypothesis that the less invasive strategy, stenting, was not inferior to endarterectomy. RESULTS: The primary end point occurred in 20 patients randomly assigned to undergo carotid-artery stenting with an emboli-protection device (cumulative incidence, 12.2 percent) and in 32 patients randomly assigned to undergo endarterectomy (cumulative incidence, 20.1 percent; absolute difference, -7.9 percentage points; 95 percent confidence interval, -16.4 to 0.7 percentage points; P=0.004 for noninferiority, and P=0.053 for superiority). At one year, carotid revascularization was repeated in fewer patients who had received stents than in those who had undergone endarterectomy (cumulative incidence, 0.6 percent vs. 4.3 percent; P=0.04). CONCLUSIONS: Among patients with severe carotid-artery stenosis and coexisting conditions, carotid stenting with the use of an emboli-protection device is not inferior to carotid endarterectomy.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15470212

Am J Cardiol (2005);95:297-300
Symptomatic patients have similar outcomes compared with asymptomatic patients after carotid artery stenting with emboli protection
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In a single-center cohort of 174 consecutive patients, we sought to evaluate whether the use of emboli protection devices (EPDs) results in equivalent rates of adverse events in symptomatic and asymptomatic patients after carotid artery stenting (CAS) with EPDs. Death or stroke occurred in 3.3% in the symptomatic group and in 3.5% of the asymptomatic group at 30 days (p = NS). At 6 months, there was also no significant difference in the rate of stroke or death between the groups. Unlike surgical revascularization, symptomatic patients did not have a greater risk for stroke and death compared with asymptomatic patients after CAS with EPDs.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15642577