Int J Mol Med 2003 Mar;11(3):365-8

Percutaneous transluminal angioplasty against arteriosclerosis obliterans in dialysis patients.

Tsuchida K, Takemoto Y, Sugimura K, Yoshimura R, Nakatani T.

The incidence of peripheral arteriosclerosis is on the increase in chronic hemodialysis patients. Recently, the intervention (IV) treatment is conducted to deal with this problem. IV was performed in 4 dialysis patients against the complication of arteriosclerosis obliterans (ASO) but the result was unsuccessful in 3 of them. These 3 failure cases were investigated to find the problems associated with percutaneous transluminal angioplasty (PTA). Cases 1, 2 and 3 had intermittent claudication while case 4 had gangrenous toes as the major complaint. The symptoms in these cases were attributable to 90-100% stenosis and occlusion of superficial femoral artery, bilateral iliac arteries, bilateral superficial femoral-popliteal artery, branch of right iliac artery and left iliac artery region, respectively. IV was successful in case 1 but failed in cases 2 and 4 because the catheter itself did not go through due to the severe stenosis of vessel or the procedure of forcefully dilating the vessel caused dispersion of minute thrombi. In case 3, acute myocardial infarction occurred at 10 h after successful IV, resulting in sudden death. In view of the extent of invasion, IV is a treatment method selected against ASO in dialysis patients. However, the method has a high risk of causing thrombus formation, vessel rupture and organ failure. In this regard, it is advisable to evaluate the systemic condition and conduct IV if the extent of stenosis is mild.

Complement Ther Med 2002 Sep;10(3):170-5

The effects of a low frequency acoustic waveform on peripheral vascular disease: a pilot study.

Candela LL, Wallmann HW, Witt CS.

OBJECTIVE: To evaluate the effects of a low frequency acoustic waveform on peripheral vascular disease (PVD). DESIGN: Pilot study utilizing a one-group pre-intervention, post-intervention design. SETTING: Adults with peripheral vascular disease were recruited through local advertisements. The study was conducted at a local facility housing the electroacoustic transducer. INTERVENTION: A 25-min exposure to an electroacoustic transducer. OUTCOME MEASURES: Pre- and post-measurement of Doppler ultrasound blood-flow velocities in 10 arteries, ankle brachial index (RBI), foot assessment, and 1-week post telephone survey. RESULTS: A significant increase was noted in the right ankle brachial index (RABI) but not the left. Blood flow increased in all arteries, significantly in four. Thirteen participants reported improvement in symptom of peripheral vascular disease over the following week. CONCLUSIONS: While conclusions must be viewed cautiously, the significant differences noted warrant further study to examine effects of acoustic waveforms on peripheral vascular disease.

Catheter Cardiovasc Interv 2003 Feb;58(2):252-60

Balloon angioplasty and stenting of multiple intralobar pulmonary arterial stenoses in adult patients.

Rothman A, Levy DJ, Sklansky MS, Grossfeld PD, Auger WR, Ajami GH, Behling CA.

Balloon angioplasty and stent placement for pulmonary arterial stenoses in children are well-established therapies. In contrast, management of isolated peripheral pulmonary arterial stenoses in adults remains relatively unexplored. Four women (ages 18-63 years) with multiple discrete intralobar pulmonary arterial stenoses were treated with balloon angioplasty. Initially, 4-5 stenoses were dilated in each patient. The mean minimum diameter of the stenoses increased from 1.3 to 3.1 mm ($P < 0.001$), and the mean ratio of right ventricular to aortic systolic pressure decreased from 0.92 to 0.62 ($P < 0.05$). Each patient had marked symptomatic improvement. However, three patients developed recurrence of symptoms 4-24 months after angioplasty, and two had angiographic evidence of restenosis at previously dilated sites. These restenoses were treated with repeat angioplasty or stent implantation (three stents in each patient). One of these two patients developed near-occlusive restenosis of the stents and had successful bilateral lung transplantation. The other patient had a third catheterization with successful implantation of three additional stents. The third patient with recurrent symptoms died 2 years later, without further intervention. Transcutaneous catheter therapy for multiple intralobar pulmonary arterial stenoses in adults is highly successful acutely, but restenosis is common within several months. For some patients, balloon angioplasty and stent implantation may provide definitive management, while for others these procedures may serve as a bridge to lung transplantation.

Rev Cardiovasc Med 2002;3 Suppl 1:S35-40

Use of glycoprotein IIb/IIIa platelet inhibitors in peripheral vascular interventions.

Ansel GM, George BS, Botti CF, Silver MJ.

With the expanding use of endovascular techniques for the treatment of peripheral vascular disease, consideration of glycoprotein IIb/IIIa receptor inhibitors to enhance the safety and efficacy of these procedures has increased. The scientific literature shows the benefits with the use of these agents in coronary vasculature interventions. However, data evaluating treatment with glycoprotein IIb/IIIa receptor inhibitors during peripheral vascular procedures is limited, with the vast majority of the trials investigating abciximab. With the varied vascular beds and end organs that may be affected by peripheral vascular intervention, the safety and efficacy may need to be studies for each area. The current literature ranging from carotid stenting to thrombolysis and mechanical thrombectomy for acute limb ischemia is reviewed, and recommendations are discussed on the use of these agents. The forthcoming results of controlled clinical trials should further clarify the clinical applications of these agents in peripheral vascular intervention.

Ann Vasc Surg 2002 Dec;16(6):797-804

Current status of thrombolysis for peripheral arterial occlusive disease.

Ouriel K.

Acute peripheral arterial occlusion occurs as a result of thrombosis or embolism. A reduction in the prevalence of rheumatic heart disease accounts for a shift in the frequency of embolic to thrombotic occlusions. Also, a dramatic increase in the number of lower extremity arterial bypass graft procedures explains the predominance of graft occlusions in most recent series of patients with acute limb ischemia. While open surgical procedures remain the gold standard in the treatment of peripheral arterial occlusion, thrombolytic agents have been employed as an alternative to primary surgical revascularization in patients with acute limb ischemia. Systemic administration of thrombolytic agents, while effective for small coronary artery clots, fails to achieve dissolution of the large peripheral arterial thrombi. Catheter-directed administration of the agents directly into the occlusive thrombus is the only means of effecting early recanalization. Prior to 1999, urokinase was the sole agent used in North America for peripheral arterial indications, but the loss of the agent from the marketplace forced clinicians to turn to alternate agents, specifically alteplase and reteplase. Interest in the use of platelet glycoprotein inhibitors and mechanical thrombectomy devices also rose, coincident with the loss of urokinase from the marketplace. Most clinicians welcome the predicted return of urokinase to the marketplace. New investigative trials should be organized and executed to answer some of the remaining questions related to thrombolytic treatment of peripheral arterial disease. Foremost in this regard remains the question of which patients are best treated with percutaneous thrombolytic techniques and which are best treated with primary operative intervention. Ultimately, however, the thrombolytic agents are but one tool in the armamentarium of the vascular practitioner. This review is directed at providing the practicing clinician with the basic fund of knowledge necessary when determining the most appropriate intervention in a particular patient with peripheral arterial occlusion, be it thrombolytic therapy, percutaneous mechanical thrombectomy, primary surgical revascularization, or a combination of the three.

Circulation 2002 Oct 8;106(15):1909-12

Missed opportunities to treat atherosclerosis in patients undergoing peripheral vascular interventions: insights from the University of Michigan Peripheral Vascular Disease Quality Improvement Initiative (PVD-QI2).

Mukherjee D, Lingam P, Chetcuti S, Grossman PM, Moscucci M, Luciano AE, Eagle KA.

BACKGROUND: Peripheral vascular disease is a manifestation of systemic atherosclerosis and is associated with an increased risk of cardiovascular morbidity and mortality. METHODS AND RESULTS: We examined clinical outcomes in 66 consecutive patients undergoing peripheral vascular interventions at our institution between January 2001 and October 2001. At hospital discharge and at 6 months, lifestyle modifications and use of evidence-based therapy was suboptimal. At 6 months, a significant proportion continued to smoke (22.7%) and only half of the patients exercised, controlled their weight, or modified their diet for lipid control. The use of antiplatelet therapy was 77.2%; of angiotensin-converting enzyme, 35.9%; of beta-blockers, 42.5%; and of statins, 50%. Twelve of the 66 patients (18.2%) had a clinical event of death, myocardial infarction, or stroke. An appropriateness algorithm for use of secondary prevention measures was created with the use of evidence-based therapy guidelines, and a composite appropriateness variable was also created. The use of evidence-based therapy was associated with a significant reduction of the composite of death, myocardial infarction, and stroke at 6 months (OR 0.02, 95% CI 0.01 to 0.44, P=0.01). CONCLUSIONS: Atherosclerosis risk factors are very prevalent in patients with peripheral vascular disease, but these patients receive less than optimal treatment after a predominantly technical vascular intervention. Effective secondary prevention with appropriate lifestyle interventions and evidence-based medical therapy needs to be strongly encouraged and implemented in these patients.

Radiology 2002 Oct;225(1):21-6

Vascular inflammation and percutaneous transluminal angioplasty of the femoropopliteal artery: association with restenosis.

Schillinger M, Exner M, Mlekusch W, Rumpold H, Ahmadi R, Sabeti S, Haumer M, Wagner O, Minar E.

PURPOSE: To determine the association of pre- and postprocedural serum levels of C-reactive protein (CRP), serum amyloid A (SAA), and fibrinogen at 6-month evaluation of restenosis after percutaneous transluminal angioplasty (PTA) of the femoropopliteal artery. MATERIALS AND METHODS: In a prospective cohort study, 172 consecutive patients with peripheral artery disease of Fontaine stage IIa, IIb, or III who underwent successful PTA of the superficial femoral and popliteal arteries were included. Patency at 6 months was evaluated by using oscillography, ankle-brachial index, and color-coded duplex ultrasonography. The association of restenosis and CRP, SAA, and fibrinogen levels at baseline, 24 hours, and 48 hours after intervention was assessed by means of multivariate analysis with adjustment for known risk factors for restenosis. RESULTS: Restenosis was found in 56 patients (33%) within 6 months. CRP values at baseline (adjusted odds ratio, 2.2; 95% CI: 1.1, 4.2) and 48 hours after intervention (adjusted odds ratio, 2.3; 95% CI: 1.6, 3.1) were independently associated with 6-month restenosis. SAA and fibrinogen values at any time interval were not significantly associated with patency in the multivariate models. CONCLUSION: The extent of vascular inflammation as measured by means of acute-phase reactants before and after PTA of the femoropopliteal artery is associated with 6-month restenosis. Baseline and 48-hour CRP levels were independent predictors of postangioplasty outcome.

J Intern Med 2002 Sep;252(3):225-32

Extensive use of peripheral angioplasty, particularly infrapopliteal, in the treatment of ischaemic diabetic foot ulcers: clinical results of a multicentric study of 221 consecutive diabetic subjects.

Faglia E, Mantero M, Caminiti M, CaravaggI C, De Giglio R, Pritelli C, Clerici G, Fratino P, De Cata P, Paola LD, Mariani G, Poli M, Settembrini PG, Sciangula L, Morabito A, Graziani L.

OBJECTIVE: To evaluate the feasibility, technical effectiveness and limb salvage potential of percutaneous transluminal angioplasty (PTA), particularly infrapopliteal, in diabetic subjects with ischaemic foot ulcer. DESIGN: Intervention study with PTA in consecutive series. SETTING: Six Diabetology Foot Centres and one Cardiovascular Catheterization Laboratory in Italy. SUBJECTS: Two hundred and twenty-one consecutive diabetic subjects hospitalized for ischaemic foot ulcer. INTERVENTION: Peripheral arterial occlusive disease (PAOD) was investigated by means of foot pulses assessment, ankle-brachial-index (ABI), transcutaneous oxygen tension (TcPO2) and duplex scanning. If non-invasive parameters suggested PAOD, angiography was performed and a PTA was carried out during the same session. MAIN OUTCOME MEASURES: PTA feasibility, improvement of ABI and TcPO2, limb salvage rate, clinical recurrence. RESULTS: On angiography, two patients had stenoses which were <50% of the vessel diameter. PTA was performed in 191 (85.3%) of the 219 subjects with stenoses >50%, even when longer than 10 cm and/or multiple/calcified. In 11 patients (5.8%) PTA was performed in the proximal axis exclusively, in 81 (42.4%) patients in the infrapopliteal axis exclusively and in 99 (51.8%) in both the femoropopliteal and infrapopliteal axis. Both ABI and TcPO2 improved significantly after PTA ($P < 0.0001$). Clinical recurrence occurred in 14 subjects: 10 of whom underwent a second successful PTA. Of the 191 patients who underwent PTA, 10 (5.2%) underwent an above-the-ankle amputation. CONCLUSIONS: PTA, including infrapopliteal, is feasible in most diabetic subjects with ischaemic foot ulcer and is effective for foot revascularization. Clinical recurrence was infrequent and the procedure could successfully be repeated in most cases. In subjects treated successfully with PTA the above-the-ankle amputation rate was low. PTA should be considered as the revascularization treatment of first choice in all diabetic subjects with foot ulcer and PAOD.

J Vasc Surg 2002 Sep;36(3):625-8

Distal septic emboli and fatal brachiocephalic artery mycotic pseudoaneurysm as a complication of stenting.

Pruitt A, Dodson TF, Najibi S, Thourani V, Sherman A, Cloft H, Caliendo A, Smith RB 3rd.

The use of percutaneous angioplasty with subsequent intravascular metallic stent placement has gained increasing acceptance over the past decade. Infections of these stents appear to be uncommon; however, the rarity of this complication may in part be the result of a lack of availability of long-term follow-up data. A number of examples of infected cardiac and peripheral vascular stents have been reported, often with fatal consequences. Herein, we report a 74-year-old woman who underwent subclavian and brachiocephalic artery angioplasty and stent placement for symptomatic stenoses. Six months after the initial intervention, the patient returned with restenosis of the stents and underwent repeat angioplasty to restore full patency. Two weeks later, the patient was readmitted with generalized malaise and multiple erythematous, macular lesions on the right forearm and hand. Blood cultures grew Staphylococcus aureus, and a computed tomographic scan of the chest showed a large brachiocephalic artery pseudoaneurysm with surrounding hematoma. Despite prompt surgical intervention, this complication proved ultimately fatal. Infections of metallic endovascular stents are potentially life-threatening complications and must be addressed urgently, including possible surgical intervention.

J Neurol 2002 Aug;249(8):988-92

Percutaneous arterial interventional treatment of exercise-induced neurogenic intermittent claudication due to ischaemia of the lumbosacral plexus.

Wohlgemuth WA, Stoehr M.

Radiological interventional therapy is described in seven patients with a distinct clinical syndrome of exercise-induced neurogenic intermittent claudication due to a reversible ischaemia of the lumbosacral plexus during walking accompanied by transient neurologic deficits. This condition was presumably caused by a reversible vascular steal phenomenon during exertion. The underlying vascular conditions were stenoses of the internal and/or common iliac arteries. All patients underwent percutaneous transluminal angioplasty (PTA) during the period from 1988 to 2001; an additional stent was placed in two patients. After a mean follow-up period of 18 months, four patients were asymptomatic, two had an improvement in walking-distance of 300 m and 800 m, respectively, and one patient developed a peripheral intermittent claudication without neurological complaints. In four patients, however, a further intervention was required. In patients with intermittent claudication due to exercise induced ischaemia of the lumbosacral plexus, a successful treatment is possible by means of PTA. Repeat intervention is justified if symptoms recur.

Am Heart J 2002 Jun;143(6):961-5

Prevalence and clinical correlates of peripheral arterial disease in the Framingham Offspring Study.

Murabito JM, Evans JC, Nieto K, Larson MG, Levy D, Wilson PW.

BACKGROUND: Peripheral arterial disease (PAD) is associated with an increased risk for mortality. We sought to assess the prevalence of PAD and its risk factors in a population-based sample. METHODS: We examined 1554 males and 1759 females with a mean age of 59 years who attended a Framingham Offspring Study examination from 1995 to 1998. PAD was defined by an ankle-brachial blood pressure index of <0.9. Age- and sex-adjusted and multivariable logistic regression analyses were performed to identify factors associated with PAD. RESULTS: The prevalences of PAD, current intermittent claudication, lower extremity bruits and surgical intervention were 3.9%, 1.9%, 2.4% and 1.4% in males and 3.3%, 0.8%, 2.3% and 0.5% in females. Hypercholesterolemia, high-density lipoprotein cholesterol, triglyceride, diabetes, hypertension, current smoking, pack-years of smoking, body mass index, fibrinogen, and prevalent coronary disease were associated with PAD in age- and sex-adjusted analyses. Odds ratios and 95% CIs for significant associations identified from multivariable analyses are as follows: each 10 years of age, 2.6 (2.0, 3.4); hypertension, 2.2 (1.4, 3.5); smoking, 2.0 (1.1, 3.4); 10 pack-years of smoking, 1.3 (1.2, 1.4); 50 mg/dL of fibrinogen, 1.2 (1.1, 1.4); 5 mg/dL of high-density lipoprotein, 0.9 (0.8, 1.0); coronary disease, 2.6 (1.6, 4.1). CONCLUSIONS: Smoking cessation and hypertension control are important goals in the aim to reduce PAD and its associated impact on quality of life, functional decline, and risk for subsequent cardiovascular disease.

Circulation 2002 Jun 4;105(22):2646-52

Roxithromycin treatment prevents progression of peripheral arterial occlusive disease in Chlamydia pneumoniae seropositive men: a randomized, double-blind, placebo-controlled trial.

Wiesli P, Czerwenka W, Meniconi A, Maly FE, Hoffmann U, Vetter W, Schulthess G.

BACKGROUND: Evidence has been provided that the atherosclerotic process may be associated with chronic infection with Chlamydia pneumoniae. The effect of antibiotic treatment on peripheral arterial occlusive disease has not been investigated yet. METHODS AND RESULTS: Forty C pneumoniae seropositive men suffering from peripheral arterial occlusive disease were randomly assigned to receive either roxithromycin (300 mg daily) or placebo for 28 days. During the 2.7-year follow-up, the number of invasive revascularizations per patient, the walking distance before intervention (in patients without intervention at study end), and the change of carotid plaque size were assessed. Five interventions were performed on 4 patients (20%) in the roxithromycin group, and 29 interventions were performed on 9 patients (45%) in the placebo group. Limitation of walking distance to 200 m or less was observed in 4 patients (20%) in the roxithromycin group and in 13 patients (65%) in the placebo group. The effect of macrolide treatment on the number of interventions per patient and on preinterventional walking distance was significant. Possible confounding variables such as classical vascular risk factors were excluded by multiple regression analyses. Carotid plaque areas monitored over 6 months decreased in the roxithromycin group (mean relative value, 94.4%) but remained constant in the placebo group (100.2%). Regression of carotid plaque size observed in roxithromycin-treated patients was significant for soft plaques. CONCLUSIONS: This study indicates that macrolide treatment for 1 month is effective in preventing C pneumoniae seropositive men from progression of lower limb atherosclerosis for several years.

Curr Cardiol Rep 2003 Mar;5(2):141-7

Ultrasound and angiography in the selection of patients for carotid endarterectomy.

Alexandrov AV.

The risk of ischemic stroke increases proportionately to the severity of carotid stenosis, and carotid endarterectomy is a durable procedure that reduces this risk. Although a combination of noninvasive tests, such as ultrasound and magnetic resonance angiography (MRA), have low misclassification rates compared with invasive angiography, the need for invasive angiography may not yet be obviated. Ultrasound appears to be a cost-effective screening strategy for a significant carotid stenosis that warrants angiographic confirmation and possible intervention. A combination of ultrasound and MRA appears to be the most common clinical pathway that can be accurate and cost-effective, if rigorous local validation of diagnostic criteria is performed. Ultrasound further supplements angiography by providing information about plaque morphology and physiologic measurements of collateralization of flow and vasomotor reactivity when additional tests, such as transcranial Doppler, are performed. Ultrasound and various angiographic imaging modalities have complementary value in patient selection for carotid endarterectomy. Currently, more invasive angiograms are being performed, due to a variety of new experimental interventions such as angioplasty and stenting, a subject of current clinical trials.

Cardiovasc Res 2003 Feb 1;57(2):544-553

Effects of local all-trans-retinoic acid delivery on experimental atherosclerosis in the rabbit carotid artery.

Herdeg C, Oberhoff M, Baumbach A, Schroeder S, Leitritz M, Blattner A, Siegel-Axel DI, Meisner C, Karsch KR.

BACKGROUND: Retinoids regulate a variety of biological processes and play an important role in cell differentiation and proliferation. All-trans retinoid acid (atRA) is known to inhibit smooth muscle cell growth and thus is supposed to have favorable effects on the incidence of restenosis after percutaneous coronary interventions. The broad biological spectrum, however, leads to numerous severe side effects which limit the clinical use of a systemic application of atRA. In order to avoid systemic side effects, local delivery of atRA is preferable. The aim of this study was to evaluate the effects of atRA on the response to injury in a second-injury model of experimental balloon angioplasty. METHODS: After induction of a fibromuscular plaque in the right carotid artery of 40 New Zealand rabbits, 35 animals underwent balloon angioplasty of the preformed plaque formation. Subsequent local atRA delivery (10 ml, 10 &mgr;M) with the double-balloon catheter was performed in 15 animals. Five animals received vehicle only as sham controls, and five animals were solely electrostimulated, 15 animals served as control group with balloon angioplasty only. Vessels were excised 7 days (n=15) and 28 days (n=30) after intervention. Immunocytochemistry with antibodies against smooth muscle alpha-actin and myosin, bromodeoxyuridine, macrophages, collagen I and III and von Willebrand factor was performed. Quantitative analysis was done by computerized morphometry. RESULTS: After local atRA delivery in vivo, the extent of stenosis was markedly reduced with 21.78.3% (meanS.D.) 4 weeks after intervention compared to 31.813.4% in balloon-dilated animals (P=0.0937). Both a reduced early neointimal proliferation (P=0.0002) and an increase in overall vessel diameter (4 weeks after intervention, P=0.0264) contributed to a limitation of restenosis in atRA-treated animals. Immunocytochemistry revealed a more intense alpha-actin staining pattern after local atRA therapy indicating redifferentiating effects of atRA on vascular smooth muscle cells. CONCLUSIONS: Local delivery of atRA led to limitation of restenosis formation in this animal model. The concept of a local atRA therapy might be a promising way to exploit the potential of atRA for vascular indications while minimizing the severe side effects of systemic retinoid therapy.

Catheter Cardiovasc Interv 2003 Feb;58(2):139-46

Initial multicenter experience with a novel distal protection filter during carotid artery stent implantation.

Grube E, Colombo A, Hauptmann E, Londero H, Reifart N, Gerckens U, Stone GW.

Atheroembolization resulting in transient or permanent neurologic impairment is the most common complication of catheter-based percutaneous carotid artery intervention. Protection of the distal cerebral vasculature during carotid stent implantation may enhance procedural safety. Carotid stent implantation with distal cerebral protection using the FilterWire EX was performed in 35 consecutive patients undergoing 36 procedures at six centers. The FilterWire was delivered and deployed successfully in all 36 cases, and embolic material was retrieved from 74% of procedures. The 30-day rate of major adverse events (death, major or minor stroke) was 0%. Transient ipsilateral periprocedural neurologic ischemia developed in two patients (5.7%), both resolving within 30 min. Distal cerebral protection with the FilterWire during carotid stenting is feasible and safe, results in capture and extraction of atheroembolic debris in the majority of patients while affording uninterrupted cerebral perfusion, and in this initial multicenter experience was associated with a high rate of procedural success without major complications.

Biol Pharm Bull 2003 Jan;26(1):56-60

Saiko-ka-Ryukotsu-Borei-To Inhibits Intimal Thickening in Carotid Artery after Balloon Endothelial Denudation in Cholesterol-fed Rats.

Chung HJ, Maruyama I, Tani T.

Oral administration of Saiko-ka-Ryukotsu-Borei-To (SRB), a traditional Chinese formulation, dose dependently inhibited intimal thickening in carotid artery injured by balloon endothelial denudation in cholesterol-fed rats. SRB also inhibited vascular smooth muscle cell (VSMC) proliferation, which is assessed by counting the VSMCs immunoreactive with antiproliferating cell nuclear antigen (PCNA) antibody in the intimal area. VSMC proliferation is considered to play a central role in the development of intimal thickening. SRB slightly, but not significantly, reduced serum total cholesterol and low-density lipoprotein cholesterol. These results indicate that the suppressive effect of SRB on intimal thickening may result from its inhibitory effect against VSMC proliferation, but does not depend on lowering of lipid levels. The balloon injury model used in this study has similar pathological processes to restenosis after percutaneous coronary intervention (PCI). Therefore the present results may provide a new therapeutic strategy using SRB to reduce restenosis after PCI in the treatment of patients with ischemic coronary artery disease. Furthermore, since it is considered that artery restenosis after balloon injury in PCI is "accelerated atherosclerosis, " SRB may have beneficial effects in atherosclerosis that develops over a long clinical course in hyperlipidemia, diabetes, etc.

Cardiol Clin 2002 Nov;20(4):589-97

Percutaneous treatment for carotid stenosis.

Mukherjee D, Yadav JS.

Stroke is the leading cause of serious long-term disability in the United States. A substantial portion of strokes are caused by atherosclerotic carotid artery disease. The conventional risk factors for coronary atherosclerosis are also responsible for carotid atherosclerosis. Carotid stenosis is encountered in medical practice in either symptomatic or asymptomatic states. In symptomatic patients, medical management with antiplatelet agents does not provide adequate protection against stroke. Carotid endarterectomy can help reduce the risk of a subsequent stroke. Asymptomatic patients with severe carotid stenosis can also benefit from surgical intervention if endarterectomy can be performed at a low operative risk. In recent years, percutaneous carotid stenting using self-expanding stents has become popular for the treatment of carotid stenosis. Although this initial experience has been reported from a high-risk patient population, the results are encouraging, with acceptable periprocedural stroke rates. Moreover, emboli protection devices, modern adjuvant pharmacotherapy, and modern self-expanding stents were not utilized in these studies. With rapidly expanding technology and advances in interventional pharmacology, improvement of clinical outcome is likely. Table 3 summarizes current recommendations for carotid stenting based on a panel of cardiologists, radiologists, and vascular surgeons. At this stage, randomized trials to compare endarterectomy with carotid stenting are underway. Cautious optimism is necessary until the optimal equipment, emboli protection devices, and adjuvant pharmacotherapies are fully investigated. Until then, carotid stenting should be restricted to high-risk candidates for carotid endarterectomy, including patients with severe cardiac comorbidities, previous neck surgeries or radiation, restenosis after endarterectomy, or other technical contraindications for surgery.

Curr Opin Cardiol 2002 Nov;17(6):671-6

Carotid artery stenting: acute and long-term results.

Shawl FA.

The objective of this study was to evaluate the safety and efficacy of carotid artery stenting (CAS) in high-risk patients. Carotid endarterectomy (CEA) has been shown to be more effective than medical therapy but has limitations. CAS may be a reasonable alternative, particularly in high-risk patients. The authors evaluated prospectively the safety and efficacy of CAS in 299 consecutive patients who underwent CAS of 343 extracranial carotid arteries. Of the patients enrolled, 210 (70%) would have been excluded from the major trials of CEA, and 84 (28%) were referred by vascular surgeons. This series represents a very high-risk group that included patients with unstable angina, previous ipsilateral CEA, contralateral carotid occlusion, and other severe comorbid illnesses. Seventy-four (25%) patients were aged 80 years or more. All patients had independent neurologic examination before and after the procedure. Three hundred seventy-six stents were deployed in 343 arteries. Procedural success was 99%. Mean stenosis was 75 12% before and 7 8% after the procedure. Ninety-two patients had coronary intervention. Only 56 (19%) patients were North American Symptomatic Carotid Endarterectomy Trial (NASCET) eligible. During the initial hospitalization and 30 days post-CAS, there were two (0.6%) major and seven (2.3%) minor strokes. There were no myocardial infarctions or deaths during or within 30 days of CAS. None of the NASCET-eligible patients had a stroke. At a mean follow-up period of 26 13 months, eight (2.7%) patients had asymptomatic restenosis. No additional major strokes or neurologic deaths occurred. In conclusion, CAS is feasible, can be performed even in high-risk patients, and is associated with a low restenosis rate.

Rev Cardiovasc Med 2002;3 Suppl 1:S35-40

Use of glycoprotein IIb/IIIa platelet inhibitors in peripheral vascular interventions.

Ansel GM, George BS, Botti CF, Silver MJ.

With the expanding use of endovascular techniques for the treatment of peripheral vascular disease, consideration of glycoprotein IIb/IIIa receptor inhibitors to enhance the safety and efficacy of these procedures has increased. The scientific literature shows the benefits with the use of these agents in coronary vasculature interventions. However, data evaluating treatment with glycoprotein IIb/IIIa receptor inhibitors during peripheral vascular procedures is limited, with the vast majority of the trials investigating abciximab. With the varied vascular beds and end organs that may be affected by peripheral vascular intervention, the safety and efficacy may need to be studies for each area. The current literature ranging from carotid stenting to thrombolysis and mechanical thrombectomy for acute limb ischemia is reviewed, and recommendations are discussed on the use of these agents. The forthcoming results of controlled clinical trials should further clarify the clinical applications of these agents in peripheral vascular intervention.

Eur Radiol 2002 Oct;12(10):2451-6

Clinical results of carotid artery stenting with a nitinol self-expanding stent (SMART stent).

Drescher R, Mathias KD, Jaeger HJ, Bockisch G, Demirel E, Gissler HM, Hauth E.

Our objective was to assess the technical feasibility and the clinical results of internal carotid artery (ICA) stenting using a nitinol self-expanding stent (SMART stent). In 13 patients 13 high-grade stenoses of the internal carotid artery were treated via an implantation of a SMART stent. In all cases a predilation of the stenosis and a postdilation within the stent were performed. Follow-up examinations were carried out in all patients after a period of 6 months. In each case the implantation of the stent was performed without technical complications. In 12 of 13 cases the stent was placed in the patients' internal carotid artery, in 1 case from the internal to the common carotid artery (CCA). The average degree of stenosis of 78% (70-95%) was reduced to an average of 2.8% (0-21%). The 6-month follow-up angiography showed an average degree of restenosis of 11.8% (0-29%) in 8 of 13 patients. Duplex sonography in the remaining 5 patients demonstrated patent stents. One patient showed brief neurological symptoms during the intervention. No further complications occurred during follow-up time. Treatment of internal carotid artery stenosis with the SMART stent seems technically feasible, safe, and promises long-term patency.

Vasc Endovascular Surg 2002 Sep-Oct;36(5):393-6

Endovascular intervention for stenosis following carotid stent-supported angioplasty--a case report.

Bates MC, AbuRahma AF.

This report is on a patient with symptomatic late restenosis after carotid stent-supported angioplasty (CSSA). Initially, the patient underwent carotid endarterectomy (CEA) with primary closure in response to an index transient ischemic attack 13 months before CSSA. He returned with angiographic evidence of recurrent carotid artery stenosis. A balloon-expandable stent was deployed with technical success. Follow-up angiography 1 year later showed an asymptomatic, noncritical in-stent restenosis (50%). Three years after the initial stent placement, the patient presented with ischemic symptoms and a carotid duplex confirming critical restenosis. The patient was successfully treated by deployment of a stent within a stent and showed significant hemodynamic improvement. This is a case report of late progressive restenosis, which raises concerns about long-term patency of CSSA in patients with aggressive postendarterectomy recurrence.

J Am Coll Cardiol 2002 Sep 4;40(5):890-5

Feasibility and efficacy of balloon-based neuroprotection during carotid artery stenting in a single-center setting.

Schluter M, Tubler T, Mathey DG, Schofer J.

We sought to prospectively assess the feasibility and in-hospital efficacy of the PercuSurge GuardWire temporary balloon-occlusive system for neuroprotection during carotid angioplasty and stenting (CAS).Carotid angioplasty and stenting harbors a risk of distal embolization. Cerebral protection devices are currently under clinical investigation.Ninety-six consecutive patients with carotid bifurcation disease underwent a total of 102 CAS procedures with the intention to use the GuardWire for neuroprotection.GuardWire deployment was achieved in 99 procedures performed in 93 patients (97%). Device failure (n = 3) and severe neurologic responses to balloon occlusion of the targeted carotid artery (n = 2) accounted for five additional procedures that were essentially concluded without neuroprotection, for a total of 94 procedures completed as intended in 88 patients (92% procedural feasibility rate). Carotid angioplasty and stenting was performed successfully in 94 patients (100 procedures). There were no in-hospital deaths; but three patients (3.1%) sustained strokes, and two patients experienced transient ischemic attacks, for a total periprocedural complication rate of 5.2%. One major stroke occurred with the GuardWire in place, whereas two minor strokes were observed in patients in whom the device could not be deployed. Thus, successful neuroprotected CAS without major neurologic events was achieved in 87 patients (91%).The GuardWire temporary balloon-occlusive system is feasible as an adjunct to CAS in the majority of patients. It is associated with a 3.1% rate of major periprocedural neurologic complications. Adverse neurologic reactions to balloon occlusion may prohibit effective use of the system in about 2% of patients.

Radiology 2002 Aug;224(2):529-35

Inflammatory response to stent implantation: differences in femoropopliteal, iliac, and carotid arteries.

Schillinger M, Exner M, Mlekusch W, Haumer M, Ahmadi R, Rumpold H, Wagner O, Minar E.

PURPOSE: To investigate the postintervention course of serum acute-phase reactants after stent implantation in the femoropopliteal, iliac, and carotid arteries. MATERIALS AND METHODS: This prospective cohort study included 274 consecutive patients who underwent stent implantation in the femoropopliteal (n = 95), iliac (n = 70), and carotid (n = 109) arteries. C-reactive protein (CRP), serum amyloid A (SAA), and fibrinogen levels were measured at baseline and at 48 hours after intervention. Polynomial logistic regression analysis was applied to assess the independent association of the course of acute-phase reactants and the site of stent implantation. RESULTS: Stent implantation in the femoropopliteal artery was associated with a higher postintervention increase in CRP (P =.01), SAA (P =.04), and fibrinogen (P =.01) values compared with values with iliac artery stent implantation, with adjustment for age, sex, fluoroscopy duration, contrast agent dose, complication occurrence, stenosis grade, total vessel occlusion, and stent cumulative length. No significant difference in the postintervention course of CRP (P =.9) and SAA (P =.1) levels was determined for stents implanted in the carotid artery compared with those implanted in the iliac artery; however, a higher increase in fibrinogen levels (P =.04) was noted. CONCLUSION: Stent implantation in the muscular femoropopliteal artery was associated with a more extensive vascular inflammatory response than was stent implantation in the elastic iliac and carotid arteries, independent of lesion morphology and interventional factors.

Int Angiol 2002 Jun;21(2):138-44

Subclavian carotid transposition for symptomatic subclavian artery stenosis or occlusion. A comparison with the endovascular procedure.

Ballotta E, Da Giau G, Abbruzzese E, Mion E, Manara R, Baracchini C.

BACKGROUND: Although subclavian-carotid transposition (SCT), among all extrathoracic revascularization procedures, has emerged as the treatment of choice for symptomatic subclavian artery (SA) stenosis or occlusion, some authors advocate percutaneous transluminal angioplasty with stenting as the optimum primary therapy. Aim: to assess safety, efficacy and durability of SCT in the treatment of symptomatic SA stenosis or occlusion. METHODS: Design: review of a prospectively maintained vascular surgical registry. Setting: University vascular surgical service. Patients: 39 patients requiring surgery for symptomatic stenosis or occlusion of the proximal SA from September 1985 to August 1999. Intervention: SCT. Measures: data were collected prospectively from hospital charts and office medical records to determine demographics, risk factors, presenting clinical manifestation, blood pressure differentials, location of the SA lesion and early postoperative outcome. Long-term follow-up was available in all patients. Patency of the revascularization was determined by physical examination and non-invasive laboratory studies. RESULTS: The perioperative mortality and morbidity rates were 2.5% (1 of 39) and 2.5% (1 of 39), respectively. Immediate relief of symptoms was achieved in 100% of cases. Mean follow-up was 6.8 years. Revascularization neither failed during the follow-up period, nor did patients have recurrent symptoms. The overall survival rates at 1, 3, 5 and 10 years were 100%, 100%, 86% and 68%. Overall late mortality rate was 18.4%: no death was stroke related. CONCLUSIONS: SCT is a very safe and effective surgical procedure for the treatment of symptomatic SA atherosclerotic disease, ensuring an excellent long-term patency.

Angiology 2002 May-Jun;53(3):279-85

Carotid atherosclerosis in type 2 diabetes mellitus: potential role of endothelin-1, lipoperoxides, and prostacyclin.

Kalogeropoulou K, Mortzos G, Migdalis I, Velentzas C, Mikhailidis DP, Georgiadis E, Cordopatis P.

Factors were studied that may initiate macroangiopathy or enhance or aggravate its pathogenesis in patients with type 2 diabetes mellitus. A total of 151 diabetics were compared with healthy controls (n=50); all patients and subjects were normotensive and without renal failure. Plasma endothelin-1 and free radical levels were measured. In addition, plasma prostacyclin levels were assessed by assaying its stable, spontaneous, breakdown product 6-keto-prostaglandin-F1a. Diabetics were divided into three groups: those with clinically evident macroangiopathy and those with early or without atherosclerosis (as determined by the carotid intima-media thickness. Plasma endothelin-1 levels were increased in all diabetics with atherosclerosis. Plasma free radical levels were increased in diabetics with macroangiopathy when compared with control subjects. The plasma levels of 6-keto-prostaglandin-F1a were slightly, but significantly, decreased in the diabetics with macroangiopathy when compared with control subjects. The carotid intima-media thickness was significantly greater in diabetics without macroangiopathy when compared with the controls. Furthermore, the intima-media thickness increased significantly in this group of diabetics but not in the controls over a 30-month follow-up period. Several factors may contribute to atherogenesis in diabetics. These include increased plasma endothelin-1 and free radical levels as well as a deficiency of prostacyclin. These factors may become targets for intervention as well as markers of disease progression.

J Vasc Surg 2002 May;35(5):966-72

Protected carotid stenting: safety and efficacy of the MedNova NeuroShield filter.

Macdonald S, Venables GS, Cleveland TJ, Gaines PA.

OBJECTIVE: Neuroprotection during carotid stenting has the potential to reduce procedural atheroembolic sequelae. We report the United Kingdom experience of NeuroShield (MedNova Ltd, Horsham, West Sussex, United Kingdom). METHODS: We performed a prospective cohort analysis of 50 consecutive patients (50 lesions) in a regional vascular tertiary referral center (catchment area one million) that provides an institutional service for the short term. The subjects were all the patients referred for carotid stenting after preassessment by a multidisciplinary team. All the patients underwent pretreatment with antiplatelet agents. Forty-two patients had atherosclerotic stenosis of the carotid bifurcation between 70% and 95% (with North American Symptomatic Carotid Endarterectomy Trial criteria). Six patients had restenosis after endarterectomy. Two had previous local radiotherapy. Forty-two patients were symptomatic (amaurosis fugax/central retinal artery occlusion in 11 cases, and hemispheric transient ischemic attack/cerebrovascular accident in 31 cases). Eight patients were asymptomatic with bilateral high-grade stenoses, with six cases before coronary artery bypass grafting. The intervention performed was protected primary carotid stenting. Outcome measures were procedural atheroembolic events, including all-stroke and death rates up to 30 days, and analysis of retrieved debris in a subset of 11 cases. RESULTS: The technical success rate was 50/50 (100%) for stenting and 49/50 (98%) for filter placement/retrieval. Technical complications comprised nonsymptomatic spasm at the filter site (flow limiting in two cases and non-flow limiting in five cases). Procedural events were one minor stroke (patient fully recovered within 48 hours) in a complex clinical setting and one ventricular fibrillation arrest in a patient before coronary artery bypass grafting who was resuscitated without neurologic event. At 30 days, the death or major disability from stroke rate was 2/50 (4%). No cases were atheroembolic. The all-stroke/death rate was 3/50 (6%). The two deaths were the result of a fatal hemorrhagic stroke that occurred at 4 days and was thought to be caused by reperfusion and a perforated ventricle caused by a temporary pacing wire. One femoral pseudoaneurysm followed failed closure device deployment and required percutaneous thrombin injection. The mean particle number per patient was 12 (range, 0 to 41). The mean particle diameter was 284.9 microm(range, 31 to 1430 microm). The mean ellipsoid volume load was 0.1602 mm(3) (range, 0.0005 to 0.1968 mm(3)). CONCLUSION: Carotid stenting protected with NeuroShield is safe. The filter traps embolic debris liberated during the procedure.
Stroke 2002 May;33(5):1308-14

Carotid artery stenting protected with an emboli containment system.

Whitlow PL, Lylyk P, Londero H, Mendiz OA, Mathias K, Jaeger H, Parodi J, Schonholz C, Milei J.

BACKGROUND AND PURPOSE: Fear of distal embolization and stroke has aroused concern regarding carotid stenting. Devices to protect the cerebral circulation may make carotid stenting safer. METHODS: A multidisciplinary study group tested a balloon occlusion-aspiration emboli entrapment device in conjunction with carotid stenting. The device consists of an elastomeric balloon on a steerable wire with a detachable adapter that inflates and deflates the distal temporary occlusion balloon. An aspiration catheter is used to remove trapped emboli after stenting and before occlusion balloon deflation. RESULTS: Seventy-five patients with severe internal carotid artery stenosis were treated with stents deployed with this cerebrovasculature protection system. All 75 patients (100%) had grossly visible particulate material aspirated, and all were treated successfully without major or minor stroke or death at 30 days. Preintervention stenosis was 8110%, and residual stenosis was 57%. Nine patients (12%) had angiographic evidence of thrombus before intervention, but no patient had thrombus or vessel cutoff after the procedure. Four patients (5%) developed transient neurological symptoms during protection balloon occlusion, but symptoms resolved with balloon deflation. The 22 to 667 particles aspirated per patient ranged from 3.6 to 5262 microm in maximum diameter (mean, 203256 microm). These particles included fibrous plaque debris, lipid or cholesterol vacuoles, and calcific plaque fragments. CONCLUSIONS: Protected carotid stenting was performed successfully and safely in this study early in the experience with cerebrovascular protection devices. Particulate emboli are frequent with stenting, and cerebral protection will likely be necessary to minimize stroke. Randomized trials comparing protected carotid stenting with endarterectomy are warranted.

Ann Vasc Surg 2002 Mar;16(2):168-75

Surgical management of acute complications and critical restenosis following carotid artery stenting.

Owens EL, Kumins NH, Bergan JJ, Sparks SR.

Carotid artery angioplasty with stenting (CAS) is being increasingly used in the treatment of extracranial carotid artery stenosis. As in other catheter-based approaches to the treatment of arterial disease, surgical intervention may be required because of either acute complications or correct critical restenosis. We have reviewed our experience managing early complications and critical in-stent restenoses after CAS in a tertiary care university hospital and a Veterans Affairs Medical Center. During the last 5 years, 22 carotid arteries (21 patients) underwent CAS. One patient developed thrombosis and rupture of the carotid artery during stenting. Two other patients (3 arteries) developed critical restenosis within 12 months. Subsequent surgical reconstructions included an internal carotid artery (ICA)-to-external carotid artery (ECA) transposition and a common carotid artery (CCA)-to-ICA bypass with reversed saphenous vein (RSV). The patient who underwent CCA-to-ICA bypass later required subclavian-to-ICA bypass because of rapidly progressive intimal hyperplasia and subsequent occlusion of the CCA. The other patient has not had surgical repair because of his deteriorating condition and significant co-morbidities. During the same time period, two additional patients were referred from outside institutions specifically for surgical intervention after carotid stenting. One had delayed rupture of the carotid artery 1 day after stenting and underwent urgent surgical repair. Another patient had early, critical restenosis within the stent and underwent placement of a CCA-to-ICA interposition graft using RSV. Acute treatment failures after CAS can be successfully managed using standard surgical techniques. Patients who develop critical in-stent restenosis requiring surgical repair may need more challenging surgical reconstructions to maintain cerebral perfusion.

Vasc Endovascular Surg 2002 Mar-Apr;36(2):145-54

Vascular complications arising from maldeployed stents.

Kitchens C, Jordan W Jr, Wirthlin D, Whitley D.

The authors present 6 unusual vascular complications secondary to maldeployed or undeployed vascular stents. They retrospectively reviewed patients referred for complications of vascular stent placement from September 1998 to March 1999. Information on patient history was obtained from a computerized database and clinical document file. Radiographic information was obtained from arteriograms, ultrasound, and computed tomography imaging. Case 1 describes an undeployed stent in the superior mesenteric artery with subsequent thrombosis in addition to celiac occlusion secondary to attempted balloon angioplasty. Case 2 refers to a malpositioned stent placed in the aortic arch and proximal left common carotid artery. Case 3 involves an undeployed coronary stent that migrated to the right distal posterior tibial artery, causing vascular occlusion and chronic pain. In Case 4, an attempted stent placement into the left iliac artery resulted in an undeployed stent lodged across the aortic bifurcation. Case 5 illustrates a partially deployed stent occluding the left renal artery that was unamenable to further angioplasty. Case 6 demonstrates arterial dissection with a pseudoaneurysm following stent placement for right subclavian stenosis. Five patients required operative intervention. Increased use of stents may escalate the number of complications requiring operative intervention. Foreign bodies can migrate distally and potentiate thrombotic occlusion of vessels. Caution must be used not only at the time of deployment but also in the follow-up period. Continued surveillance becomes important after vascular stent placement.

Am Surg 2002 Mar;68(3):275-9; discussion 279-80

Carotid artery restenosis: an ongoing disease process.

Trisal V, Paulson T, Hans SS, Mittal V.

Recurrence of carotid artery stenosis after primary endarterectomy is a well-known entity. The treatment and optimal management of the disease process, however, is a matter of ongoing debate. We retrospectively reviewed carotid endarterectomies for recurrent disease performed at a community hospital over the past 21 years to evaluate the outcome of surgical intervention. Eighty-two recurrences occurred in 1648 carotid endarterectomies. Females had a slightly higher recurrence rate as compared with males, and the majority of patients had risk factors in the form of hypertension, peripheral vascular disease, or cigarette smoking. All endarterectomies were repaired with a patch angioplasty by either a vein or a prosthetic graft. One patient died secondary to complications of coronary artery disease. None of the patients developed any postoperative neurological event or permanent nerve damage. A subgroup of 11 patients with recurrent carotid artery stenosis with contralateral occlusion underwent 14 endarterectomies with no neurological complications. In conclusion occlusive carotid disease is an ongoing phenomenon, and continued surveillance is recommended. Surgical treatment of recurrent disease is a safe option. Endarterectomies for recurrent carotid disease in the presence of contralateral occlusion can be performed safely.

J Vasc Surg 2002 Mar;35(3):576-9

Arterial infection and staphylococcus aureus bacteremia after transfemoral cannulation for percutaneous carotid angioplasty and stenting.

Culver DA, Chua J, Rehm SJ, Whitlow P, Hertzer NR.

In this report, we present a patient who developed an infected femoral artery after repuncture cannulation for carotid angioplasty and intraluminal stenting. The case was complicated by persistent bacteremia and a delay in diagnosis before it was managed successfully with an autogenous replacement graft and appropriate antibiotics. Overt stent infection is exceedingly rare, but according to the literature describing transfemoral coronary artery intervention, the spectrum of clinical syndromes related to infection of the arterial puncture site includes local invasion, pseudoaneurysm formation, septic embolization to the distal limb, and bacteremia. The diagnosis requires a high degree of clinical suspicion and is often delayed. Although the incidence of infectious complications reported for percutaneous intra-arterial interventions historically has been low, the absolute number of these complications almost certainly will increase in the future because of the expanding array of interventional procedures that is becoming available.

Stroke 2002 Mar;33(3):725-7

Abciximab bolus injection does not reduce cerebral ischemic complications of elective carotid artery stenting: a randomized study.

Hofmann R, Kerschner K, Steinwender C, Kypta A, Bibl D, Leisch F.

BACKGROUND AND PURPOSE: Abciximab has been shown to significantly reduce thromboembolic complications of coronary artery stenting. A prospective, randomized study was performed to test whether abciximab has comparable beneficial effects in carotid artery stenting. METHODS: Seventy-four consecutive patients undergoing elective stenting of the carotid artery were included in the study. Standard antithrombotic medication consisted of aspirin, clopidogrel, and heparin. In addition, half of the patients received an abciximab bolus of 0.25 mg/kg body weight given prophylactically before the intervention. RESULTS: The procedure was successful in all but 1 patient. In patients receiving abciximab, ischemic complications consisted of 4 transient ischemic attacks, 1 minor stroke, 1 nonfatal major stroke, and 1 fatal stroke caused by cerebral hemorrhage. In the control group, 2 transient ischemic attacks and 1 major nonfatal stroke occurred. In summary, the total number of periprocedural ischemic events was 7 (19%) in the abciximab group and 3 (8%) in the control group. Nonischemic complications consisted of 1 inguinal hematoma requiring blood transfusions in each group. CONCLUSIONS: Abciximab bolus given prophylactically before elective carotid artery stenting does not reduce ischemic complications.

J Am Coll Cardiol 2002 Mar 6;39(5):841-6

Multicenter evaluation of carotid artery stenting with a filter protection system.

Al-Mubarak N, Colombo A, Gaines PA, Iyer SS, Corvaja N, Cleveland TJ, Macdonald S, Brennan C, Vitek JJ.

OBJECTIVES: The aim of this study was to evaluate the feasibility and safety of carotid artery stenting (CAS) with a filter protection system. BACKGROUND: Neurologic events linked to the embolization of particulate matter to the cerebral circulation may complicate CAS. Strategies designed to capture embolic particles during carotid intervention are being evaluated for their efficacy in reducing the risk of these events. METHODS: Between September 1999 and July 2001, a total of 162 patients (164 hemispheres) underwent CAS with filter protection (NeuroShield, MedNova Ltd., Galway, Ireland) according to prospective protocols evaluating the filter system at three institutions. RESULTS: Angiographic success was achieved in 162 of the procedures (99%) and filter placement was successful in 154 (94%) procedures. Carotid access was unsuccessful in two cases (1%) and filter placement in eight cases (5%). Of the latter, five procedures were completed with no protection and three were completed using alternative protection devices. On an intention-to-treat basis, the overall combined 30-day rate of all-stroke and death was 2% (four events: two minor strokes and two deaths). This includes one minor stroke in a patient with failed filter placement and CAS completed without protection. There was one cardiac arrhythmic death and one death from hyperperfusion-related intracerebral hemorrhage. There were no major embolic strokes. CONCLUSIONS: Carotid artery stenting with filter protection is technically feasible and safe. Early clinical outcomes appear to be favorable and need to be confirmed in a larger comparative study.

Stroke 2002 Feb;33(2):456-61

Cerebral protection during carotid artery stenting: collection and histopathologic analysis of embolized debris.

Angelini A, Reimers B, Della Barbera M, Sacca S, Pasquetto G, Cernetti C, Valente M, Pascotto P, Thiene G.

BACKGROUND AND PURPOSE: Histopathologic analysis was performed to better understand quantity, particle size, and composition of embolized debris collected in protection filters during carotid artery stent implantation. METHODS: Elective carotid stent implantation with the use of a distal filter protection was attempted in 38 consecutive lesions (36 patients) of the internal carotid artery presenting >70% diameter stenosis (mean, 82.111.1%). Mean age of the patients was 70.77.7 years; 75% were men, and 50% of patients had previous neurological symptoms. RESULTS: In 37 lesions (97.4%) it was possible to position the filter device, and in all lesions a stent was successfully implanted. The only complication occurring in the hospital and during the 30-day follow-up was 1 death due to acute myocardial infarction. Neurological sequelae did not occur. Histomorphometric analysis was performed on the filters. Presence of debris was detected in 83.7% of filters. The mean surface area of the polyurethane membrane filter covered with material was 53.219.8%. Particle size ranged from 1.08 to 5043.5 microm (mean, 289.5512 microm) in the major axis and 0.7 to 1175.3 microm (mean, 119.7186.7 microm) in the minor axis. Collected debris consisted predominantly of thrombotic material, foam cells, and cholesterol clefts. CONCLUSIONS: By the use of distal protection filters during carotid artery stenting, it was possible to collect particulate debris potentially leading to distal vessel occlusion in a high percentage of cases. Qualitative analysis of embolized material showed debris dislocated during the percutaneous intervention from atheromatous plaques.

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Stroke 2002 Feb;33(2):456-61

J Invasive Cardiol , 2001 13(5):375-81

Outcomes following extracranial carotid artery stenting in high-risk patients.

Paniagua D, Howell M, Strickman N, Velasco J, Dougherty K, Skolkin M, Toombs B, Krajcer Z.

BACKGROUND: Carotid artery angioplasty and stenting has become a viable alternative to carotid endarterectomy (CEA), especially for patients considered at high risk for post-operative complications. This study investigated the feasibility, safety and long-term outcome of carotid artery stenting (CAS) in high-risk patients. METHODS: From July 1995 to November 2000, sixty-two consecutive patients considered to be at high risk for post-operative complications of CEA were followed prospectively after undergoing extracranial CAS procedures. RESULTS: Sixty-two patients [37 men (60%) and 25 women (40%)] underwent a total of 69 CAS

procedures. The mean age was 67 +/- 9 years (range, 32-89 years). Comorbid conditions included hypertension in 95% and severe coronary artery disease in 58%. Sixteen patients (26%) had a previous ipsilateral CEA, twenty-one percent had a history of neck radiation and 32% had a history of significant contralateral carotid artery disease. Fifty-two patients (84%) were symptomatic. All 69 CAS procedures were technically successful. The major post-operative complications were two minor strokes (2.8%), one major stroke (1.4%) and one fatal major stroke (1.4%). The mean length of follow-up was 17 months (range, 4 months to 5.6 years). Two patients (2.8%) have suffered ipsilateral neurologic events following CAS. Long-term follow-up revealed restenosis at 6 months in 4 patients (5.7%). CONCLUSIONS: Carotid artery angioplasty and stenting is safe and feasible. This procedure produces satisfactory outcomes in patients who are at high risk for post-operative complications of CEA.

J Am Coll Cardiol, 2001 ;37(8):2074-9

Emergency stenting to treat neurological complications occurring after carotid endarterectomy.

Anzuini A, Briguori C, Roubin GS, Pagnotta P, Rosanio S, Airoldi F, Carlino M, Pagnotta P, Di Mario C, Sheiban I, Magnani G, Jannello A, Melissano G, Chiesa R, Colombo A.

OBJECTIVES: The purpose of this study was to assess the efficacy of emergency stent implantation for the treatment of perioperative stroke after carotid endarterectomy (CEA). BACKGROUND: Carotid endarterectomy has been proven safe and effective in reducing the risk of stroke in symptomatic and asymptomatic patients with >60% carotid artery stenosis. However, perioperative stroke has been reported in 1.5% to 9% of CEA cases. The management of such a complication is challenging. Recently, percutaneous transluminal carotid angioplasty with stent deployment has emerged as a valuable and alternative strategy for the treatment of carotid artery disease. METHODS: Between April 1998 and February 2000, 18 of the 995 patients (1.8%) who had CEA in our institution experienced perioperative major or minor neurological complications. Of these, 13 patients underwent emergency carotid angiogram and eventual stent implantation, whereas the remaining five had surgery re-exploration. RESULTS: Carotid angiogram was performed within 20+/-10 min and revealed vessel flow-limiting dissection (five cases) or thrombosis (eight cases). Percutaneous transluminal carotid angioplasty with direct stenting (self-expandable stent) was performed in all 13 cases. Angiographic success was 100%. Complete remission of neurological symptoms occurred in 11 of the 13 patients treated by stent implantation and in one of the five patients treated by surgical re-exploration (p =

0.024). CONCLUSIONS: Stent implantation seems to be a safe and effective strategy in the treatment of perioperative stroke complicating CEA, especially when carotid dissection represents the main anatomic problem

Circulation ,2001 ;104(1):12-5

Cerebral protection with filter devices during carotid artery stenting.

Reimers B, Corvaja N, Moshiri S, Sacca S, Albiero R, Di Mario C, Pascotto P, Colombo A.

BACKGROUND: Distal embolization of debris during percutaneous carotid artery stenting may result in neurological deficit. Filter devices for cerebral protection potentially reduce the risk of embolization. METHODS AND RESULTS: Elective carotid stent implantation using 3 different types of distal filter protection devices was attempted in 88 consecutive lesions (84 patients) in the internal carotid artery that had >70% diameter stenosis (mean, 78.7+/-10.7%). Procedures were performed in 3 different centers. The mean age of the patients was 69+/-8 years, 75% were men, and 35.7% had neurological symptoms. In 86 lesions, a stent was successfully implanted (97.7%). In 83 of these 86 procedures (96.5%), it was possible to position a filter device. In 53% of filters, there was macroscopic evidence of debris. Collected material consisted of lipid-rich macrophages, fibrin material, and cholesterol clefts. Neurological complications during the procedure, in the hospital, and at 30 days of clinical follow-up occurred in only one patient (1.2%). This patient suffered a minor stroke that resolved within 1 week. Two major adverse cardiac events (2.3%) occurred during the 30 days of follow-up. CONCLUSIONS: Filter protection during carotid artery stenting seems feasible and safe. In the present series, the incidence of neurological complications was low.

Circulation ,2001 23;104(17):1999-2002

Effect of the distal-balloon protection system on microembolization during carotid stenting.

Al-Mubarak N, Roubin GS, Vitek JJ, Iyer SS, New G, Leon MB.

BACKGROUND: The distal-balloon protection system is being evaluated for its efficacy in preventing embolic neurological events during carotid stenting (CAS). We sought to determine the effect of this system on the frequency of Doppler-detected microembolic signals (MES) during CAS. METHODS AND RESULTS: Using transcranial Doppler, we compared the frequency of MES during CAS in 2 groups: 39 patients without distal protection and 37 who used the distal-balloon protection system (GuardWire). There were no significant differences in the clinical or angiographic characteristics between the 2 groups. Three phases with increased MES counts were identified during unprotected CAS; these were stent deployment, predilation, and postdilation (75+/-57, 32+/-36, and 27+/-25 METS, respectively). The distal-balloon protection significantly reduced the frequency of MES during CAS (MES counts: 164+/-108 in the control versus 68+/-83 in the protection group; P=0.002), particularly during these 3 phases. MES in the protection group were detected predominantly during sheath placement, guidewire manipulation, and distal-balloon deflation. CONCLUSION: Three phases with increased MES counts were identified during unprotected CAS (eg, stent deployment, predilation, and postdilation). The distal-balloon protection system significantly reduced the frequency of MES during CAS, particularly during these 3 phases.

Circulation ,2001 ;104(23):2791-6

Balloon-protected carotid artery stenting: relationship of periprocedural neurological complications with the size of particulate debris.

Tubler T, Schluter M, Dirsch O, Sievert H, Bosenberg I, Grube E, Waigand J, Schofer J.

BACKGROUND: Carotid artery stenting (CAS) has been advocated as an alternative to endarterectomy. To prevent cerebral atheroembolism during CAS, distal balloon occlusion of the target artery increasingly is employed during the procedure. A correlation of the size of captured particles with the incidence of periprocedural neurological complications (PNCs) has not been attempted. METHODS AND RESULTS: In a 4-center, phase-1 trial, 54 patients (46 men; age, 69+/-8 years) underwent 58 CAS procedures using the PercuSurge GuardWire system for distal protection. Aspirated debris was sent for histological/cytological analysis. Stent placement was successful in all cases. Mean balloon occlusion time was 10.4+/-4.0 minutes (range, 3.0 to 22.0 minutes). Three patients (5.2%) experienced PNCs: 1 prolonged reversible ischemic neurological deficit that resolved in </=48 hours, 1 stroke, and 1 transient ischemic attack. Relevant particles (those with an area >/=10 000 micrometer(2)) were found in 48 aspirates (83%). The median number of particles, their maximum diameter,

and their maximum area were all significantly higher in the aspirates obtained during procedures associated with PNCs than in aspirates obtained during procedures not associated with PNCs. However, pronounced overlap in the distributions (PNCs versus no PNCs) of the number and maximum diameter of particles precluded any predictive inferences. In contrast, a maximum particle area >800 000 micrometer(2) (>0.8 mm(2)) was associated with a 60% chance of having a PNC. CONCLUSIONS: Despite balloon protection, PNCs occurred in 5.2% of patients who underwent CAS procedures. The maximum area of aspirated particles seems to be an indicator of increased risk for PNCs.

Stroke, 2001 32(10):2287-91

Role of conventional angiography in evaluation of patients with carotid artery stenosis demonstrated by Doppler ultrasound in general practice.

Qureshi AI, Suri MF, Ali Z, Kim SH, Fessler RD, Ringer AJ, Guterman LR, Budny JL, Hopkins LN.

BACKGROUND AND PURPOSE: Previous studies have suggested that patients with carotid stenosis who are candidates for endarterectomy can be effectively identified on the basis of carotid Doppler ultrasound alone. Before widespread acceptance of this policy, the accuracy of carotid Doppler ultrasound outside selected centers and clinical trials needs to be evaluated. We performed a 12-month prospective study to evaluate the accuracy of Doppler ultrasound in identifying patients for carotid intervention in general practice settings. METHODS: Each patient referred to our endovascular service for diagnostic angiography to evaluate for carotid stenosis was interviewed and examined by a neurologist. Subjects consisted of symptomatic patients with >/=50% stenosis and asymptomatic patients with >/=60% stenosis by Doppler ultrasound. Information pertaining to demographic and cerebrovascular risk factors and the results of the carotid Doppler ultrasound were recorded. The severity of stenosis on angiograms was measured with North American Symptomatic Carotid Endarterectomy Trial criteria by a blinded observer. The results of both studies were compared to determine the relative accuracy of ultrasound results. RESULTS: Of 130 patients (mean age, 69+/-8.8 years) who met Doppler ultrasound criteria, 22 (17%) and 8 patients (6%) were found to have 30% to 49% or <30% stenosis by angiography, respectively. The positive predictive value of carotid Doppler ultrasound for identifying appropriate symptomatic candidates for carotid intervention (angiographic stenosis >/=50%) was 80%, with a false-positive value of 20%. The positive predictive value of carotid Doppler ultrasound for identifying appropriate asymptomatic candidates for carotid intervention (angiographic stenosis >/=60%) was 59%, with a

false-positive value of 41%. Carotid endarterectomy or angioplasty and stent placement were undertaken subsequently in 60 (46%) of the patients. In 94 patients who underwent cerebral angiography alone, no complications were observed. CONCLUSIONS: The present accuracy of carotid Doppler ultrasound in general practice does not justify its use as the sole basis of selecting appropriate patients for carotid intervention. Given the relatively low rate of associated morbidity with present day techniques, additional confirmatory studies such as angiography should be performed in every patient before a decision regarding intervention is made.

J Am Coll Cardiol , 2001;38(4):1040-6

Preliminary results of endovascular abdominal aortic aneurysm exclusion with the AneuRx stent-graft.

Howell MH, Strickman N, Mortazavi A, Hallman CH, Krajcer Z.

OBJECTIVES: This study evaluated the clinical effectiveness of the Medtronic AneuRx stent-graft in patients with infrarenal abdominal aortic aneurysms (AAAs) who were treated in an endovascular suite. BACKGROUND: The use of endovascular stent-graft prosthesis for the treatment of AAAs is receiving increasing attention as an alternative to standard surgical repair. Endovascular treatment of AAAs offers the potential to avoid the significant morbidity and mortality associated with surgical repair. METHODS: In this series, 215 patients have undergone AAA exclusion with the AneuRx stent-graft. Six-month follow-up is available in 132 patients; one-year follow-up is available in 84 and two-year follow-up in 22. RESULTS: Of the patients, one hundred ninety-two (89%) were male; 87% had hypertension, and 58.6% were American Society of Anesthesiologists grade IV or higher. The procedural success was 99.5%; we were unable to place the device in one patient. There was no procedural or one-month mortality. There were no acute conversions to surgical repair. One patient had a non-Q-wave myocardial infarction 24 h after the procedure. Endoleaks were present in 82 patients (42%) at discharge, 15 patients (11.3%) at six months and 10 patients (11.9%) at one year. Twenty-two patients had a secondary procedure for endoleak repair of which three were conversions to surgical repair. Twelve late deaths have occurred, none due to device failure or AAA rupture. Mean hospital stay was 1.9 days. CONCLUSIONS: These results reveal that infrarenal AAAs can be safely and successfully treated in an endovascular suite with the AneuRx stent-graft. Further follow-up is needed to determine the long-term efficacy of endoluminal treatment to prevent rupture and death due to AAAs.

Catheter Cardiovasc Interv ,2001;54(1):1-5

Vertebral artery stenting.

Jenkins JS, White CJ, Ramee SR, Collins TJ, Chilakamarri VK, McKinley KL, Jain SP.

The safety and efficacy of endoluminal stenting in treating atherosclerotic vertebral artery disease was evaluated in 38 vessels in 32 patients. Indications for revascularization included diplopia (n = 4), blurred vision (n = 4), dizziness (n = 23), transient ischemic attacks (n = 4), drop attack (n = 1), gait disturbance (n = 1), headache (n = 2), and asymptomatic critical stenosis (n = 1). Success (< 20% residual diameter stenosis, without stroke or death) was achieved in all 32 patients (100%). One patient experienced a transient ischemic attack (TIA) 1 hr after the procedure. At follow-up (mean, 10.6 months), all patients (100%) were alive and 31/32 (97%) were asymptomatic. One patient (3%) had in-stent restenosis at 3.5 months and underwent successful balloon angioplasty. Endoluminal stenting of vertebral artery lesions is safe, effective, and durable as evidenced by the low recurrence rate. Primary stent placement is an attractive option for atherosclerotic vertebral artery stenotic lesions. Cathet Cardiovasc Intervent 2001;54:1-5. Copyright 2001 Wiley-Liss, Inc.

JAMA ,2001;286(11):1317-24

Peripheral arterial disease detection, awareness, and treatment in primary care.

Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, Krook SH, Hunninghake DB, Comerota AJ, Walsh ME, McDermott MM, Hiatt WR.

CONTEXT: Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis that is common and is associated with an increased risk of death and ischemic events, yet may be underdiagnosed in primary care practice. OBJECTIVE: To assess the feasibility of detecting PAD in primary care clinics, patient and physician awareness of PAD, and intensity of risk factor treatment and use of antiplatelet therapies in primary care clinics. DESIGN AND SETTING: The PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS)

program, a multicenter, cross-sectional study conducted at 27 sites in 25 cities and 350 primary care practices throughout the United States in June-October 1999. PATIENTS: A total of 6979 patients aged 70 years or older or aged 50 through 69 years with history of cigarette smoking or diabetes were evaluated by history and by measurement of the ankle-brachial index (ABI). PAD was considered present if the ABI was 0.90 or less, if it was documented in the medical record, or if there was a history of limb revascularization. Cardiovascular disease (CVD) was defined as a history of atherosclerotic coronary, cerebral, or abdominal aortic aneurysmal disease. MAIN OUTCOME MEASURES: Frequency of detection of PAD; physician and patient awareness of PAD diagnosis; treatment intensity in PAD patients compared with treatment of other forms of CVD and with patients without clinical evidence of atherosclerosis. RESULTS: PAD was detected in 1865 patients (29%); 825 of these (44%) had PAD only, without evidence of CVD. Overall, 13% had PAD only, 16% had PAD and CVD, 24% had CVD only, and 47% had neither PAD nor CVD (the reference group). There were 457 patients (55%) with newly diagnosed PAD only and 366 (35%) with PAD and CVD who were newly diagnosed during the survey. Eighty-three percent of patients with prior PAD were aware of their diagnosis, but only 49% of physicians were aware of this diagnosis. Among patients with PAD, classic claudication was distinctly uncommon (11%). Patients with PAD had similar atherosclerosis risk factor profiles compared with those who had CVD. Smoking behavior was more frequently treated in patients with new (53%) and prior PAD (51%) only than in those with CVD only (35%; P <.001). Hypertension was treated less frequently in new (84%) and prior PAD (88%) only vs CVD only (95%; P <.001) and hyperlipidemia was treated less frequently in new (44%) and prior PAD (56%) only vs CVD only (73%, P<.001). Antiplatelet medications were prescribed less often in patients with new (33%) and prior PAD (54%) only vs CVD only (71%, P<.001). Treatment intensity for diabetes and use of hormone replacement therapy in women were similar across all groups. CONCLUSIONS: Prevalence of PAD in primary care practices is high, yet physician awareness of the PAD diagnosis is relatively low. A simple ABI measurement identified a large number of patients with previously unrecognized PAD. Atherosclerosis risk factors were very prevalent in PAD patients, but these patients received less intensive treatment for lipid disorders and hypertension and were prescribed antiplatelet therapy less frequently than were patients with CVD. These results demonstrate that underdiagnosis of PAD in primary care practice may be a barrier to effective secondary prevention of the high ischemic cardiovascular risk associated with PAD.

Catheter Cardiovasc Interv, 2001 ;54(4):442-7

Transradial approach for renal artery stenting.

Scheinert D, Braunlich S, Nonnast-Daniel B, Schroeder M, Schmidt A, Biamino G, Daniel WG, Ludwig J.

Ercutaneous interventional procedures in the renal arteries are usually performed using a femoral or brachial vascular access. The transradial approach, which has been extensively investigated for coronary angiography and intervention, could be an attractive new technique for renal artery angioplasty and stenting. In 18 patients with hemodynamically relevant unilateral renal artery stenosis (mean diameter stenosis, 83% +/- 18%; right, n = 7; left, n = 11), interventional treatment with PTA and stenting was performed using a left (n = 16) or right (n = 2) radial artery access. Indications for the transradial approach were acute aorto-renal angles or severe peripheral arterial obstructions. After engagement of the renal artery ostium with a 6 Fr Multipurpose guiding catheter (length, 125 cm; Cordis) the stenosis was passed with a 0.014" guidewire followed by stent implantation (ACS Multi-Link RX Ultra, Guidant; length, 18 mm; diameter, 5 mm). Direct stenting was successfully performed in 16 cases. Predilatations were required in two cases. In five patients, optimal stent expansion was achieved by additional postdilatations. A primary technical success (residual stenosis < 30%) could be achieved in all cases. There were no periprocedural complications. According to color-coded doppler ultrasound, all access site arteries showed a normal perfusion. Clinically blood pressure control was improved in 11 patients with a significant reduction in systolic and diastolic blood pressure values. Serum creatinine values dropped from 1.81 +/- 0.3 mg/dl to 1.49 +/- 0.3 mg/dl (P < 0.001). Transradial renal artery angioplasty and stenting is technically feasible and safe. Particularly in patients with unfavorable vessel anatomy, this new cranio-caudal approach is an attractive alternative technique.

Journal of the American College of Cardiology, 1997;30:3:664-669

Infrapopliteal Transcatheter Interventions for Limb Salvage in Diabetic Patients: Importance of Aggressive Interventional Approach and Role of Transcutaneous Oximetry

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Objectives. This study sought to determine whether infrapopliteal transcatheter interventions can salvage ischemic limbs in diabetic patients referred for below the knee amputation at our institution.
Background. The value of transcatheter interventions in diabetic crural arteries is controversial. Tissue oxygen partial pressure (TcO2) levels <40 mm Hg predict poor wound healing.
Methods. Percutaneous interventions were performed in 29 consecutive diabetic patients in need of limb salvage. Technical success was defined as <20% residual vessel stenosis. Clinical success was defined as the

avoidance of amputation and achievement of wound healing. At hospital discharge, patients were treated with Coumadin and aspirin. Ankle-brachial index (ABI) and TcO2 measurements were obtained before and after the intervention.

Results. After 12-month follow-up, six patients had persistent wounds, whereas 23 experienced wound healing. Forty of the 50 infrapopliteal arteries successfully dilated were occluded, with a mean (±SD) lesion length of 18.0 ± 3.5 cm. After the procedure, TcO2 improved from 27.82 ± 9.97 mm Hg (95% confidence interval [CI] 23.95 to 31.69) to 54.5 ± 14.73 mm Hg (95% CI 48.79 to 60.21, $p < 0.0001$), whereas the ABI did not ($p > 0.2$). TcO2 predicted procedural and clinical success ($p < 0.0182$).

Conclusions. Infrapopliteal transcatheter interventions in diabetic patients may salvage the majority of limbs doomed to amputation. Although TcO2 measurements are valuable in predicting wound healing and success after interventions, ABI measurements are not.

Circulation, 1998 ;97: 1239-1245

Predictors of Stroke Complicating Carotid Artery Stenting

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Background-The evolving technique of carotid stenting is being evaluated as an alternative to endarterectomy. Identification of the factors that predispose a patient to neurological complications would facilitate further refinement of the technique and optimize patient selection.

Methods and Results-We analyzed the impact of various clinical, morphological, and procedural determinants on the development of procedural strokes in 231 patients who underwent elective (primary) stenting of 271 extracranial carotid arteries. The mean age of the patients was 68.7±10 years, 165 (71%) were males, and 139 (60%) had symptoms attributed to the lesion treated. This series represented a high-risk subset with 164 patients (71%) having significant coronary artery disease, 91 (39%) having bilateral disease, and 28 (12%) having contralateral carotid occlusion. Of the treated vessels, 59 (22%) had prior carotid endarterectomy, 66 (24%) had ulcerated plaques, and 87 (32%) had calcified lesions. Only 37 treated vessels (14%) would have been eligible for inclusion in the North American Symptomatic Carotid Endarterectomy Trial (NASCET). There were 17 (6.2%) minor and 2 (0.7%) major strokes during and within 30 days of the procedure. NASCET-eligible patients had a low (2.7%) risk of procedural strokes after carotid stenting. The results of multivariate analysis

revealed advanced age (P=.006) and presence of long or multiple stenoses (P=.006) as independent predictors of procedural strokes.
Conclusions-During this procedural developmental phase of carotid stenting, neurological complications were highly dependent on patient selection. Advanced age and long or multiple stenoses were independent predictors of procedural stroke.

The American Journal of Cardiology, 1998;82:5:632-637

Influence of guidewire and catheter type on the frequency of cerebral microembolic signals during left heart catheterization

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Cerebral embolization is a serious complication during diagnostic heart catheterization. To date there have been no studies to determine whether the technique and the catheter type influence the frequency of cerebral microembolic signals (MES's) during left ventricular catheterization. Twenty-two patients had a leading straight tip guidewire protruding 5 to 10 cm outside the coronary catheters when the latter was advanced over the aortic arch (group A), whereas in 21 patients the guidewire was withdrawn in the descending part of the aorta (group B). Transcranial Doppler of the left middle cerebral artery was performed to monitor the number of cerebral MES's. When a protruding guidewire was used to advance the coronary catheters over the aortic arch, MES's were detected in 86% of the patients compared with 29% when the catheters were advanced without a guidewire (relative risk = 4.6, p = 0.00001). The number of MES's per patient also was significantly higher when a guidewire was used (median 9 vs 0) (p = 0.000004). In group A, a higher number of MES's was detected when a right Judkins catheter was advanced over the aortic arch than when a left Judkins catheter was advanced (median 6.5 vs 1) (p = 0.0005) and in patients who previously had a myocardial infarction than in those who had not (median 11 vs 4) (p = 0.007). This study strongly suggests that the risk of embolization is greater when straight tip guidewires are used to advance catheters over the aortic arch during left ventricular heart catheterization, especially in patients with a history of myocardial infarction.

N Engl J Med ,1998;339:1441-7

The Fall and Rise of Carotid Endarterectomy in the United States and Canada

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Background. Randomized clinical trials have demonstrated the efficacy of carotid endarterectomy in the prevention of stroke when the procedure is performed in regional centers of surgical excellence. However, the relative effects of these studies on the rates of carotid endarterectomy in the United States and Canada have been unclear.

Methods. We calculated the annual rate of carotid endarterectomy in the U.S. states of California and New York and in the Canadian province of Ontario from 1983 through 1995. We also studied whether patients in the early 1990s were selectively referred to hospitals with high volumes of procedures and historically low in-hospital mortality rates.

Results. Rates of carotid endarterectomy fell in all three regions from 1984 to 1989 (from 126 to 66 per 100,000 adults 40 years of age or older in California, from 65 to 40 per 100,000 in New York, and from 40 to 15 per 100,000 in Ontario), after the publication of studies demonstrating that the rates of complications of carotid endarterectomy were unacceptably high. However, the clinical trials of the 1990s, which showed benefit from carotid endarterectomy, were associated with a dramatic resurgence in the rates of the procedure from 1989 to 1995 (from 66 to 99 per 100,000 in California, from 40 to 96 per 100,000 in New York, and from 15 to 38 per 100,000 in Ontario). These increased rates were not associated with proportionally greater numbers of referrals of patients to hospitals with low mortality rates.

Conclusions. There have been a dramatic fall and a rise in the rates of carotid endarterectomy in both the United States and Canada, which correlate with the publication of first unfavorable and then favorable clinical studies. The absence of selective referral of patients to centers with the lowest mortality rates raises questions about whether the benefits of carotid endarterectomy in the general population are similar to those demonstrated in the clinical trials.

Journal of the American College of Cardiology, 32:1336-1344

Restoring vascular nitric oxide formation by L-arginine improves the symptoms of intermittent claudication in patients with peripheral arterial occlusive disease

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Background. Administration of L-arginine improves nitric oxide (NO) formation and endothelium-dependent vasodilation in atherosclerotic patients.

Objectives. We investigated in this double-blind, controlled study whether prolonged intermittent infusion therapy with L-arginine improves the clinical symptoms of patients with intermittent claudication, as compared with the endothelium-independent vasodilator prostaglandin E1, and control patients.

Methods. Thirty-nine patients with intermittent claudication were randomly assigned to receive 2 × 8 g L-arginine/day, or 2 × 40μg prostaglandin E1 (PGE1)/day or no hemodynamically active treatment, for 3 weeks. The pain-free and absolute walking distances were assessed on a walking treadmill at 3 km/h, 12% slope, and NO-mediated, flow-induced vasodilation of the femoral artery was assessed by ultrasonography at baseline, at 1, 2 and 3 weeks of therapy and 6 weeks after the end of treatment. Urinary nitrate and cyclic guanosine-3', 5'-monophosphate (GMP) were assessed as indices of endogenous NO production.

Results. L-Arginine improved the pain-free walking distance by 230 ± 63% and the absolute walking distance by 155 ± 48% (each $p < 0.05$). Prostaglandin E1 improved both parameters by 209 ± 63% and 144 ± 28%, respectively (each $p < 0.05$), whereas control patients experienced no significant change. L-Arginine therapy also improved endothelium-dependent vasodilation in the femoral artery, whereas PGE1 had no such effect. There was a significant linear correlation between the L-arginine/asymmetric dimethylarginine (ADMA) ratio and the pain-free walking distance at baseline ($r = 0.359$, $p < 0.03$). L-Arginine treatment elevated the plasma L-arginine/ADMA ratio and increased urinary nitrate and cyclic GMP excretion rates, indicating normalized endogenous NO formation. Prostaglandin E1 therapy had no significant effect on any of these parameters. Symptom scores assessed on a visual analog scale increased from 3.51 ± 0.18 to 8.3 ± 0.4 (L-arginine) and 7.0 ± 0.5 (PGE1; each $p < 0.05$), but did not significantly change in the control group (4.3 ± 0.4).

Conclusions. Restoring NO formation and endothelium-dependent vasodilation by L-arginine improves the clinical symptoms of intermittent claudication in patients with peripheral arterial occlusive disease.

The American Journal of Cardiology, 1998;82:1077-1081

Acute hemodynamic changes during carotid artery stenting

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To determine the clinical significance of acute hemodynamic disturbances during stenting in the carotid sinus region, we assessed the relation between intraprocedural changes in heart rate (HR) and blood pressure (BP) and adverse neurologic and cardiac outcomes. Eighteen patients underwent carotid stenting with the Wallstent (Schneider Inc). Suitable candidates had at least 60% diameter stenosis of the carotid artery by angiography. Initial and nadir HR and BP were recorded during the predilatation, stent delivery, and postdilatation periods. Bradycardia was defined as HR ≤60 beats/min and hypotension as systolic BP 100 mm Hg. Nineteen Wallstents were successfully deployed in all 19 carotid arteries. Some degree of bradycardia or hypotension occurred in 68% of carotid stent procedures, but administration of vasoactive medications was necessary in only 7 patients (37%) with more persistent hemodynamic disturbances. Hypotension or the need for continuous vasopressor therapy was significantly more common during postdilatation (32%) than in the predilatation period (5%) ($p = 0.02$). Bradycardia was not reduced by prophylactic atropine. In 1 patient the hemodynamic response to stenting may have contributed to an adverse neurologic and cardiac outcome. Thus, despite frequent fluctuations in HR and BP, most carotid stenting procedures were performed with excellent overall results, even in patients at high risk.

Journal of the American College of Cardiology, 1998;32:90-96

Stent implantation versus balloon angioplasty in chronic coronary occlusions: results from the GISSOC trial

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Objectives. In this multicenter, randomized trial we evaluated whether stent implantation after successful recanalization of a chronic coronary occlusion reduced the incidence of restenosis.
Background. Percutaneous transluminal coronary angioplasty (PTCA) in chronic total occlusions is associated with a higher rate of angiographic restenosis and reocclusion than PTCA in subtotal stenoses. Preliminary reports have suggested a decreased restenosis rate after stent implantation in coronary total occlusions.
Methods. We randomly assigned 110 patients with recanalized total occlusion to Palmaz-Schatz stent

implantation, followed by 1 month of anticoagulant therapy versus no other treatment. The primary end point was the minimal lumen diameter (MLD) of the treated segment at follow-up, as determined by quantitative angiography at a core laboratory.

Results. Repeat coronary angiography was performed 9 months after the procedure in 88% of patients. The MLD (mean ± SD) at follow-up was 1.74 ± 0.88 mm in patients assigned to stent implantation and 0.85 ± .75 mm in patients assigned to PTCA ($p < 0.001$). Stent implantation was associated with a lower incidence of restenosis (defined as diameter stenosis ≥50% at follow-up) (32% vs. 68%, $p < 0.001$) and reocclusion (8% vs. 34%, $p = 0.003$) than balloon PTCA. Likewise, stent-treated patients had less recurrent ischemia (14% vs. 46%, $p = 0.002$) and target lesion revascularization (5.3% vs. 22%, $p = 0.038$), but experienced a longer hospital stay.

Conclusions. Palmaz-Schatz stent implantation after successful balloon PTCA of chronic total occlusions improves the midterm angiographic and clinical outcome and could be the preferred treatment option in selected patients with occluded vessels.

Circulation, 1998; 98: 642-647

Four-Year Follow-up of Palmaz-Schatz Stent Revascularization as Treatment for Atherosclerotic Renal Artery Stenosis

Gerald Dorros, Michael Jaff, Lynne Mathiak, Isa I. Dorros, Adam Lowe, Kelly Murphy, and Thomas He

Background-Stent revascularization is perceived as superior to balloon angioplasty and surgical revascularization, but the paucity of stent publications precludes even historical comparison with surgical data. Methods and Results-Palmaz-Schatz stent revascularization of renal artery stenosis was successfully performed on 163 consecutive patients for poorly controlled hypertension or preservation of renal function. Of these, 145 were eligible for ≥6-month clinical follow-up of the effect of the procedure on renal function, blood pressure control, number of antihypertensive medications, and survival. At 4 years, systolic and diastolic blood pressures significantly decreased (from 166±26 to 148±22 mm Hg and from 86±14 to 80±11 mm Hg, respectively; $P<0.05$), and blood pressure control was more facile in approximately half of the patients. Creatinine decreased or remained stable in approximately two thirds of the patients. The cumulative probability of survival was 74±4% at 3 years, with few deaths related to end-stage renal disease. Survival was good in patients with normal (92±4%) baseline renal function, fair (74±7%) in those with mildly impaired renal function, and poor (52±7%) in patients with elevated baseline creatinine levels ≥(2.0 mg/dL). The

combination of impaired renal function and bilateral disease adversely affected survival.
Conclusions-Renal artery stent revascularization in the presence of normal or mildly impaired renal function had a beneficial effect on blood pressure control and a nondeleterious effect on renal function. Survival was adversely affected by renal dysfunction despite adequate revascularization. Early diagnosis and adequate revascularization before the onset of renal dysfunction could beneficially affect blood pressure control, preserve or prevent deterioration of renal function, and improve patient survival.

N Engl J Med ,1998;339:1415-25

Benefit of Carotid Endarterectomy in Patients with Symptomatic Moderate or Severe Stenosis

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Background. Previous studies have shown that carotid endarterectomy in patients with symptomatic severe carotid stenosis (defined as stenosis of 70 to 99 percent of the luminal diameter) is beneficial up to two years after the procedure. In this clinical trial, we assessed the benefit of carotid endarterectomy in patients with symptomatic moderate stenosis, defined as stenosis of less than 70 percent. We also studied the durability of the benefit of endarterectomy in patients with severe stenosis over eight years of follow-up.
Methods. Patients who had moderate carotid stenosis and transient ischemic attacks or nondisabling strokes on the same side as the stenosis (ipsilateral) within 180 days before study entry were stratified according to the degree of stenosis (50 to 69 percent or <50 percent) and randomly assigned either to undergo carotid endarterectomy (1108 patients) or to receive medical care alone (1118 patients). The average follow-up was five years, and complete data on outcome events were available for 99.7 percent of the patients. The primary outcome event was any fatal or nonfatal stroke ipsilateral to the stenosis for which the patient underwent randomization.
Results. Among patients with stenosis of 50 to 69 percent, the five-year rate of any ipsilateral stroke (failure rate) was 15.7 percent among patients treated surgically and 22.2 percent among those treated medically (P=0.045); to prevent one ipsilateral stroke during the five-year period, 15 patients would have to be treated with carotid endarterectomy. Among patients with less than 50 percent stenosis, the failure rate was not significantly lower in the group treated with endarterectomy (14.9 percent) than in the medically treated group

(18.7 percent, P=0.16). Among the patients with severe stenosis who underwent endarterectomy, the 30-day rate of death or disabling ipsilateral stroke persisting at 90 days was 2.1 percent; this rate increased to only 6.7 percent at 8 years. Benefit was greatest among men, patients with recent stroke as the qualifying event, and patients with hemispheric symptoms.

Conclusions. Endarterectomy in patients with symptomatic moderate carotid stenosis of 50 to 69 percent yielded only a moderate reduction in the risk of stroke. Decisions about treatment for patients in this category must take into account recognized risk factors, and exceptional surgical skill is obligatory if carotid endarterectomy is to be performed. Patients with stenosis of less than 50 percent did not benefit from surgery. Patients with severe stenosis (greater than or equal to 70 percent) had a durable benefit from endarterectomy at eight years of follow-up.

Lancet ,1998; 351: 1379-87

Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST)

European Carotid Surgery Trialists Collaborative Group*

Background. Our objective was to assess the risks and benefits of carotid endarterectomy, primarily in terms of stroke prevention, in patients with recently symptomatic carotid stenosis.

Methods. This multicentre, randomised controlled trial enrolled 3024 patients. We enrolled men and women of any age, with some degree of carotid stenosis, who within the previous 6 months had had at least one transient or mild symptomatic ischaemic vascular event in the distribution of one or both carotid arteries. Between 1981 and 1994, we allocated 1811 (60%) patients to surgery and 1213 (40%) to control (surgery to be avoided for as long as possible). Follow-up was until the end of 1995 (mean 6·1 years), and the main analyses were by intention to treat.

Findings. The overall outcome (major stroke or death) occurred in 669 (37·0%) surgery-group patients and 442 (36·5%) control-group patients. The risk of major stroke or death complicating surgery (7·0%) did not vary substantially with severity of stenosis. On the other hand, the risk of major ischaemic stroke ipsilateral to the unoperated symptomatic carotid artery increased with severity of stenosis, particularly above about 7080% of the original luminal diameter, but only for 23 years after randomisation. On average, the immediate risk of surgery was worth trading off against the long-term risk of stroke without surgery when the stenosis was greater than about 80% diameter; the Kaplan-Meier estimate of the frequency of a major stroke or death at 3

years was 26·5% for the control group and 14·9% for the surgery group, an absolute benefit from surgery of 11·6%. However, consideration of variations in risk with age and sex modified this simple rule based on stenosis severity. We present a graphical procedure that should improve the selection of patients for surgery.
Interpretation. Carotid endarterectomy is indicated for most patients with a recent non-disabling carotid-territory ischaemic event when the symptomatic stenosis is greater than about 80%. Age and sex should also be taken into account in decisions on whether to operate.

Circulation, 1999 99: 3155-3160

Health-Related Quality of Life After Angioplasty and Stent Placement in Patients With Iliac Artery Occlusive Disease : Results of a Randomized Controlled Clinical Trial

Johanna L. Bosch, Yolanda van der Graaf, and Maria G. M. Hunink

Backround-To assess the quality of life in patients with iliac artery occlusive disease, we compared primary stent placement versus primary angioplasty followed by selective stent placement in a multicenter randomized controlled trial.
Methods and Results-Quality-of-life assessments were completed by 254 patients in a telephone interview. Assessment measures consisted of the RAND 36-Item Health Survey 1.0, time tradeoff, standard gamble, rating scale, health utilities index, and EuroQol-5D. The interviews were performed before treatment and after 1, 3, 12, and 24 months. When the 2 treatments were compared, no significant difference was observed ($P>0.05$). All measurements showed a significant improvement in the quality of life after treatment ($P<0.05$). The RAND 36-Item Health Survey measures physical functioning, role limitations caused by physical problems, and bodily pain and the EuroQol-5D were the most sensitive to the impact of revascularization.
Conclusions-Health-related quality of life improves equally after primary stent placement and primary angioplasty with selective stent placement in the treatment of intermittent claudication caused by iliac artery occlusive disease.

Lancet ,1999; 353: 217984

Low-dose and high-dose acetylsalicylic acid for patients undergoing carotid endarterectomy: a randomised

controlled trial

D Wayne Taylor, Henry J M Barnett, R Brian Haynes, Gary G Ferguson, David L Sackett, Kevin E Thorpe, Denis Simard, Frank L Silver, Vladimir Hachinski, G Patrick Clagett, R Barnes, J David Spence, for the ASA and Carotid Endarterectomy (ACE) Trial Collaborators*

Background. Endarterectomy benefits certain patients with carotid stenosis, but benefits are lessened by perioperative surgical risk. Acetylsalicylic acid lowers the risk of stroke in patients who have experienced transient ischaemic attack and stroke. We investigated appropriate doses and the role of acetylsalicylic acid in patients undergoing carotid endarterectomy.
Methods. In a randomised, double-blind, controlled trial, 2849 patients scheduled for endarterectomy were randomly assigned 81 mg (n=709), 325 mg (n=708), 650 mg (n=715), or 1300 mg (n=717) acetylsalicylic acid daily, started before surgery and continued for 3 months. We recorded occurrences of stroke, myocardial infarction, and death. We compared patients on the two higher doses of acetylsalicylic acid with patients on the two lower doses.
Findings. Surgery was cancelled in 45 patients, none were lost to follow-up by 30 days, and two were lost by 3 months. The combined rate of stroke, myocardial infarction, and death was lower in the low-dose groups than in the high-dose groups at 30 days (5·4 vs 7·0%, p=0·07) and at 3 months (6·2 vs 8·4%, p=0·03). In an efficacy analysis, which excluded patients taking 650 mg or more acetylsalicylic acid before randomisation, and patients randomised within 1 day of surgery, combined rates were 3·7% and 8·2%, respectively, at 30 days (p=0·002) and 4·2% and 10·0% at 3 months (p=0·0002).
Interpretation. The risk of stroke, myocardial infarction, and death within 30 days and 3 months of endarterectomy is lower for patients taking 81 mg or 325 mg acetylsalicylic acid daily than for those taking 650 mg or 1300 mg.

The American Journal of Cardiology, 83:6:862-867

Clinical and angiographic predictors of recurrent restenosis after percutaneous transluminal rotational atherectomy for treatment of diffuse in-stent restenosis

Juergen vom Dahl, Peter W. Radke, Phillip K. Haager, Karl-Christian Koch, Frank Kastrau, Thorsten Reffelmann, Uwe Janssens, Peter Hanrath, Heinrich G. Klues

Due to the widespread use of stents in complex coronary lesions, stent restenosis represents an increasing problem, for which optimal treatment is under debate. ?ebulking?of in-stent neointimal tissue using percutaneous transluminal rotational atherectomy (PTRA) offers an alternative approach to tissue compression and extrusion achieved by balloon angioplasty. One hundred patients (70 men, aged 58 ± 11 years) with a first in-stent restenosis underwent PTRA using an incremental burr size approach followed by adjunctive angioplasty. The average lesion length by quantitative angiography was 21 ± 8 mm (range 5 to 68) including 22 patients with a length ≥40 mm. Twenty-nine patients had complete stent occlusions with a lesion length of 44 ± 23 mm. Baseline diameter stenosis measured 78 ± 17%, was reduced to 32 ± 9% after PTRA, and further reduced to 21 ± 10% after adjunctive angioplasty. Primary PTRA was successful in 97 of 100 patients. Clinical success was 97%, whereas 2 patients developed non-Q-wave infarctions without clinical sequelae. Clinical follow-up was available for all patients at 5 ± 4 months without any cardiac event. Angiography in 72 patients revealed restenosis in 49%, with necessary target lesion reintervention in 35%. The incidence of rerestenosis correlated with the length of the primarily stented segment and the length of a first in-stent restenosis. Thus, PTRA offers an alternative approach to treat diffuse in-stent restenosis. Neointimal debulking of stenosed stents can be achieved effectively and safely. PTRA resulted in an acceptable recurrent restenosis rate in short and modestly diffuse lesion, whereas the restenosis rate in very long lesions remains high despite debulking.

Circulation, 1999 99: 498-504

Delayed Treatment of Traumatic Rupture of the Thoracic Aorta With Endoluminal Covered Stent

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Background-Stent grafting is emerging as a new treatment for several pathological conditions involving the thoracic aorta. We studied the feasibility and safety of this technique for delayed treatment of ruptures of the aortic isthmus.

Methods and Results-Nine patients (14 to 76 years old; mean, 37 years; male/female ratio, 8/1) underwent stent grafting of the aortic isthmus in subacute (n=5) or chronic (n=4) aortic traumatic rupture after a motor accident. In subacute ruptures, this treatment was delayed (1 to 8 months; mean, 5.4 months) because of the severity of

other associated injuries. Stent grafting was technically successful (defined as complete exclusion of the pseudoaneurysmal sac) in all patients. Short-term fever and biological inflammatory syndrome occurred in 3 patients. Two major complications occurred: in 1 patient, an early occlusion of the left subclavian artery was treated by placement of 2 Palmaz stents. In another patient, an atelectasis related to an increase of preexisting compression of the left main bronchus by the pseudoaneurysmal sac was successfully treated by temporary placement of an endobronchial silicone stent. Mean follow-up was 11.6 months (range, 3 to 21 months). Thrombosis of the pseudoaneurysmal sac was found in all patients.
Conclusions-In the absence of available extended follow-up about the safety and effectiveness of endovascular grafting, this approach seems to be a viable therapeutic option for traumatic rupture of the aortic isthmus, but appropriately controlled prospective studies are needed before we can recommend its widespread use.

Circulation, 2000; 102: 2228-2232

Peripheral Arterial Disease in Randomized Trial of Estrogen With Progestin in Women With Coronary Heart Disease : The Heart and Estrogen/Progestin Replacement Study

Judith Hsia, Joel A. Simon, Feng Lin, William B. Applegate, Molly T. Vogt, Donald Hunninghake, and Margaret Carr

Background-Postmenopausal estrogen use has been associated with reduced carotid atherosclerosis in observational studies, but this relationship has not been confirmed in a clinical trial. The impact of estrogen on atherosclerotic disease in other peripheral arteries is unknown.
Methods and Results-Postmenopausal women with coronary heart disease (CHD) and an intact uterus (n=2763) were randomly assigned to conjugated equine estrogens (0.625 mg) combined with medroxyprogesterone acetate (2.5 mg) daily or to placebo in a secondary CHD prevention trial. This analysis focuses on incident peripheral arterial procedures and deaths in the 2 treatment groups; peripheral vascular disease was a predefined secondary outcome. During a mean of 4.1 years of follow-up, 311 peripheral arterial events were reported in 213 women, an annual incidence of 2.9%. The number of women who had peripheral arterial events was 99 among those assigned to active estrogen/progestin and 114 among those assigned to placebo, a nonsignificant difference (relative hazard 0.87, 95% CI 0.66 to 1.14). In the placebo group, hypertension and diabetes mellitus were independently associated with higher rates of peripheral arterial events, and plasma HDL cholesterol and body mass index were associated with lower rates of peripheral arterial events. In the

estrogen/progestin group, current smoking and diabetes were independent predictors of peripheral arterial events. Incident peripheral arterial disease was not a significant predictor of coronary, cardiovascular, or total mortality.

Conclusions-Treatment with oral conjugated estrogen plus medroxyprogesterone acetate was not associated with a significant reduction in incident peripheral arterial events in postmenopausal women with preexisting CHD.

Cathet. Cardiovasc. Intervent. 50:160-167, 2000

Global experience in cervical carotid artery stent placement

Michael H. Wholey, Mark Wholey, Klaus Mathias, Gary S. Roubin, Edward B. Diethrich, Michel Henry, Steven Bailey, Patrice Bergeron, Gerry Dorros, Gustave Eles, Peter Gaines, Camilo R. Gomez, Bill Gray, Juan Guimaraens, Randal Higashida, David Sai Wah Ho, Barry Katzen, Antonio Kambara, Vijay Kumar, Jean C. Laborde, Martin Leon, Michael Lim, Hugo Londero, Juan Mesa, Alejandro Musacchio, Subbarao Myla, Steve Ramee, Adolfo Rodriguez, Kenneth Rosenfield, Noboyuki Sakai, Fayaz Shawl, Horst Sievert, George Teitelbaum, Jacque G. Theron, Prochazka Vaclav, Carlos Vozzi, Jay S. Yadav, Shin-Ichi Yoshimura

The purpose of this article is to review and update the current status of carotid artery stent placement in the world. Surveys to major interventional centers in Europe, North and South America, and Asia were initially completed in June 1997. Subsequent information from these 24 centers in addition to 12 new centers has been obtained to update the information. The survey asked the various questions regarding the patients enrolled, procedure techniques, and results of carotid stenting, including complications and restenosis. The total number of endovascular carotid stent procedures that have been performed worldwide to date included 5,210 procedures involving 4,757 patients. There was a technical success of 98.4% with 5,129 carotid arteries treated. Complications that occurred during the carotid stent placement or within a 30-day period following placement were recorded. Overall, there were 134 transient ischemic attacks (TIAs) for a rate of 2.82%. Based on the total patient population, there were 129 minor strokes with a rate of occurrence of 2.72%. The total number of major strokes was 71 for a rate of 1.49%. There were 41 deaths within a 30-day postprocedure period resulting in a mortality rate of 0.86%. The combined minor and major strokes and procedure-related death rate was 5.07%.

Restenosis rates of carotid stenting have been 1.99% and 3.46% at 6 and 12 months, respectively. The rate of neurologic events after stent placement has been 1.42% at 6-12-month follow-up. Endovascular stent treatment of carotid artery atherosclerotic disease is growing as an alternative for vascular surgery, especially for patients that are high risk for standard carotid endarterectomy. The periprocedure risks for major and minor strokes and death are generally acceptable at this early stage of development and have not changed significantly since the first survey results.

Journal of the American College of Cardiology, 2000;35:7:1721-1728

Safety and efficacy of elective carotid artery stenting in high-risk patients

Fayaz Shawl, Waleed Kadro, Michael J. Domanski, Fernando L. Lapetina, Aleem A. Iqbal, Kathy G. Dougherty, David D. Weisher, Jaime F. Marquez, S. Tariq Shahab

OBJECTIVES
We sought to evaluate the safety and efficacy of carotid artery stenting (CAS) in high risk patients.
BACKGROUND
Carotid endarterectomy (CE) has been shown to be more effective than medical therapy, but it has limitations. Carotid artery stenting may be a reasonable alternative, particularly in high-risk patients.
METHODS
We prospectively evaluated the safety and efficacy of CAS in 170 consecutive patients who underwent the procedure in 192 carotid arteries. Of the patients enrolled, 129 (76%) would have been excluded from the major trials of CE and 54 (32%) were referred by vascular surgeons. This series represents a very high-risk group that included patients with unstable angina, previous ipsilateral CE, contralateral carotid artery occlusion and other severe comorbid illnesses. Only 25 (24%) of 104 symptomatic patients would have met the North American Symptomatic Carotid Endarterectomy Trial (NASCET) entry criteria. The patients' mean age was 73 ± 8 years (95 confidence interval [CI] 57 to 89), and 42 patients (25%) were ≥80 years old. Patients had an independent neurologic examination before and after the procedure.
RESULTS
The procedural success rate was 99%, including 73 patients who had a coronary intervention. Mean carotid artery stenosis was 78 ± 10% before (95 CI 58 to 98) and 2 ± 3% after the procedure (95 CI -4 to 8). During the initial hospital period and 30 days after CAS, there was one major and two category 2 minor strokes, as well as

two category 1 minor strokes (total 30-day stroke rate was 2.9% for treated patients or 2.6% for treated arteries). There were no myocardial infarctions or deaths during or within 30 days of CAS. None of the NASCET-eligible patients had a stroke. At a mean follow-up of 19 ± 11 months, three patients (2%) had asymptomatic restenosis. No other major strokes or neurologic deaths occurred.

CONCLUSIONS

Carotid artery stenting is feasible, can be performed even in high-risk patients and is associated with a low restenosis rate.

Journal of the American College of Cardiology, 2000;36:4:1239-1244

Basic fibroblast growth factor in patients with intermittent claudication: results of a phase I trial

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OBJECTIVES

This phase I study was designed to evaluate the safety, tolerability and pharmacokinetics of intra-arterial basic fibroblast growth factor (bFGF) in patients with atherosclerotic peripheral arterial disease (PVD) and intermittent claudication. We also assessed the effects of basic fibroblast growth factor (bFGF) on calf blood flow as a measure of biologic activity.

BACKGROUND

Preclinical studies have shown that bFGF, an angiogenic peptide, promotes collateral development in animal models of myocardial and hind limb ischemia. The safety and efficacy of bFGF in patients is unknown, and early clinical trials are underway in coronary and peripheral arterial disease.

METHODS

A double-blind, placebo-controlled, dose-escalation trial was conducted in patients with claudication demonstrating ankle/brachial index <0.8. Patients were randomly assigned to placebo (n = 6), 10 μg/kg of bFGF (n = 4), 30 μg/kg of bFGF once (n = 5) and 30 μg/kg of bFGF on two consecutive days (n = 4). Study drug was infused into the femoral artery of the ischemic leg. Detailed safety information including retinal photography for neovascularization were obtained through one year. Calf blood flow was measured with strain gauge plethysmography in the two higher dose treatment groups and in four placebo patients at baseline, one month and three to seven months after treatment.

RESULTS

Intra-arterial bFGF was safe and well-tolerated. The half-life was 46 ± 21 min. Calf blood flow increased at one month by 66 ± 26% (mean ± SEM) and at six months by 153 ± 51% in bFGF-treated patients (n = 9, p = 0.002). Flow did not change significantly in the placebo group.

CONCLUSIONS

In this initial randomized, double-blind, placebo-controlled trial in patients with atherosclerotic PVD and claudication, bFGF was well-tolerated. The data suggest a salutary biologic effect, and initiation of phase 2 trials is warranted.

Circulation, 2000 ;102: 1671-1677

Effect of Renal Artery Stenting on Renal Function and Size in Patients with Atherosclerotic Renovascular Disease

Paul S. Watson, Peter Hadjipetrou, Stephen V. Cox, Thomas C. Piemonte, and Andrew C. Eisenhauer

Background-Renal artery stenting is widely performed, but little is known about its effectiveness in preserving renal function and size in patients with renovascular disease and chronic renal insufficiency. We studied the effect of renal artery stenting on renal function and size in patients with obstructive renovascular disease and chronic renal insufficiency.

Methods and Results-Stent deployment was performed in patients with chronic renal insufficiency (creatinine >1.5 mg · dL-1) and global renovascular obstruction (bilateral renal artery stenosis or unilateral stenosis in the presence of a solitary or single functional kidney). The effect of renal artery stenting on renal function was assessed by comparing the slopes of the regression lines derived from the reciprocal of serum creatinine versus time plotted before and after stent deployment. Renal size was assessed by serial ultrasound of pole-to-pole kidney length. Stenting was successful in all 61 vessels in 33 patients. Twenty-five patients had complete follow-up (mean 20±11 months). Before stent deployment, all patients exhibited a negative slope, indicating progressive renal insufficiency. After stent deployment, the slopes were positive in 18 and less negative in 7 patients. Thus, the mean slope increased from -0.0079 to 0.0043 dL · mg-1 · mo-1 (P<0.001). Ultrasonography on 41 kidneys revealed preservation of size, with the kidney length measuring 10.4±1.4 cm at baseline and 10.4 ±1.1 cm at last follow-up (P=NS). Patient survival at 20±11 months was 90%.

Conclusions-In patients with chronic renal insufficiency and global obstructive atherosclerotic renovascular

disease, renal artery stenting improves or stabilizes renal function and preserves kidney size.

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21. Health-Related Quality of Life After Angioplasty and Stent Placement in Patients With Iliac Artery Occlusive Disease : Results of a Randomized Controlled Clinical Trial

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Circulation 1999 99: 3155-3160.

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23. Clinical and angiographic predictors of recurrent restenosis after percutaneous transluminal rotational atherectomy for treatment of diffuse in-stent restenosis

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24. Delayed Treatment of Traumatic Rupture of the Thoracic Aorta With Endoluminal Covered Stent

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Circulation 1999 99: 498-504.

25. Peripheral Arterial Disease in Randomized Trial of Estrogen With Progestin in Women With Coronary Heart Disease : The Heart and Estrogen/Progestin Replacement Study

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26. Global experience in cervical carotid artery stent placement

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27. Safety and efficacy of elective carotid artery stenting in high-risk patients

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Journal of the American College of Cardiology, 2000;35:7:1721-1728

28. Basic fibroblast growth factor in patients with intermittent claudication: results of a phase I trial

Daisy F. Lazarous, Ellis F. Unger, Stephen E. Epstein, Annette Stine, Josefino L. Arevalo, Emily Y. Chew, Arshed A. Quyyumi

Journal of the American College of Cardiology, 2000;36:4:1239-1244

29. Effect of Renal Artery Stenting on Renal Function and Size in Patients with Atherosclerotic Renovascular Disease

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