Am J Cardiol (2005);95:511-4
A novel, low-profile filter-wire (Interceptor) embolic protection device during saphenous vein graft stenting
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A novel, low-profile filter embolic protection device was deployed in 26 patients who underwent stent deployment for saphenous vein graft stenoses in a multicenter trial. Major adverse cardiovascular events were observed in only 2 patients (7.7%) and angiographic flow grades were improved.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15695142

Am J Cardiol (2005);95:173-7
Determinants of 30-day adverse events following saphenous vein graft intervention with and without a distal occlusion embolic protection device
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Distal balloon occlusion was approved as a means of embolic protection during saphenous vein graft intervention based on its ability to decrease major adverse clinical events (MACEs) by 42% in the 801-patient Saphenous Vein Graft Angioplasty Free of Emboli Randomized (SAFER) trial. However, the cost and technical complexity of this device have limited its widespread use and prompted some to avoid its use in cases that appear at "low risk" for complications. If predictors of MACEs and their potential decrease by distal balloon occlusion could be identified, this would have important clinical implications in this challenging population. We therefore used standard demographic and angiographic variables and 2 new angiographic markers (extent of graft degeneration and estimated volume of plaque in the target lesion) to construct multivariable logistic regression models of 30-day of MACEs in the SAFER trial. Independent correlates of increased 30-day MACEs were more extensive vein graft degeneration ($p = 0.0001$) and bulkier lesions (larger estimated plaque volume, $p = 0.0005$). Use of a distal balloon occlusion device was independently predictive of lower 30-day rates of MACE ($p = 0.01$), with uniform benefit across risk strata (no significant interaction between device use and independent angiographic risk factors). Thus, the risk of 30-day MACEs after percutaneous intervention in aortocoronary saphenous vein grafts is increased in more diffusely diseased grafts and in bulkier lesions, but a significant benefit of the GuardWire was seen across all levels of MACE risk rather than just those perceived to be at highest risk.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15642547

Circulation (2004);109:1489-96
Improved survival with radial artery versus vein conduits in coronary bypass surgery with left internal thoracic artery to left anterior descending artery grafting
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BACKGROUND: Given its proven survival benefit, left internal thoracic artery to left anterior descending (LITA-LAD) grafting has become a fundamental part of CABG. This grafting also led to increased use of other arterial conduits, of which the radial artery is most popular. Whether radial grafting improves survival beyond that achieved by LITA-LAD alone is not known. METHODS AND RESULTS: We compared 6-year outcomes in propensity-matched CABG-LITA-LAD patients (925 each) divided into those with > or =1 radial grafts and those with vein-only grafting. Matched patients had essentially identical demographics, comorbidities, coronary disease, and operative data. Perioperative outcomes, including death (radial, 11 [1.2%]; vein, 10 [1.1%]), were similar for the 2 groups. Cumulative 0- to 6-year survival was better for radial patients (risk ratio, 0.675), particularly after 3 years (P<0.03). Six-year survival in vein (86.8%) and radial (92.1%) patients indicated 67% greater overall vein mortality. Incidence rates of radial and vein repeated catheterization (190 of 925 [20.5%] versus 199 of 925 [21.5%]) and revascularization (8.8% versus 8.5%) were similar. Angiography data in restudied symptomatic patients showed a trend for greater radial patency. Vein failure (66 of 161 [41%]) was significantly worse than radial failure (46 of 157 [29.3%]) in patients receiving both types of grafts (P=0.039). CONCLUSIONS: Using radial as a second arterial conduit in CABG-LITA-LAD as opposed to vein grafting improves long-term outcomes as a result of decreased late deaths, especially after the third postoperative year.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15023868

Circulation (2004);109:1735-40
Embolic protection with filtering or occlusion balloons during saphenous vein graft stenting retrieves identical volumes and sizes of particulate debris
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BACKGROUND: Distal embolization of plaque particulate liberated during stenting may cause periprocedural complications. The number, size, and volume of debris released during stenting, however, have not been quantified, rendering embolic protection approaches empiric. We used a novel method of microparticle size assessment to measure volume and characterize individual sizes of particles captured by the PercuSurge GuardWire balloon or a vascular filter during saphenous vein graft stenting. METHODS AND RESULTS: Braided nitinol filters (average distal pore size 100 microns) were used in 47 saphenous vein grafts in 44 patients. The PercuSurge GuardWire was used in 17 saphenous vein grafts in 16 patients. Particulate debris was subjected to microparticle size analysis (RapidVue, Beckman Coulter). All samples contained particulate debris. For both filter and GuardWire populations, most particles were <100 microm in longest dimension (87% and 90% of particles, respectively), and the distribution of particle sizes was identical. Total embolic load per lesion for both filters and GuardWire aspirates was also similar: median embolic load per filter was 16 mm3 (range 2 to 84 mm3). Median embolic load per GuardWire was also 16 mm3 (range 7 to 42 mm3). Histopathologic analysis demonstrated that most samples contained plaque elements and platelet-rich thrombus. CONCLUSIONS: During

saphenous vein graft interventions, particulate retrieved with a vascular filtering device or an occlusion balloon was similar in amount and character. This supports the notion that unless soluble mediators play an important role in adverse acute clinical events after stenting, the clinical efficacy of filtering devices may be equal to that of occlusion devices.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15066954

Catheter Cardiovasc Interv (2004);63:148-51
Applicability of distal protection for aortocoronary vein graft interventions in clinical practice
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Percutaneous revascularization of diseased saphenous vein grafts is associated with increased risk of adverse events, although the use of distal protection mitigates this to a significant extent. However, anatomic characteristics may preclude the use of such devices in a proportion of vein grafts intended for percutaneous treatment. We reviewed our consecutive experience of saphenous vein graft interventions from 1 May 2001 through 30 April 2002 to determine suitability for distal protection. Relevant angiographic characteristics included lesion within 5 mm of the ostium; lesion < 20 mm from the distal anastomosis; planned distal landing site of the occlusion balloon < 3 mm or > 6 mm in diameter; total occlusion of the vein graft; or lesion in a sequential vein graft distal to the first anastomosis. One hundred twenty-seven patients (140 procedures, 147 vein grafts) were treated. One or more of the angiographic exclusion criteria for a balloon occlusion protection system existed in 57% of grafts, while 42% had exclusions for a filter device. A large number of patients with vein graft disease intended for percutaneous treatment have anatomic exclusions to available distal protection technology.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15390255

Am J Cardiol (2004);93:963-8
Relation of final lumen dimensions in saphenous vein grafts after stent implantation to outcome
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Larger final lumen dimensions after percutaneous coronary interventions in native coronary arteries lead to lower restenosis rates. We sought to determine the impact of stent expansion, as assessed by intravascular ultrasound, on clinical results of stent implantation in saphenous vein grafts (SVGs). We identified 226 consecutive patients who underwent intravascular ultrasound-guided stenting of 234 de novo SVG lesions. Patients were divided into 2 groups based on the final stent cross-sectional area (CSA):

associated with (1) increased rates of in-hospital non-Q-wave myocardial infarction (29% vs 17%, p = 0.05), (2) any myocardial infarction (26% vs 8%, p = 0.003) at 1-year follow-up, and (3) no improvement in target vessel revascularization at 1 year (31% vs 26%, p = 0.3). Aggressive stent expansion in SVG lesions resulted in higher myocardial infarction rates and, unlike native arteries, no improvement in target vessel revascularization rate at 1 year. A less aggressive stent implantation strategy in SVGs than in native coronary lesions appears prudent.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15081436

J Am Coll Cardiol (2004);44:2149-56
Long-term patency of saphenous vein and left internal mammary artery grafts after coronary artery bypass surgery: results from a Department of Veterans Affairs Cooperative Study
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OBJECTIVES: This study defined long-term patency of saphenous vein grafts (SVG) and internal mammary artery (IMA) grafts. BACKGROUND: This VA Cooperative Studies Trial defined 10-year SVG patency in 1,074 patients and left IMA patency in 457 patients undergoing coronary artery bypass grafting (CABG). METHODS: Patients underwent cardiac catheterizations at 1 week and 1, 3, 6, and 10 years after CABG. RESULTS: Patency at 10 years was 61% for SVGs compared with 85% for IMA grafts (p < 0.001). If a SVG or IMA graft was patent at 1 week, that graft had a 68% and 88% chance, respectively, of being patent at 10 years. The SVG patency to the left anterior descending artery (LAD) (69%) was better (p < 0.001) than to the right coronary artery (56%), or circumflex (58%). Recipient vessel size was a significant predictor of graft patency, in vessels >2.0 mm in diameter SVG patency was 88% versus 55% in vessels </=2.0 mm (p < 0.001). Other positive significant predictors of graft patency were use of aspirin after bypass, older age, lower serum cholesterol, and lowest Canadian Functional Class (p < 0.001 to 0.058). CONCLUSIONS: The 10-year patency of IMA grafts is better than SVGs. The 10-year patency for SVGs is better and the 10-year patency for IMA grafts is worse than expected. The 10-year patency of SVGs to the LAD is better than that to the right or circumflex. The best long-term predictors of SVG graft patency are grafting into the LAD and grafting into a vessel that is >2.0 mm in diameter.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15582312

N Engl J Med (2004);351:2302-9
A randomized comparison of radial-artery and saphenous-vein coronary bypass grafts
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BACKGROUND: In the past decade, the radial artery has frequently been used for coronary bypass surgery despite concern regarding the possibility of graft spasm. Graft patency is a key predictor of long-term survival. We therefore sought to determine the

relative patency rate of radial-artery and saphenous-vein grafts in a randomized trial in which we controlled for bias in the selection of patients and vessels. METHODS: We enrolled 561 patients at 13 centers. The left internal thoracic artery was used to bypass the anterior circulation. The radial-artery graft was randomly assigned to bypass the major vessel in either the inferior (right coronary) territory or the lateral (circumflex) territory, with the saphenous-vein graft used for the opposing territory (control). The primary end point was graft occlusion, determined by angiography 8 to 12 months postoperatively. RESULTS: Angiography was performed at one year in 440 patients: 8.2 percent of radial-artery grafts and 13.6 percent of saphenous-vein grafts were completely occluded (P=0.009). Diffuse narrowing of the graft (the angiographic "string sign") was present in 7.0 percent of radial-artery grafts and only 0.9 percent of saphenous-vein grafts (P=0.001). The absence of severe native-vessel stenosis was associated with an increased risk of occlusion of the radial-artery graft and diffuse narrowing of the graft. Harvesting of the radial artery was well tolerated. CONCLUSIONS: Radial-artery grafts are associated with a lower rate of graft occlusion at one year than are saphenous-vein grafts. Because the patency of radial-artery grafts depends on the severity of native-vessel stenosis, such grafts should preferentially be used for target vessels with high-grade lesions.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15564545

J Am Coll Cardiol (2004);44:1801-8
Cost-effectiveness of distal embolic protection for patients undergoing percutaneous intervention of saphenous vein bypass grafts: results from the SAFER trial
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OBJECTIVES: The goal of this research was to determine the incremental cost and cost-effectiveness of embolic protection in patients undergoing percutaneous revascularization (PCI) of diseased saphenous vein bypass grafts (SVGs). BACKGROUND: Distal protection using the GuardWire balloon occlusion device has been shown to reduce major ischemic complications in patients undergoing SVG PCI, but the cost-effectiveness of this approach is unknown. METHODS: We prospectively measured medical resource utilization and cost for 801 patients undergoing SVG intervention who were randomized to distal protection using the GuardWire (n = 406) or conventional treatment (n = 395) in the Saphenous Vein Graft Angioplasty Free of Emboli Randomized (SAFER) trial. Long-term survival and cost-effectiveness were projected based on observed 30-day outcomes and a validated survival model for postcoronary artery bypass graft patients. RESULTS: Compared with conventional treatment, distal protection increased initial procedural costs by approximately $1,600

CONCLUSIONS: For patients undergoing PCI of diseased SVGs, distal protection using the GuardWire system is an attractive use of limited health care resources.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15519010

J Am Coll Cardiol (2004);44:53-6
Clinical, angiographic, and intravascular ultrasound characteristics of early saphenous vein graft failure
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OBJECTIVES: We sought to examine saphenous vein graft (SVG) lesions that fail within the first year after operation. BACKGROUND: Saphenous vein grafts remain patent for approximately 10 years; however, up to 15% to 20% of SVGs become occluded within the first year. METHODS: We studied 100 patients who underwent percutaneous coronary intervention (PCI) for early (<1 year post-implantation) SVG failure lesions and compared them with a diabetes- and hypercholesterolemia-matched cohort of late SVG failures (>1 year). Coronary angiography and intravascular ultrasound images were analyzed. RESULTS: The majority of patients in both groups were males who presented with unstable angina; 36% were diabetic. Graft ages were 6.0 +/- 2.9 months and 105.4 +/- 50.8 months, respectively. The early SVG failure lesion location was more often ostial or proximal (62% vs. 42%, respectively). Early SVG failures were angiographically smaller than late failures (reference: 2.47 +/- 0.86 mm vs. 3.26 +/- 0.83 mm, $p < 0.001$) but had similar lesion lengths. Intravascular ultrasound showed that early failure lesions had smaller proximal and distal reference lumen areas (7.3 +/- 6.8 mm2 vs. 10.6 +/- 3.8 mm2, $p = 0.026$) and greater reference plaque burden than late failures (52.3% vs. 36.1%, $p < 0.001$). After PCI, 20.6% of early and 30.6% of late failure lesions had creatine kinase-myocardial band (CK-MB) greater than twice normal. CONCLUSIONS: Early SVG failure is mostly proximal or ostial, lesions appear focal, and early SVGs appear smaller than late SVGs. Intravascular ultrasound shows significant reference segment plaque burden, suggesting more severe, diffuse SVG disease.
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