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STATE-OF-THE-ART PAPER

Saphenous Vein Graft Intervention

Michael S. Lee, MD,* Seung-Jung Park, MD,‡ David E. Kandzari, MD,§
Ajay J. Kirtane, MD, SM,‖ William F. Fearon, MD,† Emmanouil S. Brilakis, MD, PHD,¶
Paul Vermeersch, MD,# Young-Hak Kim, MD,‡ Ron Waksman, MD,**
Julinda Mehilli, MD,†† Laura Mauri, MD,‡‡ Gregg W. Stone, MD‖

Los Angeles and Palo Alto, California; Seoul, South Korea; Atlanta, Georgia; New York, New York; Dallas, Texas; Antwerp, Belgium; Washington, DC; Munich, Germany; and Boston, Massachusetts

Saphenous vein grafts are commonly used conduits for surgical revascularization of coronary arteries but are associated with poor long-term patency rates. Percutaneous revascularization of saphenous vein grafts is associated with worse clinical outcomes including higher rates of in-stent restenosis, target vessel revascularization, myocardial infarction, and death compared with percutaneous coronary intervention of native coronary arteries. Use of embolic protection devices is a Class I indication according to the American College of Cardiology/American Heart Association guidelines to decrease the risk of distal embolization, no-reflow, and periprocedural myocardial infarction. Nonetheless, these devices are underused in clinical practice. Various pharmacological agents are available that may also reduce the risk of or mitigate the consequences of no-reflow. Covered stents do not decrease the rates of periprocedural myocardial infarction and restenosis. Most available evidence supports treatment with drug-eluting stents in this high-risk lesion subset to reduce angiographic and clinical restenosis, although large, randomized trials comparing drug-eluting stents and bare-metal stents are needed. (J Am Coll Cardiol Intv 2011;4:831–43) © 2011 by the American College of Cardiology Foundation

The long-term success of surgical coronary revascularization is limited by accelerated atherosclerosis and intimal fibrosis of the saphenous vein graft (SVG) after its use as a vascular conduit. At 1 year, the incidence of 1 or more total SVG occlusions has been reported to be as high as 41% after on-pump bypass surgery (Table 1) (1–8). Because of increased morbidity and mortality with repeat coronary artery bypass graft surgery, SVG intervention is considered by many to be the preferred revascularization modality in patients with diseased SVGs and accounts for approximately 5% to 10% of all percutaneous coronary interventions (PCI) (9–14).

From the *University of California–Los Angeles Medical Center, Los Angeles, California; †Stanford University Medical Center, Palo Alto, California; ‡University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea; §Piedmont Heart Institute, Atlanta, Georgia; ‖Columbia University Medical Center and the Cardiovascular Research Foundation, New York, New York; ¶Veterans Affairs North Texas Healthcare System, and University of Texas Southwestern Medical Center, Dallas, Texas; #Antwerp Cardiovascular Institute Middelheim, AZ Middelheim, Antwerp, Belgium; **Washington Hospital Center, Washington, DC; ††Deutsches Herzzentrum, Technische Universität, Munich, Germany; and the ‡‡Brigham and Woman's Hospital, Boston, Massachusetts. Dr. Lee has received honoraria from Boston Scientific, St. Jude Medical, Daiichi-Sankyo, Bristol-Myers Squibb, and Merck. Dr. Park has received consulting fees from Cordis; lecture fees from Cordis, Medtronic, and Boston Scientific; and research grants from Cordis and Medtronic. Dr. Kandzari has received research/grant support from Abbott Vascular, Cordis, and Medtronic Cardiovascular, and consulting honoraria from Abbott Vascular and Medtronic. Dr. Kirtane has served as a consultant and speaker for Medtronic Cardiovascular, Abbott Vascular, and Boston Scientific. Dr. Fearon has received a research grant from St. Jude Medical. Dr. Brilakis received speaker honoraria from St. Jude Medical and Terumo; received research support from Abbott Vascular and InfraReDx; and his spouse is an employee of Medtronic. Dr. Kim has received lecture fees from Cordis. Dr. Waksman received consulting and speaker fees from Biotronik, Medtronic, Boston Scientific, and received research grants from Biotronik, Boston Scientific, The Medicines Company, Glaxo-SmithKline, Schering-Plough, and Sanofi-Aventis. Dr. Mehilli received lecture fees from Abbott and Terumo. Dr. Mauri received research grants from Abbott, Cordis, Boston Scientific, Medtronic, Bristol-Myers Squibb, Sanofi-Aventis, Eli Lilly, Daiichi Sankyo, and consulting fees from Abbott, Cordis, and Medtronic. Dr. Stone is a consultant to Abbott Vascular, Boston Scientific, and Medtronic. Dr. Vermeersch has reported that he has no relationships relevant to the contents of this paper to disclose.

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In this review, we describe the risk factors for complications after SVG intervention and discuss the optimal procedural treatment strategies regarding periprocedural anticoagulation, choice of stent, and measures to mitigate the risks of distal embolization.

Pathobiology of SVG

SVG intervention remains technically challenging and is associated with higher rates of periprocedural myocardial infarction, in-hospital mortality, restenosis, and occlusion compared with PCI of native coronary arteries largely because of the friable, degenerated atheromatous and thrombotic debris that develop when SVGs deteriorate (15). Progression of disease outside the stented segment can also lead to high rates of target vessel revascularization. Therefore, treatment of native coronary artery lesions is preferred to treatment of degenerated SVG if feasible.

Abbreviations and Acronyms

BMS = bare-metal stent(s)
CI = confidence interval
CK-MB = creatine kinase-myocardial band
DES = drug-eluting stent(s)
FDA = U.S. Food and Drug Administration
FFR = fractional flow reserve
HR = hazard ratio
MACE = major adverse cardiac event(s)
OR = odds ratio
PCI = percutaneous coronary intervention
PTFE = polytetrafluorethylene
SVG = saphenous vein graft
TIMI = Thrombolysis In Myocardial Infarction

A recognized consequence of SVG intervention is distal embolization of atheroembolic debris with decreased epicardial and microvascular perfusion due to capillary plugging and vasospasm from the release of neurohumoral factors such as serotonin. Distal embolization may result in the slow or no-reflow phenomenon in approximately 10% to 15% of cases and is associated with periprocedural angina and ischemic ST-segment changes (16). In such instances, subsequent myocardial infarction occurs in 31% of patients and in-hospital mortality increases 10-fold (17). However, distal embolization remains difficult to predict (18).

Predictors of Adverse Clinical Events

Periprocedural creatine kinase-myocardial band (CK-MB) elevation after successful SVG intervention was common (ranging from 15% to 47%) (19,20). The use of embolic protection devices has been systematically associated with periprocedural myocardial infarction rates <10% (21,22). Differences in myocardial infarction rates between studies may also be explained by differences in myocardial infarction definitions, the sensitivity and frequency of biomarker measurement, and the complexity of SVG disease studied. Hong et al. (19) reported that 15% of patients experienced major CK-MB release exceeding 5× the upper limit of normal following SVG PCI. Although the association of periprocedural myonecrosis and late clinical outcomes is controversial among patients undergoing native vessel PCI, even minor elevations of CK-MB (1× to 5× normal) after SVG intervention have been associated with increased mortality at 1 year (6.5% vs. 4.8%, $p < 0.05$), with CK-MB release exceeding 5× the upper limit of normal increasing 1-year mortality by 144%. Multivariate analysis revealed that major CK-MB release after SVG intervention was a powerful independent predictor of late mortality (odds ratio [OR]: 3.3, 95% confidence interval [CI]: 1.7 to 6.2).

Lesion length, greater angiographic degeneration of SVGs, and larger estimated plaque volume have been identified as predictors of 30-day major adverse cardiac events (MACE) after SVG intervention (23–25). This may be explained by the fact that the greater the amount of plaque, the greater the likelihood of distal embolization after intervention, leading to myocardial infarction.

Patient sex also appears to be a significant predictor of outcomes after SVG intervention. Women had higher 30-day cumulative mortality rates (4.4% vs. 1.9%, $p = 0.02$) compared with men (26). Furthermore, women had a higher incidence of vascular complications (12% vs. 7.3%, $p = 0.006$) and post-procedural acute renal failure (8.1% vs. 4%, $p = 0.02$).

In a 172-patient study of SVG intervention with drug-eluting stents (DES), chronic renal insufficiency (serum creatinine ≥1.5 mg/dl) was the only significant predictor of 1-year MACE (hazard ratio [HR]: 2.2, 95% CI: 1.1 to 4.3, $p = 0.03$) (27). A trend was also present toward higher rates of target vessel revascularization in the renal insufficiency group (21.8% vs. 10.3%, HR: 2.42, 95% CI: 0.94 to 6.24, $p = 0.059$). Similar results were observed with bare-metal stents (BMS). Overall mortality rates were significantly higher in patients with renal insufficiency ($p < 0.001$) (28).

Table 1. Saphenous Vein Graft Occlusion Rates From Selected Studies

Study/First Author (Ref. #)	1 Year	5 Years	10 Years
PRAGUE-4 (1)	41 (per patient on-pump)	NA	NA
	51 (per patient off-pump)	NA	NA
PREVENT IV (2)	41.7 (per patient)	NA	NA
	26.6 (per SVG)	NA	NA
Fitzgibbon et al. (3)	19 (per SVG)	25 (per SVG)	40 (per SVG)
RIGOR (4)	31 (per patient)	NA	NA
	19 (per SVG)	NA	NA
Halabi et al. (5)	39.3 (per patient)	NA	NA
Khot et al. (6)	30.1 (SVG)	NA	NA
ROOBY (7)	28.7 (per patient on-pump)	NA	NA
	36.5 (per patient off-pump)	NA	NA
Goldman et al. (8)	20 (per patient)	31 (per patient)	39 (per patient)

Values are %.
NA = not available; PREVENT IV = Project of Ex Vivo Vein Graft Engineering via Transfection; RIGOR = Reduction in Graft Occlusion Rates; ROOBY = Veterans Affairs Randomized On/Off Bypass study.

Decision to Perform SVG Percutaneous Intervention

The decision regarding whether or not to intervene in a diseased SVG should be guided by the patient's symptoms, angiographic evidence of a significant stenosis, and noninvasive evidence of myocardial ischemia in the region subtended by the SVG. Even though the role of intravascular ultrasound or fractional flow reserve (FFR) measurement in assessing the significance of SVG disease has not been well studied, FFR can be performed in an SVG in a similar fashion as in a native coronary vessel. The pressure sensor should be positioned in the distal two-thirds of the native vessel so the entire conduit can be interrogated. Intravenous adenosine should be administered to induce hyperemia and a slow pullback of the pressure wire can be performed to distinguish focal from diffuse disease. Prospective validation of an FFR cutoff value of 0.75 to 0.80 to detect hemodynamically significant SVG stenosis has not been performed. Nonetheless, this cutoff is generally used in clinical practice. Of note, however, SVG disease progresses more rapidly than native coronary artery disease, and the safety of deferring intervention on a diseased SVG with a nonischemic FFR has not been studied.

Adverse clinical events occurring >12 months after initial SVG intervention most frequently resulted from disease progression at untreated intermediate lesions (29). Because SVG disease can progress rapidly, some have advocated prophylactically stenting intermediate SVG lesions as opposed to continuing with medical therapy alone. In the small (57-patient) randomized VELETI (Treatment of Moderate Vein Graft Lesions With Paclitaxel Drug-Eluting Stents) trial, the 1- and 3-year MACE rates were significantly lower in patients in whom moderate (30% to 60%) SVG stenoses were treated with paclitaxel-eluting stents compared with patients who received medical treatment (3% vs. 19%, $p = 0.09$ at 1 year, and 3% vs. 26%, $p = 0.02$ at 3 years), thus supporting a strategy of plaque sealing with DES in moderate nonangiographically significant lesions in degenerated SVGs at increased risk for disease progression and adverse clinical events (30,31). However, this trial was an imaging study that was not powered for clinical endpoints. The 450-patient VELETI II (Sealing Moderate Coronary Saphenous Vein Graft Lesions With Paclitaxel-Eluting Stents) trial (NCT01223443) is currently randomizing patients with intermediate SVG lesions to either SVG intervention with paclitaxel-eluting stents versus medical therapy alone and has a primary clinical rather than angiographic endpoint.

Treatment of Occluded SVGs

In a study of 34 patients with chronic total SVG occlusion for which percutaneous revascularization was attempted, successful recanalization with stent implantation was low (68%) (32). At a median follow-up of 18 months, the rates of in-stent restenosis and target vessel revascularization were unacceptably high (68% and 61%, respectively) in patients who underwent successful stenting despite a high use of DES (95%). Given the poor short- and long-term outcomes of percutaneous revascularization in chronic total occlusion of SVGs, percutaneous revascularization should rarely be considered except for acute occlusion in the setting of myocardial infarction. Instead, attempts to recanalize the native coronary artery are preferred if feasible.

Antithrombin and Antiplatelet Therapy

The preferred parenteral antithrombotic therapy during SVG intervention has not been studied in a dedicated, prospective clinical trial. Several studies demonstrated that the role of glycoprotein IIb/IIIa antagonists in SVG intervention is limited given their failure to demonstrate a reduction in periprocedural myocardial infarction (33–35). However, 1 post hoc analysis demonstrated a trend toward improved procedural success when glycoprotein IIb/IIIa antagonists were used in conjunction with filter-based embolic protection ($p = 0.058$) but the MACE was not different at 30 days (36). In a single center, retrospective observational study, bivalirudin was associated with a significant reduction in major CK-MB elevation and a trend toward lower in-hospital non–Q-wave myocardial infarction, repeat revascularization, and vascular complications compared with unfractionated heparin (37). In the subset of 329 patients who underwent SVG intervention in ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy Trial) (38), the rates of ischemic bleeding and net clinical endpoints were similar with bivalirudin monotherapy, bivalirudin plus a glycoprotein IIb/IIIa antagonist, and heparin plus a glycoprotein IIb/IIIa antagonist. Minor bleeding complications were lower with bivalirudin alone compared with heparin plus a glycoprotein IIb/IIIa antagonist (26% vs. 38%, $p = 0.05$). Thus, bivalirudin may offer a safety advantage over other antithrombotic regimens, with equal or greater suppression of adverse ischemic events, although this conclusion is not definitive in the absence of an adequately powered randomized trial.

Stent Type Selection

Bare-metal stents. The SAVED (Saphenous Vein de Novo) trial reported that compared with balloon angioplasty, BMS were associated with higher procedural success (92% vs. 69%, $p < 0.001$), a trend toward a reduction in angiographic restenosis (36% vs. 47%, $p = 0.11$), and lower MACE through 240 days (26% vs. 38%, $p = 0.04$) (39). Since the SAVED report, the overwhelming majority of SVG intervention has been performed with stents, and subsequent

randomized trials have compared BMS with covered stents or DES (Table 2).

Covered stents. Stents covered with a mesh, most commonly polytetrafluorethylene (PTFE), have a theoretical advantage over conventional stents because they may "trap" friable atheroemboli and prevent distal embolization and serve as a smooth-muscle cell barrier and therefore decrease restenosis. However, 3 prospective randomized trials failed to demonstrate benefit with covered stents. SYMBIOT III (A Prospective, Randomized Trial of a Self-Expanding PTFE Stent Graft During SVG Intervention–Late Results) (40) compared the self-expandable PTFE-covered nitinol Symbiot stent (Boston Scientific Corp., Natick, Massachusetts) with BMS. At 8 months, the incidence of MACE between the Symbiot group and BMS was similar (30.6% vs., 26.6%, p = 0.43). A trend toward increased target lesion revascularization with the Symbiot stent was also observed (23.5% vs. 15.6%, p = 0.055). The RECOVERS (Randomized Evaluation of Polytetrafluoroethylene-Covered Stent in Saphenous Vein Grafts) trial (41) randomized 301 patients to treatment with either the PTFE-covered JoStent balloon-expandable stent (Jomed International AB, Helsingborg, Sweden) or BMS. The PTFE group had a higher incidence of 30-day MACE (10.9% vs. 4.1%, p = 0.047), mainly attributed to increased incidence of myocardial infarction (10.3% vs. 3.4%, p = 0.037). At 6 months, the restenosis rate was similar between the 2 groups (24.2% vs. 24.8%, p = 0.237), and the MACE rate was not different (23.1% vs. 15.9%, p = 0.153). The BARRICADE (Barrier Approach to Restenosis: Restrict Intima to Curtail Adverse Events) trial (42) also randomized 243 patients to treatment with either the PTFE-covered JoStent balloon-expandable stent (Jomed) or BMS. At 5-year follow-up, target vessel failure was higher in the JoStent group than in the BMS group (68.3% vs. 51.8%, p = 0.007), emphasizing the dismal long-term prognosis of SVG treatment with either BMS or covered stents.

Two other covered stents have shown promise in the treatment of degenerated SVGs although long-term head-to-head comparison data with BMS are lacking. In the SESAME first in human trial (43), 20 patients who underwent SVG intervention with a novel nanosynthesized, membrane-covered self-expanding superelastic all-metal endoprosthesis stent (SESAME stent, Advanced Bioprosthetic Surfaces, Ltd., San Antonio, Texas) had a 0% rate of MACE at 30 days. At 9 months, the MACE rate was 14% (3 patients underwent repeat intervention: 1 underwent target lesion revascularization for restenosis at the overlap of 2 stents and 2 underwent target vessel revascularization for lesions outside the stented segment). Preliminary results with the MGuard stent (InspireMD, Tel Aviv, Israel), a BMS with a polymeric net attached to its surface, demonstrated favorable early performance in a study that included 16 patients who underwent SVG intervention with no angiographic/procedural complications, and no adverse events up to 30 days (44).

Table 2. Clinical Outcomes of Randomized Stent Trials in Saphenous Vein Grafts

	SYMBIOT III			BARRICADE			RECOVERS			SOS			RRISC			ISAR-CABG		
	PTFE	BMS	p Value	PTFE	BMS	p Value	PTFE	BMS	p Value	PES	BMS	p Value	SES	BMS	p Value	DES	BMS	p Value
MACE																		
1 yr	30.6	26.6	0.43	39.2*	28.0*	0.07	23.1†	15.9†	0.15	37	49	0.20	15.8†	29.7†	0.15	15.4	22.1	0.03
3 yrs	NA	NA	NA	60.2	37.0	0.001	NA	NA	NA	54	77	0.49	58	41	0.13	NA	NA	NA
5 yrs	NA	NA	NA	68.3	51.8	0.007	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Death																		
1 yr	2.6‡	4.7‡	0.29	7.0	5.0	0.51	2.6†	2.8†	0.92	12	5	0.27	2.6†	0†	0.99	5.2	4.7	0.82
3 yrs	NA	NA	NA	18.8	11.2	0.13	NA	NA	NA	24	13	0.19	29	0	<0.001	NA	NA	NA
5 yrs	NA	NA	NA	29.8	22.3	0.20	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MI																		
1 yr	9.2	10.9	0.61	14.2	11.3	0.53	14.1†	5.5†	0.02	15	31	0.10	2.6†	0†	0.99	4.2	6.0	0.27
3 yrs	NA	NA	NA	21.0	14.1	0.21	NA	NA	NA	17	46	0.01	18	5	0.15	NA	NA	NA
5 yrs	NA	NA	NA	26.2	17.4	0.16	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
TLR																		
1 yr	23.5	15.6	0.06	28.2	21.1	0.46	9.6†	8.3†	0.84	5	28	0.003	5.3†	21.6†	0.05	7.2	13.1	0.02
3 yrs	NA	NA	NA	37.4	21.8	0.02	NA	NA	NA	10	41	0.004	24	30	0.55	NA	NA	NA
5 yrs	NA	NA	NA	43.9	29.6	0.04	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

*Target vessel failure (composite of all-cause death, MI, or clinically driven target vessel revascularization). †6 months. ‡Cardiac death.

BARRICADE = Barrier Approach to Restenosis: Restrict Intima to Curtail Adverse Events study; BMS = bare-metal stent(s); DES = drug-eluting stent(s); ISAR-CABG = Prospective, Randomized Trial of Drug-Eluting Stents Versus Bare Metal Stents for the Reduction of Restenosis in Bypass Grafts; MACE = major adverse cardiac event(s); MI = myocardial infarction; NA = not available; PTFE = polytetrafluorethylene; RECOVERS = Randomized Evaluation of Polytetrafluoroethylene-Covered Stent in Saphenous Vein Grafts; RRISC = Reduction of Restenosis in Saphenous Vein Grafts With Cypher Sirolimus-Eluting Stent; SOS = Stenting of Saphenous Vein Grafts; SYMBIOT III = A Prospective, Randomized Trial of a Self-Expanding PTFE Stent Graft During SVG Intervention–Late Results; TLR = target lesion revascularization.

Drug-eluting stents. The RRISC (Reduction of Restenosis in Saphenous Vein Grafts With Cypher Sirolimus-Eluting Stent) trial (21), which included 75 patients, reported that sirolimus-eluting stents (Cordis, Warren, New Jersey) reduced late loss, the binary restenosis rate, and target lesion and vessel revascularization compared with BMS at 6-month follow-up. However, the DELAYED RRISC (Death and Events at Long-Term Follow-Up Analysis: Extended Duration of the Reduction of Restenosis in Saphenous Vein Grafts With Cypher Stent) study (45), which was a post hoc analysis of RRISC trial at 3 years, reported similar rates of target vessel revascularization. Although statistically underpowered for clinical outcomes, significantly higher all-cause mortality at 3 years was reported with sirolimus-eluting stents compared with BMS. The SOS (Stenting of Saphenous Vein Grafts) trial (22), which included 80 patients randomized to either paclitaxel-eluting stents (Taxus, Boston Scientific Corp., Maple Grove, Minnesota) or BMS, demonstrated a significant reduction in MACE driven by lower target lesion revascularization rates with paclitaxel-eluting stents without increased death or myocardial infarction through nearly 3-year follow-up (46). The primary endpoint of these 2 small trials was angiographic restenosis, and the results showed similar angiographic restenosis rates at 6- (RRISC) and 12-month (SOS) follow-up but higher mortality at long-term follow-up in the RRISC trial. ISAR-CABG (Prospective, Randomized Trial of Drug-Eluting Stents Versus Bare Metal Stents for the Reduction of Restenosis in Bypass Grafts), which randomized 610 patients with diseased SVGs to DES and BMS, the primary endpoint of MACE at 1-year post index PCI was lower in the DES group than in the BMS group (15.4% vs. 22.1%, $p = 0.03$) and was mainly driven by a nearly 50% relative reduction in the risk of target lesion revascularization (7.2% vs. 13.1%, $p = 0.02$), with nonsignificant differences in mortality (47).

A meta-analysis comparing DES with BMS in SVG intervention (which also included nonrandomized studies) has also reported lower mortality, MACE, target lesion revascularization, and target vessel revascularization without increased risk of myocardial infarction or stent thrombosis (48). Eight other meta-analyses comparing DES with BMS in SVG intervention have demonstrated consistent results of improved efficacy with DES and no significant safety hazard (48–55).

Two ongoing trials are comparing DES with BMS in SVGs: 1) BASKETSAVAGE (Basel Stent Kosten Effektivitäts Trial–Saphenous Venous Graft Angioplasty Using Glycoprotein IIb/IIIa Receptor Inhibitors and Drug-Eluting Stents) (NCT00595647); and 2) the Veterans' Affairs Cooperative Study #571, DIVA (Drug Eluting Stents Versus Bare-Metal Stents in Saphenous Vein Graft Angioplasty) trials (NCT01121224).

Choice of DES in SVG. In a multicenter analysis of 172 real-world patients comparing first-generation DES, SVG intervention with sirolimus- and paclitaxel-eluting stents resulted in nonsignificant differences in survival (HR: 1.28, 95% CI: 0.39 to 4.25, $p = 0.69$) and target vessel revascularization (HR: 2.54, 95% CI: 0.84 to 7.72, $p = 0.09$) (56). Outcomes comparing second-generation stents in SVG intervention are not yet available; the SOS-Xience V (Prospective Evaluation of the Xience V Everolimus-Eluting Stent in Saphenous Vein Graft Atherosclerosis: The Stenting of Saphenous Vein Grafts Xience V Angiographic Study) (NCT00911976) will provide initial results with the everolimus-eluting stent in 2011.

SVG Intervention Technique

Pre-dilation versus direct stenting. As opposed to pre-dilation with balloon angioplasty, direct stenting has the potential benefit of trapping debris and decreasing distal embolization that may occur from repeated balloon inflations. In a registry of unselected patients who underwent SVG intervention, direct stenting was associated with a nearly 50% reduction in CK-MB elevations greater than 4× normal (13.6% vs. 23%, $p < 0.12$), overall lower maximum CK-MB release (9.5 vs. 19.6, $p < 0.001$), and fewer non–Q-wave myocardial infarctions (10.7% vs. 18.4%, $p < 0.02$) (57). A prospective randomized trial is needed to determine whether pre-dilation versus direct stenting is effective in reducing distal embolization.

Small stent diameter. In a study of 209 SVG lesions treated with DES, Hong et al. (58) examined the outcomes of 3 groups according to the ratio of the stent diameter to the average intravascular ultrasound reference lumen diameter (group I: <0.89, group II: 0.9 to 1.0, and group III: >1.0). Plaque intrusion volume as defined as the amount of tissue extrusion through the stent struts after SVG intervention was smallest in group I (group I: 0.25 ± 0.68 mm^3, group II: 0.40 ± 0.68 mm^3, and group III: 0.75 ± 1.34 mm^3; $p = 0.007$). The incidence of CK-MB elevation >3× normal was 6% in group I, 9% in group II, and 19% in group III ($p = 0.03$) without an increase in clinical events at 1 year. The incidence of 1-year target lesion revascularization (group I: 13%, group II: 9%, and group III: 15%; $p = 0.5$) and target vessel revascularization (group I: 13%, group II: 13%, and group III: 15%; $p = 0.9$) was similar. While the concept of undersized stent selection to reduce distal embolization is intriguing, such a method must be balanced by theoretically possibly higher rates of restenosis and stent thrombosis. Therefore, a prospective, randomized study is required to confirm the theoretical benefits of this technique.

Embolic protection devices. Distal embolization is common in SVG interventions. Particulate debris has been retrieved from as many as 91% of distal embolic protection devices (59). Despite the class I American College of Cardiology/

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