Long-Term Follow-Up of a High Risk Cohort After Stent Implantation in Saphenous Vein Grafts

AARON FRIMERMAN, MD, ELDAD RECHAVIA, MD, NEAL EIGLER, MD, FACC,
MONICA R. PAYTON, BS, PAC, RAJ MAKKAR, MD, FRANK LITVACK, MD, FACC

Los Angeles, California

Objectives. We sought to provide short- and long-term clinical outcomes of a high risk cohort treated with stents in saphenous vein grafts (SVGs).

Background. Data on the long-term outcome of SVG stenting in high risk patients are limited.

Methods. Johnson & Johnson stents were implanted in the SVGs of 186 patients (302 stents, 244 lesions). Ninety percent of patients presented with myocardial infarction (MI) or unstable angina (mean ±SD ejection fraction [EF] 44 ± 11%, patient age 71 ± 9 years, graft age 9.4 ± 5 years). Using a risk score classification, 155 patients (83%) were defined as high risk for repeat surgical repair or angioplasty.

Results. The procedural success rate was 97.3%, with 2.7% major complications (death, Q wave MI, coronary artery bypass graft surgery [CABG]). Clinical follow-up was obtained in 177 patients (mean 19.1 ± 13.5 months, range 7 to 59). Event rates were 10% for death; 9% for MI; 11% for repeat CABG; and 15% for repeat angioplasty (total events 45%). Kaplan-Meier estimated survival and event-free survival at 4 years were 0.79 ± 0.06 and

0.29 ± 0.07, respectively. Predictors of death were congestive heart failure (p < 0.01) and EF <44% (p < 0.05). Predictors of combined events of death, MI and CABG were low EF (p < 0.01) and high SVG age (>10 years, p < 0.01). There were 66 revascularization procedures (35% of patients), 24% of which were in nontarget lesions. Fifty-three percent of the cardiac events occurred during the first year of follow-up. Of the 160 survivors, 36% were free of angina, 49% were in Canadian Cardiovascular Society functional class I or II, and 15% were in class III or IV. Sixty-nine percent of patients were in class I or II according to the Specific Activity Scale, and 31% of patients were in class III or IV.

Conclusions. Balloon-expandable stent implantation in the SVGs of high risk patients is associated with a low early complication rate. Expected survival rates are good, as are the anginal and functional classifications, but there is a high rate of recurrent events and need for repeat revascularization. Vein graft stenting is an acceptable palliative option in many high risk patients.

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Patients undergoing coronary artery bypass graft surgery (CABG) often require repeat revascularization over time. Revascularization rates of 19% at 10 years and 30% at 12 years have been reported (1). These events are usually the result of saphenous vein graft (SVG) failure, which has been reported to be as high as 75% at 10 years (1–3). As several million people worldwide have undergone CABG over the past two decades, a large cohort of patients with previous CABG now exists, establishing a significant public health and economic problem.

Treatment of patients previously operated on by either transcatheter or surgical revascularization is frequently problematic. Repeat CABG has a periprocedural death and myo-

cardial infarction (MI) rate of 2% to 5% and 2% to 8%, respectively. Five-year event-free and angina-free survival rates have been reported as 64% and 50%, respectively (2,4,5). Some patients are not well suited for reoperation because of small or diffusely diseased target vessels, poor left ventricular function or a lack of available conduit or comorbid conditions. Percutaneous transluminal coronary angioplasty (PTCA) may be performed with relatively high angiographic success rates, although intraprocedural complications including distal embolization, no-reflow and MI are substantially higher than those with native coronary angioplasty. The 6-month restenosis rates have been unacceptably high—>50% in several studies (6,7).

Deployment of stents in SVG lesions has become the standard of care in many centers in the United States and abroad. Several studies have reported high procedural success rates and acceptable major complication rates. Although no randomized trial data are yet available, the 6-month clinical outcomes and angiographic restenosis rates have been viewed as lower than those expected with balloon angioplasty alone (8–12). Data on the widely used balloon expandable Johnson & Johnson stent are limited by the exclusion of some high risk conditions including MI, diffuse graft disease, thrombus or slow flow and ostial or distal location. Follow-up data are also

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Abbreviations and Acronyms

CABG	=	coronary artery bypass graft surgery
CI	=	confidence interval
CCS	=	Canadian Cardiovascular Society
ECG	=	electrocardiogram, electrocardiographic
EF	=	ejection fraction
MI	=	myocardial infarction
PTCA	=	percutaneous transluminal coronary angioplasty
SAS	=	Specific Activity Scale
SVG	=	saphenous vein graft
TIMI	=	Thrombolysis in Myocardial Infarction

Table 1. Clinical Characteristics of 186 Patients

Age (yr)	71 ± 9
Male gender	156 (84%)
Diabetes mellitus	46 (25%)
Hypertension	98 (53%)
Cholesterol >200 mg/dl	98 (53%)
History of smoking at any time	84 (45%)
History of CHF	46 (25%)
Unstable angina	159 (85%)
Recent MI (<1 mo)	38 (20%)
Previous MI (>1 mo)	84 (45%)
Previous multiple CABG	56 (30%)
Previous PTCA at intervention site	31 (17%)
LVEF (%)	44 ± 11*
High surgical risk	97 (52%)
Procedural risk	
Low	5 (3%)
Moderate	91 (49%)
High	75 (40%)
Very high	15 (8%)

*Data are available for 88% of patients. Data presented are mean value ± SD or number (%) of patients. CABG = coronary artery bypass graft surgery; CHF = congestive heart failure; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

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limited in duration (8,10,12). However, the Johnson & Johnson stent is commonly used for the treatment of these exact clinical problems, although little is known about the long-term outcomes in such patients.

We present our experience with balloon expandable stents in the vein grafts of consecutive patients with a variety of high risk clinical and angiographic characteristics. We provide long-term clinical follow-up results as well as comprehensive statistical analysis with respect to the correlates of adverse long-term events.

Methods

Patients. Between April 1991 and October 1995, 186 patients had balloon expandable stents placed in vein grafts at Cedars-Sinai Medical Center. Patients had clinical evidence of myocardial ischemia related to the treated vessel, with the stenotic lesion >50% in diameter in any location within the vein graft. Patients with contraindications to antiplatelet or anticoagulation therapy or vein graft diameter <3 mm were excluded (clinical characteristics of patient cohort are summarized in Table 1). Patient therapy was selected at the discretion of the physician after written informed consent by the patient. The investigational vein graft stenting protocol was approved by the Institutional Review Board. The patients who received stents do not represent all patients with SVG disease treated during the study period.

All the patients had multivessel coronary artery disease or left main coronary stenosis. One hundred thirteen patients (61%) were >70 years and 32 (17%) were >80 years of age. One hundred twenty two patients (66%) had an history of MI, including 38 (20%) within 30 days of angioplasty. One hundred fifty nine patients (85%) presented with rest angina (Braunwald class II or III [13]) and 167 (90%) presented with an unstable coronary syndrome (either unstable angina [Braunwald classes I to III] or acute MI).

Stent implantation. All the lesions were predilated by conventional PTCA, and stents were deployed by balloon inflation. Ninety percent of stents were further expanded with large or high pressure balloons at the operator's discretion. In 30 patients (16%), at the operator's discretion, the final stent apposition in the artery was evaluated by intravascular ultrasound imaging. Mean maximal balloon size and pressure were 3.8 ± 0.6 mm and 13.4 ± 4 atm, respectively. The balloon/artery ratio was 1.18 ± 0.23:1.

Medical regimen. All patients were pretreated with aspirin (325 mg/day); 75 patients (40%) received premedication with dipyridamole (75 mg three times a day). Heparin was given during the procedure and titrated to maintain an activated clotting time >300 s. All patients continued to receive aspirin indefinitely. Sixty six percent of the patients received warfarin after the procedure, as previously recommended (14). The more recently treated patients (18%) received ticlopidine (250 mg twice a day for 2 to 4 weeks) without additional warfarin, and 16% of patients received both warfarin and ticlopidine.

Follow-up. Within 18 h of the procedure, serum creatine kinase levels were measured and a 12-lead electrocardiogram (ECG) was obtained. Infarction was diagnosed if the total CK level was >200 IU with positive (>5%) MB isoform. Long-term clinical follow-up was obtained using two standard questionnaires. One was sent to the patient's referring physician and included detailed medical information of clinical events (death, MI or any revascularization procedure), symptom classification (Canadian Cardiovascular Society [CCS] classification) and functional/activity class (Specific Activity Scale [SAS]) (15). Another questionnaire was sent directly to the patients and included the previously mentioned events as well as self-assessment of symptom and activity level, by CCS and SAS classifications. If forms were not returned, patients were interviewed by telephone. In case of discordance between the patient's and the physician's functional assessments, the patient's assessment was considered to be more reliable. Follow-up angiography was performed for clinical indications

only. Restenosis was defined as >50% diameter narrowing at the stent site. Available medical records and angiographic data were analyzed to validate the information and to determine target vessel and target site failure.

Angiographic analysis. The cineangiograms of all the patients were reviewed by a single experienced observer (A.F.). Qualitative analysis of the angiographic data included assessment of the Thrombolysis In Myocardial Infarction trial (TIMI) flow grade, lesion type by morphology (modified American Heart Association/American College of Cardiology classes A, B1, B2 and C as defined by Ellis et al. [16]) and the presence of thrombus. Quantitative angiographic measurements included 1) reference vessel diameter; 2) minimal lumen diameter and percent stenosis before and at the end of the procedure; 3) acute gain; 4) lesion length; and 5) recipient artery diameter. End-diastolic frames with the most severe narrowing in the projection that best demonstrated the target lesion were selected throughout the study. The measurements were performed using an automated computer-assisted edge-detection algorithm with magnification calibrated from the guiding catheter diameter (Imagecomm Systems), as previously reported (17).

Statistical analysis. Data are expressed as mean value ± SD. Survival rates were estimated using the Kaplan-Meier method for freedom from: 1) death; 2) death and Q wave MI; 3) death, MI and CABG; and 4) death, MI, CABG and catheter-based revascularization. Predictors of time to event were determined by the Cox proportional hazards model. Fifty clinical, anatomic and technical variables were analyzed to determine their importance as predictors of time to event. These variables included age, gender, diabetes mellitus, hypertension, hyperlipidemia, smoking, family history, previous MI, recent MI, unstable angina, ejection fraction (EF), heart failure, previous multiple CABGs, vein graft age, restenosis lesion, bailout procedure, suboptimal result, stent number, balloon size and maximal pressure, stented graft to different coronary arteries (left anterior descending, left circumflex, right artery), stented site in graft (proximal, mid, distal), warfarin therapy, ticlopidine therapy, lesion type (A, B1, B2, C), thrombus in graft, lesion length, multiple lesion treated, stent overlap, preprocedure and postprocedure TIMI flow grade (0–1,2,3), reference vein graft diameter, recipient artery diameter, preprocedure and postprocedure minimal lumen diameters and percent stenosis, acute lumen gain and early complications.

The Mann-Whitney U test was used to compare nonparametric variables. A p value <0.05 was considered significant. All analyses were performed using BMDP Statistical Software (University of California Press, Berkeley).

Definitions. Patients were scored for high surgical risk or high procedural risk according to previously published criteria:

High surgical risk. These patients had one or more of the following variables: severe or multiple comorbid condition (e.g., renal insufficiency, pulmonary disease); poor left ventricular function (EF <40%); more than one previous CABG (18).

High procedural risk. Patients were graded by predictors of major angioplasty complications: unstable angina, recent MI, age >70 years and type C lesion. Risk scores were classified into four classes: low (none of the previously mentioned risk factors present), moderate (one or two risk factors present), high (three risk factors) and very high (more than three risk factors) (19).

Procedural success. These patients had successful stent deployment with <50% residual stenosis and without major in-hospital complications, including death, Q wave MI, surgical or catheter-based revascularization and subacute thrombosis.

Minor complications. This group included postprocedure thrombus or embolus; Nonocclusive coronary dissection with good flow; stent loss or stent migration without chest pain or ECG changes; noncoronary dissection, fistula, pseudoaneurysm and surgical repair; and significant bleeding or hematoma, stroke, fever and repeat angiogram within 48 h after stent deployment without significant narrowing in the stent site.

Results

Demographics. The mean target vein graft age was 9.4 ± 4.5 years, and 89% of the grafts were ≥4 years old. Internal mammary artery grafts were used in 80 patients (43%). Sixty-nine patients (37%) had a left ventricular EF <45%, and 46 patients (25%) had history of congestive heart failure (New York Heart Association class III or IV). Fifty-six patients (30%) had previous repeat CABG; 14 (7.5%) had severe or multiple comorbid conditions (e.g., renal insufficiency, pulmonary disease); and 97 (52%) were defined as high surgical risk and 90 (48%) as high or very high procedural risk. One hundred fifty-five patients (83%) were defined as either high surgical or procedural risk. Sixty-four patients (34%) underwent catheter-based angioplasty before the index stenting (72 procedures—72% balloon angioplasty, 18% stent placement, 8% laser, 1% directional atherectomy), and 43% of these procedures were performed at the index stent site. Of the 244 total lesions, 17% were restenotic.

Immediate results and angiographic findings. Table 2 provides the location of the stents and qualitative angiographic variables. Of 302 stents placed in 244 lesions, 292 were Johnson & Johnson 15-mm long, articulated coronary stents and 10 were Johnson & Johnson 10-mm long biliary stents. In 48 patients (26%), multiple lesions were treated in a single graft, and in 8 patients, stents were placed in two separate vein grafts in the same procedure. Of the 186 patients, 109 (59%) received a single stent and 77 (41%) received multiple stents (2 stents in 47 patients, 3 stents in 22 patients, 4 stents in 7 patients and 5 stents in 1 patient). Sixty-five percent of the treated lesions were type B2 (40%) or C (25%). The quantitative angiographic data of these patients are summarized in Table 3.

Complications. Procedural success was achieved in 181 patients (97.3%). In five patients (2.7%), the procedure was unsuccessful because of major complications (Table 4). Two

Table 2. Characteristics of 244 Lesions and Distribution of 302 Stents

Graft age (yr)	9.4 ± 4.5
Stent distribution in SVG to	
LAD	129 (43%)
LCx/OM	90 (30%)
RCA	83 (27%)
Treated lesion location in SVG	
Ostial	57 (19%)
Proximal	66 (22%)
Body	133 (44%)
Distal	46 (15%)
Patients with multiple stents	77 (41%)
Lesion characteristics	
Eccentric	37%
Calcified	2.4%
Diffuse	22.5%
Thrombus	11.5%
Lesion type	
A	20%
B1	15%
B2	40%
C	25%

Data presented are mean value ± SD; number (%) of stents, lesions or patients; or percent of lesions. LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; OM = obtuse marginal; RCA = right coronary artery; SVG = saphenous vein graft.

deaths occurred after subacute thrombosis. Both patients had type C lesions that were treated by multiple and overlapping stents deployed at maximal balloon pressure of 10 to 12 atm, and they were treated with warfarin but not ticlopidine. Two patients had Q wave MI. One patient with diffuse coronary and vein graft disease had persistence rest angina after stent placement. Repeat CABG was performed during his hospital

Table 3. Angiographic Data Before and After Stenting

Reference vessel diameter (mm)	3.3 ± 0.6
Lesion length (mm)	9.9 ± 6.2
MLD (mm)	
Before stenting	0.7 ± 0.4
After stenting	2.9 ± 0.5
% diameter stenosis	
Before stenting	76 ± 11
After stenting	10 ± 12
Immediate gain (mm)	2.4 ± 0.7
TIMI flow grade	
Before stenting	
0–1	12%
2	52%
3	36%
After stenting	
0–1	0
2	10%
3	90%
Maximal balloon size (mm)	3.8 ± 0.6
Maximal balloon pressure (atm)	13.4 ± 4

Data presented are mean value ± SD or percent of patients. MLD = minimal lumen diameter; TIMI = Thrombolysis in Myocardial Infarction.

Table 4. In-Hospital Outcome of 186 Patients

Major complication	
Death	2 (1.1%)
Q wave MI	2 (1.1%)
CABG	1 (0.5%)
Total major complications	5 (2.7%)
Other complications	
Non–Q wave MI	3 (1.6%)
Thrombosis (acute/subacute)	3 (1.6%)
Nonocclusive vein graft dissection	9 (4.8%)
Stroke	1 (0.5%)
Bleeding*	15 (8%)
Peripheral vascular complications†	9 (4.8%)
Total minor complications	42 (22.6%)

*Significant reduction in hemoglobin (>3 g/dl) or need for transfusion. †Arterovenous fistula, pseudoaneurysm or surgical vascular repair. Data presented are number (%) of patients. Abbreviations as in Table 1.

stay. There were no deaths or emergency CABGs during the procedure. Non Q wave MI occurred in three patients (1.6%).

Late clinical follow-up. Of 181 eligible patients with successful stent placement, clinical follow-up was obtained in 177 (98%) at an average of 19.1 ± 13.5 months (range 7 to 59). The incidence of hierarchic major clinical events (events in descending order of severity: death followed by MI, CABG and catheter-based revascularization) was 45% (Table 5). There were three noncardiac deaths (one suicide, two complications of noncardiac surgery). Of the 14 cardiac deaths, five were sudden (one had an angiographically patent stent shortly before death) and one was due to congestive heart failure. The other deaths were caused by the coronary disease. Rates of nonfatal MI, repeat CABG and catheter-based revascularization were 9% (n = 15), 11% (n = 20) and 15% (n = 27), respectively.

Clinically guided repeat angiography was performed in 73 patients (41%) at 13.5 ± 12 months. Target site restenosis was found in 45 patients (62% of this selected group with a high probability of clinical restenosis or 25% of the total follow-up group). Of the 66 revascularization procedures (26 CABGs, 29

Table 5. Clinical Follow-Up Outcomes of 177 Patients

	Nonhierarchic*	Hierarchic†
Major event		
Death, total	17 (17%)	17 (10%)
Death, cardiovascular	14 (14%)	14 (8%)
Nonfatal MI	17 (17%)	15 (9%)
CABG	26 (26%)	20 (11%)
Catheter-based revascularization	40 (40%)	27 (15%)
Total major cardiac events	96 (97%)	76 (43%)
Total major events	99 (100%)	79 (45%)
Total revascularization procedures	66 (66%)	
Nontarget lesion revascularization	16 (16%)	
No major event		98 (55%)

*Number of events of each type (proportion using total of all events as denominator). †Number of events in descending order of severity and the percentage of patients with event. Abbreviations as in Table 1.

Table 6. Follow-Up Angina Pectoris and Activity Classes in Surviving Patients

	Event Free (n = 100)	Clinical Events (n = 60)*	Total Survivors (n = 160)
Angina pectoris†			
No angina	39 (39%)	19 (32%)	58 (36%)
CCS class I	18 (18%)	23 (38%)	41 (26%)
CCS class II	31 (31%)	6 (10%)	37 (23%)
CCS class III	10 (10%)	10 (17%)	20 (12.5%)
CCS class IV	2 (2%)	2 (3%)	4 (2.5%)
CCS median class	I	I	I
Activity class			
SAS I	48 (48%)	16 (27%)	64 (40%)
SAS II	19 (19%)	27 (45%)	46 (29%)
SAS III	27 (27%)	7 (12%)	34 (21%)
SAS IV	6 (6%)	10 (16%)	16 (10%)
SAS median class	II	II	II

*Ninety-three percent of patients underwent a repeat revascularization procedure. †Data presented are number (%) of patients, unless otherwise indicated. CCS = Canadian Cardiovascular Society; SAS = Specific Activity Scale (I = best; IV = worst).

balloon angioplasties and 11 stent placements), 16 (24%) were not associated with the index stent location and were performed as the result of disease progression elsewhere (10 in nontarget vessel and 6 in nontarget site in same vessel).

Of the 160 survivors, 58 (36%) were free of angina, 78 (49%) were in CCS class I or II and 24 (15%) were in CCS class III or IV. The SAS activity level was class I or II in 110 (69%) and class III or IV in 50 (31%) patients. There were no significant differences in angina (p = 0.28) or activity (p = 0.33) classes between the event-free patients and the patients with clinical events (after repeat revascularization in 93%)

(Table 6). There was 5% discordance between the patient's and the physician's functional assessment.

Survival and event-free survival. The mean (±SD) Kaplan-Meier estimated survival at 4 years was 0.79 ± 0.06 (95% confidence interval [CI] 67% to 91%). Freedom from cardiac death at 4 years was 0.82 ± 0.06 (95% CI 70% to 94%). Freedom from MI at 4 years was 0.71 ± 0.06 (95% CI 59% to 83%), and event-free survival at 4 years (from MI, CABG and catheter-based revascularization) was 0.29 ± 0.08 (95% CI 14% to 46%) (Figure 1).

Using the Cox proportional hazards model, predictors of death (total) were congestive heart failure (p < 0.01) and low left ventricular EF (<44%) (p < 0.05). Predictors of the combined events of death, MI and CABG were low left ventricular EF (p < 0.01) and high vein graft age (>10 years) (p < 0.01). There were no other significant clinical, anatomic or technical predictors of adverse clinical events. Fifty-three percent of the cardiac events occurred during the first year of follow-up and 36% occurred during the first 6 months.

Ostial versus graft body stenting. Forty patients (22%) had stents placed only at the graft's ostium and 99 (53%) had stents placed only in the body of the graft. Ostial and graft body ages were 8.7 ± 4.5 and 9.8 ± 4 years, respectively (p = 0.2). In the ostial group, there were no major early complications, but in the graft body group there were 4 (4%) major complications (1 death, 2 Q wave MIs and 1 CABG; p = 0.04). The ostial group had a 55% long-term event rate, with 5% nontarget site revascularization and 0.27 ± 0.1 Kaplan-Meier estimated event-free survival at 3 years. The graft body group had a 42% long-term event rate (13% nontarget site revascularization), with 0.35 ± 0.08 Kaplan-Meier estimated event-free survival at 3 years (p = 0.06).

Figure 1. Kaplan-Meier survival curves of major cardiac events: death, MI, repeat CABG and repeat catheter-based intervention (INTV).
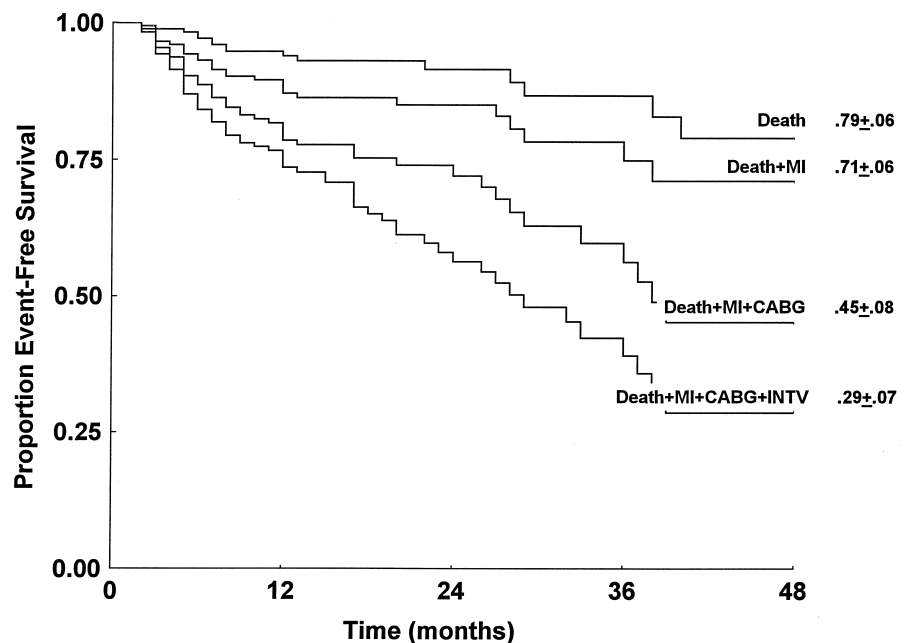
Discussion

This study is different from previous reports of vein graft stenting by virtue of the high risk nature of the patient cohort and their length of clinical follow-up. Previous reports have evaluated the results of Johnson & Johnson stents in SVGs. The multicenter study by Wong et al. (8) included patients with focal stenosis with relatively good flow in vein graft shafts. That study specifically excluded patients with MI, ostial location, distal or diffuse disease and thrombotic lesions. Similarly, Fenton et al. (12) excluded patients with MI and those with tortuous, thrombotic or diminished flow. Piana et al. (10) excluded patients with diffuse disease or thrombotic vein graft lesions. Several previous studies with balloon angioplasty have established that these clinical and angiographic characteristics are associated with higher early procedural risks and less favorable intermediate- and long-term outcomes (19–22). Our cohort had a relatively advanced age (mean 71 ± 9 years) and reduced left ventricular function (left ventricular EF 44 ± 11%), as well as complex lesion morphology (65% had type B2 and C lesions) and a high frequency of presentation with acute coronary syndromes (90%). Eighty-three percent of patients were defined as high risk for either surgical repair or angioplasty by well established risk score classifications (18,19). The length of clinical follow-up in this cohort allows for statistical estimation of 4-year outcomes.

Immediate results. This study corroborates previous reports that stent placement may be undertaken with an expectation of high procedural success and low early complication rates, even in patients with complications. The procedural success rate in our study was 97.3%, and the major complication rate was 2.7%. These data are in line with those of previous reports of balloon or self-expanding stents (8,11,14,17,23). The 1.1% in-hospital mortality rate in this study is lower than that previously reported for second bypass surgery, where mortality rates vary from 2% to 5% (4). Three patients (1.6%) in the cohort had subacute stent thrombosis within the first 7 days of the procedure. Each of these patients had a high grade lesion and was treated with more than one stent. Each of them received anticoagulant therapy with warfarin but no ticlopidine. The lack of major early complications in the SVG ostium-only stent group compared with the 4% complication rate in the SVG body-only stent group may be explained by the relative paucity of friable material in the ostium. This cohort had a high proportion of patients with ostium-only stenting (22%). This may in part explain the low incidence of distal embolization. We report a 13% incidence of peripheral vascular or bleeding complications. These complications are likely to be associated with the frequent use of warfarin and may well be mitigated by the current practice of withholding that drug and using ticlopidine in most patients (24).

Long-term results. These data provide interesting insight into long-term outcomes of patients after they have had vein graft stenting. The Kaplan-Meier estimate of 4-year survival of 0.79 ± 0.06 is consistent with that of previous reports for

PTCA and CABG. Repeat CABG has been reported to provide 70% to 90% survival, balloon angioplasty a 78% survival rate at 4 years and the self-expanding Walstent an estimated 83% survival rate at 5 years (4,23,25–27). Fifty clinical, angiographic and technical variables were analyzed to determine predictors of time to death. Of these, only congestive heart failure and low left ventricular EF predicted early death. Vein graft age >10 years was found to be a predictor of combined events (death, MI or CABG), as has been reported in relation to CABG reoperation (1–3). Notwithstanding the relatively good survival data, recurrent events were disturbingly frequent. The Kaplan-Meier estimate of 4-year survival was 0.79 ± 0.06, but the 4-year event-free survival was only 0.29 ± 0.07. Of the total 66 repeat surgical or transcatheter revascularization procedures (approximately two-thirds were transcatheter), 16 (24%) were procedures performed on or associated with lesions not related to the previously stented sites. This corroborates previously reported data (10) that progression of disease is an important contributor to morbidity in these patients. Despite the more favorable early outcome in the ostial-only group versus the body-only group, the long-term estimated event-free survival is worse in the ostial group (0.27 ± 0.1 vs. 0.35 ± 0.08 at 3 years, p = 0.06). There was no significant difference in graft age between the two groups (ostial 8.7 ± 4.5 vs. body 9.8 ± 4 years, p = 0.2), which could account for these differences. These data reflect the problem of maintaining long-term patency of an aorto-ostial lesion treated by either PTCA or a new device. More than one-half of the clinical events occurred within 12 months, indicating a need for close vigilance in these patients during the first year after the procedure. The majority of late interventions were related to disease progression outside the target site. Seventy percent of all nontarget site revascularization procedures were performed 2 years or later after the index stenting. The mean time to revascularization in this group was 23 ± 12 months.

The results with respect to follow-up angina pectoris and activity classes in surviving patients are relatively favorable. Of the 160 survivors, 58 (36%) had no angina and only 24 (15%) were in CCS angina class III or IV. Sixty-nine percent of patients reported an SAS class of I or II, whereas only 31% reported class II or III. There were no significant differences in either CCS (angina) or SAS class in patients who proceeded through their follow-up event-free compared with those who had clinical events, although 93% of the cohort with events underwent repeat revascularization.

Study limitations. These data are based on patients treated at a single center and evaluated retrospectively. The center is a large tertiary care teaching hospital and as such may not be free of selection bias. Because the study was not randomized, conclusions must be based on historic comparisons and contemporary clinical experience. Routine angiographic follow-up was not part of our clinical practice, so insufficient data are available to provide conclusions about the frequency and nature of in-stent restenosis.

Conclusions. The management of patients who have had a previous operation and who present with vein graft disease is

complex and must be individualized. The present study provides several messages for clinicians. First, even in a high risk patient cohort, stent implantation may be performed safely in most patients. Second, such patients undergoing vein graft stenting have an excellent prognosis for survival considering the number of older patients and the frequency of comorbid conditions. Third, vein graft stenting should be considered a palliative procedure that provides a good expectation of relief from disabling angina as well as a good functional activity level, but with a disturbingly high frequency of repeat revascularization procedures. Despite the obvious limitations of vein graft stenting, for many patients it may represent the best available therapeutic option. Other patients, especially those in relatively good physical condition or in whom an internal mammary graft is possible, may be best served by repeat CABG. Finally, there is a major need for improved therapies. The possibilities include but are not limited to complete arterial revascularization during the first bypass operation; aggressive attention to modification of risk factors known to be associated with progression of vein graft disease; effective therapies for the prevention of in-stent restenosis (e.g., drugs, brachytherapy), and the availability of new synthetic or bioprosthetic bypass conduits. Until such time that new therapies become available, the judgment of the clinician and patient, based on an understanding of contemporary outcomes, will be relied on.

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