Long-term clinical outcome of coronary artery stenting or coronary artery bypass grafting in patients with multiple-vessel disease

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Objective: Recent large-scale observational studies have shown better outcomes after coronary artery bypass grafting than after angioplasty or stenting in patients with multiple-vessel disease. The time frames of these studies, however, include periods of varying behavior with respect to patient selection, stent technique and design, and medical therapy. Our objective was to examine long-term outcomes of coronary stenting and coronary artery bypass grafting, including those performed in the contemporary era of aggressive medical therapy.

Methods: We examined in-hospital and long-term follow-up data from consecutive patients with multivessel coronary artery disease who underwent isolated initial revascularization by coronary stenting or coronary artery bypass grafting between 1995 and 2003. Cox proportional hazards modeling with propensity scoring and propensity-based case matching were used to compare long-term survival and correct for baseline differences between the populations.

Results: A total of 6847 patients were studied (stenting 3917, coronary artery bypass grafting 2930). Each patient had 1 to 9 years of follow-up (median 3.5 years). Unadjusted long-term mortalities were similar for coronary artery bypass grafting and stenting (hazard ratio 1.1, 95% confidence interval 0.9–1.2, $P = .21$). Matched comparison of 3488 patients (1856 in each group) with similar likelihoods of undergoing coronary stenting or coronary artery bypass grafting, however, suggested that coronary artery bypass grafting provided better long-term survival (hazard ratio 0.7, 95% confidence interval 0.6–0.9; $P = .004$).

Conclusion: During a 9-year period, in physician-selected patients with favorable demographic characteristics for both revascularization procedures, coronary artery bypass grafting was associated with better long-term survival than stent-assisted angioplasty.

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Recent large-scale observational studies have reported better outcomes with coronary artery bypass grafting (CABG) than with coronary stenting in patients with multivessel coronary artery disease (CAD).[1,2] The reported adjusted hazard ratios [HRs] for the long-term risk of death in these two studies ranged from 0.43 to 0.76 for patients who underwent CABG relative to patients who underwent percutaneous coronary intervention (PCI). This divergence in findings from those of randomized trials calls into question the generalizability of the randomized trial results to unselected populations and suggests that the selection criteria used in these trials are an important determinant of PCI performance. The periods encompassed by each of these studies, however, predate both thorough understanding of appropriate patient selection and numerous improvements in stent design and in antithrombotic and antiatherosclerotic medical therapy.

To examine the impact on survival of first-time revascularization with PCI with coronary stenting instead of elective CABG, we examined long-term mortality among

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Abbreviations and Acronyms
BARI       = Bypass Angioplasty Revascularization
             Investigation
CABG       = coronary artery bypass grafting
CAD        = coronary artery disease
CI         = confidence interval
HR         = hazard ratio
MI         = myocardial infarction
OR         = odds ratio
PCI        = percutaneous coronary intervention
THIRDBase  = Texas Heart Institute Research Database
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patients with multivessel CAD enrolled in the Texas Heart Institute Research Database (THIRDBase). THIRDBase is a comprehensive, longitudinal clinical registry of outcomes for more than 150,000 patients treated for cardiovascular disease at the Texas Heart Institute at St Luke's Episcopal Hospital. It includes a wide range of data for all patients admitted to our institution with a diagnosis of cardiovascular disease. Standard methods of survival comparison (Cox proportional hazards modeling and propensity-weighted scoring) and a more stringent statistical method (propensity-based case matching) were used to make our results comparable with those of previous studies.

Materials and Methods
Study Population
All patients included in the study were residents of Texas with multivessel CAD who underwent an isolated first revascularization procedure by either coronary stenting or CABG at the Texas Heart Institute between January 1995 and December 2003. Patients were excluded if they had previous CABG, also required a valve operation, were undergoing primary PCI for an acute myocardial infarction [MI], had left main CAD, or had a limited life expectancy at the time of revascularization because of malignancy. Baseline data on patient characteristics were obtained prospectively for both groups. Coronary anatomic and procedural characteristics, in-hospital outcomes, and vital status as of December 31, 2004, were collected for all patients. Survivorship was determined from the United States Department of Vital Statistics Database, and follow-up was complete for 100% of patients. Our long-term survival analyses included both short- and long-term survival data (perioperative and long-term survivals were not considered separately).

Written, informed consent was obtained at hospital admission from all patients registered in THIRDBase. All data we analyzed were stripped of personal identifiers. We obtained approval for this project from the Committee for the Protection of Human Subjects, the institutional review board for the University of Texas Health Science Center at Houston, on November 11, 2004 (HSC-SHIS-04-009).

Patient histories were obtained by interview at hospital or clinic presentation and were entered prospectively into the database. Variables defined were the number of diseased vessels, left ventricular ejection fraction, urgency of the procedure, hyper-

tension (defined as blood >130/90 mm Hg or current use of antihypertensive medications), angina severity (defined according to the Canadian Cardiovascular Society classification system), congestive heart failure severity (classified according to New York Heart Association criteria), family history of CAD, previous MI, renal insufficiency (defined as a serum creatinine level ≥2 mg/dL), diabetes mellitus (defined as a fasting blood sugar level >125 mg/dL or the use of antidiabetic agents), peripheral vascular disease, transient ischemic attack, cerebrovascular disease, abdominal aortic aneurysm, and chronic obstructive pulmonary disease.

Statistical Analysis
The Pearson χ^2 test was used to analyze discrete variables, and the Student t test was used to analyze continuous variables. Logistic regression and Cox proportional hazard models that used a forward stepwise variable selection process were developed to determine which clinical and angiographic variables were associated with late mortality. This HR (or odds ratio [OR]) is the ratio of the mortality in the stenting group to that in the CABG group at any given point in time, controlling for differences in patient demographic characteristics or risk factors.

To express survival differences in percentages, long-term mortality was evaluated with Cox proportional hazards modeling, with propensity scoring to adjust for differences in baseline characteristics influencing each patient's likelihood of being treated with stenting versus CABG, and with an analysis that involved stringent case matching according to propensity scores. Propensity scores were computed from as many patient characteristics and early outcome variables as possible. For the case-matched study population, pairs of patients with similar propensity scores were selected from the two treatment groups. This method yielded very similar stenting (n = 1856) and CABG (n = 1856) groups, which were compared in subsequent late-outcome analyses. Analyses were performed with SAS 6.09 software (SAS Institute, Inc, Cary, NC) for the VAX/VMS operating system.

Results
Patient Characteristics
Between 1995 and 2004, a total of 6847 patients with multivessel CAD (CABG n = 3917, stenting n = 2930) who underwent an isolated first revascularization procedure and who were enrolled in the THIRDBase were included in this study. Follow-up extended up to 9 years, with median durations of 3.0 years (25th–75th interquartile range 2.0–7.4 years) for the stenting group and 3.9 years (25th–75th interquartile range 1.1–5.0 years) for the CABG group.

The prevalences of diabetes (33%) and reduced left ventricular systolic function (ejection fraction <50%, 32%) were high in this study population, particularly in the CABG group (Table 1). The CABG group also had higher prevalences of advanced age, male sex, smoking, previous MI, unstable angina, congestive heart failure, peripheral vascular disease, cerebrovascular accident, and chronic obstructive pulmonary disease. Of the listed variables, only hypercholesterolemia, obesity, and female sex were more

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TABLE 1. Patient data according to revascularization method

	CABG (n = 2634)	Stenting (n = 3845)	P value
Demographic data			
Mean age (y)	62.5%	61.7%	.015
Age >65 y	45.1%	43.7%	.23
Female	26.0%	27.1%	.29
Risk factors			
Diabetes mellitus	37.6%	29.4%	<.001
Insulin requirement	12.0%	7.4%	.001
Hypertension	74.8%	75.5%	.59
Hypercholesterolemia	58.4%	66.2%	<.001
Smoking	49.8%	47.8%	.11
Obesity (body mass index >26 kg/m^2)	19.6%	21.2%	.11
Other medical history data			
Family history of coronary artery disease	36.2%	38.3%	.075
History of myocardial infarction	34.1%	29.5%	<.001
History of unstable angina	54.2%	52.1%	.079
History of congestive heart failure	13.9%	11.7%	.009
New York Heart Association functional class IV	11.1%	10.4%	.38
History of nonsurgical valve disease	4.8%	5.5%	.16
History of peripheral vascular disease	17.8%	15.8%	.025
History of chronic renal insufficiency	12.2%	12.2%	.99
Previous cerebrovascular accident	5.9%	5.0%	.097
History of chronic obstructive pulmonary disease	22.9%	19.6%	.001
Angiographic data			
Disease type and extent			<.001
Two-vessel disease	23.1%	72.8%	
Three-vessel disease	73.5%	27.2%	
Left ventricular function			<.001
Ejection fraction ≥50%	64.0%	71.1%	
Ejection fraction 35%–49%	24.6%	20.8%	
Ejection fraction ≤34%	11.3%	8.1%	
Urgent procedure	5.7%	4.9%	.16

CABG, Coronary artery bypass grafting.

common in the stenting group. Most patients in the CABG group (76%) had three-vessel CAD, whereas those in the stenting group had a more variable degree of CAD: 72% had two-vessel CAD, and 27% had three-vessel CAD. Urgent procedures accounted for 5.3% of all cases (5.7% for CABG, 4.9% for stenting, P = .1571).

Patients in the CABG group each had an average of 3.4 distal anastomoses performed. A left internal thoracic graft to the left anterior descending coronary artery was used in 93% of patients. In the stenting group, glycoprotein IIb and IIIa inhibitors were used in 18% of stenting procedures.

Predictors
Several significant predictors of mortality were identified (Table 2). The multivariable logistic regression model showed that the strongest predictors of mortality in the CABG group were age older than 65 years (OR 2.2, 95% confidence interval [CI] 1.8–2.7) and history of chronic renal insufficiency (OR 1.9, 95% CI 1.5–2.3). The significant predictors of mortality in the stenting group included age older

than 65 years (OR 2.8, 95% CI 2.1–3.8) and history of chronic renal insufficiency (OR 2.2, 95% CI 1.6–3.1).

Short-term Survival Analysis
Adjusted in-hospital mortality was higher in the CABG group than in the stenting group (2.0% vs 0.3%, $P <$ .0001). Risk of in-hospital death was also higher in the CABG group (HR 2.9, 95% CI 1.7–4.7). Additionally, CABG was associated with greater risks of Q-wave MI (3.6% vs 1.0%, $P <$ .0001) and periprocedural major stroke (2.5% vs 0.2%; $P <$ .0001) than was stenting. A higher rate of repeat revascularization during initial hospitalization was noted in the stenting group (0.1% vs 2.5%, $P <$ .0001). The rates of the composite in-hospital end point of death, MI, stroke, and repeat revascularization were 7.3% in the CABG group and 4.0% in the stenting group ($P <$ .0001).

Long-term Mortality
Unadjusted long-term mortality was similar between the CABG group and the stenting group (OR 1.1, 95% CI

TABLE 2. Variables associated with long-term mortality in Cox regression analysis

	CABG		Stenting	
	Odds ratio	95% Confidence interval	Odds ratio	95% Confidence interval
Age >65 y	2.2	1.8–2.7	2.8	2.1–3.8
New York Heart Association functional class IV	1.5	1.1–2.0	NS	
History of valve disease not treated surgically	1.6	1.1–2.0	NS	
History of chronic obstructive pulmonary disease	1.5	1.2–1.8	NS	
Previous cerebrovascular accident	1.6	1.2–2.2	NS	
History of peripheral vascular disease	1.7	1.4–2.1	NS	
History of chronic renal insufficiency	1.9	1.5–2.3	2.2	1.6–3.1
History of congestive heart failure	1.8	1.4–2.3	2.1	1.3–3.4
Diabetes mellitus	1.6	1.3–2.1	1.7	1.1–2.6

CABG, Coronary artery bypass grafting; *NS,* not significant.

1.0–1.2, log-rank test $P = .27$). After adjustment with a multivariate model, no difference in mortality was observed between the CABG and stenting groups (OR 0.9, 95% CI 0.7–1.1). Propensity adjustment, however, revealed a rather strongly favorable result for surgically treated patients (HR 0.8, 95% CI 0.7–0.9, $P = .0005$).

Matched Groups

We matched 3712 patients (1856 from each group) with respect to their likelihood of being assigned to undergo CABG or stenting according to their clinical, angiographic, and demographic characteristics (Table 3). Between these two groups, there were no significant differences in age, sex distribution, or the prevalences of current smoking, diabetes, hypercholesterolemia, presentation with unstable angina, or history of MI. The angiographic characteristics of both groups of patients were also similar; both groups had large proportions of patients with two-vessel CAD. The average number of totally occlusive lesions was 1.2 in the CABG group and 1.4 in the stenting group ($P = .049$). Similar to the outcome of adjusting observed values, the matched population without adjustment in observed values revealed a significant difference in favor of surgery at 9 years (HR 0.7, 95% CI 0.6–0.9, $P = .004$).

TABLE 3. Patient data by revascularization procedure in case-matched patients

	CABG (n = 1856)	Stenting (n = 1856)	P value
Demographic data			
Age >65 y	41.0%	42.0%	.54
Female	28.9%	27.7%	.41
Risk factors			
Any diabetes mellitus	28.9%	28.8%	.94
Hypertension	72.1%	71.7%	.78
Hypercholesterolemia	65.0%	62.8%	.17
Smoking	50.3%	49.5%	.62
Obesity (body mass index >26 kg/m^2)	19.5%	19.3%	.86
Other medical history data			
Family history of coronary artery disease	38.3%	40.0%	.30
History of myocardial infarction	10.3%	11.3%	.33
History of unstable angina	58.4%	55.9%	.12
History of congestive heart failure	12.1%	11.7%	.75
New York Heart Association functional class III or IV	68.6%	68.8%	.91
History of valve disease	4.6%	3.9%	.31
History of peripheral vascular disease	15.3%	14.3%	.42
History of chronic renal insufficiency	12.1%	10.1%	.06
Previous cerebrovascular accident	4.2%	4%	.67
History of chronic obstructive pulmonary disease	20.2%	19.4%	.58
Urgent procedure	5.7%	4.7%	.22
Totally occlusive lesions per patient (mean no.)	1.2	1.4	.049

CABG, Coronary artery bypass grafting.

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TABLE 4. Large-scale observational studies of percutaneous coronary intervention versus coronary artery bypass grafting with long-term follow-up

	Thoraxcenter,[7] 1995–1999		Cleveland Clinic,[1] 1995–1999		New York State,[2] 1997–2000		Northern New England,[6] 1994–2001		Current study, 1995–2004	
	CABG	PCI	CABG	PCI	CABG	PCI	CABG	PCI	CABG	PCI
Mean follow-up (y)	7		5.2		1.9	1.6	3.6		3.5	
No. of patients	409	1640	5161	872	22,102	37,212	4295	10,198	2930	3917
Received stents	NA	100%	NA	70%	NA	100%	NA	64%	NA	100%
Mean age (y)	63	61	64	65	67	65	64	62	63	62
Diabetes mellitus	15%	23%	40%	30%	33%	25%	34%	26%	37%	30%
History of chronic renal insufficiency	—*	—*	3%	6%	3%	6%	3%	2%	12%	12%
Three-vessel disease	80%	23%	74%	33%	69%	19%	50%	13%	73%	27%
Depressed (<50%) left ventricular EF	23%	13%	Mean EF 54%		NR	19%	14%	6%	36%	29%
Mortality										
30-d	0.2%	1.0%	1.3%	1.1%	1.8%	0.7%	1.7%†	0.5%†	1.4%†	0.3%†
Long-term‡	0.59 (0.38–0.9)		0.43 (0.35–0.54)		0.64–0.75		0.86 (0.77–0.97)		0.8 (0.7–0. 9)	

CABG, Coronary artery bypass grafting; *PCI,* percutaneous coronary intervention; *NA,* not applicable; *EF,* ejection fraction; *NR,* not reported. *Excluded by design. †Risk-adjusted 30-day mortality. ‡Long-term mortality data are reported as hazard ratios.

Discussion

The patients included in this study represent a broad population of patients with CAD of varied clinical presentation who would be candidates for either CABG or stenting in the current era. Reflecting current clinical practice, CABG was generally reserved for patients with higher-risk profiles, more lesions, and worse left ventricular systolic function. The results of our survival analysis, stringently adjusted for these confounding factors—including number of diseased vessels—suggest that, for primary revascularization at least, performing CABG rather than PCI with stenting carries a greater short-term cost in terms of complications and mortality but provides more effective protection and improved survival in the long term.

Our findings have variable companionship in the literature. The Bypass Angioplasty Revascularization Investigation (BARI) found poorer 7-year survival after angioplasty (65%) than after CABG (80%) in patients being treated for diabetes.[3] A separate analysis of BARI registry data[4] disagreed with those of randomized trial data with respect to the outcomes of patients with diabetes: patients with diabetes treated percutaneously and those treated surgically had identical survival rates (84%) during 7 years. A review of the characteristics of the percutaneously treated patients in the BARI trial and registry[5] found that registry patients treated percutaneously had fewer lesions at baseline and that their lesion characteristics were more favorable for PCI. These observations highlight the impact of patient selection on long-term outcome after a PCI procedure.

During the performance and follow-up of several randomized trials comparing angioplasty with CABG, the coronary stent was introduced and rapidly became a standard of care. Many clinicians assume that stenting is more beneficial for long-term survival than is angioplasty alone, but this assumption has not been tested in a randomized trial. Our data suggest that in an unselected population of patients with multivessel CAD first revascularization with CABG is associated with better survival rates than those associated with coronary stenting. These results are in agreement with those of similarly designed large-scale retrospective studies, despite differences in study design and population (Table 4). In the Cleveland Clinic,[1] New York State Registries,[2] Northern New England,[6] and Thoraxcenter[7] database analyses, CABG was associated with lower long-term mortality than was stenting.

On the other hand, our findings contradict those of the Stent or Surgery trial (SoS),[8] ERACI II,[9] and Randomized Intervention Treatment of Angina (RITA)[10] randomized trials. Like BARI and the trials of balloon angioplasty without stenting, these three studies found no difference in 5-year survival between patients treated with stenting or CABG. Also like BARI, these studies found that patients with diabetes may fare slightly less well when treated percutaneously. In our study, the improved survivals in the CABG group in both the risk-adjusted analyses and the case-matched comparison suggests that our findings were not merely the result of an unequal distribution of risk factors. An intriguing potential explanation for the difference between our results and those of other randomized trials is the inclusion in our study of patients with treatment similar to current practice patterns. After the publication of the BARI data and the accumulation of experience with long-term stent failure by

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clinicians, physician acceptance of these data was somewhat heterogeneous. Our institution's increasing tendency during recent years to use PCI (rather than surgical) therapy in patients with complex or bifurcation lesions and in patients with diabetes and severe CAD may be responsible for the differences between our results and those of randomized controlled trials in terms of the outcomes of the two treatment strategies.

Moreover, CAD progression during follow-up is a potential adverse outcome of both techniques.[11]). Medical therapy, including the routine use of angiotensin-converting enzyme inhibitors, long-term dual antiplatelet therapy, and far more aggressive lipid-lowering therapy, has evolved significantly since the previous registry studies were published. Both saphenous vein grafts and native vessels receive the protection of more aggressive medical therapy. Still, CAD progression does occur. Failure of a percutaneously treated vessel because of lesion progression at an untreated site may have greater impact on the subtended tissue than does lesion progression after CABG, in which two or more vessels may share the responsibility (albeit unevenly). As a result, patients who undergo CABG may receive greater relative benefit from these medical innovations while being less susceptible to catastrophe in the case of CAD progression than those who undergo PCI. Attempts to treat percutaneously patients or vessels in which eventual treatment failure is probable (eg, patients with diabetes mellitus, extensive atherosclerotic burden, small vessels with long lesions, or bifurcations) may highlight this contrast between the two revascularization methods.

Hannan and colleagues[2] used the powerful New York State revascularization reporting system to examine outcomes in more than 59,000 patients treated between 1997 and 2000. Patients with previous revascularization procedures and left main coronary artery stenosis were excluded. Survival after 3 years was better in the stenting group than in the CABG group. After adjustment for baseline risk factors, however, CABG was associated with superior survival not only in the population as a whole but, surprisingly, in almost every subgroup examined, including patients with two-vessel CAD without left anterior descending coronary artery involvement.

Brener and associates[1] examined the survivals of patients treated surgically or percutaneously at the Cleveland Clinic from 1995 to 1999, excluding patients who had been refused treatment by a cardiac surgeon because of "comorbidity or a lack of appropriate target vessels" and patients who were undergoing primary treatment for acute MI, who died during the procedure, or who had no social security number. Only 70% of the percutaneously treated patients underwent stent implantation. After 5 years, survivals were similar in patients who underwent PCI (16%) and those who underwent CABG (14%), despite the fact that the CABG group had more risk factors at baseline. After propensity matching was used to

correct for this difference in baseline risk, the CABG group appeared to have superior survival (OR 2.3, 95% CI 1.9–2.9). We also excluded patients with acute MI in this study, but we included patients with any other high-risk surgical profile, and our PCI population was restricted to those who received stents.

The Thoraxcenter study[7] examined a population similar in size and characteristics to that of the Cleveland Clinic study, save that only patients who received a stent in two or more vessels were included. The finding that 8-year survival was marginally better in the CABG group (87.5%) than in the stenting group (82%) ($P = .06$) was driven almost solely by the inclusion of patients with left main CAD.

Additionally, the Cleveland Clinic[1] and Northern New England[6] studies included patients treated with balloon angioplasty only (without stenting). In contrast, the New York State Registries[2] and Thoraxcenter[7] trials restricted their PCI populations to stent recipients; however, these two studies differed substantially in the demographic characteristics of their populations.

Limitations
Even large observational studies such as this one can be biased by baseline differences between treatment groups. The main limitation of this study is that although the observations that prompted physicians to refer patients for coronary revascularization may be important markers of outcome, we could not obtain these data. We have attempted to nullify the effects of these data and other potential confounding variables by using Cox and propensity analysis. The differences in the results of the Cox and propensity analyses are a source of interest. Although it is possible that propensity adjustment overcorrects for differences in baseline variables, this seems unlikely given the results seen in the matched populations. A more probable explanation is that the ability of the proportional hazards model to separate the effects of individual variables may exclude the effect of physician judgment. Propensity adjustment or matching by examining the confluence of variables affecting referral for a given procedure may be a more powerful means of statistical adjustment for a study such as this.

Long-term follow-up data on the need for repeat procedures or control of angina were not available. It is well established, however, that CABG is more reliable than bare-metal stenting in preventing symptom recurrence and the need for repeat procedures. Our goal was to examine the effect of that difference on long-term survival in a nonrandomized population.

A limitation of both our study and all other comparative studies of CABG and PCI is that their findings may quickly be outdated by technologic advances. One such advance is the advent of drug-eluting stents, which dramatically reduce the need for repeat revascularization after stent placement. There is not yet clear-cut evidence, however, that these stents

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improve survival. We therefore may still draw inferences about comparative survival from populations with bare-metal stents. Additionally, uses of adjunct devices, such as cutting balloon, laser, and rotational atherectomy, although rare in our population, were not recorded, so the influences of such devices on outcome are not known. Further, advances in preoperative evaluation, including more precise coronary artery and myocardial imaging and diagnostic techniques, have allowed more appropriate patient selection and surgical planning. Improvements in cardiopulmonary perfusion and careful myocardial protection, as well as the use of off-pump and on-pump beating-heart techniques in selected cases, have also decreased perioperative morbidity and mortality.

Implications

In this large, longitudinal database study performed during the modern era of percutaneous coronary stenting, physician-selected strategies for first-time revascularization with CABG were associated with better long-term survival than was stent-assisted angioplasty.

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