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Seven-Year Outcome in the Bypass Angioplasty Revascularization Investigation (BARI) By Treatment and Diabetic Status

The BARI Investigators*

OBJECTIVES To compare seven-year survival in the Bypass Angioplasty Revascularization Investigation (BARI) patients randomly assigned to percutaneous transluminal coronary angioplasty (PTCA) versus coronary artery bypass grafting (CABG).

BACKGROUND The primary results of BARI reported no significant difference in five-year survival between CABG and PTCA groups. However, among patients with treated diabetes mellitus, a subgroup not specified a priori, a striking difference was seen in favor of CABG.

METHODS Symptomatic patients with multivessel disease (n = 1,829) were randomly assigned to initial treatment strategy of CABG or PTCA and followed for an average of 7.8 years. The intention-to-treat principle was used to extend the initial five-year BARI treatment comparisons.

RESULTS Kaplan-Meier estimates of seven-year survival for the total population were 84.4% for CABG and 80.9% for PTCA ($p = 0.043$). This difference could be explained by the 353 patients with treated diabetes mellitus for whom estimates of seven year survival were 76.4% CABG and 55.7% PTCA ($p = 0.0011$). Among the remaining 1,476 patients without treated diabetes, survival was virtually identical by assigned treatment (86.4% CABG, 86.8% PTCA, $p = 0.72$). The PTCA group had substantially higher subsequent revascularization rates than the CABG group (59.7% vs. 13.1%, $p < 0.001$); however, the changes between the five- and seven-year rates were similar for the two groups.

CONCLUSIONS At seven years, there was a statistically significant survival advantage for patients randomized to CABG compared with PTCA. Among patients with treated diabetes mellitus, the benefit of CABG over PTCA seen at five years was more pronounced at seven years; among nondiabetic patients, there was essentially no treatment difference. (J Am Coll Cardiol 2000; 35:1122–9) © 2000 by the American College of Cardiology

In 1987, The National Heart, Lung and Blood Institute (NHLBI) initiated the Bypass Angioplasty Revascularization Investigation (BARI) to compare long-term survival among patients with multivessel disease and severe angina or ischemia randomly assigned to an initial revascularization strategy of percutaneous transluminal coronary angioplasty (PTCA) versus coronary artery bypass grafting (CABG) (1). The five-year survival rate was 89.3% in the CABG group compared with 86.3% in the PTCA group, a statistically nonsignificant difference (2) consistent with results from other randomized clinical trials comparing PTCA and CABG (3–5). However, within the subgroup of BARI patients with treated diabetes mellitus, a subgroup not specified a priori, a difference was observed in favor of bypass surgery (6). The excess mortality associated with PTCA was almost entirely attributable to cardiac causes, and the substantial benefit of CABG was seen only in the majority of patients who received internal mammary artery (IMA) grafts during surgery. Since the publication of the initial BARI results, other authors have retrospectively compared long-term mortality among diabetic patients after CABG and PTCA in databases from observational studies (7,8) and randomized trials (9,10). These comparisons, each limited by either selection biases or sample size, were inconsistent, with some confirming and others not supporting the BARI diabetes finding.

This report extends the randomized treatment comparison in BARI to seven years and allows further evaluation of

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From the National Heart, Lung and Blood Institute, Bethesda, Maryland; Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pennsylvania; and the BARI Investigative Sites. * Please see appendix for BARI Investigators.
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Abbreviations and Acronyms

BARI = Bypass Angioplasty Revascularization Investigation
CABG = coronary artery bypass grafting
CAD = coronary artery disease
CCS = Canadian Cardiovascular Society
IMA = internal mammary artery
LAD = left anterior descending coronary artery
MI = myocardial infarction
NHLBI = National Heart, Lung and Blood Institute
PTCA = percutaneous transluminal coronary angioplasty
QMI = Q wave myocardial infarction
SVG = saphenous vein graft

the initial BARI hypothesis as well as the findings in the subgroup of treated diabetic patients.

METHODS

Patients were eligible for BARI if they had angiographically documented multivessel coronary disease with clinically severe angina or objective evidence of ischemia requiring revascularization and were suitable for both CABG and PTCA as an initial revascularization procedure. The published protocol (1) contains a detailed description of study aims, patient selection, exclusion criteria, procedure guidelines, definitions and administrative structure.

Between August 1988 and August 1991, 1,829 patients were randomized at 18 North American centers. Screening results and baseline characteristics of the BARI randomized patients have been published (11–14). Briefly, at baseline, the average age was 61.5 years, 73% of patients were male, 64% had unstable angina, 41% had triple-vessel disease, 9% had congestive heart failure and 19% had treated diabetes.

By protocol, initial revascularization was required to be performed within two weeks of randomization. Scheduled multiple stages of PTCA were counted as a single procedure, and new interventional devices, such as stents, were not used during initial revascularization. Follow-up clinic visits were conducted at four to 14 weeks and at one, three and five years, with telephone contacts at six months and at two and four years. After five years, follow-up contacts were performed annually by telephone.

Outcome ascertainment. All-cause mortality was the primary outcome measure for BARI. Each patient was contacted to determine vital status as of September 15, 1997. At each follow-up, the occurrence of myocardial infarctions (MIs) and subsequent procedures and angina status were assessed. All ECG's were interpreted at a Central ECG Laboratory. Q wave myocardial infarction (QMI) was defined as new two-grade worsening of the Minnesota Q wave Code (15,16) or new left bundle branch block with abnormal cardiac enzymes. Q wave myocardial infarction during the four-day period after a revascularization procedure was diagnosed by the Q wave criterion alone.

Angiographic definitions. Angiographic definitions used in BARI have been described previously (17). Vessel disease was determined by the number of myocardial territories (anterior, lateral and inferior/posterior) affected by significant lesions (stenosis ≥50% in a vessel with reference diameter over 1.5 mm). Lesion complexity was categorized using American Heart Association/American College of Cardiology Consensus Panel (18) criteria. Abnormal left ventricular function was defined by ejection fraction below 50% as measured by a contrast left ventriculogram or when ejection fraction was unavailable, as the sum of five regional wall motion scores (each scored 1 = normal to 5 = dyskinetic) (19) greater than 10. Of the 1,829 randomized patients, 1,354 had ejection fraction measures, 424 additional patients had wall motion scores and 51 patients were missing any measure of left ventricular function at baseline.

Clinical subgroups. As with the five-year outcomes (2), treatment comparisons were made within a priori subgroups of patients specified by protocol (defined by severity of angina, number of diseased vessels, left ventricular function and lesion complexity) and the subgroups of patients with and without treated diabetes (defined as use of insulin or oral hypoglycemic agents at study entry). Outcome comparisons were also made in additional subgroups defined by age, gender, history of congestive heart failure, peripheral vascular disease, smoking history and baseline ECG results.

Statistical methods. Treatment comparisons were made by the intention-to-treat principle. Kaplan-Meier (20) estimates were used to report cumulative rates of survival, survival free of QMI and repeat revascularization. Kaplan-Meier curves were compared using the log-rank test (21); comparisons were stratified by clinical center for survival and survival free of QMI. Cox regression (22) was used to test for departure from a common relative risk across clinical centers. For assessment of overall outcomes, 95% confidence intervals were calculated for treatment differences. In order to account for multiple treatment comparisons, 99% confidence intervals were used within a priori subgroups in the entire population and 99.5% confidence intervals within other subgroups.

Angina rates were compared cross sectionally at each follow-up for surviving patients who completed that follow-up. Angina was classified as stable or unstable, and stable angina was further classified according to the criteria of the Canadian Cardiovascular Society (CCS) (23). Chi-square statistics were computed at each follow-up for presence of stable or unstable angina versus no stable or unstable angina.

The seven-year p values reported in this article were not adjusted with respect to sequential evaluation of the BARI follow-up data since there was no statistical plan for seven-year treatment comparisons in the original five-year BARI study.

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RESULTS

Vital status as of September 15, 1997 was ascertained for 1,778 patients (97%; mean follow-up 7.7 years, range 6 to 9 years). The remaining 3% were censored when they withdrew consent or were lost to follow-up. As of September 15, 1997, 1,414 patients (77% of total) had reached their seven-year study anniversary, of whom 83% were alive at seven years. Subsequent procedure, QMI and angina outcomes were included through the time of death or last follow-up preceding September 15, 1997. The average follow-up time for these end points was 7.2 years.

Mortality. There was a steady divergence between the survival curves for the 914 patients assigned at random to CABG and the 915 patients assigned to PTCA ($p = 0.043$; Fig. 1A). Seven-year survival rates for the total population were 84.4% for CABG and 80.9% for PTCA. Results did not vary significantly among clinical centers ($p = 0.55$).

The observed treatment difference could be attributed to a substantial and statistically significant treatment difference in the subgroup of the 353 patients with treated diabetes mellitus ($p = 0.0011$, Fig. 1B). Estimates of seven-year survival were 76.4% for diabetic patients assigned to CABG and 55.7% for those assigned to PTCA. Compared with the five year survival rates, the seven-year survival rates were 4.1% lower in the CABG group and 10.8% lower in the PTCA group.

Among the 1,476 patients without treated diabetes at time of entry, cumulative survival was virtually identical; seven-year survival was 86.4% for the CABG group and 86.8% for the PTCA group (Fig. 1C).

Among the subgroups analyzed (column 1, Figs. 2 and 3), the subgroup of treated diabetic patients was the only one with a significant treatment difference at seven years. While statistical power is limited to detect differences in subgroups of a subgroup, it is noted that among the 1,476 patients without treated diabetes at baseline, no treatment effects were observed for any subgroup (column 3, Figs. 2 and 3). In contrast, among the 353 patients with treated diabetes, a uniform advantage of CABG was seen overall and among all subgroups (column 2, Figs. 2 and 3) although the results were not always statistically significant. Thus, it appears that the CABG advantage was consistently confined to all treated diabetic patients in BARI and not confounded by differences in other patient characteristics.

For diabetic patients who were assigned to and received CABG, those who received at least one IMA graft had better seven-year survival (83.2%, $n = 140$) compared with those who received only saphenous vein grafts (SVGs) (54.5%, $n = 33$). The survival rate in the diabetic SVG group was almost identical to that for diabetic patients who received PTCA (55.5%, $n = 170$). Among the nondiabetic patients who received their assigned treatment, these three groups had nearly identical survival rates (86.5% IMA vs. 85.2% SVG only vs. 86.8% PTCA).

Freedom from death or QMI. The survival rates for freedom from death and QMI were not significantly different for the two treatment groups ($p = 0.46$); seven-year rates were 75.3% and 73.5% for the CABG and PTCA groups, respectively. Among diabetic patients, there was a statistically significant difference favoring CABG for survival free of QMI (65.2% CABG vs. 50.0% PTCA, $p = 0.049$), while among nondiabetic patients, these rates were similar (77.8% CABG vs. 78.9% PTCA, $p = 0.57$).

Repeat revascularization. After the initial procedure, the estimated seven-year repeat revascularization rates were 13.1% for patients initially assigned to CABG and 59.7% for patients initially assigned to PTCA ($p < 0.001$; Table 1). Repeat revascularization rates were not statistically different for CABG patients who received at least one IMA graft and those who received only SVG (13.2% IMA vs. 10.9% SVG). After initially higher repeat revascularization rates for the PTCA arm during the first year, cumulative repeat revascularization rates increased at a similar pace over subsequent years. Compared with the five-year rates, the seven-year estimates for the percentage of patients having at least one repeat revascularization were 5.0% and 5.7% higher for the CABG and PTCA groups, respectively.

As seen in Table 1, bypass surgery was used as a repeat revascularization procedure among 1.7% of patients assigned to CABG and 35.5% of those assigned to PTCA, and PTCA was used as a repeat revascularization procedure among 12.1% of patients assigned to CABG and 37.3% of those assigned to PTCA. Twelve percent of patients assigned to PTCA received both PTCA and CABG after their initial procedure.

Among patients initially assigned to CABG, repeat revascularization rates were similar for those with and without treated diabetes (11.1% vs. 13.5%, $p = 0.45$). In contrast, among patients initially assigned to PTCA, repeat revascularization rates were higher for those with treated diabetes than for nondiabetic patients (69.9% vs. 57.8%, $p = 0.0078$), and, in particular, the rate of subsequent CABG was higher for diabetic PTCA patients compared with nondiabetic PTCA patients (48% vs. 33.3%, $p = 0.014$). Much of this difference can be attributed to the fifth and sixth years of follow-up when a sharp rise in the number of CABG procedures for diabetics occurred.

Angina. After the first three years when the CABG group had significantly less angina, the five-year angina rates were closer but still statistically different (20.3% PTCA vs. 15.6% CABG, $p = 0.015$, Fig. 4). Among survivors who completed their seven-year follow-up (note, 23% of the patients had less than seven years of follow-up), the seven-year treatment difference in angina was not statistically significant (15.1% PTCA vs. 11.4% CABG, $p = 0.075$). Within both the PTCA group and the CABG group, the angina rate decreased between five and seven years in the cross-sectional analysis presented as well as in an analysis that was limited to those patients who completed their seven year

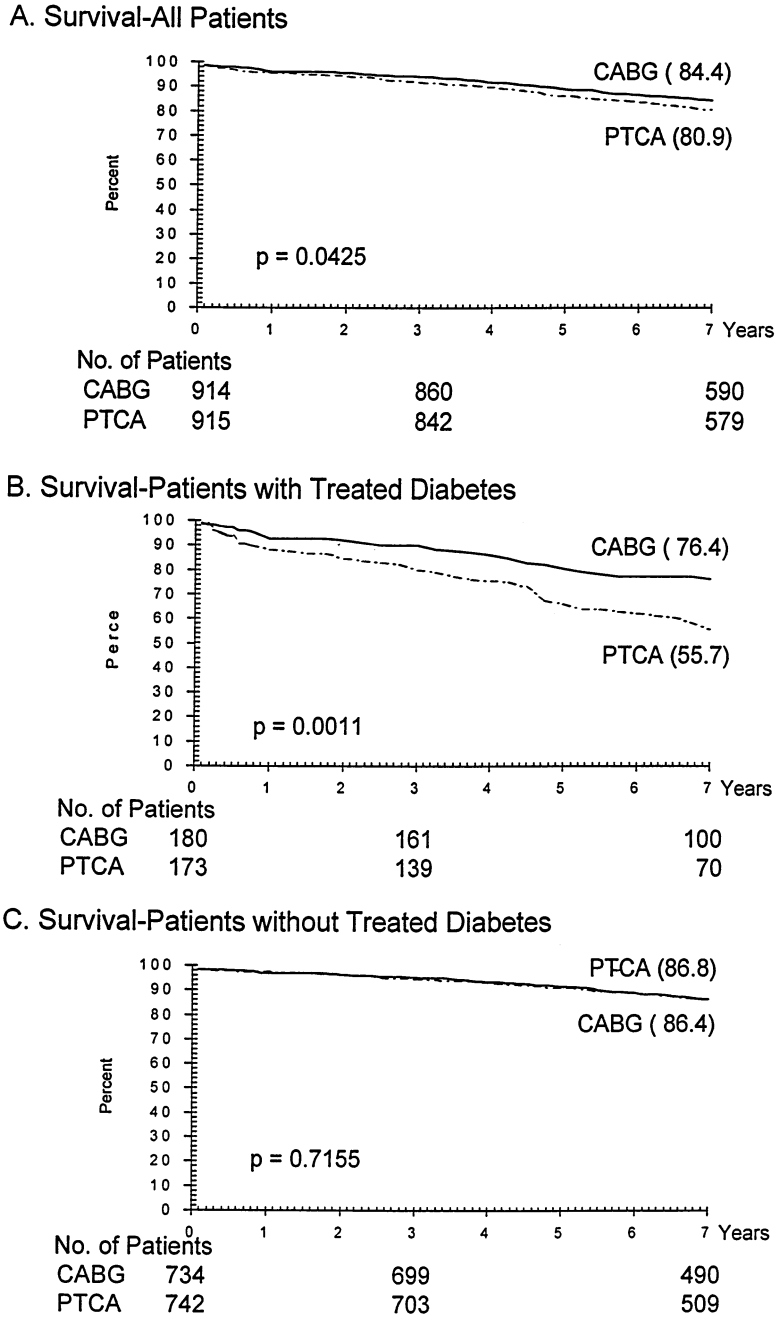

Figure 1. Kaplan-Meier estimates of overall survival for all BARI randomized patients (**Panel A**), for randomized patients with treated diabetes (**Panel B**) and for randomized patients without treated diabetes (**Panel C**). **Solid lines** indicate patients assigned to CABG and **dashed lines** indicate patients assigned to PTCA. The numbers of patients at risk are shown below the graph at baseline, three years and seven years. CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.

follow-up. The large majority of angina reported throughout follow-up was stable CCS class I or II.

DISCUSSION

Previous reports from BARI had demonstrated a trend toward better survival in those assigned to CABG compared with PTCA among symptomatic multivessel coronary artery disease (CAD) patients. We now report a statistically significant survival benefit at seven years for all patients assigned to CABG as compared with PTCA. However, this treatment difference was limited to those patients with treated diabetes mellitus. Among the remaining 1,476 patients without treated diabetes, survival rates between the two treatment arms were virtually identical at seven years.

Diabetes results. The report of the BARI five-year outcome among diabetic patients generated appropriate con-

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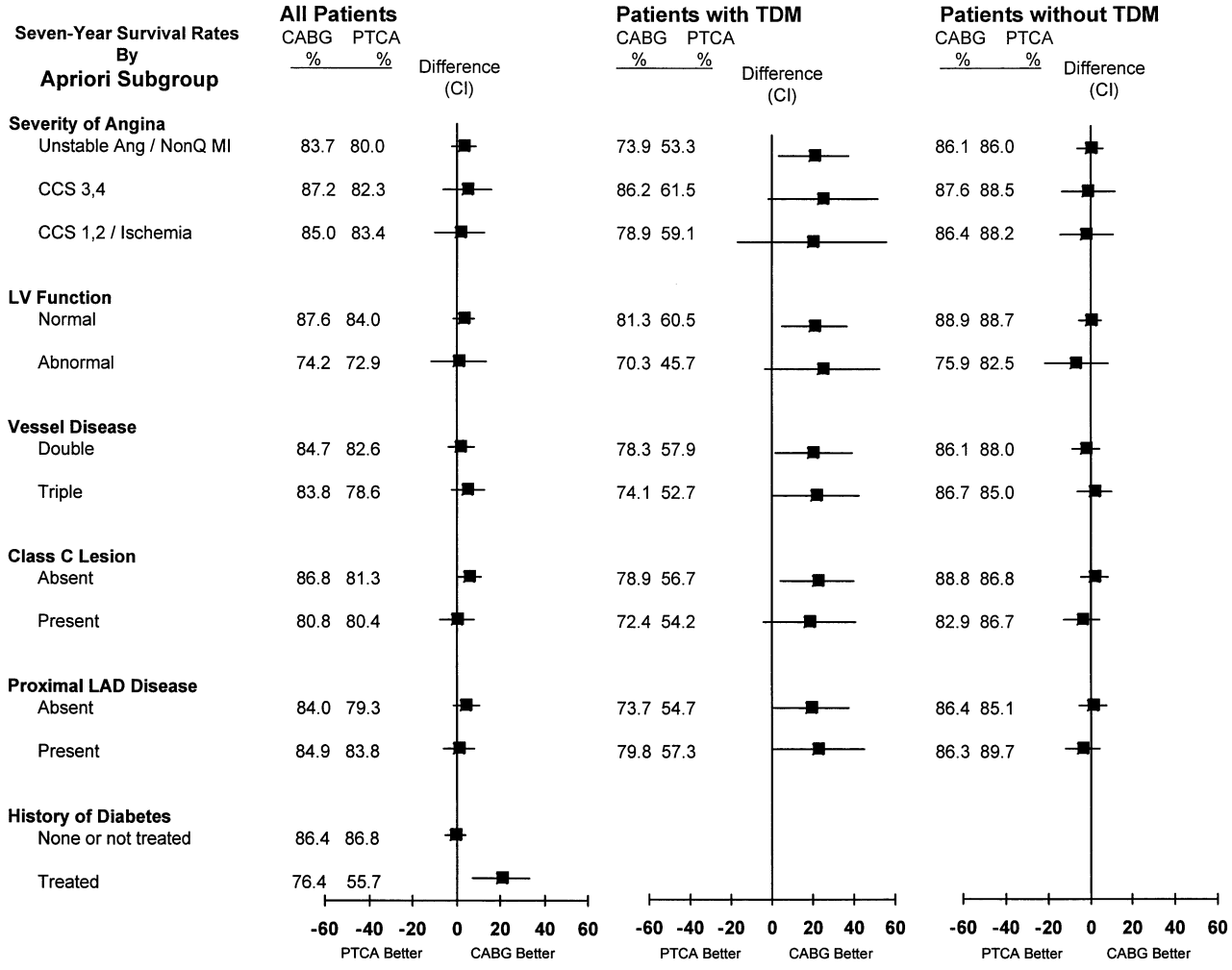

Figure 2. Seven-year estimated survival rates for all patients, for patients with treated diabetes and for patients without treated diabetes according to subgroups selected a priori on the basis of baseline characteristics. Ninety-nine percent confidence intervals (CI) of the difference between the seven-year survival rates for the CABG group and the PTCA group are shown in the first column, and 99.5% CI are shown in the second and third column. CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty; CCS = Canadian Cardiovascular Society; LAD = left anterior descending artery; LV = left ventricle; QMI = Q wave myocardial infarction.

cern about the potential of a spurious finding. While recognizing the hazards of subgroup analysis, the BARI diabetes result was generally accepted by investigators based on the limited number of subgroups specified before the end of the trial and the magnitude of the observed treatment difference, which was clinically, as well as statistically, substantial.

The seven-year outcome, which demonstrates a steadily increasing advantage of CABG compared with PTCA, provides further support for the conclusion reached after five years of follow-up that, in the population of patients in the BARI trial with treated diabetes, survival was significantly better with CABG than with PTCA. It is important to emphasize the distinctive features of those diabetics who were randomized in BARI. As a group, the treated diabetic patients in both treatment groups were at higher risk than other BARI patients regarding extent of CAD, left ventricular function, history of congestive heart failure, peripheral vascular disease and prior MI; in addition, a greater proportion of diabetics were women and African Americans. Recent data from other studies have suggested that stents (24,25) and newer antiplatelet therapy (26), neither of which were used in BARI, may improve the prognosis of diabetic patients after angioplasty. Critical variables regarding hyperglycemia at baseline and the degree of glycemic control are, unfortunately, not available in this study.

Other subgroup results. With the exception of the subgroup of diabetic patients, there was no significant treatment difference within any of the subgroups for all-cause mortality. Moreover, it is striking that there was no apparent trend suggesting that CABG is the preferred treatment in other high risk subgroups (abnormal left ventricular function, triple-vessel disease, presence of left anterior

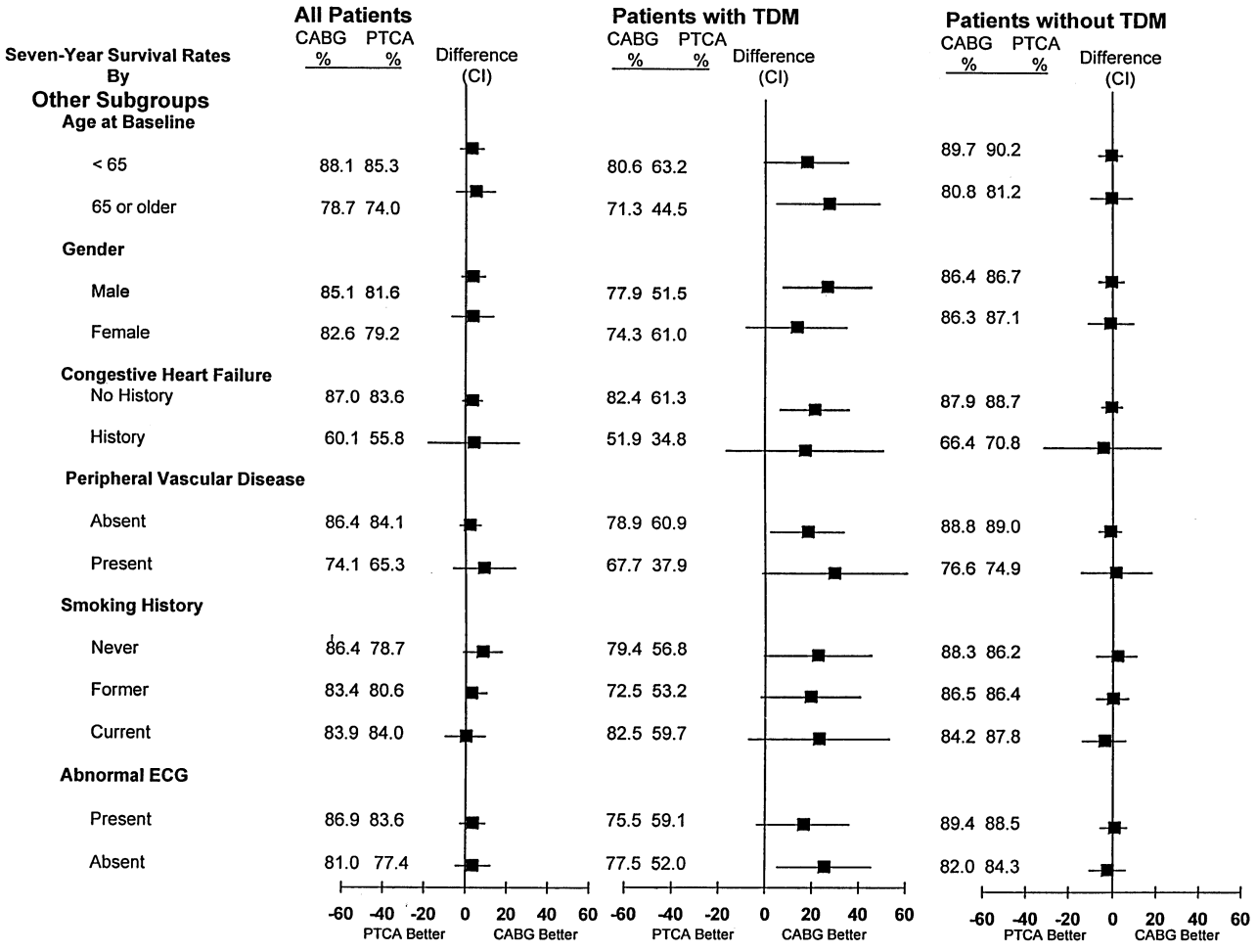

Figure 3. Seven-year estimated survival rates for all patients, for patients with treated diabetes and for patients without treated diabetes according to additional subgroups selected on the basis of baseline characteristics. Ninety-nine-and-one-half percent confidence intervals (CI) of the difference between the seven-year survival rates for the CABG group and the PTCA group are shown. CABG = coronary artery bypass grafting.

descending coronary artery [LAD] disease, presence of class C lesions). Given that patients with left main disease, as well as those with triple-vessel disease and poor left ventricular function, have a proven benefit with CABG relative to conservative management (27,28), the natural intuition might be that patients with more severe angiographic profiles would derive greater benefit from CABG versus PTCA. In this regard, it must be kept in mind that BARI represents a cohort of PTCA eligible patients, not a requirement in the earlier CABG versus conservative management studies. However, multivessel patients eligible for PTCA are precisely the patients for whom the clinical dilemma between PTCA and CABG is relevant.

Subsequent procedures and angina. The cumulative percentage of CABG patients who received at least one subsequent revascularization increased from 8.1% to 13.1% between year 5 and year 7, and this seven-year rate did not depend on whether the patient received IMA grafts (vs. only SVGs) during the initial revascularization. The absolute increase in the subsequent revascularization rate between years 5 and 7 was similar for the two treatment groups, probably reflecting the progression of CAD rather than the initial treatment strategy of CABG versus PTCA. Angina rates were lower in the CABG group during the entire seven-year follow-up period in BARI, but the absolute treatment difference narrowed over time. Interestingly, a smaller proportion of PTCA patients and CABG patients had angina at seven years compared with five years. The additional revascularization procedures, along with better awareness of medical therapy, may have influenced this important drop in angina rates.

Conclusions from BARI. We concluded that, in patients with symptomatic multivessel CAD eligible for either revascularization procedure, survival with an initial strategy of CABG was significantly better than survival with an initial strategy of PTCA. The clinical implications of the BARI results clearly depend on whether a patient has diabetes. The majority of "BARI-like" patients, those without treated

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Table 1. Estimated Subsequent Revascularization Procedures Rates at 7 Years

	All Patients		Diabetic Patients		Nondiabetic Patients	
Subsequent Procedure	CABG (n = 914)	PTCA (n = 915)	CABG (n = 180)	PTCA (n = 173)	CABG (n = 734)	PTCA (n = 742)
None	86.9	40.3	88.9	30.1	86.5	42.2
PTCA only	11.4	24.3	9.3	21.9	11.8	24.5
1	7.5	15.8	6.7	12.8	7.7	16.3
2	3.0	5.3	2.6	2.7	3.1	5.7
≥3	0.8	3.1	0.0	6.4	1.0	2.5
CABG only	0.9	22.6	1.7	27.0	0.8	21.8
1	0.9	22.1	1.7	25.5	0.8	21.5
≥2	0.0	0.5	0.0	1.5	0.0	0.3
Both CABG and PTCA	0.7	12.9	0.0	21.0	0.9	11.5
1 PTCA and 1 CABG	0.4	7.4	0.0	7.5	0.6	7.4
≥2 PTCA and 1 CABG	0.2	4.9	0.0	11.5	0.3	3.9
≥1 PTCA and 2 CABG	0.0	0.6	0.0	1.9	0.0	0.3

CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.

diabetes, can be safely treated with either PTCA or CABG. The clinical implications are more difficult for revascularization candidates with diabetes. It is likely that some diabetics can do quite well with PTCA. However, because the limited BARI diabetes data have been unable to elucidate the mechanism or the initial characteristics of patients for whom CABG is preferable, identifying such patients at this time is difficult. The protective effect of CABG was observed only among patients who had an IMA graft. The conservative course would be to treat all BARI-like diabetic patients with CABG using an IMA graft whenever possible. A second question is whether BARI-like diabetic patients who have already undergone PTCA should undergo CABG. There is a suggestion that within BARI this is already occurring; that is, an increase in the subsequent CABG rate among diabetic patients who initially received PTCA is apparent between the fifth and sixth years of follow-up, corresponding to the release of the five-year BARI findings.

To make informed clinical decisions for all diabetic

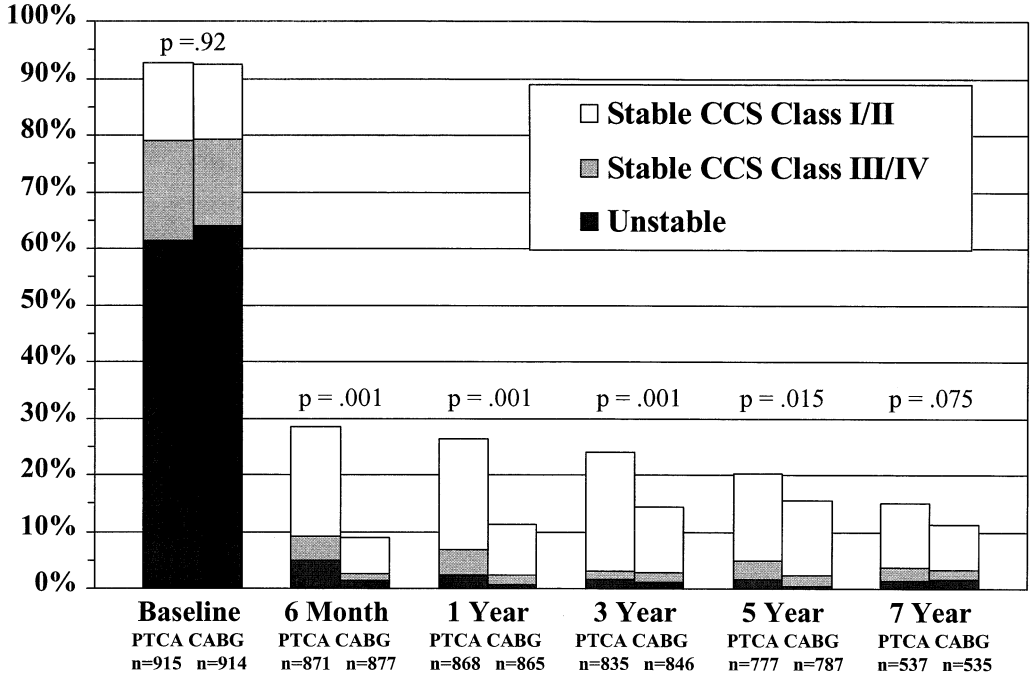

Figure 4. Angina status at baseline, 6 months, 1 year, 3 years, 5 years and 7 years after study entry among surviving patients randomized to PTCA and CABG. P values for the treatment difference between the percentage of patients with angina are presented on top of the bars for each follow-up. CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.

patients requiring revascularization, more information is required. Based on the BARI results, diabetic patients with multivessel disease and unstable or severe symptoms should receive CABG rather than balloon PTCA. Nevertheless, with the use of new percutaneous devices and minimally invasive surgical techniques, strategies involving less severe symptoms and earlier intervention could be prudent. Hence, a true dilemma still exists about the optimal type and timing of revascularization for diabetic patients.

Reprint requests and correspondence: Dr. Katherine M. Detre, c/o BARI Coordinating Center, University of Pittsburgh, Room 127 Parran Hall/130 DeSoto Street, Pittsburgh, Pennsylvania 15261.

APPENDIX

A complete list of the BARI Investigators is published in Reference 6.

This article was prepared by Edwin L. Alderman, MD, Maria Mori Brooks, PhD, Martial Bourassa, MD, Robert M. Califf, MD, Bernard R. Chaitman, MD, Katherine Detre, MD, DrPH, David Faxon, MD, Robert Frye, MD, Regina M. Hardison, MS, Mark Hlatky, MD, Richard Holubkov, PhD, Robert H. Jones, MD, Sheryl F. Kelsey, PhD, Hartzell Schaff, MD, Richard J. Shemin, MD, George Sopko, MD, MPH, Kim Sutton-Tyrrell, DrPH, David O. Williams, MD, on behalf of the BARI Investigators. Dr. Frye as study chair assumes responsibility for overall content and integrity of this article.

National Heart, Lung, and Blood Institute, Bethesda, MD (G.S.), Graduate School of Public Health, University of Pittsburgh, Pittsburgh, PA (M.M.B., K.D., R.M.H., R.H., S.F.K., K.S.T.) and the BARI Investigative Sites (E.L.A., M.B., R.M.C., B.R.C., D.F., R.F., M.H., R.H.J., H.S., R.J.S., D.O.W.)

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