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Survival Following Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Anatomic Subsets in Which Coronary Artery Bypass Surgery Improves Survival Compared With Medical Therapy

Results From the Bypass Angioplasty Revascularization Investigation (BARI)

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OBJECTIVES We sought to compare survival after coronary artery bypass graft (CABG) and percutaneous transluminal coronary angioplasty (PTCA) in high-risk anatomic subsets.

BACKGROUND Compared with medical therapy, CABG decreases mortality in patients with three-vessel disease and two-vessel disease involving the proximal left anterior descending artery (LAD), particularly if left ventricular (LV) dysfunction is present. How survival after PTCA and CABG compares in these high-risk anatomic subsets is unknown.

METHODS In the Bypass Angioplasty Revascularization Investigation (BARI), 1,829 patients with multivessel disease were randomized to an initial strategy of PTCA or CABG between 1988 and 1991. Stents and IIb/IIIa inhibitors were not utilized. Since patients in BARI with diabetes mellitus had greater survival with CABG, separate analyses of patients without diabetes were performed.

RESULTS Seven-year survival among patients with three-vessel disease undergoing PTCA and CABG (n = 754) was 79% versus 84% (p = 0.06), respectively, and 85% versus 87% (p = 0.36) when only non-diabetics (n = 592) were analyzed. In patients with three-vessel disease and reduced LV function (ejection fraction <50%), seven-year survival was 70% versus 74% (p = 0.6) in all PTCA and CABG patients (n = 176), and 82% versus 73% (p = 0.29) among non-diabetic patients (n = 124). Seven-year survival was 87% versus 84% (p = 0.9) in all PTCA and CABG patients (including diabetics) with two-vessel disease involving the proximal LAD (n = 352), and 78% versus 71% (p = 0.7) in patients with two-vessel disease involving the proximal LAD with reduced LV function (n = 72).

CONCLUSION In high–risk anatomic subsets in which survival is prolonged by CABG versus medical therapy, revascularization by PTCA and CABG yielded equivalent survival over seven years. (J Am Coll Cardiol 2001;38:1440–9) © 2001 by the American College of Cardiology

In several clinical trials, revascularization by coronary artery bypass graft (CABG) surgery increased survival compared with medical therapy in patients with three-vessel disease and two-vessel disease when the proximal left anterior descending artery (LAD) was involved, with or without left ventricular (LV) dysfunction (1–6). Although percutaneous transluminal coronary angioplasty (PTCA) was originally utilized for patients with symptomatic single-vessel disease, multiple clinical trials have found that long-term survival among patients with multivessel disease (MVD) undergoing PTCA is similar to that of patients treated surgically (7–12). The largest such trial was the Bypass Angioplasty Revascularization Investigation (BARI), an international randomized clinical trial supported by the National Heart, Lung, and Blood Institute in which an initial strategy of PTCA or CABG was compared among patients with symptomatic MVD (12). Five-year survival among patients assigned to PTCA was similar to that of patients assigned to CABG (12). However, it is unclear whether PTCA is associated with similar survival to CABG specifically in those anatomic subsets in which randomized trials have shown CABG to prolong survival compared with medical therapy.

Accordingly, we performed this study specifically analyzing anatomic subsets in BARI nominally identical to those in which a benefit from CABG relative to medical therapy

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Abbreviations and Acronyms

BARI = Bypass Angioplasty Revascularization Investigation
CABG = coronary artery bypass graft
EF = ejection fraction
IMA = internal mammary artery
LAD = left anterior descending artery
LV = left ventricular
MVD = multivessel disease
PTCA = percutaneous transluminal coronary angioplasty
TIMI = Thrombolysis In Myocardial Infarction

was reported (1–6). Such subgroup analyses were specified by the BARI design.

METHODS

The BARI trial protocol, including a detailed description of the study aims, patient selection, exclusion criteria, procedure guidelines, definitions and administrative structure, has been published (13–18). Briefly, patients were eligible for BARI if they had MVD with either severe angina or objective evidence of marked myocardial ischemia requiring revascularization and were suitable for both PTCA and CABG. Between August 1988 and August 1991, 1,829 patients (12% of patients screened) from 18 clinical centers were enrolled in the randomized trial. Patients were followed up an average of 7.7 years until September 15, 1997, when 77% had seven years of follow-up (and 97% had vital status ascertained). Although the primary end point of BARI was survival at five years, a subsequent analysis revealed greater survival at seven years among CABG patients (84.4% vs. 80.9%, $p = 0.043$). The difference in survival was entirely due to diabetic patients. Diabetic patients in BARI, defined as patients receiving insulin or oral hypoglycemic therapy, had greater survival with CABG than PTCA (76.4% vs. 55.7%, $p = 0.0011$); non-diabetic patients had similar seven-year survival (86.4% vs. 86.8%, $p = 0.72\%$). In the current study, subgroup analyses, most of which were prespecified by protocol, were carried out on patients with and without diabetes who had three-vessel disease and two-vessel disease including the proximal LAD, with and without LV dysfunction. Left ventricular dysfunction was defined as an LV ejection fraction (EF) $<50\%$ (or, if the LVEF was missing, as the sum of five regional wall motion scores >10).

Initial revascularization procedures. A central laboratory using a quantitative angiographic coding system (18) analyzed LV and coronary angiographic findings. Successful dilatation, defined as a reduction in luminal diameter narrowing $\geq 20\%$, a final lumen diameter narrowing $<50\%$, and Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow, was achieved in all lesions treated by PTCA in 60.3% of patients who underwent PTCA. The 891 patients who received their treatment had 2,252 lesions attempted. The success rate for dilation of each lesion was 79.7%.

STATISTICS. Results are summarized as means and medians for continuous variables and percentages for categorical variables. Within each subgroup defined by vessel disease, EF and presence of proximal LAD disease, treatment differences (CABG vs. PTCA) were analyzed by Wilcoxon Rank Sum test for continuous variables and chi-square testing for categorical variables. Seven-year event rates were estimated from life table analyses using the product limit method. Cox proportional hazards regression models were used to obtain adjusted relative risks and analyze interactions between treatment and key variables regarding seven-year survival.

RESULTS

Baseline characteristics. The baseline characteristics of all patients, and patients without diabetes, with three-vessel disease, three-vessel disease with reduced ventricular function, two-vessel disease (including the proximal LAD) and two-vessel disease (including the proximal LAD) with reduced ventricular function are presented in Table 1 stratified by treatment. In all of these subgroups, baseline characteristics were comparable among patients randomly assigned to PTCA and CABG.

The angiographic characteristics of patients in each of the subsets are presented in Table 2. These characteristics were also comparable between treatment groups.

Seven-year survival. Survival curves of patients with three-vessel disease ($n = 754$) are shown in Figure 1. An internal mammary artery (IMA) was used in 86.1% of CABG patients. The mean LVEF was $55.8 \pm 11.4\%$ in the two groups. There was a strong trend toward a lower survival among the PTCA ($n = 378$) vs. CABG ($n = 376$) patients (79% vs. 84%, $p = 0.06$) at seven years. Survival curves of patients with three-vessel disease and reduced ventricular function are shown in Figure 2. The mean LVEF was $41 \pm 6.4\%$ in the PTCA and CABG groups; an IMA was used in 87.7% of CABG patients. Survival at seven years was similar between PTCA ($n = 94$) and CABG ($n = 82$) patients (70% vs. 74%, $p = 0.6$).

When patients with diabetes are excluded from analysis, the survival curves of non-diabetic patients with three-vessel disease reveal no difference in survival between the PTCA ($n = 302$) and CABG ($n = 290$) groups (85% vs. 87%, $p = 0.36$) at seven years (Fig. 3). Similarly, survival of non-diabetic patients with three-vessel disease and reduced ventricular function ($n = 124$) was not statistically different (82% vs. 73%, $p = 0.29$) among PTCA and CABG patients (Fig. 4).

Survival of all patients with two-vessel disease including the proximal LAD ($n = 352$) are shown in Figure 5. An IMA was used in 86.3% of CABG patients; the mean LVEF was $56.7 \pm 11.7\%$ in the two groups. No survival difference was seen between the PTCA ($n = 172$) and CABG ($n = 180$) groups (87% vs. 84%, $p = 0.9$) at seven years, overall. Among patients with two-vessel disease

Table 1. Baseline Clinical Characteristics of Patients in the Different Anatomic Subgroups of the Study Population by Assigned Treatment

	3VD		3VD No DM		3VD LVEF <50%		2VD pLAD		2VD pLAD LVEF <50%	
Characteristic	CABG (n = 376)	PTCA (n = 378)	CABG (n = 290)	PTCA (n = 302)	CABG (n = 82)	PTCA (n = 94)	CABG (n = 180)	PTCA (n = 172)	CABG (n = 35)	PTCA (n = 37)
Age, yr										
Mean	61.3	62.4	61.3	62.2	59.2†	63.2	61.7	60.7	60.8	60.1
Median	62.3	62.7	62.4	62.5	59.6†	63.6	63.0	60.9	63.9	60.2
Age >65, %	39	39	40	37	29	43	41	34	43	27
Age >75, %	5	8	5	7	4	7	8	6	3	3
Female, %	26	25	22	22	26	23	27	27	26	22
Treated DM, %	23	20	0	0	32	28	19	18	31	41
Hypertension, %	55	50	49	45	48	44	45	45	51	38
Hypercholesterolemia, %	45	44	44	43	46	41	43	36	45	34
History of CHF, %	9	9	7	6	15	22	8	9	26	22
Prior MI, %	60	54	59	55	84	75	50	56	79	86
Angina at baseline										
Unstable or with MI, %	73	70	71	71	71	77	67	71	74	72
CSC class II/IV, %	14	16	14	15	14	10	17	13	15	14
CSC class I/II, %	13	14	14	14	15	13	16	16	12	14
Prior smoking, %	68	69	70	72	71	68	65	70	74	76
Current smoker, %	22	23	24	25	28	28	23	27	29	30
BMI >30, %	32	26	27	22	33	26	33	29	34	35
COPD, %	5	7	5	7	5	9	3	5	9	3
PVD, %										
Cerebrovascular/TIA, %	7	8	6	7	5*	14	5	8	3	5
Other atherosclerosis, %	18	19	15	18	18	20	13	14	15	11
Carotid disease, %	74	79	77	76	61†	81	82†	70	86†	51
Creatinine >1.5 mg/dl, %	3	5	2	3	1	5	1	0	3	0

*$p < 0.05$; †$p < 0.01$.

BMI = body mass index; CABG = coronary artery bypass graft; CHF = congestive heart failure; COPD = chronic obstructive pulmonary lung disease; CSC = Canadian Society Classification; DM = diabetes mellitus; LVEF = left ventricular ejection fraction; MI = myocardial infarction; pLAD = proximal left anterior descending artery involvement; PTCA = percutaneous transluminal coronary angioplasty; PVD = peripheral vascular disease; TIA = transient ischemic attack; VD = vessels diseased.

Table 2. Angiographic Characteristics of Patients With Three-Vessel Disease by Assigned Treatment

Characteristic	3VD		3VD No DM		3VD LVEF <50%		2VD pLAD		2VD pLAD LVEF <50%	
	CABG (n = 376)	PTCA (n = 378)	CABG (n = 290)	PTCA (n = 302)	CABG (n = 82)	PTCA (n = 94)	CABG (n = 180)	PTCA (n = 172)	CABG (n = 35)	PTCA (n = 37)
Vessels diseased										
Mean	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0
Median	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0
Proximal LAD lesions										
Mean	0.7	0.7	0.6	0.7	0.6	0.7	1.2	1.2	1.2	1.2
Median	1	1	1	1	1	1	1	1	1	1
No. of significant proximal LAD lesions										
Mean	0.4	0.4	0.4	0.4	0.4	0.4	1.1	1.0	1.0	1.0
Median	0	0	0	0	0	0	1	1	1	1
Frequency of significant proximal LAD disease	42%	39%	40%	40%	43%	40%	100%	100%	100%	100%
Any proximal LAD disease	57%	55%	54%	55%	56%	55%	100%	100%	100%	100%
Total No. of lesions										
Mean	7.7	7.8	7.5	7.7	7.8	7.7	6.1	6.1	6.4	5.9
Median	7	8	7	7	8	7	6	6	7	6
No. of significant lesions										
Mean	4.3	4.4	4.2	4.3	4.5	4.5	2.9	3.0	2.9	3.0
Median	4	4	4	4	4	4	3	3	3	3
≥3 significant lesions	99%	97%	99%	98%	100%	98%	57%	56%	54%	62%
Any class C lesions	49%	48%	50%	49%	65%	59%	33%	31%	49%	38%
MJI > 66	71%	69%	73%	67%	78%	79%	31%*	47%	37%	38%
Abnormal LV function	22%	26%	20%	23%	100%	100%	20%	22%	100%	100%
Any major ECG abnormality	48%	46%	46%	45%	72%	70%	39%	49%	66%	73%

*$p < 0.01$.

ECG = electrocardiographic; MJI = myocardial jeopardy index; Other abbreviations as in Table 1.

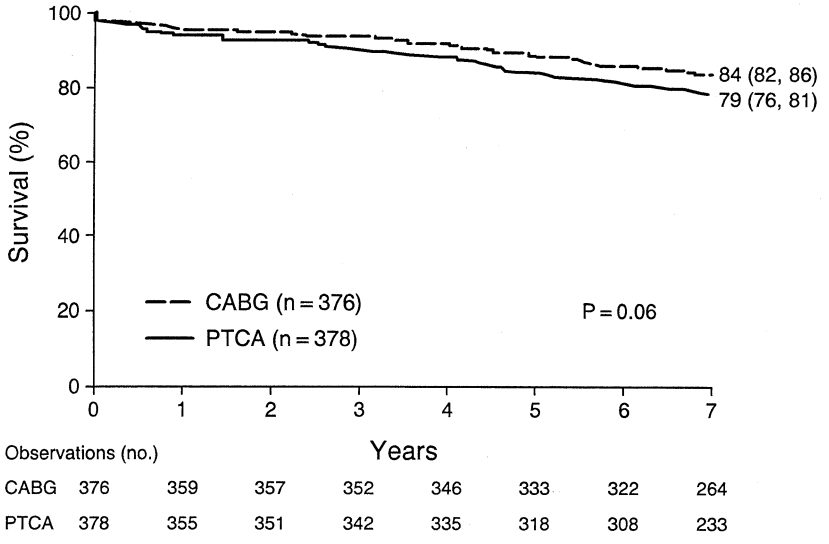

Figure 1. Survival curves of patients with three-vessel disease in the Bypass Angioplasty Revascularization Investigation undergoing percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG).

including the proximal LAD and reduced ventricular function (n = 72), the mean LVEF was 40.0 ± 6.0%, and an IMA was used in 74.3% of CABG patients. There was no survival difference between the PTCA (n = 37) and CABG (n = 35) groups (78% vs. 71%, p = 0.7) (Fig. 6). If only non-diabetic patients with two-vessel disease including the proximal LAD are analyzed (n = 287), seven-year survival was better in the PTCA patients compared with the CABG patients (93% vs. 86%, p = 0.27), although the difference was not statistically significant (Fig. 7). Seven-year survival among non-diabetic patients with two-vessel disease including the proximal LAD and reduced ventricular function tended to be greater among patients treated with PTCA (90% vs. 67%, p = 0.13), although only 46 such patients were enrolled in BARI (Fig. 8).

Multivariate analysis. A Cox regression model revealed that the choice of treatment (PTCA or CABG) was not significantly different for patients with two- versus three-vessel disease in terms of survival at seven years. Similarly, there was no interaction between choice of treatment and the presence of normal and abnormal LV function in terms of survival at seven years.

Subsequent revascularization procedures. In BARI, among the 915 randomized patients assigned to initial PTCA, 215 patients (23.5%) underwent one or more subsequent PTCA procedures, 197 patients (21.5%) underwent CABG, and an additional 113 patients (12.4%) underwent both subsequent PTCA and CABG during the seven-year follow-up period.

Among the 914 patients assigned to initial CABG, nine patients (1.0%) underwent a subsequent CABG procedure,

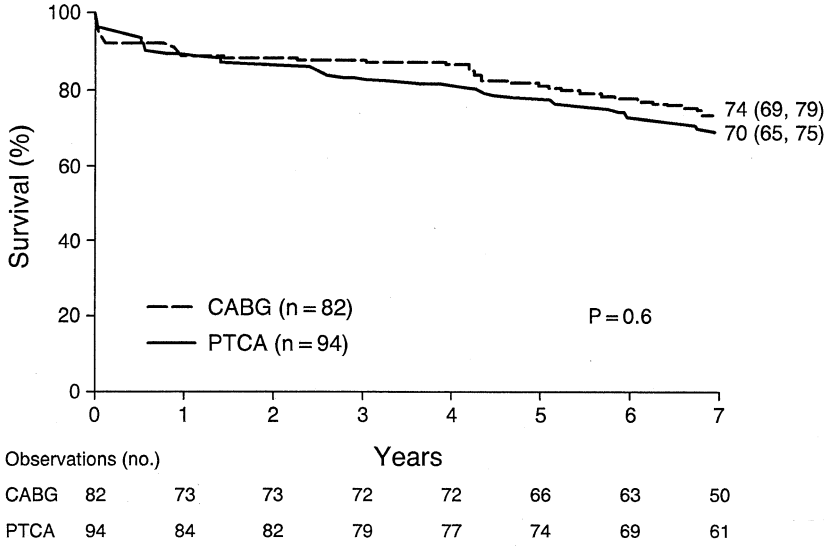

Figure 2. Survival curves of patients with three-vessel disease and reduced ventricular function undergoing percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG) in the Bypass Angioplasty Revascularization Investigation.

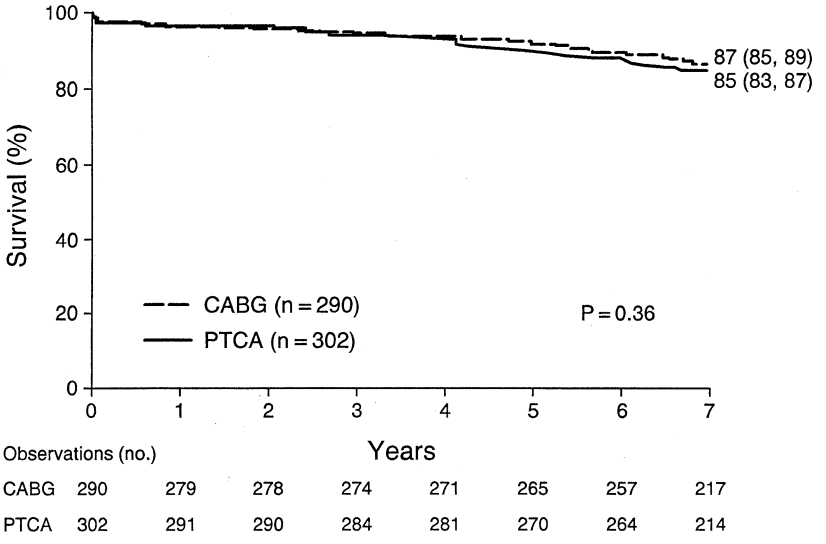

Figure 3. Survival curves of nondiabetic patients with three-vessel disease reveal no difference in survival between the percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG) groups at seven years.

91 patients (10.0%) underwent one or more PTCA, and an additional seven patients (0.8%) underwent both CABG and PTCA during the seven-year follow-up period.

DISCUSSION

Coronary artery bypass graft has been shown to increase survival compared with medical therapy in patients with three-vessel coronary artery disease and two-vessel disease when the proximal LAD was involved, with or without LV dysfunction (1–6). Cardiologists may therefore be reluctant to recommend PTCA for such patients, even when PTCA would be an option for revascularization. The purpose of the analyses reported was to determine whether such reluctance is justified.

Overall, the BARI trial, which compared an initial strategy of PTCA or CABG (12) in patients with MVD, did not find a difference in survival at five years. At seven years, survival was greater among patients treated with CABG (19). The BARI patients with diabetes mellitus who underwent PTCA as an initial revascularization strategy had a significantly higher five- and seven-year mortality compared with those who underwent CABG if IMA grafts were utilized (12,19). No difference in five- or seven-year survival was seen between PTCA and CABG among non-diabetic patients.

Although the conclusion from the BARI investigators indicating that CABG is the preferred initial revascularization strategy for patients with diabetes has been met with controversy, the magnitude of the difference in survival and consistency with other trials suggests CABG is the preferred therapy for diabetic patients with three-vessel disease,

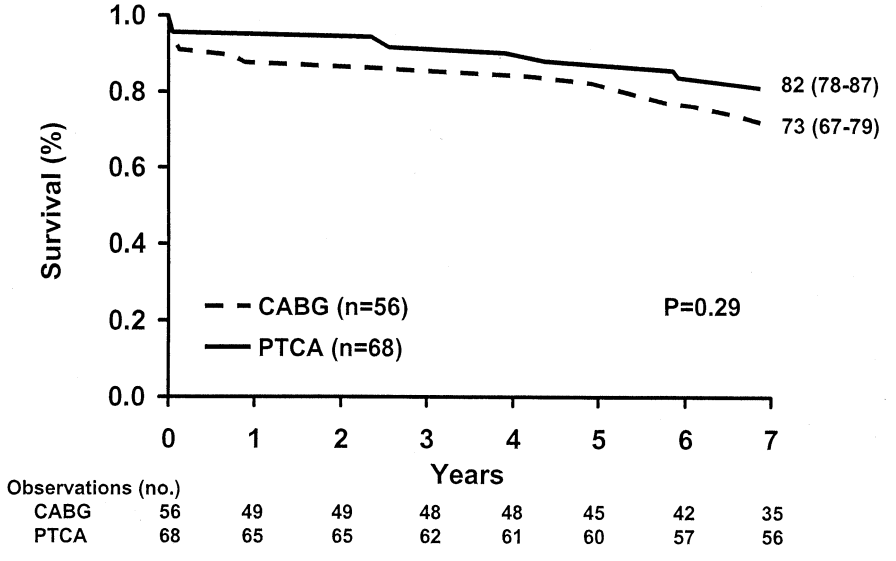

Figure 4. Survival of non-diabetic patients with three-vessel disease and reduced ventricular function. CABG = coronary artery bypass graft; PTCA = percutaneous transluminal coronary angioplasty.

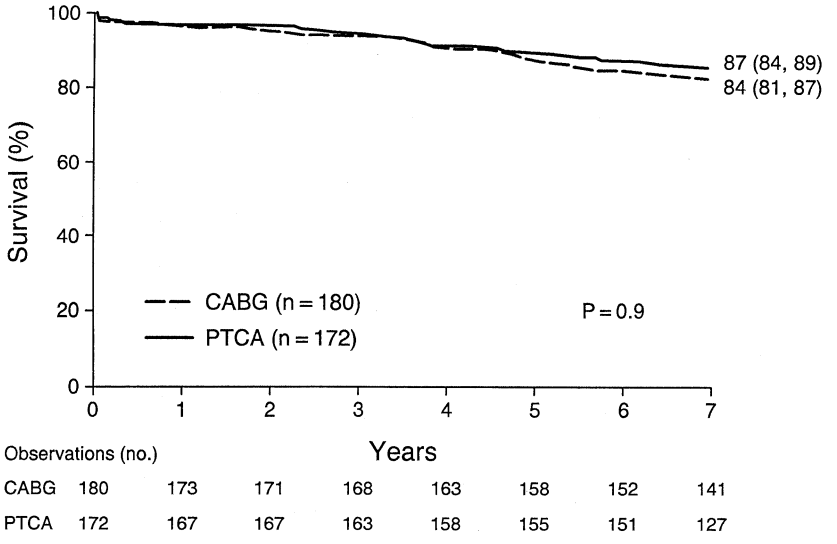

Figure 5. Survival of all patients with two-vessel disease including the proximal left anterior descending artery. Abbreviations as in Figure 4.

particularly those diabetic patients with diffuse disease in whom a larger number of lesions require treatment. In the BARI registry of clinically and angiographically eligible patients who were not randomized, the outcome among diabetic patients treated with PTCA was similar to that of diabetic patients treated surgically (20). This is undoubtedly because diabetic patients in the BARI registry with the most extensive disease were treated surgically.

In our current analyses, there were no significant differences in seven-year survival between patients initially treated with PTCA or CABG in any of the high-risk anatomic subgroups analyzed. However, the trend toward greater survival among patients with three-vessel disease who underwent CABG undoubtedly represents a true benefit of surgery among diabetic patients with three-vessel disease that did not reach statistical significance, because of the small sample size. When diabetic patients with three-vessel disease were excluded from subsequent analyses, survival with PTCA and CABG was similar among non-diabetic patients. Conclusions from these analyses are consistent with the main conclusion by the BARI investigators that survival among patients assigned to an initial strategy of PTCA was similar to that of patients treated with CABG, except in diabetic patients (12). Analyses of patients with and without diabetes with two-vessel disease including the proximal LAD revealed similar survival rates at seven years among patients initially treated with PTCA and CABG, whether or not LV dysfunction was present. When diabetics were excluded from analysis, seven-year survival among patients with two-vessel disease including the proximal LAD with or without reduced ventricular function revealed a trend favoring PTCA.

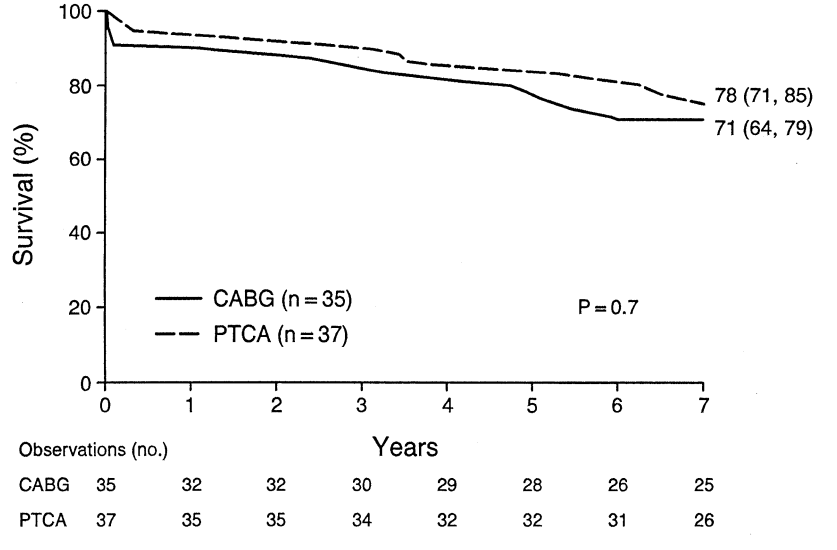

Figure 6. Survival of all patients with two-vessel disease including the proximal left anterior descending artery and reduced ventricular function. Abbreviations as in Figure 4.

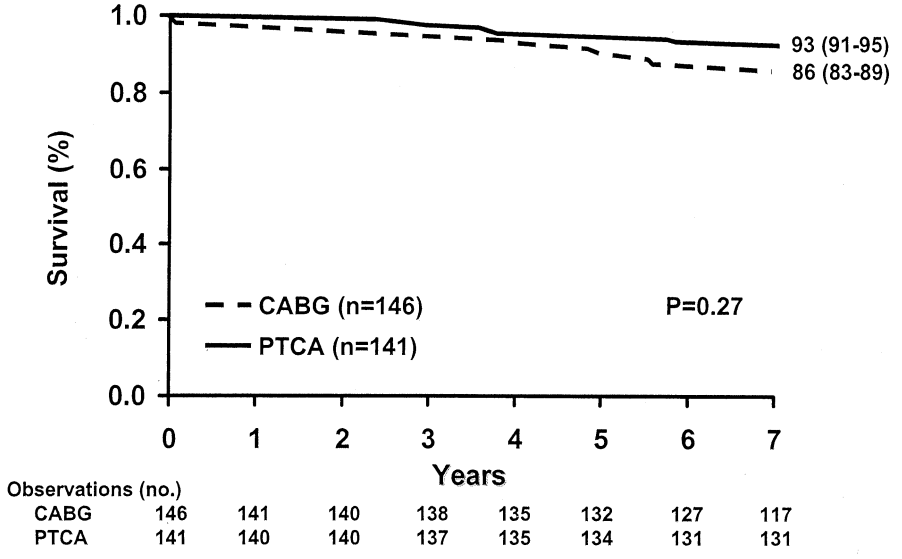

Figure 7. Survival of non-diabetic patients with two-vessel disease including the proximal left anterior descending artery. Abbreviations as in Figure 4.

Implications for comparisons between PTCA and medical therapy. If CABG prolongs survival compared with medical therapy in certain anatomic subgroups, and PTCA has a similar survival to CABG in several of those anatomic subgroups, one might infer that PTCA may also provide a survival advantage compared with patients treated medically. However, when examining trials comparing PTCA versus CABG in patients with MVD, it must be remembered that enrollment in the trials was limited to patients whose coronary disease is amenable to both techniques. In BARI, only 33% of patients with MVD who were clinically eligible for BARI were amenable to PTCA, whereas 93% of patients with MVD were amenable to CABG (16). In general, unsuitable candidates for PTCA had more diffuse and severe coronary disease, more frequently had occluded vessels and ostial lesions and worse LV function (16).

In addition, since the trials comparing medical therapy with CABG were performed, CABG has improved a great deal. The left IMA was used in approximately 15% of patients in those early randomized trials; it was utilized in 83% of CABG procedures in BARI and was associated with improved survival and event-free survival following CABG (13). However, medical therapy has also markedly improved; thus, it is possible that CABG would no longer be superior to medical therapy in these subgroups.

Finally, all of the analyses of high-risk patients included too few patients to provide statistical certainty that there was no significant difference in mortality between PTCA and CABG. Based on the observed seven-year mortality in the CABG group in each of the anatomic subsets, appropriately sized samples would require (with a beta of 0.8 and alpha of 0.05) between 7,408 and 16,080 patients to be

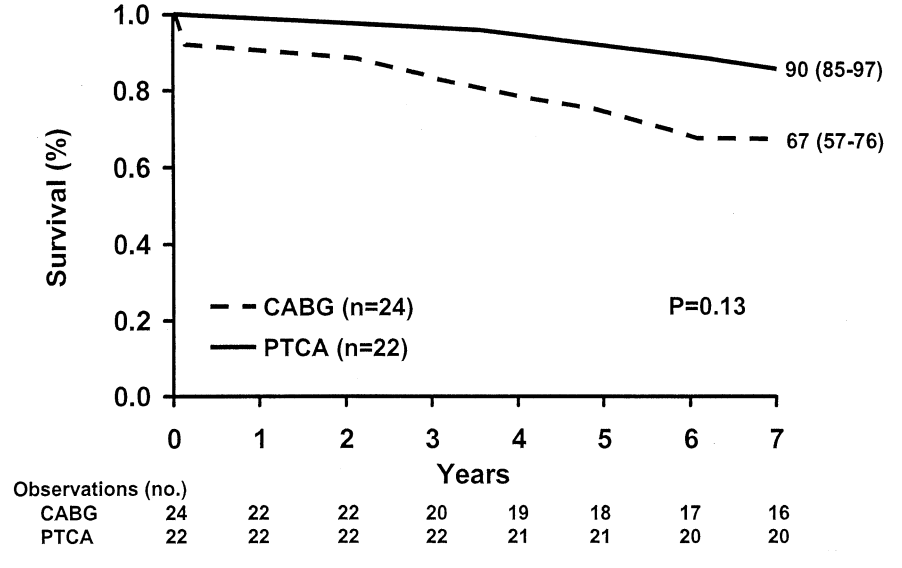

Figure 8. Survival of non-diabetic patients with two-vessel disease including the proximal left anterior descending artery and reduced ventricular function. Abbreviations as in Figure 4.

Table 3. Observed Survival With 95% Confidence Intervals for Patients Undergoing PTCA vs. Observed Survival for CABG Patients in the Different Anatomic Subsets*

Subset	No. of Patients	Observed 7-Year Survival With PTCA	PTCA Survival: 95% Confidence Intervals	Observed 7-Year Survival With CABG
3VD, ↓ LVEF; no DM	124	82	78–87	73
3VD; no DM	592	85	83–87	87
2VD, proximal LAD, ↓ LVEF; all patients	72	78	71–85	71
2VD, proximal LAD, ↓ LVEF; no DM	46	90	85–97	67
2VD, proximal LAD; all patients	352	87	84–89	84
2VD, proximal LAD; no DM	287	93	91–95	86

*The lower estimate for 95% confidence intervals equals or exceeds, in most cases, the observed survival with CABG in each of the subsets, suggesting that it is unlikely that PTCA would be associated with a significantly lower survival if appropriately sized prospective studies were performed.

CABG = coronary artery bypass graft; LAD = left anterior descending artery; LVEF = left ventricular ejection fraction; no DM = no patients with diabetes mellitus; PTCA = percutaneous transluminal coronary angioplasty; VD = vessels diseased.

sufficiently powered to detect a relative 10% increase in mortality in the PTCA arm compared with the CABG arm. However, the 95% confidence intervals for the observed survival seen with PTCA in BARI (Table 3) reveal that the lower estimated survival with PTCA in most of these anatomic subsets is equal to or greater than the actual survival seen with CABG in BARI. Therefore, it is unlikely that survival after PTCA would be significantly lower than survival after CABG, had appropriately sized samples been available for analysis. It should be remembered that the largest study comparing surgical and medical therapy upon which the survival benefits of CABG were established, the Coronary Artery Surgery Study (n = 780), was only slightly larger than the largest subset of patients analyzed in the current study, patients with three-vessel disease (n = 754), and smaller than the total number of patients analyzed in the current study (n = 1,829). For all these reasons, BARI should not be considered to provide evidence about the relative survival benefit of PTCA versus medical management.

Recent advances in percutaneous revascularization. The advances and refinements to PTCA affect not only the frequency of a repeat revascularization procedure but also mortality (21). A lower mortality has been found among patients treated with both stents and the IIb/IIIa inhibitor abciximab versus balloon angioplasty (even if abciximab was used) among more than 2,400 patients enrolled in the EPISTENT trial (22). The benefit of a stent and abciximab was greatest among patients with diabetes mellitus (22). Whether the outcome of diabetic (and other) patients would have been improved had stents and these potent antiplatelet agents been widely used, although likely, remains speculative. Further studies are required to clarify the role of stents and platelet glycoprotein IIb/IIIa inhibitors in diabetic patients with MVD.

CONCLUSIONS

Data from the BARI trial show no difference in seven-year survival between an initial strategy of PTCA or CABG among non-diabetic patients with three-vessel, and among all patients with two-vessel disease involving the proximal LAD, amenable to both procedures. Although such patients have been shown to live longer when treated with CABG versus medical therapy, these data provide evidence that PTCA may be offered to such patients as an initial revascularization without compromising their seven-year survival.

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