Increased Incidence of Periprocedural Complications Among Patients With Peripheral Vascular Disease Undergoing Myocardial Revascularization in the Bypass Angioplasty Revascularization Investigation

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Background—Risks of coronary artery bypass graft surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA) may be different in the presence of peripheral vascular disease (PVD).

Methods and Results—We analyzed outcomes of 550 patients with PVD enrolled in the Bypass Angioplasty Revascularization Investigation randomized trial and registry. Compared with 1770 patients without PVD, those with PVD were older and had a greater prevalence of medical comorbid conditions. No significant differences in coronary anatomy or PTCA success rates were found. The risk of any major complication (death, myocardial infarction, stroke, coma, or emergency revascularization) after PTCA was significantly higher among patients with PVD (11.7% versus 7.8%, $P=0.027$). In multivariate analysis, this represented a 50% increase in the odds of having any major complication (multivariate odds ratio, 1.5; $P=0.032$). Among patients undergoing CABG, the risk of major complications was found to be markedly higher for patients with PVD (12%) than those without (6.1%, $P=0.003$) even after controlling for baseline differences (multivariate odds ratio, 1.8; $P=0.018$). Major differences between the PTCA and CABG groups were related primarily to a higher risk of neurological complications in PVD patients who had CABG (multivariate odds ratio, 2.8; $P<0.001$).

Conclusions—We conclude that patients with PVD are at high risk for periprocedural complications after myocardial revascularization, in particular neurological events. **(*Circulation*. 1999;100:171-177.)**

Key Words: angioplasty ■ grafting ■ coronary disease ■ peripheral vascular disease ■ revascularization

Whether myocardial revascularization is indicated for treatment of coronary artery disease (CAD) for a patient depends on an assessment of anticipated risks and benefits, both short-term and long-term, of each available treatment alternative. For invasive therapies such as coronary artery bypass graft surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA), acute periprocedural risks must be outweighed by the potential to accrue future benefits for the therapy to be in the patient's best interest.[1,2] As such, patient or procedural characteristics that influence periprocedural risks must be considered when one counsels a patient.

Patients with systemic coexisting disease, such as peripheral vascular disease (PVD), renal insufficiency, or cancer, are at increased risk for periprocedural complications and have poorer long-term outcomes than those without PVD.[3,4] Few recent data are available describing periprocedural risks of myocardial revascularization among patients with vascular disease.[5–7] The purpose of the present analysis was to examine periprocedural risks of CABG surgery and PTCA among patients with PVD enrolled in the Bypass Angioplasty Revascularization Investigation (BARI).

Methods

The BARI study protocol and the overall results have been reported previously in detail.[8,9] BARI was the largest of a series of studies comparing PTCA and CABG in patients with multivessel coronary artery disease and enrolled patients over a 3-year period, from August 1988 through August 1991. Patients with multivessel coronary artery disease were considered angiographically eligible if, in the opinion of their physicians, revascularization was indicated and their arteries were anatomically suitable for both CABG and PTCA. Patients <17 years or >80 years old were excluded, as were patients with single-vessel coronary artery disease or primary valvular, myocardial, or congenital heart disease or previous revascularization procedures.

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This report is based on 1783 patients drawn from the randomized trial (56 of 1829 randomized patients either did not receive their assigned treatment or had missing PVD data) plus 1808 patients drawn from the registry who underwent nonrandomized PTCA or CABG within 3 months after enrollment. For the purpose of this analysis, PVD was defined as either atherosclerosis of the lower extremities or extracranial cerebrovascular disease. Atherosclerosis of the lower extremities was considered to be present if there was a history of lower-extremity vascular surgery, abdominal aortic aneurysm, or intermittent claudication. Extracranial cerebrovascular disease was considered to be present if there was a history of stroke, transient ischemic attacks, carotid endarterectomy, or carotid artery disease documented by the presence of bruits, duplex ultrasonography, or angiography.

Long-term follow-up (average, 5.4 years) has been performed, and information relating to vital status, myocardial infarction, angina pectoris, or repeat revascularization procedures has been collected. Ascertainment of vital status is 98% complete. Successful PTCA was defined as improvement in coronary artery diameter stenosis of ≥20%, with a final residual stenosis <50% and Thrombolysis in Myocardial Infarction (TIMI) grade III flow, in the absence of a major complication. Myocardial infarction was defined as the presence of new pathological Q waves, in accordance with the Minnesota code, or development of new left bundle-branch block, with abnormal cardiac enzyme levels. ECG and coronary angiographic analyses (except registry patients) were performed at core laboratories. Cause of death and occurrence of myocardial infarction were adjudicated by committee review. The University of Pittsburgh was the coordinating center for the BARI study, including data management and statistical analysis.

Statistical Methods

Demographic and baseline clinical characteristics were compared for patients with and those without PVD by treatment strategy. Student's *t* test or the Wilcoxon test was used to compare continuous distributions. χ^2 tests were used to compare proportions. Because of the small number of individual in-hospital events in each patient group, Fisher's exact tests were used to compare in-hospital complication rates. In addition, 3 composite variables were defined. These were "major events" (death/myocardial infarction/stroke/coma), "major events including emergency revascularization" (death/myocardial infarction/stroke/coma/emergency revascularization), and "neurological events" (stroke/coma/transient ischemic attack/dementia).

Logistic regression was used to assess the likelihood of an in-hospital complication associated with treatment strategy, adjusting for other risk factors. Multivariate models were developed for the combined population of randomized and registry patients as well as for randomized patients alone. For both models, covariates included age, sex, treated diabetes mellitus at baseline, history of congestive heart failure, and blood pressure. To control for possible treatment selection bias among registry patients, a variable created by logistic regression and indicating the likelihood of undergoing CABG on the basis of baseline characteristics was also included in the model ("propensity score").

Results

PVD was identified in 550 of 3591 patients: cerebrovascular disease in 349 (9.7%) and lower-extremity vascular disease in 268 (7.5%). Baseline clinical and demographic characteristics are tabulated in Table 1. In comparison with patients without PVD, those with PVD tended to be older (65.9 versus 60.9 years for the CABG group [$P<0.001$] and 64.7 versus 60.7 years for the PTCA group [$P<0.001$]). A larger proportion of patients with PVD were female (32% versus 25% for the CABG group [$P=0.023$] and 36% versus 25% for the PTCA group [$P<0.001$]). Medical comorbid conditions such as diabetes mellitus, chronic obstructive pulmonary disease, or chronic renal insufficiency were significantly more common among patients with PVD.

Baseline coronary anatomic characteristics are tabulated in Table 2. There were few differences between patients with PVD and those without PVD. Mean ejection fraction was 56.7% to 58.3% in all groups, and 16% to 21% had an ejection fraction <50%. The distribution of 1-, 2-, and 3-vessel coronary artery disease was not different, nor were the mean numbers of lesions per patient or the numbers of chronic total occlusions. In the PTCA group, the myocardial jeopardy index was slightly lower for those without PVD than for those with PVD (58.3 versus 60.6, $P=0.030$). No difference in the distribution of American College of Cardiology/American Heart Association class A, B, or C lesions was found between groups.

Patients Undergoing PTCA

PTCA success rates were only slightly lower for patients with PVD: 567 of 663 (85.5%) target lesions in patients with PVD were dilated successfully. In comparison, 3220 of 3671 (87.7%) target lesions in patients without PVD were dilated successfully ($P=0.117$). Abrupt closure of the dilated vessel occurred in 4.8% of lesions in patients with PVD and in 4.0% of lesions in patients without PVD. Specific reasons for PTCA were identifiable in 228 lesions (46% failure to cross, 52% failure to dilate, 2% not attempted for clinical reasons).

In-hospital procedural complication rates are tabulated in Table 3. In comparison with 1770 patients without PVD, the 316 patients with PVD who had PTCA had a greater incidence of death (2.2% versus 0.6%, $P=0.012$) but not of Q-wave myocardial infarction (2.5% versus 2.5%). Sixteen of 18 deaths were cardiac in nature. The incidence of major neurological complications was low, regardless of the presence or absence of PVD. Nonetheless, the incidence of any major complication (death, myocardial infarction, stroke, coma, or emergency revascularization) was significantly higher among patients with PVD than those without PVD (11.7% versus 7.8%, respectively, $P=0.027$). Because patients with PVD had higher baseline risk profiles, age, sex, diabetes mellitus, congestive heart failure, and blood pressure were controlled for with multivariate analysis. In multivariate analysis, the odds of having any major complication after PTCA were >50% greater for patients with PVD (multivariate odds ratio, 1.5; $P=0.032$) than for those without PVD.

Patients Undergoing CABG

Two hundred thirty-four patients with PVD and 1271 without PVD underwent CABG. The incidence of death or Q-wave myocardial infarction (9.4% versus 5.5%, $P=0.036$) was significantly higher in the presence of PVD. Similarly, the risk of major neurological complications (stroke, coma, transient ischemic attack, or dementia) was significantly higher in the presence of PVD (4.7% versus 1.2%, $P=0.001$), even after controlling for baseline patient differences (multivariate odds ratio, 2.8; $P<0.001$). Among patients with PVD, the risk of neurological complications after CABG was especially high in the presence of carotid atherosclerosis (6.2% versus 1.3% with lower-extremity vascular disease, $P<0.001$). Neurological complications after CABG occurred both with and without previous

TABLE 1. Comparison of Clinical and Demographic Characteristics of Study Groups

	Group			
Characteristic	CABG/PVD	CABG/No PVD	PTCA/PVD	PTCA/No PVD
No. of patients	234	1271	316	1770
Age, y				
Mean	65.9*	60.9	64.7*	60.7
>65, %	61	37	51	36
>75, %	9	6	13	6
Sex, %				
Male	68†	75	64*	75
Female	32	25	36	25
Race, %				
White	92	92	91	93
Black	6	5	8	4
Other	2	3	<1	3
PVD, %				
Stroke/TIA	37	0	38	0
Carotid surgery	11	0	14	0
Lower-extremity disease	48	0	50	0
Other comorbid conditions, %				
COPD	10‡	4	12*	4
Chronic renal insufficiency (serum creatinine >1.5)	5‡	2	6*	1
Malignancy	5	5	9*	5
Other	42*	27	36*	26
Treated diabetes mellitus, %	29*	17	25*	15
History of myocardial infarction, %	53	53	50	52
History of congestive heart failure, %	13*	6	11*	6
History of hypercholesterol, %	50	43	45	45
Familial premature CAD, %	48	51	47	49
History of hypertension, %	60*	48	62	45
History of smoking, %	70	67	79*	69
Mean years quit	12.3	12.5	12.5	12.5
Current smoker, %	22	21	35*	23
History angina, %	98	95	95	95

TIA indicates transient ischemic attack; COPD, chronic obstructive pulmonary disease.
*$P \leq 0.001$.
†$P \leq 0.05$. Note: All comparisons are PVD vs no PVD within groups (ie, CABG/PVD vs CABG/no PVD, PTCA/PVD vs PTCA/no PVD) by Student's *t* test.
‡$P \leq 0.01$.

neurological symptoms (incidence, 2.1% and 1.7%, respectively). The overall risk of any major complication (death, myocardial infarction, stroke, coma) after CABG was markedly higher for patients with PVD (12% versus 6.1% [$P=0.003$]; multivariate odds ratio, 1.8 [$P=0.019$]).

Multivariate Logistic Regression Analysis in Patients With PVD

Results of multivariate regression of predictors of periprocedural complications among patients with PVD are presented in Table 4. Congestive heart failure and renal dysfunction (serum creatinine >1.5) were particularly powerful correlates of complications, especially procedural mortality. Multivariate odds ratios of death were 5.30 (95% CI, 1.26 to 22.29) if there was a history of congestive heart failure and 13.45 (95% CI, 3.07 to 58.90) in the presence of an increased creatinine level.

Among all patients with PVD, the risk of major complications, including death, myocardial infarction, stroke, coma, or emergency revascularization, was similar whether patients had PTCA or CABG (11.7% versus 12.0%; multivariate odds ratio, 1.0; 95% CI, 0.6 to 1.7). Excluding emergency revascularization, however, patients treated with CABG were at greater risk (12% CABG versus 4.4% PTCA; multivariate

TABLE 2. Comparison of Coronary Artery Anatomic Characteristics of Study Groups

	Group			
Characteristic	CABG/PVD	CABG/No PVD	PTCA/PVD	PTCA/No PVD
No. of patients with evaluable angiograms	234	1271	316	1770
Mean No. of ≥50% lesions	2.46	2.43	2.37	2.31
No. of diseased epicardial arteries				
1, %	<1	1	2	2
2, %	52	54	59	65
3, %	47	45	39	33
Total No. of lesions				
Mean	5.55	5.75	5.42	5.40
≤5, %	58	53	58	60
6 or 7, %	19	25	23	20
≥8, %	23	22	19	20
Mean No. of diffuse lesions	0.48	0.47	0.49	0.40
Any, %	34	31	29	26
Mean No. of proximal lesions	1.7	1.6	1.6	1.6
Any, %	85	87	84	84
Proximal LAD lesion, %	57	56	50	50
Ejection fraction				
Mean, %	58.3	57.5	56.7	57.2
<50%, %	21	18	19	16
Myocardial jeopardy index				
Mean	63.8	63.2	60.6*	58.3
Jeopardy index ≥75, %	26	25	20	15
Dominance				
Right, %	85	86	82	85
Left, %	8	6	9	6
Mixed, %	6	8	9	9
No. of occlusions				
None, %	68	69	72	70
1, %	29	27	26	28
≥2, %	3	4	2	2

LAD indicates left anterior descending coronary artery.
*P=0.030.

odds ratio, 3.32; 95% CI, 1.58 to 6.95). The major differences were higher observed rates of periprocedural myocardial infarction (7.3% CABG versus 2.5% PTCA) and neurological complications (stroke, coma, transient ischemic attack, dementia) after CABG in comparison with PTCA (4.7% versus 0.3%; multivariate odds ratio, 13.99; 95% CI, 1.76 to 111.05). These differences were not seen among the randomized trial subset, however, and should be interpreted with caution. Wide CIs associated with the multivariate odds ratios were found and were due primarily to the relatively low number of observed events.

Among the 550 patients with PVD, 12 major neurological events (stroke, coma, transient ischemic attack, dementia) occurred, 10 of which occurred in patients with identifiable extracranial cerebrovascular disease. In contrast, for patients without PVD, no difference in the incidence of neurological complications was observed whether patients were treated with CABG or PTCA (1.2% versus 0.6%, P=NS), indicating that the risk is attributable almost entirely to the presence of PVD.

Discussion

The results of the present study indicate that patients with clinical evidence of PVD are at significantly higher risk for procedural complications after either PTCA or CABG. Clinicians frequently encounter patients with combined coronary and peripheral vascular disease and must consider whether such patients should undergo myocardial revascularization. The current data aid in formulating risk assessments to allow clinical decision making. Rates of complications, in particular abrupt closure after PTCA and neurological complications after CABG, among these patients may be higher than generally appreciated and merit special consideration, because data generated in populations without PVD may not be

TABLE 3. Procedural Complications Stratified by Presence or Absence of PVD

	CABG/PVD (n=234)		CABG/no PVD (n=1271)		PTCA/PVD (n=316)		PTCA/no PVD (n=1770)	
Complication	No.	%	No.	%	No.	%	No.	%
Death	5	2.1	16	1.3	7	2.2*	11	0.6
Q-wave MI	17	7.3	55	4.3	8	2.5	44	2.5
Death or Q-wave MI	22	9.4*	70	5.5	14	4.4	53	3.0
Death, MI, or emergency CABG	22	9.4	70	5.5*	29	9.2	113	6.4
Stroke	6	2.6*	10	0.8	0	0.0	3	0.2
Coma	3	1.3†	0	0.0	0	0.0	5	0.3
Emergency CABG	1	0.4	0	0.0	20	6.3	85	4.8
Emergency PTCA	0	0.0	1	0.1	11	3.5	36	2.0
Elective CABG	0	0.0	0	0.0	6	1.9*	76	4.3
Elective PTCA	0	0.0	0	0.0	6	1.9	31	1.8
Death/MI/stroke/coma/emergency CABG/emergency PTCA	28	12.0†	78	6.1	37	11.7*	138	7.8
Death/MI/stroke/coma	28	12.0†	78	6.1	14	4.4	57	3.2
Stroke/coma/TIA/dementia	11	4.7‡	15	1.2	1	0.3	11	0.6
Abrupt closure outside laboratory	0	0.0	0	0.0	10	3.2	34	1.9
Abrupt closure in laboratory	1	0.4	0	0.0	31	9.8	141	8.0

MI indicates myocardial infarction; TIA, transient ischemic attack.

*$P \leq 0.05$. Note: All comparisons are PVD vs no PVD within treatment groups (ie, CABG/PVD vs CABG/no PVD; PTCA/PVD vs PTCA/no PVD).

†$P \leq 0.01$.

‡$P \leq 0.001$.

directly applicable to patients with PVD. The present data pertain to periprocedural risks only, and it should be borne in mind that patients with PVD and left main or 3-vessel CAD may still derive a net long-term benefit from CABG.[3,4,10,11] Direct randomized data in populations with PVD are lacking, however.

That the risks of coronary revascularization are significantly higher among patients with PVD is not unexpected. These patients tend to be older, more frequently are smokers, and have ≥1 major medical coexisting conditions. However, even after multivariate analysis controlling for age and coexisting medical conditions, the presence of PVD remained an independent marker of periprocedural risk. Interestingly, coronary angiographic findings did not differ significantly by presence or absence of PVD (at least for the qualitative variables that could be described). Coronary angiography may have been insensitive in disclosing abnormalities of the vessel wall that may have predisposed to complications such

TABLE 4. Multivariate Logistic Regression Analysis: Odds of Clinical End Points in Patients With PVD

	Death	Death/MI	Death/MI/Stroke/Coma	Stroke/Coma/Dementia	Death/MI/Stroke/Coma/Emergency Revascularization
Randomized and registry patients					
CABG vs PTCA	1.54 (0.38, 6.19)	2.50 (1.16, 5.42)	3.32 (1.58, 6.95)	13.99 (1.76, 111.05)	0.98 (0.56, 1.69)
Congestive heart failure	5.30 (1.26, 22.29)	2.19 (0.87, 5.54)	2.52 (1.08, 5.87)	1.15 (0.23, 5.82)	1.76 (0.84, 3.68)
Renal dysfunction (Cr >1.5)	13.45 (3.07, 58.90)	5.22 (1.78, 15.33)	4.07 (1.41, 11.76)	1.63 (0.19, 14.35)	1.78 (0.67, 4.70)
Treated diabetes mellitus	0.10 (0.01, 0.99)	0.40 (0.15, 1.04)	0.46 (0.20, 1.08)	1.10 (0.30, 3.97)	0.77 (0.41, 1.47)
Randomization	1.54 (0.37, 6.49)	0.60 (0.29, 1.25)	0.67 (0.34, 1.34)	0.97 (0.29, 3.23)	1.05 (0.61, 1.81)
Propensity for CABG	1.77 (0.72, 4.28)	1.99 (1.21, 3.27)	1.19 (1.13, 2.83)	1.35 (0.61, 2.94)	1.54 (1.08, 2.19)
Randomized patients only					
CABG vs PTCA	0.69 (0.16, 3.06)	1.02 (0.38, 2.78)	1.58 (0.63, 3.94)	6.82 (0.81, 57.83)	0.50 (0.24, 1.04)
Congestive heart failure	1.57 (0.27, 9.04)	0.79 (0.16, 3.96)	1.11 (0.29, 4.20)	1.07 (0.12, 9.70)	0.82 (0.26, 2.61)
Renal dysfunction (Cr >1.5)	7.86 (1.65, 37.45)	5.46 (1.52, 19.62)	4.00 (1.16, 13.82)	2.48 (0.26, 23.36)	1.80 (0.55, 5.91)
Treated diabetes mellitus	*	0.51 (0.13, 1.94)	0.54 (0.17, 1.76)	0.96 (0.17, 5.47)	0.83 (0.35, 1.98)

MI indicates myocardial infarction; Cr, creatinine. Values are odds ratios (95% CI).

*Treated diabetes mellitus was not controlled in the multivariate model because of the zero cell problem.

as acute myocardial infarction or abrupt closure. The presence of systemic atherosclerosis may indicate more advanced, aggressive, and high-risk vascular disease, including that of the coronary arterial bed, but this hypothesis remains unproved.

The present study extends previous observations of neuropsychiatric morbidity after CABG.[12,13] Among patients receiving CABG, the presence of PVD correlated with an extraordinarily high risk of stroke. Such patients frequently have atherosclerosis of the ascending aorta and extracranial cerebral vessels, which correlates with a high prevalence of demonstrable systemic atheroembolism at autopsy.[14] The increased incidence of neurological complications after cardiopulmonary bypass and CABG most likely represents a combination of factors, including inherent risk in aortic cannulation in these patients, relatively poor intracranial cerebral perfusion pressure, and atheroembolism.

The present study also has implications for the subset of patients with coronary artery disease undergoing noncardiac procedures. Patients scheduled for peripheral vascular surgery, in particular, are frequently referred for coronary angiography with selective coronary revascularization in an attempt to reduce the risks of subsequent noncardiac surgery.[15–17] Decision analyses have suggested that coronary angiography before vascular surgery only be performed when the risk of vascular surgery is relatively high (>5%) and the anticipated risk of coronary angiography plus selective revascularization is relatively low (<3%).[18,19] Our data would suggest that recommendations to proceed with coronary angiography before noncardiac surgery be made cautiously and not be carried out as a matter of routine clinical practice, but a prospective, randomized trial is needed to address this issue definitively.

Since the BARI study was performed, new revascularization techniques such as rotational atherectomy, intracoronary stents, or minimally invasive surgical approaches to CABG, in which cannulation of the ascending aorta is not required, have been introduced. Whether these newer percutaneous and surgical techniques will result in a lower risk of periprocedural complications among patients with PVD remains to be determined.

Strengths and Limitations

Conclusions drawn on the basis of these data are strengthened by the detailed and careful prospective enrollment of patients as well as the prospective surveillance for complications patients had as part of the main study. Several limitations to these data exist. First, because nonrandomized registry patients were included and baseline randomization (in the trial) was not stratified according to the presence of vascular disease, conclusions pertaining to comparisons between PTCA and CABG treatments should be drawn with caution. Second, patients with single-vessel disease were excluded from enrollment. Thus, these data may not be generalizable to those patients, who may have a lower intrinsic risk of procedural complications. Third, as mentioned above, although this was a relatively recent cohort, advances in both CABG and PTCA techniques have not only continued but even accelerated. Fourth, although no gross coronary anatomic differences between patients with and those without PVD were documented, angiography is limited by the ability to visualize only the lumen of vessels, and it is possible that more severe mural disease of the coronary arteries or diffuse mural disease was not appreciated. Despite some inherent limitations, our data represent the largest recent series of relatively unselected patients with PVD undergoing myocardial revascularization. The presence of PVD was prospectively searched for and identified, minimizing misclassification, selection bias, and major problems with post hoc analyses.

Conclusions and Recommendations

In multivariate analysis, patients with PVD had a significantly higher risk of major periprocedural complications after either CABG or PTCA than patients without PVD. These risks should specifically be taken into account before treatment recommendations are made. In counseling of individual patients, these data aid in the assessment of cumulative risk-benefit ratios. Among patients with PVD, myocardial revascularization may remain indicated if the higher short-term risks are outweighed by future anticipated benefits. Additional clinical research is needed to further define such risks and benefits.

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