

Health-Related Quality of Life After Percutaneous Coronary Intervention Versus Coronary Bypass Surgery in High-Risk Patients With Medically Refractory Ischemia

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OBJECTIVES	We compared six-month health-related quality of life (HRQL) for high-risk patients with medically refractory ischemia randomized to percutaneous coronary intervention (PCI) versus coronary artery bypass graft (CABG) surgery.
BACKGROUND	Mortality rates after PCI and CABG surgery are similar. Therefore, differences in HRQL outcomes may help in the selection of a revascularization procedure.
METHODS	Patients were enrolled in a Veterans Affairs multicenter randomized trial comparing PCI versus CABG for patients with medically refractory ischemia and one or more risk factors for adverse outcome; 389 of 423 patients (92%) alive six months after randomization completed an Short Form-36 (SF-36) health status survey. Primary outcomes were the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36. Multivariable analyses were used to evaluate whether PCI or CABG surgery was associated with better PCS or MCS scores after adjusting for over 20 baseline variables.
RESULTS	There were no significant differences in either PCS scores (38.7 vs. 37.3 for PCI and CABG, respectively; $p = 0.23$) or MCS scores (45.5 vs. 46.1, $p = 0.58$) between the treatment arms. In multivariable models, there remained no difference in HRQL for post-PCI versus post-CABG patients (for PCS, absolute difference = $0.56 \pm$ standard error of 1.14, $p = 0.63$; for MCS, absolute difference = -1.23 ± 1.12 , $p = 0.27$). We had 97% power to detect a four-point difference in scores, where four to seven points is a clinically important difference.
CONCLUSIONS	High-risk patients with medically refractory ischemia randomized to PCI versus CABG surgery have equivalent six-month HRQL. Therefore, HRQL concerns should not drive decision-making regarding selection of a revascularization procedure for these patients. (J Am Coll Cardiol 2003;41:1732-8) © 2003 by the American College of Cardiology Foundation

Multiple studies have demonstrated equivalent mortality between percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) surgery (1-9). At the same time, these investigations have consistently shown that patients who undergo PCI are much more likely to have recurrent angina and to require repeat procedures. Because angina is an important determinant of health-related quality of life (HRQL) (10-12), PCI patients could have worse HRQL outcomes compared with CABG patients despite equivalent mortality. On the other hand, CABG surgery is more invasive, and concerns remain about the impact of cardiopulmonary bypass on neurocognitive outcomes

(13,14). Consequently, it is important to compare HRQL outcomes after PCI versus CABG surgery, because any significant differences may influence the choice of revascularization procedure.

Few randomized trials have included HRQL comparisons after PCI versus CABG surgery, and these studies have had conflicting results (15-19). Furthermore, HRQL outcomes have not been evaluated in high-risk patients, because they have been excluded from randomized trials (1-9,13). Specifically, previous trials have excluded patients with prior heart surgery, very recent myocardial infarction (MI), and severe left ventricular dysfunction.

The Department of Veterans Affairs (VA) Angina With Extremely Serious Operative Mortality (AWESOME) study was specifically designed to compare outcomes after randomization to PCI versus CABG surgery for patients with medically refractory angina who were at high risk for adverse outcome (20). The primary clinical results of the AWESOME study demonstrated equivalent mortality between the PCI and CABG arms (21). The purpose of this study was to compare six-month HRQL outcomes after randomization to PCI versus CABG surgery in the AWESOME trial.

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Manuscript received August 9, 2002; revised manuscript received December 31, 2002, accepted February 13, 2003.

Abbreviations and Acronyms	
AWESOME	= Department of Veterans Affairs Angina With Extremely Serious Operative Mortality study
BARI	= Bypass Angioplasty Revascularization Investigation trial
CABG	= coronary artery bypass graft
CABRI	= Coronary Angioplasty versus Bypass Revascularization Investigation trial
EAST	= Emory Angioplasty Versus Surgery trial
HRQL	= health-related quality of life
IABP	= intra-aortic balloon pump
MCS	= Mental Component Summary
MI	= myocardial infarction
PCI	= percutaneous coronary intervention
PCS	= Physical Component Summary
RITA	= Randomized Intervention Treatment of Angina study
SF-36	= Short Form-36
VA	= Veterans Affairs

METHODS

Study population. The AWESOME randomized controlled trial was conducted at 16 VA medical centers between February 1995 and March 2000. The methods and primary clinical outcomes (mortality, recurrent unstable angina, and repeat revascularization procedure outcomes) have previously been published (20,21). To be enrolled in the AWESOME study, patients had to have evidence of myocardial ischemia refractory to medical management and one or more risk factors for adverse outcome with CABG surgery, including prior open-heart surgery, age >70 years, left ventricular ejection fraction <0.35, MI within seven days, or need for an intra-aortic balloon pump (IABP) to stabilize blood pressure. Eligible patients underwent coronary angiography. Patients with the following criteria were excluded from the study: single-vessel circumflex disease, unprotected left main stenosis >50%, no graftable or dilatable vessels, and/or comorbidity likely to limit patient life expectancy to <6 months. Patients with coronary anatomy deemed acceptable for randomization between PCI and CABG surgery by both the participating cardiothoracic surgeon and interventional cardiologist were approached for informed consent to participate in the trial. Human subject approval was obtained from the Hines Veterans Affairs Cooperative Studies Program Coordinating Center Human Rights Committee and the institutional review boards at all participating sites.

Of the 2,431 patients who met initial eligibility criteria for the study before coronary angiography, 781(32%) had coronary anatomy deemed acceptable for randomization to either revascularization method. These patients were approached for informed consent, and 454 (58%) consented to participate in the study. All patients enrolled in the study who were alive six months after randomization were sent a Short Form-36 (SF-36) health status survey. If patients did

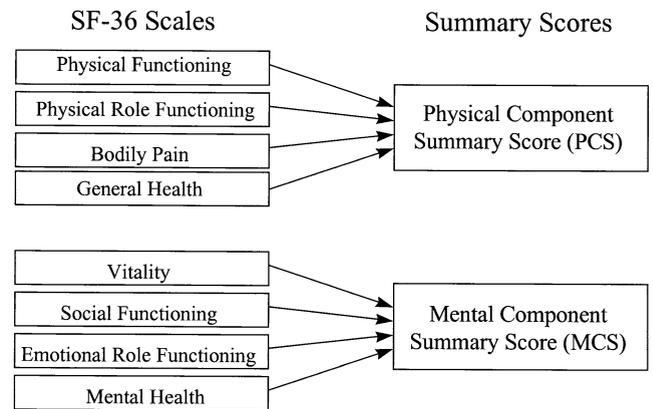


Figure 1. The relationship between the eight original scales of the Short Form-36 (SF-36) and the two summary scores. Figure adapted from Ware and Kosinski (27); reproduced with permission; SF-36 Health Survey, copyright 1988, 2002 by Medical Outcomes Trust and QualityMetric Inc. All rights reserved; SF-36 is a registered trademark of the Medical Outcomes Trust.

not respond to the initial survey, a second mailed survey was sent. If patients failed to return the mailed surveys, telephone administration of the survey was attempted. Of the 454 randomized patients, 423 (93.2%) were alive at six months, and 389 (92%) of these patients completed an SF-36 health status survey. A similar proportion of patients from the PCI group (n = 193, 91.5%) and CABG surgery group (n = 196, 92.5%) completed the SF-36. A six-month HRQL assessment was chosen because there was a reasonable expectation of full recovery from both procedures (e.g., it coincides with the primary timeframe for restenosis after PCI), and because numerous prior studies of HRQL after PCI and CABG surgery have assessed this time period (10,22-25).

Variables. The outcome variables for this study were from the six-month SF-36 health status survey. This survey contains 36 questions that are used to measure eight health constructs including physical functioning, physical role functioning, bodily pain, general health, vitality, social functioning, emotional role functioning, and mental health (26,27). For example, with regard to physical health, patients are asked to rate how much their health limits their ability to do a series of activities ranging from bathing to running. As another example related to mental health, patients are asked to rate how much trouble they have had with work or other regular daily activities due to emotional problems such as feeling depressed or anxious. The complete SF-36 can be viewed at www.sf36.com.

The Physical Component Summary (PCS) and Mental Component Summary (MCS) scores, reflecting overall physical and mental health status, respectively, are derived from the eight original scales of the SF-36 (Fig. 1). The summary scores are standardized to the general U.S. population (mean \pm SD; 50 \pm 10), allowing easier norm-based interpretation. Scoring of the SF-36 for the original eight scales and the PCS and MCS summary scores followed the methods of Ware *et al.* (27).

Table 1. Baseline Characteristics of the Study Population by Treatment Group

Variables	CABG (n = 196)	PCI (n = 193)	p Value
Demographic			
Age, mean (SD), yrs	67.3 (9.1)	67.6 (9.3)	0.80
Age >70 yrs	52.6	52.3	0.97
BSA mean (SD), m ²	2.05 (0.22)	2.06 (0.22)	0.94
Male gender	98.5	98.9	0.67
Race/ethnicity			0.66
Caucasian	88.2	85.3	
African American	5.6	5.8	
Hispanic	5.6	7.4	
Other	0.5	1.6	
Cardiac history			
Prior PCI	21.7	18.1	0.38
Prior CABG surgery	30.1	29.0	0.81
Prior cardiac arrest	2.1	2.2	0.97
MI within 7 days	30.6	34.2	0.45
LVEF <0.35	21.9	17.1	0.23
IABP required to stabilize blood pressure	0.5	2.1	0.17
SBP mean (SD), mm Hg	129.0 (19.6)	127.9 (21.0)	0.61
DBP mean (SD), mm Hg	71.1 (11.5)	71.0 (11.0)	0.96
Pulse, mean (SD), beats/min	68.8 (11.30)	67.0 (13.2)	0.17
Normal sinus rhythm on ECG	91.9	86.1	0.09
Q waves on ECG	33.5	36.7	0.55
New ST- or T-wave changes on ECG	52.1	49.7	0.67
Intravenous nitroglycerin	28.6	32.1	0.45
Beta-blockers	78.9	78.9	0.99
Non-cardiac history			
Serum creatinine, mean (SD), mg/dl	1.27 (0.88)	1.17 (0.35)	0.18
Cerebrovascular disease	19.9	15.5	0.26
Peripheral vascular disease	19.5	12.4	0.07
Chronic obstructive pulmonary disease	25.8	18.6	0.09
Diabetes mellitus	33.9	27.9	0.21
Current smoker	32.6	37.7	0.38
Hypertension	71.9	67.4	0.33

All values expressed as percentages unless otherwise noted.

BSA = body surface area; CABG = coronary artery bypass graft; DBP = diastolic blood pressure; ECG = electrocardiogram; IABP = intra-aortic balloon pump; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention; SBP = systolic blood pressure.

The primary predictor variable of interest for this study was randomization to either PCI or CABG surgery. Other candidate predictor variables included the wide array of demographic, cardiac history, and noncardiac history variables listed in Table 1. There was <5% missing data for all of the Table 1 variables except current smoking (27%) and peripheral vascular disease (6%), and there were no differences in missing data between the PCI and CABG surgery cohorts.

Statistical analyses. The objective of this study was to determine whether patients randomized to PCI versus CABG surgery were at risk for worse six-month physical and/or mental health status outcomes. Primary analyses were conducted with the PCS and MCS scores from the SF-36 as outcome variables. Secondary analyses were conducted using the original eight scales of the SF-36 as outcome variables.

Baseline characteristics of the patients randomized to PCI versus CABG surgery were compared using *t* tests for continuous variables and chi-square tests for categorical variables. We also compared baseline characteristics be-

tween patients who did and did not complete the six-month SF-36 survey. The bivariate relationship between revascularization assignment (PCI vs. CABG) and the SF-36 outcome variables was evaluated using least-squares linear regression. Then, a series of multiple linear regression models were developed to: 1) determine the predictors of PCS and MCS scores for the overall study population, and 2) assess PCI versus CABG surgery as a predictor of HRQL, adjusted for baseline patient characteristics.

Regression models were developed by applying backward selection to the Table 1 variables (*p* < 0.05 to remain in model), and then adding the revascularization variable (PCI vs. CABG) to the selected models. Unselected regression models were also developed including all of the variables listed in Table 1 as well as the revascularization assignment variable (PCI vs. CABG) to maximally control for confounding. The results of the selected and unselected models were similar, and the parameter estimates from the selected models are presented in this article.

Subgroup analyses were performed to compare HRQL outcomes between the PCI and CABG cohorts within the

Table 2. Comparison of Unadjusted Physical and Mental Health Status Outcomes From the SF-36

SF-36 Scale	Mean CABG Cohort Score (95% Confidence Limit)	Mean PCI Cohort Score (95% Confidence Limit)	p Value
Physical health outcomes			
Physical Component Summary	37.3 (35.8–38.9)	38.7 (37.1–40.2)	0.23
Physical functioning	53.7 (49.6–57.9)	56.7 (52.8–60.6)	0.30
Physical role functioning	40.1 (34.0–46.2)	43.8 (37.4–50.3)	0.41
Bodily pain	62.7 (59.3–66.1)	64.8 (61.4–68.3)	0.38
General health	47.2 (43.9–50.5)	49.2 (45.9–52.4)	0.40
Mental health outcomes			
Mental Component Summary	46.1 (44.7–47.6)	45.5 (44.0–47.1)	0.58
Vitality	46.5 (43.2–49.8)	47.1 (43.8–50.4)	0.80
Social functioning	59.0 (54.8–63.1)	60.2 (56.1–64.3)	0.68
Emotional role functioning	65.8 (60.0–71.6)	62.7 (56.5–68.8)	0.47
Mental health	65.9 (63.0–68.7)	65.5 (62.5–68.5)	0.88

CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; SF-36 = Short Form-36.

following patient groups: age >70 years versus <70 years, Caucasian versus non-Caucasian race, and stratified by prior CABG surgery, MI within seven days, diabetes, and chronic obstructive pulmonary disease. These subgroups were chosen because these factors have been associated with HRQL in other studies (28,29).

All analyses were conducted with an intention-to-treat approach based on initial randomization, and there was only one crossover in the PCI cohort and six crossovers in the CABG surgery cohort in the six-month follow-up period. All analyses were done using SAS version 8.02 (SAS Institute, Cary, North Carolina). Power calculations were done using PASS software 2000 (NCSS Statistical Software, Kaysville, Utah). We had 82% power to detect a three-point difference, and 97% power to detect a four-point difference, in PCS and MCS scores between the PCI and CABG cohorts, where four to seven points is considered a minimal clinically important difference (27,30).

RESULTS

Baseline characteristics of the study population are compared between the PCI and CABG surgery cohorts in Table 1. There were no significant differences in demographics, prior cardiac history, and noncardiac history between patients assigned to PCI versus CABG surgery. Overall, the mean age of the study population was 67.4 years, and over one-half of the patients were >70 years old. Approximately 30% of the patients had a history of prior CABG surgery, 32% of the patients had experienced an MI within seven days, 20% had a left ventricular ejection fraction <0.35, and 1.3% required an IABP before randomization. There was a significant burden of comorbidity, including diabetes (31%), chronic obstructive pulmonary disease (22%), and peripheral vascular disease (16%). There were no significant differences in baseline characteristics between those patients that did or did not complete the six-month SF-36 survey except for IABP (1.3% for responders, 5.9% for nonresponders, $p = 0.04$).

Unadjusted physical and mental health status outcomes

are compared between patients assigned to PCI versus CABG surgery in Table 2 and Figures 2 and 3. There were no significant differences in physical or mental health status outcomes between the PCI and CABG cohorts. In subgroup analyses, there were no significant differences in PCS or MCS scores for the age, race, prior CABG surgery, recent MI, diabetes, and chronic obstructive pulmonary disease subgroups. In diabetics, there was a trend toward lower PCS scores for patients assigned to CABG surgery versus PCI (34.7 vs. 38.1, $p = 0.10$), but no difference in MCS scores (46.0 vs. 46.5, $p = 0.83$).

In multivariable analyses, significant predictors of worse six-month physical health status (PCS scores) for the total study population were chronic obstructive pulmonary disease, diabetes, and elevated serum creatinine (Table 3). Significant predictors of worse six-month mental health status (MCS scores) were current smoking and a history of hypertension. Treatment with a beta-blocker was associated with better six-month mental health status.

Revascularization assignment (PCI vs. CABG) was not significantly associated with any of the SF-36 outcome variables in the multivariable models. After adjustment for

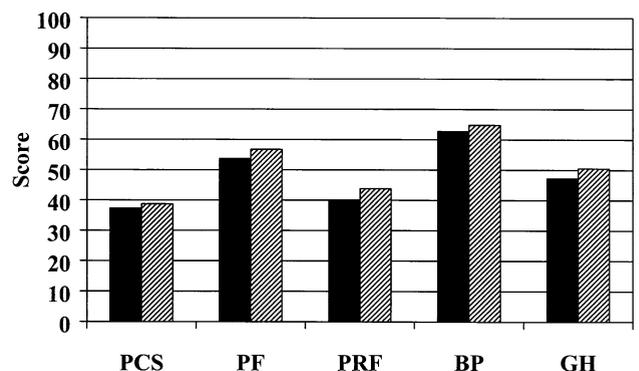


Figure 2. Comparison of Short Form-36 physical health scale scores between patients randomized to percutaneous coronary intervention and coronary artery bypass graft surgery. BP = bodily pain; GH = general health; PCS = Physical Component Summary; PF = physical functioning; PRF = physical role functioning. **Solid bars** = coronary artery bypass graft surgery; **hatched bars** = percutaneous coronary intervention.

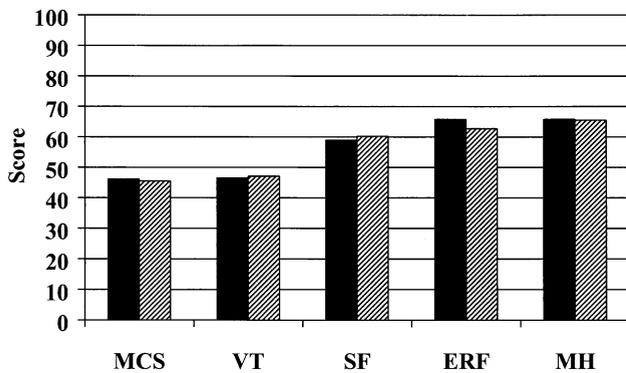


Figure 3. Comparison of Short Form-36 mental health scale scores between patients randomized to percutaneous coronary intervention and coronary artery bypass graft surgery. ERF = emotional role functioning; MCS = Mental Component Summary; MH = mental health; SF = social functioning; VT = vitality. **Solid bars** = coronary artery bypass graft surgery; **hatched bars** = percutaneous coronary intervention.

demographic, cardiac history, and noncardiac history variables, the absolute difference in PCS scores for post-PCI versus post-CABG patients was $0.56 \pm$ standard error of 1.14 ($p = 0.63$), and the absolute difference in MCS scores was $-1.23 \pm$ standard error of 1.12 ($p = 0.27$).

DISCUSSION

The objective of this study was to compare six-month HRQL outcomes for high-risk patients with medically refractory angina who were randomized to PCI versus CABG surgery. We found equivalent HRQL outcomes for the post-PCI and post-CABG patients. Similar results were noted in analyses adjusting for over 20 demographic, cardiac, and comorbid variables, as well as in subgroup analyses.

This study expands the previous literature by the inclusion of high-risk patients excluded from previous trials, namely those with prior heart surgery, age >70 , ejection fraction <0.35 , MI within seven days, and/or need for preprocedure IABP. A previous meta-analysis stated that no firm conclusions could be drawn with regard to outcomes after PCI versus CABG surgery for high-risk patients

Table 3. Multivariable Risk Models for Physical and Mental Component Summary Scores for the Overall Study Population*

Variables	Parameter Estimate (Standard Error)	p Value
Physical Component Summary		
Chronic obstructive pulmonary disease	-3.67 (1.34)	<0.01
Diabetes mellitus	-2.95 (1.18)	0.01
Serum creatinine (per 1 mg/dl increment)	-2.28 (0.86)	<0.01
Mental Component Summary		
Current smoking	-3.64 (1.24)	<0.01
Hypertension	-2.72 (1.18)	0.02
Beta-blockers	+3.06 (1.28)	0.02

*Adjusted for the demographic, cardiac history, and noncardiac history variables listed in Table 1.

because there was only observational data (31). This study helps close this gap in the literature.

Multiple previous studies have demonstrated improvements in HRQL from pre- to postprocedure for both PCI and CABG surgery (10,12,22-25,32), but few studies have compared HRQL outcomes between the two procedures. Furthermore, the results of previous randomized trials comparing HRQL after PCI versus CABG surgery have been inconsistent. The Coronary Angioplasty versus Bypass Revascularization Investigation (CABRI) trial found equivalent one-year HRQL outcomes for patients randomized to PCI versus CABG surgery (15). The Bypass Angioplasty Revascularization Investigation (BARI) trial found better physical function for CABG surgery patients compared with PCI patients in the first three years after revascularization, but HRQL outcomes were equivalent after three years (16,17). Finally, both the Randomized Intervention Treatment of Angina (RITA) study and Emory Angioplasty Versus Surgery Trial (EAST) found that patients randomized to PCI had some HRQL impairment compared with those randomized to CABG surgery (18,19).

Therefore, the results of this study are consistent with both the CABRI and BARI long-term follow-up studies. The reasons why the results of this study, as well as CABRI and BARI, differ from the RITA and EAST trials are unknown. However, the HRQL deficits for PCI patients in RITA and EAST were directly correlated to recurrent angina. One may speculate that advances in PCI such as stents may have reduced post-PCI angina burden. Also, HRQL assessment varied substantially for each study. For example, the EAST trial used physician-assigned angina class as a quality-of-life measure, whereas we used the SF-36 health status survey to quantify overall physical and mental health status as reported by the patient.

Interest in evaluating the outcomes of diabetic patients after coronary revascularization has increased with the publication of subgroup analysis from the BARI trial and observational data demonstrating improved survival among diabetics who undergo CABG surgery compared with PCI (33,34). In the AWESOME study, survival was not significantly different for diabetics receiving CABG surgery versus PCI (35). In our study, diabetes was a predictor of worse physical health status in our overall study population, and we found a trend toward worse physical health status in diabetics assigned to CABG surgery. Thus, it is possible that the survival benefit in diabetics after CABG surgery may be partially offset by worse HRQL. Because both the BARI diabetic substudy and this study evaluated diabetics in subgroup analyses, and because there have been important advances in both CABG surgery (e.g., off-pump bypass) and PCI (e.g., drug-eluting stents), future studies simultaneously evaluating both survival and quality of life after randomization to CABG surgery versus PCI in diabetics with multivessel coronary artery disease are warranted.

A strength of this study was the focus on HRQL

outcomes, which is consistent with the goal of promoting patient-centeredness to improve the quality of care in the U.S. as set forth by the Institute of Medicine (36). Also, many HRQL studies are observational, raising concerns about comparability of patients and concerns about comparison of outcomes. A major strength of this study was the randomized trial design, supporting comparability of the PCI and CABG cohorts with regard to both measured and unmeasured confounders. Additional strengths of this study included the high survey response rate and the use of a validated and reliable tool for the assessment of physical and mental health status (12,26,27). Finally, we had adequate power to detect clinically important differences between the PCI and CABG surgery groups.

Study limitations. Potential limitations of this study should be addressed. First, this clinical trial included a select group of high-risk VA patients. Results may not be generalizable to lower risk patients or to non-VA settings. Second, there was only one assessment of HRQL six months after randomization. Longitudinal assessment would be ideal to evaluate changes over time and the trajectory of HRQL outcomes for the PCI and CABG surgery cohorts. Finally, we only had a general measure of HRQL, and it would be ideal to evaluate both general and disease-specific HRQL.

Conclusions. We found that high-risk patients with medically refractory ischemia randomized to PCI versus CABG surgery have equivalent six-month HRQL outcomes. Therefore, HRQL concerns should not drive decision-making regarding selection of a revascularization procedure for these patients.

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