Percutaneous Coronary Intervention Versus Coronary Bypass Graft Surgery for Diabetic Patients With Unstable Angina and Risk Factors for Adverse Outcomes With Bypass

Outcome of Diabetic Patients in the AWESOME Randomized Trial and Registry

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OBJECTIVES
This study compared survival after percutaneous coronary intervention (PCI) with survival after coronary artery bypass graft surgery (CABG) among diabetics in the Veterans Affairs AWESOME (Angina With Extremely Serious Operative Mortality Evaluation) study randomized trial and registry of high-risk patients.

BACKGROUND
Previous studies indicate that CABG may be superior to PCI for diabetics, but no comparisons have been made for diabetics at high risk for surgery.

METHODS
Over five years (1995 to 2000), 2,431 patients with medically refractory myocardial ischemia and at least one of five risk factors (prior CABG, myocardial infarction within seven days, left ventricular ejection fraction <0.35, age >70 years, or an intra-aortic balloon being required to stabilize) were identified. A total of 781 were acceptable for CABG and PCI, and 454 consented to be randomized. The 1,650 patients not acceptable for both CABG and PCI constitute the physician-directed registry, and the 327 who were acceptable but refused to be randomized constitute the patient-choice registry. Diabetes prevalence was 32% (144) among randomized patients, 27% (89) in the patient-choice registry, and 32% (525) in the physician-directed registry. The CABG and PCI survival rates were compared using Kaplan-Meier curves and log-rank tests.

RESULTS
The respective CABG and PCI 36-month survival rates for diabetic patients were 72% and 81% for randomized patients, 85% and 89% for patient-choice registry patients, and 73% and 71% for the physician-directed registry patients. None of the differences was statistically significant.

CONCLUSIONS
We conclude that PCI is a relatively safe alternative to CABG for diabetic patients with medically refractory unstable angina who are at high risk for CABG.

Randomized clinical trials comparing percutaneous coronary intervention (PCI) with coronary artery bypass graft surgery (CABG) have demonstrated comparable long-term survival (1–11) in most patient populations, with the important exception of diabetics. The Bypass Angioplasty Revascularization Investigation (BARI) study (12,13) showed a significant and sustained survival benefit for CABG at five years in treated diabetics, and similar findings were noted in other randomized studies and large databases (2,14). These findings are reflected in current guidelines which favor CABG over PCI in most diabetics with two- or three-vessel coronary artery disease (CAD) who require revascularization (15,16). Such recommendations are not...
universally accepted because contemporary PCI, characterized by widespread use of stents and glycoprotein IIb/IIIa receptor blocking drugs, is more effective in diabetics than the balloon angioplasty techniques used in BARI.

The choice of revascularization remains uncertain. Several studies have failed to demonstrate a survival benefit for CABG over PCI in diabetics (3,17). Even the BARI registry showed comparable survival for diabetics who chose PCI over CABG (18). The choice of revascularization for diabetic patients who are at high risk for CABG is also uncertain. These patients might have equivalent or superior outcomes with a less invasive PCI procedure. The recently concluded, Angina With Extremely Serious Operative Mortality Evaluation (AWESOME), was a randomized clinical trial of PCI versus CABG among patients with medically refractory ischemia who were at high risk for CABG because of one or more of the following high-risk factors: prior heart surgery; myocardial infarction (MI) within seven days; left ventricular ejection fraction (LVEF) <0.35; age >70 years; intra-aortic balloon being required to stabilize (19,20). Eligible patients who were deemed by study physicians to be suitable for both CABG and PCI were asked to participate in the randomized trial. Eligible patients who were acceptable to both operators as candidates for either CABG or PCI but who refused to be randomized were entered into a prospective patient-choice registry. This article reports the outcomes of the high-risk diabetic patients in the randomized clinical trial and the physician-directed and patient-choice registries of the AWESOME study.

**METHODS**

The AWESOME was a nationwide, prospective, randomized clinical trial designed to compare CABG and PCI survival for patients with medically refractory unstable angina and at high risk of adverse outcomes with CABG. Patients were enrolled at 16 Veterans Affairs medical centers over a five-year period (1995 to 2000). The AWESOME protocol, baseline characteristics, and survival for the randomized patients have been previously reported (19,20).

Screening identified 2,431 clinically eligible patients who met the three criteria (medically refractory, unstable angina, at least one additional high-risk factor). Medically refractory was defined as anginal symptoms despite aspirin and/or heparin and control of heart rate and blood pressure as previously described (19). Unstable angina was defined as rest angina with electrocardiographic changes or known CAD; recurrent rest angina; or stabilized rest angina with a subsequent positive stress test. High risk for CABG was defined as age >70 years, one or more prior open-heart operations, LVEF <0.35, MI within seven days, or intra-aortic balloon pump necessary. The diagnosis of MI required hospitalization and cardiac enzyme or troponin elevation. After coronary angiography had been reviewed by both interventional cardiologist and surgeon, 781 (32%) who were acceptable to both operators as candidates for CABG or PCI were approached for informed consent, and 454 (58%) consented to a randomized choice of revascularization. Randomization was stratified by age and prior heart surgery. The 327 patients who refused random allocation were entered into a patient-choice registry. The 1,650 patients for whom physician consensus would not allow random assignments were entered into a physician-directed registry. Patient data, including the presence or absence of diabetes, were entered by the study nurses into an interactive data management system as previously described (19).

**Statistical analysis.** Differences in baseline variable frequencies were judged by chi-square tests. Long-term survival was measured by Kaplan-Meier survival estimates, which were plotted. The statistical significance of global differences between survival curves was judged by log-rank tests. Differences between CABG and PCI 36-month
survival were computed along with z tests of the differences. All comparisons of randomized patients are based on intention to treat.

RESULTS

Patients treated with either insulin or oral hypoglycemic drugs were classified as diabetic for the purposes of this study. Among the 144 randomized diabetic patients, 79 were assigned to CABG and 65 to PCI. Among the 525 physician-directed diabetic patients, 238 were selected for CABG, 194 for PCI, and 93 received medical care. Among the 89 patient-choice diabetic patients, 20 chose CABG, 65 chose PCI, and four patients chose medical care.

Table 1 presents baseline characteristics of randomized, all registry, physician-directed, and patient-choice diabetic patients. The randomized and registry diabetic patients have similar baseline profiles except for prior CABG and Thrombolysis in Myocardial Infarction (TIMI) no flow, which have higher rates in the registry, and the differences are statistically significant (chi-square; p < 0.05). The physician-directed and patient-choice patients have similar baseline profiles except for number of vessel diseases, which has a higher rate of three-vessel disease in the physician-directed patients and for which the difference is statistically significant (chi-square; p < 0.01).

Table 2 presents baseline characteristics of randomized, physician-directed, and patient-choice diabetic patients assigned to CABG or PCI. The baseline characteristics of diabetic patients randomized to CABG or PCI are similar, and none of the differences is statistically significant. Both physician-directed and patient-choice patients assigned to CABG have significantly higher rates of older patients. Physician-directed patients assigned to CABG have significantly higher rate of three-vessel disease and lower rates of prior PCI, prior CABG, prior MI, and TIMI no flow.
relative to physician-directed patients assigned to PCI. Patient-choice patients assigned to CABG have significantly lower rates of three-vessel disease and show lower rates relative to those assigned to PCI for prior CABG, prior MI, and TIMI no flow, but the differences are not statistically significant. The lower rate of prior CABG in both physician-directed and in patient-choice registries was also observed among the non-diabetic patients. This pattern may reflect the reluctance of physicians to operate on patients with a patent left internal mammary artery to the left anterior descending coronary artery.

Table 3 presents short-term outcomes of randomized and registry patients assigned to CABG or PCI. The large majority of patients assigned to revascularization were revascularized, and over 96% were revascularized as assigned (94% assigned to CABG received CABG; 98% assigned to PCI received PCI). Approximately 80% of the CABG patients received left internal mammary artery (78%, 78%, and 79% of the randomized, physician-directed, and patient-choice, respectively); the corresponding right internal mammary artery frequencies were 3%, 2%, and 0% for the randomized, physician-directed, and patient-choice, respectively. The CABG and PCI survival to 30 days and to six months did not differ significantly. Overall in-hospital mortality in the 324 diabetic patients treated by PCI did not differ significantly from the in-hospital mortality in the 337 diabetics treated by CABG (4% vs. 7%).

Table 4 presents 36-month CABG and PCI survival, survival free of recurrent unstable angina, and survival free of unstable angina or repeat revascularization for the randomized, physician-directed, and patient-choice diabetic

<table>
<thead>
<tr>
<th>Outcome</th>
<th>CABG</th>
<th>PCI</th>
<th>Difference</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomized</td>
<td>72%</td>
<td>81%</td>
<td>−9%</td>
<td>9%</td>
</tr>
<tr>
<td>Physician-directed</td>
<td>73%</td>
<td>71%</td>
<td>−2%</td>
<td>6%</td>
</tr>
<tr>
<td>Patient choice</td>
<td>85%</td>
<td>89%</td>
<td>−4%</td>
<td>11%</td>
</tr>
<tr>
<td>Survival free of unstable angina</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomized</td>
<td>61%</td>
<td>61%</td>
<td>0%</td>
<td>14%</td>
</tr>
<tr>
<td>Physician-directed</td>
<td>62%</td>
<td>44%</td>
<td>18%</td>
<td>10%</td>
</tr>
<tr>
<td>Patient choice</td>
<td>72%</td>
<td>53%</td>
<td>19%</td>
<td>20%</td>
</tr>
<tr>
<td>Survival free of unstable angina or repeat revascularization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomized</td>
<td>54%</td>
<td>49%</td>
<td>5%</td>
<td>18%</td>
</tr>
<tr>
<td>Physician-directed</td>
<td>59%</td>
<td>38%</td>
<td>21%</td>
<td>12%</td>
</tr>
<tr>
<td>Patient choice</td>
<td>72%</td>
<td>46%</td>
<td>26%</td>
<td>22%</td>
</tr>
</tbody>
</table>

Abbreviations as in Table 3.

Figure 1. Kaplan-Meier five-year survival curves of coronary artery bypass graft surgery (CABG) (circle) and percutaneous coronary intervention (PCI) (cross) for randomized patients.
Figure 2. Kaplan-Meier five-year survival curves of CABG (circle) and PCI (cross) for physician-directed patients. Abbreviations as in Figure 1.

Figure 3. Kaplan-Meier five-year survival curves of CABG (circle) and PCI (cross) for the patient-choice cohort. Abbreviations as in Figure 1.
Figure 4. Kaplan-Meier curves of CABG (circle) and PCI (cross) five-year survival free of unstable angina for randomized patients. Abbreviations as in Figure 1.

Figure 5. Kaplan-Meier curves of CABG (circle) and PCI (cross) five-year survival free of unstable angina for physician-directed patients. Abbreviations as in Figure 1.
The table also shows the CABG-PCI differences and the standard errors of the differences.

Figures 1 to 3 present the five-year Kaplan–Meier survival curves and a global log-rank test of CABG versus PCI survival differences over the five-year period for randomized patients and the two registry cohorts. The CABG and PCI number of patients (N) for each time period are shown at the bottom of the plots. None of the three log-rank tests is statistically significant.

Figures 4 to 6 present the five-year Kaplan–Meier survival free of unstable angina and a global log-rank test of CABG versus PCI survival differences over the five-year period for randomized patients and the two registry cohorts. The log-rank test for the physician-directed cohort is statistically significant (p < 0.0001).

Figures 7 to 9 present the five-year Kaplan–Meier survival free of unstable angina and repeat revascularizations and a global log-rank test of CABG versus PCI survival differences over the five-year period for randomized patients and the two registry cohorts. The log-rank test for the physician-directed cohort is statistically significant (p < 0.0001).

Table 5 shows the percent of diabetic patients allocated to CABG overall and for selected high-risk subsets. The percent allocated to PCI is the complement of the percent allocated to CABG. For example, the 55% of all physician-directed diabetic patients allocated to CABG implies that the remaining 45% were allocated to PCI. Table 5 shows that the choice of CABG differs greatly between the two registry cohorts (55% in physician-directed vs. 24% in patient-choice). The difference between these two cohorts is large and statistically significant (p < 0.01). Table 5 also shows how the presence of other high-risk factors influences the choice of revascularization within the two registry cohorts. Within the physician-directed cohort, 77% of the age >70 patients were allocated to CABG versus 44% for the younger patients. This large and statistically significant difference suggests that physicians favor CABG over PCI for older patients. Physicians appear to favor PCI over CABG for patients with prior CABG or prior PCI. The other high-risk factors do not appear to change preferences in the physician-directed cohort. Among the patient-choice cohort, older patients are more likely to receive CABG than younger diabetic patients (33% vs. 14%), but both age groups favor PCI over CABG. The other high-risk factors do not appear to change patient preference for PCI in the patient-choice cohort.
DISCUSSION

The outcome of diabetic patients in the AWESOME randomized trial and registry suggests that PCI is a reasonable option for diabetics with two- or three-vessel CAD and medically refractory angina who are at risk for adverse outcomes with CABG because of prior CABG, recent MI, poor left ventricular function, age >70, or instability necessitating intra-aortic balloon pump (19–21). There is no survival advantage with CABG, but there is less recurrent unstable angina and the need for repeat revascularization with surgery.

Diabetes is associated with adverse outcomes for both CABG and PCI (17). Operative mortality for CABG is higher for diabetics than for non-diabetics (22–29), and diabetes is an important risk factor for the development of serious postoperative complications, including renal failure and sternal wound infection (30–33). Complications of CABG in diabetics result in a significant clinical and economic burden (34–38), underscoring the importance of alternative therapies for diabetic patients, especially for diabetic patients at high risk for CABG. Unfortunately, mortality for PCI is also higher for diabetics than for non-diabetics (39–45), and restenosis rates are significantly higher for diabetics than for non-diabetics (with restenosis rates for balloon angioplasty approaching 50%). Previously reported data do not provide support for either CABG or PCI as an initial strategy for diabetics with multivessel CAD who are at high risk for adverse outcomes with CABG.

There are important differences between the AWESOME study and earlier studies such as BARI and the Emory Angioplasty Surgery Trial (EAST) which showed a benefit for CABG in diabetics. The AWESOME study enrolled patients at higher risk for adverse outcomes with CABG than were enrolled in BARI and EAST. For example, patients with prior CABG were excluded from BARI and EAST. This may have had an important influence on the outcome of the study. A recent analysis of mortality in the BARI study showed that approximately 50% of the survival benefit for CABG in the diabetic patients could be explained by a lower mortality during Q-wave MI. In contrast, there was no difference in the incidence of Q-wave MI between diabetics undergoing CABG or PCI (46). Although Q-wave MI was relatively rare in diabetics enrolled in the study (8% incidence in five-year follow-up), the mortality rate strikingly was sevenfold higher in diabetics randomized to angioplasty compared with CABG (46). Importantly, this survival benefit...
Figure 8. Kaplan-Meier curves of CABG (circle) and PCI (cross) five-year survival free of unstable angina and repeat revascularizations for physician-directed patients. Abbreviations as in Figure 1.

Figure 9. Kaplan-Meier curves of CABG (circle) and PCI (cross) five-year survival free of unstable angina and repeat revascularizations for the patient-choice cohort. Abbreviations as in Figure 1.
for CABG was almost entirely limited to patients who received at least one internal mammary artery graft (46). These findings have therapeutic implications. Firstly, diabetic patients with prior CABG (especially those with durable patent internal mammary grafts) might be expected to retain a survival benefit from their first operation and so conceivably would have less benefit from a re-operation compared with the benefit of angioplasty. This hypothesis was not tested in BARI because all patients with prior CABG were excluded from the trial. Secondly, the outcome of MI in diabetics has improved in recent years (even in very high-risk groups) as a result of intensive therapy with angiotensin-converting enzyme inhibitors (47), insulin (48), and early revascularization (49). These advances in therapy of MI would be expected to narrow the difference in survival between diabetics with CAD treated by an initial strategy of CABG or PCI.

Another major cause of the difference between the outcomes in the BARI study and the outcomes that can be expected today with PCI in diabetics is the widespread use of stents and glycoprotein IIb/IIIa receptor blockers in contemporary practice. The BARI study enrolled patients between 1988 and 1991, and balloon angioplasty was the only procedure performed in patients randomized to the PCI arm of BARI. It has now been recognized that stents and glycoprotein IIb/IIIa receptor blockers reduce restenosis and long-term mortality in diabetics with multi-vessel disease. Diabetic patients were a prospectively defined subset in the multicenter Evaluation of Platelet IIb/IIIa Inhibitor for Stenting Trial (EPISTENT) in which patients were randomized to stent-placebo, stent-abciximab, or balloon-abciximab (50). The combined six-month rate of death, MI, or target-vessel revascularization occurred in 25.2% of stent-placebo, 23.4% of balloon-abciximab, and only 13.0% of stent-abciximab patients in that study (p = 0.005). The one-year mortality rate for diabetics in EPISTENT was 4.1% for stent-placebo and 1.2% for stent-abciximab patients (p = 0.11). In the AWESOME study, overall use of stents was 54% and overall use of glycoprotein IIB/IIIa antagonists was 11% (20,21).

The outcome of diabetic patients randomized between April 1997 and June 1998 to either CABG or PCI with stenting in the Arterial Revascularization Therapy Study (ARTS) trial has been recently published (50). In that study, event-free one-year survival in diabetics treated with stenting was 63.4% compared with 84.4% with CABG (p < 0.001). In contrast, there was no difference in outcomes at one year among non-diabetics. Importantly, ARTS excluded all patients with prior CABG, MI within one week, ejection fraction <30%, and prior stroke. Thus the findings of ARTS cannot be extrapolated to the high-risk population enrolled in AWESOME. Furthermore, the long-term outcome of diabetics enrolled in ARTS is still unknown.

### Table 5. Percentage Allocation to CABG Among Randomized, Physician-Directed, and Patient-Choice Diabetic Patients by High-Risk Baseline Subsets

<table>
<thead>
<tr>
<th>High-Risk Subset</th>
<th>Randomized (n = 144)</th>
<th>Physician-Directed (n = 432)</th>
<th>Patient Choice (n = 85)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All diabetics (%)</td>
<td>55</td>
<td>55</td>
<td>24</td>
</tr>
<tr>
<td>Age &gt;70 (%)</td>
<td>60</td>
<td>77†</td>
<td>33*</td>
</tr>
<tr>
<td>Age ≤70 (%)</td>
<td>50</td>
<td>40</td>
<td>14</td>
</tr>
<tr>
<td>Prior CABG (%)</td>
<td>63</td>
<td>25†</td>
<td>18</td>
</tr>
<tr>
<td>No prior CABG (%)</td>
<td>51</td>
<td>74</td>
<td>28</td>
</tr>
<tr>
<td>MI &lt; 7 days (%)</td>
<td>49</td>
<td>60</td>
<td>19</td>
</tr>
<tr>
<td>No MI &lt; 7 days (%)</td>
<td>58</td>
<td>53</td>
<td>26</td>
</tr>
<tr>
<td>Prior MI (%)</td>
<td>54</td>
<td>50†</td>
<td>18</td>
</tr>
<tr>
<td>No prior MI (%)</td>
<td>57</td>
<td>61</td>
<td>27</td>
</tr>
<tr>
<td>LVEF &lt; 0.35 (%)</td>
<td>60</td>
<td>52</td>
<td>24</td>
</tr>
<tr>
<td>LVEF &gt; 0.35 (%)</td>
<td>54</td>
<td>56</td>
<td>24</td>
</tr>
<tr>
<td>IABP (%)</td>
<td>50</td>
<td>44</td>
<td>0</td>
</tr>
<tr>
<td>No IABP (%)</td>
<td>55</td>
<td>56</td>
<td>24</td>
</tr>
<tr>
<td>Prior PCI (%)</td>
<td>59</td>
<td>35†</td>
<td>35</td>
</tr>
<tr>
<td>No prior PCI (%)</td>
<td>54</td>
<td>60</td>
<td>21</td>
</tr>
<tr>
<td>Prior CHF (%)</td>
<td>77</td>
<td>49</td>
<td>33</td>
</tr>
<tr>
<td>No prior CHF (%)</td>
<td>53</td>
<td>56</td>
<td>23</td>
</tr>
</tbody>
</table>

Statistically significant difference between overall and risk group percent allocation to CABG: *p < 0.05, †p < 0.01.

IABP = intra-aortic balloon pump. Other abbreviations as in Table 1.

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APPENDIX

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