Randomized, Controlled Trial of Coronary Artery Bypass Surgery Versus Percutaneous Coronary Intervention in Patients With Multivessel Coronary Artery Disease
Six-Year Follow-Up From the Stent or Surgery Trial (SoS)

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Background—The Stent or Surgery Trial is a randomized, controlled trial comparing percutaneous coronary intervention with coronary artery bypass grafting (CABG) for patients with multivessel disease. Initial results at a median follow-up of 2 years showed a survival advantage for patients randomized to CABG. This article reports survival outcome at a median follow-up of 6 years.

Methods and Results—A total of 988 (n=488 percutaneous coronary intervention, n=500 CABG) patients were randomized at 53 centers during the period from 1996 to 1999. Investigators established survival status from hospital or community medical records or national databases or by direct contact with patients and their relatives. All-cause mortality was compared with hazard ratios and confidence intervals calculated from Cox proportional hazards models. Prespecified subgroup analyses for diabetes mellitus, angina grade, and angiographic severity of coronary disease at baseline were performed with tests for interaction. At a median follow-up of 6 years, 53 patients (10.9%) died in the percutaneous coronary intervention group compared with 34 (6.8%) in the CABG group (hazard ratio 1.66, 95% confidence interval 1.08 to 2.55, \(P=0.022\)). Little evidence was found that the treatment effect on mortality differed between subgroups according to baseline angina grade (interaction test \(P=0.52\)), the severity of coronary disease \((P=0.92)\), or diabetic status \((P=0.15)\).

Conclusions—At a median follow-up of 6 years, a continuing survival advantage was observed for patients managed with CABG, which is not consistent with results from other stent-versus-CABG studies. (Circulation. 2008;118:381-388.)

Key Words: trials ■ stents ■ angioplasty ■ coronary disease ■ mortality ■ surgery

A number of randomized trials have compared revascularization by percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) in the management of coronary artery disease.1,2 Only the more recent studies3–6 have involved the routine use of coronary stents. The Stent or Surgery (SoS) trial is an international, multicenter trial that randomized patients with multivessel coronary artery disease to revascularization with CABG or PCI with bare-metal stent technology.

At a median follow-up of 2 years, the incidence of all-cause mortality in patients managed with PCI was 4.5% \((n=22)\) compared with 1.6% \((n=8)\) for patients managed with CABG (hazard ratio 2.91, 95% confidence interval [CI] 1.29 to 6.53, \(P=0.01\)). The study was not designed or powered to detect differences in mortality, and this finding was unexpected.

A meta-analysis of 4 randomized trials, Arterial Revascularization Therapies Study (ARTS), Argentine Randomized Study (ERACI II), SoS, and the Medicine, Angioplasty, or Surgery Study for multivessel coronary artery disease (MASS II), reported no difference in mortality at 1 year for patients managed with PCI or CABG.7 More recently, ARTS, ERACI II, and MASS II have reported 5-year clinical outcomes and found no difference in mortality between the 2 revascularization strategies.8–10 The aim of the present study was to report long-term survival in the SoS trial and to examine outcomes in subgroups, including patients with diabetes mellitus, prespecified in the original trial analysis plan.
Methods

The design and principal results of the trial have been published previously.\textsuperscript{2,11–13} Patients were recruited from 53 study centers in 11 European countries and Canada between November 5, 1996, and December 12, 1999. Patients with multivessel coronary artery disease were considered for inclusion and enrolled if the consensus view of the trial surgeon and interventionist was that revascularization was clinically indicated and appropriate by either strategy. Patients were excluded if they had previous thoracotomy or coronary revascularization or required intervention for pathology of the valves, great vessels, or aorta. Trial operators were required to perform optimum coronary revascularization in accordance with current local practice. Interventionists were permitted to use any commercially available stent. No protocol restrictions were in place with respect to anesthesia, equipment, technique or adjunctive medication schedules. Equivalent revascularization was encouraged but not mandatory. Incomplete revascularization was defined as a residual stenosis >50% or residual stenosis <50% with Thrombolysis In Myocardial Infarction (TIMI) flow <3 in at least 1 epicardial artery or principal branch. The primary outcome of the trial was the rate of repeat revascularization after the index procedure. Secondary outcomes included death or nonfatal Q-wave myocardial infarction, all-cause mortality, symptoms of angina, medication requirements, cost and cost-effectiveness at 1 year, and neuropsychological outcomes (performed in a substudy of 143 patients).

Ethical Approval

All study centers had appropriate local ethics committee approval for the trial, and all patients recorded their informed consent for participation on consent forms printed in the local language and approved by the local ethics committees.

Six-Year Follow-Up

The requests for follow-up data were initiated after the last patient randomized into the study had accrued 5 years of follow-up. A total of 30 patients died during the initial trial follow-up of SoS, and all of these events had been scrutinized by a clinical events committee.\textsuperscript{4} Investigators were asked to evaluate the survival status of all other patients from hospital or community medical records or national databases or by direct contact with patients or their relatives. The cause of death was reported if known, and investigators were requested to classify the cause of death as cardiac, vascular, cancer, other noncardiovascular, or unknown. Reported sudden deaths were classified as cardiac. For individual patients, the date of death or the last date on which the patient was known to be alive was used in the statistical analyses.

Statistical Analysis

Analyses were based on the intention-to-treat principle. All tests of significance were 2-sided. A comparison was made between the treatment groups for all-cause mortality. The hazard ratio and CI were calculated from a Cox proportional hazards model. In accordance with the original trial analysis plan, outcome measures were also analyzed after adjustment for age, angina grade, diabetes mellitus, left ventricular ejection fraction, and angiographic severity of coronary disease at baseline. Subgroup analyses, prespecified in the original analysis plan, were performed for diabetes mellitus, angina grade, and angiographic severity of coronary disease at baseline (2-vessel disease versus 3-vessel disease). Hazard ratios and CIs were calculated for each subgroup together with formal tests for interaction. To facilitate comparison with other studies, additional data are presented for mortality at 5 years. Kaplan-Meier estimates were used for the event rates and comparisons at 5 years. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript as written.

Results

Trial Profile

The trial profile is shown in Figure 1. In the PCI group, 1 patient died while waiting for revascularization, and 7 patients received CABG as the index procedure. In the CABG group, 2 patients refused any revascularization procedure and were treated medically. A further 11 patients randomized to CABG received a PCI procedure. Clinical follow-up was available on 100% of patients at 1 year. The mortality status
of 479 (98%) of 488 patients randomized to PCI and 485 (97%) of 500 patients randomized to CABG was available at 5 years.

### Baseline Characteristics

Baseline characteristics, presented in Table 1, were similar between the 2 groups. The mean age of participants was 61 years, and 79% were men. Severe angina (Canadian Cardiovascular Society class 3 or 4) was present in 46% of patients, and 24% had an acute coronary syndrome as the presenting complaint. Two-vessel disease was present in 57% of patients, and 42% had 3-vessel disease. At the time of randomization, 3 patients had 1-vessel disease, which represents a breach of protocol. These patients were included in all analyses. One and 2 vessels were occluded in 15% and 2% of patients, respectively.

### Procedural Details

A summary of procedural details is presented in Table 1. In the patients who received PCI as allocated, 94% of attempted lesions were successfully revascularized (mean of 2.7 lesions and 2.0 epicardial vessels per patient). Stents were implanted in 78% of lesions, 16% of lesions had balloon angioplasty, and 6% of lesions were not revascularized. In the 487 patients who received CABG as allocated, the mean number of bypass grafts was 2.8 per patient. A pedicle left internal mammary artery graft was used in 81% of patients. Bilateral internal mammary grafts (left and right internal mammary artery) were used in a further 11% of patients. Additionally, 1% of patients had an isolated right internal mammary artery graft. Hence, some form of internal mammary conduit was used in 93% of individuals. Seven percent of the trial population did not manifest disease of the left anterior coronary artery at baseline. Sixteen procedures were performed without cardiopulmonary bypass.

### Clinical Outcomes at Median Follow-Up of 2 Years

A summary of clinical outcomes from the initial report is presented in Table 1. Patients allocated to PCI had a higher rate of repeat revascularization (20.7%; n = 110) than patients managed with CABG (6.0%; n = 30; hazard ratio 3.85, 95% CI 2.56 to 5.79, P < 0.001). The incidence of death or nonfatal Q-wave myocardial infarction was similar in both groups (9.4% [n = 46] in the PCI group and 9.8% [n = 49] in the CABG group; hazard ratio 0.95, 95% CI 0.63 to 1.42, P = 0.80; Figure 2). Death occurred in 4.5% (n = 22) of the PCI group compared with 1.6% (n = 8) of the CABG group (hazard ratio 2.91, 95% CI 1.29 to 6.53, P = 0.01).

### Mortality Follow-Up at 6 Years

At a median follow-up of 6 years (maximum 8 years), 53 patients (10.9%) had died in the PCI group compared with 34 (6.8%) in the CABG group (hazard ratio 1.66, 95% CI 1.08 to 2.55, P = 0.022; Figure 3). An analysis adjusted for specified baseline variables yielded similar results.

Table 2 shows the classification of the cause of death as reported by investigators or adjudicated by a clinical events committee for early deaths. A difference was observed in the numbers of events due to noncardiovascular causes (PCI: 25, CABG: 11), a finding also noted in the initial trial report (PCI = 9, CABG = 3). The majority of these deaths were reported as being cancer related (20 in the PCI group and 8 in the CABG group). Little evidence was found that the treatment effect on mortality differed between subgroups according to baseline angina grade (interaction test P = 0.52) or the severity of coronary disease (P = 0.92; Figure 2).

Other studies have published survival data to 5 years. To facilitate comparison, we observed that in SoS, at 5 years, 39 deaths (8.1%) had occurred in the PCI group compared with...
21 (4.3%) in the CABG group, an absolute risk difference of 3.8% (95% CI 0.8% to 6.8%, \(P = 0.014\)).

**Diabetic Patients**

In the SoS trial, outcomes in diabetic patients have not been the subject of an independent publication. Slightly more insulin-dependent patients were in the PCI group (19 [4%] versus 9 [2%] in the CABG group), but fewer patients had their illness controlled with oral hypoglycemic agents or diet alone in the PCI group (49 [10%] versus 65 [13%] in the CABG group). Beyond this, no systematic differences in baseline characteristics could be observed between diabetic and nondiabetic patients in the 2 revascularization groups.

Clinical outcomes at a median follow-up of 2 years are shown in Table 3. At this stage of follow-up, little evidence was found of a difference in the impact of treatment strategy on outcomes in diabetic and nondiabetic patients.

Mortality results at a median follow-up of 6 years for diabetic and nondiabetic patients are summarized in Figure 2. Among the diabetic patients, 17.6% of patients (12 of 68) died in the PCI group compared with 5.4% (4 of 74) in the CABG group. Among the nondiabetic patients, 9.8% of patients (41 of 420) died in the PCI group compared with 7.0% (30 of 426) in the CABG group. The statistical test for interaction gave little evidence that the treatment effect on mortality differed between diabetic and nondiabetic patients (\(P = 0.15\)). Furthermore, among patients randomized to CABG, the mortality rate for diabetic patients (5.4%) was less than that for nondiabetic patients (7.0%), and mortality was higher in the PCI arm for both diabetic and nondiabetic patients.

**Discussion**

In SoS, we found that patients with multivessel disease managed with CABG rather than PCI had a lower mortality...
rate at a median follow-up of 6 years. Theoretical reasons exist why CABG may offer a mortality advantage over PCI. A functioning bypass graft will continue to protect a native coronary vessel, even if it is subject to disease progression or abrupt closure at any site proximal to the graft anastomosis. CABG revascularization sometimes is associated with more complete revascularization, particularly if native vessels are occluded at presentation. Observational studies of PCI practice have suggested that failure to successfully reopen an occluded vessel at PCI is associated with an increased subsequent mortality. Finally, CABG may provide a more appropriate method of revascularization for patients with long-segment or diffuse disease, a pattern often seen in patients with diabetes mellitus.

The survival advantage for patients managed with surgery in SoS was not observed in comparable studies. The ARTS, ERACI II, and MASS II studies have now reported 5-year clinical outcomes. Although all trials were a comparison of treatment strategies for patients with multivessel disease, some important differences were present in patient populations, procedural requirements, and end-point definitions. In brief, ARTS excluded high-risk PCI, and approximately two thirds of patients had 2-vessel disease. Equivalent revascularization was mandated in ARTS and encouraged in SoS and MASS II, whereas functional revascularization was required in ERACI II. SoS was a pragmatic study with minimal restriction on patient selection, procedure performance, and adjunctive therapy schedules.

In SoS, the 5-year PCI mortality rate was as expected (8.1%) and was similar to that in ARTS (8.0%) and ERACI II (7.1%) but lower than that in MASS II (11.6%). The higher PCI mortality rate in the MASS II study was attributed by the authors to higher-risk patients enrolled. In this latter study, the majority of patients had triple-vessel disease, and 93% had proximal left anterior descending artery involvement. The nature and completeness of PCI revascularization in SoS were similar to the other studies. Among PCI patients, ARTS (72%) had the highest proportion of patients with complete revascularization compared with SoS (54%), ERACI II (51%), and MASS II, which had the lowest (41%). In SoS, 97% of patients received at least 1 stent, and overall median stent use was 2.0 per patient, which is a favorable comparison to ARTS, which had a protocol requirement for 2 stents per patients, and ERACI II, which reported a mean of 1.4 stents per patient. In MASS II, 72% of patients received at least 1 stent.

SoS is remarkable for the low observed mortality in patients managed with surgery: At 5 years, the mortality rate in the CABG arm was 4.3% compared with 7.6% in ARTS, 11.5% in ERACI II, and 7.9% in MASS II. In the surgical groups, the proportion of patients with complete surgical revascularization was high in all studies (SoS 86%, ART 84%, and ERACI II 85%). Internal mammary artery use was also consistently high: SoS 97%, ART 93% (reported arterial conduits), and MASS II 92%, and ERACI II 89%.

Individual studies have low to moderate power to detect a difference in mortality, and a meta-analysis of randomized, controlled trials may help provide more robust information. Hoffman and colleagues reported a meta-analysis of pooled data from 13 randomized, controlled trials comparing percutaneous transluminal coronary angioplasty (PTCA) with CABG (only 4 trials used stents) that recruited 7964 patients. Combining all trials, and at 5-years follow-up, there was a significant survival advantage for patients managed with CABG, with an absolute risk difference approaching 2%.

### Table 2. Classification of Death at Median Follow-Up of 6 Years

<table>
<thead>
<tr>
<th>Category</th>
<th>PTCA</th>
<th>CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>22</td>
<td>17</td>
</tr>
<tr>
<td>Cardiac</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Vascular</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Noncardiovascular</td>
<td>25</td>
<td>11</td>
</tr>
<tr>
<td>Cancer</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Unknown</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>34</td>
</tr>
</tbody>
</table>

### Table 3. Clinical Outcomes in Diabetic and Nondiabetic Patients at Median Follow-Up of 2 Years

<table>
<thead>
<tr>
<th>Outcome by Category</th>
<th>PCI</th>
<th>CABG</th>
<th>Hazard Ratio (95% CI)</th>
<th>Interaction Test P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat revascularization</td>
<td>0.55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No diabetes</td>
<td>84/420 (20.0)</td>
<td>26/426 (6.1)</td>
<td>3.65 (2.35 to 5.67)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>17/68 (25.0)</td>
<td>4/74 (5.4)</td>
<td>5.25 (1.77 to 15.60)</td>
<td></td>
</tr>
<tr>
<td>Death or MI</td>
<td>0.58</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No diabetes</td>
<td>39/420 (9.3)</td>
<td>40/426 (9.4)</td>
<td>1.00 (0.64 to 1.55)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>7/68 (10.3)</td>
<td>9/74 (12.2)</td>
<td>0.73 (0.27 to 1.97)</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>0.95</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No diabetes</td>
<td>19/420 (4.5)</td>
<td>7/426 (1.6)</td>
<td>2.88 (1.21 to 6.85)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>3/68 (4.4)</td>
<td>1/74 (1.4)</td>
<td>3.11 (0.32 to 29.90)</td>
<td></td>
</tr>
</tbody>
</table>

Values are n (%) unless otherwise indicated.

*P for interaction test with a proportional hazards model.
that compared PCI with CABG and reported similar survival rates at 5 years of follow-up (89.7% versus 90.7%). A meta-analysis of individual patient data from SoS, ART, ERACI II, and MASS II is planned.

A substantial proportion of contemporary PCI is now performed with drug-eluting stent (DES) technology. Compared with bare-metal stent devices, DES devices reduce the risk of restenosis and the need for subsequent repeat revascularization.\(^{17,18}\) A registry study recruited patients with the inclusion criteria used in the ARTS study and treated all patients with PCI using DES technology. A comparison of clinical results with historical controls from the surgical group in the original ARTS trial suggested clinical equivalence to CABG for all key outcome measures.\(^{19}\)

More recently, concern has been raised about the possibility of an increased rate of late stent thrombosis observed with the use of DES.\(^{20–24}\) In December 2006, the US Food and Drug Administration reviewed the use of DES both on and off label. Presentations were made of key randomized and registry data by both academic groups and industry. The hearings concluded that for established on-label indications, no evidence existed for an increased rate of death or myocardial infarction in patients managed with DES. A possible small increase in the rate of late stent thrombosis was offset by improved clinical outcomes, with a reduced rate of restenosis and subsequent repeat revascularization procedures. It would appear that many DES are implanted in off-label settings, and although clinical data for these patients are limited, the rate of late stent thrombosis may be increased compared with levels observed with bare-metal stent devices and in current trials of DES technology. The potential impact of DES on long-term mortality after multivessel stent implantation is currently difficult to assess.

The Bypass Angioplasty Revascularization Investigation (BARI) trial, a randomized comparison of balloon angioplasty (PTCA) versus CABG, first highlighted a survival benefit for diabetic patients managed with CABG that was 80.6% in the CABG group versus 65.5% in PTCA group at a follow-up of 5 years.\(^{25,26}\) In the meta-analysis performed by Hoffman and colleagues,\(^{1}\) survival data from 4 trials that reported on diabetic patients were combined. At 4 years, patients managed with CABG had a lower mortality rate than those randomized to PTCA; however, at 6.5 years, this difference was reduced and was no longer significant. In the meta-analysis performed by Bravata and colleagues,\(^{2}\) 6 studies reported on diabetic patients, and the 5-year survival rate was higher for CABG by only 0.2%, with a wide confidence interval for this estimate. The BARI trial investigators have now reported 10-year survival in the diabetic and nondiabetic populations.\(^{27}\) A statistical test of interaction provided little evidence that the treatment allocation affected mortality (\(P=0.12\)), although the authors emphasize a survival advantage for diabetic patients managed with CABG (57.8%) compared with PCI (45.5%).

Information from the stent era was presented by Mercado and colleagues\(^{7}\) with a meta-analysis of 1-year results from trials of PCI with bare-metal stents versus CABG. Mortality occurred in 5.6% of diabetic patients in the PCI group versus 3.5% of diabetic patients in the CABG group (hazard ratio 1.61, 95% CI 0.72 to 3.61, \(P=0.245\)). Longer-term data are now available, and Table 4 shows mortality rates at 5 years for diabetic and nondiabetic patients for the ARTS, ERACI II, and SoS trials. Individual trials have not demonstrated a statistically significant difference in mortality for diabetic patients managed with PCI or CABG, which may be a reflection of limited sample size; a meta-analysis of these studies is planned.

The optimal revascularization strategy in diabetics is currently being evaluated in a number of randomized trials, including the CARDia (Coronary Artery Revascularization in Diabetes),\(^{28}\) FREEDOM (Comparison of Two Treatments for Multivessel Coronary Artery Disease in Individuals with Diabetes),\(^{29}\) and VA CARDS (Coronary Artery Revascularization in Diabetes)\(^{30}\) studies. PCI strategies in these trials include the use of DES, which may have a substantial impact on the need for additional revascularization but a more limited effect on the subsequent rates of death or myocardial infarction.

The present study has some limitations. Long-term follow-up was restricted to an assessment of vital status. Data on other clinical events such as myocardial infarction, repeat revascularization, and angina status may have provided more information about the clinical course of the 2 treatment strategies. The absolute number of deaths is small, and therefore, caution should be taken in interpreting the observed mortality difference, which has a wide CI. The trial was not powered to detect moderate treatment differences in mortality, and the difference observed at a median of 2 years was unexpected. Furthermore, the observed hazard ratios have attenuated over 5 years of follow-up, with the lower boundary of the confidence interval now close to 1. An imbalance in the incidence of noncardiovascular death may further complicate interpretation of the data. Cancer was reported as the predominant cause of noncardiovascular death, affecting 20 patients in the PCI group compared with 8 in the CABG group. The types of cancer are wide ranging and, where specified, include lung, gastric, esophageal, ovarian, and lymphoma tumors. In the classification of the cause of death, the initial 30 of 87 deaths were adjudicated by a clinical events committee, whereas subsequent events were investigator reported. This may limit the reliability of an assessment of differences in cardiovascular and noncardiovascular events.

In summary, in the SoS cohort of patients at a median follow-up of 6 years, we observed a continuing survival advantage for patients managed with CABG, although this includes a persisting imbalance in noncardiovascular death. These results are not wholly consistent with the other stent-versus-CABG studies. We found little evidence that the
treatment effect on mortality differed between diabetic and non-diabetic patients, and further information from trials specifically designed to examine this issue are awaited, as are the results of carefully conducted meta-analyses using individual patient data from trials comparing stent versus CABG.

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Disclosures
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References
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