Everolimus-Eluting Stents or Bypass Surgery for Multivessel Coronary Disease

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ABSTRACT

BACKGROUND
Results of trials and registry studies have shown lower long-term mortality after coronary-artery bypass grafting (CABG) than after percutaneous coronary intervention (PCI) among patients with multivessel disease. These previous analyses did not evaluate PCI with second-generation drug-eluting stents.

METHODS
In an observational registry study, we compared the outcomes in patients with multivessel disease who underwent CABG with the outcomes in those who underwent PCI with the use of everolimus-eluting stents. The primary outcome was all-cause mortality. Secondary outcomes were the rates of myocardial infarction, stroke, and repeat revascularization. Propensity-score matching was used to assemble a cohort of patients with similar baseline characteristics.

RESULTS
Among 34,819 eligible patients, 9223 patients who underwent PCI with everolimus-eluting stents and 9223 who underwent CABG had similar propensity scores and were included in the analyses. At a mean follow-up of 2.9 years, PCI with everolimus-eluting stents, as compared with CABG, was associated with a similar risk of death (3.1% per year and 2.9% per year, respectively; hazard ratio, 1.04; 95% confidence interval [CI], 0.93 to 1.17; P = 0.50), higher risks of myocardial infarction (1.9% per year vs. 1.1% per year; hazard ratio, 1.51; 95% CI, 1.29 to 1.77; P<0.001) and repeat revascularization (7.2% per year vs. 3.1% per year; hazard ratio, 2.35; 95% CI, 2.14 to 2.58; P<0.001), and a lower risk of stroke (0.7% per year vs. 1.0% per year; hazard ratio, 0.62; 95% CI, 0.50 to 0.76; P<0.001). The higher risk of myocardial infarction with PCI than with CABG was not significant among patients with complete revascularization but was significant among those with incomplete revascularization (P=0.02 for interaction).

CONCLUSIONS
In a contemporary clinical-practice registry study, the risk of death associated with PCI with everolimus-eluting stents was similar to that associated with CABG. PCI was associated with a higher risk of myocardial infarction (among patients with incomplete revascularization) and repeat revascularization but a lower risk of stroke. (Funded by Abbott Vascular.)
Coronary-artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) are treatment options for patients with multivessel coronary artery disease. Prior studies have shown a mortality benefit of CABG, as compared with PCI. However, these studies compared CABG with balloon angioplasty, bare-metal stents, or first-generation drug-eluting stents. Second-generation drug-eluting stents have thinner struts and have thinner and more biocompatible polymer with more uniform polymer coating of the strut surface, resulting in less inflammation and thrombogenicity, as compared with the first-generation drug-eluting stents and even bare-metal stents.

Consequently, the newer-generation drug-eluting stents, especially the everolimus-eluting stent, have been shown to reduce the risks of death, myocardial infarction, and stent thrombosis, as compared with bare-metal stents or first-generation drug-eluting stents. However, previous studies did not compare CABG with PCI with the use of second-generation drug-eluting stents. The recommendations of various national and international guidelines are based on studies of CABG versus PCI with the use of older-generation stents, but these guidelines have been applied routinely to contemporary practice.

Our objective was to evaluate the outcomes with CABG, as compared with PCI with the use of everolimus-eluting stents, in patients who had multivessel coronary artery disease. We used a contemporary clinical-practice registry to identify participants.

Methods

Study Design and Oversight
This study was a registry-based analysis involving patients with multivessel coronary artery disease who underwent isolated CABG surgery and patients who underwent PCI with everolimus-eluting stents between January 1, 2008, and December 31, 2011, in New York. The study was designed by the first and last authors and was funded by Abbott Vascular. The registry data were collected by the data coordinators at participating hospitals. The second and fifth authors performed the analysis. The first author prepared the first draft of the manuscript, which was then reviewed and edited by the coauthors.

The sponsor, who had no role in the design or conduct of the study, had the right to suggest changes to the manuscript, but final decisions regarding the content were made solely by the authors. The first and last authors accept full responsibility for the accuracy and completeness of the reported analyses and interpretations of the data.

Registries
The patients included in the study were identified from the Cardiac Surgery Reporting System (CSRS) and Percutaneous Coronary Intervention Reporting System (PCIRS) registries of the New York State Department of Health. No informed consent was required, because the data are anonymized. To obtain follow-up information, the CSRS and PCIRS were linked with the New York State Vital Statistics Death registry with the use of patient identifiers and to the Statewide Planning and Research Cooperative System registry with the use of patient identifiers, unique hospital identifiers, and dates of admission, surgery, and discharge. Details regarding the registries are included in the Supplementary Appendix, available with the full text of this article at NEJM.org.

Study Population
Patients were eligible for inclusion in the study if they had multivessel disease, which was defined as severe stenosis (≥70%) in at least two diseased major epicardial coronary arteries, and if they had undergone either PCI with implantation of an everolimus-eluting stent or CABG. Exclusion criteria were the following: revascularization within 1 year before the index procedure; previous cardiac surgery (CABG or valve surgery), because such patients are less likely to undergo repeat CABG than to undergo PCI; severe left main coronary artery disease (degree of stenosis, ≥50%); PCI with a stent other than an everolimus-eluting stent or with a combination of stents; myocardial infarction within 24 hours before the index procedure; and unstable hemodynamics or cardiogenic shock.

Outcomes
The primary outcome of the study was all-cause mortality. Various secondary outcomes were also assessed, including the rates of myocardial infarc-
tion, stroke, and repeat revascularization. Myo-
cardial infarction was defined as either pro-
dural, if it occurred as a complication after PCI or
CABG (defined in both the CSRS and PCIRS reg-
stries as the presence of new Q waves), or sponta-
nous, if it was diagnosed at readmission (i.e.,
as an emergency admission with a principal di-
a gnost ic of myocardial infarction or a principal
diagnosis of cardiogenic shock with a secondary
diagnosis of myocardial infarction).

Stroke was categorized as occurring either
within 30 days (in which case it was presumed
to be a complication of the index procedure) or
after 30 days (on the basis of readmission with a
principal diagnosis of stroke). Repeat revascu-
larization was identified as any unstaged revas-
larization after the index procedure; staged revas-
larization was defined as non–target-
vessel revascularization within 90 days after the
index procedure. In addition, short-term events
(those occurring in the hospital or ≤30 days af-
after the procedure) were tabulated separately.

STATISTICAL ANALYSIS

Given the differences in the baseline characteris-
tics between eligible participants in the two
groups (Table 1), propensity-score matching was
used to identify a cohort of patients with similar
baseline characteristics. The propensity score is a
conditional probability of having a particular ex-
posure (PCI with everolimus-eluting stents ver-
sus CABG) given a set of baseline measured co-
v ariates.9,10 The propensity score was estimated
with the use of a nonparsimonious multivariable
logistic-regression model,11 with PCI with the
use of everolimus-eluting stents as the dependent
variable and all the baseline characteristics out-
lined in Table 1 as covariates. Matching was per-
formed with the use of a 1:1 matching protocol
without replacement (greedy-matching algo-
grithm), with a caliper width equal to 0.2 of the
standard deviation of the logit of the propensity
score. Standardized differences were estimated
for all the baseline covariates before and after
matching to assess prematch imbalance and post-
match balance.12 Standardized differences
of less than 10.0% for a given covariate indicate
a relatively small imbalance.12

In the matched cohort, paired comparisons
were performed with the use of McNemar’s test
for binary variables and a paired Student’s t-test
or paired-sample test for continuous variables.
The comparative risks of primary and secondary
outcomes were further adjusted for in the
matched cohort with the use of a Cox propor-
tional-hazards regression model that was strati-
fied on the matched pair to preserve the benefit
of matching.

Prespecified subgroup analyses were per-
formed on the basis of two types of characteris-
tics. Anatomical subgroups were based on three-
vessel disease versus two-vessel disease, with or
without involvement of the territory of the
proximal left anterior descending coronary ar-
tery, and on complete revascularization versus
incomplete revascularization in the PCI cohort.
Clinical subgroups were based on age (<80 years
vs. ≥80 years), diabetes status (yes or no), and
left ventricular ejection fraction (≥40% vs.
<40%). In the subgroup analyses, to maintain
the baseline balance between the PCI group and
the CABG group, only the corresponding
matched pairs in a subgroup were chosen. For
example, in the subgroup of patients with dia-
betes, only the matched pairs of patients with dia-
betes in the PCI group and in the CABG group
were included in the analysis. Tests for interac-
tion were performed to assess for heterogeneity
of treatment effect among subgroups.

Analyses of the primary and secondary out-
comes were also performed in a separate pro-
pensity-matched cohort of patients who under-
went CABG versus those who underwent PCI
with first-generation drug-eluting stents (siroli-
imus-eluting or paclitaxel-eluting stents) and in a
propensity-matched cohort of patients who un-
derwent PCI with everolimus-eluting stents ver-
sus those who underwent PCI with first-genera-
tion drug-eluting stents.

All reported P values are two-sided and have
not been adjusted for multiple testing. All the
analyses were performed with the use of SAS
software, version 9.3 (SAS Institute).

RESULTS

STUDY POPULATION

We identified 34,819 patients with multivessel
disease who met our inclusion criteria (Fig. 1), of
whom 16,876 (48.5%) underwent PCI with evero-

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<th>Characteristic</th>
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<th></th>
<th>After Matching</th>
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<td>CABG (N=17,943)</td>
<td>Standardized Difference</td>
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<td>CABG (N=9223)</td>
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<td></td>
<td></td>
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<td>65.1±11.1</td>
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<td>&lt;20%</td>
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<td>20–29%</td>
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<td>40–49%</td>
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<td>15.7</td>
<td>15.4</td>
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<td>≥50%</td>
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<td>29.1</td>
<td>0.5</td>
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<td><strong>Previous myocardial infarction (%)</strong></td>
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<td>1–7 Days before treatment</td>
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<td>8.6</td>
<td>17.0</td>
<td>16.8</td>
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<td>23.0</td>
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<td>2.0</td>
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<td>1.0</td>
<td>8.9</td>
<td>0.4</td>
<td>0.5</td>
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<td>&gt;20 Days before treatment</td>
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<td>22.4</td>
<td>12.1</td>
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<td>Peripheral arterial disease (%)</td>
<td>8.6</td>
<td>11.6</td>
<td>9.9</td>
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<td>COPD (%)</td>
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<td>12.5</td>
<td>25.4</td>
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<td><strong>Congestive heart failure (%)</strong></td>
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<td></td>
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<td>93.9</td>
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<td>At current admission</td>
<td>3.7</td>
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<tr>
<td>Before current admission</td>
<td>2.4</td>
<td>3.1</td>
<td>4.4</td>
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limus-eluting stents and 17,943 (51.5%) underwent CABG (Table 1). Before propensity-score matching, there were differences between the two groups in several of the baseline variables (Table 1). With the use of propensity-score matching, 9223 patients who underwent PCI with the use of everolimus-eluting stents were matched with 9223 patients who underwent CABG. The C-statistic for the model was 0.814. After matching, the standardized differences were less than 10.0% for all variables, indicating only small differences between the two groups (Table 1).

### SHORT-TERM OUTCOMES

Short-term outcomes (in the hospital or ≤30 days after the index procedure) favored PCI with everolimus-eluting stents over CABG. PCI was associated with significantly lower risks of death (0.6% vs. 1.1%; hazard ratio, 0.49; 95% confidence interval [CI], 0.35 to 0.69; P<0.001) and stroke (0.2% vs. 1.2%; hazard ratio, 0.18; 95% CI, 0.11 to 0.29; P<0.001), but there was no significant difference between the two groups in the risk of myocardial infarction (0.5% and 0.4%, respectively; hazard ratio, 1.37; 95% CI, 0.89 to 2.12; P=0.16).

### PRIMARY OUTCOME

After a mean follow-up of 2.9 years, PCI with everolimus-eluting stents was associated with a risk of death that was similar to that associated with CABG (3.1% and 2.9% per year, respectively; hazard ratio, 1.04; 95% CI, 0.93 to 1.17; P=0.50).
MYOCARDIAL INFARCTION

PCI with everolimus-eluting stents was associated with a higher risk of a first myocardial infarction than was CABG (1.9% vs. 1.1% per year; hazard ratio, 1.51; 95% CI, 1.29 to 1.77; P<0.001) (Table 2 and Fig. 2B). This higher risk of myocardial infarction after PCI was driven by a higher risk of spontaneous myocardial infarction (hazard ratio, 1.55; 95% CI, 1.31 to 1.82; P<0.001), with no significant difference between the two study groups in the risk of procedural myocardial infarction (hazard ratio, 1.36; 95% CI, 0.68 to 2.71; P=0.39). The higher risk of myocardial infarction after PCI with everolimus-eluting stents, as compared with CABG, was not significant in matched pairs in which the patient in the PCI group had complete revascularization but was significant in pairs in which the patient in the PCI group had incomplete revascularization (P=0.02 for interaction) (Table S1 in the Supplementary Appendix). The results were generally similar in other subgroups (Tables S1 and S2 in the Supplementary Appendix) with a higher risk of myocardial infarction with PCI than with CABG, although there was a nonsignificant trend toward a less pronounced difference among patients with two-vessel disease than among those with three-vessel disease (P=0.14 for interaction) (Table S1 in the Supplementary Appendix).

STROKE

PCI with everolimus-eluting stents was associated with a lower risk of a first stroke than was CABG (0.7% vs. 1.0% per year; hazard ratio, 0.62; 95% CI, 0.50 to 0.76; P<0.001) (Table 2 and Fig. 2C). The difference was driven largely by a lower short-term (≤30 days) risk of stroke with PCI with everolimus-eluting stents, as compared with CABG (hazard ratio, 0.18; 95% CI, 0.11 to 0.29; P<0.001), with no significant difference in a landmark analysis that examined only events after 30 days (hazard ratio, 1.05; 95% CI, 0.81 to 1.37; P=0.69). The results were generally similar in subgroup analyses (Tables S1 and S2 in the Supplementary Appendix).

REPEAT REVASCULARIZATION

PCI with everolimus-eluting stents was associated with a higher risk of a first repeat-revascularization procedure than was CABG (7.2% vs. 3.1% per year; hazard ratio, 2.35; 95% CI, 2.14 to 2.58; P<0.001) (Table 2 and Fig. 2D). This difference
was less pronounced among patients with two-vessel disease than among those with three-vessel disease (P=0.02 for interaction), although CABG was favored in both (Table S1 in the Supplementary Appendix). Similarly, the difference between PCI and CABG was less pronounced in the subgroup of patients who had complete revascularization than it was in the subgroup of those who had incomplete revascularization (P=0.001 for interaction), again with CABG favored in both (Table S1 in the Supplementary Appendix). The results were largely similar (in favor of CABG) in the other subgroups (Tables S1 and S2 in the Supplementary Appendix). Among all repeat revascularizations in the two study groups, most repeat revascularizations were performed by means of PCI (92.6%), with only a minority being performed by means of CABG (7.4%).

**SENSITIVITY ANALYSIS**

In an analysis of CABG versus PCI with first-generation drug-eluting stents (6128 matched pairs), CABG was associated with nonsignificantly lower rates of death (2.7% and 3.0% per year, respectively; P=0.21) and with significantly lower risks of myocardial infarction (P<0.001) and revascularization (P<0.001) but with a trend toward a higher risk of stroke (P=0.05) (Table S3 in the Supplementary Appendix). In an analysis of PCI with everolimus-eluting stents versus PCI with first-generation drug-eluting stents (8801 matched pairs), everolimus-eluting stents were associated with lower risks of myocardial infarction (P<0.001) and revascularization (P=0.03) but similar risks of other outcomes (Table S4 in the Supplementary Appendix).

**DISCUSSION**

In a contemporary cohort of patients with multivessel coronary artery disease, the risk of death associated with PCI with everolimus-eluting stents was similar to that associated with CABG. PCI was associated with a higher risk of myocardial infarction (mainly among patients who had incomplete revascularization) and repeat revascularization, whereas CABG was associated with an increased risk of stroke. Short-term results favored PCI, with lower risks of death and stroke.

Randomized trials comparing PCI with CABG have not been typically powered to evaluate differences in the rates of myocardial infarction, stroke, and death from any cause; instead, they have been based on composite outcomes that include repeat revascularization. To create data sets of sufficient size to analyze these less frequent outcomes, one option is to perform meta-analyses of clinical-trial data. For example, one recent meta-analysis included six trials (involving 6055 patients) comparing PCI with the use of either first-generation drug-eluting stents or bare-metal stents with CABG. Rates of death, myocardial infarction, and repeat revascularization were significantly lower with CABG than with PCI, with a trend toward a higher rate of stroke with CABG.

Another approach is to use clinical-practice registries or other observational data sets. For example, in one analysis that included nearly 190,000 patients from the American College of Cardiology Foundation PCI Registry and the Society of Thoracic Surgeons Adult Cardiac Surgery Database, in which adjustment was made for propensity scores and inverse probability weighting, mortality at 4 years was lower among patients who had undergone CABG than among those who had undergone PCI (78% of whom had received first-generation drug-eluting stents).

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**Table 2. Risk of Primary and Secondary Outcomes in the Propensity-Score–Matched Cohort.**

<table>
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<tr>
<th>Outcome</th>
<th>No. of Patients with Event</th>
<th>Event Rate %/yr</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
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<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PCI</td>
<td>768</td>
<td>3.10</td>
<td>1.04 (0.93–1.17)</td>
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<td>2.86</td>
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<td>PCI</td>
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<td>1.51 (1.29–1.77)</td>
<td>&lt;0.001</td>
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<td>1.13</td>
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<td><strong>Stroke</strong></td>
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<tr>
<td>PCI</td>
<td>178</td>
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<td>0.62 (0.50–0.76)</td>
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<tr>
<td>PCI</td>
<td>1793</td>
<td>7.25</td>
<td>2.35 (2.14–2.58)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CABG</td>
<td>883</td>
<td>3.10</td>
<td>Reference</td>
<td></td>
</tr>
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</table>

* The propensity-score–matched cohort included 9223 patients in the PCI group and 9223 patients in the CABG group.
The relevance of these previous studies to current-day PCI with second-generation drug-eluting stents is debatable. Restenosis and stent thrombosis are two potentially serious complications of PCI, which are associated with significant increases in the rates of myocardial infarction and death. A wealth of data from studies of second-generation drug-eluting stents, especially everolimus-eluting stents, have shown reductions in the risks of death, myocardial infarction, and stent thrombosis when such stents are compared with bare-metal stents or first-generation drug-eluting stents. Data from the New York State registries show a gradual bridging of the gap between CABG and PCI with respect to mortality, from the balloon-angioplasty era (40 to 50% reduction in mortality with CABG among patients with three-vessel disease), to the bare-metal–stent era (24 to 36% reduction), to the era of first-generation drug-eluting stents (20 to 29% reduction), to the use of second-generation drug-eluting stents (no significant reduction in the present study). Data from the New York State registries also show decreases in the rate of repeat revascularization with PCI, from the balloon-angioplasty era (37.0% of patients), to the bare-metal–stent era (30.6%), to the era of first-generation drug-eluting stents (30.6%), to the use of second-generation drug-eluting stents (19.4% in the present study).

**Figure 2.** Cumulative Risks of the Study Outcomes in the Matched Cohort.

In each panel, the inset shows the same data on an enlarged y axis.
In the current study, PCI with the use of everolimus-eluting stents was associated with a higher risk of myocardial infarction than CABG. However, this difference in risk was not significant in the subgroup of matched pairs in which the patients who underwent PCI had complete revascularization. Incomplete revascularization has been shown to be associated with a significant increase in the risks of death and myocardial infarction. Thus, the choice between CABG and PCI with everolimus-eluting stents may depend on whether complete revascularization can be achieved with PCI. If the answer is yes, the choice between PCI and CABG should be made on the basis of weighing the short-term risk of death and stroke with CABG against the long-term risk of repeat revascularization with PCI. If complete revascularization does not appear to be feasible on the basis of anatomy, our data then suggest that such patients do better with CABG.

Some limitations of our analysis should be considered. This was a nonrandomized, observational study and hence suffers from potential selection and ascertainment bias despite robust propensity-score matching. The registries did not capture variables such as hypertension, hyperlipidemia, and smoking status, factors that affect long-term outcomes; therefore these variables could not be included in the propensity scores. The database does not distinguish between the role of propensity score in observational studies for causal effects. Biometrika 1983; 70:41-55.

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