Comparison of Coronary Artery Stenting Outcomes in the Eras Before and After the Introduction of Drug-Eluting Stents

Edward L. Hannan, PhD; Michael Racz, PhD; David R. Holmes, MD; Gary Walford, MD; Samin Sharma, MD; Stanley Katz, MD; Robert H. Jones, MD; Spencer B. King III, MD

Background—Few studies have compared medium-term outcomes for drug-eluting stents (DES) and bare metal stents, and most are relatively small randomized controlled trials. Furthermore, since the introduction of DES, there has been increased use and duration of use of clopidogrel, statins, and other evidence-based therapies. The purpose of the present study was to compare outcomes for patients who underwent stenting in the eras before and after the introduction of DES.

Methods and Results—New York state patients undergoing stenting in all nonfederal hospitals in the state were studied. Patients were excluded if they had a previous revascularization. Risk factors that were significant predictors of adverse outcomes were used to adjust adverse outcome rates. The study included 11,436 patients who received stents between October 1, 2002, and March 31, 2003, and 12,926 patients who underwent stenting between October 1, 2003, and March 31, 2004. Death rates, the combined end point of death and myocardial infarction (MI), nonfatal MI requiring readmission, target vessel revascularization, and target lesion revascularization were compared at 2 years. Patients in the DES era had significantly better risk-adjusted outcomes for death/MI (adjusted hazard ratio, 0.90; 95% confidence interval, 0.83 to 0.97), 9.9% versus 10.8%; nonfatal MI requiring readmission (adjusted hazard ratio, 0.86; 95% confidence interval, 0.76 to 0.97); target vessel revascularization (adjusted hazard ratio, 0.60; 95% confidence interval, 0.56 to 0.64), 11.2% versus 17.9%; and target lesion revascularization (hazard ratio, 0.55; 95% confidence interval, 0.51 to 0.59), 8.4% versus 14.7%.

Conclusions—Patients in the DES era experienced lower rates of death/MI, nonfatal MI, target vessel revascularization, and target lesion revascularization, but there were no differences in the rates of death. These improvements are likely a result of increased use of clopidogrel, statins, and dual antiplatelet therapy, in addition to the introduction of DES. (Circulation. 2008;117:2071-2078.)

Key Words: drug-eluting stents ■ bare metal stents ■ mortality ■ myocardial infarction ■ stents

Coronary stents are the preferred mode of percutaneous coronary intervention (PCI) compared with balloon angioplasty as a result of demonstrated reduction in early morbidity and the need for subsequent revascularization.1–8 Nevertheless, restenosis has continued to be a problem in coronary stenting, and recent efforts have led to the development of drug-eluting stents (DES).

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Randomized controlled trials (RCTs) have documented lower clinical and angiographic restenosis, target lesion revascularization (TLR), and major adverse cardiac event rates with drug-eluting stents.9–23 However, these RCTs were relatively small and were not powered to detect differences in relatively rare events such as long-term mortality or myocardial infarction (MI). Furthermore, reports about the danger of late stent thrombosis among DES patients24,25 led to a Food and Drug Administration meeting that addressed the safety of DES.26–28

The purpose of this study was to use an observational database to track New York State patients who underwent stenting in the time period when only bare metal stents (BMS) were available and as a time period after the introduction of DES. The study compares the time periods with regard to 2-year death rates, MI/death, nonfatal MI requiring readmission, and repeat TLR and target vessel revascularization (TVR) after adjustment for differences in baseline risk factors between patients undergoing stent placement in each time period.

Methods

Databases

The New York State Percutaneous Coronary Intervention Reporting System (PCIRS) registry was developed in 1991 to collect informa-

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on all New York patients undergoing PCIs in nonfederal hospitals. For each of these patients, the registry contains information on demographics, comorbidities, left ventricular function, hemodynamic state, vessels diseased and attempted coronary vessels, hospital and operator identifiers, and in-hospital adverse outcomes. The registry also contains information on the type(s) of device used for each attempted lesion, including BMS and DES.

Patient identifiers in the registry were used to obtain data on repeat in-state revascularizations by creating a patient-level longitudinal file based on the PCIRS and its companion registry in New York, the Cardiac Surgery Reporting System. Deaths occurring among New York State patients after discharge from the hospital were obtained by matching the PCIRS to New York’s Vital Statistics Death file using patient identifiers.

PCIRS was also linked with New York State’s administrative acute care discharge reporting system, the Statewide Planning and Research Cooperative System (SPARCS). SPARCS contains patient demographics (age, sex, race), diagnoses and procedures, admission and discharge dates, and discharge disposition for all patients discharged from nonfederal acute care hospitals in New York. PCIRS and SPARCS records were matched using unique hospital identifiers, along with patient identifiers and admission, surgery, and discharge dates. Subsequent emergency hospitalizations with MI as the principal diagnosis were then identified. MIs that occurred as a complication in the index admission also were captured.

Study Group and End Points

The study includes patients who underwent stenting from October 1, 2002, to March 31, 2003, and patients who underwent stenting from October 1, 2003, to March 31, 2004. The first time period was chosen so that it was close to but before the time when DES were introduced in April 2003; the second period was chosen so that it would represent a time when most patients were undergoing DES. Patients were excluded if they had a previous revascularization (10 102 cases) or were from out of state (776 cases). All other patients undergoing PCI between October 1, 2002, and March 31, 2003 (11 436 patients), were followed up through December 31, 2004, and all patients undergoing PCI between October 1, 2003, and March 31, 2004 (12 926 patients), were followed up through December 31, 2005.

End points in the study were 2-year death, death/MI, nonfatal MI requiring readmission, TVR, and TLR. MI included return to the hospital with MI as a principal diagnosis and MI occurring in the index admission as a complication. Although subsequent coronary artery bypass graft (CABG) surgery after discharge could not be confirmed to be related to the target lesion or the target vessel, it was assumed to be related to them on the basis of the assumption that this would be true more often than not. In other analyses, none of the subsequent CABG surgery was included as evidence of TVR or TLR, and the results were very similar.

Statistical Analysis

The main purposes of the present study were to compare the types of patients who underwent stenting in the pre-DES era and DES era and to examine differences in adverse outcomes (death, death/MI, nonfatal MI requiring readmission, TVR, and TLR) between the 2 time periods. Another purpose identified at the beginning of the study was to compare outcomes for subsets of high-risk patients (diabetics, patients ≥80 years of age, who were diabetics, who had multivessel disease, and who had an MI within 24 hours before receiving a stent). Subsequent analyses compared the outcomes of DES and BMS received in the second time period (without the subset analyses) using the same methods.

For nonfatal MI requiring readmission, TVR, and TLR, patients who died before experiencing the adverse event were censored. All tests were 2 sided and conducted at the 0.05 level, and all analyses were conducted in SAS 9.1 (SAS Institute Inc, Cary, NC).

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

There were a total of 722 deaths among the 11 436 patients in the pre-DES era and 778 deaths among the 12 926 patients in the DES era. Of the stent patients in the DES era, 9 415 (72.8%) received at least 1 DES. A total of 92.9% of the DES were sirolimus-eluting stents. The mean follow-up time for the pre-DES era was 704 days (SD, 132 days); the mean follow-up time for the DES era was 704 days (SD, 129 days).

Table 1 presents differences in prevalences of all available patient risk factors between the 2 eras. As noted, there were significant differences between the 2 time periods with respect to race, the presence of previous acute MIs, congestive heart failure, renal failure, and anatomic group.

Table 2 demonstrates that risk-adjusted rates were lower but not significantly different in the DES era (0.72% versus 0.61%, $P=0.28$ for in-hospital deaths; and 0.44% versus 0.30%, $P=0.09$ for same-stay CABG).

Table 3 presents unadjusted and adjusted HRs (DES/pre-DES) for the 2 groups of patients. Although there was no difference in mortality rates, DES era patients had significantly better unadjusted outcomes for death/MI (HR, 0.91; 95% confidence interval [CI], 0.84 to 0.98), nonfatal MI requiring readmission (HR, 0.87; 95% CI, 0.78 to 0.98), TVR (HR, 0.62; 95% CI, 0.58 to 0.66), and TLR (HR, 0.57; 95% CI, 0.52 to 0.61). Patients in the DES era also had significantly better risk-adjusted outcomes for death/MI (adjusted HR, 0.90; 95% CI, 0.83 to 0.97), nonfatal MI requiring readmission (adjusted HR, 0.86; 95% CI, 0.76 to 0.97), TVR (adjusted HR, 0.60; 95% CI, 0.56 to 0.64), and TLR (adjusted HR, 0.55; 95% CI, 0.51 to 0.59). These results were essentially the same when hospitals were added to the models to control for differences in hospital quality.

Figures 1 through 4 presents adjusted survival curves for the 2 eras. The later versus earlier 2-year adverse adjusted outcome rates were 5.9% versus 6.3% for death and 9.9% versus 10.8% for death/MI, respectively. The 2-year rates for TVR and TLR were 11.2% versus 17.9% and 8.4% versus 14.7%, respectively.

Table 4 presents adjusted HRs for the DES era relative to the pre-DES era for subgroups of patients (diabetics, patients ≥80 years of age, patients with multivessel disease, and patients who had an MI within 24 hours before receiving a stent) undergoing stent placement. There were no differences...
The only difference for death/MI was for multivessel disease (adjusted HR, 0.88; 95% CI, 0.78 to 0.98). In addition, patients with multivessel disease in the DES era had a lower risk-adjusted nonfatal MI rate (adjusted HR, 0.81; 95% CI, 0.69 to 0.95). All 4 subgroups experienced lower adjusted repeat revascularization rates in the DES era.

For diabetics, the adjusted HRs were 0.62 for TVR and 0.54 for TLR. For patients of ≥80 years of age, adjusted HRs were...

<table>
<thead>
<tr>
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<th></th>
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<tr>
<td>Age, y</td>
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<td>20.0</td>
<td>0.25</td>
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<td>&lt;50</td>
<td>13.8</td>
<td>14.3</td>
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<td>50–59</td>
<td>24.9</td>
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<tr>
<td>60–69</td>
<td>27.4</td>
<td>27.4</td>
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<tr>
<td>70–79</td>
<td>23.0</td>
<td>23.0</td>
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</tr>
<tr>
<td>≥80</td>
<td>11.0</td>
<td>11.0</td>
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<tr>
<td>Gender, %</td>
<td>65.6</td>
<td>65.5</td>
<td>0.99</td>
</tr>
<tr>
<td>Male</td>
<td>34.4</td>
<td>34.5</td>
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<tr>
<td>Hispanic ethnicity, %</td>
<td>8.1</td>
<td>8.6</td>
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<tr>
<td>Race, %</td>
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<td>83.8</td>
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<tr>
<td>White</td>
<td>8.5</td>
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<tr>
<td>Black</td>
<td>8.2</td>
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<tr>
<td>Previous MI, %</td>
<td>8.9</td>
<td>9.1</td>
<td>0.001</td>
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<td>≤6 h</td>
<td>2.9</td>
<td>2.7</td>
<td></td>
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<tr>
<td>6–11 h</td>
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<td>1–7 d</td>
<td>19.3</td>
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<td>8–14 d</td>
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<tr>
<td>15–20 d</td>
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<td>0.4</td>
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<tr>
<td>≥20 d</td>
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<td>8.2</td>
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<tr>
<td>None</td>
<td>54.7</td>
<td>57.5</td>
<td></td>
</tr>
<tr>
<td>Carotid/cerebrovascular disease, %</td>
<td>6.3</td>
<td>6.2</td>
<td>0.69</td>
</tr>
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<td>Peripheral vascular disease, %</td>
<td>4.9</td>
<td>5.2</td>
<td>0.33</td>
</tr>
<tr>
<td>Hemodynamically unstable, %</td>
<td>1.0</td>
<td>0.8</td>
<td>0.20</td>
</tr>
<tr>
<td>Shock, %</td>
<td>0.17</td>
<td>0.23</td>
<td>0.32</td>
</tr>
<tr>
<td>Congestive heart failure, %</td>
<td>6.9</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td>This admission</td>
<td>1.9</td>
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<tr>
<td>Before this admission</td>
<td>91.2</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td>Malignant ventricular arrhythmia, %</td>
<td>0.7</td>
<td>0.6</td>
<td>0.33</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease, %</td>
<td>6.6</td>
<td>6.4</td>
<td>0.53</td>
</tr>
</tbody>
</table>

LAD indicates left anterior descending coronary artery.

in mortality rates, and the only difference for death/MI was for multivessel disease (adjusted HR, 0.88; 95% CI, 0.78 to 0.98). In addition, patients with multivessel disease in the DES era had a lower risk-adjusted nonfatal MI rate (adjusted HR, 0.81; 95% CI, 0.69 to 0.95). All 4 subgroups experienced lower adjusted repeat revascularization rates in the DES era. For diabetics, the adjusted HRs were 0.62 for TVR and 0.54 for TLR. For patients of ≥80 years of age, adjusted HRs were...
0.67 for TVR and 0.68 for TLR. For patients with multivessel disease, adjusted HRs were 0.58 for TVR and 0.52 for TLR, and for patients with a preprocedural MI, the ratios were 0.66 and 0.68.

When the use of BMS and BMS/DES in the DES era was compared with the use of DES only, patients with BMS only experienced significantly worse results for each of the 5 outcomes: death: adjusted HR, 1.50; 95% CI, 1.29 to 1.75); death/MI: adjusted HR, 1.39; 95% CI, 1.23 to 1.57; nonfatal MI requiring readmission: adjusted HR, 1.34; 95% CI, 1.11 to 1.62; TVR: adjusted HR, 1.38; 95% CI, 1.23 to 1.55; and TLR: adjusted HR, 1.64; 95% CI, 1.44 to 1.87. Patients with BMS/DES experienced worse outcomes than DES patients for TVR (adjusted HR, 1.41; 95% CI, 1.19 to 1.67) and TLR (adjusted HR, 1.72; 95% CI, 1.42 to 2.08) but not for death (adjusted HR, 1.08; 95% CI, 0.83 to 1.39), death/MI (adjusted HR, 1.12; 95% CI, 0.92, 1.38), or nonfatal MI (adjusted HR, 1.18; 95% CI, 0.88 to 1.58).

Discussion

Until recently, DES had largely replaced BMS as the primary PCI despite their much higher cost. Undoubtedly, this enthusiastic adoption of DES was a result of several studies that compared DES favorably with BMS with regard to target lesion and/or target vessel stenosis and/or repeat revascularization rates.9–23

However, there has been considerable recent concern that DES are associated with higher rates of stent thrombosis, particularly late stent thrombosis, and thus pose danger with regard to MI and death. There have been numerous studies, Food and Drug Administration hearings, and extensive news coverage of the dangers of late stent thrombosis associated with DES.24–28,31,32

For instance, in a meta-analysis of 14 recent studies, Bavry et al24 found that the incidence of late thrombosis (>6 months after the index procedure) was 4.4 events per 1000 among DES patients and 0.6 events per 1000 among BMS patients (risk ratio, 3.67; 95% CI, 1.30 to 10.38; P=0.014). Eisenstein et al25 found that extended clopidogrel use in DES patients who were event free at 6 months was highly associated with a reduced risk of death (2.0% with versus 5.3% without; P=0.03) or death/MI (3.1% versus 7.2%; P=0.02) at 2 years. Extended clopidogrel use was not associated with lower adverse event rates for BMS patients. Lagerqvist et al32 found that at 3 years, the mortality rate was significantly higher in patients with DES (adjusted risk ratio, 1.18; 95% CI, 1.04 to 1.35).

Despite these recent findings about higher stent thrombosis rates for DES and higher mortality rates for DES patients without extended clopidogrel use, it is unclear whether there are higher long-term rates of MI or death for DES than for BMS. For example, in a pooled analysis of data from 4 RCTs, Spaulding et al33 found no significant differences at 4 years between sirolimus-eluting stents and BMS in death, MI, or stent thrombosis. In an analysis of 14 RCTs, Kastrati et al34 found no significant difference between sirolimus-eluting stents and BMS in the risk of death or in the combined risk of death or MI with a mean follow-up ranging from 12 to 59 months. In a recent observational study, Williams et al35 found a trend toward a lower adjusted 1-year death/MI rate for DES (HR, 0.74; 95% CI, 0.52 to 1.07) with only 397 BMS patients in the study.

Our study is a departure from typical RCTs or observational studies comparing performance of DES and BMS. Instead, we examined whether stent patients (some of whom received DES and some of whom did not) are faring better

### Table 3. HRs (DES Era/Pre-DES Era) for Patients Undergoing Stent Placement in New York

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted HR for DES Era/Pre-DES Era Cases (95% CI)</th>
<th>Adjusted* HR for DES Era/Pre-DES Era Cases (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-y Death</td>
<td>0.95 (0.86–1.06)</td>
<td>0.94 (0.84–1.04)</td>
</tr>
<tr>
<td>2-y Death/MI</td>
<td>0.91 (0.84–0.98)</td>
<td>0.90 (0.83–0.97)</td>
</tr>
<tr>
<td>2-y Nonfatal MI requiring readmission</td>
<td>0.87 (0.76–0.98)</td>
<td>0.86 (0.76–0.97)</td>
</tr>
<tr>
<td>2-y TVR</td>
<td>0.62 (0.58–0.66)</td>
<td>0.60 (0.56–0.64)</td>
</tr>
<tr>
<td>2-y TLR</td>
<td>0.57 (0.52–0.61)</td>
<td>0.55 (0.51–0.59)</td>
</tr>
</tbody>
</table>

*Adjusted for number of vessels diseased, region of disease (left anterior descending artery involvement or proximal left anterior descending artery involvement), left main disease, age, female gender, black race, ejection fraction, preprocedural MI, peripheral vascular disease, cerebrovascular disease, hemodynamic instability, shock, congestive heart failure, chronic obstructive pulmonary disease, diabetes, and renal failure.
since the introduction of DES and the increased use of clopidogrel, statins, and dual antiplatelet therapy.

The study, which had the advantage of a 2-year follow-up and an even larger number of patients than published meta-analyses of RCTs, found significantly better 2-year risk-adjusted outcomes for patients in the DES era (death/MI: 9.9% versus 10.8%; adjusted HR, 0.90; 95% CI, 0.83 to 0.97; nonfatal MI requiring readmission: adjusted HR, 0.86; 95% CI, 0.76 to 0.97; TVR: 11.2% versus 17.9%; adjusted HR, 0.60; 95% CI, 0.56 to 0.64; and TLR: 8.4% versus 14.7%; adjusted HR, 0.55; 95% CI, 0.51 to 0.59).

It is important to note that in addition to the use of DES in 73% of the patients undergoing stenting in the second period, patients also undoubtedly used medical therapies such as clopidogrel, statins, and antiplatelet therapy more often in that period. Although there is widespread agreement that TVR and TLR have decreased with the use of DES, the impact of these medical treatments may have decreased death/MI rates independently of the impact of DES, and the extent is impossible to discern.

A potential source of bias in any observational study is that 1 group of patients might be less likely to die or undergo subsequent revascularization because they were not as sick as the other group with respect to characteristics related to these outcomes. In our study, because we included all patients undergoing stenting in each era, there were not large differences in baseline characteristics, as evidenced in Table 1. Patients in the first era were more likely to be nonwhite, to have previous acute MIs >1 day before stenting, and to have congestive heart failure at admission. However, patients in the second era were more likely to have renal failure and 3-vessel disease. Nevertheless, we attempted to minimize selection bias by adjusting for differences in baseline risk factors using Cox proportional-hazards models.

Despite these efforts, there is a possibility that patients in the 2 eras differed with regard to unmeasured characteristics related to adverse outcomes. For example, lesion characteristics (length, diameter, etc) and vessel size and calcification were not available in the registry and may have differed over time. However, this seems relatively unlikely because all stent patients in each time period were included in the study. There was an increase in the number of stent patients in the second period, but part of the reason for this increase was a tendency to use stenting more in patients with 3-vessel disease.

Another caveat is that we were unable to capture stent thromboses. Although we were able to capture longer-term death and MI, they are not always related to stent thromboses. However, we do not expect that the percentage of unrelated deaths and MIs would vary tremendously between the 2 eras in a study as large as this one. It also is possible that return to the hospital with an MI may be inaccurate for patients who
did not undergo repeat revascularization given that these data were obtained from an administrative database. However, there is no reason to believe that this would lead to bias in favor of either time period.

In addition, we were unable to capture whether subsequent CABG surgery was for target lesion and target vessel restenosis because the CABG surgery registry does not contain data on lesions and vessels attempted. We assumed that subsequent CABG surgery was related to target lesions and target vessels and have reported our findings in this manner. Therefore, the rates reported may be artificially increased. However, only 25% and 24% of the TLRs were attributed to CABG surgery in the 2 time periods, respectively. In addition, to test for bias that could occur if 1 type of stent was associated with a higher percentage of subsequent CABG procedures that were related to TVR or TLR, we repeated the analyses assuming that none of the subsequent CABG surgeries were related to TVR or TLR and obtained very similar (and significant) HRs.

It also should be noted that the study does not address the appropriateness of the procedures performed. This is of interest given the results of the recent Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial, which demonstrated that optimal medical therapy does not result in a significantly different death/MI rate than PCI plus optimal medical therapy for stable coronary artery disease.36

Furthermore, we restricted ourselves to New York State residents because we were not able to capture deaths or subsequent revascularizations for patients who moved to another state after discharge. However, results from a similar study comparing outcomes of CABG surgery and balloon angioplasty in New York indicate that very few deaths are missed because of patients moving out of state.37

Despite these caveats, this observational study adds important information to our knowledge of coronary stenting. First, it provides data on the use of different stent types in real practice in a large population-based setting. In addition, it is the first study to examine whether patients in such a setting have fared better over time as a result of the introduction of new devices and therapy. Furthermore, it is a large study with a relatively long follow-up that has sufficient statistical power to identify differences of reasonable magnitude.

**Table 4. Adjusted HRs (DES Era/Pre-DES Era) for Various Subgroups of Patients Undergoing Stent Placement**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted* HR (DES Era/Pre-DES Era) (95% CI)</th>
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<tbody>
<tr>
<td></td>
<td>Diabetics (n=6199)</td>
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<tr>
<td>2-y Death</td>
<td>0.94 (0.79–1.12)</td>
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<tr>
<td>2-y Death/MI</td>
<td>0.93 (0.81–1.06)</td>
</tr>
<tr>
<td>2-y Nonfatal MI requiring readmission</td>
<td>0.89 (0.73–1.10)</td>
</tr>
<tr>
<td>2-y TVR</td>
<td>0.62 (0.55–0.70)</td>
</tr>
<tr>
<td>2-y TLR</td>
<td>0.54 (0.47–0.62)</td>
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</tbody>
</table>

*HRs compare BMS cases in the time period October 1, 2002, through March 31, 2003, with all stent cases in the time period October 1, 2003, through March 31, 2004. HRs were adjusted for number of vessels diseased, region of disease (left anterior descending artery involvement or proximal left anterior descending artery involvement), left main disease, age, female gender, black race, ejection fraction, preprocedural MI, peripheral vascular disease, cerebrovascular disease, hemodynamic instability, shock, congestive heart failure, malignant ventricular arrhythmia, chronic obstructive pulmonary disease, diabetes, and renal failure.

†For death/MI, the respective numbers of cases were 5880 for diabetics, 2541 for age $\geq$80 years, 9486 for multivessel disease, and 3849 for acute MI. These are different from the numbers at the top of the table because of patients lost in the process of matching PCIRS and SPARCS.
Acknowledgments
We would like to thank Kenneth Shine, MD, the former chair of New York State’s Cardiac Advisory Committee (CAC), and the remainder of the CAC for their encouragement and support of this study. We also thank Paula Waselaukas, Kimberly S. Cozzens, Rosemary Lombardo, Cynthia Johnson, and the cardiac surgery departments and cardiac catheterization laboratories of the participating hospitals for their tireless efforts to ensure the timeliness, completeness, and accuracy of the registry data.

Disclosures
Dr Sharma is the recipient of a research grant from Boston Scientific and has speakers’ bureau appointments with Boston Scientific, Abbott Vascular, and Lilly. Dr Katz serves as an expert witness for Abbott Vascular, and Lilly. Dr King receives royalties from Cordis and serves as a consultant/advisory board member of Medtronic. The other authors report no conflicts.

References

CLINICAL PERSPECTIVE

Few studies have compared medium-term outcomes for drug-eluting stents (DES) and bare metal stents, and most of those are relatively small, randomized controlled trials. Furthermore, since the introduction of DES, there has been increased use and duration of use of clopidogrel, statins, and other evidence-based therapies. The purpose of this study was to compare outcomes for patients who underwent stenting in the eras before and after the introduction of DES. In New York state, patients undergoing stenting in nonfederal hospitals who had not undergone any previous revascularization were studied. Risk factors that were significant predictors of adverse outcomes were used to adjust adverse outcome rates. The study included 11436 patients who received stents between October 1, 2002 and March 31, 2003 (the pre-DES era) and 12926 patients who underwent stenting between October 1, 2003 and March 31, 2004 (the DES era). Mortality, the combined endpoint mortality/myocardial infarction, target vessel revascularization, and target lesion revascularization rates were compared at 2 years. Patients in the DES era had significantly better risk-adjusted outcomes for mortality/myocardial infarction (adjusted hazard ratio, 0.90; 95% confidence interval, 0.83 to 0.97), 9.9% versus 10.8%; target vessel revascularization (adjusted hazard ratio, 0.60; 95% confidence interval, 0.56 to 0.64), 11.2% versus 17.9%; and target lesion revascularization (hazard ratio, 0.55; 95% confidence interval, 0.51 to 0.59), 8.4% versus 14.7%. In conclusion, patients in the DES era experienced lower mortality/myocardial infarction, target vessel revascularization, and target lesion revascularization rates, but there were no differences in mortality. These improvements are likely to be a result of increased use of clopidogrel, statins, and dual antiplatelet therapy in addition to the introduction of DES.
Comparison of Coronary Artery Stenting Outcomes in the Eras Before and After the Introduction of Drug-Eluting Stents
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