Clinical and Economic Outcomes of Percutaneous Coronary Interventions in the Elderly: An Analysis of Medicare Claims Data

Mary Ann Clark, MHA; Ameet Bakhai, MD, MRCP; Michael J. Lacey, MS; Elise M. Pelletier, MS; David J. Cohen, MD, MSc

Background—Outcomes after percutaneous coronary intervention (PCI) have been documented extensively in clinical trials and single-center series, but few data exist on the clinical and economic outcomes after PCI in an unselected population.

Methods and Results—We used the Medicare Standard Analytic File to identify all initial PCI procedures performed in 1998 among a random sample of 5% of all Medicare beneficiaries ≥65 years of age. These patients (n=9868) were followed up for 1 year after PCI to identify clinical outcomes, medical resource use, and costs. Between 1 month and 1 year after PCI, 16.9% of patients required ≥1 repeat revascularization procedures. Mean 1-year medical care costs increased 5-fold among patients with repeat revascularization compared with those without ($26 186 versus $5344; P<0.001). After adjustment for baseline differences, the independent cost of repeat revascularization was $19 074 (95% CI, 18 440 to 19 707). Assuming from previous studies that 85% of repeat revascularization procedures over the first year of follow-up are attributable to restenosis, the estimated clinical restenosis rate was 14.4%, and the 1-year economic burden of restenosis to the healthcare system was $2747 per initial PCI procedure.

Conclusions—Among unselected elderly patients undergoing PCI, repeat revascularization occurs in ≈14% and increases 1-year healthcare costs by $19 000 per occurrence. These findings have important implications for the cost-effectiveness of new treatments that substantially reduce restenosis. (Circulation. 2004;110:259-264.)

Key Words: angioplasty ■ cost-benefit analysis ■ epidemiology ■ restenosis ■ stents

Since its development, percutaneous coronary intervention (PCI) has been limited by the need for subsequent revascularization procedures to treat restenosis. Although coronary stenting has resulted in lower rates of both angiographic and clinical restenosis compared with balloon angioplasty, angiographic studies continue to document restenosis in 20% to 40% of patients treated with stenting, depending on a variety of clinical and lesion-specific characteristics. The true rate of clinically significant coronary restenosis in contemporary clinical practice is more difficult to determine. Most data on rates of restenosis are derived from studies that also incorporated angiographic follow-up. These studies may be biased by the “oculostenotic reflex,” however, leading to higher rates of repeat revascularization than would have occurred in the absence of angiographic follow-up. Even clinical trials that do not incorporate angiographic follow-up may not reflect routine clinical practice because of selection biases inherent in such studies.

For the same reasons, little is known about the true economic burden of restenosis because these data typically are derived from clinical trials or single-center series that may not be applicable to the overall population of PCI patients. Such economic data are particularly relevant now because the advent of drug-eluting stents promises substantial reductions in restenosis and its associated costs but higher initial procedural costs (because of the cost of the stents themselves). To determine the potential economic impact of such therapies, we used Medicare data to determine the rates of repeat revascularization procedures and their associated costs in an unselected, elderly population undergoing contemporary PCI.

Methods

Data Sources and Study Population

The data sources for our study were the Medicare Standard Analytic Files (SAFs) for 1997 to 1999. These files contain all inpatient, outpatient, physician, and supplier claims submitted to Medicare for 5% of all beneficiaries enrolled in the fee-for-service Medicare Program. The SAFs contain patient characteristics; details regarding hospitalizations, diagnostic testing, and therapeutic procedures; phy-
sician services (inpatient and outpatient); and cost data in the form of Medicare payments for each service. Unique patient identification numbers allow patients to be tracked longitudinally.

Our study population consisted of all patients ≥65 years of age who underwent PCI between January 1, 1998, and December 31, 1998, and were continuously enrolled in the Medicare Part A fee-for-service program for 1 year before and after their PCI. Patients were identified by the presence of Current Procedural Terminology (CPT)-4 or International Classification of Diseases (ICD)-9 procedure codes for coronary stenting (ICD-9 code 36.06 or CPT-4 codes 92980 or 92981), PTCA (ICD-9 codes 36.01, 36.02, 36.05, or 36.09 or CPT-4 codes 92982, 92983, or 92984), or atherectomy (CPT-4 codes 92995 and 92996). To eliminate patients whose treatment was likely to have been for restenosis, we excluded patients who had undergone another PCI during the 12-month interval preceding the index PCI for our study. Patients who died during the first 30 days after PCI were also excluded.

**Outcome Measures**

The primary outcome of interest for our study was the occurrence of repeat revascularization between 31 and 365 days after the index procedure. Because claims databases (such as the Medicare SAFs) do not allow identification of the specific lesions treated, we estimated clinical restenosis rates by multiplying the observed rates of repeat revascularization between 31 and 365 days after PCI by a factor of 0.85. This factor was based on previous studies from our group and others demonstrating that during the first year of follow-up, 85% to 90% of all repeat revascularization procedures reflect target vessel revascularization (TVR). Additional outcomes tracked included death, myocardial infarction (MI), rehospitalization, and diagnostic catheterization. Costs were assessed from the Medicare payment perspective and exclude any beneficiary cost-sharing such as co-insurance and deductibles. We also performed a secondary analysis including only cardiovascular-specific resource use and costs based on prespecified diagnostic and procedural codes.

**Statistical Analysis**

Discrete data are reported as frequencies and were compared by Fisher’s exact test. Continuous data are reported as mean±SD and were compared by t tests or the Wilcoxon rank-sum test as appropriate. Analyses were performed with SAS version 8.2. For all comparisons, a value of *P*<0.05 was considered statistically significant.

We used multivariable linear regression to identify the independent effect of repeat revascularization between 1 and 12 months on follow-up medical care costs during the same time frame. The final model adjusted for demographic factors (age, gender, race, census region), comorbid conditions (defined based on ICD-9 codes), and procedural factors (saphenous vein graft intervention, stent placement). A parallel model was constructed with cardiovascular-specific costs as the dependent variable. For each model, we used the appropriate regression coefficient to estimate the independent cost of repeat revascularization, along with its associated 95% CI.

Finally, we calculated the economic burden of restenosis per treated patient using the estimated clinical restenosis rate (as defined above) and the independent cost of repeat revascularization (derived from the regression analyses). The aggregate burden to the US Medicare Program was estimated by inflating the economic burden in the 5% SAF data by a factor of 20.

**Results**

**Patient Population**

A total of 13 311 patients underwent ≥1 PCI in 1998 and were included in the SAF. After exclusion of 973 patients who had a PCI within the previous year, 860 patients who were not continuously enrolled during the study period, 1250 patients who were <65 years of age, and 360 patients who died during the initial 30 days, the remaining 9868 patients comprised the overall study population. Baseline characteristics of the population are summarized in Table 1.

**Clinical Outcomes and Restenosis**

Between 1 month and 1 year after the index procedure, 16.9% of the study cohort required ≥1 repeat revascularization procedures (the Figure). The rates of repeat PCI and bypass surgery were 13.2% and 4.9%, respectively. From these data, the estimated 1-year clinical restenosis rate was 14.4% (ie, 16.9%×0.85). There were no significant differences in 1-year mortality between those patients who did and those who did not require late repeat revascularization (Table 2). In contrast, patients in the repeat revascularization group were more likely to have experienced an MI during follow-up.

**Follow-Up Resource Use and Costs**

Resource use during the first year after PCI is summarized in Table 2. Patients in the repeat revascularization group required an average of 1.30 repeat revascularization (0.98 PCI, 0.33 CABG) procedures during follow-up (excluding any procedures during the first 30 days). As expected, all measures of medical resource use were increased among the repeat revascularization group. Patients who required repeat revascularization experienced more hospital admissions (1.58 versus 0.33 per patient; *P*<0.001) and aggregate hospital days during follow-up (8.04 versus 2.13 days; *P*<0.001) than patients who did not require repeat revascularization.

**TABLE 1. Baseline Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients (n=9868)</th>
<th>Patients With Repeat Revascularization &gt;30 Days (n=1667)</th>
<th>Patients Without Repeat Revascularization &gt;30 Days (n=8201)</th>
<th><em>P</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>73.4±5.8</td>
<td>73.0±5.5</td>
<td>73.5±5.8</td>
<td>0.004</td>
</tr>
<tr>
<td>Age ≥75 y, %</td>
<td>39.8</td>
<td>38.0</td>
<td>40.2</td>
<td>NS</td>
</tr>
<tr>
<td>Male, %</td>
<td>57.2</td>
<td>58.1</td>
<td>57.0</td>
<td>NS</td>
</tr>
<tr>
<td>Nonwhite, %</td>
<td>8.6</td>
<td>7.7</td>
<td>8.3</td>
<td>NS</td>
</tr>
<tr>
<td>Stenting as initial PCI, %</td>
<td>79.5</td>
<td>81.4</td>
<td>79.1</td>
<td>0.033</td>
</tr>
<tr>
<td>Acute MI as principal diagnosis, %</td>
<td>28.2</td>
<td>23.8</td>
<td>29.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Saphenous vein graft PCI, %</td>
<td>5.0</td>
<td>6.5</td>
<td>4.7</td>
<td>0.004</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>33.8</td>
<td>41.5</td>
<td>32.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Comorbid conditions, n</td>
<td>3.2±1.7</td>
<td>3.6±1.7</td>
<td>3.1±1.7</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
ian encounters and outpatient services also were increased by 35% to 88%.

Medical care costs between 31 and 365 days of follow-up are summarized in Table 3. Follow-up medical care costs were \( \approx \$21,000 \) higher for patients with repeat revascularization compared with those who did not require repeat revascularization (\$26,186 (median, \$19,803) versus \$5,344 (median, \$17,69); \( P<0.001 \)), of which \( \approx 80\% \) were related to inpatient services, 15% to physician services (including office visits), and 5% to other outpatient services. Similar differences were observed when we restricted our analysis to cardiovascular-related costs.

After adjustment for potential confounding factors, the cost difference between the repeat revascularization group and the group without repeat revascularization decreased from \( \$20,842 \) without adjustment to \( \$19,074 \) (Table 4). Applying the independent costs of repeat revascularization to the estimated rate of clinical restenosis in our cohort suggests that clinical restenosis adds \( \$2,747 \) (ie, \( \$19,074 \times 14.4\% \)) to the 1-year cost of care for each PCI patient.

**Incidence of any repeat revascularization, repeat PCI, or bypass surgery between 1 and 12 months after initial PCI among 9,866 unselected elderly patients.**
We also performed stratified analyses to determine the impact of selected patient characteristics on the incidence, cost, and economic burden of restenosis (Table 5). Increasing age (particularly >80 years) was associated with a significant reduction in both the incidence and adjusted cost of repeat revascularization. As a result, the estimated economic burden of restenosis decreased from $≈2800 per patient for those <80 years of age to just $1524 per patient for those ≥85 years of age. The presence of diabetes or chronic renal insufficiency was associated with substantial increases in both the incidence and cost of repeat revascularization (relative increases of 39% and 20% to 55%, respectively), so the estimated economic burden of restenosis ranged from $2244 per patient (for nondiabetics) to $5539 per patient (for patients with chronic renal failure).

### Discussion

Although restenosis after PCI has been the focus of extensive research over the past 2 decades, most studies have examined...
select patients enrolled in clinical trials or single-center series. Our study is the first to examine both the rates of restenosis and their economic consequences in a contemporary, unselected, elderly population. In this population, we found that 17% of all PCI patients required repeat revascularization procedures during the first year of follow-up (excluding early events), and these events were associated with substantial costs to the healthcare system. For each patient who underwent repeat revascularization, follow-up medical care costs were increased by $19 000 per patient, even after adjustment for differences in baseline patient characteristics. Given current PCI volumes, these findings imply that the aggregate cost to the Medicare Program for treatment of restenosis is $700 million per year.

Comparison With Previous Studies

Although the rate of restenosis after PCI has been well documented in clinical trials, few contemporary multicenter studies have determined the restenosis rate in a true population-based registry. Rankin and colleagues used a provincial registry to examine the outcomes of all PCI procedures performed between 1994 and 1997 in British Columbia. They found that the rate of TVR decreased from 24% to 17% over the study period, concurrent with an increase in stent use from 14% to 59% of all PCI procedures. More recently, Williams and colleagues examined 1-year outcomes of PCI performed at 15 centers in the United States and Canada between 1997 and 1998. In their series, stents were used in 70% of patients, and the 1-year TVR rate was 17.3% (12.0% repeated PCI, 6.8% CABG) (K.M. Detre, personal communication, July 31, 2002).

In our series, the estimated TVR rate at 1 year (14.4%) was somewhat lower than in these 2 previous series. There are several possible explanations for these findings. First, the rate of stent use in our study was 14% to 35% higher than in the previous 2 registries. In addition, we excluded patients who had undergone a PCI procedure within the year preceding their index procedure so as to restrict our analysis to patients undergoing treatment for de novo coronary lesions rather than restenosis. Third, we excluded repeat revascularization procedures performed within 30 days of PCI from our primary analysis. In contrast, both the British Columbia registry and the NHLBI Dynamic Registry included early TVR procedures in their outcomes, which occurred in 3.7% and 5.6% of patients, respectively. Finally, the patients in our study were substantially older than those included in the 2 previous registries (mean age, 73 versus 62 to 63 years). Several previous studies and the present study have demonstrated that independent of other factors, older patients are less likely to undergo repeat revascularization procedures.

Although TVR was less frequent than previously reported in this elderly population, we found that the costs associated with repeat revascularization are substantially higher than have previously been reported. Previous studies from our group and others have reported 1-year restenosis-related costs of $10 000 to $12 000. In this study, however, the need for repeat revascularization increased 1-year costs by $19 000 per patient. Whether these differences relate to the more complex patient population included in the present study or to the more complete capture of follow-up resource utilization afforded by use of administrative data is uncertain.

Study Limitations

The principal limitation of our study is the absence of detailed angiographic data; we were unable to distinguish target lesion
revascularization during follow-up from procedures for other new lesions. Consequently, we were able only to estimate the true rate of clinical restenosis and the economic burden of restenosis in the Medicare population. Although use of a clinical data set would have clarified the true restenosis rate, the use of an administrative data set in our study provides substantial advantages in terms of both generalizability of our findings and the ability to capture virtually all follow-up resource use and costs.

Clinical and Policy Implications
Despite substantial improvements in PCI outcomes over the past decade, we found that clinically significant restenosis continues to occur in >14% of elderly patients within the first year after PCI and adds $2747 per patient on average to the cost of follow-up care after PCI. These findings thus suggest that treatments such as drug-eluting stents, which have been shown to reduce the risk of clinically significant restenosis by 70% to 75%, may result in cost offsets approaching $2000 per treated patient in the current Medicare population. Given the current cost of drug-eluting stents relative to bare metal stents (≈$2000 more) and mean stent use of ≈1.5 per procedure, however, our analysis suggests that it is unlikely that drug-eluting stents will be cost saving for the overall Medicare PCI population. Nonetheless, if the effectiveness of drug-eluting stents in more challenging populations is similar to their overall effectiveness, true long-term cost savings might still be achieved in selected high-risk groups (such as diabetics or patients with chronic renal insufficiency).

Even if these newer stents do not fully offset their costs, they may still be cost-effective if the additional health benefits of reduced restenosis are considered to be worth the additional cost from a societal perspective. Moreover, if some patients who typically receive coronary bypass surgery are treated with drug-eluting stent procedures, further savings to the Medicare Program might be realized.

Acknowledgment
This study was supported in part by a grant from Boston Scientific Corporation.

Disclosure
Drs Clark, Lacey, and Pelletier are employees and stockholders of Boston Scientific Corp. Dr Bakhai has collaborated on projects with stent manufacturing companies.

References
Clinical and Economic Outcomes of Percutaneous Coronary Interventions in the Elderly: An Analysis of Medicare Claims Data
Mary Ann Clark, Ameet Bakhai, Michael J. Lacey, Elise M. Pelletier and David J. Cohen

Circulation. 2004;110:259-264; originally published online June 28, 2004;
doi: 10.1161/01.CIR.0000135589.85501.DB
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2004 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/110/3/259

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org//subscriptions/