This study is the first to estimate costs and medical resource use assocated with restenosis involving bare metal stents in managed care percutaneous coronary intervention patients.

Clinical and Economic Effects of Coronary Restenosis After Percutaneous Coronary Intervention in a Managed Care Population

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ABSTRACT

Purpose: The epidemiology of coronary restenosis after percutaneous coronary intervention (PCI) has been documented extensively in clinical trials, but no data exist on the clinical and economic burden of restenosis in a managed care population.

Design: Retrospective cohort with a nationally representative managed care claims database (IHCIS, Waltham, Mass.) representing 2.8 million members.

Methodology: Patients undergoing initial PCI between 1/1/00 and 12/31/00 (N=3,258) were identified and followed to 1 year. Clinical events, resource use, and costs between 1 month and 1 year after the initial PCI were identified. The clinical restenosis rate was estimated by multiplying the observed repeat revascularization rate by 0.85, based on previously published studies. All costs are reported from a managed care perspective in Year 2000 dollars.

Principal findings: Overall, 14.7 percent of patients required 1 or more repeat revascularization procedures between 1 month and 1 year after initial PCI, which implies an estimated clinical restenosis rate of 12.5 percent. Mean 1-year costs were nearly 6-fold higher among patients with and without repeat revascularization ($31,954±$31,857 vs. $5,474±$12,006, $P<.001$). After adjusting for baseline imbalances, the independent incremental cost for each patient with repeat revascularization was $24,955 (95 percent confidence interval, $23,401–$26,510). Annual follow-up costs attributable to restenosis were $3,118 per initial PCI recipient (i.e., $24,955 × 12.5 percent).

Conclusion: Clinical restenosis occurred in approximately 12.5 percent of real-world managed care PCI patients and increased health care costs by an average of $3,118 per patient. These findings have important implications for the cost-effectiveness of new treatments that substantially reduce restenosis.

Key terms: restenosis, stent, cost-effectiveness, managed care, costs, epidemiology

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INTRODUCTION

Percutaneous coronary revascularization (PCI) is one of the most common reasons for hospitalization in the United States, with more than 760,000 procedures every year (HCUPNet 2002). Although coronary stenting with conventional bare metal stents (i.e., non-drug-eluting) has resulted in substantial improvements in both short- and long-term outcomes of PCI compared with balloon angioplasty alone, it remains limited by restenosis (i.e., renarrowing of the treated vessel) in 20 to 40 percent of patients, depending on various clinical and lesion-specific characteristics (Serruys 1999).

While some episodes of restenosis are silent clinically, many result in recurrent myocardial ischemia and its associated symptoms, leading to additional percutaneous or surgical revascularization procedures. Recently, two drug-eluting stents

(Taxus, Boston Scientific Corp., Natick, Mass.; Cypher, Cordis Corp., Miami, Fla.) have been demonstrated to reduce the incidence of both angiographic and clinically significant restenosis by 60 to 80 percent and have received approval for use in the United States (Stone 2004, Holmes 2004). Given the high cost of these devices (approximately $2000 more per stent than conventional bare metal designs), important concerns about their potential economic impact remain as barriers to their universal application (O'Neill 2003).

Although the process of restenosis has been studied extensively in clinical trials, limited data exist on the true rate of clinically significant restenosis in contemporary clinical practice. This true rate is difficult to determine. Most data on restenosis rates derive from studies that also incorporate angiographic follow up. These studies may be biased by the "oculostenotic reflex," leading to substantially higher rates of repeat revascularization than would have occurred in the absence of angiographic follow up (Serruys 1998, Topol 1995).

Further, even clinical trials that do not incorporate angiographic follow up may not reflect the true restenosis rate in routine clinical practice, due to the selection biases inherent in such studies. Thus, little is known about the true economic burden of restenosis. Most data regarding the effects of restenosis on long-term costs after PCI are derived from clinical trials (Cohen 1995, Topol 1999) or from single-center series (Peterson 1999), and thus may not be applicable to the overall population of PCI patients.

Given that approximately 40 percent of all PCI procedures are performed within the managed care system (HCUPNet 2002), such "real world" data are critical to understanding the overall clinical and economic burden of restenosis to managed care plans. Accordingly, we performed a retrospective study to determine the true rate of clinically significant restenosis after PCI and its associated costs in an unselected managed care population. Because the first drug-eluting coronary stent (DES) came on the market in 2003, our analysis focuses on real-world clinical and economic effects prior to the widespread use of DES. This information could be helpful to payers in assessing the economic value of drug-eluting stent technology.

MAKING THE CASE FOR QUALITY CARE: THE ARGUMENT FOR DRUG-ELUTING STENTS

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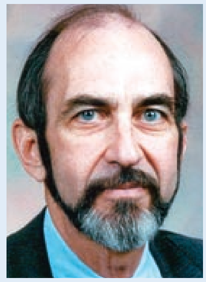

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In trying to match up the business case with improvements in the quality of health care, there is often a financial disconnect between the provider of the service and the recipient. The bare-metal stent (BMS) was approved in August 1994; Medicare reimbursement was approved effective October 1997. These stents substantially improved short- and long-term outcomes compared to balloon angioplasty. In substituting drug-eluting stents (DES) for bare-metal stents, the initial additional cost of approximately $2,000 reduced the incidence of restenosis by 60 percent to 80 percent. The hospital shouldered the additional cost, while the patient and society benefited from lower restenosis rates. Eventually, economic equilibrium was achieved, and the institutional provider was paid an additional amount to cover the cost of the stent.

But isn't there a better way? The analysis by Clark and colleagues, who are either employees or paid consultants for a DES manufacturer, provides a straightforward economic analysis. Based on an objective literature review, they indicate that if MCOs paid for 304,000 percutaneous cardiac interventions annually and 60 percent to 80 percent of the expected 38,000 restenoses could be avoided by DES, then the cost saving would be between $569 million and $759 million (22,800 to 30,400 times $24,955/procedure).

Approximately 10 percent would be subtracted from the cost savings due to the additional cost of $2,000/case for the DES and $575/case for 5 additional months of clopidogrel. Additionally, DES permitted a 20 percent reduction in cardiac surgery cases — another cost-savings factor not included. In broader terms, for the entire U.S. health care system, realized cost savings should amount to between $1.4 billion and $1.9 billion. In the future, when the business case for an innovation in care quality is evident from technical and economic analyses, earlier reimbursement provisions for the additional costs will facilitate the transition to new and better therapeutic forms.

METHODS

Data sources and study population

The Managed Care Benchmark Database from Integrated Healthcare Information Services (Waltham, Mass.) was the data source for our study. This database contains all medical (inpatient, outpatient, physician, ancillary) and pharmacy claims from a national sample of 30 managed care health plans, covering approximately 2.8 million lives from 1999 to 2001. This database is representative in terms of age and sex distribution compared with national enrollment in managed care plans. Regional representation, however, is biased toward the East Coast. These claims contain patient characteristics that include demographic information; diagnoses; detailed information about hospitalizations, diagnostic testing, and therapeutic procedures; physician services (inpatient as well as outpatient); prescription drug use; and cost data in the form of managed care reimbursement rates for each service. Unique patient-identification numbers allow patients to be tracked longitudinally.

Our study population comprised all patients who underwent PCI between 1/1/2000 and 12/31/2000 and who were continuously enrolled in their managed care health plans in 1999 and through their index procedure date in 2000. Patients with less than 1 year of postprocedure enrollment were included in our analyses, but their data were censored at the time of dropout. Patients were identified based on the presence of CPT-4 procedure codes for coronary stenting (92980, 92981), PTCA (92982/4), and atherectomy (92995/6). To eliminate patients whose treatment in 2000 was likely to have been for restenosis, those who had undergone another PCI in the 12-months preceding the index PCI for our study were excluded.

We identified comorbid conditions that may affect restenosis rates and follow-up costs on the basis of International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes. Specific comorbid conditions of interest included diabetes mellitus, acute myocardial infarction (as a principal diagnosis at the time of the index procedure), hypertension, congestive heart failure, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disease, chronic renal failure, rheumatoid arthritis or osteoarthritis, affective disorders, neoplasms, and HIV.

Outcome measures

The primary outcomes of interest for our study were the rates of repeat revascularization procedures that occurred between 31 days and 1 year after the index procedure and the associated medical resource utilization and costs. Repeat revascularization procedures within the first 30 days of the index procedure were excluded, as previous studies have demonstrated that restenosis is exceedingly rare within the first 30 days of PCI. Thus, procedures during the first month are much more likely to be for thrombotic complications (e.g., abrupt closure, stent thrombosis) or planned staging for multivessel disease (Schuhlen 1998, Cutlip 2001, Cutlip 2002).

Given that claims databases do not allow identification of the specific lesions treated, we estimated clinical restenosis rates by multiplying the observed rates of repeat revascularization by a factor of 0.85. This factor was based on previous studies that suggest that during the first year of follow up, 85 to 90 percent of all repeat revascularization procedures after PCI reflect target vessel revascularization (Cutlip 2002, Kimmel 2002).

Resource utilization and medical care costs including hospitalizations, physician encounters, outpatient facility visits, prescription drugs, and specific cardiovascular (CV) diagnostic procedures were assessed for the 1-year follow-up period, as well. Physician encounters included medical visits and procedures during follow up. To avoid double-counting, we considered more than one service billed by the same physician on the same day as a single encounter. Patient visits to hospital outpatient clinics and emergency rooms were tabulated in a similar manner to assess medical resource use in hospital outpatient facilities. All costs were assessed from a managed care reimbursement perspective and include member cost-sharing such as coinsurance and deductibles. Using this perspective enables payers to evaluate the economic effects of clinical restenosis in this population in terms of total fees paid to providers. We also performed a secondary analysis including only CV-specific resource utilization and costs — defined on the basis of 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 plus or minus 1 standard deviation and were compared by t-tests or the Wilcoxon rank-sum test, as appropriate. The Kaplan-Meier method was used to estimate 1-year rates of repeat revascularization. All analyses were performed using SAS version 8.2. For all comparisons, a *P*-value less than .05 was considered statistically significant.

We used multivariable linear regression to identify the independent effect of repeat revascularization on follow-up medical care costs, while adjusting for baseline differences. Four models were created sequentially: (1) unadjusted; (2) adjusted only for demographic factors (age, gender, race, geographic region); (3) adjusted for demographic and clinical factors (comorbid conditions previously listed); and (4) adjusted for demographic, clinical, and procedural factors (stent placement). Similar models were constructed using CV-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 percent confidence interval. Although the follow-up cost data were not normally distributed, given the large sample size, the use of untransformed data for the regression analysis was reasonable under the Central Limit Theorem. Moreover, log transformation of the cost data did not appreciably improve the model fit compared with use of untransformed data. Finally, we calculated the economic burden of restenosis per treated patient using the estimated clinical restenosis rate (as defined previously) and the independent cost of repeat revascularization (derived from the regression analyses).

RESULTS

Patient population and early outcomes

A total of 3,582 patients underwent at least 1 PCI in 2000 and were included in the Managed Care Benchmark Database. After excluding 266 patients who had a coronary revascularization within the year preceding their index procedure and 58 patients who were not continuously enrolled in 1999 through their index procedure date, the study population comprised the remaining 3,258 patients (Table 1). The mean age was 61.3 years, and 76 percent were men. About one third of the population had diabetes mellitus, and approximately one fifth had a principal diagnosis of acute myocardial infarction. On average, patients had approximately 2.7 major comorbid conditions, of which hypertension (79 percent), congestive heart failure (39 percent), and diabetes mellitus (34 percent) were most frequent.

During the 30-day follow-up period, 6.1 percent underwent at least 1 additional revascularization procedure (including 2.3 percent PCI and 0.7 percent bypass surgery during the same initial hospitalization). Mean costs for the index hospitalization — including inpatient, outpatient, professional, ancillary, and pharmacy costs — were $16,528 per patient, and 30-day follow-up costs were $1,996 per patient.

Late clinical outcomes and restenosis

Overall, 478 patients required 1 or more repeat revascularization procedures between 31 days and 365 days after their index procedure, with a Kaplan-Meier incidence of 14.7 percent. The 1-year rates of repeat PCI and bypass surgery were 12.5 percent and 2.3 percent, respectively. Approximately 90 percent of patients who required repeat revasculariza-

TABLE 1 Baseline characteristics

Characteristic	All patients (N=3,258)	Patients with repeat revascularization (n=478)	Patients without repeat revascularization (n=2,780)	*P*-value
Mean age (years)	61.3±11.1	61.6±11.5	61.2±11.0	NS
Age group (%)				NS
<50 years	13.8	15.1	13.6	
50–59 years	33.8	30.5	34.4	
60–69 years	28.2	27.8	28.3	
70–79 years	17.7	19.3	17.4	
≥80 years	6.5	7.3	6.4	
Male (%)	76.0	74.3	76.3	NS
Stenting as initial PCI (%)	89.3	88.7	89.4	NS
AMI as principal diagnosis (%)	22.1	16.5	23.1	.001
Saphenous vein graft PCI (%)	1.8	2.7	1.7	NS
Diabetes mellitus (%)	32.1	42.1	30.4	<.001
Mean number of comorbid conditions*	2.74±1.63	3.12±1.61	2.68±1.62	<.001

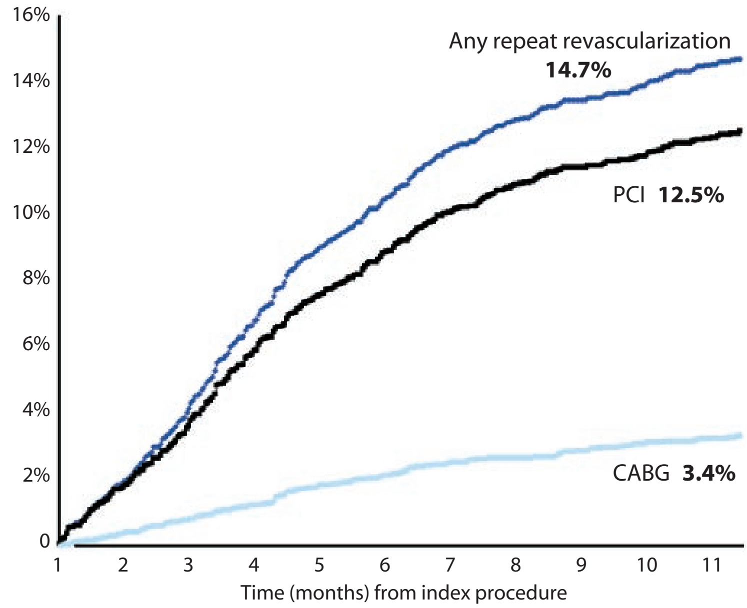
AMI=acute myocardial infarction; NS=not significant; PCI=percutaneous coronary intervention.

* Includes all comorbid conditions in the Charlson Index except cardiac valve disease, epilepsy and other neurologic disorders, benign neoplasms, asthma, acute renal failure, and cardiac conduction defects.

tion presented within the first 9 months of follow up (Figure 1). Based on these data and the proportion of repeat revascularization events that have been shown to involve target-vessel revascularization in previous studies, the estimated 1-year clinical restenosis rate in a typical managed care population was 12.5 percent (i.e., 14.7 percent*0.85).

FIGURE 1

Incidence of any repeat revascularization, repeat percutaneous coronary intervention (PCI) , or bypass surgery between 1 month and 12 months after initial PCI in 3,258 unselected managed care patients.



CABG=coronary artery bypass graft.

Follow-up resource use and costs

Resource use during the first year after PCI for patients with and without repeat revascularization is summarized in Table 2. Patients who were in the repeat-revascularization group required an average of 1.29 repeat-revascularization procedures during follow up (excluding any procedures during the first 30 days after initial PCI) — 1.05 PCI procedures per patient and 0.23 coronary artery bypass graft (CABG) procedures per patient. Thus, for every 1,000 patients treated with initial PCI, there were 154 repeat PCI procedures and 34 CABG procedures during the first year of the follow-up period.

All measures of medical-resource utilization were increased substantially among the repeat-revascularization group, as was expected. Those patients who required repeat revascularization experienced more hospital admissions (1.91 vs. 0.34 per patient, $P<.001$) and aggregate hospital days during follow up (8.43 vs. 2.03 days, $P<.001$) than did those patients who did not require additional revascularization. The repeat-revascularization group also had 65 percent more physician encounters and 57 percent more outpatient visits, 2 times as many ancillary services, and 19 percent more prescriptions during the first year of follow up. Patients in the repeat-revascularization group were more likely to have undergone diagnostic catheterization and stress testing during follow up, as well.

Medical care costs (managed care reimbursement) during the period between 31 and 365 days of follow up are summarized in Table 3.

Follow-up medical care costs per patient were approximately $30,000 higher for those with repeat revascularization as compared with patients who did not require repeat revascularization ($39,869±$43,389 vs. $10,062±$17,861, $P<.001$). Of this difference, approximately 72 percent was related to inpatient services, 20 percent was related to physician services (including office visits), and 5 percent was related to outpatient services. Ancillary and prescription drug costs made up the remaining costs. Similar differences were observed when we restricted our analysis to CV-related costs.

To estimate the costs that were directly attributable to repeat revascularization, we developed a series of multivariable models to adjust for potential confounding factors between the repeat revascularization and no repeat-revascularization groups (Table 4). Imbalances in patient demographics and clinical and procedural characteristics accounted for 8 percent of the difference in total costs for patients with and without repeat revascularization. The cost difference decreased from $29,806 without adjustment to $27,380 after controlling for all model variables.

A similar trend emerged when examining CV-specific costs, with the cost difference decreasing from $26,480 without adjustment to $24,955 after controlling for potential confounders. Applying the independent costs of repeat revascularization to the estimated rate of clinical restenosis in our cohort suggests that clinical restenosis adds $3,118 per patient (i.e., $24,955 × 0.147 × 0.85) to the 1-year cost of care for each managed care PCI patient.

DISCUSSION

Although restenosis after PCI has been the focus of extensive research during the past 2 decades, most studies have examined select patients who were enrolled in clinical trials or single-center series. Population-based studies to date have been restricted to the U.S. Medicare population (Clark 2004). This study is the first, to our knowledge, to examine these outcomes and costs in a managed care population. In this population, we found that approximately 15 percent of all PCI patients required 1 or more repeat revascularization procedures during the first year of follow-up (excluding early events), and these events were associated with substantial health care costs. For each patient who underwent repeat revascularization, follow-up CV-related medical care costs were increased by about $25,000 per patient — even after adjusting for differences in baseline patient characteristics. The PCI volumes in this managed care database imply that the aggregate cost to a 2.8 million member managed care plan for treatment of restenosis is more than $10 million/year ($3,118*3258 initial PCI patients).

Comparison with previous studies

Although the rate of restenosis after PCI has been well documented in clinical trials, few contemporary studies have determined the restenosis rate in a true population-based registry. Rankin and colleagues (1999) studied the outcomes of all PCI procedures performed between 1994 and 1997 in British Columbia. They found that the rate of repeat target vessel revascularization decreased from 24 percent to 17 percent over the study period, while stent use increased from 14 percent to 59

TABLE 2 Resource utilization between 31 and 365 days

Resource	Repeat-revascularization group (n=478)	No repeat-revascularization group (n=2,780)	Difference (95% CI)	*P*-value
AMI %	6.0	25.9	2.5	<.001
Repeat-revascularization procedures				
All procedures	1.29±0.60	0.0	NA	NA
PCI	1.05±0.66	0.0	NA	NA
CABG	0.23±0.44	0.0	NA	NA
Hospital admissions (mean/SD)				
All admissions	1.91±1.52	0.34±0.91	1.57 (1.47–1.67)	<.001
Aggregate hospital days (all admissions)	8.43±23.77	2.03±10.32	6.40 (5.12–7.68)	<.001
Cardiovascular admissions	1.54±1.22	0.20±0.65	1.34 (1.26–1.41)	<.001
Aggregate hospital days (cardiovascular admissions)	5.84±10.79	0.96±5.34	4.88 (4.26–5.50)	<.001
Diagnostic catheterizations (without PCI) (%)	41.4	9.8	31.6	<.001
Stress test* (%)	74.3	57.4	16.9	<.001
Outpatient visits (mean/SD)				
All visits	11.84±15.27	7.56±11.90	4.28 (3.07–5.49)	<.001
Cardiovascular visits	8.95±13.09	5.21±9.82	3.74 (2.73–4.74)	<.001
Professional services (mean/SD)				
All encounters	28.26±21.76	17.02±15.42	11.24 (9.64–12.85)	<.001
Cardiovascular encounters	19.74±16.07	9.40±9.27	10.34 (9.32–11.36)	<.001
Ancillary services (mean/SD)				
All services	3.61±7.20	1.77±5.85	1.83 (1.25-2.42)	<.001
Cardiovascular services	2.17±5.11	0.66±3.20	1.51 (1.16–1.85)	<.001
Prescriptions (mean/SD)				
All prescriptions	21.25±15.74	17.91±14.37	3.34 (1.93–4.76)	<.001
Cardiovascular prescriptions	14.15±10.47	11.90±9.50	2.25 (1.31–3.18)	<.001

CABG=coronary artery bypass graft; CI=confidence interval; NA=not applicable; PCI=percutaneous coronary intervention; SD=standard deviation.

* Includes exercise tolerance test (ETT), ETT-echocardiogram, ETT-nuclear, pharmacologic stress tests (adenosine nuclear, persantine nuclear, dobutamine echo).

TABLE 3 Follow-up medical care costs — between 31 and 365 days

Cost	Repeat-revascularization group (n=478)	No repeat-revascularization group (n=2,780)	Difference (95% CI)	*P*-value
Total costs	$39,869±43,389	$10,062±17,861	$29,806 (27,533–32,079)	<.001
Hospital inpatient	$24,832±36,321	$3,258±13,592	$21,573 (19,755–23,392)	<.001
Outpatient	$3,239±5,229	$1,879±4,516	$1,360 (911–1,809)	<.001
Professional	$8,827±6,820	$2,848±3,232	$5,979 (5,594–6,364)	<.001
Ancillary	$917±2,954	$443±1,901	$474 (271–677)	<.001
Pharmacy	$2,054±1,970	$1,634±2,005	$420 (226–614)	<.001
Total cardiovascular costs	$31,954±31,857	$5,474±12,006	$26,480 (24,880–28,080)	<.001
Hospital inpatient	$21,171±27,918	$1,950±10,199	$19,221 (17,837–20,604)	<.001
Outpatient	$2,313±3,074	$1,058±1,784	$1,255 (1,059–1,452)	<.001
Professional	$6,931±4,420	$1,476±1,783	$5,455 (5,226–5,684)	<.001
Ancillary	$407±784	$111±405	$297 (250–343)	<.001
Pharmacy	$1,131±989	$878±756	$253 (176–330)	<.001

CI=confidence interval.

TABLE 4 Estimated effects of repeat revascularization on risk-adjusted 1-year medical care costs

	Total medical care costs		**Cardiovascular medical care costs**	
	Cost difference	***95% CI***	***Cost difference***	***95% CI***
Unadjusted	$29,806	(27,533–32,079)	$26,480	(24,880–28,080)
Adjusted for demographics	$29,710	(27,446–31,975)	$26,436	(24,837–28,035)
Adjusted for demographics and clinical characteristics	$27,380	(25,236–29,524)	$24,955	(23,401–26,510)
Adjusted for demographics, clinical characteristics, and procedural characteristics*	$27,380†	(25,235–29,525)	$24,955‡	(23,401–26,510)

*Final risk-adjusted model included the following factors: age groups (age group 60–69 as reference), gender, geographic region, HIV, neoplasms, diabetes mellitus, affective disorders, schizophrenia and other related disorders, hypertension, coronary heart failure, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disorder, chronic renal failure, rheumatoid arthritis, osteoarthritis, acute myocardial infarction as primary diagnosis, saphenous vein grafts/percutaneous coronary intervention, and stenting as the index procedure

†Model R^2 =0.29

‡Model R^2 =0.31

percent. In 2000, Williams and colleagues examined 1-year outcomes of PCI performed at 15 diverse centers in the United States and Canada between 1997 and 1998. In this series, stents were used in 70 percent of patients and the 1-year total vascular regeneration (TVR) rate was 17.3 percent (12.0 percent repeat PCI and 6.8 percent CABG) (Detre 2002).

In this series, the estimated clinical restenosis rate at 1 year (12.5 percent) was somewhat lower than was seen in these two previous series.

There are several possible explanations for these findings. First, the rate of stent use in our study (approximately 79 percent) was higher than in the previous two registries. Because stenting has been found to reduce restenosis across virtually all lesion types (Serruys 1999), it is likely that the higher rate of stenting in our series accounts in part for the lower rates of TVR that we observed. In addition, we excluded patients who had undergone a PCI procedure within the year preceding their index procedure in an attempt to restrict our analysis to patients undergoing treatment for *de novo* coronary lesions rather than restenosis. Given that it is well recognized that treatment of in-stent restenosis is associated with higher rates of recurrent restenosis compared with treatment of *de novo* lesions (Anderson 2002), our selection criteria may have produced somewhat more favorable outcomes.

Third, we excluded repeat revascularization procedures performed within 30 days of PCI from our primary analysis. This was necessary in our study, as we sought to isolate those events related to treatment of restenosis from either staged revascularization procedures or acute ischemic complications. In contrast, the British Columbia registry and the National Heart, Lung, and Blood Institute Dynamic Registry included early TVR procedures in their outcomes, which occurred in 3.7 percent and 5.6 percent of patients, respectively (Rankin 1999, Williams 2000).

We recently performed a similar claims-based analysis of PCI outcomes in the U.S. Medicare population for 1999 (Clark 2004). In this study, we found that the incidence of any repeat revascularization by 1-year follow up was 16.9 percent, with an estimated clinical restenosis rate of 14.4 percent. The explanation for the slightly lower rate of apparent clinical restenosis in the managed care population is unknown, but it may relate in part to the lower rates of vein graft PCI and higher rates of stenting during PCI in the current study compared with the Medicare population.

Costs of restenosis

Although, our study shows the incidence of repeat revascularization to be lower than in many previous reports, 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 approximately $10,000 to $19,000 (Topol 1995, Cohen 1995, Clark 2004). In this study, however, the need for repeat revascularization increased 1-year costs by more than $27,000 per patient.

There could be several reasons for the higher costs found in this population. First, our managed care claims data represent claims paid by managed care plans in 2000 — a more recent year of data than previously published. Second, our claims database probably provides a more complete capture of follow-up resource utilization than either clinical trials or Medicare claims data. In particular, no previous studies have examined the effects of repeat revascularization on outpatient pharmacy costs, which represented approximately 5 percent of total follow-up costs in our managed care population. Finally, managed care payers tend to pay at rates higher than Medicare rates. Consequently, the corresponding incremental costs due to restenosis would be greater.

Clinical and policy implications

Despite substantial improvements in PCI outcomes over the past decade, we found that clinically significant restenosis continues to occur in approximately 12.5 percent of patients within the first year after PCI and adds approximately $3,118 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 demonstrated effectiveness in reducing clinical restenosis by 60 percent to 80 percent (Holmes 2004, Stone 2004), could offset approximately $1,870 to $2,494 per treated patient in a general managed care PCI population. Assuming 304,000 PCI procedures per year are paid by managed care (HCUPNet 2002) and that 12.5 percent of these procedures are due to restenosis, DES could reduce the number of managed care PCIs by 20,000 to 27,000. Total cost offsets to managed care plans could be as high as $674 million. Similarly, a recent Medicare study suggests that total cost offsets to the Medicare Program due to DES could be as high as $611 million ($764 million*80 percent) (Clark 2004).

Therefore, aggregate offsets due to this new technology could result in a reduction of over 50,000 procedures and more than $1 billion in costs within the U.S. health system. Among subgroups for which clinical and angiographic restenosis rates tend to be higher than average (e.g., diabetes, small coronary vessels, long lesions) (Cutlip 2002), the cost and procedure offsets would be projected to be even greater.

Given the current difference in price between drug-eluting and bare metal stents (approximately $1,660) and the average number of stents per procedure (1.5), these stents may not completely offset all costs. Even if these newer stents do not fully offset their costs, they may still be cost-effective if, from a societal perspective, the additional health benefits of reduced restenosis are considered to be worth the additional cost. One recent study has shown that DES are cost effective within the parameters of a clinical trial (Cohen 2004). Moreover, if patients who typically receive coronary bypass surgery are treated with DES procedures and achieve comparable long-term outcomes, further savings to payers might be realized.

The cost-effectiveness of drug-eluting stents in this patient population will be studied in upcoming clinical trials. Validation of these projections will necessitate additional studies to determine the extent to which DES reduce angiographic and clinical restenosis across the full spectrum of PCI patients that were included in our study.

Study limitations

Our study has several limitations. First, since detailed angiographic data were not available in the Managed Care Benchmark Database, we were unable to distinguish target lesion revascularization from procedures performed on other vessels or new lesions within the target vessel that were not treated during the index procedure. As a result, we were only able to estimate the true rate of clinical restenosis and the economic burden of restenosis in a managed care population. Nonetheless, we believe that our estimates of these rates are conservative, based on previous studies demonstrating that 85 to 90 percent of repeat revascularization procedures occurring between 1 month and 1 year after PCI are due to restenosis (Cutlip 2002, Kimmel 2002).

While use of a clinical data set would have clarified the true restenosis rate, the use of an administrative dataset in our study provides substantial advantages in terms of the ability to generalize our findings and to capture virtually all follow-up resource utilization and costs.

Although the ability to make generalizations from this study about all managed care plans could be affected by its overrepresentation of East Coast plans, its age and sex distribution is representative of other managed care plans. Second, we used managed care reimbursement rates as our measure of cost.

While other measures of medical care costs (such as charges multiplied by cost-to-charge ratios) might have been considered, our measure has the advantage of representing the total costs to providers that are covered by one key decision maker — managed care payers.

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