Journal of the American College of Cardiology
© 1999 by the American College of Cardiology
Published by Elsevier Science Inc.
Vol. 33, No. 6, 1999
ISSN 0735-1097/99/$20.00
PII S0735-1097(99)00051-0



# Acute and Long-term Cost Implications of Coronary Stenting

Eric D. Peterson, MD, MPH, FACC,* Patricia A. Cowper, PhD, Elizabeth R. DeLong, PhD,† James P. Zidar, MD, FACC,* Richard S. Stack, MD, FACC,* Daniel B. Mark, MD, MPH, FACC*
*Durham, North Carolina*

**OBJECTIVES** We compared the acute and one year medical costs and outcomes of coronary stenting with those for balloon angioplasty (percutaneous transluminal coronary angioplasty) in contemporary clinical practice.

**BACKGROUND** While coronary stent implantation reduces the need for repeat revascularization, it has been associated with significantly higher acute costs compared with coronary angioplasty.

**METHODS** We studied patients treated at Duke University between September 1995 and June 1996 who received either coronary stent ($n = 384$) or coronary angioplasty ($n = 159$) and met eligibility criteria. Detailed cost data were collected initially and up to one year following the procedure. Our primary analyses compared six and 12 month cumulative costs for coronary angioplasty- and stent-treated cohorts. We also compared treatment costs after excluding nontarget vessel interventions; after limiting analysis to those without prior revascularization; and after risk-adjusting cumulative cost estimates.

**RESULTS** Baseline clinical characteristics were generally similar between the two treatment groups. The mean in-hospital cost for stent patients was $3,268 higher than for those receiving coronary angioplasty ($14,802 vs. $11,534, $p < 0.001$). However, stent patients were less likely to be rehospitalized (22% vs. 34%, $p = 0.002$) or to undergo repeat revascularization (9% vs. 26%, $p = 0.001$) than coronary angioplasty patients within six months of the procedure. As such, mean cumulative costs at 6 months ($19,598 vs. $19,820, $p = 0.18$) and one year ($22,140 vs. $22,571, $p = 0.26$) were similar for the two treatments. Adjusting for baseline predictors of cost and selectively examining target vessel revascularization, or those without prior coronary intervention yielded similar conclusions.

**CONCLUSIONS** In contemporary practice, coronary stenting provides equivalent or better one-year patient outcomes without increasing cumulative health care costs. (J Am Coll Cardiol 1999;33: 1610–8) © 1999 by the American College of Cardiology

Efforts to reduce the rate of abrupt vessel closure and restenosis associated with percutaneous balloon intervention have led to the development and testing of coronary stents (1–3). In randomized trials, elective stent use improved the acute clinical success rate of the procedure and reduced the rate of repeat revascularization compared with conventional balloon angioplasty (percutaneous transluminal coronary angioplasty) (4,5). However, stent implantation is costly (6–8) and was initially thought to require aggressive post-procedure oral anticoagulation (9). This adjuvant therapy resulted in increased bleeding complications, longer in-patient hospital stays and was associated with higher acute care costs (10–12). While the reduced need for subsequent revascularization procedures associated with stenting partially offset their initial expense (13,14) at one year, costs for patients receiving stents remained $800 to $4,600 higher than for those receiving conventional coronary angioplasty (13,15,16).

Since these initial studies, the use of coronary stents in clinical practice has changed significantly. First, a post-stent antiplatelet regimen including ticlopidine and aspirin has been developed as an effective alternative to the use of oral anticoagulation (17–19). This newer regimen is less likely to cause bleeding complications and avoids the need for extended hospitalizations. Second, the spectrum of patients receiving stents has broadened considerably since the initial randomized trials. While early studies included predominately low-risk patients (e.g., those with discrete, de novo lesions in a single native vessel), current stent use includes their implantation in more complex lesions, during multivessel interventions and in patients presenting with restenotic lesions (2,3,20,21).

The purpose of this study was to compare the economic and clinical outcomes of patients undergoing stenting with

From the *Division of Cardiology, Department of Medicine and; †the Division of Biometry, Department of Community and Family Medicine, Duke University Medical Center, Durham, North Carolina. This study was supported by a research grant from Johnson & Johnson Interventional Systems, Warren, New Jersey.
Manuscript received July 28, 1998; revised manuscript received January 5, 1999, accepted January 20, 1999.

**Abbreviations and Acronyms**

| | |
|---|---|
| ACT | = activated clotting time |
| CCS | = Canadian Cardiovascular Society |
| COPD | = chronic obstructive pulmonary disease |
| ICU | = intensive care unit |
| IVUS | = intravascular ultrasound |
| LAD | = left anterior descending artery |
| MI | = myocardial infarction |

those receiving balloon angioplasty in a contemporary tertiary care practice setting. Specifically, using an observational interventional database, we compared the initial and follow-up clinical event rates and costs in patients receiving a stent (and treated with ticlopidine/aspirin regimen) with those for a clinically similar cohort of patients undergoing conventional balloon angioplasty.

## METHODS

**Sample selection.** All patients who underwent percutaneous coronary intervention at Duke University Medical Center between September 1, 1995 and June 30, 1996 were considered for the study. The baseline procedure was defined as a patient's first percutaneous revascularization during this time period. Patients were excluded from this cohort if at baseline:

1) the procedure involved laser, rotational or directional atherectomy or TEC devices;
2) a non-Palmaz-Schatz coronary stent was implanted;
3) the left main or a saphenous vein graft was revascularized;
4) acute myocardial infarction (MI) occurred within two days preceding the procedure;
5) the revascularization was part of a staged series of interventional procedures; or
6) an emergency bypass surgery immediately followed the procedure.

Finally, because we wanted to compare outcomes in patients who were candidates for either balloon angioplasty or stent placement, patients with a target vessel diameter (as assessed by the largest balloon size) of less than 2.7 mm in diameter were excluded from the coronary angioplasty group.

**Treatment protocol.** Patients receiving coronary stents were pretreated with aspirin (325 mg per day) and ticlopidine (250 mg twice a day), ideally starting 24 h prior to the procedure. Ticlopidine therapy was continued for up to four weeks following stent implantation. Our standard laboratory practice is to use high pressure balloon inflation to assure adequate stent strut expansion. Intravascular ultrasound (IVUS) was not routinely employed, and use of abciximab was left to the operator's discretion. In-lab heparin use included a 10,000 unit bolus with additional heparin as needed to maintain an activated clotting time (ACT) >300 s (for those not receiving abciximab) and an initial heparin bolus of 5,000 units and a target ACT of 200 to 250 s (for those receiving abciximab). Conventional coronary angioplasty was performed using standard techniques with a goal of achieving a residual stenosis diameter of <30%. Coronary angioplasty patients also received aspirin, heparin and abciximab using regimens similar to those described for stent patients. After the procedure all intervention patients went to a monitored nonintensive care unit (ICU) setting unless procedural complications required more intensive monitoring. Our standard practice was to discharge both stent and coronary angioplasty patients who had no major complications on the day following the procedure.

**Data collection.** Baseline clinical and demographic data related to the index hospitalization were obtained from the Duke Distributed Information System for Clinical Care and a supplementary interventional catheterization laboratory database. The databases include basic demographic data (age, race, gender), comorbid illnesses, baseline clinical characteristics, preprocedure and postprocedure laboratory and diagnostic tests, in-lab procedure descriptors, procedural complications and transfusion data (22).

Follow-up resource use and health status was assessed through telephone interviews conducted at 6 and 12 months following the procedure. The telephone interview determined the dates and locations of any hospitalizations, outpatient catheterizations, the occurrence of major clinical events (MI, death, revascularization), the severity of angina (Canadian Cardiovascular Society [CCS] angina class) and work status. Patient-reported clinical events and resource use during follow-up were confirmed by obtaining the hospital discharge summaries and hospital billing information. In addition, we used the Duke clinical databases to identify any unreported Duke hospitalizations or outpatient procedures. This study protocol was reviewed and approved by the internal review board of our institution.

Follow-up hospital admissions were classified as being for cardiac or noncardiac indications by the study investigators who were blinded to treatment status. Cardiac hospitalizations included those for any type of chest pain, revascularization procedure, congestive heart failure, arrhythmia and other miscellaneous cardiovascular diagnoses. Hospitalizations for clearly unrelated illnesses (e.g., fractures, cancer) were considered to be noncardiac, unless the event was determined to be a possible direct complication of a cardiac procedure (e.g., readmission for pseudoaneurysm repair).

**Cost calculation methodology.** Baseline cost data were extracted from the Duke Transition 1 Accounting System (Transition Systems, Inc., Boston, Massachusetts). This system contains detailed cost records at the intermediate product level within each department. Specifically, the cost of an admission was calculated by multiplying the quantity of each resource used (e.g., hours of care by inpatient unit, hours in the catheterization lab, number of diagnostic tests by type of test, among others) by the unit cost of the resource, and then totalling the resultant individual resource costs.

Follow-up resource use was limited to cardiac hospitalizations and outpatient catheterizations. The cost of subsequent cardiac care at Duke was also calculated using the Transition 1 accounting system. Subsequent cardiac care cost at hospitals other than Duke was estimated from hospital charge data using standard department-level cost-to-charge methodology (23). Physician fees were based on the 1996 North Carolina Medicare Physician Fee Schedule. Professional fees were assigned for major cardiac procedures (inpatient and outpatient catheterization, percutaneous intervention, bypass surgery) and daily inpatient care on routine and critical care units. Finally, all costs were standardized to 1996 dollars.

**Statistical analyses.** Because physicians do not routinely record prior to the procedure whether a stent or balloon angioplasty procedure was planned, an intention-to-treat analysis was not possible in this study. Instead, we classified patients based on whether they received a coronary stent during their procedure. Procedures classified as stent cases may include those where initial balloon angioplasty was attempted but suboptimal results (i.e., coronary dissection) necessitated coronary stent placement. Balloon angioplasty cases may include those in which stent placement was planned but was not technically feasible and those in which the initial balloon dilation resulted in such good angiographic outcomes that stent placement was deferred.

Our primary cost analyses compared baseline, six and 12 month cumulative costs for the coronary angioplasty and stent cohorts. Secondary outcomes included six-month and one-year clinical event rates: death, myocardial infarction, rehospitalization rates, need for repeat revascularization procedures, CCS angina class and work status. Clinical risk factors, costs and clinical events were compared using chi-square or Wilcoxon tests as appropriate. Baseline hospitalization costs were examined at the department level. Cumulative costs were compared using Student *t* tests after log transformation.

In addition to comparing the cost and outcomes for all cardiac rehospitalizations, we also conducted several secondary analyses to assess the robustness of the results. First, we excluded follow-up revascularizations in vessels other than the baseline target vessel. Second, we repeated the analyses after excluding patients with prior coronary revascularization procedures. This patient subsample is more consistent with the inclusion criteria from prior randomized clinical trials (4,5). Finally, because this study was observational and treatment selection factors could lead to baseline differences in risk factors between treatment groups, we adjusted our baseline and cumulative cost comparisons for potential confounding clinical risk factors.

Our risk-adjustment strategy involved four steps. First, baseline costs were risk adjusted using multiple regression analysis after log transformation. Variables considered as candidates in the model included the following: demographics (age, race, gender), comorbid illness (chronic pulmonary obstructive disease (COPD), congestive heart failure, diabetes mellitus), disease severity (prior MI, prior revascularization procedure, multivessel disease and baseline CCS angina class), a proxy for the size of the intervened coronary vessel (largest dilator balloon size used) and initial treatment strategy (stent vs. coronary angioplasty). Second, the probability of readmission was modeled using logistic regression, adjusting for similar explanatory variables. Third, the cost of hospitalization given readmission was modeled using multiple regression (after log transformation). Finally, Monte Carlo analysis was used to estimate the risk-adjusted cumulative costs at one year, based on the risk-adjusted estimates of baseline cost, probability of readmission and cost of readmission (24).

## RESULTS

**Patient sample.** Of the 1,039 unique patients at Duke University Medical Center who underwent conventional balloon angioplasty or received a Palmaz-Schatz coronary stent between September 1, 1995 and June 30, 1996, 530 received coronary angioplasty and 509 received at least one coronary stent. We excluded 258 coronary angioplasty patients (51%) in whom the largest balloon used for dilation was less than 2.7 mm. Of the remaining patients in both groups, we excluded 92 patients (12%) who received intervention for left main or saphenous vein graft disease, 111 patients (14%) whose procedure occurred within two days of an acute myocardial infarction, 14 patients (2%) with staged revascularization procedures, 18 patients (3%) with missing baseline or follow-up data and 4 patients (<1%) who required emergent bypass surgery (1 stent patient and 3 coronary angioplasty patients). Thus, our final data set included 384 stent and 159 coronary angioplasty patients.

**Baseline characteristics.** Demographic characteristics of patients were generally similar in the stent and coronary angioplasty groups (Table 1). The mean age was 60 and 62 years, respectively, in the stent and coronary angioplasty groups. More than half of both groups were white men. Prior myocardial infarction, CCS angina class and comorbid illnesses were also similar in the two treatment groups. Stent patients were less likely to have undergone prior bypass surgery (9% vs. 17%, $p = 0.01$) or coronary angioplasty (17% vs. 23%, $p = 0.09$) than percutaneous transluminal coronary angioplasty patients. The target lesion was more often in the left anterior descending (LAD) coronary artery in stent patients than in coronary angioplasty patients (33% vs. 21%, $p = 0.006$). Finally, multivessel coronary intervention was attempted in 9% of stent cases and 6% of coronary angioplasty cases.

**Table 1.** Baseline Characteristics for Stent and PTCA Patients

| | Stent (n = 384) | PTCA (n = 159) | p Value |
|---|---|---|---|
| Mean Age (yr) | 60 | 62 | 0.09 |
| Gender (% male) | 67 | 73 | 0.21 |
| Race (% white) | 84 | 83 | 0.87 |
| History of (%) | | | |
| Myocardial infarction | 54 | 59 | 0.30 |
| Chronic pulmonary disease | 12 | 9 | 0.49 |
| Congestive heart failure | 9 | 13 | 0.24 |
| Diabetes mellitus | 22 | 27 | 0.17 |
| Prior Procedures (%) | | | |
| Bypass surgery | 9 | 17 | 0.01 |
| PTCA only | 17 | 23 | 0.09 |
| # Diseased Vessels (%) | | | 0.58 |
| One | 72 | 71 | |
| Two | 21 | 15 | |
| Three | 7 | 14 | |
| CCS Angina Class (%) | | | 0.07 |
| No angina | 22 | 28 | |
| Class I or II | 13 | 16 | |
| Class III or IV | 65 | 56 | |
| Location of Intervention (%) | | | 0.006 |
| RCA | 42 | 47 | |
| LAD | 33 | 21 | |
| LCX | 16 | 26 | |
| Multivessel Intervention (%) | 9 | 6 | |

**Table 2.** Baseline Hospitalization Resource Use

| | Stent (n = 384) | PTCA (n = 159) | p Value |
|---|---|---|---|
| Length of Stay (days) | | | 0.80 |
| Mean | 3.6 | 3.8 | |
| Median | 3.0 | 3.0 | |
| Post Procedure LOS[1] (days) | | | 0.62 |
| Mean | 2.2 | 2.3 | |
| Median | 1.0 | 2.0 | |
| Mean Department Cost ($) | | | |
| Catheterization laboratory | 9,780 | 6,224 | < 0.001 |
| Room-intensive care unit | 1,368 | 1,402 | 0.79 |
| Room-routine care | 1,309 | 1,419 | 0.88 |
| Emergency room | 787 | 756 | 0.35 |
| Laboratory tests | 385 | 345 | 0.01 |
| Pharmacy | 302 | 289 | 0.89 |
| Other | 871 | 1,100 | 0.90 |
| In-Hospital Costs ($) | | | < 0.001 |
| Mean | 14,802 | 11,534 | |
| Median | 12,766 | 9,165 | |
| Professional Fee ($) | | | < 0.001 |
| Mean | 1,863 | 1,816 | |
| Median | 1,740 | 1,657 | |
| Total In-Hospital Costs ($) | | | < 0.001 |
| Mean | 16,665 | 13,350 | |
| Median | 14,629 | 10,764 | |

LOS = length of stay.

**Resource use during index hospitalization.** The total length of stay for stent and coronary angioplasty patients was similar, averaging 3.6 and 3.8 days, respectively (Table 2). The length of stay after the procedure was also similar in the two groups. Despite similar lengths of stay, the mean total cost of hospital care was over $3,200 higher in the stent group than in the coronary angioplasty group ($14,802 vs. $11,534, $p < 0.001$). The cost differential in the stent group was due almost entirely to higher catheterization lab costs ($9,780 vs. $6,224, $p < 0.001$) with all other departmental costs being similar (Table 2). The higher catheterization lab costs arose primarily from the cost of stents and to some extent to slightly increased use of coronary angioplasty balloons (Table 3). In contrast, abciximab was used in slightly fewer stent than coronary angioplasty cases (28% vs. 35%, $p = 0.15$).

**Follow-up events.** During the six months following their baseline procedure, stent patients were significantly less likely to be readmitted for cardiac care than coronary angioplasty patients (22% vs. 34%, $p = 0.002$) (Table 4). Cardiac catheterization was performed half as often in stent patients (17% vs. 35%, $p = 0.001$). Coronary revascularization procedures were also used significantly less often in stent patients than in patients undergoing coronary angioplasty with 7% versus 20% ($p = 0.001$) receiving a repeat percutaneous coronary intervention within six months and 3% versus 8% ($p = 0.01$) requiring bypass surgery. Of note, 73% of coronary angioplasty patients who required a repeat percutaneous coronary intervention within six months received a stent as a part of their follow-up procedure, thereby confirming their baseline eligibility for stent implantation.

**Table 3.** Baseline Catheterization Resource Use

| | Stent (n = 384) | PTCA (n = 159) | p Value |
|---|---|---|---|
| Balloons | | | |
| Mean number | 2.1 | 1.8 | |
| Mean cost ($) | 1,759 | 1,479 | < 0.001 |
| Stents* | | | |
| Mean number | 1.5 | 0.07 | |
| Mean cost ($) | 3,629 | 169 | < 0.001 |
| Abciximab | | | |
| % Patients | 28 | 35 | |
| Mean cost ($) | 661 | 817 | 0.15 |
| Guide Caths/Wire | | | |
| Mean cost ($) | 481 | 490 | 0.64 |
| Contrast Dye | | | |
| Mean cost ($) | 556 | 504 | 0.04 |
| Other | | | |
| Mean costs ($) | 2,694 | 2,765 | 0.82 |
| Total ($) | | | < 0.001 |
| Mean cost | 9,780 | 6,224 | |
| Median cost | 8,971 | 5,763 | |

*Stents in the PTCA group include stents placed in repeat procedures during the baseline hospitalization.

**Table 4.** Follow-up Resource Use and Clinical Outcomes

| | 6-Month Event Rates | | | 1-Year Event Rates | | |
|---|---|---|---|---|---|---|
| | Stent (n = 384) | PTCA (n = 159) | p Value | Stent (n = 384) | PTCA (n = 159) | p Value |
| Readmissions (%)* | 22 | 34 | 0.002 | 29 | 42 | 0.006 |
| One | 15 | 21 | | 17 | 23 | |
| Multiple | 7 | 13 | | 12 | 19 | |
| Cardiac Catheterization (%) | 17 | 35 | 0.001 | 27 | 43 | 0.001 |
| Any Repeat Revascularization (%) | 9 | 26 | 0.001 | 14 | 30 | 0.001 |
| Percutaneous intervention | 7 | 20 | 0.001 | 11 | 24 | 0.001 |
| Coronary bypass surgery | 3 | 8 | 0.01 | 6 | 11 | 0.03 |
| Death (%) | 3 | 2 | 0.6 | 3 | 3 | 0.7 |
| Myocardial Infarction (%) | 1 | 4 | 0.013 | 2 | 5 | 0.04 |
| Any Angina (%) | 27 | 36 | 0.07 | 23 | 29 | 0.14 |
| CCS Class 1 or 2 | 20 | 28 | | 17 | 19 | |
| CCS Class ≥3 | 7 | 8 | | 6 | 10 | |
| Work Status* (% employed) | 86 | 66 | 0.001 | 75 | 63 | 0.06 |

*Percentage of those employed at baseline who were working at follow-up.

Resource use after the initial six month follow-up period was low in both treatment groups. By one year 29% of stent patients had at least one readmission compared with 42% of coronary angioplasty patients (p = 0.006). Similarly, stent patients were half as likely as coronary angioplasty patients to receive a repeat revascularization procedure by one year (14% vs. 30%, p = 0.001).

In terms of patient clinical outcomes, death during follow-up was uncommon (3%) in both groups. Stent patients were slightly less likely to have a myocardial infarction in the one-year follow-up period (2% vs. 5%, p = 0.04). In addition, stent patients reported slightly less angina at six months (27% vs. 36%, p = 0.07) and at one year (23% vs. 29%, p = 0.14). If employed at baseline, stent patients were also more likely than coronary angioplasty patients to remain employed six months (86% vs. 66%, p = 0.001) and one year (75% vs. 63%, p = 0.06) following the procedure.

**Follow-up costs.** The initial expense associated with stent placement ($3,268) was completely offset by higher costs for the coronary angioplasty-treated patients during the first six months of follow-up (Fig. 1). Thus, cumulative mean costs were equivalent in stent and coronary angioplasty groups at six months ($19,598 vs. $19,820, respectively; p = 0.18). Costs during months 7 through 12 were low in both groups (Table 5), resulting in similar one-year cumulative costs for the two therapies ($22,140 for stent, $22,571 for coronary angioplasty, p = 0.26).

We repeated this cumulative cost analysis after excluding the costs associated with nontarget vessel interventions. This analysis eliminated approximately 12% of all repeat interventions. While removal of nontarget revascularization reduced costs slightly for both intervention groups, the cumulative one-year costs for the two treatment strategies remained similar ($21,966 for stent and $21,795 for coronary angioplasty, p = 0.14).

We also repeated the cost analyses after excluding all patients who had been revascularized prior to the baseline intervention. In this de novo intervention subgroup, stent patients (n = 285) continued to have lower rates of rehospitalization (29% vs. 40%, p = 0.04), cardiac catheterization (26% vs. 39%, p = 0.02) and revascularization procedures (14% vs. 31%, p = 0.001) than coronary angioplasty patients (n = 95) during one-year follow-up. Additionally, one-year cumulative health care costs for de novo stent patients remained similar to those for de novo coronary angioplasty patients ($22,255 vs. $21,810, p = 0.32).

**Risk-adjusted cumulative one-year costs.** Risk-adjusted costs were based on three components: baseline costs, the probability of rehospitalization and the cost of any follow-up hospitalizations. The impact of risk factors on each of the components was examined using regression analysis. Baseline in-patient hospital costs increased with increasing patient age, congestive heart failure, COPD and

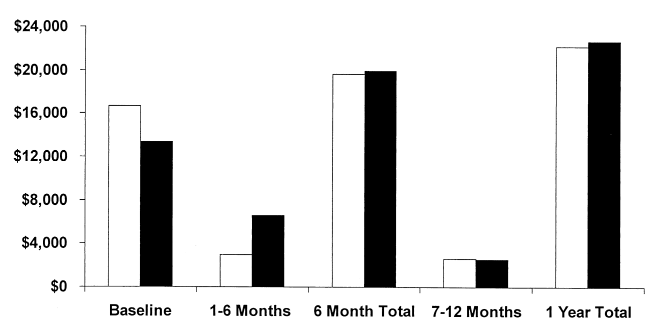


**Figure 1.** Displays mean baseline in-hospital costs for Stent **(light bar)** and PTCA **(dark bar)**. It also displays mean 1–6 month and 7–12 month follow-up cardiac costs and cumulative six-month and one-year cardiac costs for each treatment.

**Table 5.** Summary of Baseline and Follow-up Costs*

| | Stent (n = 384) | PTCA (n = 159) | |
|---|---|---|---|
| | Mean | Mean | p Value |
| Baseline | | | |
| Hospital cost | 14,802 | 11,534 | |
| Inpatient professional fees | 1,861 | 1,732 | |
| Total | 16,663 | 13,266 | < 0.001 |
| 1–6 Month Follow-up | | | |
| Hospital costs | 2,451 | 5,431 | |
| Inpatient professional fees | 339 | 789 | |
| Outpatient catheterization† | 144 | 333 | |
| Total | 2,935 | 6,554 | < 0.001 |
| Cumulative 6-Month Costs | | | |
| Hospital cost | 17,254 | 16,965 | |
| Inpatient professional fees | 2,201 | 2,521 | |
| Outpatient catheterization† | 144 | 333 | |
| Total | 19,598 | 19,820 | 0.18 |
| 7–12 Month Follow-up | | | |
| Hospital cost | 2,025 | 2,213 | |
| Inpatient professional fees | 285 | 309 | |
| Outpatient catheterization† | 231 | 229 | |
| Total | 2,542 | 2,751 | 0.11 |
| Cumulative 1-Year Costs | | | |
| Hospital cost (all patients) | 19,279 | 19,178 | |
| Inpatient professional fees | 2,486 | 2,831 | |
| Outpatient catheterization† | 375 | 561 | |
| Total | 22,140 | 22,571 | 0.26 |

*All costs expressed in 1996 dollars. †Includes professional fees.

prior MI. After risk adjustment, treatment group (coronary angioplasty) remained the strongest independent predictor of baseline cost.

The probability of rehospitalization within six months was less affected by baseline risk factors with only diabetes mellitus (p = 0.003) and COPD (p = 0.11) appearing related. Initial treatment with coronary angioplasty was, however, strongly associated with increased rates of rehospitalization. The cost of rehospitalization during the first six months was inversely related to the maximum balloon size used for dilation (a proxy for vessel size) and by initial treatment. Patients with smaller coronary vessels and those undergoing coronary angioplasty had significantly higher costs for rehospitalization (owing to the higher rates of repeat revascularization during these rehospitalizations). During the second six month follow-up period, event rates were low in both groups and the probability of rehospitalization was unrelated to baseline risk factors or treatment group. Similarly, the cost of rehospitalization was only weakly associated with a baseline history of COPD.

To calculate cumulative risk-adjusted costs for stent and coronary angioplasty patients, we used a Monte Carlo analysis which incorporated regression-based cost and probability estimates. Figure 2 shows the cumulative risk-adjusted mean cost (with 25th and 75th percentile confidence limits) for a 60-year old male patient with a single vessel baseline intervention (using a 3.0 mm balloon) with three alternative risk profiles: no comorbid illness, with diabetes mellitus and with multiple comorbid conditions. For patients without comorbid illness, stent and coronary angioplasty patients had similar one-year mean cumulative health care costs ($20,336 vs. $20,320). As expected, cumulative health care cost estimates rose with increasing comorbidity in both treatment groups. However, as those with increasing baseline risk were more likely to require repeat intervention, the relative effect of initial treatment strategy on cumulative costs increased. For example, among those with diabetes, patients receiving stents had $1,400 lower estimated one-year mean costs than those receiving coronary angioplasty ($21,300 vs. $22,700).

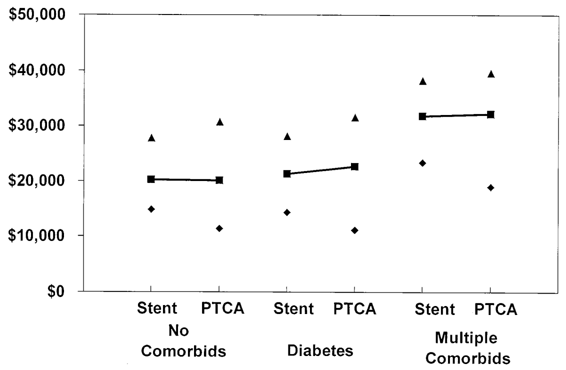


**Figure 2.** Displays risk-adjusted one year cumulative cost estimates for patients receiving either a coronary stent or PTCA under three clinical scenarios: 1) a 60-year old patient without comorbid illness, 2) the same aged patient with diabetes mellitus, and 3) the same aged patient with multiple comorbid illnesses (diabetes, chronic lung disease, congestive heart failure, history of myocardial infarction and multivessel coronary disease). The **solid squares** mark the mean for each treatment under each scenario. The diamond and triangles represent the 75th and 25th percentile confidence intervals surrounding this mean estimate.

## DISCUSSION

This study compared one-year clinical outcomes and cumulative resource use for patients receiving a coronary stent and adjuvant ticlopidine/aspirin therapy with those patients receiving balloon angioplasty only. Our results suggest that the acute expense associated with stent implantation can be largely offset within six months by reductions in the need for repeat interventions. Thus, in contemporary practice, coronary stenting appears to lead to improved patient outcomes without increasing long-term resource requirements when compared with conventional balloon angioplasty.

Our study represents one of the first long-term economic analyses comparing stenting with ticlopidine/aspirin therapy to conventional coronary angioplasty. Consistent with other case series, we found that in-hospital costs associated with stenting had declined by approximately 20% after the

JACC Vol. 33, No. 6, 1999
May 1999:1610–8

**Table 6.** Baseline Characteristics and 1-Year Event Rate Comparison With Prior Randomized Studies

| | Duke (n = 543) | STRESS* (n = 207) | Benestent† (n = 516) | Benestent II‡ (n = 405) |
|---|---|---|---|---|
| Baseline Characteristics (%) | | | | |
| Mean age (yr) | 60 | 61 | 57 | 59 |
| Gender (% male) | 69 | 72 | 81 | 78 |
| History of (%) | | | | |
| Myocardial infarction | 55 | 35 | 19 | 26 |
| Diabetes mellitus | 23 | 15 | n/a | 12 |
| Prior procedures (%) | | | | |
| Bypass surgery | 11 | 1 | 1 | 2 |
| PTCA | 24 | 3 | 2 | 7 |
| One Year Outcomes (%) | | | | |
| Any revascularization (Stent vs. PTCA) | 14 vs. 30 | 15 vs. 21 | 26 vs. 33 | 8 vs. 17 |
| Percutaneous intervention (Stent vs. PTCA) | 11 vs. 24 | 13 vs. 18 | 18 vs. 27 | 8 vs. 17 |
| Coronary bypass surgery (Stent vs. PTCA) | 6 vs. 11 | 6 vs. 11 | 8 vs. 6 | 1 vs. 1 |

*Source: STRESS Economic Substudy population (15). †Source: Benestent one year analysis (27). ‡Source: Preliminary results from Benestent II Economic Substudy (16,29).

initiation of ticlopidine/aspirin in place of oral anticoagulation (25,26). These cost reductions were due primarily to reductions in lengths of stay following the procedure. While the acute cost of coronary stenting has declined, we found that stenting remains $3,200 more expensive than coronary angioplasty, due almost entirely to the cost of the 1.5 stents placed on average per case (Table 3).

In contrast to previous randomized trials (15,27,28), we found that the acute added costs of stents were largely, if not entirely, offset by lower rehospitalization costs within six months of the procedure (Tables 4 and 5). Several factors may account for the different findings. First, our patient population had higher baseline risk than patients enrolled in the randomized trials (Table 6). In particular, both stent and coronary angioplasty patients had higher rates of diabetes mellitus, more frequent prior coronary intervention and required more multivessel baseline interventions than those enrolled in randomized trials. One would expect that, if the relative benefits of stent implantation are constant across patient types, the absolute benefits of stenting (in terms of reducing follow-up revascularization procedures) will be greatest in those patients with the highest baseline risk for restenosis.

Second, while we attempted to minimize treatment selection bias by applying stringent inclusion criteria, we may not have completely eliminated this bias in our observational analysis. To address this, we investigated the robustness of our findings by restricting our analysis to target vessel interventions and second, to a sample of patients without a history of revascularization. In both of these subsets, our overall results were unchanged. Furthermore, we risk-adjusted cumulative costs for baseline clinical predictors of cost. Again, the risk-adjusted analyses demonstrated that stent-treated patients had similar or lower cumulative one-year treatment costs compared with those receiving coronary angioplasty.

Comparison of the relative effectiveness of stents found in our study versus those from prior randomized trials serves as a final check for selection biases. Our study found that stents were associated with a 53% reduction in the need for repeat revascularization. This relative effectiveness for stenting was higher than that noted in the STRESS and Benestent I study (15,27) but was quite similar to that reported in the preliminary results from the clinical follow-up arm of the Benestent II trial, a contemporary stent study (28,29). Indeed, others have reported that stent restenosis rates are declining over time with more experience and improved deployment techniques (30,31).

A third difference between our study and prior randomized trials concerns treatment classification. In contrast to prior randomized trials (which used an intention to treat analysis and had up to 20% initial treatment crossover rates), our study classified all patients by the initial treatment they received. As a result, initial procedure cost estimates in our coronary angioplasty cohort were lower (without crossover stent costs), but follow-up intervention rates may have been increased in this treatment group (as none initially received a stent). Alternatively, by including patients who required stent placement for initial suboptimal angioplasty results (24%) or bail-out (3%) indications, our initial and follow-up cost estimates in our stent cohort may actually have been inflated as these complicated patients may have had worse outcomes. Finally, our coronary angioplasty cohort included patients in whom stent placement was not technically possible (e.g., ostial or bifurcation lesions) and who may be more prone to restenosis. While we did not have detailed angiographic characteristics to address this issue, the fact that three-quarters of patients initially undergoing only coronary angioplasty received a stent in a follow-up intervention suggests that this bias was minimal.

**Clinical and economic implications.** Our study has several clinical and economic implications. First, it is reassuring to note that the clinical benefits of coronary stenting (in terms of decreasing repeat interventions) found in early randomized trials appear to be mirrored in our current observational cohort. While our study was a nonrandomized comparison, our study population more likely reflects present day clinical practice (with higher baseline patient risk factors and more complex interventional procedures). Thus, the results support the generalization of the findings from more selective populations in randomized trials.

Our study also investigated the impact of stenting on a patient's angina and work status (Table 5). We found that stent patients were slightly more likely to be angina-free at six months and one year than those initially receiving coronary angioplasty (73% vs. 64%, $p = 0.07$) and (77% vs. 71%, $p = 0.14$), respectively. This impact of stents on anginal status is similar to that seen in prior randomized studies (5). For those initially employed, 86% of stent patients were employed at six months versus 66% for coronary angioplasty patients ($p = 0.001$). At one year, these comparison employment rates were 75% versus 63% ($p = 0.06$), respectively.

From an economic standpoint, we found that the acute hospital costs of stent implantation in the era of ticlopidine/aspirin remained considerably higher than conventional coronary angioplasty, but both therapies had similar long-term cumulative costs. In a prospective fee-for-service environment, stent implantation can presents a "lose-lose situation" from a hospital's cost perspective. Stent use drives up procedural costs while lowering downstream revenue from repeat procedures. From a societal economic viewpoint, however, stents appear to be becoming an almost dominant strategy relative to coronary angioplasty, providing better long-term patient outcomes (fewer symptoms and repeat hospitalizations) at similar expense.

## STUDY LIMITATIONS

Several limitations of this study must be considered. First, and most importantly, our study was observational and comparability of the two study treatment cohorts cannot be definitively established. Second, our study reflects findings from a single high-volume university hospital and outcomes in other settings may be significantly different. Third, interventional technology is changing rapidly and these results do not reflect the potential impact of newer coronary stent designs (32) or more wide-spread use of glycoprotein IIb/IIIa receptor inhibitors (33–35). Fourth, our follow-up study did not include costs for cardiac medications or office visits. As patients receiving stents had fewer downstream symptoms, our current estimates may have underestimated the economic benefits of stenting relative to coronary angioplasty. We also did not include indirect costs associated with loss of employment. Again, as stent patients working at baseline were more likely to remain employed during follow-up procedures, stent implantation may actually be cost-saving if direct and indirect costs are considered.

## CONCLUSIONS

In conclusion, our study of contemporary stent and coronary angioplasty strategies appears to demonstrate that stents improve patient outcomes at little, if any, additional long-term cost. As stent prices are likely to decline with increased competition from newly approved stents, the economic attractiveness of this technology seems assured.

**Acknowledgments**
We thank Bernie McCants and Barbara Lytle for assistance in obtaining accurate and complete follow-up data, Judy Stafford and Russ Harwood for assisting in our database programming needs and Tracey Simons for editing the manuscript.

**Reprint requests and correspondence:** Dr. Eric D. Peterson, Box 3236, Duke University Medical Center, Durham, North Carolina 27710. E-mail: peter016@mc.duke.edu.

## REFERENCES

1. Hermans WR, Rensing BJ, Strauss BH, Serruys PW. Prevention of restenosis after percutaneous transluminal coronary angioplasty: the search for a "magic bullet." Am Heart J 1991;122:171–87.
2. Pepine CJ, Holmes DR, Block PC, et al. ACC expert consensus document. Coronary artery stents. J Am Coll Cardiol 1996;28:782–94.
3. Holmes DR, Hirshfeld J, Faxon DP, Vliestra RE, Jacobs A, King SB III. ACC expert consensus document on coronary artery stents. J Am Coll Cardiol 1998;32:1471–82.
4. Serruys PW, de Jaegere P, Kiemeneij F, et al. A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331:489–95.
5. Fischman DL, Leon MB, Baim DS, et al. A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331:496–501.
6. Cohen DJ, Breall JA, Ho KKL, et al. The economics of elective coronary revascularization: comparison of costs and charges for conventional angioplasty, directional atherectomy, stenting and bypass surgery. J Am Coll Cardiol 1993;22:1052–9.
7. Ellis SG, Miller DP, Brown KJ, et al. In-hospital costs of percutaneous coronary revascularization. Critical determinants and implications. Circulation 1995;92:741–7.
8. Nino CL, Freed M, Blankenship L, Grines CL, O'Neill WW, Safian RD. Procedural cost of new interventional devices. Am J Cardiol 1994;74:1165–6.
9. Block PC. Coronary stents and other endothelial devices. N Engl J Med 1991;324:52–3.
10. Schatz RA, Goldberg S, Leon MB, et al. Clinical experience with the Palmaz-Schatz coronary stent. J Am Coll Cardiol 1991;17:155B–9B.
11. Carrozza JP, Kuntz RE, Levine MJ, et al. Angiographic and clinical outcome of intracoronary stenting: immediate and long-term results from a large single-center experience. J Am Coll Cardiol 1992;20:328–37.
12. Eeckhout E, Goy JJ, Vogt P, Stauffer JC, Sigwart U, Kappenberger L. Complications and follow-up after intracoronary stenting: critical

analysis of a 6 year single-center experience. Am Heart J 1994;127: 262–72.
13. Cohen DJ, Breall JA, Ho KKL, et al. Evaluating the potential cost-effectiveness of stenting as a treatment for symptomatic single-vessel coronary disease. Circulation 1994;89:1859–74.
14. Califf RM. Restenosis: the cost to society. Am Heart J 1995;130: 680–4.
15. Cohen DJ, Krumholz HM, Sukin CA, et al. In-hospital and one-year economic outcomes after coronary stenting or balloon angioplasty. Results from a randomized clinical trial. Circulation 1995;92:2480–7.
16. Van Hout BA, van der Woude T, de Jaegere P, et al. Cost effectiveness of stent implantation versus PTCA: the BENESTENT experience. Semin Interv Cardiol 1996;1:263–8.
17. Colombo A, Hall P, Nakamura S, et al. Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 1995;91:1676–88.
18. Mahan VK, Salzmann C, Kaufmann U, Meier B. Coronary stenting without anticoagulation. Cathet Cardiovasc Diagn 1995;34:137–40.
19. Schomig A, Neumann FJ, Kastrati A, et al. A randomized comparison of antiplatelet and anticoagulant therapy after the placement of coronary artery stents. N Engl J Med 1996;334:1084–9.
20. Peterson ED, Lansky AJ, Muhlbaier LH, et al. Evolving trends in angioplasty device selection: a National Cardiovascular Network (NCN) database report (Abstr). J Am Coll Cardiol 1997;29:495A.
21. Itoh A, Hall P, Maiello L, et al. Intracoronary stent implantation in native coronary arteries and saphenous vein grafts: a consecutive experience with six types of stents without a prolonged anticoagulation. Mayo Clin Proc 1997;72:101–11.
22. Mark DB, Nelson CL, Califf RM, et al. Continuing evolution of therapy for coronary artery disease: initial results from the era of coronary angioplasty. Circulation 1994;89:2015–25.
23. Lave JR, Pashos CL, Anderson GF, et al. Costing medical care: using Medicare administrative data. Medical Care 1994;32:JS77–89.
24. Fishman GS. Monte Carlo: Concepts, Algorithms and Applications. New York: Springer-Verlag, 1996.
25. Vaitkus PT, Adele C, Wells SK, Zehnacker JP. The evolving costs of intracoronary stents. Am Heart J 1998;136:132–5.
26. Goods CM, Liu MW, Iyer SS, et al. A cost analysis of coronary stenting without anticoagulation versus stenting with anticoagulation using warfarin. Am J Cardiol 1996;78:334–6.
27. Macaya C, Serruys PW, Ruygrok P, et al. Continued benefit of coronary stenting versus balloon angioplasty: one-year clinical follow up of Benestent trial. J Am Coll Cardiol 1996;27:255–61.
28. Serruys PW, Van Hout BA, Bonnier H, et al. Randomised comparison of implantation of heparin-coated stents with balloon angioplasty in selected patients with coronary artery disease (Benestent II). Lancet 1998;352:673–81.
29. Van Hout BA, Cohen DJ, Koens BAH, Serruys PW. Costs and effects of stent implantation versus balloon angioplasty (abstr). J Am Coll Cardiol 1998;31:50A.
30. Bauters C, Hubert E, Prat A, et al. Predictors of restenosis after coronary stent implantation. J Am Coll Cardiol 1998;31:1291–8.
31. Bermejo J, Botas J, Garcia E, et al. Mechanisms of residual lumen stenosis after high-pressure stent implantation. A quantitative coronary angiography and intravascular ultrasound study. Circulation 1998;98:112–8.
32. Serruys PW, Kutryk MJB. Handbook of Coronary Stents. 2nd ed. London: Martin Dunitz, 1998.
33. The EPILOG Investigators. Platelet glycoprotein IIb/IIIa receptor blockade and low-dose heparin during percutaneous coronary revascularization. N Engl J Med 1997;336:1689–96.
34. The CAPTURE Investigators. Randomized placebo-controlled trial of abciximab before and during coronary intervention in refractory unstable angina: the CAPTURE Study. Lancet 1997; 349:1429–35.
35. The EPISTENT Investigators. Randomised placebo-controlled and balloon-angioplasty-controlled trial to assess safety of coronary stenting with use of platelet glycoprotein-IIb/IIIa blockade. Evaluation of platelet IIb/IIIa inhibitor for stenting. Lancet 1987;352:81–2.