Evaluating the Potential Cost-effectiveness of Stenting as a Treatment for Symptomatic Single-Vessel Coronary Disease

Use of a Decision-Analytic Model

David J. Cohen, MD; Jeffrey A. Breall, MD, PhD; Kalon K.L. Ho, MD; Richard E. Kuntz, MD, MS; Lee Goldman, MD, MPH; Donald S. Baim, MD; Milton C. Weinstein, PhD

Background Coronary stenting appears to provide more predictable immediate results and lower rates of restenosis than conventional balloon angioplasty for selected lesion types, but its hospital costs are significantly higher. This study was designed to evaluate the potential cost-effectiveness of Palmaz-Schatz coronary stenting relative to conventional balloon angioplasty for the treatment of patients with symptomatic, single-vessel coronary disease.

Methods and Results We developed a decision-analytic model to predict quality-adjusted life expectancy and lifetime treatment costs for patients with symptomatic, single-vessel coronary disease treated by either Palmaz-Schatz stenting (PSS) or conventional angioplasty (PTCA). Estimates of the probabilities of overall procedural success (PTCA, 97%; PSS, 98%), abrupt closure requiring emergency bypass surgery (PTCA, 1.0%; PSS, 0.6%), and angiographic restenosis (PTCA, 37%; PSS, 20%) were derived from review of the literature published as of September 1993. Procedural costs were based on the true economic (ie, variable) costs of each procedure at Boston's Beth Israel Hospital. On the basis of these data, coronary stenting was estimated to result in a higher quality-adjusted life expectancy than conventional angioplasty but to incur additional costs as well. Compared with conventional angioplasty, stenting had an estimated incremental cost-effectiveness ratio of $23 600 per quality-adjusted life year gained. Although the cost-effectiveness ratio for stenting changed with variations in assumptions about the relative costs and restenosis rates, it remained less than $40 000 per quality-adjusted year of life gained—and thus was similar to many other accepted medical treatments—unless the stent angiographic restenosis rate was >23%, the angioplasty restenosis rate was <34%, or the cost of stenting (including vascular complications) exceeded that of conventional angioplasty by more than $3000. The alternative strategy of secondary stenting (initial angioplasty followed by stenting only for symptomatic restenosis) was estimated to be both less effective and less cost-effective than primary stenting over a wide range of plausible assumptions and thus does not appear to be cost-effective when primary stenting is also an option.

Conclusions Decision-analytic modeling can be used to evaluate the potential cost-effectiveness of new coronary interventions. Our analysis suggests that despite its higher cost, elective coronary stenting may be a reasonably cost-effective treatment for selected patients with single-vessel coronary disease. Primary stenting is unlikely to be cost-effective for lesions with a low probability of restenosis (eg, <30%) or for patients for whom the cost of stenting is expected to be much higher than usual (eg, because of a high risk of vascular complications). Given the sensitivity of the cost-effectiveness ratios to even modest variations in the relative restenosis rates and cost estimates, future studies will be necessary to determine more precisely the cost-effectiveness of coronary stenting for specific patient and lesion subsets. (Circulation. 1994;89:1859-1874.)

Key Words • angioplasty • cost-effectiveness • stents

Despite numerous technical advances over the past 15 years, percutaneous transluminal coronary angioplasty (PTCA) remains limited by difficulties in dilating certain types of lesions, abrupt vessel closure,1,2 and late restenosis.3-5 To address these and other limitations, several new mechanical revascularization techniques have been developed. Although no new device has completely eliminated the drawbacks of conventional angioplasty, intracoronary stenting is one promising technique that appears to provide more predictable immediate results and potentially a reduced rate of subsequent restenosis for selected types of lesions.6-8 The potential advantages of such new procedures, however, are not without a price. They may produce new or more frequent complications (eg, vascular repair, stent thrombosis), and several studies have suggested that initial treatment costs for these devices (particularly coronary stenting) are significantly higher than those for conventional angioplasty.9-12 Consequently, several investigators have cautioned that widespread application of these procedures might have a deleterious impact on national health care expenditures, thus tempering the general level of enthusiasm for these techniques.13,14

Few modern medical advances, however, are truly cost-saving. Even widely acclaimed treatments such as bypass surgery for left main coronary disease,15...
\[ \beta \text{-blocker therapy after myocardial infarction,}^{16} \text{ or thrombolytic therapy for acute myocardial infarction}^{17} \text{ prolong life only by increasing health care costs. These treatments are thus best viewed in terms of their cost-effectiveness—that is, by whether their benefits (ie, improvement in the quality or duration of life) are “worth the cost.”}^{18,19} \text{ Any evaluation of the cost-effectiveness of a new technology must therefore take into account both the costs and benefits of the treatment relative to its alternatives. Accordingly, we undertook the present study to examine the potential costs, benefits, and the resulting cost-effectiveness of coronary angioplasty relative to conventional angioplasty for the treatment of patients with symptomatic single-vessel coronary disease.} \]

**Methods**

We developed a decision model to compare the costs and the clinical effectiveness of different strategies for treating patients with symptomatic, single-vessel coronary disease. Because previous studies have suggested that angioplasty is a cost-effective alternative to medical or surgical therapy for symptomatic patients with anatomically suitable, single-vessel coronary disease\(^{20}\) and because PTCA is currently the recommended initial treatment for such patients,\(^{21}\) we considered only percutaneous revascularization techniques among the initial therapeutic options. The specific strategies we evaluated were (1) angioplasty, (2) coronary stenting, and (3) initial angioplasty followed by coronary stenting for symptomatic restenosis (secondary stenting). In the first two strategies, we assumed that patients with symptomatic restenosis would be treated by repeat balloon angioplasty.

**Patient Population**

Our decision analysis was designed to be applied to a patient population with symptomatic, single-vessel coronary disease that is amenable to either conventional angioplasty or Palmaz-Schatz stenting. In general, such patients tend to have discrete (\(\leq 15 \text{ mm in length}\)) coronary stenoses located in a relatively straight portion of a native coronary artery whose reference diameter is \(\geq 3.0 \text{ mm}\).\(^{22}\) Although we did not attempt to stratify patients according to clinical or demographic characteristics (eg, age, left ventricular function, or prior myocardial infarction) in our baseline analysis, the influence of these characteristics was explored in sensitivity analyses.

**Short-term Decision Model**

Fig 1 depicts the initial therapeutic decision and the immediate and short-term (6-month) outcomes of the chosen procedure. In structuring the decision tree, we made several simplifying assumptions: First, we assumed that patients in whom balloon angioplasty was complicated by abrupt closure or threatened abrupt closure refractory to conventional measures would undergo emergency stenting. If emergency stenting was unsuccessful, we assumed that the patient would undergo emergency bypass surgery. Second, we assumed that any patient in whom the stenosis was not crossed or adequately dilated would be referred for elective bypass surgery. These assumptions are reasonable for the patient population under consideration, in whom both significant angina and a coronary stenosis involving a large coronary artery are present. We did not consider failure to cross the lesion with a guide wire as a cause of procedural failure, since this outcome should be identical for both procedures and therefore should not affect their relative costs or effectiveness in our analysis.

After initially successful percutaneous revascularization, patients were at risk for subacute thrombosis of the treated artery, which could result in a fatal myocardial infarction, repeat balloon angioplasty, or emergency bypass surgery. Finally, during the first 6 months after successful PTCA or stenting, patients were at risk for angiographic restenosis (defined as a recurrence of a stenosis \(>50\%\) diameter) that could potentially cause recurrent anginal symptoms. In our model, patients with symptomatic restenosis were assumed to require repeat revascularization (by either PTCA or coronary stenting) as specified by the particular revascularization strategy. In our baseline analysis, we assumed that patients with recurrent symptomatic restenosis would undergo a maximum of three percutaneous revascularization attempts before undergoing elective bypass surgery. The effect of varying this assumption was studied by sensitivity analysis. Patients who remained free from symptomatic restenosis at the end of a 6-month cycle (or who had undergone successful bypass surgery) were assumed to have been removed from the risk pool for short-term restenosis, and their remaining quality-adjusted life expectancy and treatment costs were estimated by use of a second model based on the natural history of treated single-vessel coronary disease (the Post-Revasc model).

**Data Sources for the Short-term Model**

The probabilities of procedural success, abrupt closure requiring emergency stenting or bypass surgery, subacute thrombosis, procedural failure (without emergency bypass surgery), and death with each of the revascularization techniques were derived from a review of the literature published as of September 1993 (Table 1, References 22 to 48). In the absence of published, head-to-head clinical trials, we attempted to minimize selection bias by including only studies that used techniques and definitions comparable to ours (see “Appendix”).

**Costs**

See Table 2 and References 49 to 57. We have previously reported hospital costs for 300 patients who underwent elective single-vessel revascularization by angioplasty (113 patients), directional coronary atherectomy (34 patients), or Palmaz-Schatz coronary stenting (64 patients) as well as bypass surgery (89 patients, including both single-vessel and multivessel disease) at the Beth Israel Hospital between January 1, 1990, and December 31, 1991.\(^{10}\) Since hospital charges frequently fail to reflect the economic costs of a procedure,\(^{58-60}\) we measured true economic costs using resource-based cost accounting. Briefly, cardiac catheterization laboratory costs were based on measured resource utilization for each procedure, including angioplasty balloons, devices (eg, atherectomy catheters, stents), guiding catheters, guide wires, and contrast dye. Additional laboratory and personnel cost estimates were based on an average cost per procedure and were adjusted for actual procedure duration. The costs of emergency bypass surgery and vascular surgical repair (when necessary) were included in this analysis. Hospital room and nursing costs were determined from hospital accounting data and adjusted for each patient’s measured relative nursing intensity.\(^{61}\) Finally, we determined the costs of all other hospital services (laboratory and radiological testing, drugs and intravenous fluids, blood transfusions, operating room, and anesthesia services) on the basis of the number of units of each service used, with the cost of each unit of service estimated as the charge per unit multiplied by the specific cost-to-charge ratio for the hospital department that provided the service.

Physicians’ professional fees were based on the 1991 Medicare reimbursement levels for single-vessel angioplasty and single-vessel bypass surgery. The angioplasty professional fee was also applied to coronary stenting, because third-party payers did not distinguish among these different procedures at the time of this study. Estimates for the cost of myocardial infarction and the average annual costs of outpatient care were derived from the published literature and the Coronary Heart Disease policy model.\(^{20,55,62}\) All costs were converted to 1991.
A  
**Initial Therapeutic Decision:**

![Diagram of Initial Therapeutic Decision]

B  
**Procedure Sub-tree:**

![Diagram of Procedure Sub-tree]

C  
**Initial Success Sub-tree:**

![Diagram of Initial Success Sub-tree]
TABLE 1. Baseline Estimates for Results of Interventional Procedures

<table>
<thead>
<tr>
<th>Variable (References)</th>
<th>PTCA</th>
<th>Stenting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural mortality rate (1)</td>
<td>0.002</td>
<td>0.002</td>
</tr>
<tr>
<td>Probability of emergency bypass surgery*</td>
<td>0.01</td>
<td>0.006</td>
</tr>
<tr>
<td>De novo lesion (2,7,22-25)</td>
<td>0.01</td>
<td>0.006</td>
</tr>
<tr>
<td>Multiplier for restenosis lesion (7,23-31)</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Probability of subacute thrombosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective procedure (2,7,24,32)</td>
<td>0.005</td>
<td>0.02</td>
</tr>
<tr>
<td>Emergent procedure (33,34)</td>
<td>...</td>
<td>0.15</td>
</tr>
<tr>
<td>Probability of failure to dilate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>De novo lesion (1,7)</td>
<td>0.02</td>
<td>0.015</td>
</tr>
<tr>
<td>Restenosis lesion (26,28,29,31)</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>Angiographic restenosis rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>De novo lesion (3-5,7,23,34-40)</td>
<td>0.37</td>
<td>0.20</td>
</tr>
<tr>
<td>Multiplier for second procedure† (7,23,26-30,41)</td>
<td>1.1</td>
<td>1.4</td>
</tr>
<tr>
<td>Multiplier for third procedure (30,31,42)</td>
<td>1.5</td>
<td>...</td>
</tr>
<tr>
<td>Probability of vascular complication (7,24,43,44)</td>
<td>0.01</td>
<td>0.13</td>
</tr>
<tr>
<td>Probability of symptoms with angiographic restenosis (45-48)</td>
<td>0.70</td>
<td>0.70</td>
</tr>
</tbody>
</table>

PTCA indicates percutaneous transluminal coronary angioplasty.
*We assumed that 5% of angioplasty patients would have abrupt closure or threatened abrupt closure refractory to conventional treatment and would undergo emergent stenting, with emergency bypass surgery only if stenting was unsuccessful.
†These factors correspond to angiographic restenosis rates for secondary PTCA and stenting of 40% and 28%, respectively.

dollars by use of the medical care component of the Consumer Price Index.

Quality-of-Life Adjustments

See Table 2. For patients with single-vessel coronary disease, no intervention has been shown to prolong life, and it is thus unlikely that differences would exist among the procedures considered in this analysis. Nevertheless, both bypass surgery and angioplasty improve angina, reduce medication requirements, and increase exercise tolerance compared with medical therapy in patients with symptomatic, single-vessel coronary disease. Thus, differences in quality of life might exist among revascularization strategies as a consequence of their differential ability to avoid further procedures (either repeat percutaneous revascularization or bypass surgery) and to mitigate the symptoms, inconvenience, and anxiety associated with restenosis.

When both the duration and quality of life are important, outcomes can be measured in quality-adjusted life years (QALYs). In this context, 1 year of life without angina or hospitalization is assumed to be a year of perfect health and is assigned a value of 1.0 QALY. Previous studies have demonstrated that patients are generally willing to "trade" 1 year of life with severe angina for 0.7 years of perfect life. Thus, each year of life with significant angina is valued at 0.7 QALYs. No study has specifically examined the quality of life of patients with restenosis, but we assumed that patients with symptomatic restenosis would have a utility of 0.8 (QALY per year) — intermediate between that of mild (0.9) and severe (0.7) angina — during the period when restenosis was present. Thus, over a 6-month period, a patient who experienced symptomatic restenosis was assumed to have accrued only 0.4 QALY (ie, 0.5 years × 0.8 QALY per year). In contrast, a patient without restenosis would have accrued 0.5 QALY (ie, 0.5 years × 1 QALY per year) during the same half-year period. To avoid errors arising from these assignments, these values were subjected to extensive sensitivity analysis. Patients with clinically silent restenosis were assumed to have a quality of life equal to those patients without restenosis. Finally, we adjusted quality-of-life measurements to account for the short-term morbidity of vascular complications, subsequent nonfatal myocardial infarctions, and further revascularization procedures (Table 2), basing these adjustments on the estimated duration of hospitalization and recuperation for each event.

Postrevascularization Model

Patients who survived our short-term model (either by remaining free from restenosis for a full 6-month cycle or by undergoing successful bypass surgery) entered the Post-Revasc model—a Markov (state-transition) model of life after successful angioplasty or bypass surgery (Fig 2). Patients who did not require bypass surgery entered the model in the first health state (Stable Post-PTCA), and patients who underwent successful bypass surgery entered the second state (Stable Post-Bypass Surgery). During each cycle of the Post-Revasc model (assumed to last 6 months), patients could experience one of four possible events: they could die, suffer a myocardial infarction, undergo angioplasty, or undergo bypass surgery. In addition, during each cycle, patients who were asymptomatic could develop chronic stable angina (detail not shown in Fig 2). As in the short-term model, patients who underwent angioplasty in the postrevascularization model could develop symptomatic restenosis requiring repeat angioplasty. Transition probabilities for each event were a function of the particular health state as well as the time interval after bypass surgery (Table 3, References 70 to 87) and were derived from the published literature (see "Appendix"). All future costs and health benefits were discounted at 5% per year.

Analytic Method

For each strategy, we calculated the expected lifetime cost and quality-adjusted life expectancy, ranking the available strategies in order of increasing cost. Strategies with lower
quality-adjusted life expectancies and higher costs than an available alternative were considered to be dominated by the remaining strategies and were excluded from further consideration. For each of the remaining strategies (with higher expected costs but also higher quality-adjusted life expectancy), we calculated the incremental cost-effectiveness ratio by dividing any difference in cost by the difference in quality-adjusted life expectancy. All analyses were performed using the SMLTREE software package (James Hollenberg, MD, New York, NY).

### Results

#### Primary Analysis

Under our baseline assumptions, our model predicted that a 55-year-old man with symptomatic, single-vessel coronary disease treated by angioplasty alone would have a quality-adjusted life expectancy of 19.24 years and an expected lifetime treatment cost of $52100 (Table 4). In comparison, the strategy of initial stenting produced a slightly greater estimated quality-adjusted life expectancy (19.28 QALYs) but at a somewhat higher cost ($52,700), with an estimated incremental cost-effectiveness ratio of $23,600 per QALY gained compared with angioplasty alone. Conversely, the strategy of initial angioplasty followed by stenting only for symptomatic restenosis was estimated to be both less effective and less cost-effective than initial stenting (incremental cost-effectiveness ratio of $72,500/QALY compared with angioplasty alone). Although the absolute differences in quality-adjusted life expectancy with primary stenting (0.04 QALYs) were small, these gains are reasonable considering the time-limited nature of the restenosis process, the availability of elective bypass surgery to treat recurrent restenosis, and the generally excellent long-term prognosis for patients with single-vessel coronary disease. In fact, our model predicted that an intervention that completely eliminated abrupt closure and restenosis in this population would provide an average quality-adjusted life expectancy of 19.31 QALYs—an increase of only 0.07 QALYs compared with conventional angioplasty.

#### Sensitivity Analysis: Overall Effectiveness of Stenting

Since our model was based on a number of assumptions, we performed sensitivity analyses to determine whether plausible variations in these assumptions would alter our findings. Although the absolute differences in quality-adjusted life expectancy remained small, stenting was estimated to be more effective than angioplasty alone over a wide range of alternative assumptions. Holding each of our other baseline assumptions constant, stenting was estimated to yield a greater quality-
adjusted life expectancy unless the absolute reduction in the restenosis rate by stenting was <3%, the stent emergency bypass surgery rate was >5%, the stent thrombosis rate was >8%, or the probability of death from stent thrombosis was >24%. Our model estimated that quality-adjusted life expectancy would be greater for conventional angioplasty, however, if the disutility (ie, 1–utility) of life with a vascular complication were >0.20—ie, more than twice the disutility of life with restenosis.

**Sensitivity Analysis: Cost-effectiveness of Stenting**

We also performed sensitivity analyses to determine which factors exerted the most influence on the cost-effectiveness of stenting and how plausible variations in these assumptions would alter our results (Table 5). The cost-effectiveness of coronary stenting was most sensitive to variations in the relative restenosis rates of stenting and conventional angioplasty. At any PTCA restenosis rate, the cost-effectiveness ratio for initial stenting became less favorable (ie, more $/QALY gained) as the stent restenosis rate increased (Fig 3). For example, if the true restenosis rate for primary stenting were as high as 30% (compared with our baseline estimate of 20%), the cost-effectiveness ratio for initial stenting would increase to $120 000/QALY. Similarly, if the true angioplasty restenosis rate were only 30% (compared with our baseline estimate of 37%), stenting would also be less cost-effective, with a cost-effectiveness ratio of $82 100/QALY. Conversely, if the true angioplasty restenosis rate were higher than 43% (with a stent restenosis rate of 20%) or if the restenosis rate of stenting for de novo lesions were lower than 13% (with an angioplasty restenosis rate of 37%), initial coronary stenting would actually become the dominant strategy—that is, it would be both more effective and cost-saving compared with conventional angioplasty.

In a three-way sensitivity analysis, we explored the effect of simultaneous variations in the stent and PTCA restenosis rates on the cost-effectiveness of stenting at three different cost-effectiveness thresholds—$20 000/QALY, $40 000/QALY, and $60 000/QALY. If one were willing to spend up to $40 000/QALY—similar to the cost-effectiveness of treating mild diastolic hypertension—stenting remained cost-effective unless the stent restenosis rate were >23% or the angioplasty restenosis rate were <34% (Fig 4). In general, initial stenting remained cost-effective at this threshold level ($40 000/QALY) only if it reduced the PTCA restenosis rate by >14%. If one were willing to spend only up to $20 000/QALY, however, stenting would be cost-effective only if it reduced the PTCA restenosis rate by >18% to 20%.

The cost-effectiveness of coronary stenting also proved highly sensitive to variations in the cost of stenting. As the cost of stenting relative to PTCA increased, initial stenting became progressively less cost-effective in our model. For example, if the cost of initial hospitalization for stenting including any vascular complications were actually $8400 (ie, $3000 higher than the cost of PTCA), the cost-effectiveness ratio for
stenting would increase to $40 000/QALY. Conversely, if the cost of stenting were reduced by $700 (to $7200, just $1800 more than conventional angioplasty), our model predicted that initial stenting would actually be less expensive than PTCA in the long run.

The cost-effectiveness of stenting was less sensitive to plausible variations in any other individual assumptions of the model. For example, the cost-effectiveness ratio for initial stenting remained <$40 000/QALY so long as the probability of emergency bypass surgery with angioplasty was >0.6% (Fig 5). If, however, the probabilities of both abrupt closure and restenosis with conventional angioplasty were somewhat lower than our baseline estimates, the cost-effectiveness of stenting would change dramatically. For example, if PTCA had an emergency bypass surgery rate of only 0.7% and an angiographic restenosis rate of only 30%, the estimated cost-effectiveness ratio of stenting would rise to $102 000/QALY—much higher than most generally accepted medical programs.86 Similarly, the cost-effectiveness of stenting was relatively insensitive to plausible variations in the probabilities of procedure-related complications. As expected, as the probability of either subacute thrombosis or a major vascular complication after stenting was increased, coronary stenting became somewhat less cost-effective in our model. Nonetheless, given our other baseline assumptions, the cost-effectiveness ratio for initial stenting remained <$40 000/QALY unless the probability of subacute stent thrombosis exceeded 3.5% (with a 13% vascular complication rate) or the probability of a major vascular complication exceeded 18% (with a 2% stent thrombosis rate) (Fig 6).

The estimated cost-effectiveness ratio for coronary stenting remained between $10 000 and $40 000 per quality-adjusted year of life gained when any other individual assumption in either the short-term or the Post-Revasc model was varied (Table 5). Furthermore, the strategy of initial angioplasty with subsequent

<table>
<thead>
<tr>
<th>Probability/Rate (References)</th>
<th>Baseline Estimate</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual cardiac mortality after successful 1-vessel PTCA or CABG (49,51,70-78)</td>
<td>0.004</td>
<td>0.002-0.007</td>
</tr>
<tr>
<td>Annual probability of recurrent severe angina</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After successful 1-vessel PTCA (73,79)</td>
<td>0.009</td>
<td>0.006-0.01</td>
</tr>
<tr>
<td>After successful 1-vessel CABG (64,66,60,81)</td>
<td>0.007</td>
<td>0.005-0.008</td>
</tr>
<tr>
<td>After repeat CABG (64)</td>
<td>0.028</td>
<td>0.01-0.04</td>
</tr>
<tr>
<td>Probability of continued severe angina</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After successful 1-vessel PTCA or CABG (60,65-67,74,76,79,82-84)</td>
<td>0.05</td>
<td>0.03-0.10</td>
</tr>
<tr>
<td>After successful repeat CABG (84)</td>
<td>0.20</td>
<td>0.05-0.30</td>
</tr>
<tr>
<td>Annual probability of nonfatal myocardial infarction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After successful 1-vessel PTCA (51,70,72)</td>
<td>0.016</td>
<td>0.005-0.016</td>
</tr>
<tr>
<td>After successful 1-vessel CABG (49,51,60,63,71,76-78,81,85)</td>
<td>0.005-0.027*</td>
<td></td>
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<tr>
<td>Annual probability of late PTCA</td>
<td></td>
<td></td>
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<tr>
<td>After successful 1-vessel PTCA (51,70)</td>
<td>0.031</td>
<td>0.025-0.40</td>
</tr>
<tr>
<td>After successful 1-vessel CABG (51,71,87)</td>
<td>0.013</td>
<td>0.013-0.022</td>
</tr>
<tr>
<td>Annual probability of late CABG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After successful 1-vessel PTCA (51,70)</td>
<td>0.008</td>
<td>0.006-0.01</td>
</tr>
<tr>
<td>After successful 1-vessel CABG (51,54,71,86)</td>
<td>0.005-0.019*</td>
<td></td>
</tr>
</tbody>
</table>

*Probability indicates percutaneous transluminal coronary angioplasty; CABG, coronary artery bypass graft surgery. Similarities between the cost-effectiveness of coronary stenting varied between $10 000 and $40 000 per quality-adjusted year of life gained with any other individual assumption in either the short-term or the Post-Revasc model was varied (Table 5). Furthermore, the strategy of initial angioplasty with subsequent

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Average Quality-Adjusted Life Expectancy (QALYs)</th>
<th>Average Cost ($)</th>
<th>Incremental Cost-effectiveness ($/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioplasty</td>
<td>19.24</td>
<td>52 100</td>
<td>Baseline case</td>
</tr>
<tr>
<td>Angioplasty with stenting for restenosis</td>
<td>19.25</td>
<td>52 400</td>
<td>72 500</td>
</tr>
<tr>
<td>Initial stent</td>
<td>19.28</td>
<td>52 700</td>
<td>23 600</td>
</tr>
</tbody>
</table>

QALYs indicates quality-adjusted life years. Baseline assumptions for a 55-year-old man with symptomatic, single-vessel coronary disease. Life years and costs discounted at 5% per year for the cost-effectiveness ratios. Incremental cost-effectiveness ratios calculated relative to angioplasty alone.
stenting only for symptomatic restenosis remained both less effective and less cost-effective than initial stenting over the full range of plausible values for each individual variable (including the restenosis rates and costs of angioplasty and stenting). Only when the restenosis rate for stenting restenotic lesions was <22% (i.e., only 1.1 times the restenosis rate for de novo lesions) did the incremental cost-effectiveness ratio for secondary stenting become lower than that for primary stenting.

Mechanisms of the Long-term Benefits of Coronary Stenting

Coronary stenting may provide clinical benefit over conventional angioplasty by three potential mechanisms: (1) by reducing the incidence of severe dissection and abrupt closure, thereby avoiding emergency bypass surgery; (2) by reducing the incidence of restenosis; and (3) by eliminating elastic recoil as a cause of unsuccessful angioplasty. To determine the relative contributions of each of these mechanisms to the overall clinical benefit of stenting, we constructed separate models in which the benefits of stenting over conventional PTCA were alternately restricted to one of the three mechanisms. When the benefits of stenting were restricted to the prevention of abrupt closure, this mechanism accounted for only 9% of the overall improvement in quality-adjusted life expectancy predicted by our full model (Fig 7). When the benefits of stenting were restricted to the reduction of restenosis, however, 88% of the full benefit of stenting was realized. The remaining 3% of the predicted benefits of stenting derived from the minor improvement in procedural success obtained by eliminating elastic recoil.

### Table 5. Incremental Cost-effectiveness of Initial Stenting: One-Way Sensitivity Analyses

<table>
<thead>
<tr>
<th>Variable</th>
<th>Low Estimate</th>
<th>ΔC/ΔE ($/QALY)</th>
<th>High Estimate</th>
<th>ΔC/ΔE ($/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Angioplasty results</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergent CABG rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De novo lesion</td>
<td>0.006</td>
<td>38 500</td>
<td>0.015</td>
<td>9700</td>
</tr>
<tr>
<td>Restenosis lesion</td>
<td>0.002</td>
<td>26 100</td>
<td>0.01</td>
<td>21 200</td>
</tr>
<tr>
<td><strong>Procedural failure rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De novo lesion</td>
<td>0.01</td>
<td>34 300</td>
<td>0.05</td>
<td>14 200</td>
</tr>
<tr>
<td>Restenosis lesion</td>
<td>0.008</td>
<td>23 500</td>
<td>0.012</td>
<td>22 900</td>
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<tr>
<td><strong>Angiographic restenosis rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De novo lesion</td>
<td>0.30</td>
<td>82 200</td>
<td>0.45</td>
<td>DS*</td>
</tr>
<tr>
<td>Prior restenosis</td>
<td>0.35</td>
<td>27 100</td>
<td>0.50</td>
<td>21 500</td>
</tr>
<tr>
<td><strong>Stent results</strong></td>
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<tr>
<td>Emergent CABG rate</td>
<td>0.001</td>
<td>17 900</td>
<td>0.011</td>
<td>30 300</td>
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<tr>
<td><strong>Procedural failure rate</strong></td>
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<td></td>
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<tr>
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<td>18 700</td>
<td>0.03</td>
<td>39 700</td>
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<tr>
<td>Restenosis lesion</td>
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<td>0.03</td>
<td>23 600</td>
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<td></td>
<td></td>
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<tr>
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<td>0.10</td>
<td>DS*</td>
<td>0.30</td>
<td>121 000</td>
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<tr>
<td>Prior restenosis</td>
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<td>28 800</td>
<td>0.40</td>
<td>23 600</td>
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<tr>
<td><strong>Subacute thrombosis rate</strong></td>
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<td>Elective procedure</td>
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<td>15 600</td>
<td>0.035</td>
<td>40 100</td>
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<tr>
<td>Emergent procedure</td>
<td>0.10</td>
<td>26 700</td>
<td>0.20</td>
<td>21 800</td>
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<tr>
<td><strong>Vascular complication rate</strong></td>
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<td>0.15</td>
<td>31 000</td>
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<td><strong>General variables</strong></td>
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<td>Age of patient</td>
<td>40</td>
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<tr>
<td>Number of procedures before elective CABG</td>
<td>2</td>
<td>13 600</td>
<td>4</td>
<td>27 400</td>
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<td>Costs ($)</td>
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<td>PTCA</td>
<td>5000</td>
<td>25 800</td>
<td>6000</td>
<td>20 400</td>
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<td>DS*</td>
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<td>Bypass surgery</td>
<td>17 000</td>
<td>29 800</td>
<td>24 000</td>
<td>19 100</td>
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ΔC/ΔE indicates incremental cost-effectiveness of initial stenting compared with both alternative strategies (angioplasty only or secondary stenting); QALY, quality-adjusted life year; CABG, coronary artery bypass graft surgery; and PTCA, percutaneous transluminal coronary angioplasty.

*DS indicates dominant strategy; initial stenting both more effective and less expensive than the alternative strategies.
Although initial hospital costs for stenting were $2500 higher than those for PTCA, our model estimated that these initial costs would be partially offset by a $1900 reduction in follow-up treatment costs (from $45 800 to $43 900). Thus, the net incremental cost of stenting over conventional angioplasty was only $600. Sensitivity analysis demonstrated that $1560 (81%) of these long-term cost savings was a result of restenosis prevention alone, $220 (12%) resulted from reduced abrupt closure, and the remaining $130 (7%) was attributable to reduced elastic recoil (Fig 7).

Discussion

During the past 5 years, there has been an explosive growth in the development of new devices for the treatment of obstructive coronary disease. Although most research has focused on the ability of these devices to improve the short- and long-term success and safety of coronary revascularization, the ultimate goal of any such treatment is to improve the quality or the duration of life. Moreover, it has become increasingly evident that health care resources are limited and that responsible decisions about the use of new and potentially expensive technologies must therefore consider both clinical and economic factors. The techniques of cost-effectiveness analysis can be used to provide a framework for evaluating any medical technology or program and to compare its clinical benefit and economic cost with the available alternatives.

This study is the first to apply the principles of cost-effectiveness analysis to the evaluation of new devices for coronary revascularization. It demonstrates the power of decision-analytic techniques to synthesize data from a variety of sources so as to develop rational guidelines for the revascularization of patients with symptomatic coronary disease. In addition, the use of decision modeling enables us to identify the most important determinants of cost-effectiveness for these procedures and thus to identify specific situations (eg, patient or lesion characteristics) in which one or another procedure may be favored.
Overall Effectiveness of New Coronary Interventions

Under our baseline assumptions, our model predicts that the strategy of initial coronary stenting—given its lower abrupt closure and restenosis rates—will result in a greater quality-adjusted life expectancy than initial angioplasty. Although the absolute differences in quality-adjusted life expectancy with primary or secondary stenting are small for any individual patient (0.01 to 0.04 QALY, Table 4), these gains are reasonable considering the time-limited nature of the restenosis process, the availability of elective bypass surgery to treat recurrent restenosis, and the generally excellent long-term prognosis for patients with single-vessel coronary disease.74 In fact, our model suggests that it is unrealistic to expect palliative treatments that do not modify the underlying disease process to provide significant further gains in either quality or duration of life for patients with single-vessel coronary disease. Given the longer initial hospital stay and the higher incidence of vascular complications with coronary stenting, it is likely that some patients would still prefer conventional angioplasty over coronary stenting. Nonetheless, our analysis suggests that so long as the disutility (ie, 1−utility) of life with a vascular complication is no more than twice the disutility of a single episode of restenosis, quality-adjusted life expectancy would be greater with initial stenting. Thus, although the individual decision between stenting and conventional angioplasty is clearly a "toss-up,"90 most patients would be expected to prefer stenting unless the impact of restenosis on quality of life was small compared with that of a vascular complication.

Incremental Cost-effectiveness Analysis: Determinants of the Cost-effectiveness of Coronary Stenting

For a patient with single-vessel coronary disease amenable to PTCA and stenting, our model estimates that elective stenting has an incremental cost-effectiveness ratio of $23,600 per quality-adjusted year gained relative to PTCA. Incremental cost-effectiveness ratios of <$20,000 per QALY gained—such as those for coronary artery bypass grafting for left main coronary disease23 or the treatment of severe hypertension (diastolic blood pressure >105 mm Hg)90—are generally viewed as quite favorable. Incremental cost-effectiveness ratios between $20,000 and $40,000 per additional QALY are also consistent with many other accepted treatments such as...
hemodialysis, treatment of mild hypertension with diuretics, and implantable defibrillator treatment for survivors of out-of-hospital cardiac arrest. Conversely, cost-effectiveness ratios >$60,000/QALY are higher than those of most accepted treatments and are therefore generally regarded as unattractive. Thus, under our baseline assumptions, initial coronary stenting appears to have a cost-effectiveness ratio that is favorable compared with other widely practiced medical interventions.

It is important to recognize that the results of this analysis are sensitive to several critical assumptions of our model—mainly the relative restenosis rates for angioplasty and stenting. If the reduction in restenosis by stenting is less than we have assumed, coronary stenting would be significantly less cost-effective than is suggested by our model. For example, if one were willing to pay up to $40,000/QALY (similar to the cost-effectiveness of hemodialysis or treating mild hypertension), stenting would remain a cost-effective initial treatment only if the absolute difference in restenosis rates was ≥14% (Fig 4). Recent randomized trials suggest that such a reduction in the PTCA restenosis rate by stenting may be feasible.

Conversely, our analysis suggests that regardless of the acceptable cost-effectiveness ratio, the strategy of secondary stenting is not cost-effective when initial stenting is also an option. Over a wide range of alternative assumptions, we found that secondary stenting was both less effective and less cost-effective than initial stenting (Table 4). Thus, even if one were willing to pay the high cost of secondary stenting, greater overall health benefits could be achieved at a lower cost by practicing initial stenting instead.

**Effect of Variations in the Cost of Stenting on Cost-effectiveness**

Our analysis also demonstrates that the cost-effectiveness of coronary stenting is highly dependent on the cost of stenting relative to angioplasty. Consequently, it will be important to verify our cost estimates in a variety of patient populations and clinical settings—ideally in the form of a multicenter, randomized clinical trial. One factor that can clearly affect the cost of stenting is the overall incidence of vascular complications. Our previous study suggests that a major vascular complication increases the in-hospital cost of stenting by approximately $5000. In the present study, sensitivity analysis demonstrates that an increase in the rate of major vascular complications from 13% to 20% without a corresponding decrease in the subacute stent thrombosis rate would increase the cost-effectiveness ratio for stenting to $44,000/QALY. Since elderly and female patients appear to be at increased risk for vascular complications, coronary stenting is likely to be less cost-effective in such high-risk patients unless the risks of abrupt closure and restenosis after conventional angioplasty are also increased in this population. Conversely, modest increases in the incidence of vascular complications might be acceptable if they are associated with a lower rate of stent thrombosis. Our analysis suggests that the cost-effectiveness ratio for stenting would be unchanged if more aggressive anticoagulation reduced the stent thrombosis rate by 1% while increasing the incidence of vascular complications by no more than 3% (Fig 6).

Variations in the cost of stenting from different payer perspectives can also alter the apparent cost-effectiveness of stenting. Whereas our earlier study demonstrated that the true cost of stenting is 50% higher than that of conventional angioplasty (an absolute difference of $2500), other studies have found that hospital charges for stenting are 70% to 100% greater than charges for PTCA. If we use these charge values, the apparent cost-effectiveness ratio for initial coronary stenting would increase dramatically to $90,000 to $147,000/QALY. Whereas such ratios may be relevant to some third-party payers who actually pay charges, they cannot be compared directly with cost-effectiveness ratios established for other medical programs, which are generally based on costs. If the goal of the analysis is to facilitate efficient resource allocation within the overall health-care system, cost-effectiveness analysis based on actual resource costs is more appropriate.

Finally, this study demonstrates that it is unlikely that current stent technology will prove to be cost-saving compared with PTCA. Our model predicts that cost savings would occur only if the incremental cost of stenting over PTCA were <$1800 (ie, $700 below present levels) or if the stent restenosis rate were <13%. Although neither of these thresholds appears to be attainable with current technology, they might be obtained with a nonthrombogenic stent (which would not require prolonged hospitalization for initiation of anticoagulation) or by use of collagen plugs at the vascular puncture site to reduce the incidence of expensive vascular complications. Alternatively, development of a stent coated with a potent antiproliferative agent might achieve the reduction in restenosis necessary to result in significant cost savings, despite an unchanged acute hospital cost.
pay” for health benefits) on our model, sensitivity analysis can be used to identify the optimal revascularization strategy for any combination of abrupt closure and restenosis rates (Fig 5). Although initial coronary stenting appears reasonably cost-effective under our baseline assumptions, our analysis demonstrates that stenting would be significantly less cost-effective if applied to patients whose probabilities of abrupt closure and restenosis with conventional angioplasty are both very low (eg, <3% and <30%, respectively). Conversely, the cost-effectiveness of coronary stenting would improve significantly in patients for whom the expected rates of abrupt closure or restenosis are significantly higher than our baseline values.

Recent studies suggest that the immediate and long-term results of both conventional angioplasty and newer devices depend on a variety of patient- and lesion-specific characteristics. For example, complex lesions, female sex, and the presence of unstable angina have all been associated with an increased risk of abrupt vessel closure during conventional angioplasty,2,96 and careful patient selection can identify a “low-risk” population whose probability of emergency bypass surgery is <1% with angioplasty.97 Moreover, several studies have found both vessel size and location to be important predictors of restenosis after coronary intervention.98,99 Other features that may affect the absolute restenosis rates include diabetes, cholesterol level, and recent myocardial infarction.100 It is thus possible that for an individual patient, the particular combination of angiographic and clinical features might alter the relative restenosis and abrupt closure rates and thereby change the cost-effectiveness ratios sufficiently to favor PTCA over stenting. Unfortunately, without detailed knowledge of the immediate and long-term results of both angioplasty and stenting in specific patient subsets, such a patient-by-patient analysis is not feasible. When more detailed information from randomized trials (eg, Benestent, STRESS) or the New Approaches to Coronary Intervention (NACI) registry becomes available, it could be combined with our model to assess the cost-effectiveness of stenting in patients with specific angiographic and clinical characteristics.

Our analysis has important implications for future clinical trials in interventional cardiology. Currently, such trials are designed to detect an arbitrary “clinically significant” reduction in the restenosis rate. However, our analysis suggests that for coronary stenting to be reasonably cost-effective, it must reduce angiographic restenosis by at least 14% compared with conventional angioplasty (eg, an absolute reduction from 37% to 23%). Smaller reductions in the rate of angiographic restenosis (on the order of 5% to 10%) might be biologically and clinically significant but are unlikely to be cost-effective given the additional cost of stenting. Decision-analytic models such as ours might thus be used to provide estimates of clinically and economically significant effects in the design of future randomized device trials.

Study Limitations

The major limitation of this study is the use of observational data for our estimates of the immediate success, emergency bypass surgery, and restenosis rates of angioplasty and stenting. Nonetheless, our model is based on pooled data from the best studies currently available, and we have attempted to minimize bias by identifying studies involving comparable patients and using similar definitions wherever possible. Moreover, Kuntz et al98 have demonstrated that the varying angiographic restenosis rates after PTCA and stenting can be explained by differences in postprocedure luminal diameter attainable by these techniques. In a hypothetical 3.3-mm artery, this model predicts that angioplasty will have a restenosis rate of 42%, whereas the restenosis rate for stenting will be 25%. The fact that our estimates for the restenosis rates of angioplasty and stenting are comparable to those predicted by this quantitative model further supports our results. Until randomized trials comparing stenting with PTCA are completed, however, our model cannot offer definitive proof of the cost-effectiveness of stenting. It nonetheless serves to demonstrate which factors are the main determinants of cost-effectiveness and the range of values over which stenting is likely to be cost-effective compared with PTCA.

Another limitation is our use of procedural costs derived from a single-center experience. Although others have reported different “cost” estimates,9,12 those studies are based on hospital charges that frequently bear little relation to true economic costs.58 Our study, conversely, was based on the true economic (ie, resource) costs of each of these procedures, reflecting the most appropriate approach to cost-effectiveness analysis from the societal perspective.88,101

Finally, our study does not apply to patients with multivessel disease or prior bypass surgery. Although such patients currently represent approximately half of the annual US angioplasty volume, there is considerable controversy as to whether angioplasty or bypass surgery is more effective for this patient population.75,76 Moreover, it is unclear how many patients with multivessel disease would actually be candidates for revascularization using these new devices exclusively and how many would require a combination of devices and conventional angioplasty.

Conclusions

This study demonstrates how decision-analytic techniques can be used to model the cost-effectiveness of alternative techniques for coronary intervention. In the case of coronary stenting, our analysis demonstrates that the major determinants of cost-effectiveness are the relative restenosis rates for angioplasty and stenting and the incremental cost of stenting. Using the best data currently available, our decision-analytic model suggests that despite its higher acute cost, coronary stenting may be a reasonably cost-effective initial treatment for patients with symptomatic single-vessel coronary disease. Conversely, the strategy of initial angioplasty followed by stenting only for symptomatic restenosis was estimated to be both less effective and less cost-effective than primary stenting over a wide range of plausible assumptions and thus does not appear to be cost-effective when primary stenting is also an option.

When additional detailed results of randomized clinical trials and controlled observational studies become available in the future, they could be incorporated into our model to allow more precise definition of the cost-effectiveness of coronary stenting for specific types
of patients and lesions. Given the sensitivity of the cost-effectiveness ratios to even modest variations in either the relative restenosis rates or the cost of stenting compared with PTCA, it is likely that these studies will demonstrate that primary coronary stenting is most cost-effective for lesions with a higher than usual likelihood of restenosis or abrupt closure and in patients with a relatively low probability of developing a vascular complication. Conversely, in patients for whom the risks of restenosis and abrupt closure with conventional angioplasty are both low (eg, <30% and <3%, respectively), the cost-effectiveness ratio for primary stenting is likely to be unfavorable.

Appendix

Data Sources for the Short-term Model

Probabilities of Procedural Success and Complications

For the immediate results of single-vessel PTCA, we used the data from the second National Heart, Lung, and Blood Institute multicenter PTCA registry. The rate of abrupt closure with angioplasty was derived from the series of De Feyter et al. and Kuntz et al., whereas the rate of emergency bypass surgery was based on the more recent report by Scott et al. These studies suggest that although the overall incidence of abrupt closure or threatened abrupt closure with PTCA remains 5% to 7%, the availability of perfusion balloon therapy and emergency coronary stenting has reduced the rate of emergency bypass surgery to only 1%. For the immediate results of elective Palmaz-Schatz coronary stenting, we used our own published experience, published data from the US multicenter Palmaz-Schatz stent registry, and preliminary results from the multicenter STRESS trial. The immediate results of emergency coronary stenting appear to be somewhat worse than those for elective stenting; these were based on the US multicenter experience reported by Hermann et al. For infrequent events whose probabilities are unknown (eg, procedural mortality of stenting and PTCA), it was assumed that the rates would be equivalent between the two procedures. (See Table 1.)

Probability of Restenosis

We restricted our analysis to those studies that used a uniform definition of restenosis (>50% diameter stenosis at follow-up) measured by quantitative coronary angiographic techniques. Since a high rate of angiographic follow-up is essential to accurately determine true restenosis rates, we did not consider studies with <70% angiographic follow-up. Although the angiographic restenosis rates for conventional angioplasty vary widely, the vast majority of studies have found this rate to be 30% to 45%. In the absence of randomized clinical trials comparing PTCA with stenting, it is impossible to know the true angioplasty restenosis rate in lesions also suitable for coronary stenting. We estimated the probability of angiographic restenosis after conventional PTCA to be 37%—the midpoint of the published data. This estimate was eventually subjected to extensive sensitivity analysis. Since we estimated that only 70% of patients with angiographic restenosis would develop symptomatic restenosis, this value corresponds to a clinical restenosis rate of 26% (ie, 0.7 × 37%). To estimate the probability of angiographic restenosis after repeat PTCA (after one or more episodes of restenosis), we converted the available clinical restenosis rates to the appropriate angiographic equivalents by dividing each rate by 0.7. The restenosis rates for stenting of restenotic lesions, however, are based on angiographic follow-up. (See Table 2.)

Data Sources for the Post-Revasc Model

Late Mortality

Although angioplasty is a relatively new technique, a large number of studies with 5- to 10-year follow-up suggest that the average excess cardiac mortality after successful single-vessel angioplasty is 0.3% to 0.7% per year. Studies of single-vessel bypass surgery compiled during the era of modern myocardial preservation and revascularization techniques suggest similar late cardiac mortality rates. Age-specific, noncardiac mortality was assumed to be equal among treatment groups and was estimated from US life tables. (See Table 3.)

Late Cardiac Events After Single-Vessel Angioplasty

Late event rates after successful angioplasty for single-vessel disease were derived from three major studies. Weintraub et al. reported annual rates of myocardial infarction, repeat angioplasty, and bypass surgery over a 6-year follow-up period in 1492 patients with angiographically proven late patency after angioplasty. This patient population is comparable to those patients without restenosis who we assumed would enter the Post-Revasc model. Fierzman et al. reported the 5-year clinical follow-up of 537 patients treated with isolated LAD angioplasty, and Webb et al. reported the 8- to 11-year follow-up of 143 patients who underwent successful angioplasty between 1978 and 1981. To eliminate events caused by short-term restenosis (which are incorporated in our short-term model), we considered only events occurring after the first follow-up year in our calculation of event rates from these studies.

Late Cardiac Events After Single-Vessel Bypass Surgery

The reported rates of late angioplasty after successful single-vessel bypass surgery range from 0.5% to 1.8% per year. Studies of the probability of nonfatal myocardial infarction after single-vessel bypass surgery to allow the annual probability of myocardial infarction to increase with time. To avoid extrapolating beyond the available data, we assumed that the annual probability of myocardial infarction remains constant beyond 15 years after bypass surgery. The rate of repeat bypass surgery after initial single-vessel bypass grafting also increases from 0.4% per year to 1.5% per year with increasing duration of follow-up. We therefore constructed a second Weibull model to predict this rate.

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Evaluating the potential cost-effectiveness of stenting as a treatment for symptomatic single-vessel coronary disease. Use of a decision-analytic model.

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