

Cost-Effectiveness of Coronary Stenting in Acute Myocardial Infarction

Results From the Stent Primary Angioplasty in Myocardial Infarction (Stent-PAMI) Trial

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Background—Although several randomized trials have demonstrated that coronary stenting improves angiographic and clinical outcomes for patients with acute myocardial infarction (AMI), the cost-effectiveness of this practice is unknown. The objective of the present study was to evaluate the long-term costs and cost-effectiveness (C/E) of coronary stenting compared with primary balloon angioplasty as treatment for AMI.

Methods and Results—Between December 1996 and November 1997, 900 patients with AMI were randomized to undergo balloon angioplasty (PTCA, n=448) or coronary stenting (n=452). Detailed resource utilization and cost data were collected for each patient's initial hospitalization and for 1 year after randomization. Compared with conventional PTCA, stenting increased procedural costs by \approx \$2000 per patient ($\6538 ± 1778 versus $\$4561 \pm 1598$, $P < 0.001$). During the 1-year follow-up period, stenting was associated with significant reductions in the need for repeat revascularization and rehospitalization. Although follow-up costs were significantly lower with stenting ($\$3613 \pm 7743$ versus $\$4592 \pm 8198$, $P = 0.03$), overall 1-year costs remained \approx \$1000/patient higher with stenting than with PTCA ($\$20\,571 \pm 10\,693$ versus $\$19\,595 \pm 10\,990$, $P = 0.02$). The C/E ratio for stenting compared with PTCA was \$10 550 per repeat revascularization avoided. In analyses that incorporated recent changes in stent technology and pricing, the 1-year cost differential fell to $<$ \$350/patient, and the C/E ratio improved to \$3753 per repeat revascularization avoided. The cost-utility ratio for primary stenting was $<$ \$50 000 per quality-adjusted life year gained only if stenting did not increase 1-year mortality by $>0.2\%$ compared with PTCA.

Conclusions—As performed in Stent-PAMI, primary stenting for AMI increased 1-year medical care costs compared with primary PTCA. The overall cost-effectiveness of primary stenting depends on the societal value attributed to avoidance of symptomatic restenosis, as well as on the relative mortality rates of primary PTCA and stenting. (*Circulation*. 2001; 104:3039-3045.)

Key Words: myocardial infarction ■ angioplasty ■ stents ■ cost-benefit analysis

Primary angioplasty for acute myocardial infarction (AMI) improves rates of arterial patency and reduces the incidence of death or reinfarction compared with thrombolytic therapy.^{1,2} Nonetheless, primary balloon angioplasty (PTCA) remains limited by recurrent ischemia or reinfarction during the initial hospitalization in 10% to 15% of patients, as well as by restenosis or reocclusion of the infarct-related artery in the ensuing months.^{1,3} Although stenting originally was believed to be contraindicated in AMI, recently several randomized clinical trials have demonstrated that this approach results in lower residual stenoses, less frequent arterial dissection, and

improved short- and long-term outcomes compared with conventional PTCA.^{4–6}

Whether these clinical benefits justify the higher cost of stenting for patients with AMI currently is unknown. By reducing both early and late complications, it is possible that primary stenting could produce cost savings sufficient to fully offset the higher initial procedural costs. Moreover, even if this approach were not cost saving, it could still be cost-effective if the clinical benefits were commensurate with the additional cost.⁷ To evaluate the cost-effectiveness of stenting in AMI, we performed a prospective economic evaluation in conjunction with the Stent-PAMI trial.

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Methods

Patient Population

Between December 1996 and November 1997, 900 patients were enrolled in the Stent-PAMI trial, a randomized trial to compare the clinical and angiographic outcomes of stenting versus PTCA in patients undergoing direct angioplasty for AMI. Details of the study protocol and the 6-month clinical and angiographic results have been described previously.⁶ Patients presenting within 12 hours of AMI were referred for emergent coronary angiography. If angiography demonstrated coronary anatomy suitable for either PTCA or stent implantation, the patient was eligible for randomization. The institutional review boards at each clinical site approved the study protocol, and all patients provided informed consent before enrollment.

Randomization and Treatment Protocol

Eligible patients were randomized to treatment with either balloon angioplasty or the heparin-coated, Palmaz-Schatz stent (Cordis, Johnson and Johnson). Balloon angioplasty and stenting were performed according to standard techniques. For patients assigned to PTCA, crossover to stenting was discouraged unless necessary to treat a severe dissection or an unacceptable PTCA result (>50% residual stenosis). After PTCA, additional heparin was generally given for 24 to 48 hours in accord with standard practice,¹ whereas prolonged heparin administration was discouraged after stent implantation. After stent placement, patients received ticlopidine (250 mg BID) for 1 month.

Assessment of In-Hospital Outcomes and Clinical Follow-up

Detailed case report forms including baseline patient characteristics, procedural details, and clinical events during the initial hospitalization and 1-year follow-up period were completed by a research coordinator at each site and submitted to the data-coordinating center. An independent clinical events committee, blinded to treatment assignment, reviewed all major end points. Bleeding complications were defined as the need for surgical vascular repair, transfusion of ≥ 2 units of blood, or any retroperitoneal or intracranial bleed.

Determination of Medical Care Costs

Medical care costs for the initial hospitalization and for the 1-year follow-up period were assessed using a combination of "bottom-up" and "top-down" methods, as has been described previously.⁸

Cardiac Catheterization Laboratory Costs

Detailed resource utilization was recorded for each catheterization laboratory procedure, and the cost of each item was estimated on the basis of the mean hospital acquisition cost for the item in 1998. The cost of the heparin-coated stent was set at \$1500 on the basis of the typical price of other stents during the study period. Costs of additional disposable equipment, non-physician personnel, overhead, and depreciation for the cardiac catheterization laboratory were estimated on the basis of the average cost per procedure at Beth Israel Hospital in 1998 and were adjusted for actual procedure duration.

Other Hospital Costs

All other hospital costs were determined using top-down accounting methods based on each hospital's annual Medicare cost report. Itemized bills were obtained for each patient's initial hospitalization and any subsequent cardiovascular hospitalizations during the 1-year follow-up period. Hospital room and nursing costs were based on the average per diem cost for the specific patient care unit multiplied by the length of stay on the unit. Ancillary costs were determined by multiplying itemized hospital charges by the cost center-specific cost-to-charge ratio obtained from the hospital's Medicare cost report. All costs were converted to 1998 dollars on the basis of the medical care component of the consumer price index.

For those admissions with missing billing information (19.5%), nonprocedural hospital costs were imputed on the basis of a linear regression model developed using the hospital admissions for which complete billing information were available ($n=1012$). Independent variables for this model included length of stay, length of stay in the intensive care unit, vascular complications, and revascularization procedures (model $R^2=0.63$). A clinical events committee, blinded to treatment assignment, evaluated all repeat revascularization procedures to determine whether they were "clinically driven." Any procedures and their associated hospitalizations not judged to be clinically driven were excluded from our economic analysis ($n=59$ for the PTCA group and $n=61$ for the stent group).

Physician Costs

Professional fees for in-patient services (admission, daily care), major cardiac procedures (coronary revascularization, stent placement, diagnostic catheterization), and surgical procedures were estimated using the 1998 Medicare Fee Schedule for Massachusetts.

Statistical Analysis

Discrete data are reported as frequencies, whereas continuous data are reported as mean \pm SD. Cost data are reported as both mean and median values. Discrete variables were compared by Fisher's exact test. Normally distributed continuous variables were compared by Student's t test. Cost and other non-normally distributed data were compared by the Wilcoxon rank-sum test. All statistical analyses and cost-effectiveness analyses were performed according to the intention-to-treat principal.

Cost-Effectiveness Analysis

Because stenting was the more costly treatment strategy under each of our analytic scenarios, we performed a cost-utility analysis in which the effectiveness measure was the difference in quality-adjusted life expectancy between the 2 treatment groups. For this analysis, the EuroQol health status instrument⁹ was administered to 771 study patients at 1, 6, and 12 months after randomization, and utility weights were assigned to each patient on the basis of a published regression model.¹⁰ Weighted averages of utility values at the 3 follow-up time points were used to derive a mean quality-adjusted life expectancy for each patient and treatment group over the 1-year study period.¹¹ Because utility weights and survival data were not collected beyond the 1-year follow-up period, we used several alternative assumptions about the relative mortality rates of stenting and balloon angioplasty in the Stent-PAMI population and explored the effects of these alternative assumptions in sensitivity analyses.

Because there was no difference in 1-year mortality between the 2 treatment groups and the major benefit of stenting in the trial was a reduction in the need for repeat revascularization,⁶ we also performed a disease-specific cost-effectiveness analysis. For this analysis, the end point was the incremental cost per repeat revascularization avoided by stenting compared with PTCA alone. This cost-effectiveness ratio was calculated by dividing the difference in mean 1-year medical care costs for the 2 treatment groups by the difference in repeat revascularization rates (including both target vessel and non-target vessel procedures). Because the direct economic benefits of reduced repeat revascularization are already captured in the numerator of the cost-effectiveness ratio, we considered only the health benefits of avoiding recurrent angina and the need for additional revascularization procedures in the denominator of this disease-specific ratio.^{12,13} This form of cost-effectiveness ratio is analogous to the cost per event-free survivor that has been used in previous economic studies of coronary revascularization.^{14,15}

Results

Patient Population

Baseline characteristics of the study population are summarized in Table 1. Patients in the stent group were, on average, 2 years older than those in the balloon group (61 versus 59

TABLE 1. Baseline Clinical and Angiographic Characteristics

	Stent Group (n=452)	Balloon Group (n=448)
Age, y	61±12	59±13*
Sex, % male	74.8	74.8
Diabetes, %	15.9	14.1
Current smoker, %	38.2	39.7
Prior myocardial infarction, %	10.8	11.8
Infarct-related vessel		
Left anterior descending, %	39.8	43.5
Circumflex, %	13.7	13.6
Right coronary, %	46.0	42.6
Graft, %	0.4	0.2
Multivessel disease, %	46.0	44.0
Ejection fraction, %	48±12	48±11

**P*=0.05 vs stent group.

years, *P*=0.05). Otherwise, the treatment groups were well matched.

Procedural Resource Utilization and Cost

Table 2 summarizes selected resource utilization measures and costs for the initial revascularization procedures. In general, catheterization laboratory resource utilization was somewhat greater for the stent group than for the PTCA group. Stenting was performed in 98% of the stent group, and bailout stenting was required in 15% of the PTCA group (*P*<0.001). Thus, as expected, patients assigned to stent implantation required more stents than those assigned to conventional PTCA (1.5 versus 0.2 stents/patient, *P*<0.001).

In addition, the overall procedure duration was ≈8 minutes longer for the stent group than for the PTCA group, and patients assigned to stent implantation required more angioplasty balloons, radiographic contrast, and guidewires than did the balloon group. Initial procedural cost (excluding physician fees) was nearly \$2000 higher for the stent group than for the PTCA group (\$6538±1778 [median \$5926] versus \$4561±1598 [median \$3900], *P*<0.001).

Initial Hospital Outcomes, Resource Utilization, and Costs

Despite the improved immediate angiographic results provided by stent implantation, initial hospital outcomes and resource utilization were similar for the 2 treatment groups (Table 3). There were no significant differences in in-hospital mortality or nonfatal reinfarction between the 2 groups. Although the stent group tended to require less frequent repeat revascularization before hospital discharge as well as less frequent repeat diagnostic catheterization, these differences did not achieve statistical significance. Finally, despite the use of less intensive postprocedural anticoagulation in the stent group, there were no significant differences in the incidence of bleeding complications or in postprocedure length of stay between the stent and balloon groups, respectively. As a result, repeat procedure costs and hospital room and ancillary costs were similar for the 2 groups, and overall initial medical care costs (including physician fees) were ≈\$1900 higher on average for the stent group compared with those for the PTCA group (\$16 959±15 078 [median \$15 260] versus \$15 004±11 464 [median \$13 573], *P*<0.001).

TABLE 2. Procedural Resource Utilization and Cost

	Unit Cost, US \$	Stent Group (n=452)	Balloon Group (n=448)	<i>P</i>
Procedure duration, min	21.26	97±38	89±36	<0.001
Contrast volume, mL	0.35	337±142	309±122	0.01
Guiding catheters, n	80	1.2±0.6	1.2±0.6	0.67
Guidewires, n	80	1.4±0.9	1.2±0.5	<0.001
Balloon catheters, n	320	1.9±0.9	1.6±0.8	<0.001
Stents, n	1500	1.5±0.7	0.2±0.6	<0.001
Abciximab used, n	450/vial	5.8%	4.5%	0.47
Resource costs, US \$				
Room/overhead		2062±773 (1956)	1892±591 (1838)	<0.001
Supplies/drugs		825±217 (789)	775±201 (746)	0.43
Devices		3499±1665 (2842)	1751±1481 (1262)	<0.001
Personnel*		152±38 (145)	143±37 (139)	<0.001
Total procedural cost, US \$		6538±1778 (5926)	4561±1598 (3900)	<0.001

Values in parentheses are medians.

*Personnel costs include only non-physician personnel.

TABLE 3. Initial Hospital Outcomes, Resource Consumption, and Costs

	Stent Group (n=452)	Balloon Group (n=448)	P
Death, %	1.8	0.9	0.39
Nonfatal MI, %	0.2	1.0	0.25
Repeat revascularization, %			
Any	5.1	6.3	0.45
PCI	4.6	5.8	0.46
CABG	0.4	0.5	0.69
Diagnostic catheterization, %	4.4	6.5	0.19
Bleeding complication, %	6.2	7.1	0.58
Length of stay, days			
Total	5.4±4.6 (4)	5.6±4.8 (4)	0.65
ICU/CCU	2.4±2.5 (2)	2.5±2.7 (2)	0.61
Medical costs, US \$			
Initial procedure	6538±1778 (5926)	4561±1598 (3900)	<0.001
Repeat procedures	271±1273 (0)	329±1446 (0)	0.52
Hospital room/ancillary	8153±5370 (6580)	8387±5378 (7548)	0.36
Physician fees	1997±596 (1862)	1727±606 (1543)	<0.001
Total	16 959±15 078 (15 260)	15 004±11 464 (13 573)	<0.001

Values in parentheses are medians.

PCI indicates percutaneous coronary intervention; ICU/CCU, intensive care unit.

Follow-up Medical Resource Utilization and Costs

During the 1-year follow-up period, medical resource utilization was substantially lower among patients assigned to initial stent implantation than among patients assigned to conventional PTCA (Table 4). The incidence of subsequent hospitalization was reduced by 22% with stenting compared with PTCA (24.3% versus 31.0%, $P=0.03$), and the need for ≥ 1 repeat revascularization procedure was reduced by 42% (13.1% versus 22.5%, $P<0.001$). As a result, mean follow-up medical care costs were nearly \$1000 per patient lower for the stent group than for the PTCA group (\$3613±7743 versus \$4592±8198, $P=0.03$), reflecting significant reductions in all cost categories (Table 4). These cost savings were insufficient to fully offset the higher initial cost of stenting, however; aggregate 1-year medical care costs were \$976 higher for the stent group than for the PTCA group ($P=0.02$).

Because stent technology and pricing have changed considerably since the time frame of the Stent-PAMI trial, we performed a sensitivity analysis to account for the economic impact of these changes. In the United States, balloon-expandable stents are currently available in lengths ≤ 38 mm, whereas in the trial, only 15-mm stents were available. In our updated analysis, we therefore assumed that patients who received 2 contiguous 15-mm stents (26% of the stent group) would now be treated by a single long stent, and that patients who required three 15-mm stents (6%) would require only 2

current-generation stents. A second technical advance since the Stent-PAMI trial has been the development of stent delivery systems that incorporate a high-pressure balloon. Consequently, in our updated analysis we assumed that those patients who required an additional balloon catheter for the sole purpose of high-pressure postdilation (56% of the stent group and 7% of the balloon group) would no longer require this additional balloon. Finally, increasing competition has resulted in substantial reduction in the price of stents. On the basis of a survey of 5 Stent-PAMI sites, we estimated that the average price for short stents (≤ 18 mm) in 2000 was \$1350, whereas the average price for long stents (20 to 38 mm) was \$1800. Under these updated assumptions, the mean difference in initial procedural cost between the stent and PTCA groups fell to \$1286 (\$5959±1975 versus \$4673±1928, $P<0.001$) and the overall 1-year cost difference was only \$343 (\$19 722±10 991 [median \$16 328] versus \$19 379±10 621 [median \$16 092], $P=0.21$).

Cost-Utility Analysis

Serial utility assessment during the 1-year follow-up period demonstrated a difference of 0.015 quality-adjusted life years (QALYs) in favor of the stent group (0.85 ± 0.18 versus 0.83 ± 0.19 , $P=0.27$). This difference was largely due to better quality-adjusted life expectancy for those patients who did not require repeat revascularization compared with those who did (0.86 ± 0.18 versus 0.80 ± 0.19 QALYs, $P=0.003$). If we assumed no differences in either mortality or quality of life beyond the 1-year time frame of the trial, the base-case cost-utility ratio for stenting compared with PTCA was \$65 066 per QALY gained (Table 5, Scenario A). Using our updated cost assumptions based on current stent technology and pricing, the cost-utility ratio improved to \$22 067/QALY gained (Table 5, Scenario B). Even under these favorable assumptions, however, there was considerable uncertainty in the cost-utility ratios. Bootstrap simulation demonstrated that the cost-utility ratio for stenting was $< \$50\,000/\text{QALY}$ in 64.4% of samples, whereas balloon angioplasty was economically dominant (ie, less costly with greater quality-adjusted life expectancy) in 7.6% of samples.

Impact of Late Mortality

At 1-year follow-up, there was a trend toward higher 1-year mortality among patients randomized to stenting compared with conventional PTCA (5.5% versus 3.1%, $P=0.10$). We therefore performed a sensitivity analysis in which we projected long-term survival for the 2 treatment groups on the basis of the observed 1-year mortality rates in the trial. We assumed that there would be no further differences in annual costs, utilities, or mortality rates beyond the 1-year follow-up period. Life expectancy for MI survivors, conditional on surviving the first year after MI, was estimated using the Coronary Heart Disease Policy Model¹⁶ as 10.43 years (8.24 discounted years) for a typical 60-year-old Stent-PAMI patient. Under these assumptions, balloon angioplasty was an economically dominant strategy with lower overall costs and a 0.14-QALY gain in quality-adjusted life expectancy (Table 5, Scenario D). Stenting was projected to improve overall quality-adjusted life expectancy only if the 1-year mortality

TABLE 4. Follow-up Resource Utilization and Costs

	Stent Group (n=452)	Balloon Group (n=448)	P
Repeat hospitalization (% of patients)	24.3	31.0	0.03
Repeat revascularization (% of patients)	13.1	22.5	<0.001
CABG	3.3	3.4	0.56
PCI	10.4	19.6	<0.001
No. hospital admissions	158	193	N/A
No. revascularization procedures			
CABG	15	15	N/A
PCI	47	88	N/A
Hospital days	1.8±4.8 (0)	2.0±4.8 (0)	0.04
Follow-up costs, US \$			
Repeat procedures	505±1777 (0)	912±2208 (0)	<0.001
Hospital room/ancillary	2931±6947 (0)	3485±6785 (0)	0.02
Physician fees	423±1277 (0)	538±1362 (0)	0.002
Total follow-up costs	3613±7743 (0)	4592±8198 (0)	0.03
Aggregate 1-year costs, US \$	20 571±10 693 (17 008)	19 595±10 990 (16 229)	0.02

Values in parentheses are medians.

PCI indicates percutaneous coronary intervention; N/A, not applicable.

difference in favor of balloon angioplasty was <0.3%, and the cost-utility ratio was <\$50 000/QALY only if the excess mortality with stenting was <0.2% (Figure 1).

Disease-Specific Cost-Effectiveness

In our disease-specific analysis, the incremental cost-effectiveness ratio for stenting compared with PTCA was \$10 509 per repeat revascularization avoided (ie, \$976/0.094). Under our updated cost assumptions, the cost-effectiveness of routine stenting for AMI was improved to \$3753 per repeat revascularization avoided. Bootstrap simulation demonstrated that stenting was economically dominant in 32.9% of samples, whereas the cost-effectiveness ratio remained <\$10 000 per

repeat revascularization avoided—similar to the cost-effectiveness of elective stenting in the Belgium Netherlands Stent (Benestent) II trial¹⁴—in 77.9% of samples.

Discussion

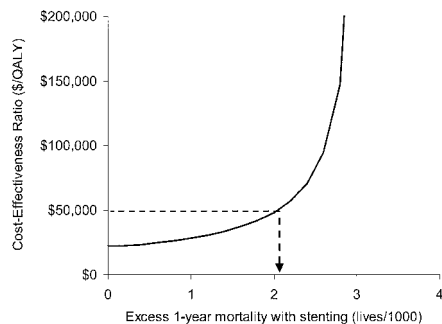
Although the economic impact of coronary stenting for elective PCI is well established, to date no studies have specifically examined the cost-effectiveness of primary stenting for AMI. In our prospective economic study alongside the Stent-PAMI trial, we found that coronary stenting increased initial hospital costs by ≈\$1950 per patient compared with PTCA alone. Although stenting led to significant reductions in medical resource utilization and follow-up costs, overall

TABLE 5. Cost-Effectiveness of Stenting in the Stent-PAMI Trial Under Alternative Assumptions About Procedural Cost and Long-Term Survival

Scenario	Δ Cost, US \$ (95% CI)*	Δ QALYs (95% CI)*	C/E Ratio (\$/QALY)	% <\$50,000 per QALY*	% Dominant*	% Dominated*
(A) Primary costs, no survival difference	958 (−180, 2164)	0.015 (−0.003, 0.032)	65 066	41.7	8.3	9.4
(B) Updated costs, no survival difference	324 (−807, 1513)	0.015 (−0.003, 0.032)	22 067	64.4	29.9	7.6
(C) Primary costs, extrapolated survival†	958 (−180, 2164)	−0.14 (−0.38, 0.03)	Dominated	12.5	0.9	85.8
(D) Updated costs, extrapolated survival†	324 (−807, 1513)	−0.14 (−0.38, 0.03)	Dominated	34.7	2.6	64.1

*Percentages and CIs are based on 1000 bootstrap simulations of trial results.

†Lifetime survival and quality-adjusted life expectancy for PTCA and stent patients were projected on the basis of 1-year mortality results from Stent-PAMI and long-term survival projections from the Coronary Heart Disease Policy Model.¹⁶



Relationship between excess 1-year mortality with stenting (versus balloon angioplasty) and the cost-utility ratio for primary stenting in Stent-PAMI. If one were willing to spend $\leq \$50\,000/\text{QALY}$, stenting would be reasonably cost-effective as long as the excess 1-year mortality did not exceed 0.2% (ie, 2 lives per 1000). Balloon angioplasty was the economically dominant strategy if 1-year mortality for stenting exceeded that for PTCA by $>0.3\%$.

1-year costs remained $\approx \$1000$ per patient higher with stenting compared with primary balloon angioplasty. Since the time frame of the Stent-PAMI trial, technical improvements in coronary stenting and increasing price competition have narrowed the initial cost difference between stenting and balloon angioplasty. Even under these updated assumptions, however, aggregate 1-year costs remained $\approx \$300$ per patient higher with stenting.

Whether this additional cost of coronary stenting is warranted cannot be answered definitively by our study. We found that the cost-effectiveness of stenting for AMI was highly dependent on the relative long-term mortality rates for stenting and PTCA. Although the differences in mortality observed in Stent-PAMI were not statistically significant, there was a trend toward lower 1-year mortality with conventional PTCA compared with stenting. When we extrapolated these 1-year mortality rates over the lifetime of the Stent-PAMI population, primary PTCA was projected to both improve quality-adjusted life expectancy (by 0.14 QALYs) and reduce overall healthcare costs. According to this model, quality-adjusted life expectancy with stenting would be greater than with PTCA only if the 1-year mortality benefit of PTCA were $<0.3\%$ (ie, 3 lives per 1000 patients treated). Thus, if one takes the Stent-PAMI results to represent the best estimate of long-term survival after PTCA or stenting, PTCA appears to be an economically dominant strategy.

On the other hand, the Stent-PAMI results are also consistent with the premise that there is no difference in overall mortality between primary PTCA and stenting. Under this alternative assumption, we found that initial stenting was associated with an increase in quality-adjusted life expectancy of 0.02 QALYs and an incremental cost-utility ratio of $\$65\,000/\text{QALY}$ gained. In our updated analysis, this cost-utility ratio improved to $\$22\,000/\text{QALY}$ gained—a level that is clearly well within the range of other accepted therapies in the US healthcare system.¹⁷

Whether the Stent-PAMI results represent a true mortality difference or simple play of chance is currently open to debate. Several other randomized trials of stenting compared with PTCA for AMI (including the recently completed, 2000-patient Controlled Abciximab and Device Investigation

to Lower Late Angioplasty Complications [CADILLAC] trial) have failed to demonstrate such a difference.^{4,5} In fact, many of these studies have demonstrated lower mortality rates with stenting than with conventional PTCA. Nonetheless, our findings serve to highlight the critical importance of even a modest increase in long-term mortality on the population-level effectiveness and cost-effectiveness of stenting for AMI.

Limitations

Our study has several limitations. As an unblinded trial, it would have been unethical to withhold bailout stenting from patients in the balloon arm who had an unequivocal indication for such therapy. Although crossover of patients from the PTCA group to stent implantation was discouraged, 15% of patients assigned to the PTCA group received ≥ 1 bailout stents to treat an unacceptable PTCA result during the initial procedure. It is likely that the ready availability of bailout stenting reduced the clinical benefits of initial stenting in the study population both by encouraging more aggressive balloon angioplasty (which may be associated with lower rates of restenosis) as well as by reducing the rates of costly events such as reinfarction during the index hospitalization.^{18,19} Thus, the results of our economic analysis should be viewed as a comparison of 2 clinical strategies—initial balloon angioplasty (with provisional stenting for poor results) and initial coronary stenting—rather than a pure comparison of 2 competing technologies.

Moreover, one must recognize that even under our most favorable assumptions, there was considerable uncertainty in our cost-effectiveness ratios. Such uncertainty is common in empirical cost-effectiveness analyses, however. Because cost-effectiveness analysis is intended to inform decisions rather than to prove hypotheses, our approach was to use the point estimates from the trial as the best estimate of the true cost-effectiveness and to perform extensive sensitivity analyses to demonstrate those factors that were the key sources of variability/uncertainty.²⁰

Conclusions

On the basis of the results of the Stent-PAMI trial, primary stenting for AMI reduces follow-up medical care costs compared with primary balloon angioplasty but does not fully offset the higher initial costs of stent treatment. The economic value of primary stenting for AMI thus depends critically on the societal value assigned to avoidance of symptomatic restenosis and the need for repeat revascularization, as well as on the relative mortality rates of primary PTCA and stenting. If there is no difference in mortality between PTCA and stenting, primary stenting appears to be reasonably cost-effective compared with alternative healthcare programs. On the other hand, even modest increases in 1-year mortality (on the order of 0.5% to 1.0%) would outweigh the restenosis benefits of stenting in this setting. Further studies are needed to better define these long-term mortality rates and to investigate the clinical and economic value of pharmacological adjuncts to stenting in the AMI setting.

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