Economic Assessment of Platelet Glycoprotein IIb/IIIa Receptor Blockade With Abciximab and Low-Dose Heparin During Percutaneous Coronary Revascularization

Results From the EPILOG Randomized Trial

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Background—In the EPILOG trial (Evaluation in PTCA to Improve Long-term Outcome with abciximab GP IIb/IIIa blockade), abciximab administered with weight-adjusted heparin diminished the risk of ischemic complications within 30 days by 56% among patients undergoing percutaneous coronary revascularization, without increased bleeding complications.

Methods and Results—A prospective economic assessment was performed in the 2792 patients enrolled in EPILOG. Patients were randomized to receive placebo with standard-dose weight-adjusted heparin, abciximab with low-dose weight-adjusted heparin, or abciximab with standard-dose weight-adjusted heparin during percutaneous coronary intervention. Hospital billing data for the baseline hospitalization were collected for 2581 patients (92.4% of total) and imputed for the remainder, with physician fees estimated from the Medicare Fee Schedule. For the baseline hospitalization, medical costs (hospitalization and physician fees) averaged $9632 for the placebo arm compared with $8758 ($P = 0.005) and $9092 ($P = 0.176) for the abciximab with low-dose and standard-dose heparin arms, respectively. Inclusive of average drug cost ($1454 to $1457), the net incremental baseline cost of these 2 abciximab strategies was $583 with low-dose weight-adjusted heparin and $914 with standard-dose weight-adjusted heparin. During 6-month follow-up, average hospital costs were not significantly different in the 3 treatment groups; cumulative net incremental costs were $1236 and $1268 in the abciximab with low-dose and standard-dose heparin groups, respectively.

Conclusions—Treatment with abciximab and low-dose, weight-adjusted heparin during percutaneous coronary revascularization reduces ischemic events and associated costs, thereby offsetting some of the cost of the drug. The suppression of bleeding complications associated with this agent by heparin dose reduction optimizes the economic attractiveness of this treatment strategy. (Circulation. 2000;102:2923-2929.)
associated with abciximab therapy could be nearly eliminated by weight-adjustment and reduction of conjunctive heparin dosing, with a resultant 56% reduction in ischemic complications over the first 30 days. Given the enhanced efficacy and reduced bleeding complications in EPILOG compared with EPIC, we hypothesized that the net costs associated with this therapy might be substantially reduced. We herein report the results of a prospective economic analysis performed within the EPILOG trial.

Methods

Patient Population and Protocol

The details of EPILOG have been described previously. In brief, 2792 patients undergoing elective or urgent percutaneous coronary revascularization were enrolled between February and December 1995 at 69 investigational sites in the United States and Canada. Patients with acute myocardial infarction or unstable angina associated with ECG changes during the previous 24 hours were excluded. The protocol was approved by the Institutional Review Board at each clinical site, and patients gave informed consent.

All patients were treated with aspirin and randomized in a double-blind fashion to 1 of 3 treatment groups: placebo with standard-dose, weight-adjusted heparin; abciximab with standard-dose, weight-adjusted heparin; or abciximab with low-dose, weight-adjusted heparin. Procedural use of heparin was discouraged, and vascular sheaths were to be removed within 2 to 6 hours (during abciximab infusion). Guidelines were provided for use of coronary stents and management of vascular access sites, uncontrolled bleeding, urgent coronary artery bypass surgery, thrombocytopenia, and blood transfusions. The primary efficacy end point was a composite of death, myocardial infarction, or urgent repeat revascularization within 30 days. Major bleeding was defined by a hemoglobin drop of >5 g/dL or intracranial hemorrhage, and minor bleeding was classified by a hemoglobin drop of >3 to 5 g/dL or gross hematuria or hematemesis.

Summary of Principal EPILOG Clinical Outcomes

As reported previously, the incidence of the composite end point at 30 days was 11.7% in the placebo group, 5.2% in the abciximab with low-dose heparin group (58% relative risk reduction, \( P<0.0001 \)), and 5.4% in the abciximab with standard-dose heparin group (54% relative risk reduction, \( P<0.0001 \)). Major end-point components that were reduced by abciximab include myocardial infarction (8.7% versus 3.7% and 3.8% in the placebo, abciximab with low-dose heparin, and abciximab with standard-dose heparin groups, respectively), urgent repeat percutaneous coronary revascularization (3.8% versus 1.2% and 1.5%, respectively), and urgent CABG surgery (1.7% versus 0.4% and 0.9%, respectively). Stents were reserved for manifest or abrupt closure and were utilized in 11.8% of patients. Rates of major bleeding unassociated with CABG surgery were 1.1% in the placebo group, 1.1% in the abciximab with low-dose heparin group, and 1.9% in the abciximab with standard-dose heparin group; rates of minor bleeding were 3.3%, 4.0%, and 7.6%, respectively. By 6-month follow-up, differences among treatment groups observed at 30 days with regard to death, myocardial infarction, and urgent repeat revascularization were maintained. However, overall repeat revascularization rates were not different (19.4% versus 19.0% and 18.4%, respectively) owing to a trend toward excess nonurgent revascularization procedures in the abciximab treatment groups (13.8% versus 16.7% and 15.4%, respectively, \( P=NS \)).

Design of the Economic Substudy

A prospective economic substudy of patients within the EPILOG trial was performed in which medical costs and medical resource consumption were assessed. Methods were identical to those used in the EPIC trial. Hospital bills were collected for all hospitalizations during the study period, except for those at Canadian, Veteran’s Administration (VA), or military hospitals or other hospitals that based charges on a per diem rate. Of the 2792 patients randomized, 111 (4.0%) and 86 (3.1%) were enrolled at Canadian and VA or other per diem sites, respectively. Of the 2595 remaining patients, hospital bills were successfully collected for the index hospitalization on 2581 (92.4% of total enrollment, 99.5% of patients hospitalized at centers that generated bills). Complete hospitalization cost data through 6-month follow-up were collected on 2474 (88.6%) of the 2782 patients surviving to initial hospital discharge. Summary UB 92 bill forms were obtained for each hospitalization, and charges were converted to costs by use of department-specific cost-to-charge ratios obtained from each hospital’s annual Medicare Cost Report. Physician fees were estimated based on the resource-based relative value Medicare Fee Schedule (1994 North Carolina version). Physician activities used to estimate fees included admission evaluation (intensive care unit [ICU] and non-ICU), daily follow-up care (ICU, non-ICU), cardiac catheterization, coronary angioplasty, CABG surgery, and management of major bleeding. The cost of abciximab was calculated from the weight-adjusted dose, assigning a cost of $450 per 10-mg vial and assuming that partially unused vials remaining at the end of the patient’s treatment would be wasted. Costs for outpatient care (aside from cardiac catheterization) were not assessed.

For the 211 patients for whom baseline hospitalization cost could not be obtained due to unavailable bills, all-inclusive or per diem charges, or unavailable cost-to-charge ratios, hospital costs were imputed. Multivariable linear regression modeling was applied to estimate the cost of major resources and selected complications (hospital length of stay, catheterization, percutaneous revascularization, stent placement, CABG surgery, and major and minor bleeding unassociated with coronary bypass surgery), with data from patients with complete hospital cost collection. This model was then used to impute costs for patients with missing data. Because the results of analyses with and without the imputed cost data were unchanged, only the total cohort data (including imputed values) are presented in this article.

Data Analysis

Descriptive statistics are presented as counts and percentages for discrete variables and medians and interquartile ranges (25th to 75th percentile) for continuous variables. Cost data are presented as means and SDs, as the most relevant estimate of total costs associated with a particular treatment strategy in a large number of patients. Because of the skewed distribution of cost data, some variables are presented as medians reflecting the cost to treat a “typical” patient. All analyses were performed according to the intention-to-treat principle. Pairwise comparisons of costs and hospital stay durations between each abciximab arm and the placebo arm were performed by the van der Waerden normal scores test, with Fisher’s exact test used to assess differences in repeat hospitalization rates. Confidence intervals for differences in costs were computed with the bias-corrected bootstrap with 16,000 samples.

The association of costs with procedures or ischemic and bleeding end points was explored with the multivariable linear regression model that had been used to impute costs for patients with unavailable bills. Estimates of the costs of major resources were derived from this model were multiplied by incidence rates to calculate the estimated average costs for such events among all randomized patients within each treatment group.

Results

Baseline Characteristics

Baseline characteristics and clinical outcome in the EPILOG trial have been reported previously in detail. Median age was 60 years (interquartile range 51 to 68 years), 72% were men, and 90% were white. Diabetes mellitus was present in 23% of patients, hypertension in 59%, peripheral vascular disease in 9%, and tobacco use within the prior year in 33%. The primary indication for revascularization was unstable angina.
in 48% of patients, recent myocardial infarction in 21%, and stable ischemia or a positive functional study in 31%. Multivessel coronary artery disease was present in 47% of patients, and median left ventricular ejection fraction was 55% (interquartile range 50% to 65%). Baseline characteristics were well-balanced among the 3 randomized treatment groups.

Medical Resource Consumption
The composite efficacy end point of death, myocardial infarction, or urgent revascularization during the baseline hospitalization occurred in 10.8% of patients in the placebo group, 4.9% of patients in the abciximab with low-dose heparin group (54% relative risk reduction, \(P<0.001\)), and 5.6% of patients in the abciximab with standard-dose heparin group (48% relative risk reduction, \(P<0.001\)). Medical hospital resource consumption during the initial hospitalization is summarized in Table 1 according to treatment group. The median length of hospitalization tended to be shorter in the abciximab treatment groups. Patients randomized to abciximab required fewer CABG surgery, repeat percutaneous revascularization, or cardiac catheterization procedures, with a trend toward fewer unplanned (“bailout”) stents in the abciximab with low-dose heparin group. Rates of myocardial infarction were reduced by abciximab. Bleeding events were not increased relative to placebo in the abciximab with low-dose heparin arm but were somewhat increased in the abciximab with standard-dose heparin arm.

Medical resource consumption during the follow-up period between baseline hospital discharge and 6 months is also summarized in Table 1. Although there were no significant differences in rates of rehospitalization, catheterization, or revascularization, these events tended to occur more frequently among patients randomized to abciximab.

Medical Costs
Hospital costs and associated physician fees for the baseline hospitalization (exclusive of abciximab drug cost) are listed in Table 2. Costs tended to be lower among patients randomized to receive abciximab compared with placebo; these differences were statistically significant for the abciximab with low-dose heparin group. Total costs for the baseline hospitalization were reduced by $874 by abciximab with low-dose heparin (95% CI $341 to $1396; \(P<0.005\)) and by $540 by abciximab with standard-dose heparin (95% CI $380 to $1121; \(P=0.176\)). Including the cost of the weight-adjusted abciximab ($1457 and $1454 in the low-dose and standard-dose heparin groups, respectively), the total net costs of this therapy during the baseline hospitalization were $583 (95% CI $19 to $1079; \(P<0.001\)) in the abciximab with low-dose heparin group and $914 (95% CI $380 to $1458; \(P<0.001\)) in the abciximab with standard-dose heparin group.

To analyze the sources of cost differentials between the placebo and abciximab treatment groups during the baseline hospitalization, multivariable linear regression was per-
formed. Table 3 summarizes the estimated savings in baseline hospital costs (not including physician fees) associated with abciximab therapy due to reduction in ischemic events and associated procedures (“efficacy”), as well as the estimated increased costs due to bleeding complications. Rates of ischemic and bleeding events from which these estimates were derived have been detailed in Table 1. Of the $806 of baseline hospital cost savings in the abciximab with low-dose heparin group, $603 was allocated by the regression model to efficacy, principally owing to the reduction in CABG surgery rates, use of unplanned stenting, and hospital length of stay. Similarly, of the $489 of baseline hospital cost savings in the abciximab with standard-dose heparin group, $484 was allocated to efficacy because of reduced hospital length-of-stay and rates of bypass surgery, repeat percutaneous coronary intervention, and myocardial infarction. There were essentially no excess costs ($2) associated with bleeding among patients randomized to abciximab with low-dose heparin, whereas $40 in cost savings was lost among patients treated with abciximab with standard-dose heparin owing to the modest increase in major and minor bleeding events. A small proportion of the observed cost savings ($205 and $45 in the abciximab with low-dose heparin and standard-dose heparin groups, respectively) was not accounted for by the efficacy or bleeding variables included in the multivariable regression model.

Table 4 shows the hospital costs over the 6-month follow-up period after baseline hospital discharge. There were no significant differences in follow-up costs among the 3 treatment groups. Nevertheless, there was a trend toward increased hospital costs among patients receiving abciximab, due to increased rates of nonurgent revascularization in these treatment groups (see Table 1). Costs accumulated gradually over time after the baseline hospitalization discharge. By 6 months, total follow-up hospitalization costs were $653 higher compared with placebo in the abciximab with low-dose heparin group (95% CI $1609 higher to $118 lower; \( P = 0.144 \)) and $355 higher in the abciximab with standard-dose heparin group (95% CI $430 lower to $1275 higher; \( P = 0.429 \)). Cumulative net costs (including abciximab cost) over the entire 6-month study period (hospitalization plus follow-up) were therefore $1236 higher than with placebo in the abciximab with low-dose heparin group (95% CI $209 to $2345) and $1268 higher in the abciximab with standard-dose heparin group (95% CI $265 to $2406).

Cumulative frequency distribution curves for total baseline hospital and cumulative 6-month costs (inclusive of abciximab drug cost) are shown in the Figure. Abciximab therapy was associated with increased costs in the majority of patients, with neutral or reduced costs in the remainder due to prevention of adverse events.

**Discussion**

The EPILOG trial demonstrated that abciximab administered with low-dose, weight-adjusted heparin diminishes the risk of acute ischemic complications by up to 56% in patients undergoing percutaneous coronary revascularization, without associated increased risk of bleeding. The present prospective economic assessment of EPILOG demonstrates that this clinical efficacy is associated with important economic benefits. Baseline hospitalization costs were significantly reduced by $874 by abciximab with low-dose heparin (exclusive of the cost of abciximab itself), with a trend toward a $540 cost savings by abciximab with standard-dose heparin. Thus, improved clinical outcome with abciximab with low-dose heparin leads to cost savings during initial hospitaliza-
tion that offset 60% of the average per-patient cost of this agent. Over a 6-month follow-up, an incremental benefit of abciximab in reducing nonurgent revascularization events or costs was not observed, with a trend toward increased resource utilization and costs in the abciximab-treated patients.

The baseline hospitalization costs assessed in this economic analysis represent a relevant measure of the costs experienced by hospitals operating under noncapitated payment systems. With such payment arrangements, costs incurred during the initial hospitalization are often reimbursed at a fixed level, although subsequent hospitalization costs are generally billed and reimbursed separately. Thus, for cost savings to recoup the price of a new drug therapy from a provider perspective, they must accrue during the hospitalization period in which that drug is administered, rather than as a delayed cost savings over long-term follow-up. In this regard, the findings of the EPILOG economic analysis are particularly germane, because cost offsets due to efficacy from abciximab occurred during the baseline hospitalization period. It should be noted, however, that $68 of the total $874 cost savings in the abciximab plus low-dose heparin arm were attributable to reductions in physician fees (not included in hospital payments) and therefore would not be realized by the hospital. The attenuation of the economic benefit of abciximab observed over 6-month follow-up in EPILOG due to repeat revascularization procedures would be relevant, however, to capitated payors or healthcare systems.

Baseline hospitalization cost savings with abciximab in EPILOG arose primarily from reduction in the need for repeat revascularization procedures, less bailout stenting, and shortened hospital lengths of stay (Table 3). Interestingly, periprocedural myocardial infarction was also associated with an estimated cost of $1180 by regression analysis, independently

<table>
<thead>
<tr>
<th>Event</th>
<th>Estimated Cost, $</th>
<th>abciximab + LD Heparin</th>
<th>abciximab + SD Heparin</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG</td>
<td>10 380</td>
<td>176</td>
<td>117</td>
</tr>
<tr>
<td>Repeat PCI</td>
<td>2467</td>
<td>50</td>
<td>54</td>
</tr>
<tr>
<td>Repeat catheterization</td>
<td>2018</td>
<td>35</td>
<td>25</td>
</tr>
<tr>
<td>Stent</td>
<td>1293</td>
<td>120</td>
<td>25</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1180</td>
<td>57</td>
<td>53</td>
</tr>
<tr>
<td>Hospital days</td>
<td>1076</td>
<td>165</td>
<td>209</td>
</tr>
<tr>
<td>Total efficacy (95% CI)</td>
<td>603 (121, 1013)</td>
<td>484 (86, 921)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bleeding</th>
<th>Savings [Costs] vs Placebo, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding</td>
<td>3295</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>343</td>
</tr>
<tr>
<td>Total bleeding (95% CI)</td>
<td>[2] (−47, 26)</td>
</tr>
<tr>
<td>Other†</td>
<td>205</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>806 (265, 1283)</td>
</tr>
</tbody>
</table>

$R^2$ for the regression model, 0.72.
*Regression model coefficient (hospital costs only).
†Difference between observed cost savings and cost savings predicted by multivariable model.

Abbreviations as in Table 1.

### Table 4. Follow-Up Hospitalization Costs

<table>
<thead>
<tr>
<th></th>
<th>Placebo + SD Heparin</th>
<th>Abciximab + LD Heparin</th>
<th>Abciximab + SD Heparin</th>
<th>Placebo</th>
<th>Abciximab + LD Heparin</th>
<th>Abciximab + SD Heparin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital cost, $</td>
<td>3152±8034</td>
<td>3731±9383</td>
<td>3468±8990</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician fees, $</td>
<td>415±970</td>
<td>490±1039</td>
<td>455±1019</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total costs, $</td>
<td>3568±8813</td>
<td>4221±10 270</td>
<td>0.144</td>
<td>3923±9880</td>
<td>0.429</td>
<td></td>
</tr>
<tr>
<td>Difference from placebo</td>
<td>. . .</td>
<td>653</td>
<td>355</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cumulative 6-month costs, $*</td>
<td>13 200±11 608</td>
<td>14 436±12 223</td>
<td>0.025</td>
<td>14 468±12 001</td>
<td>0.022</td>
<td></td>
</tr>
<tr>
<td>Difference from placebo</td>
<td>. . .</td>
<td>1236</td>
<td>1268</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are mean±SD. Abbreviations as in Table 1.

Median values were 0 in all categories.

*Cumulative 6-month costs = baseline hospitalization plus follow-up costs, inclusive of abciximab cost.
of consequent use of repeat revascularization procedures or prolonged duration of hospitalization. Importantly, however, a major bleeding event was estimated to cost $3295, more than any other single event except CABG surgery, highlighting the potential for bleeding complications to markedly attenuate any cost savings achieved through reduction in ischemic end points.

It is thus instructive to compare the economic outcome in EPILOG to that in the prior study of abciximab during coronary intervention, the EPIC trial. As in EPILOG, clinical efficacy in EPIC was associated with a cost savings during the initial hospitalization, estimated by regression analysis to be $444 per patient compared with placebo therapy. However, with the increase due to abciximab in rates of major and minor bleeding, this economic savings due to efficacy was offset by a estimated $531 cost due to bleeding. Inclusive of drug cost, then, the net incremental cost of abciximab therapy during the baseline hospitalization in EPIC was $1550. In contrast, the EPILOG trial demonstrated that clinical efficacy of abciximab could be uncoupled from bleeding complications by dose reduction and weight adjustment of concurrent heparin dosing. As a result, economic savings due to reduced ischemic events were not offset by costs of bleeding complications, and the net incremental cost of abciximab therapy during the baseline hospitalization in EPILOG was $583, only 38% of that in the earlier EPIC trial. These findings establish the importance of careful heparin dosing during abciximab administration to optimize not only clinical outcome but the economic attractiveness of this therapy as well.

Outcome over the 6 months after baseline hospitalization also differed between the EPIC and EPILOG trials. In EPIC, follow-up rates of repeat revascularization and rehospitalization were reduced by abciximab, resulting in a $1270 cost savings over the follow-up period. This finding was not reproduced in EPILOG, where rates of elective revascularization were nonsignificantly increased in the abciximab groups. As a result, follow-up hospital costs were $355 to $653 higher among patients randomized to abciximab compared with placebo in EPILOG. Moreover, it remains unclear whether the need for late revascularization procedures and their associated economic costs were actually increased by abciximab therapy in the EPILOG trial. Such a finding may have been spurious because of statistical chance, and an excess risk for elective revascularization procedures with abciximab was not observed among patients receiving stents in the recent Evaluation of Platelet Inhibition in Stenting (EPISTENT) trial. Alternatively, the reduction in periprocedural myocardial infarction risk by abciximab in EPILOG might have predisposed to more frequent late revascularizations.

Economic analyses have also been published for 2 other trials of GP IIb/IIIa blockade during percutaneous coronary intervention. In EPISTENT, abciximab among patients undergoing stenting was associated with an incremental baseline hospital cost of $1305 and a cumulative incremental cost over 1 year of $932. Based on the observed mortality benefit of abciximab, the cost-effectiveness ratio was calculated to be $6213 per added life-year, a value that compares favorably with other accepted medical therapies. In the Randomized Efficacy Study of Tirofiban for Outcomes and Restenosis (RESTORE) trial, there was no significant differ-

Cumulative frequency distribution curves for baseline hospitalization costs (top) and cumulative 6-month costs (bottom), inclusive of abciximab drug cost, for 3 treatment groups.
ence in hospital costs among patients receiving placebo or tirofiban during coronary angioplasty, in part because of the relatively low acquisition cost of tirofiban (≈$700). Important, however, clinical efficacy of tirofiban therapy in RESTORE was marginal, because this agent did not significantly reduce the incidence of death, myocardial infarction, or urgent revascularization by 30 days (24% relative risk reduction in RESTORE, P=0.052, compared with the 56% relative risk reduction observed in EPILOG); it is therefore difficult to compare the economic profiles of abciximab and tirofiban in these 2 trials.

This study has several limitations. First, outpatient costs (aside from cardiac catheterization) were not considered, nor were indirect or productivity costs, such as those related to loss of employment. Such costs may have been somewhat reduced by abciximab because of fewer complications during the baseline hospitalization or increased owing to late revascularization procedures. Second, the use of summary UB 92 bill forms to estimate costs is only an approximation that has been validated in selective instances, but not in all hospitals. Moreover, owing to the large number of physicians providing care to patients in this trial, we were unable to directly collect physician bills and instead estimated professional costs using the Medicare Fee Schedule; this method of estimation captured all “big ticket” items, however, such as rehospitalizations and cardiac procedures. Third, cost-effectiveness analyses were not performed, because abciximab did not result in a statistically significant reduction in mortality in this trial, and utility was not assessed. Finally, the relevance of these findings in a trial of balloon angioplasty are unclear in the current era, in which elective stenting is the predominant means of percutaneous coronary revascularization. The reduction of clinical ischemic events by abciximab among stented patients in the EPISODE trial was equivalent to that among patients undergoing balloon angioplasty in EPILOG, however, and the economic analysis in that trial suggested that this treatment strategy also has a favorable economic profile in stented patients.

**Summary**

Prospective economic analysis in the EPILOG trial demonstrates that reduction in ischemic events during the baseline hospitalization among patients receiving abciximab offsets more than half of the cost of the drug, resulting in a net incremental baseline hospitalization cost of therapy with abciximab and low-dose heparin of $583. Suppression of bleeding complications associated with this agent by heparin dose reduction optimizes the economic attractiveness of this treatment strategy.

**Acknowledgments**

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**References**

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