

“Many institutions have shortened the infusion of eptifibatide already,” noted Dr. Fung. “The findings of our trial confirm that this change is safe and has the benefit of lower rates of major bleeding.” Because the overall sample size was relatively modest (624 patients) and the trial was designed as a non-inferiority comparison with a 10% absolute difference boundary, larger confirmatory trials are needed to validate these results.

## Comparison of Eptifibatide and Abciximab as Adjunct to Primary PCI

The EVA-AMI trial compared two intravenous glycoprotein IIb/IIIa inhibitors (GPI), eptifibatide and abciximab, as adjuncts to primary percutaneous coronary intervention (PCI) with respect to several measures of myocardial perfusion. The study represents the first head-to-head comparison of two GPIs in primary PCI for ST-elevation myocardial infarction (STEMI).

EVA-AMI involved 430 STEMI patients with fewer than 12 hours of symptoms and who were scheduled for primary PCI. The patients were randomly assigned to either eptifibatide (double bolus followed by 24-hour infusion; 226 patients) or abciximab (bolus followed by 12-hour infusion; 201 patients). All patients received aspirin, clopidogrel, and unfractionated heparin or enoxaparin.

The primary endpoint was ST resolution at 1 hour after PCI. ST resolution is a marker of myocardial perfusion and has been closely linked to short- and long-term mortality after STEMI, thus making it an ideal surrogate endpoint for comparing adjunctive therapies in reperfusion. Electrocardiograms were performed at baseline and 1 hour after PCI; ST resolution of more than 70% was considered to be complete, and resolution between 30% and 70% was considered to be partial.

Myocardial perfusion, as assessed by TIMI flow grade after PCI, did not differ significantly between eptifibatide and abciximab (82.4% vs 84.3%). Electrocardiographic data after PCI were available for 220 patients. The rates of complete ST resolution between the two groups were similar (63.1% for the eptifibatide group and 59.6% for the abciximab group) and met the criteria for noninferiority (Table 1). However, significantly more patients in the abciximab group had no ST resolution (14.7% vs 5.4%;  $p=0.021$ ). With regard to in-hospital clinical events, the two GPIs did not differ significantly

with respect to rates of death, myocardial infarction, heart failure, target vessel revascularization, or minor or major bleeding (Table 1).

**Table 1. Comparison of Eptifibatide and Abciximab in the EVA-AMI Trial.**

	Eptifibatide	Abciximab
TIMI grade 3 flow	82.4%	84.3%
ST resolution		
>70%	63.1%	59.6%
≥30%	31.5%	25.7%
None	5.4%*	14.7%*
Death	3.5%	3.5%
Myocardial infarction	1.5%	0
Heart failure	6.4%	8.5%
Target vessel revascularization	2.7%	4%
Major bleeding	1.8%	0
Minor bleeding	4.1%	4.5%

\* $p=0.021$ ; all of the other comparisons were not statistically significant.

Uwe Zeymer, MD, Herzzentrum Ludwigshafen, Germany, who reported the findings of the study, noted that processing of the study data has not been completed. The study’s clinical events committee has not yet evaluated the clinical events and serious adverse events, and collection of 6-month follow-up data is still ongoing.

“Because eptifibatide is less expensive than abciximab, it may be a valid alternative to abciximab for patients with STEMI undergoing primary PCI,” said Dr. Zeymer.

## Quality of Life and Cost-Effectiveness Associated with the Late Opening of a Total Occluded Artery

Quality-of-life and cost-effectiveness analyses of data from patients in the Occluded Artery Trial (OAT) have shown that a strategy of routine percutaneous coronary intervention (PCI) has modest symptom benefits that diminish over time. The strategy is also more expensive than optimal medical therapy alone.

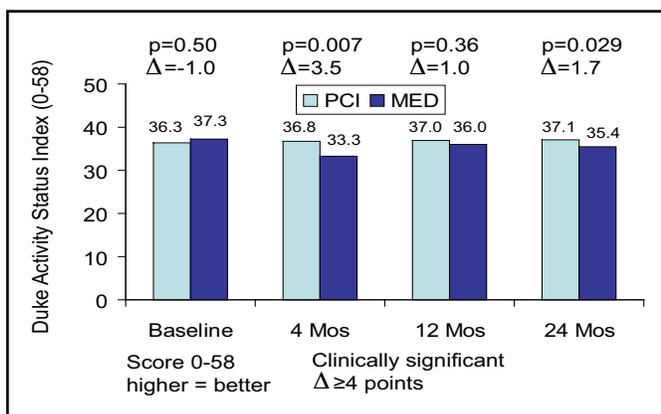
In OAT, high-risk asymptomatic patients with a total occluded coronary artery 3-28 days after myocardial infarction (MI) were randomly assigned to either PCI or medical therapy alone and followed for up to 4

years. High-risk was defined as an ejection fraction <50% or proximal occlusion of a main coronary artery. The findings indicated that late opening of the total occluded artery with PCI did not reduce the occurrence of the primary endpoint (a composite of death, nonfatal MI, or heart failure).

Daniel B. Mark, MD, MPH, Duke Clinical Research Institute, Durham, NC, reported the findings of both the quality-of-life and economic analyses. The quality-of-life analysis was carried out on data for 951 patients from the main OAT study. Structured interviews were conducted at baseline (median 6 days post MI) and at 4, 12, and 24 months. The two principal instruments used were the Duke Activity Status Index (DASI) and the SF-36 Mental Health Inventory (MHI); several other quality-of-life instruments were used to determine secondary endpoints.

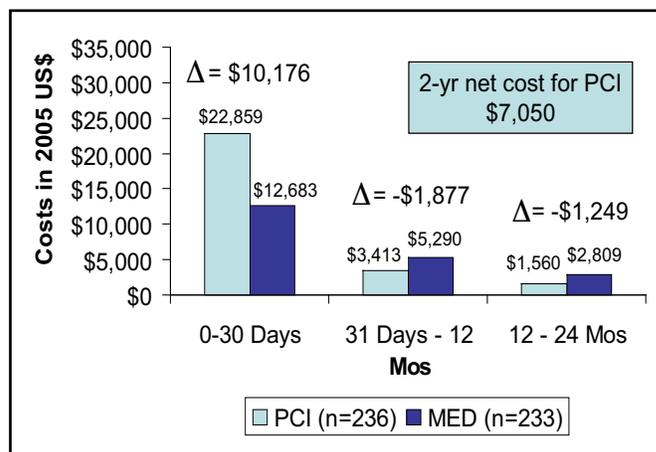
Dr. Mark reported that PCI was associated with a clinically significant benefit in physical functioning at 4 months ( $p=0.007$ ), according to DASI scores. However, this benefit was not sustained at the 1-year or 2-year follow-up (Figure 1). PCI also had no clinically or statistically significant effect on psychological well-being, according to scores on the SF-36 MHI. Angina on effort decreased over time in both groups, and affected more patients in the medical therapy alone group, but the difference was not significant.

**Figure 1. OAT QoL Substudy: Duke Activity Status Index (DASI).**



The economic analysis focused on data from 469 patients from the main OAT study who had been treated in US centers. The costs for PCI at 30 days were \$10,176 higher than the costs for medical therapy alone; at 1 and 2 years, the costs associated with medical therapy were slightly higher than those associated with PCI. At the end of 2 years, the net excess cost of PCI was slightly over \$7,000 (Figure 2).

**Figure 2. OAT Economic Substudy: Medical (Hosp + MD) Cost in USD by Rx Strategy.**



Dr. Mark concluded, “The economic analysis showed that a strategy of routine PCI at 3-38 days after infarction in patients with an occluded infarct artery was substantially more expensive than optimal medical therapy alone out to 2 years and that the small symptom benefit observed was insufficient to make PCI an economically attractive strategy in OAT-eligible patients.”

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