Coronary stenting and platelet glycoprotein inhibitors were more effective than was t-PA for acute myocardial infarction

Schömig A, Kastrati A, Dirschinger J, et al, for the Stent versus Thrombolysis for Occluded Coronary Arteries in Patients with Acute Myocardial Infarction Study Investigators. Coronary stenting plus platelet glycoprotein IIb/IIIa blockade compared with tissue plasminogen activator in acute myocardial infarction. N Engl J Med. 2000 Aug 10;343:385-91.

QUESTION

In patients with acute myocardial infarction (MI), is coronary stenting plus platelet glycoprotein IIb/IIIa blockage as effective as tissue plasminogen activator (t-PA)?

DESIGN

Randomized (unclear allocation concealment*), unblinded*, controlled trial with 6-month follow-up.

SETTING

Hospital in Germany.

PATIENTS

140 patients (mean age 59 y, 74% men) who presented within 12 hours of symptom onset, had chest pain for \geq 20 minutes, and had ST-segment elevation of \geq 0.1 mV in \geq 2 limb leads or \geq 0.2 mV in \geq 2 contiguous precordial leads on surface electrocardiography. Exclusion criteria included recent history of stroke, trauma, or major surgery; active bleeding; suspected aortic dissection; and uncontrolled hypertension.

INTERVENTION

71 patients were allocated to stent plus abciximab given as a bolus of 0.25 mg/kg of body

weight followed by a continuous infusion at a rate of $10 \mu g/min$ for 12 hours, and 69 were allocated to intravenous alteplase, bolus dose of <math>15 mg followed by a 90-minute infusion in which 0.75 mg/kg (maximal dose 50 mg) was given over 30 minutes followed by 0.5 mg/kg (maximal dose 35 mg) over a period of 60 minutes.

MAIN OUTCOME MEASURES

Degree of myocardial salvage and a composite end point of death, reinfarction, or stroke.

MAIN RESULTS

88% of the patients had scintigraphic results. A greater degree of myocardial salvage occurred in the stent group than in the alteplase group (16.1% vs 7.4% of the left ventricle, salvage index 0.57 vs 0.26, P < 0.001). At 6 months, the incidence of death, reinfarction, or stroke was lower in the

stent group than in the alteplase group (P = 0.02) (Table).

CONCLUSION

In patients with acute myocardial infarction, coronary stenting plus abciximab led to a greater degree of myocardial salvage and better clinical outcomes than did fibrinolysis with tissue plasminogen activator.

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*See Glossary.

Stenting plus abciximab vs alteplase at 6 months in acute myocardial infarctiont

Outcome	Stenting	Alteplase	RRR (95% CI)	NNT (CI)
Composite of death, reinfarction, or stroke	9%	23%	66% (12 to 87)	7 (5 to 36)

 $\mbox{\dag} \mbox{Abbreviations}$ defined in Glossary; RRR, NNT, and CI calculated from data in article.

COMMENTARY

Schömig and colleagues have shown that the combination of primary stenting and abciximab is superior to t-PA as a reperfusion strategy in acute MI. Are the results sufficiently persuasive that one should recommend this as the preferred strategy for most patients? Not yet. First, the sample size for this trial (n = 140) is clearly small in this era of megatrials and was made on the basis of the primary outcome event—the salvage index. In comparison, the meta-analysis of direct angioplasty and thrombolysis included 2606 patients (1). Clinical outcomes were secondary, and surely the authors themselves must be surprised at the extent of clinical benefit. Second, it is not clear whether the clinical benefit is a result of the combination of stent and abciximab or of the poor results with t-PA; the mortality rate seems far higher than would be expected in this young, hemodynamically stable cohort.

This scenario—unprecedented clinical benefit in a small study designed to look at an intermediate or surrogate outcome—is familiar.

More often than not, a larger confirmatory trial subsequently shows the initial benefit is far smaller, if present at all. Therefore, cautious enthusiasm would seem to be the prudent approach until further studies are completed. Finally, even if the results are confirmed, the logistics and cost of primary stenting with or without novel adjuvant antithrombotic therapy may restrict its use to selected institutions or health care systems; for the others, intravenous thrombolytic therapy is cost-effective and widely applicable.

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Reference

 Weaver WD, Simes RJ, Betriu A, et al. Comparison of primary coronary angioplasty and intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review. JAMA. 1997;278:2093-8.

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