THERAPEUTICS

Prehospital fibrinolysis was as good as primary angioplasty after myocardial infarction

Bonnefoy E, Lapostolle F, Leizorovicz A, et al. **Primary angioplasty versus prehospital fibrinolysis in acute myocardial infarction: a randomised study.** Lancet. 2002;360:825-9.

QUESTION

In patients with myocardial infarction (MI), is primary angioplasty better than prehospital fibrinolysis and transfer for possible rescue angioplasty?

DESIGN

Randomized (allocation concealed*), blinded (outcome assessors),* controlled trial with 30-day follow-up (Comparison of Angioplasty and Prehospital Thrombolysis in Acute Myocardial Infarction [CAPTIM] study group).

SETTING

27 tertiary care hospitals in France and their mobile emergency care units.

PATIENTS

840 patients (median age 58 y, 82% men) with symptoms of MI for ≤ 6 hours. Exclusion criteria were known bleeding disorders or contraindication to fibrinolysis, severe renal or hepatic insufficiency, aortofemoral bypass or hampered femoral artery access, cardiogenic shock, history of coronary artery bypass graft surgery, current oral anticoagulant treatment, or expected duration of hospital transfer > 1 hour. Follow-up data were available for 837 patients (99.6%).

INTERVENTION

All patients received an intravenous (IV) bolus of heparin, 5000 U, and aspirin, 250 to 500 mg, orally or IV. Patients were allocated to primary angioplasty involving immediate transport to the hospital for coronary angiography and angioplasty if needed (n = 421), or to prehospital fibrinolysis with an IV bolus of alteplase, 15 mg, and alteplase infusion, 0.75 mg/kg of body weight for 30 minutes and 0.50 mg/kg for the next 60 minutes (n = 419).

MAIN OUTCOME MEASURES

Composite of death, nonfatal MI, and nonfatal disabling stroke at 30 days. Secondary outcomes were cardiovascular mortality, refractory recurrent ischemia, cardiogenic shock, severe bleeding, and emergency revascularization.

MAIN RESULTS

Analysis was by intention to treat. The groups did not differ for the composite endpoint (Table). Of the secondary outcomes, unplanned revascularization was required more frequently in the prehospital fibrinolysis group than in the primary angioplasty group (34.5% vs 4.7%, $P < 0.001$). The groups did not differ for any other outcomes. The study was powered to detect a 5% absolute risk reduction for the primary outcome but was terminated early when, regardless of sample size, it was predicted that no differences would be seen.

CONCLUSION

In patients with myocardial infarction, primary angioplasty was no better than prehospital fibrinolysis and transfer to hospital for possible angioplasty.

Sources of funding: French Ministry of Health and AstraZeneca. BIOTRONIK GmbH provided the balloons and guide wires.

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*See Glossary.

Primary angioplasty vs prehospital fibrinolysis for early myocardial infarction†

Outcomes at 30 d	Primary	Prehospital	RRR (95% CI)	NNT
Composite endpoint	6.2%	8.2%	24% (–24 to 53)	Not significant

†Composite endpoint = death, nonfatal MI, and nonfatal disabling stroke. Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.

COMMENTARY

CAPTIM is the first randomized trial comparing prehospital fibrinolysis with primary angioplasty for acute MI. Rescue angioplasty immediately after fibrinolysis was done at the discretion of local investigators, and 26% of patients in the fibrinolysis group had the procedure. In the Assessment of the Safety and Efficacy of a New Thrombolytic Regimen (ASSENT)-3 trial (1), only about 14% had this procedure; in the Thrombolysis in Myocardial Infarction (TIMI 4) trial (2), 23.6% had an occluded artery but only 14.4% had rescue angioplasty. Furthermore, 70.4% of CAPTIM fibrinolysis patients had percutaneous coronary intervention (PCI) within 30 days. 30-day outcomes for the CAPTIM groups were similar to each other and to a nonrandomized study by Juliard and colleagues (3). Even so, the fibrinolytic group had a tendency for more recurrent ischemia and a greater need for urgent PCI.

In the primary-angioplasty group of the CAPTIM trial, 9 patients with cardiogenic shock were included. It is not clear whether shock developed after randomization or if these patients were enrolled by mistake. Their exclusion could have improved results in the primary-angioplasty group. Furthermore, only 26.6% of patients having primary angioplasty received glycoprotein IIb/IIIa inhibitors. More liberal use of these agents might have improved results of this group further, as shown in the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) trial (4).

Although the results of the CAPTIM trial are important, a direct comparison of prehospital fibrinolysis and primary PCI with additional use of glycoprotein IIb/IIIa inhibitors is needed to settle the issue.

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