Is primary angioplasty more effective than prehospital fibrinolysis in diabetics with acute myocardial infarction? Data from the CAPTIM randomized clinical trial

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Aims The CAPTIM study randomized patients managed within 6 h of acute ST-segment elevation myocardial infarction to primary angioplasty or prehospital fibrinolysis (rt-PA), with immediate transfer to a centre with interventional facilities. It found a similar incidence of the primary endpoint of death, recurrent MI, or stroke at 30 days with both strategies. We report here the outcome in the diabetic subgroup.

Methods and results The relationship of diabetic status (diabetics, n = 103, non-diabetics, n = 731) and treatment strategy with the occurrence of the primary endpoint and of death was analysed. Compared with non-diabetics, diabetics had a higher baseline risk profile, a higher rate of the primary endpoint (14.6 vs. 5.6%; P = 0.002), and a high rate of mortality (8.7 vs. 3.1%; P = 0.01) at 30 days. The incidence of the primary endpoint tended to be higher in diabetics randomized to prehospital fibrinolysis compared with those randomized to primary angioplasty [21.7 vs. 8.8% (10/46 vs. 5/57); RR: 2.47 (0.91–6.74); P = 0.09]. This difference was driven by the higher mortality in the fibrinolysis group [13.0 vs. 5.3% (6/46 vs. 3/57); RR: 2.47 (0.7–9.4); P = 0.29]. For non-diabetics, no such trend was observed. Compared with non-diabetics, diabetics had a much higher rate of rescue angioplasty (41.4 vs. 23.5%; P = 0.01) and a higher mortality after rescue angioplasty [17.4 vs. 0% (4/23 vs. 0/90); P = 0.001].

Conclusion These results suggest that diabetic patients presenting within 6 h of an acute myocardial infarction may derive particular benefit from a strategy of primary angioplasty. However, the small number of diabetic patients in this subgroup analysis does not allow a final conclusion and a specifically designed study is warranted.

Introduction Patients with diabetes have considerably higher mortality and morbidity rates than non-diabetic patients. Although diabetic patients have more severe baseline characteristics than non-diabetics, most studies concur that diabetes mellitus independently predicts morbidity and mortality after acute myocardial infarction (AMI).¹ Fibrinolysis reduces the mortality of patients with an AMI, regardless of the presence of diabetes.² However, patients with diabetes still have an increased risk of heart failure and death after AMI.³ A significant reduction in cardiovascular mortality was demonstrated with prehospital administration of fibrinolysis in the European Myocardial Infarction Project (EMIP) study, probably reflecting the reduction in time to treatment by 1 h.⁴ Patients with diabetes tend to present later than non-diabetics⁵ and may, therefore, derive a particular benefit from prehospital fibrinolysis.

Primary angioplasty also appears attractive in this setting but its effect on diabetic patients remains controversial.⁶,⁷ In the GUSTO IIb study, compared with fibrinolysis, primary angioplasty in diabetics was associated with a reduced rate of re-infarction but a trend towards a higher mortality.⁷

KEYWORDS Diabetes; Acute myocardial infarction; Fibrinolysis; Primary angioplasty; Reperfusion

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The CAPTIM study was a multicentre trial that randomized patients with AMI to either prehospital thrombolytic therapy (alteplase) with transfer to an interventional facility or to primary angioplasty. This trial has shown that a strategy of primary angioplasty was not better than a strategy of prehospital fibrinolysis, with provisional rescue angioplasty, in patients presenting with AMI.8 The present analysis was planned to examine the impact of diabetic status on the relative benefits of the reperfusion strategies defined in the CAPTIM study.

Methods

Study patients

The CAPTIM study has been described in detail previously.8 Briefly, out-of-hospital patients were managed by mobile intensive care units (MICU) that included a physician and carried an ECG and resuscitation equipment, including a defibrillator. The patients were eligible for inclusion if they presented within 6 h after the onset of symptoms of myocardial infarction, i.e. characteristic pain lasting for at least 30 min, or pain lasting for <30 min but still present and not responsive to nitrates, and with electrocardiographic ST-segment elevation of at least 0.2 mV in two or more contiguous leads or left bundle-branch block. Patients were excluded if they were known to have haemorrhagic diathesis or any contraindication for aspirin, or if they were not responsive to nitrates, and with electrocardiographic ST-segment elevation of at least 0.2 mV in two or more contiguous leads or left bundle-branch block. Patients were excluded if they were known to have haemorrhagic diathesis or any contraindication to fibrinolysis, severe renal or hepatic insufficiency, aorto-femoral bypass or any condition that could hamper femoral artery access, cardiogenic shock, history of coronary artery bypass (CABG), or were receiving oral anticoagulant treatment. They could also be excluded if the duration of transfer to the hospital was expected to exceed 1 h.

Randomization and treatment strategies

Eligible patients were randomly assigned at the site of initial management (usually at home or at their workplace) to the prehospital rt-PA or primary angioplasty treatment group. The MICU teams were in permanent radio contact with the MICU medical dispatcher who was in constant communication with the MICU medical dispatcher, including a defibrillator. The patients were eligible for inclusion if they presented within 6 h after the onset of symptoms of myocardial infarction, i.e. characteristic pain lasting for at least 30 min, or pain lasting for <30 min but still present and not responsive to nitrates, and with electrocardiographic ST-segment elevation of at least 0.2 mV in two or more contiguous leads or left bundle-branch block. Patients were excluded if they were known to have haemorrhagic diathesis or any contraindication to fibrinolysis, severe renal or hepatic insufficiency, aorto-femoral bypass or any condition that could hamper femoral artery access, cardiogenic shock, history of coronary artery bypass (CABG), or were receiving oral anticoagulant treatment. They could also be excluded if the duration of transfer to the hospital was expected to exceed 1 h.

Primary angioplasty patients received a 5000 U intravenous (IV) heparin bolus, 250–500 mg aspirin (orally or IV), and an IV bolus of 15 mg alteplase (rt-PA). This was followed by a rt-PA infusion of 0.75 mg/kg of body weight (not to exceed 50 mg) over a 30 min period and then 0.50 mg/kg (not to exceed 35 mg) over the next 60 min, up to a maximal total dose of 100 mg. Treatment was started by the emergency physician at the site of the intervention. All patients were then transported to the hospital. The decision to perform angiography in the hospital was left to the judgment of the investigator.

Primary angioplasty patients received a 5000 U IV bolus of heparin and 250–500 mg of aspirin (orally or IV) and were transported immediately to the hospital for coronary angiography and, if indicated, angioplasty. Angioplasty was performed according to local standards with the intention of re-establishing blood flow in the infarct-related artery as soon as possible. The infarct-related artery was the only target, except in patients whose haemodynamic parameters deteriorated despite restoration of the patency of that artery. The study protocol advised that in patients with stenoses of the left main stem or critical three-vessel disease, CABG should be strongly considered in place of angioplasty. In patients whose infarct-related arteries had thrombolysis in myocardial infarction (TIMI) grade 3 flow upon first angiography, the decision to perform angioplasty was left to the judgment of the operator.

Endpoints

The primary endpoint of the trial was a composite of death, non-fatal re-infarction, and non-fatal disabling stroke within 30 days. Secondary endpoints, which were evaluated at 30 days post-treatment included cardiovascular mortality, refractory recurrent ischaemia, cardiogenic shock, severe bleeding, and emergent revascularization (angioplasty or CABG). Severe bleeding was defined as intracranial haemorrhage or bleeding that caused haemodynamic compromise and/or required blood transfusion. Urgent revascularization was defined as revascularization required either by ongoing ischaemia following fibrinolysis (rescue angioplasty) or by refractory recurrent ischaemia.

Statistical analysis

This subgroup analysis was an a priori defined analysis that was considered of special interest to the Steering Committee. Continuous data are presented as medians with interquartile ranges unless otherwise stated. Selected baseline characteristics and clinical endpoints were compared between treatment groups using the χ² test or Fisher’s exact test for discrete variables, and the Wilcoxon rank sum test for continuous variables. Relative risks and 95% confidence intervals (CI) were used to compare treatments with regard to major clinical endpoints. Survival analysis (log-rank test) was used to compare survival time to primary endpoints between treatment groups. The relatively small number of diabetic patients dissuaded an attempt to adjust for baseline variables and no multivariate analysis was performed. All tests of significance were two-tailed. P-value <0.05 was considered statistically significant and statistical analysis was performed on the basis of intention-to-treat.

Results

Of the 840 patients enrolled in CAPTIM, 103 (12.3%) were diabetic (of whom 46 were randomized to prehospital fibrinolysis and 57 to primary percutaneous coronary intervention (PCI)) and 731 were non-diabetic (370 randomized to prehospital fibrinolysis and 361 to primary PCI). The status of six patients was unknown with regard to diabetes. Compared with non-diabetics, diabetic patients were older, were more often women, had a greater frequency of hypertension, of prior myocardial infarction, and a higher baseline systolic blood pressure (Table 1). Current smoking was more common among non-diabetics. The time from symptom onset to initial management and treatment (primary PCI or fibrinolysis) was similar in patients with and without diabetes. The same proportion of diabetics and non-diabetics were also managed within 2 h of symptoms onset. The use of cardiac medications after randomization was similar in both groups (Table 2). Diabetes more frequently underwent urgent angioplasty than non-diabetes (31.0 vs. 16.9%; P = 0.01). More specifically, emergency rescue angioplasty for failed fibrinolysis was almost twice as frequent in diabetics than in non-diabetics (41.4 vs. 23.5%; P = 0.01).

The frequency of the composite 30 day endpoint of death, non-fatal re-infarction, or non-fatal disabling stroke was higher for diabetics than for non-diabetics (Table 3) [14.6

## Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Diabetic</th>
<th>Non-diabetic</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>70±10</td>
<td>65±10</td>
<td>0.01</td>
</tr>
<tr>
<td>Sex, male</td>
<td>60%</td>
<td>55%</td>
<td>0.23</td>
</tr>
<tr>
<td>Hypertension</td>
<td>80%</td>
<td>65%</td>
<td>0.01</td>
</tr>
<tr>
<td>Prior MI</td>
<td>40%</td>
<td>30%</td>
<td>0.01</td>
</tr>
<tr>
<td>Smoking</td>
<td>35%</td>
<td>20%</td>
<td>0.01</td>
</tr>
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</table>

## Table 2

<table>
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<th>Medications</th>
<th>Diabetic</th>
<th>Non-diabetic</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>β-blockers</td>
<td>40%</td>
<td>30%</td>
<td>0.01</td>
</tr>
<tr>
<td>Statins</td>
<td>60%</td>
<td>50%</td>
<td>0.01</td>
</tr>
<tr>
<td>Diabetes</td>
<td>20%</td>
<td>5%</td>
<td>0.01</td>
</tr>
</tbody>
</table>

## Table 3

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Diabetic</th>
<th>Non-diabetic</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>5%</td>
<td>3%</td>
<td>0.01</td>
</tr>
<tr>
<td>Re-infarction</td>
<td>10%</td>
<td>5%</td>
<td>0.01</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>5%</td>
<td>2%</td>
<td>0.01</td>
</tr>
<tr>
<td>Non-fatal re-infarction</td>
<td>15%</td>
<td>10%</td>
<td>0.01</td>
</tr>
<tr>
<td>Non-fatal disabling stroke</td>
<td>10%</td>
<td>5%</td>
<td>0.01</td>
</tr>
</tbody>
</table>
vs. 5.6% (15/103 vs. 41/729); RR: 2.59 (1.5–4.5); \( P = 0.002 \). Death [8.7 vs. 3.1% (9/103 vs. 23/731); \( P = 0.01 \)] and reinfarction rate [6.3 vs. 2.3% (6/95 vs. 16/707); \( P = 0.04 \)] were also more frequent in diabetics. Most of the deaths were of cardiovascular origin in both diabetics and non-diabetics. Mortality after rescue angioplasty also tended to be higher in diabetics vs. non-diabetics [17.4 vs. 0% (4/23 vs. 0/90); \( P = 0.0014 \)]. Cardiogenic shocks were more frequent among diabetics [8.2 vs. 2.9% (8/98 vs. 21/716); \( P = 0.02 \)]. Of them, the proportion of early cardiogenic shocks (those occurring between randomization and hospital admission) was lower in diabetics [12.5 vs. 30.3% (1/8 vs. 7/21)]. In diabetics, the incidence of the primary endpoint at 30 days tended to be higher in patients randomized to prehospital fibrinolysis compared with those randomized to primary PCI [21.7 vs. 8.8% [10/46 vs. 5/57]; RR: 2.47 [0.91–6.74]; \( P = 0.09 \) (Figure 1). Much of this difference was driven by the higher mortality in the fibrinolysis group [13.0 vs. 5.3% (6/46 vs. 3/57); RR: 2.47 (0.7–9.4); \( P = 0.29 \)]. The re-infarction rates were similar in both treatment groups [7.5 vs. 5.5% (3/40 vs. 3/55); \( P = 0.69 \)]. For non-diabetics, there was no such trend for the primary endpoint [6.2 vs. 5.0% (23/369 vs. 18/360) for prehospital fibrinolysis and primary PCI, respectively; RR: 1.25 (0.68–2.27); \( P = 0.52 \)]. Mortality tended to be higher in the primary PCI group [2.4 vs. 3.9% (9/370 vs. 14/361); RR: 0.62 (0.27–1.43); \( P = 0.29 \)] and the re-infarction rate lower [3.3 vs. 1.2% (12/361 vs. 4/346); \( P = 0.07 \)]. This trend toward a higher incidence of the primary endpoint and 30 day mortality in diabetics treated with the fibrinolysis strategy is apparent within the first days after admission (Figures 2 and 3). In diabetic patients randomized within
2 h of onset of symptoms, mortality was 7.6% (4 out of 52 with 2 deaths in the angioplasty and fibrinolysis groups). Mortality in diabetics treated after 2 h was 9.8% (5 out of 51 with 4 deaths in the fibrinolysis group and 1 in the angioplasty group). Mortality in non-diabetics managed within 2 h was 3.0% (12 out of 405; 2 in the fibrinolysis group and 10 in the angioplasty group).

Diabetic patients undergoing angioplasty had a greater incidence of bleeding complications compared with those receiving fibrinolysis [5.6 vs. 0% (3/54 vs. 0/40); P = 0.26] (Table 4). Reperfusion by angioplasty was associated with a reduction in the occurrence of recurrent ischaemia in non-diabetics [7.2 vs. 3.5% (26/360 vs. 12/346); P = 0.03] but not in diabetics [7.5 vs. 7.4% (3/40 vs. 4/54); P = 1.00]. In diabetics, cardiogenic shocks were observed evenly in both treatment groups. On the contrary, cardiogenic shocks in non-diabetics were mainly observed in the primary PCI group [3.9 vs. 1.9% (14/355 vs. 7/361); P = 0.12]. Early cardiogenic shocks (occurring from randomization to hospital admission; 7/716) were all observed in the primary PCI group (P = 0.007).

**Table 3** Impact of diabetic status on primary and secondary outcomes (independently of randomized treatment assignment)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Diabetic patients n (%)</th>
<th>Non-diabetic patients n (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary endpoint</td>
<td>15 (14.6)</td>
<td>41 (5.6)</td>
<td>0.002</td>
</tr>
<tr>
<td>Death</td>
<td>9 (8.7)</td>
<td>23 (3.1)</td>
<td>0.011</td>
</tr>
<tr>
<td>Re-infarction</td>
<td>6 (6.3)</td>
<td>16 (2.3)</td>
<td>0.036</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>1 (1.1)</td>
<td>3 (0.4)</td>
<td>0.394</td>
</tr>
<tr>
<td>Death and recurrent</td>
<td>20 (19.4)</td>
<td>74 (10.2)</td>
<td>0.012</td>
</tr>
<tr>
<td>Ischaemia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular death</td>
<td>9 (8.7)</td>
<td>21 (2.9)</td>
<td>0.007</td>
</tr>
<tr>
<td>Recurrent ischaemia</td>
<td>7 (7.4)</td>
<td>38 (5.4)</td>
<td>0.471</td>
</tr>
<tr>
<td>Severe haemorrhage</td>
<td>3 (3.2)</td>
<td>7 (1.0)</td>
<td>0.102</td>
</tr>
<tr>
<td>Haemorrhagic stroke</td>
<td>0 (0.0)</td>
<td>2 (0.3)</td>
<td>1.000</td>
</tr>
<tr>
<td>Ischaemic stroke</td>
<td>1 (1.1)</td>
<td>1 (0.1)</td>
<td>0.221</td>
</tr>
<tr>
<td>Cardiogenic shock (from randomization to hospital discharge)</td>
<td>8 (8.2)</td>
<td>21 (2.9)</td>
<td>0.017</td>
</tr>
<tr>
<td>Cardiogenic shock (from randomization to hospital admission)</td>
<td>1 (1.0)</td>
<td>7 (1.0)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

**Discussion**

Diabetics had a higher incidence of morbid events than non-diabetics. Outcome at 30 days appears better among diabetics randomized to primary angioplasty compared with those randomized to prehospital fibrinolysis even with systematic transfer to a centre with an on-site catheterization facility and a high rate of rescue angioplasty.

Overall, in diabetics, outcomes were similar to those observed in other studies with a higher risk profile at baseline and a higher mortality and incidence of re-infarction and stroke. In contrast to several previous studies, in CAPTIM, diabetic patients do not present later than non-diabetics: the time to randomization and time to treatment

![Figure 1](https://academic.oup.com/eurheartj/article-abstract/26/17/1712/428538/fig1)

**Figure 1** Impact of diabetic status on the primary outcome and its components according to randomized treatment assignment.

![Figure 2](https://academic.oup.com/eurheartj/article-abstract/26/17/1712/428538/fig2)

**Figure 2** Survival without the primary endpoint according to randomized treatment assignment and diabetic status.
CAPTIM concluded that a strategy of primary angioplasty was not better than a strategy of prehospital fibrinolysis. In the diabetics, mortality was much higher with the invasive strategy (3.8 vs. 3.4%). For the diabetics, both conservative strategy (angiography and angioplasty for recurrent or provoked ischaemia only). For the non-diabetics, both strategies gave similar mortality (3.8 vs. 3.4%). For the non-diabetics, both strategies gave similar mortality (3.8 vs. 3.6). This may indicate a lower efficacy of fibrinolysis in diabetics limiting the beneficial effect of earlier administration of the fibrinolytic treatment. It is known that patients with diabetes have enhanced platelet activity, elevated procoagulant levels, and impaired intrinsic fibrinolysis. Some studies demonstrated a low patency rate in diabetic patients with diabetes after fibrinolysis. However, this point remains controversial and both the TIMI study group and the GUSTO angiographic subtrial have found similar recanalization rates after fibrinolysis in diabetic and non-diabetic patients. Such controversy does not exist for diabetic patients treated with primary PCI whose patency rates have consistently been found identical to non-diabetics.

The trend toward a better outcome with primary PCI in diabetics is apparently at odds with those conclusions. Owing to the small number of patients, it may have occurred by chance. However, some observations from this substudy suggest other hypotheses.

CAPTIM did not compare primary PCI with fibrinolysis per se but with a strategy of fibrinolysis with rescue angioplasty if needed. Angioplasty for failed fibrinolysis was needed in >40% of the diabetic patients, twice as often as in non-diabetics. This may indicate a lower efficacy of fibrinolysis in diabetics limiting the beneficial effect of earlier administration of the fibrinolytic treatment. It is known that patients with diabetes have enhanced platelet activity, elevated procoagulant levels, and impaired intrinsic fibrinolysis. Some studies demonstrated a low patency rate in diabetic patients after fibrinolysis.

CAPTIM did not compare primary PCI with fibrinolysis per se but with a strategy of fibrinolysis with rescue angioplasty if needed. Angioplasty for failed fibrinolysis was needed in >40% of the diabetic patients, twice as often as in non-diabetics. This may indicate a lower efficacy of fibrinolysis in diabetics limiting the beneficial effect of earlier administration of the fibrinolytic treatment. It is known that patients with diabetes have enhanced platelet activity, elevated procoagulant levels, and impaired intrinsic fibrinolysis. Some studies demonstrated a low patency rate in diabetic patients after fibrinolysis.

The benefit of rescue angioplasty may also differ between diabetics and non-diabetics. Among patients who underwent rescue angioplasty in CAPTIM, mortality in diabetics was much higher than in non-diabetics. In the GUSTO angiographic sub-study, rescue angioplasty was performed in 15% of diabetics and 8.6% of non-diabetics. It tended to be less successful and was associated with a higher mortality in diabetics. In the TIMI II trial, all patients were thrombolysed with rt-PA and randomized to an invasive strategy (coronary angiography and angioplasty within 18–48 h of randomization) and a conservative strategy (angiography and angioplasty for recurrent or provoked ischaemia only). For the non-diabetics, both strategies gave similar mortality (3.8 vs. 3.4%). For the diabetes, mortality was much higher with the intensive strategy (14.8 vs. 4.2%; P < 0.001).

Furthermore, glycoprotein IIb/IIIa (GPIIbIIIa) inhibition in patients with AMI improves the success rate of the stenting procedure, the rate of coronary patency, and left ventricular function. It has been proved to be particularly beneficial in diabetic patients. Post hoc analysis of the
EPILOG and EPISTENT studies has shown an improved outcome when abciximab was associated with PTCA in patients with diabetes.\textsuperscript{19,20} GPIb/IIa inhibition is not used in rescue angioplasty but commonly used during primary angioplasty. This may have contributed to the benefit of primary angioplasty in diabetics.

Limitations
As for any subgroup analysis, caution is required in interpreting the present data. Patients in the trial were randomized neither according to diabetic status nor to a decision for rescue/no rescue when failed fibrinolysis was suspected. Only pharmacologically treated diabetic patients were included in the diabetic group. The sample size was small and no adjustment for baseline variable was performed. The strong trend towards a benefit of primary PCI in diabetics is not significant and may be related to chance. Moreover, the follow-up period for this study is short (1 month), and in diabetics, events continue to occur with a sustained rate during the first year after an AMI.

Owing to these limitations, no clear recommendations can be made to help the choice of the best reperfusion strategy in diabetics with AMI. Subgroup analyses of the CAPTIM study suggest that when weighting a reperfusion strategy in patients with AMI, different categories of patients should be considered. Our group has recently shown that prehospital fibrinolysis with rescue angioplasty, if needed, appears to bring a particular benefit for patients managed within 2 h of symptoms\textsuperscript{21} whereas those managed later could have a better outcome with primary PCI. Similarly, primary PCI may be preferable to a prehospital fibrinolysis strategy in diabetic patients with AMI. To have a more definitive answer concerning the relationship of diabetes and reperfusion strategies, a specifically designed study is needed.

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References


