A prospective, observational, multicentre study comparing tenecteplase facilitated PCI versus primary PCI in Indian patients with STEMI (STEPP—AMI)

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ABSTRACT

Objective: To compare the efficacy of pharmacoinvasive strategy versus primary percutaneous coronary intervention (PCI) in patients with ST-segment elevation myocardial infarction (STEMI). Primary PCI is the preferred treatment for STEMI, but it is not a feasible option for many. A pharmacoinvasive strategy might be a practical solution in the Indian context, although few empirical data exist to guide this approach.

Methods: This is a prospective, observational, multicentre pilot study. Two hundred consecutive patients with STEMI aged 18–75 years, presenting within 12 h of onset of symptoms and requiring a reperfusion strategy, were studied from five primary PCI capable centres in South India. Patients who opted for pharmacoinvasive strategy (n=45) formed group A. Group B consisted of patients treated with primary PCI (n=155). One patient was lost to follow-up at 1 year. The primary end point was a composite of death, cardiogenic shock, reinfarction, repeat revascularisation of a culprit artery and congestive heart failure at 30 days.

Results: The primary end point occurred in 11.1% in group A and in 3.9% in group B, p=0.07 (RR=2.87; 95% CI 0.92 to 8.97). The infarct-related artery patency at angiogram was 82.2% in group A and 22.6% in group B (p<0.001). PCI was performed in 73.3% in group A versus 100% in group B (p<0.001), and a thrombus was present in 26.7% in group A versus 63.2% in group B (p<0.001). Failed fibrinolysis occurred in 12.1% in group A. There was no difference in bleeding risk, 2.2% in group A versus 0.6% in group B, (p=0.4).

Conclusions: This pilot study shows that a pharmacoinvasive strategy can be implemented in patients not selected for primary PCI in India and hints at the possibility of similar outcomes. Larger studies are required to confirm these findings.

Trial registration number: Trial is registered with Clinical trial registry of India, CTRI number: REF/2011/07/002556.

INTRODUCTION

Timely reperfusion is the most effective treatment for the ST-segment elevation myocardial infarction (STEMI).1 It has been shown in randomised trials to limit the amount of myocardial damage, which in turn results in better left ventricular function and low mortality.2 Reperfusion can be achieved through either pharmacological or mechanical means. The non-fibrin-specific thrombolytic agent streptokinase was less effective in opening the infarct-related artery (IRA), but the introduction of fibrin-specific lytic agents—like tenecteplase (TNK) has improved the patency rates substantially.3 Although they are widely available, reocclusion of the IRA continues to be a major problem. In contrast, primary percutaneous coronary...
intervention (PCI) achieves immediate and sustained patency of the IRA and has been consistently shown to be superior to the thrombolytic treatment. However, unavailability and transport delays have restricted primary PCI to only a small proportion of eligible patients. Initial timely fibrinolysis to open the IRA followed by early PCI—that is, a pharmacoinvasive strategy—to improve the patency rates is an attractive approach, particularly in developing countries like India where catheterisation facilities are limited to major cities. Randomised studies have shown the feasibility and safety of this approach in STEMI in comparison with primary PCI. The current study is a non-randomised study largely designed to assess the safety and feasibility of a pharmacoinvasive strategy in comparison to primary PCI.

MATERIALS AND METHODS

Aim
To compare the efficacy of prompt fibrinolysis coupled with contemporary antiplatelet and antithrombotic therapy at first medical contact followed by timely catheterisation in patients with STEMI within 12 h of symptom onset (ie, a pharmacoinvasive strategy) in comparison with standard primary PCI.

Study design
This is a prospective, observational, multicentre pilot study which was conducted from August 2011 to May 2013. We carried out this study as there is a strong rationale for assessing feasibility through piloting the pharmacoinvasive strategy in Indian patients presenting with STEMI, as there is little that is known about the same. The study sites are situated in South India; three sites are from the state of Tamil Nadu, one from the state of Karnataka and one from the state of Kerala. All study sites were well equipped with 24/7 facility of performing primary PCI with the aid of expert interventional cardiologists. A total of 200 patients diagnosed to have STEMI were enrolled into the study based on the inclusion/exclusion criteria. No randomisation for this study was performed due to ethical reasons, as most Indian patients with STEMI have longer presentation times compared with patients from developed countries. Although all participating hospitals are primary PCI capable hospitals, some patients opted for a pharmacoinvasive approach. The main reason for this is lack of ready finances. Comprehensive insurance coverage for all comers with STEMI was not available at all participating centres during the period of the study as STEMI care was not linked to insurance. Applying for insurance or arranging for out of pocket expenses needed time; hence, patients opted for a thrombolysis initially, and then went ahead with catheterisation and PCI once the insurance approval came or money could be arranged. This was the reason in the majority of patients who went through the pharmacoinvasive strategy. In a minority of patients, the catheterisation laboratory was not available at the time of the patient’s arrival. (Out of 45 patients in group A, only one patient underwent the pharmacoinvasive approach because the catheterisation laboratory was occupied.) Failed thrombolysis is defined as persisting or worsening chest pain or <50% resolution of ST-segment elevation after 90 min of thrombolysis in a single lead showing maximum ST-segment elevation at presentation. Written informed consent was signed by all patients.

The inclusion criteria were the following: adults aged 18–75 years with STEMI requiring either primary PCI or fibrinolysis with TNK, patients presenting with the onset of symptoms within 12 h, subjects/legally acceptable representative or impartial witness (if applicable) must be able to understand and provide their consent in the informed consent form. If a patient with STEMI has unstable haemodynamics or is not willing to read and sign the informed consent during initial presentation, then a legally acceptable representative, that is, a family member, could initially sign the informed consent. As we still have illiterate patients and family members in India, we often use a person who is not related to the study to read out the informed consent to the patient and the family members and then obtain a thumb print from them. The person who reads the consent is often called the ‘impartial witness’ and needs to sign the informed consent form as well. Patients who were participating in any other study or who were unwilling to comply with the protocol were excluded.

End points
The primary end point was a composite of death, cardio- genic shock, reinfarction, repeat revascularisation of the culprit artery and congestive heart failure at 30 days. The safety end points are bleeding end points assessed using the thrombolysis in myocardial infarction (TIMI) classification at 30 days.

Definitions used in the study are given in the online supplementary appendix.

Study protocol
Data were collected by personnel who were blinded to the study objectives and recorded the same in specially designed electronic case report form (eCRF). Each patient was given a screening number to maintain anonymity. Demographic details and baseline characteristics of the patient population were documented meticulously. Relevant medical history, salient clinical examination findings, laboratory investigations including cardiac biomarkers, ECG and echocardiogram findings were noted. Details of medication prescribed were also collected. Patients who were fibrinolysed with TNK were in group A and patients who underwent primary PCI formed group B. Figure 1 depicts the study flow. In group A, the timing and dosage of TNK was documented, and TNK was administered as per the recommended dosage based on the body weight of the patient, 30 mg if the weight is <60 kg, 35 mg if the weight is 60–70 kg, 40 mg if the weight is 70–80 kg, 45 mg if the
weight is 80–90 kg and 50 mg if the weight is >90 kg. In case of failed thrombolysis, rescue PCI was performed at the investigator’s discretion. The time to a coronary angiogram (CAG) with or without intervention, time from symptom onset to hospital presentation, door-to-balloon time, door-to-needle time and total ischaemic time were documented. During the procedure, the access site, whether or not thrombosuction was performed, the number of vessels diseased, the number of vessels stented, the type of stent used, the reasons for not performing angioplasty if the procedure was not conducted, the procedure complications if any, the adjutant medication, the use of intra-aortic balloon pulsation and the outcome of the procedure were noted. The IRA patency, TIMI flow in IRA preprocedure and postprocedure, thrombus burden and procedure success were evaluated by a blinded investigator. Bleeding events were classified using TIMI bleeding criteria.

At discharge, patients’ clinical status and prescription details were also noted. Follow-up was done at the clinic at 30 days, and telephonically at 3, 6 and 12 months. During follow-up angina status, functional status and details about any reportable events were collected.

Statistical analysis
A sample size of 200 patients was enrolled as this was a pilot study primarily designed to assess feasibility. Data from all five study sites were combined for analysis. All statistical analyses were performed using SAS software, V9.2. Continuous data were presented as n (observation count), mean, SD, minimum, median and maximum. Categorical data and the number and percentage of participants in each category were reported. We used frequency and cross tabulation to explore differences across different factors. Continuous variables were tested using the Student t test and the categorical variables were tested using the \( \chi^2 \)/Fischer’s test for the relation between each individual factor and treatment group at 5% level of significance. The total ischaemic time between the two groups was compared using the median test at 5% level of significance. Relative risk estimates were calculated along with 95% CIs and provided in the appropriate tables along with adjustments for important covariates. The Kaplan-Meier curves with log rank test were used to compare differences in outcomes as well. A p value of 0.05 was considered significant for all statistical evaluations.

RESULTS
A total of 200 patients were enrolled into this pilot study. Group A (n=45) comprised patients who were treated with the pharmacoinvasive strategy, and group B (n=155) included patients who underwent primary PCI. At the end of 1 year, one patient was lost to follow-up in group A (0.5%). There is no difference between the baseline characteristics of two groups, except that more patients in group B were in Killip’s class 1 (table 1).

Diabetes mellitus is the most prevalent risk factor at 53.3% (group A) and 50.3% (group B). Only 13.5% of the total patients were female.

In group B, 100% patients underwent PCI with stenting (table 2). In group A, 95.5% (n=43) of patients underwent coronary angiography. 82.2% (n=57) had open IRA, 12.1% (n=4) of patients had failed fibrinolysis and had to undergo urgent catheterisation. PCI was performed in 73.3% (n=37) of patients, as 2 (4.4%) patients died before the catheterisation could be performed, 2 (4.4%) patients who were in cardiogenic shock died during the procedure and 6.7% (n=3) of patients had insignificant disease; hence, no intervention was performed; 4.4% (n=2) were not willing for an intervention and 6.7% (n=3) had diffuse triple vessel disease.
Table 1 Baseline characteristic between the two groups

| Variable                  | A (n=45) | B (n=155) | p Value |
|---------------------------|----------|-----------|---------|
| Age, in years             |          |           |         |
| Median                    | 54       | 54        | 0.74    |
| IQR                       | 46–62    | 47–61     |         |
| Weight, kg                |          |           |         |
| Median                    | 65       | 65        | 0.88    |
| IQR                       | 60–71.5  | 60–70     |         |
| Killip class, n (%)       |          |           | 0.002   |
| 1                         | 20 (44.4)| 110/155 (71)|
| 2                         | 19 (42.2)| 34 (21.9) |
| 3                         | 5 (11.1) | 11 (7.1)  |
| 4                         | 1 (2.2)  | 0         |
| Male, n (%)               | 39 (86.7)| 134 (86.5)| 0.97    |
| Female, n (%)             | 6 (13.3) | 21 (13.5) |         |
| Dyslipidemia, n (%)       | 5 (11.1) | 7 (4.5)   | 0.14    |
| Hypertension, n (%)       | 14 (31.1)| 47 (30.3) | 0.91    |
| Diabetes, n (%)           | 24 (53.3)| 78 (50.3) | 0.72    |
| Smoking history, n (%)    | 12 (26.7)| 35 (22.6) | 0.56    |
| Family history, n (%)     | 3 (6.7)  | 19 (12.3) | 0.29    |
| CVA/TIA, n (%)            | 0        | 0         | NA      |
| CKD, n (%)                | 2 (4.4)  | 5 (3.2)   | 0.69    |

CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischaemic attack; NA, not applicable.

Table 2 Procedural characteristics of the two groups

| Intervention                  | A (n=45) | B (n=155) | p Value |
|-------------------------------|----------|-----------|---------|
| Number of vessel diseases, n (%) |          |           | 0.007   |
| Single vessel disease, n (%)  | 30 (66.7)| 113 (73.3)|         |
| Double vessel disease, n (%)  | 5 (11.1)| 11 (7.1)  |         |
| Triple vessel disease, n (%)  | 7 (15.5)| 31 (20.1) |         |
| Insignificant disease, n (%)  | 3 (6.7) | 0         |         |
| Culprit lesion, n (%)         |          |           | 0.10    |
| LAD                           | 25 (55.5)| 91 (58.7) |         |
| LCX                           | 2 (4.4)  | 13 (8.4)  |         |
| RAMUS                         | 1 (2.2)  | 1 (0.6)   |         |
| RCA                           | 15 (33.3)| 50 (32.2) |         |
| IRA patency, n (%)            |          |           | <0.0001 |
| Closed                        | 6 (13.3)| 120 (77.4)|         |
| Open                          | 37 (82.2)| 35 (22.6)|         |
| Thrombus present, n (%)       | 12 (26.7)| 98 (63.2)| <0.0001 |
| PCI performed, n (%)          | 33 (73.3)| 155 (100)| <0.0001 |
| Failed thrombolysis, n (%)    | 4 (12.1)| NA        |         |
| Type of stent, n (%)          |          |           | 0.85    |
| BMS                           | 14 (42.3)| 62 (40)   |         |
| DES                           | 19 (57.6)| 93 (60)   |         |
| Preprocedure TIMI flow, n (%) |          |           | <0.0001 |
| 0                             | 5 (11.6)| 112 (72.3)|         |
| 1                             | 1 (2.3) | 11 (7.1)  |         |
| 2                             | 25 (58.1)| 25 (16.1)|         |
| 3                             | 12 (27.9)| 7 (4.5)   |         |
| NA                            | 2 (4.4) | 0         |         |
| Postprocedure TIMI flow, n (%)|          |           | 0.35    |
| 1                             | 0       | 1 (0.6)   |         |
| 2                             | 14 (42.4)| 108 (69.7)|         |
| 3                             | 19 (57.6)| 46 (29.7)|         |
| Access site, n (%)            |          |           | <0.0001 |
| Femoral                       | 10 (23.3)| 90 (58.1)|         |
| Radial                        | 33 (76.7)| 65 (41.9)|         |

BMS, bare metal stent; DES, drug eluting stent; IRA, infarct-related artery; LAD, left anterior descending artery; LCX, left circumflex artery; NA, not applicable; PCI, percutaneous coronary intervention; RAMUS, ramus intermedius; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction.
other procedural details are given in table 2. Patients in group A also had better TIMI flow at CAG (TIMI 3 flow in 27.9%) and had more IRA patency (82.2%) and less thrombus burden.

The total ischaemic time, door-to-balloon time and the door-to-needle time are given in table 3. The use of medications is given in table 4. The efficacy end points are enlisted at 30 days, 3 months, 6 months and 1 year (tables 5 and 6). The safety end points are given in table 7: there is 2.2% (n=1) bleeding in group A from the access site and there is 0.6% (n=1) bleeding in group B. The cumulative event rates for the primary end point are shown in figure 2.

**DISCUSSION**

Primary PCI is the preferred method of revascularisation in STEMI management where feasible. However, its population-wide availability is limited due to various factors, especially in a developing country like India. A pharmacoinvasive strategy has been studied as a valuable alternative to primary PCI for STEMI and can be utilised to prevent time lag in availing appropriate reperfusion.

In this study, 200 patients with STEMI who underwent either primary PCI or a pharmacoinvasive strategy within 12 h of symptom onset were followed up until 1 year. The primary end point, which is a composite of death, cardiogenic shock, reinfarction, repeat revascularisation of the culprit artery and congestive heart failure, was no different between both groups at 30 days, 3 months, 6 months and 1 year, although there is a trend towards benefit from primary PCI during the early phase of follow-up, in spite of the fact that relatively affluent patients underwent primary PCI; hence, this group is expected to have better long-term outcomes due to lifestyle changes and better adherence to medication. The lack of statistical significance between both groups may be due to the limited sample size. Similar findings were reported in the STREAM study, which randomised patients with STEMI presenting within 3 h of symptom onset, who could not undergo primary PCI within 1 h of presentation, into primary PCI and pharmacoinvasive groups. The primary end point, a composite of any death, shock, reinfarction or congestive heart failure, was similar between both groups at 30 days. Previous clinical trials comparing the efficacy of both the reperfusion modalities in STEMI have shown a time dependent benefit of thrombolysis up to 3 h. In the STREAM trial, the total ischaemic time in the pharmacoinvasive arm was 100 min. In our study, the end points were comparable, despite a total ischaemic time of 245 min in the fibrinolytic subset. However, we need larger randomised controlled trials (RCTs) to confirm this benefit. Other efficacy end points like death and death or reinfarction were also similar in both groups.

A significant number of patients in group A did not require a stent implantation due to insignificant disease (6.7%). In a recent study, which was not an RCT, Kelbæk et al demonstrated that deferred stent implantation in STEMI is a feasible option. Thirty-eight percent of patients in that study had <30% residual stenosis. More interestingly, patients in group A also had better IRA patency rates and a lower thrombus burden at
catheterisation when compared with studies of fibrinolytic therapy in other healthcare systems and countries. This may relate to differences in patients with STEMI in India; however, these findings merit further evaluation.

The occurrence of failed thrombolysis requiring urgent CAG was 12.1% in this study, much lesser than that reported in the STREAM trial (36.3%). Interestingly, the mortality rate in the pharmacoinvasive group was at a standstill after the first 3 months (6.7% at 30 days, and 8.9% at 3 months, 6 months and 1 year), while in the primary PCI group patients it continued to increase (1.3% at 30 days, 2.6% at 3 months, 3.2% at 6 months and 4.5% at 1 year). This may be due the fact that 6.7% of patients in the facilitated group did not require a stent as they had insignificant disease on the angiogram; although only one patient from this group was lost to follow-up.

| Table 5  | Efficacy end points |
|----------|---------------------|
|          | A (n=45) n (%)      | B (n=155) n (%) | p Value | Relative risk |
| Death, reinfarction, repeat revascularisation of the culprit artery, cardiogenic shock, CHF | | | | |
| At 30 days | 5 (11.1) | 6 (3.9) | 0.07 | 2.87 | 0.92 to 8.97 |
| At 3 months | 6 (13.3) | 9 (5.8) | 0.10 | 2.30 | 0.86 to 6.11 |
| At 6 months | 6 (13.3) | 11 (7.1) | 0.19 | 1.88 | 0.74 to 4.80 |
| At 1 year | 6 (13.3) | 14 (9.0) | 0.40 | 1.48 | 0.60 to 3.62 |
| Efficacy end point—death | | | | |
| At 30 days | 3 (6.7) | 2 (1.3) | 0.07 | 5.17 | 0.89 to 29.98 |
| At 3 months | 4 (8.9) | 4 (2.6) | 0.07 | 3.44 | 0.90 to 13.23 |
| At 6 months | 4 (8.9) | 5 (3.2) | 0.12 | 2.76 | 0.77 to 9.83 |
| At 1 year | 4 (8.9) | 7 (4.5) | 0.26 | 1.97 | 0.60 to 6.42 |
| Efficacy end point—death/reinfarction | | | | |
| At 30 days | 3 (6.7) | 5 (3.2) | 0.31 | 2.07 | 0.51 to 8.32 |
| At 3 months | 4 (8.9) | 7 (4.5) | 0.26 | 1.97 | 0.60 to 6.42 |
| At 6 months | 4 (8.9) | 8 (5.2) | 0.36 | 1.72 | 0.54 to 5.46 |
| At 1 year | 4 (8.9) | 10 (6.4) | 0.57 | 1.38 | 0.45 to 4.18 |

CHF, congestive heart failure.

| Table 6  | Efficacy end points (after adjusting for age, sex, Killip class as covariates) |
|----------|------------------------------------------------|
|          | A (n=45) n (%) | B (n=155) n (%) | p Value | Relative risk |
| Death, reinfarction, repeat revascularisation, cardiogenic shock, CHF | | | | |
| At 30 days | 5 (11.1) | 6 (3.9) | 0.12 | 2.22 | 0.81 to 6.13 |
| At 3 months | 6 (13.3) | 9 (5.8) | 0.23 | 1.70 | 0.72 to 4.05 |
| At 6 months | 6 (13.3) | 11 (7.1) | 0.34 | 1.50 | 0.65 to 3.43 |
| At 1 year | 6 (13.3) | 14 (9.0) | 0.64 | 1.21 | 0.54 to 2.71 |

CHF, congestive heart failure.

| Table 7  | Safety end points |
|----------|-------------------|
|          | A | B | p Value |
| Bleeding | | | |
| Any bleeding, n (%) | 1 (2.2) | 1 (0.6) | 0.40 |
| Intracranial bleeding, n | 0 | 0 | NA |
| Bleeding at access site, n (%) | 1 (2.2) | 0 | 0.22 |
| TIMI bleeding | | | |
| Major, n (%) | 0 | 1 (0.6) | 1.0 |
| Requiring medical attention, n (%) | 0 | 0 | NA |
| Minimal, n (%) | 1 (2.2) | 0 | 0.22 |

NA, not applicable.
patients in the study was a composite of death, cardiogenic shock, reinfarction, repeat revascularisation of the culprit artery and congestive heart failure at 30 days, distribution between the two groups tested using a log rank test (p=0.36). There was no difference in bleeding risk between both groups. Owing to the small sample size of the study, our findings may not provide a precise estimate of outcomes (especially safety end points) and definitive conclusions await larger randomised trials.

In summary, the results of this observational study show that a pharmacoinvasive strategy can be implemented safely in patients under the age of 75 years who do not undergo primary PCI in India. These findings obviously require additional investigation, given the limited sample size. A pharmacoinvasive strategy may successfully alleviate the logistic or geographical barriers of primary PCI in the treatment of AMI, particularly in a developing country like India.

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**Competing interests** None.

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**Ethics approval** The study has been cleared by the ethics committees of the respective hospitals.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** No additional data are available.

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Appendix:

**Definitions:**

**Myocardial Infarction:**

Detection of rise and/or fall of cardiac biomarker values (preferably troponin) with at least one value above the 99th percentile of the upper reference limit and with at least one of the following:

- Symptoms of ischaemia;
- New or presumably new significant ST-T changes or new LBBB;
- Development of pathological Q waves in the ECG;
- Imaging evidence of new loss of viable myocardium, or new regional wall motion abnormality;
- Identification of an intracoronary thrombus by angiography or autopsy.

Ref: Steg PG, James SK, Atar D, Badano LP, Lundqvist C, Borger MA, Mario CD, Dickstein k, Ducrocq G, Aviles FF, Gershlick AH, Giannuzzi P, Halvorsen S, Huber K, Juni P, Kastrati A, Knuuti J, Lenzen MJ, Mahaffey KW, Valgimigli M, van ’t Hof A, Widimsky P, Zahger D. ESC guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J 2012; 33:2569-619.
TIMI bleeding criteria: (Non-CABG related bleeding)

Major

- Any intracranial bleeding (excluding microhemorrhages <10 mm evident only on gradient-echo MRI)
- Clinically overt signs of hemorrhage associated with a drop in hemoglobin of ≥5 g/dL
- Fatal bleeding (bleeding that directly results in death within 7 days)

Minor

- Clinically overt (including imaging), resulting in hemoglobin drop of 3 to <5 g/dL.

Requiring medical attention

- Any overt sign of hemorrhage that meets one of the following criteria and does not meet criteria for a major or minor bleeding event, as defined above.
- Requiring intervention (medical practitioner-guided medical or surgical treatment to stop or treat bleeding, including temporarily or permanently discontinuing or changing the dose of a medication or study drug).

- Leading to or prolonging hospitalization
-Prompting evaluation (leading to an unscheduled visit to a healthcare professional and diagnostic testing, either laboratory or imaging)

Minimal

-Any overt bleeding event that does not meet the criteria above

Ref:
Bovill EG, Terrin ML, Stump DC, Berke AD, Frederick M, Collen D, Feit F, GoreJM, Hillis LD, Lambrew CT, Leiboff R, Mann KG, Markis JE, Pratt CM, Sharkey SW, Sopko G, Tracy RP, Chesebro JH. Hemorrhagic events during therapy with recombinant tissue-type plasminogen activator, heparin, and aspirin for acute myocardial infarction: results of the Thrombolysis in Myocardial Infarction (TIMI), phase II trial. Ann Intern Med. 1991;115:256–265.

**Cardiogenic shock**

Systolic blood pressure <90mm Hg for at least 30 min (or the need for supportive measures to maintain a systolic blood pressure of >90mm Hg) in the presence of a heart rate of >60beat/min in association with signs of end-organ hypoperfusion (cold extremities, low urinary output <30mL/h and/or mental confusion) A cardiac index
<2.21L/(min m²) in the presence of a pulmonary capillary wedge pressure of >15mm Hg.

**Killip Class**

Class I: no heart failure

Class II: crackles audible half way up the chest

Class III: crackles heard in all the lung fields

Class IV: cardiogenic shock

**Reinfarction**

Reinfarction was defined as having at least 2 of the following 4 criteria: (1) recurrent ischemic symptoms lasting >15 minutes after resolution of symptoms of the index myocardial infarction, (2) occurrence of new ST-T wave changes or new Q waves, (3) a second elevation in cardiac enzymes to over the normal upper limit (or by a further 20% if already over the normal upper limit), and (4) angiographic reocclusion of a documented previously patent infarct-related artery.

Ref: Barbash, GI, Birnbaum, Y, Bogaerts, K, et al Treatment of reinfarction after thrombolytic therapy for acute myocardial infarction: an analysis of outcome and treatment choices in the Global Utilization of Streptokinase and Tissue Plasminogen Activator for
Occluded Coronary Arteries (GUSTO I) and assessment of the safety of a new thrombolytic (ASSENT 2) studies. Circulation 2001;103,954-960

**Successful and Failed Thrombolysis**

Successful reperfusion is defined as resolution of chest pain, presence of reperfusion arrhythmias, and ST segment resolution >50% in the lead with maximum ST elevation in pre-Thrombolytic ECG.

Failed thrombolysis is defined as persisting or worsening chest pain or <50% resolution of ST segment elevation after 90 minutes of thrombolysis in a single lead showing maximum ST segment elevation at presentation.