ESC STEMI Guidelines: December 2008

Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation

The Task Force on the management of ST-segment elevation myocardial infarction of the European Society of Cardiology:

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### Reperfusion Therapy: Fibrinolytic Therapy

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the absence of contraindications and if primary PCI cannot be performed within the recommended time</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>A fibrin-specific agent should be given</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Pre-hospital initiation of fibrinolytic therapy</td>
<td>IIa</td>
<td>B</td>
</tr>
</tbody>
</table>
## Recommendations

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicated in all pts with chest pain/discomfort of &lt; 12 h and with persistent ST-segment elevation or (presumed) new LBBB</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Should be considered if there is clinical and/or ECG evidence of ongoing ischaemia if symptoms started &gt; 12 h before</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Reperfusion (PCI) in stable pts presenting &gt; 12 h to 24 h after symptom onset</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td>PCI of totally occluded infarct artery in stable pts &gt; 24 h after symptom onset without signs of ischaemia</td>
<td>III</td>
<td>B</td>
</tr>
</tbody>
</table>
ESC 2008 STEMI Guidelines
Reperfusion Strategies

- **PCI-capable hospital**: primary PCI
- **Ambulance**: PCI < 2h possible
  - PCI < 2h not possible
- **Non-PCI-capable hospital**: pre-, in-hospital fibrinolysis
  - failed
  - successful

- **Time limits**
  - 2h
  - 12h
  - 24h

- **Angiography**
  - $^\#$ If PCI is not possible < 2 h of FMC, start fibrinolytic therapy as soon as possible.
  - $^\circ$ Not earlier than 3 h after start fibrinolysis
  - $^\circ$ 24/7 service

- **First Medical Contact (FMC)**

*Time FMC to first balloon inflation must be shorter than 90 min in patients presenting early (< 2 h after symptom onset), with large amount of viable myocardium and low risk of bleeding.*
The Importance of Time to Treatment

A Meta-analysis of 50,246 Pts

in placebo controlled trials of Lytic Therapy

Myocardial Reperfusion by PPCI assessed by CMR

Time to reperfusion from symptom onset: <90 90-150 150-360 <360 min

Francone et al. JACC 2009;54:2145
30-Day Mortality of STEMI Patients by % Treated Within Recommended Delays and % Receiving Reperfusion With PPCI

## PCI vs. Lysis: Importance of Presentation Delay and Baseline Characteristics

Data from NRMI 2, 3 and 4 Registries

<table>
<thead>
<tr>
<th>PCI and Fibrinolytic Mortality Are Equal (Min)</th>
<th>NonAnt MI 65+ YRS</th>
<th>Ant MI 65+ YRS</th>
<th>NonAnt MI &lt;65 YRS</th>
<th>Ant MI &lt;65 YRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI Related Delay (DB-DN) 0-120</td>
<td>20.424</td>
<td>168</td>
<td>58</td>
<td>40</td>
</tr>
<tr>
<td>Prehospital Delay (min) 0-120</td>
<td>10.614</td>
<td>179</td>
<td>148</td>
<td>103</td>
</tr>
<tr>
<td>Prehospital Delay (min) 121+</td>
<td>9.812</td>
<td>107</td>
<td>16.119</td>
<td>43</td>
</tr>
<tr>
<td>Prehospital Delay (min) 180</td>
<td>41.774</td>
<td></td>
<td>19.517</td>
<td></td>
</tr>
</tbody>
</table>

Pinto et al. Circulation, 2006


*Circulation* 2009;120;2271-2306; originally published online Nov 18, 2009;

DOI: 10.1161/CIRCULATIONAHA.109.192663

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Transport of Patients with STEMI and Initial Reperfusion Treatment

EMS Transport

Onset of symptoms of STEMI → Call 9-1-1

EMS on scene
- Encourage 12-lead ECGs
- Consider pre-hospital fibrinolytic if capable and EMS–to–needle within 30 min

EMS Transport

Pre-hospital fibrinolysis
EMS–to–needle ≤ 30 min
EMS transport
EMS-to-balloon ≤ 90 min

Patient self-transport
Hospital door-to-balloon ≤ 90 min

GOALS

5 min 8 min
Patient EMS

Dispatch 1 min

“Golden Hour” = 1st 60 min
Total ischaemic time: within 120 min

Hospital fibrinolysis:
Door–to–needle ≤ 30 min

Not PCI capable

Inter-hospital transfer

PCI capable

The Real World
Cumulative Time-to-Balloon Intervals in OTTAWA

A First Hospital Door-to-Balloon Time

Proportion of Patients (%)

Minutes

Field transfers
Interhospital transfers

P < 0.001

B ECG-to-Balloon Time

Proportion of Patients (%)

Minutes

Field transfers
Interhospital transfers

P < 0.001

C Symptom-Onset-to-Balloon Time

Proportion of Patients (%)

Minutes

Field transfers
Interhospital transfers

P < 0.001
Time delays in Transfer Patients for Primary PCI

Nallamothu et al. Circulation, 2005
MINNESOTA Study: First Door-to-Balloon

Zone 1: < 60 miles
Zone 2: 60-210 miles
MAYO STUDY: Door-to-balloon and door-to-needle times for group A (PCI-hospital), group B (regional hospital transfer for PCI), and group C (regional hospital fibrinolysis).
Mortality Estimates for 6209 Danish Patients With STEMI Treated With Primary PCI

Two Different Strategies

- **Facilitated PCI:** pharmacological reperfusion treatment delivered prior to a planned PCI in order to bridge the PCI-related time delay.

- **Pharmacoinvasive strategy:** intravenous fibrinolytic treatment, followed by coronary angiography on an urgent basis if lytic therapy failed (rescue PCI) or later to determine long-term treatment (PCI, CABG, medical).
A Conservative vs Invasive Transfer Approach

**DANAMI-2:**
benefits of PPCI even in transfer patients

- Rescue PCI: 1.8%
- Any Revasc: 17%

**CAPTIM:**
lower mortality with PHT up to 5 years

- Rescue PCI: 26%
- Any Revasc: 72%

---

**DANAMI-2: Results**

- Lytic
- Primary PCI

- Death: P=0.35
- Recurrent MI: P<0.001
- Stroke: P=0.15

**CAPTIM: 30-day & one-year result**

- P=NS

- 30-d: PHT vs PCI
- One year: PHT vs PCI

---

N Engl J Med 2003; 349: 733-42
## Comparison of key results from DANAMI-2 and CAPTIM

<table>
<thead>
<tr>
<th>Results</th>
<th>DANAMI-2 Trial</th>
<th>CAPTIM Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In-hospital fibrinolysis $(n = 562)$</td>
<td>Transfer to PPCI $(n = 567)$</td>
</tr>
<tr>
<td>Median age (years)</td>
<td>64</td>
<td>62</td>
</tr>
<tr>
<td>Median time to fibrinolysis (min)</td>
<td>169</td>
<td></td>
</tr>
<tr>
<td>Median time to PCI (min)</td>
<td></td>
<td>224</td>
</tr>
<tr>
<td>Rescue PCI (%)</td>
<td>1.8</td>
<td>26</td>
</tr>
<tr>
<td>Reinfarction (%)</td>
<td>6.2</td>
<td>1.9</td>
</tr>
<tr>
<td>Elective revascularization‡ (%)</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>30-day all-cause mortality (%)</td>
<td>8.5</td>
<td>6.5</td>
</tr>
<tr>
<td>All-cause mortality at follow-up* (%)</td>
<td>33.3</td>
<td>26.7</td>
</tr>
<tr>
<td>Cardiac mortality at follow-up* (%)</td>
<td>16.4</td>
<td>12.8</td>
</tr>
</tbody>
</table>

*In the first 30-days. ‡Follow-up was 5 years in the CAPTIM Trial and 7.8 years in the DANAMI-2 Trial. Abbreviations: CAPTIM, comparison of primary angioplasty and pre-hospital fibrinolysis in acute myocardial infarction; DANAMI, Danish Acute Myocardial Infarction; NA, not applicable; PCI, percutaneous coronary intervention; PPCI, primary percutaneous coronary intervention.
Zone 1 Protocol
- Aspirin 325 mg
- Clopidogrel 600mg
- UFH
- Beta-blocker
- PCI

Red-Zone II (90-120mins)
Blue-Zone I (<90 mins)
Protocol focus:
- Simple
- Fast
- Reduce variability

Red-Zone II (90-120mins)
Blue-Zone I (<90 mins)

Zone 2 Protocol
- Aspirin 325 mg
- Clopidogrel 600mg
- UFH
- TNK ½ dose
- Beta-blocker
- PCI
## Time to reperfusion segments (min)

<table>
<thead>
<tr>
<th>Time Segment</th>
<th>PCI Hosp</th>
<th>Zone 1 (≤60 miles)</th>
<th>Zone 2 (60-210 miles)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms to hospital</td>
<td>103 (60, 232)</td>
<td>88 (47, 195)</td>
<td>88 (44, 185)</td>
<td>0.008/ 0.002</td>
</tr>
<tr>
<td>In door – out door</td>
<td>NA</td>
<td>49 (36, 67)</td>
<td>61 (48, 83)</td>
<td></td>
</tr>
<tr>
<td>Door to fibrinolytic</td>
<td>NA</td>
<td>NA</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Transport</td>
<td>NA</td>
<td>22 (16, 31)</td>
<td>35 (26, 48)</td>
<td></td>
</tr>
<tr>
<td>Door to balloon</td>
<td>64 (44, 84)</td>
<td>95 (81, 117)</td>
<td>121 (101, 151)</td>
<td>&lt;0.001/ &lt;0.001</td>
</tr>
<tr>
<td>Total reperfusion</td>
<td>171 (118, 318)</td>
<td>195 (142, 305)</td>
<td>218 (165, 329)</td>
<td>&lt;0.001/ &lt;0.001</td>
</tr>
</tbody>
</table>
Patients presenting between 2003 and 2009

Total STEMI
N=2,228*

- ANW
  N=521
  - PPCI
    N=521
    - PPCI
      N=1,485
  - PPCI
    N=964
  - PhInv
    N=28

- Zone 1
  N=992
  - PPCI
    N=144
  - PhInv
    N=571

- Zone 2
  N=715
  - PPCI
    N=144
  - PhInv
    N=599

*Excluding no culprits. Patients presented between 2003 and 2009
## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>PPCI</th>
<th>Ph-Inv</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>62.4 ± 14.1</td>
<td>63.3 ± 13.2</td>
<td>0.18</td>
</tr>
<tr>
<td><strong>Patients ≥ 75 yrs</strong></td>
<td>343 (23.1)</td>
<td>138 (24.0)</td>
<td>0.98</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>1088 (73.3)</td>
<td>452 (75.5)</td>
<td>0.30</td>
</tr>
<tr>
<td><strong>Hyperlipidaemia</strong></td>
<td>820 (57.1)</td>
<td>327 (56.8)</td>
<td>0.88</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>850 (57.6)</td>
<td>329 (55.1)</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>233 (15.8)</td>
<td>101 (16.9)</td>
<td>0.53</td>
</tr>
<tr>
<td><strong>Current smoking</strong></td>
<td>593 (40.3)</td>
<td>242 (40.7)</td>
<td>0.87</td>
</tr>
<tr>
<td><strong>History of MI</strong></td>
<td>276 (18.7)</td>
<td>114 (10.0)</td>
<td>0.84</td>
</tr>
<tr>
<td><strong>History of CABG</strong></td>
<td>91 (6.2)</td>
<td>33 (5.5)</td>
<td>0.58</td>
</tr>
<tr>
<td><strong>History of PCI</strong></td>
<td>297 (20.1)</td>
<td>107 (17.9)</td>
<td>0.24</td>
</tr>
</tbody>
</table>
## Clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>PPCI</th>
<th>Ph-Inv</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiogenic shock before PCI</td>
<td>155 (10.4)</td>
<td>49 (8.2)</td>
<td>0.12</td>
</tr>
<tr>
<td>Cardiac arrest before PCI</td>
<td>137 (9.2)</td>
<td>39 (6.5)</td>
<td>0.044</td>
</tr>
<tr>
<td>Out of hosp cardiac arrest</td>
<td>79 (5.3)</td>
<td>24 (4.0)</td>
<td>0.21</td>
</tr>
<tr>
<td>Anterior MI</td>
<td>499 (33.8)</td>
<td>211 (35.4)</td>
<td>0.48</td>
</tr>
<tr>
<td>Killip Class 2-4</td>
<td>223 (15.0)</td>
<td>86 (14.4)</td>
<td>0.70</td>
</tr>
<tr>
<td>LBBB</td>
<td>38 (2.6)</td>
<td>9 (1.5)</td>
<td>0.14</td>
</tr>
</tbody>
</table>
Pre-PCI patency

P < 0.001

Percentage of patients

TIMI 2/3

- PPCI: 37.1%
- Ph-Inv: 72.7%

P < 0.001
## Results

<table>
<thead>
<tr>
<th></th>
<th>PCI Hosp PPCI N=496</th>
<th>Zone 1 (&lt;60) PPCI N=1,005</th>
<th>Zone 2 (60-210) Ph-Inv N=606</th>
<th>P value PCI Hosp vs. Zone 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>D2B time</strong></td>
<td>64 (44, 84)</td>
<td>95 (81, 117)</td>
<td>123 (102, 151)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Mortality hospital</strong></td>
<td>5.0%</td>
<td>4.4%</td>
<td>5.5%</td>
<td>0.76</td>
</tr>
<tr>
<td><strong>Mortality 30 day</strong></td>
<td>5.7%</td>
<td>5.2%</td>
<td>5.8%</td>
<td>0.93</td>
</tr>
<tr>
<td><strong>Re-ischaemia 30 days</strong></td>
<td>3.0%</td>
<td>0.9%</td>
<td>1.0%</td>
<td>0.014</td>
</tr>
<tr>
<td><strong>Major Bleeding</strong></td>
<td>1.4%</td>
<td>0.7%</td>
<td>1.2%</td>
<td>0.71</td>
</tr>
<tr>
<td><strong>Stroke 30 days</strong></td>
<td>1.2%</td>
<td>0.5%</td>
<td>1.0%</td>
<td>0.73</td>
</tr>
</tbody>
</table>
Kaplan-Meier survival

One-year survival

Days since presentation

Survival probability

P=NS

PPCI
Ph-Inv
STrategic Reperfusion Early After MI

Patients presenting with STEMI <3 hrs from onset of symptoms that cannot reliably undergo primary PCI <60 min

Group A

<75 years: TNK
Routine ASA

- Clopidogrel: LD 300 mg + 75 mg QD
- Enoxaparin: 30 mg IV + 1 mg/kg SC Q12h

ECG at 90 min: ST resolution ≥ 50%

YES

Diagnostic angiography + PCI / stent, if indicated > 6 hrs / < 24 hrs

NO

Rescue angiography + PCI / stent immediately

≥ 75 years: 1/2TNK
Routine ASA

- Clopidogrel: 75 mg QD
- Enoxaparin: 0.75 mg/kg SC Q12h

Group B

ASA, No lytic

Antiplatelet and anticoagulation treatment according to local standards

Standard angiography + PCI / stent immediately
Class IIa. It is reasonable for high-risk patients who receive fibrinolytic therapy as primary reperfusion therapy at a non–PCI-capable facility to be transferred as soon as possible to a PCI-capable facility where PCI can be performed either when needed or as a pharmacoinvasive strategy. Consideration should be given to initiating a preparatory antithrombotic (anticoagulant plus antiplatelet) regimen before and during patient transfer to the catheterization laboratory. *(Level of Evidence: B)*
Class IIb. Patients who are not at high risk who receive fibrinolytic therapy as primary reperfusion therapy at a non–PCI-capable facility may be considered for transfer as soon as possible to a PCI-capable facility where PCI can be performed either when needed or as a pharmacoinvasive strategy. Consideration should be given to initiating a preparatory antithrombotic (anticoagulant plus antiplatelet) regimen before and during patient transfer to the catheterization laboratory. (Level of Evidence: C)
Polls at the TCT Website (October 12, 2010)

**Poll**
Which therapy for STEMI patients would you like to learn more about?

- Pharmacologic therapy: 20%
- Aspiration thrombectomy: 38%
- Out-of-hospital reperfusion: 12%
- DES as standard of care: 30%

**Poll**
Fibrinolytic therapy should be given to STEMI patients with:

- Transfer delays up to 60 min: 22%
- Transfer delays up to 90 min: 31%
- Transfer delays up to 120 min: 32%
- Always: 6%
- Never: 9%

**Poll**
Which strategies would you like to compare for STEMI patients?

- Facilitated PCI (Y/N): 22%
- Thrombolysis vs. primary PCI: 20%
- DES vs. BMS: 39%
- Heparin vs. Bivalirudin: 19%
Conclusions

The Window for Fibrinolysis

- “Outside the window of primary PCI”
- Whether it should be given up to 12h after onset of infarction is debatable (if primary PCI is not available)
- Inter-hospital transport of STEMI patients for primary PCI remains major issue
Mortality Rates in Control and Treatment Groups for Each Prehospital Thrombolytic Trial

Recommended Logistics

- **Pre-hospital triage/care:**
  - EMS
    - unique telephone number
    - tele-consultation
  - Ambulance
    - 12-ECG recorder/defibrillator
    - staff able to provide basic and advanced life support

- **Networks:**
  - implementation of a network of hospitals with different levels of technology connected by an efficient ambulance service using the same protocol

- **Targets:**
  - < 10 min ECG transmission
  - < 5 min tele-consultation
  - < 120 min to first balloon inflation
  - < 30 min start fibrinolytic therapy
Importance of *PCI-related Delay*
Data from Randomized Trials

Betriu and Masotti
Mortality equipose: **110 min**
*Am J Card* 2005;95:100-101

Nallomothu, Antman and Bates
Mortality equipose: **62 min**
*Am J Cardiol* 2004;94:772-774

Nallomothu, Antman and Bates
Mortality equipose: **>170 min**
*Am J Cardiol* 2004;94:772-774
PCI vs. Lysis: Importance of *PCI-related Delay* in NRMI 2,3,4 Registries

Odds of Death with Fibrinolysis

Pinto et al. Circulation, 2006
Pre-hospital Management

Symptoms compatible with STEMI

EMS: Emergency Medical System; STEMI: Acute ST-segment Elevation Myocardial Infarction; GP: General Practitioner; PCI: percutaneous coronary intervention

Thick arrows: preferred patient flow; dotted line: to be avoided

EMS: Pre-hospital diagnosis, triage, care
GP/cardiologist: Self-decision
Ambulance: Private transportation

PCI-capable* hospital
Transfer if PCI possible < 2h

Non-PCI-capable hospital

*PCI-capable-hospital = 7/24 service!
Mortality and the Use of Fibrinolytics According to Age

CAPTIM: 5 Year Survival
Prehospital Thrombolysis vs Primary PCI

<2 hrs
HR 0.50 (95% CI, 0.25–0.97); P = 0.04

>2 hrs

Rate of Ischemic Events at the Available Follow-up

| Study         | Time from Fibrinolysis to Routine Early PCI (hr) | Rate
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPITAL-AMI</td>
<td>1.6</td>
<td>11.6</td>
</tr>
<tr>
<td>CARESS-in-AMI</td>
<td>2.3</td>
<td>4.4</td>
</tr>
<tr>
<td>SIAM-III</td>
<td>3.7</td>
<td>25.6</td>
</tr>
<tr>
<td>TRANSFER-AMI</td>
<td>3.9</td>
<td>17.1</td>
</tr>
<tr>
<td>GRACIA-1</td>
<td>16.7</td>
<td>9.3</td>
</tr>
<tr>
<td>NORDISTEMI</td>
<td>2.7</td>
<td>10.0</td>
</tr>
</tbody>
</table>
Impact of PCI-related delay on Mortality Benefit from Primary PCI

All patients 180 min

Medium risk 92 min

Low risk no relationship

High risk 131 min

Reperfusion Therapy: Important Time Lines

Onset of STEMI

FMC: First Medical Contact or First Diagnostic ECG

Start lytic

Reperfusion

Sheath

Patient-dependent

Organization-dependent

"PCI-related delay"

Balloon Sheath

FMC: First Medical Contact or First Diagnostic ECG
Polls at the TCT Website

Poll 1: Which therapy for STEMI patients would you like to learn more about?
- Pharmacologic therapy: 20%
- Aspiration thrombectomy: 38%
- Out-of-hospital reperfusion: 12%
- DES as standard of care: 30%

Poll 2: Fibrinolytic therapy should be given to STEMI patients with:
- Transfer delays up to 60 min: 22%
- Transfer delays up to 90 min: 31%
- Transfer delays up to 120 min: 32%
- Always: 6%
- Never: 9%

Poll 3: Which strategies would you like to compare for STEMI patients?
- Facilitated PCI (Y/N): 22%
- Thrombolysis vs. primary PCI: 20%
- DES vs. BMS: 39%
- Heparin vs. Bivalirudin: 19%
Absolute Reduction in 35-Day Mortality Versus Delay From Symptom Onset to Randomization in Patients With ST-Segment Elevation or LBBB

Relationship Between Myocardial Salvage and Survival

Mortality reduction (%)

Extent of salvage (% of area at risk)

Hours

% 0 20 40 60 80 100

Modifying factors
- Collaterals
- Ischemic preconditioning
- MVO₂

Treatment objectives

Time to treatment is critical

Opening the IRA (PCI > lysis)

Gersh B. JAMA 2005