**Clinical question.**

In patients with suspected STEMI in the ED and prehospital settings (P), does the use of fibrinolytics and immediate PTCA (I), compared with immediate PTCA (C), improve outcome (e.g. chest pain resolution, infarct size, ekg resolution, survival to discharge, 30/60 d mortality) (O)?

**Is this question addressing an intervention/therapy, prognosis or diagnosis? therapy**

**State if this is a proposed new topic or revision of existing worksheet:** NEW

**Conflict of interest specific to this question**

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet? NO

**Search strategy (including electronic databases searched).**

**Database: PubMed(humans, English, Japanese, Clinical trial, Meta-analysis, RCT)**

Step 1: hit 22 articles(revised).

(‘facilitated PCI’ or ‘facilitated percutaneous coronary intervention’ or ‘facilitated PTCA’ or ‘facilitated percutaneous transluminal coronary angioplasty’ or ‘facilitated angioplasty’) AND (thromboly* or fibrinoly*)

Step 2: hit 17 articles.

(stemi or ‘st segment elevation myocardial infarction’ or ‘st elevation myocardial infarction’ or ‘acute coronary syndrome’ or ‘acute myocardial infarction’ AND (‘emergency department’ or ‘emergency room’ or prehospital or out-of-hospital) AND (thromboly* or fibrinoly* or ‘percutaneous transluminal coronary angioplasty’ or ptca) AND ‘infarct size’ or survival or mortality or outcome or electrocardiogr* or ‘chest pain’)

Step 3: hit 122 articles(added).

(‘rescue PCI’ or ‘rescue percutaneous coronary intervention’ or ‘rescue PTCA’ or ‘rescue percutaneous transluminal coronary angioplasty’ or ‘rescue angioplasty’) AND (thromboly* or fibrinoly*)

**Database: EMBASE(humans, EMBASE+Unique MEDLINE, Cochrane Review, CCT, Meta-analysis, CRT)**

Step 1: hit 35 articles.

(‘facilitated PCI’ or ‘facilitated percutaneous coronary intervention’ or ‘facilitated PTCA’ or ‘facilitated percutaneous transluminal coronary angioplasty’ or ‘facilitated angioplasty’) AND (thromboly* or fibrinoly*)

Step 2: hit 66 articles.

(stemi or ‘st segment elevation myocardial infarction’ or ‘st elevation myocardial infarction’ or ‘acute coronary syndrome’ or ‘acute myocardial infarction’ AND (‘emergency department’ or ‘emergency room’ or prehospital or out-of-hospital) AND (thromboly* or fibrinoly* or ‘percutaneous transluminal coronary angioplasty’ or ptca) AND ‘infarct size’ or survival or mortality or outcome or electrocardiogr* or ‘chest pain’)

Step 3: hit 78 articles(added).

(‘rescue PCI’ or ‘rescue percutaneous coronary intervention’ or ‘rescue PTCA’ or ‘rescue percutaneous transluminal coronary angioplasty’ or ‘rescue angioplasty’) AND (thromboly* or fibrinoly*)

**Database: Cochrane Library**

Step 1: hit 19 articles. (Cochrane Reviews;0, Other Reviews;2, Clinical Trials;17)

(‘facilitated PCI’ or ‘facilitated percutaneous coronary intervention’ or ‘facilitated PTCA’ or ‘facilitated percutaneous transluminal coronary angioplasty’ or ‘facilitated angioplasty’) AND (thromboly* or fibrinoly*)

Step 2: hit 98 articles. (Cochrane Reviews;0, Other Reviews;1, Clinical Trials;97)

(stemi or ‘st segment elevation myocardial infarction’ or ‘st elevation myocardial infarction’ or ‘acute coronary syndrome’ or ‘acute myocardial infarction’ AND (‘emergency department’ or ‘emergency room’ or prehospital or out-of-hospital) AND (thromboly* or fibrinoly* or ‘percutaneous transluminal coronary angioplasty’ or ptca) AND ‘infarct size’ or survival or mortality or outcome or electrocardiogr* or ‘chest pain’)

Step 3: hit 75 articles(added). (Cochrane Reviews;1, Other Reviews;8, Clinical Trials;66)

(‘rescue PCI’ or ‘rescue percutaneous coronary intervention’ or ‘rescue PTCA’ or ‘rescue percutaneous transluminal coronary angioplasty’ or ‘rescue angioplasty’) AND (thromboly* or fibrinoly*)

**Database: Ichushi-web(A Japanese bibliographic database by Japan Medical Abstract Society)**

Search strategy was built with the following terms, being translated into Japanese terms;

‘facilitated PTCA’ OR ‘facilitated PTCA’ OR ‘antecedent administration’ hit 138 articles.

**Manual search with reviewing of references of previously selected articles:**

Added 8 articles

• State inclusion and exclusion criteria
### Inclusion criteria:
Human study, study comparing the thrombolysis-based facilitated, or rescue PCI versus immediate PCI, English paper or non-English paper with English abstract.

### Exclusion criteria:
- Study without PCI, reports of single cases.
- Facilitated, or rescue PCI without comparison with Primary PCI.

<table>
<thead>
<tr>
<th>Number of articles/sources meeting criteria for further review</th>
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<tr>
<td>Finally 54 articles were selected for further review; LOE(1)=17, LOE(2)=13, LOE(3)=4, LOE(4)=0, LOE(5)=20.</td>
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# Summary of evidence

## Evidence Supporting Clinical Question

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<thead>
<tr>
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<td></td>
<td>Nagao (2002), E5, E6</td>
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</table>

### Level of evidence

- **E1** = 30 days or in-hospital mortality
- **E2** = Strokes
- **E3** = Re-infarction/ischemia
- **E4** = Bleeding
- **E5** = Composite of E1toE2
- **E6** = Other clinical endpoint
## Evidence Neutral to Clinical question

<table>
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</table>

### Level of evidence

- **E1** = 30 days or in-hospital mortality
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- **E3** = Re-infarction/ischemia
- **E4** = Bleeding
- **E5** = Composite of E1 to E2
- **E6** = Other clinical endpoint

### Evidence Neutral to Clinical question

<table>
<thead>
<tr>
<th>Rating</th>
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| Good   | Armstrong (2006), E6 
Arnold (1991), E3, E6 
*Collet (2006), E1, E5 
Ellis SG(2008), E4, E5 
*Jovell (1993), E1, E5 
Ross (1999), E1, E2, E3, E4 |
|        | Danchin (2008), E1, E5 
Elli SG (2000), E5 |
|        | Bauer (2007), E1, E3, E4 
Bonnefoy (2002), E1, E2, E5 
Dudek (2008), E1, E2, E4 
Ellis K(2005), E4, E5 
Schomig (2004), E1 
Thiele (2005), E5 |
| Fair   | Inoue (2005), E1, E2, E3, E4 
Koeth (2009), E1, E5 
Kurihara (2004), E1, E3, E4 |
|        | Agati (2007), E6 
Gimelli (2000), E5, E6 
Juliard (1999), E1, E2, E3, E4, E6 
Polonski (2003), E1, E6 |
|        | Uto (2002), E1, E2, E3, E4 |
|        | Cantor (2005), E5 
Gibson (2004), E6 
Herrmann (2000), E4, E5 
Le May (2005), E5 
Rekik (2009), E6 
Sakurai (2003), E1 
Steg (2005), E1, E6 |
| Poor   | Holmes (1985), E5 
Watanabe (2006), E1, E4, E6 |

(*) = meta-analyses
## Evidence Opposing Clinical Question

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</tr>
<tr>
<td>E1 =</td>
<td>30 days or in-hospital mortality</td>
<td>E2 =</td>
<td>Strokes</td>
<td>E3 =</td>
<td>Re-infarction/ischemia</td>
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<tr>
<td>E4 =</td>
<td>Bleeding</td>
<td>E5 =</td>
<td>Composite of E1toE2</td>
<td>E6 =</td>
<td>Other clinical endpoint</td>
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</tbody>
</table>
REVIEWER'S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:

The posed question is a simple question asking the efficacy of facilitated PCI in patients with STEMI. The idea of facilitated PCI to reduce ischemic time and to increase efficacy of PCI, while waiting or transferring for PCI, has not been changed yet. However, the question is also difficult to find out answers which could be fit to a real-world patients. There are continuous developments in fibrinolytic agents, in adjunctive antiplatelet agents, catheters, balloons and stents, especially drug-eluting stents. Obviously the results are influenced by these confounders. Most studies, especially before C2005, failed to prove efficacy, feasibility and safety of fibrinolysis facilitated PCI, and numbers of RCTs have been implemented in recent years. One of the most important RCTs; ASSENT-4 PCI (2006, p569) was prematurely terminated because of adverse outcome in patients with PCI after full-dose tenecteplase thrombolysis, compared to patients treated with primary PCI. In this review, although no good quality RCTs are supporting the facilitated PCI, many of recent RCTs resulted in neutral, rather than opposing results. The FINESSE study by Ellis SG (2008, p2205) is a placebo-controlled RCT with a large number of patients with STEMI, but was prematurely terminated, because primary endpoints were identical in three treatment strategies. This means that there may be no "one size fits all" answer to the posed question. It may be necessary to add further publications to the investigations not directly comparing facilitated PCI with primary PCI in intention to include important not definitively answered questions into the scope of the worksheet.

Acknowledgements:

Sohko Yamasaki in preparing the worksheet

Citation List

ADVANCE MI trial (2005). "Facilitated percutaneous coronary intervention for acute ST-segment elevation myocardial infarction: Results from the prematurely terminated ADdressing the Value of facilitated ANgioplasty after Combination therapy or Eptifibatide monotherapy in acute Myocardial Infarction (ADVANCE MI) trial." American heart journal 150(1): 116-122.

LOE 1, opposing, poor, n=146
A prematurely terminated, according to slow recruitment, study to evaluate facilitated PCI for STEMI. A total of 148 pts were randomized (74 each), but 69 actually recieved eptifibatide + half-dose tenecteplase, and 77 actually received eptifibatide + placebo (146 pts as treated). Infarct-related artery patency and myocardial tissue perfusion on pre-PCI angiography were improved in facilitated PCI, but ST-segment resolution at 60-min was similar. Primary end point of death or new/worsening severe heart failure at 30-d was higher among pts with facilitated PCI (10% vs. 3%, p=0.09). Bleeding complications were 2-fold higher with facilitated PCI.


LOE 1, opposing, good
Metaanalysis on 9 trials (3836 pts) comparing thrombolysis with PPCI (7 trials) or reduced dose of thrombolysis + Gp IIb/IIa inhibitors (2 trials). This metaanalysis reveals an overall higher risk of intracranial hemorrhages and re-infarctions with a facilitated PCI strategy. The combination of thrombolysis + Gp IIb/IIa inhibitors reduced the re-infarction rate at the cost of more major bleedings. Patients with fibrinolysis started within 2 hrs after symptom onset and a somewhat (3-24 hrs) delayed PCI showed a trend to lower mortality


LOE 2, neutral, fair, n=66
Study investigating microvascular perfusion by myocardial contrast echocardiography in pts with STEMI treated with primary PCI (n=36), tenecteplase facilitated PCI (n=30) or tenecteplase alone. Baseline characteristics were similar. Pts treated with primary PCI and tenecteplase facilitated PCI had similarly less microvascular damage and similar myocardial salvage, compared to pts with tenecteplase only.

LOE 1, neutral, good, n=304
An open-label, randomized study in 304 pts with STEMI, comparing 3 treatment strategies: tenecteplase (+enox) and usual care (n=100, group A), tenecteplase (+enox) and catheterization (n=104, group B) and primary PCI (+ enox + 300 mg clopidogrel, group C, n=100). Primary outcome of 30d re-infarction, death, severe heart failure, cardiogenic shock, major ventricular arrhythmia and refractory ischemia were observed similarly in all 3 groups. However, combination of death and reinfarction was more frequent in group A than in group C (13% vs. 4 % p=0.02).


LOE5, opposing, good
Long term data of 1043 hospital survivors of STEMI who had angiography before discharge after rt-PA lysis (n=172), had alteplase only (n=346) or were treated with alteplase only (n=346) or placebo (n=345). It is concluded that low risk patients will not profit from additional invasive procedures.


LOE1, neutral good
Early data from a randomised study comparing rt-PA thrombolysis only with rt-PA thrombolysis + immediate PTCA indicating that the rate of re-occlusions or re-infarctions is higher with the combined treatment. On the other hand, ventricular function was better with the combination treatment provided that there was no re-occlusion or re-infarction.


LOE 1, opposing, good, n=1667
A large, but prematurely terminated because of adverse outcome, randomized study comparing 90-d outcome of the composite of death, CHF, shock in pts of STEMI (symptoms < 6 hrs) treated with primary PCI (n=838) or PCI after full-dose tenecteplase thrombolysis (n=829). In-hospital mortality was higher in facilitated PCI (6% vs. 3% p =0.0105) compared to primary PCI. The 90-d composite endpoint occurred more frequently in facilitated PCI (19% vs. 13%, p=0.0045) compared to primary PCI. Facilitated PCI group resulted in significantly more strokes (but not intracranial bleedings) and more cardiac events compared to primary PCI. Lowest 90-d mortality (3.1%) was found in the subgroup with thrombolysis in ambulances from facilitated PCI and highest (8.4%) in the subgroup with initiation of thrombolysis in a PCI centers from facilitated PCI.


LOE5, neutral good
Registry data on 2230 pts with STEMI treated with fibrinolysis only (n=1549) or fibrinolysis with additional PCI (n=690) within a median of 150 Min. After adjustment with a propensity score they was no difference with regard to death and re-Infarction but more bleedings in the +PCI group. In patients with high risk (TIMI risk score >=5, n=494) additional PCI was associated with a significant reduction of hospital mortality.


LOE 5, neutral, good, n=840
Prematurely terminated study due to cessation of findings. A randomized study in 840 STEMI pts, comparing prehospital thrombolysis (n=419) with primary PCI (n=421). Of pts randomized to prehospital thrombolysis, 26% had additional rescue PCI, and another 7% had urgent additional PCI. The primary outcome (composite of death, re MI or disabling stroke) occurred in 8.2%
of prehospital thrombolysis and in 6.2% of primary PCI (p=0.29). Single endpoints (death 3.8% vs 4.8%, re-MI 3.7 vs. 1.7 and stroke 1.0% vs. 0.0%, respectively) are similar. In conclusion, a strategy of PPCI was not better than that of prehospital thrombolysis and that of transfer to a PCI facility for possible rescue angioplasty.


LOE 5, neutral, fair, n=2598
A systematic review and meta-analysis to determine the safety, feasibility and superiority of thrombolysis followed by transfer for immediate or early PCI to conservative management, in pts of STEMI. In conclusion, there is inadequate evidence to support the hypothesis. However transfer for immediate PCI is recommended for pts with shock, hemodynamic instability or persistent ischemic symptoms after thrombolysis only.


LOE 2, supportive, good, n=254
A prospective, single-center cohort study of facilitated PCI (n=127), in comparison with matched pts (n=127) with primary PCI, to compare the effectiveness and cost-effectiveness of thrombolytic agent with GP IIb/IIIa inhibitor followed by transfer to a tertiary hospital for facilitated PCI with STEMI. In-hospital MACE was reduced by 61.3% in pts receiving facilitated compared with primary PCI (P=0.021). The rate of TIMI bleeding was similar in both groups. Bootstrap analysis confirmed that facilitated PCI would be both a more effective and less costly strategy.


LOE 1, neutral, good, n=5253
A meta-analysis of randomized trials in pts of STEMI treated with fibrinolysis to assess the potential benefits of: 1) rescue PCI vs. no PCI (n=920, 5 trials); 2) systematic and early (< or =24 h) PCI vs. delayed or ischemia-guided PCI (n=1508 6 trials); 3) fibrinolysis-facilitated PCI vs. primary PCI alone (n=2679, 4 trials). Rescue PCI for failed fibronlysis reduced mortality and the composite of death and re-infarction. Systematic and early PCI with stenting led to a not significant reduction in mortality and a significant reduction in the composite of death and re-MI in contrast to a trend of increased mortality and re-MI rate with balloon only PTCA. Fibrinolysis facilitated PCI was associated with more re-MI but had no significant influence on mortality.


LOE 2, neutral, good, n=1714
The French registry of 1714 STEMI pts, comparing 2 strategies; facilitated PCI and primary PCI. Sixty percent of pts received reperfusion therapy: 33% primary PCI, 29% iv-thrombolysis (18% prehospital). The pts had similar GRACE risk scores at entry. After thrombolysis, 96% had coronary angiography, and 84% had subsequent PCI. In-hospital mortality was similar; 4.3% for thrombolysis and 5.0% for PPCI. In pts with thrombolysis, 30-d mortality was 9.2% when PCI was not used and 3.9% when PCI was added. One-year survival was similar; 94% for thrombolysis and 92% for PPCI (P=0.31).


LOE 5, neutral, good, n=1980
Non-randomized study based on logistical selection of pts, studying outcomes of 669 STEMI pts treated with combo thrombolysis (half-dose Alteplase and abciximab) before long distance transfer (>90 min) for facilitated PCI, compared with 1311 pts treated with PPCI (transfer time <90 min). A 30-d mortality was 3.0% with facilitated PCI and 3.4% with PPCI, also re-MI rate and the composite of death + re-MI + urgent re-intervention/CABG was identical. However, there was an increase rate of hemorrhagic strokes; 0.9% with facilitated PCI vs. 0.0% with PPCI and an increased rate of (mostly minor) bleeding with the facilitated PCI.

LOE 5, neutral, good, n=659
A study based on a registry on 659 pts with STEMI treated by primary PCI (n=476) or rescue PCI (n=183), to evaluate major bleeding complications (MBC). MBC occurred in 8% of pts with rescue PCI and 6% with primary PCI (p=0.35), there were also no differences in MACE or procedural success between primary PCI and rescue PCI.


LOE 1, neutral, good, n=2452
A placebo-controlled RCT with a large number of pts with STEMI, but prematurely terminated, comparing outcome of STEMI pts treated by thrombolysis with half-dose reteplase + abciximab followed by PCI (n=828), abciximab only facilitated PCI (n=818) or primary CI + abciximab (n=806). Primary endpoint as composite of death, VF later than 48 hrs, cardiogenic shock and CHF within 90-d, was identical in all 3 groups. Compared to primary PCI rate of TIMI major and minor bleedings as well as number of transfusions was higher with facilitated PCI compared to other 2 groups.


LOE 2, neutral, good
Review of randomized studies (n=1456 pts) and registries (n=977 pts) on value of rescue (or immediate) angioplasty after failed thrombolysis (documented angiographically by more or less occluded vessels) indicating that older studies from the 1980s (resulting in harm from this strategy) may be not valid any more and that newer studies tend to be in favour for addition of early PCI at least in failed thrombolysis.


LOE 5, neutral, fair
Post hoc analysis of 3845 TIMI trial pts indicating that TIMI perfusion grades are clearly depending on symptom duration until start of thrombolysis (OR 1.14 per hour of delay) even after adjusting for TIMI flow 3 after intervention and clinical variables. This relation persisted also after rescue PCI and was also present for TIMI flow grade 3.


LOE 2, neutral, fair, n=105
A study based on a registry of 105 consecutive pts of STEMI, comparing primary PCI (n=60) with rescue PCI after thrombolysis (n=45). TIMI-3 flow was achieved in 93.3 % in the primary PCI and 88.8 % in the rescue PCI (p=0.08). Post-procedure EF was 53% in the primary PCI and 47% in the rescue PCI (p=0.014). A composite endpoint of death, re-MI, repeat PCI/CABG and recurrent angina at 6-mo occurred in 33% in the primary PCI and 26.7% in the rescue PCI (p = 0.36).


LOE 5, neutral, fair
Investigation n the role of early routine PCI (performed on average 63 Min after initiation of a reduced dose of reteplase + abciximab) compared with combo lysis alone without early PCI. Early facilitated PCI proved to be safe and effective in terms of clinical events and bleeding complications.

**LOE 2, neutral, poor, n=66**
A study based on a registry of 66 consecutive pts of STEMI, treated by primary PCI (n=11), PCI followed by streptokinase (n=15), streptokinase alone (n=11) and streptokinase followed by PCI (n=29). Incidence of re-MI was similar in all groups. Pts with PCI alone or PCI with streptokinase had a significantly decreased incidence of subsequent revascularization (less than 30% compared with 82%).


**LOE 1, neutral, fair**
A randomized study with 140 pts with STEMI, comparing monteplase facilitated PCI (n=65) with primary PCI (n=75), followed-up for 2 years. LV function at 6-mo was similar in both groups. Primary endpoint of cardiac death in 2 years was not significantly different; 3.4% vs. 5.3%. However, combination of major cardiac events were less frequent in facilitated PCI; 27.7% vs. 46.7%, p<0.05.


**LOE 5, neutral, fair, n=80**
A retrospective analysis of 80 pts of STEMI with intracoronary thrombus, comparing pts treated by primary PCI alone (n=40) or PCI after intracoronary thrombolysis (n=40). In-hospital mortality was not significant; 8.1% vs. 2.5%. Follow-up (3-6mo) study showed less frequent restenosis in PCI after ic-thrombolysis; 26.7% vs. 9.1% (but not significant), and similar in LVEF; 59% vs. 58%.


**LOE 1, neutral, good**
Metaanalysis on 5882 pts treated in 10 randomized studies testing the hypothesis that early coronary intervention after thrombolysis will reduce mortality. Results: no indication that this procedure will reduce mortality, but also no findings for worse outcomes.


**LOE 2, neutral, fair, n=340**
A non-randomized study with matched pts for 340 pts with STEMI, evaluating combination therapy of prehospital thrombolysis and standby rescue PCI (n=170) with primary PCI (n=170). In-hospital mortality was 4% overall (7 of 170), and 3% in the 155 patients in whom TIMI 3 was obtained. Severe hemorrhagic complications occurred in 14 pts (8%) with 2 fatal cerebral hemorrhages. The matched comparison with primary PTCA showed no significant difference in hospital outcome.


**LOE 1, supporting, poor**
Small randomised study to compare a low dose bolus of tenecteplase (10 mg) before PCI compared to primary PCI (284 pts in total). GP IIb/IIIa antagonists were given to both groups at PCI. The study resulted in a higher rate of IRA patency before PCI and is to small for further conclusions.

**LOE 1, opposing, good, n=4504**
A meta-analysis of 17 RCTs with 4504 pts with STEMI, assigned to facilitated (n=2237) or primary (n=2267) PCI. Comparison was made on TIMI 3 flow before and after PCI, mortality, non fatal re-infarction, strokes, urgent re-intervention rates and major bleedings. Whereas pre-procedural TIMI 3 flow was two-field higher with pre-treatment, differences after PCI regarding TIMI flow and other outcomes were worse with facilitation, particular in the thrombolytic based regimes compared to primary PCI. Strokes (hemorrhagic and ischemic) were also more frequent in the thrombolytic based regimes compared to primary PCI.


**LOE 1, neutral, fair, n=10600**
Analysis of 10600 pts treated with thrombolysis, out of a large MI registry on 34276 pts of STEMI. A total of 487 pts had additional PCI within 61 min to 24 hrs after thrombolysis. This “early PCI” group was compared with remaining 10113 pts with PCI later than 24 hrs or not at all. Unadjusted hospital mortality was 7.2% in patients receiving early PCI, compared to 11.2% in the other group (<0.01). After adjustment for age > 65 years, female gender, an anterior MI and prehospital delay > 3 hrs, there was no difference in mortality. The result was considered as due to patient selection i.e. that early PCI is more frequently used in low risk patients.


**LOE 1, neutral, fair, n=39**
A randomized study of 39 pts with STEMI, comparing pts treated by mutant t-PA (monteplase) facilitated PCI (n=19) with pts treated by primary PCI (n=20). There were no differences in peak CK and rates of major complications and no reflow or distal emboli. Observation over an average of 5.5 months revealed a tendency toward lower target lesion revascularization rates in the facilitated PCI group (17.6% vs. 31.6%) but no intergroup difference in rates of major complications.


**LOE2, supporting, fair, n=153**
A study based on a registry on 153 pts with STEMI, comparing pts treated by facilitated PCI (half-dose reteplase, when cath lab not available < 30 min or necessity of transfer, n=80) with pts treated by primary PCI (n=73). TIMI 2-3 flow at initial angiography was 42% vs. 25% (p=0.03). The overall in-hospital mortality was 3.7 vs. 9.6% (p=NS), and 2.5 vs. 4.5% (p=NS) when patients in shock at admission were not considered. No patient presented with stroke or major bleeding.


**LOE5, neutral, fair**
Randomized study comparing outcome in 86 pts with TNK facilitated angioplasty (immediately after TNK) with TNK alone (84 pts). All pts had high risk characteristics (ant. MI, Killip 3, systolic RR < 100 mmHg, involvement of > 8 leads in the ECG). Endpoint was the composite of death re-infarction, recurrent UAP or stroke at 6 months. The endpoint occurred in 21.7 % of the TNK alone group vs 9.3 % in the combo group (p=0.03) at 30 days and in 24.4 vs 11.6 % at 6 months respectively. Death rate was not different between groups but recurrent UAP was significantly higher with TNK alone at 30 days (18.1%) compared to combo therapy (7.0) p=0.04 and at 6 months 20.7 % vs 8.1 % respectively. Study is supporting the combo strategy for high risk pts with STEMI.


**LOE 5, opposing, fair, n=299**
An ancillary study from data of CAPTIM trial, evaluating cost-effectiveness and event rates (death non fatal MI and stroke) in primary PCI (n=149) and pre-hospital thrombolysis followed by PCI (n=150). The one-year primary endpoint event-rate (death,
non-fatal myocardial infarction, and stroke) was not identical in both groups (14% vs. 16.4%, p=NS). Costs were lower in the primary PCI group either during the in-hospital period and after one-year follow-up.


LOE2, supporting, fair, n=212
A non-randomized comparison of 212 pts with STEMI, comparing pts treated by reduced dose alteplase + abciximab facilitated PCI (n=113) during cath-lab off hours, with patients treated with primary PCI (n=99) during normal working hours. No significant difference was observed in major bleedings, although there was a trend toward a higher risk in the facilitated PCI group. Pts in the facilitated PCI group achieving a basal TIMI 3 flow showed improved myocardial reperfusion and better left ventricular function recovery.


LOE 2, opposing, fair, n=1090
A substudy of 1090 pts from the ASSENT-4 PCI trial, investigating the meaning of ST-resolution at 90-min. presence of Q-waves at first ECG registration and time delay from symptom onset to initiation of treatment and 90-d mortality, in pts treated by tenecteplase facilitated PCI (n=549) and pts treated by primary PCI (n=541). Pts undergoing facilitated PCI presenting >3 h with baseline Q waves also had higher 90-d mortality compared with those without Q waves (10.4 vs. 2.5%, P=0.056). Authors concluded that a fibrinolysis-facilitated PCI strategy was especially harmful in patients presenting beyond 3-hrs from symptom onset with established Q waves on their baseline ECG.


LOE 3, supporting, fair, n=1553
A study based on a retrospective evaluation from a registry data of 1553 pts with STEMI, comparing primary PCI (n=767) with facilitated PCI with transferred after initial treatment with GP IIb/IIIa inhibitor + thrombolysis (n=786). Pts with facilitated PCI had longer door-to-balloon times (162 vs. 113 min), higher baseline TIMI 3 flow rates (52.8% vs. 25.4%; p <0.001), and no increase in major adverse in-hospital outcomes. In pts treated with door-to-balloon times >90 and < or =150 minutes, pts with facilitated PCI had fewer composite major adverse clinical events (combined mortality, re-MI, emergent repeated PCI, hemorrhagic and nonhemorrhagic stroke, and nonintracranial TIMI major bleeding) compared with pts with primary PCI (RR=0.50, p=0.034).


LOE 5, opposing, poor, n=79
A non-randomized study of 79 pts of STEMI, comparing prehospital pretreatment with tirofiban (n=44) with fibrinolysis (n=35) followed by angiography and PCI, if suitable, within 24 hrs. Clinical outcome was worse in pts pretreated with fibrinolysis (bleedings, necessary transfusions) compared with pts pretreated with tirofiban.


LOE 5, supporting, fair, n=47
A non-randomized study on 47 pts with STEMI, comparing pts treated with lower dose mutant t-PA followed by angiography and rescue PCI, if needed, (n=25) with pts treated with primary PCI (n=21). Patients were assigned to 2 treatment groups by ‘one after the other’ method. There was a trend to a smaller end-systolic and end-diastolic volume of the LV in radionuclide tomography and a higher degree of myocardial salvage volume (27.5 vs. 13.6 ml, p<0.05) by treated with thrombolysis without more complications.

LOE3, supporting, fair
Non randomized study comparing early i.v. bolus thrombolysis with t-PA consecutive PCI (n=112), PCI alone (n=83). Time to TIMI-3 flow was shorter with the combination treatment, CK-MB release and peak CK was lower with the combination. There was no difference in 30 day mortality or other complications.


LOE 2, supporting, fair, n=313
A prospective, randomized study of 313 pts with STEMI, comparing pts treated with 50mg alteplase + tirofiban before PCI (n=151) with pts treated with upstream tirofiban before PCI (n=162), and 160 matched patients with acute PCI and provisional abciximab served as a control group. TIMI 2 or 3 flow was demonstrated in 87% in the combination fibrinolysis group, in 42% in the upstream tirofiban group (p < 0.0001) and 29% in the control group. 30-day mortality was 0.7% vs. 5.5% (p < 0.02) and 6.3% in the control group. No differences were assessed in bleeding complications.


LOE 2, neutral, fair, n=374
A study based on a registry data of 374 pts of STEMI, comparing pts treated with primary PCI (n=195) with pts treated with PCI very early after initial thrombolysis (rescue or immediate rescue PCI, n=179). In pts without cardiogenic shock, in-hospital mortality was 3.2% vs. 0.6% (NS) in the rescue PCI group vs. primary PCI group. In a subgroup of pts with cardiogenic shock, the mortality was 36.0% vs. 30.8%. However, after successful PTCA in this subgroup, the mortality rate dropped to 18% and 10%, respectively. Authors concluded that when available, immediate rescue PTCA should be performed in all patients, including patients with cardiogenic shock.


LOE 5, neutral, fair
A study based on a clinical data of a series of 81 pts with STEMI, investigating prognosis of pts with failed thrombolysis determined by ST resolution extent 90-min after initiation of treatment; group 1 (10%-50% STR) vs. absence of resolution group 2 (<10% STR). Total absence of STR proved to be an independent predictor of in-hospital mortality. Long-term major adverse cardiac events occurred more frequently in group 2. It is concluded that the STR assessment before rescue PCI proved to be a good and simple means to predict the short- and long-term prognosis in these patients.


LOE 1, neutral, good, n=606
A randomized study on 606 pts with STEMI, comparing pts treated with 50mg rt-PA followed by immediate rescue PCI (n=302) with pts treated with placebo followed by immediate PCI, if suitable (n=304). No differences were observed in stroke or major bleeding. Left ventricular function was similar in both treatment groups, but convalescent ejection fraction (EF) was highest with a patent infarct-related artery (TIMI-3) on cath lab arrival (62.4%) or when produced by angioplasty within an hour of bolus (62.5%).


LOE 5, neutral, fair, n=3258
A study analyzed from a registry data of 3258 pts with STEMI, comparing mortality with iv-thrombolysis (n=120), ic-thrombolysis (n=441), primary PCI (n=1822) and rescue PCI (n=240, 41 from iv-T and 199 from ic-T) and pts without reperfusion therapy (n=875). The 30-d in-hospital mortality was 12.7% for IV-T, 3.7% for IC-T, 4.8% for primary PCI, 7.9% for rescue PCI, and 14.1% in pts without reperfusion. The covariate-adjusted odds ratio was 0.38 for primary PCI, 0.30 for ic-T, 1.04 for iv-T and 0.77 for rescue PCI.


LOE5, neutral, good
Randomized study comparing rescue PCI with stenting (n=90) or balloon angiography (n=91) in STEMI patients transferred for failed thrombolysis (clinical and/or ECG criteria). Study indicated that stenting salvaged more myocardium than balloon angioplasty. Also mortality at 1 year tended to be lower with stenting (8%) vs 12 % with balloon angioplasty (p=0.35).


LOE5, opposing, good
Early key study (1988) on potential benefit of additional angioplasty after tPA thrombolysis (n=183) or conservative treatment (n=180) resulting in no additional benefit for the combination treatment. In contrast outcome was more favourable with conservative treatment regarding 14 days mortality bleeding complications, ventricular fibrillation and mortality (3 % vs 7 %). Facilitated PCI also lead to 7 % sustained re-occlusion and a high rate or recurrent ischemia during the first 24 hrs (17%).


LOE 1, opposing, good, n=725
A meta-analysis from 4 RCTs with 725 pts with STEMI, comparing efficacy and safety of a combination GP IIb/IIIa-thrombolytic therapy (n=424) with a GP IIb/IIIa inhibitor treatment alone (n=301) for a facilitated PCI strategy. Combination therapy-facilitated PCI was associated with a 2-fold increase in TIMI-3 flow upon arrival. However, it was similar between the 2 groups after PCI. Major bleeding events significantly increased in the combination therapy group (9.5% vs. 4.7%, RR=2.2; p=0.007). The 30-d mortality and 30-d re-MI rate were similar in both groups.


LOE 2, supporting, fair, n=69
A research correspondence concerning on the results of PACTOR Pilot Trial; a registry results from small groups of patients; group A as thrombolysis only (n=20), group B as half-dose thrombolysis followed by PCI (n=22) and group C as primary PCI (n=27). Ischemic time was shortest in group B (270 vs. 165 vs. 221 min, p<0.002). The differences in other clinical outcome were statistically insignificant.


LOE5, neutral, fair
Registry data on 362 consecutive patent treated with thrombolysis who had angiography within 90 Min. 60% of pts had TIMI 3 flow and were treated conservatively (in hospital mortality 4 %), 9 % had TIMI 2 and 31 % TIMI 0-1 flow. In these pts rescue PCI was attempted in 85.8 % (mortality 5.5 %, 20 % with failed PCI, 4 % with successful PCI). 8-year survival as well as MACE was identical between groups during follow up (lysis only or rescue PCI).

LOE 5, neutral, good, n=164
A randomized study in 164 pts with STEMI, comparing outcome of pre-hospital half-dose reteplase + abciximab thrombolysis with (n=82) or without (n=82) additional PCI. The infarct size was lower in pts with PCI compared to pts without PCI (5.2% vs. 10.4%; p=0.001). Complete ST-segment resolution was more frequent in pts with PCI than in pts without PCI (80.0% vs. 51.9%; p<0.001). After facilitated PCI, there was a trend towards a lower event rate in the combined clinical endpoint; complete ST-segment resolution, event rate composite of death, re-infarction, major bleeding or stroke at 6 months (15% vs. 25%, p=0.10, RR=0.57).


LOE 2, supporting, fair, n=300
An analysis from the randomized trial of Leipzig Prehosipital Fibrinolysis Study. Pts with STEMI were randomized to prehospital combination fibrinolysis (half-dose reteplase + abciximab; n=82, group A) or prehospital initiated facilitated PCI (n=82, group B), and a control group of pts with primary PCI (n=136, group C) was prospectively assessed with regard to ST segment resolution (STR) at 90-min and clinical outcome (death, re-MI and stroke) at 6 months. Complete STR was highest in group B (80%, p<0.001) than in group A (52%) and group C (52%). Complete STR resulted in lower event rates for the combined clinical end point of death, myocardial reinfarction, and stroke compared with intermediate and no STR.


LOE 3, neutral, fair, n=90
A non-randomized study of 90 pts with STEMI. Pts were assigned as primary PCI before Mar 1999 (n=37) and as mutant t-PA (monteplase) facilitated PCI after Apr 1999 (n=53). Pts with facilitated PCI acquired earlier reperfusion estimated by STR at 60-min after admission and higher TIMI 2/3 flow rate (75% vs. 35%, p<0.0001), compared to pts with primary PCI. Subacute thrombotic occlusion occurred in 2 pts with facilitated PCI and 3 in primary PCI (NS). One patient in each group died from pump failure (NS). No severe bleeding complication was found in any patient.


LOE 2, neutral, poor, n=65
A non-randomized study on 65 pts with STEMI aged between 75 to 80 years, comparing 3 treatment strategies; primary PCI (n=26), facilitated PCI with half-dose mutant t-PA (n=24), and facilitated PCI with standard mutant t-PA (n=15). Pts were assigned to each treatment strategies according to the month of admission. The rate of acquisition of TIMI-3 flow on initial CAG was significantly lower in primary PCI group than in the other two groups (7.7% in the primary PCI vs. 60% in the half + PCI and 66.7% in the standard + PCI group). The incidence of hemorrhagic complications including blood transfusion was not significantly different between primary PCI and facilitated PCI.


LOE 1, opposing, good
This randomized study compares three strategies thrombolysis (SK) only (n=)), thrombolysis (with SK) during transport to PCI (n=100, facilitated group) and transport to PCI (n=101). All pts were first .... in community hospitals. The primary composite endpoint of death re-infarction and stroke was less frequent with primary PCI (8%) compared with the .......... group (15 %) and the thrombolysis only group (23 %) mainly due to a lower rate of re-infarction in the primary PCI group. Bleeding rate with facilitated PCI was increased compared to the other groups.

LOE 1, opposing, fair, n=70
A randomized study on 70 pts with STEMI, comparing treatment with reduced dose alteplase + abciximab followed by immediate rescue PCI (n=34) and primary PCI with adjunct abciximab (n=36). In the rescue PCI group, TIMI-3 flow was achieved in 65% compared to 25% in PPCI group at first CAG (p=0.001). MACE at 1-mo were not significant (15% vs. 11%; p=NS), but there was a trend toward more events in the facilitated PCI group at 6-mo (32% vs. 14%; p=0.066), particularly in target vessel revascularization.