### WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care

**Worksheet author(s)**

Marc Claeys  
Michael Kurz  

**Date Submitted for review:** 30/01/2010

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#### Clinical question.

In patients with suspected STEMI in the emergency department setting (P), does the use of PTCA (I), compared with fibrinolytic therapy (C), improve outcome (eg. arrhythmias, infarct size, ekg resolution, survival to discharge, 30/60 d mortality) (O)?

**This question addresses an intervention/therapy?**

Old topic for revision: worksheet 234 in 2005

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#### Conflict of interest specific to this question

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet?

The author has received non-significant honorarium (<2000€) from Lilly. These relationships will not prevent the author from providing an unbiased opinion on the scientific question above

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

PubMed: myocardial infarction (MESH) AND thrombolytic therapy (MESH) AND angioplasty (MESH)  
Cochrane library: myocardial infarction (MESH) AND thrombolytic therapy (MESH) AND angioplasty (MESH)

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#### State inclusion and exclusion criteria

- **inclusion:** patients acute myocardial infarction eligible for reperfusion therapy. Studies comparing thrombolysis versus angioplasty  
- **exclusion:** facilitated PCI, cost analysis, abstracts only studies, not peer reviewed, not answer question

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#### Number of articles/sources meeting criteria for further review:

- Manual selection of 45 artikels out of collection of 143 papers.
## Summary of evidence

### Evidence Supporting Clinical Question

<table>
<thead>
<tr>
<th>Good</th>
<th>Evidence Supporting Clinical Question</th>
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</table>
* Fosbol, AHJ 2008, B/E  
Hasdai, JACC 2000, B/D/E  
Holmes JACC 1999  
Hartwell, Health Techn Ass. 2005, B/E  
Kent AMJ 2007, B  
Magid JAMA 2000, B  
Magid JAMA 2005, B  
Mehta, AHJ 2004, B/E  
Moreno, JACC 2002, E  
Zahn AJC 1997,B  
* Zahn AHJ 2001,B  
Duane, circ 2006  
Kinn J Cath cardiov Diag 1997, E  
Pinto, circ 2006, B |
| * Andersen, NEJM 2003, B/E | Boersma, EHJ 2006,B/E  
* Dalby, Dalby 2003, B/E  
deBoer, Circ 1994, E  
deBoer, JACC 1994, B/E  
* Di Mario, Lancet 2008, B/E  
Grines, AMJ 2003, B/D/E  
Grines, NEJM 1993, B/D/E  
* Grines, JACC 2002, B/D/E  
Gusto, NEJM 1997, B/E  
Hochman, NEJM 1999, B  
Hochman JAMA 2001, B  
Keeley, Lancet 2003, B/D/E  
* Thune Circ 2005, B  
Timmer Arch Int Med, 2007, B/D  
Zijlstra NEJM 1999, B/E |
| * Boersma, EHJ 2006,B/E |  
* Dalby, Dalby 2003, B/E  
deBoer, Circ 1994, E  
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| Timmer Arch Int Med, 2007, B/D |  
Zijlstra NEJM 1999, B/E |
| Zijlstra NEJM 1999, B/E |  
* Zijlstra NEJM 1993,E  
* Svensson, AHJ 2006,E  
* Widimsky EHJ 2000,E |
| Fair | Agati, JACC 1998,E  
Veen AJC 1999,E |
| Poor | Karam, JACC 1996, E |

### Level of evidence

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* with transfer to PCI centre
### Evidence Neutral to Clinical question

<table>
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<tr>
<th>Level of evidence</th>
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* with transfer to PCI centre

### Evidence Opposing Clinical Question

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<td>Steg circ 2003, B/E</td>
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<td>Fair</td>
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* with transfer to PCI centre
**REVIEWER'S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:**

<table>
<thead>
<tr>
<th>Thrombolytic therapy versus primary PCI (without transfer)</th>
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<tr>
<td>Mechanical reperfusion strategies for AMI have been introduced and tested from end of the eighties. Initial studies comparing thrombolytic therapy (TT) with primary percutaneous coronary intervention (PPCI) demonstrated improved infarct related vessel patency (TIMI 3: 50-60% versus 85-90%), accelerated myocardial reperfusion (complete (&gt;70%)ST resolution: 35% versus 27%) smaller infarct size, better left ventricular function, less late potentials and lower rate of re-oclusion in patients receiving PPCI. (2,24, 28) Subsequent randomized clinical trials could demonstrate a clinical benefit of PPCI over TT: the meta-analysis of 23 randomized trials including 3867 PCI pts and 3872 thrombolysed patients showed that PPCI was more effective than TT in reducing death (RR 22%, 7% vs 9%) reinfarction (RR 57%, 3% vs 8%) and stroke (RR: 50%, 1% vs 2%) (25). The benefits appear to sustain for 6 months. This data were confirmed in a later meta-analysis of Hartwell (19). PP resulted in a more than 50 % RR reduction in mechanical complications, including mitral regurgitation and VSR (27, 32) The relative effect varied however across the trials according to the thrombolytic agent used, the delay in performing PCI and the recruitment rate (16,17).</td>
</tr>
<tr>
<td>Large registries showed mortality benefit of primary angioplasty over thrombolysis for most subgroups, however absolute benefit is dependent on initial baseline risk profile: as mortality increases, the absolute benefit of primary angioplasty increases also (39,43) Following specific subanalysis can be highlighted:</td>
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<tr>
<td><strong>Time issue:</strong></td>
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<td>The absolute mortality reduction by PPCI widens over time (1.3% 0-1h to 4.2% &gt;6h after symptom onset) (6) The absolute mortality reduction by PPCI was significantly higher for those with &lt;35min versus &gt;35 min PPCI related time delay: 5.4% versus 2.0% (6) The hazard associated with longer treatment related delay also increases with higher baseline risk profile. This indicates that recommendation for reperfusion strategies should use more a time window rather than one time point (24,34).</td>
</tr>
<tr>
<td><strong>Cardiogenic shock</strong>; early revascularization results in an improved survival (e.g. 50% vs. 63% at six months) (21,22)</td>
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<tr>
<td><strong>Age</strong> does not affect long term effect of primary angioplasty compared with thrombolysis (15,31)</td>
</tr>
<tr>
<td><strong>Hospital related issues:</strong></td>
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<tr>
<td>* Presentation during off-hours is common and is associated with substantially longer times to treatment for PPCI but not for fibrinolytic therapy. (30)</td>
</tr>
<tr>
<td>* Primary PCI at hospitals without on-site cardiac surgery, is associated with better clinical outcomes for 6months as compared with thrombolytic therapy (5)</td>
</tr>
<tr>
<td>* Volume: AMI patients treated at hospitals with high (&gt;49)or intermediate (17-48) volumes have lower mortality with PPCI than with TT, whereas STEMI pts treated at hospitals with low angioplasty volume (&lt;17)have similar mortality outcomes with PPCI or TT. (29)</td>
</tr>
<tr>
<td><strong>AMI in CABG patients:</strong></td>
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<tr>
<td>One non-randomized study couldn’t demonstrate a significant difference between PPCI vs. TT in in-hospital mortality rate or the combined endpoint of death and non-fatal stroke (33)</td>
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<tr>
<td><strong>AMI in diabetes patients:</strong></td>
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<tr>
<td>The beneficial effect of PPCI over thrombolysis in diabetic patients are consistent with the effects in non-diabetic patients as was shown in pooled analysis of 19 trials comparing TT with PPCI covering a total of 877 diabetes patients. (37)</td>
</tr>
<tr>
<td><strong>AMI in renal failure:</strong></td>
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<tr>
<td>one small non-randomized suggested that TT might be better than PPCI.(13)</td>
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</table>
**Trombolysis versus transfer for PPCI**

Time delay related to transfer for PPCI may offset the benefit of PPCI over thrombolysis. This issue has been studied in several randomized trials. Meta-analysis of 6 clinical randomized trials, including a total of 3750 patients showed a clinical benefit of PPCI versus on-site thrombolysis in terms of reinfarction (RR 68%) and stroke (RR 56%). There was a trend to lower mortality rate (RR 19%). Transfer times were <2h. (8, 15,18, 41)

Additional subgroup analysis revealed a significant interaction between risk status and effect of PPCI. In the low risk group, there was no difference in clinical outcome whereas in high risk group outcome including mortality reduction was substantial.(12, 26,38,39)

Recent data suggest that a strategy of prehospital TT (with transfer to interventional centre with option for rescue) might be as effective as primary PCI. (7,9, 36)

**Acknowledgements:**

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**Citation List**

Reference List


   (LOE 1, Quality Good, Supporting, Summary: GUSTO IIb Angioplasty substudy data. Multicenter, multi-national RCT of PCI vs Alteplase and UFH vs Hirudin for STEMI. N=1138. Compositve endpoint at 30 day with stratification for death, re-infarction, CVA, bleeding. Core lab confirmation of PTCA success. Table 1 characteristics largely similar among both groups. PTCA shown to be favorable for composite endpoint (9.6% vs. 13.7%) @ 30 days. Mortality benefit in composite non-significant. 6 month difference non-significant. Study concludes some moderate short-term benefit and should be considered if performed at expert high volume centers.)


   (LOE 2, Quality Fair, Supporting, Summary: Relatively small n=60, cohort study examining PPCI vs. tPA. Not a RCT. Greater than 2/3 were LAD lesions. Patients with clinical failure or without TIMI 2/3 flow @ 1 month excluded. Microvascular perfusion assessed via intracoronary microbubbles. No differences in table 1 characteristics (including infarct size before reperfusion). Wall Motion Score Index (WMSI) and Contrast Score Index (CSI), for endpoints, not clinical outcomes. Demonstrated PPCI had significant improvement in microvascular perfusion and preventing infarct extension at 1 month, but NO difference in TIMI 3 flow.)


   (LOE 1, Quality Good, Supporting, Summary: Large (n~1500) Multicenter Danish RCT of onsite TT or Transfer for PTCA must be completed within 3 hours. TT patients received repeat TT before rescue angioplasty. Outcome was combined Death, reinfarct, or CVA. Randomization occurred at both non and PCI capable center. Table one characteristics similar among both group. 40% Reduction in composite endpoint for PTCA was largely driven by 75% reduction in re-infarction, other outcomes not significant. Benefit among all durations of symptoms. Among those with re-infarct, mortality jumped 4 fold.Trial stopped at 3rd interim analysis for demonstrating PTCA clearly superior, even with transfer.)

(LOE 1, Quality Fair, Neutral, Summary: WEST investigators. Multicenter RCT of STEMI patients (n=304) to TNK, TNK plus mandatory angiography, or PCI. Designed as a non-inferiority study for TNK arms to PCI. Table one similar. MACE, CHF, Shock, or Ventricular arrhythmia outcome. Trend toward difference in MACE between TNK and PCI and no difference between TNK plus mandatory angiography and PCI but not powered for such.)


(LOE 1, Quality Good, Supporting, Summary: C-PORT data. Multicenter RCT comparing IHT vs. PCI w/o onsite cardiac surgery. 451 patients enrolled. Extensive training prior to beginning. Beyond randomization, intention-to-treat. Table one similar. 10% did not receive TT, 5% no PCI. Outcome 6 month MACE and duration of hospital stay. Significant improvement in 6 week outcome and outcomes for PCI without surgery back-up vs. TT. Significantly underpowered. Study stopped @ 451 despite goal of 2250 because of funding.)


(LOE 1, Quality Good, Supporting, Summary: Meta-analysis of 22 trials (including GUSTO, DANAMI 1 and 2, CAPTIM, STOPAMI 1, STAT, etc.) back to individual patient data (n=6763) focusing on time-to-treatment rather than one method over another. Regression analysis focused on treatment, treatment delay (split into presentation delay, and PCI related delay), and 30-day mortality. Absolute (5% for FL vs 2.4% for PCI) and relative reduction (67% vs. 28% per/Breslow day) in mortality was best for efficient PCI centers (<35min delay, D2B < 65 min) in PPCI group and the absolute reduction widened over time (4.2% vs. 1.3%) KEY STUDY)


(LOE 1, Quality Fair, Neutral, Summary: RCT in France conducted by SAMU multicenter. Usual appropriate STEMI Pre-hospital FL w/ routine transfer for failure vs. PCI. N=840/1200 (terminated for funding). Balanced Table 1 characteristics. MACE endpoint, intention to treat analysis. 99.6% available for follow-up. 130 min to FL 190 min to PCI. No statistical difference in outcomes.)


(LOE 1, Quality Good, Supporting, Summary: Meta-analysis of FL vs. transfer for PCI. 6 trials (MAASTRICTH, AIRPAMI, PRAGUE 1 and 2, CAPTIM, DANAMI-2) of 3750 patients. Transfer always less than 3 hours. DANAMI gets most weight (43). MACE or individual endpoints as study specific. MACE reduction of 42% with transfer. > 50% of infarction and CVA with transfer. Trend toward decrease in all cause mortality with PCI. KEY STUDY)


(LOE 2, Quality Good, Supporting, Summary: Retrospective data from the French USIC registry (> 350 ICU’s, 1922 patients) evaluating 1 year survival following pre-hospital and in-hospital thrombolysis, PCI and no reperfusion. Table one same for all populations. 9% treated with pre-hospital thrombolysis (PHT) and mean time to PHT was shorter than IHT, PCI or none. Trend toward Immediate term and 1 year mortality better in PHT, especially with those treated in <3.5 hours form onset.)

(LOE 1, Quality Good, Supporting, Summary: RCT. 301 patients randomized to PCI or streptokinase. Infarct size (estimated by enzyme release) and LVEF via radionucleate stress testing were endpoints. TIMI 3 flow confirmed in 92% of PCI patients within 120 min. Non significant reduction in infarct size. Global and regional wall motion were better in PCI (50 vs 45% and 42 vs 34% respectively). Findings subjectively better in anterior infarcts. Observed differences in wall motion subjectively different in early presenters treated with PCI.)


(LOE 1, Quality Good, Supporting, Summary: Relatively small (n=301, but early) RCT of PTCA vs. strepto. Outcomes in-hospital mortality, recurrent infarct, or composite, and LVEF. Table 1 characteristics largely similar. TIMI 3 flow confirmed in 92% of PCI patients within 120 min. PCI improved all outcomes significantly: in-hospital mortality (7 vs 2% in PCI p 0.024), recurrent myocardial infarction (10% vs 1% for PCI, p<0.001) and either death or nonfatal reinfarction (15 vs 3% for PCI p=0.001). LVEF was 6% better in PCI patients, (44 vs 50%, p<0.001))


(LOE 1, Quality Good, Supporting, Summary: CARESS-in-AMI. International multicenter RCT of absolute transfer vs rescue PCI following TT for STEMI <75 yrs. (N= 600) ½ dose retaplase used for TT common to both groups. Outcome death, reinfarct, refractory ischemia @ 30 days. Intention to treat analysis. Table 1 characteristics of cohorts similar. Mean time from symptom onset to retaplase ~120 min, 42 min from admission to retaplase. Hospital stay 2 days longer for rescue than mandatory PCI. Composite outcome better in mandatory PCI vs elective (4.4 vs. 10.7%). Bleeding and CVA risk same.)


(LOE 3, Quality Fair, Opposing, Summary: ACSIS sub-study of STEMI. Multicenter prospective registry of consecutive STEMI patients treated with TT (mostly strepto, 10% IPA) (18%) or PCI (35%) or no treatment (55.3%). Small Evaluation of patients with renal failure on presentation (n=132). Outcomes at 7, 30, and 365 days. Table one characteristics surprisingly similar except more previous MI in no treatment group. Crude mortality lower in TT group (8.3% vs 40%, 0.03) but all other outcomes including composite 30day mortality or reinfarction non-significant.)


(LOE 2, Quality Good, Neutral, Summary: Multicenter Retrospective cohort study of 3145 pts (1050 PTCA and 2095 TT) from MITI registry 1988-1994 (n=12331). TT group mix strepto (32%), prouro (3%) but alteplase predominate (65%). No difference in Table 1 characteristics. Time to treatment sig. different (TT 1 hour vs 1.7 for PCTA). Subanalysis done for volume of PCTA showing no difference. TT group 74% underwent subsequent angiography with 32% receiving PTCA. No difference in mortality for either group during index or at 3 years. Cost for TT group lower during hospitalization and at 3year follow-up.)

(LOE 2, Quality Good, Supporting, Summary: DANAMI-2 Substudy across age groups to determine if relative risk for elderly patients was different. 1572 patients, Outcomes of total mortality and MACE. Increasing age (split in decade increments) was associated with 2.45 increased hazard ratio and higher combined outcome rate (1.51 hazard ratio). Improvement in long term combined outcome from PCI apparent across all age groups and unaffected by age.)


(LOE 1, Quality Good, Supporting, Summary: Metanalysis of RCT of PTCA vs TT for STEMI trails between 1985-1998. (n~2700) Individual patient data available for all but one study. Outcomes were total mortality, fatal or non-fatal re-infarct, death, CVA, major bleeding, and CABG all defined by individual studies at 30 days and 6months. Patients in each arm largely similar. Mortality at 30 days better for PTCA (4.3 vs 6.9%) and 6 months (6.2% vs 8.2%). Death and Reinfarction at 30 days better for PTCA (7.0 vs 12.9%) sustained at 6 months. Risk of CVA lower for PTCA. Treatment benefit did not vary among defined subgroups, however it did vary by baseline risk (defined in the study).


(LOE 1, Quality Good, Supporting, Summary: One of the very first RCT PTCA vs TT (tPA). Small (large in its day) multicenter, international RCT for STEMI within 12 hours of presentation. Radionuclotide imaging at 24 hours and 6 weeks. Intention to treat analysis. Table 1 largely similar. Mean time to randomization same, mean time to TT 32 min, 60 min to PTCA. 10% of PTCA group did not undergo therapy. 2% intercranial hemmerage in TT, 0 in PTCA. VF more common in PTCA (2% vs 0). 18 percent reduction in recurrent ischemia in PTCA group. Mortality declined by 4% in PTCA group (2.6 vs 6.5%). High risk patients benefitted more (10% mortality in TT vs 2% in PTCA). Mortality <1/2 in PTCA (5.1 vs 12%). EF similar at 6 weeks. 6 month mortality was half for PTCA (8.5 vs. 16.8%).


(LOE 1, Quality Good, Supporting, Summary: Air-PAMI trail. RCT of High risk pt (but no shock) for either on-site thrombolysis or transfer for PCTA. Small N = 183. TT was strepto with UFH or tPA. Outcomes MACE, death, CVA, or revascularization at 30 days. Transfer arm time to treatment was ~100 longer (51 vs. 155 minutes). Cath performed on 55% of TT arm @ 30 days with 52% receiving PTCA or CABG. PTCA had shorter length of stay and less ischemia. Primary endpoint better in PTCA than TT (8.4% vs 13.6%) Study designed for 430, stopped early for poor recruitment before knowing results.)


(LOE 2: review of randomised trials and registries showing mortality and morbidity benefit of PPCI vs TT. In addition the economic analysis favours PCI. Good quality)

(LOE 2, Quality Good, Supporting, Summary: GUSTO IIb Angioplasty substudy data. Multicenter, multi-national RCT of PCI vs Alteplase. Reanalysis of reperfusion choice in patients with known DM and comparison of DM status on PCI patients. N = 1138 (177 DM, 961 without) Outcomes of death, nonfatal MI or CVA at 30 days. DM patients were more often older, female, greater BMI, higher rate of HTN and PVD than non DM. DM had significantly longer time to treatment. In TT group ~ 65% underwent angiography and ~25% received subsequent intervention. In hospital CHF and cardiogenic shock more common for DM, other outcomes were similar among all patients regardless of DM status. DM with PTCA had significantly higher bleeding rates. PTCA reduced in-hospital recurrent ischemia among DM and non DM. Pts receiving PCI had better 30-day outcomes than TT group regardless of DM status. DM status did not independently affect outcome independent of reperfusion type. No difference at 6months, slightly better for DM receiving PTCA at 12 months.)


(LOE 1, Quality Good, Supporting, Summary: Large International Multicenter RCT evaluating CABG or PTCA within 6 hours of randomization vs TT for STEMI. N=302 (150/152) Other adjuncts including IABP left to discretion. Outcome 30 day and 6 month mortality. Concurrent registry to track ineligible patients for bias. Table 1 (comparison with registry) and 2 groups largely similar except TT had larger proportion of previous CABG. Mortality at 30 days similar reflecting high inhospital mortality among population. Mortality at 6 months significantly lower among those receiving PTCA.)


(LOE 1, Quality Good, Supporting, extension of previous study with prolongation of FU up to 1 year. Persistent mortality benefit after 1 year in PCI group)


(LOE 3 retrospective non randomised controled study showing less late potentials with PPCI as compared to TT. Small group of patients. Fair quality


Keywords: Angioplasty/Angioplasty,Transluminal,Percutaneous Coronary/Cardiology/drug therapy/Humans/methods/mortality/Myocardial Infarction/Randomized Controlled Trials as Topic/Reperfusion/Streptokinase/Stroke/therapeutic use/therapy/Thrombolytic Therapy/Treatment Outcome

LOE 1, meta-analysis of 23 trials comparing PPCI vs TT. Positive results in favor of PPCI (mortality and morbidity), good quality

LOE 2 non randomised controled study showing mortality benefit of PPC over TT but benefit depends on baseline risks profile and PPCI-related delay. Good quality


LOE 2: non randomised controled study showing reduction in severe mechanical complications of PPCI vs TT. Good quality


LOE 1: post hoc analysis of randomised trial in diabetes patients showing no benefit of long term outcome (including death) for PPCI vs TT. There was even more risk for reinfarction in PPCI group. Limited number of diabetes patients. Fair quality


LOE 2 non randomised controled study showing mortality benefit of PPC over TT but benefit depends on experience of operator/centre. Good quality


LOE 2 non randomised controled study suggesting that mortality benefit of PPC over TT can be offset during off-hours because of longer door-to-balloon times (whereas door-to-needle times are not affected by time of presentation). Good quality


LOE 2 non randomised controled study showing mortality and morbidity (reinfarction) benefit of PPC over TT also in elderly patients. Good quality


LOE 2: non randomised controled study showing reduction in severe mechanical complication (free wall rupture) of PPCI vs TT. Good quality


LOE 2 non randomised controled study showing similar outcome (mortality and nonfatal stroke) between PPCI and TT in post CABG patients. Good quality

LOE 2 non randomised controlled study showing mortality benefit of PPC over TT but benefit depends on baseline risk profile and PPCI-related delay. Good quality


   LOE 1 post hoc analysis of randomised controlled study showing lower mortality and less cardiogenic shock with TT vs PPCI for patients treated within the first 2 hours. mortality benefit of PPC over TT but benefit depends on baseline risk profile and PPCI-related delay. Fair quality

   LOE 1 meta-analysis of randomised trials in diabetes patients showing consistent mortality and morbidity benefit of of PPCI vs TT, as seen in non-diabetic patients. Good quality

   LOE 1 randomised controlled study showing better TIMI flow 5-7 day after PPCI (=transfer) vs TT. There was a trend to better clinical outcome with PPCI. Small sample size. Fair quality

   LOE 1 post hoc analysis of randomised controlled study showing lower mortality for transfer+PCI vs on-site TT in high risk groups. In low TIMI risk score group outcome was comparable. Fair quality

   LOE 2 non randomised controlled study showing improvement in short ann long term patency in PPCI vs TT. n in severe mechanical complication (free wall rupture) of PPCI vs TT. Fair quality

   LOE 1 randomised controlled study showing lower morbidity for tranfer+PCI vs on-site TT. Relatively small sample size. Fair quality

1997;79:264-269.
"LOE 2 non randomised controlled study showing mortality benefit of PPC over TT. Good quality"

"LOE 2 non randomised controlled study showing mortality benefit of PPC over TT in patients >3h prehospital delays. For shorter prehospital delay there was no significant difference between both treatments. Good quality"

"LOE 1 randomised controlled study showing better infarct artery patency, better left ventricular function and lower morbidity for PPCI vs TT. Small sample size. Fair quality."

"LOE 1 randomised controlled study showing better long term outcome (mortality and morbidity) for PPCI vs TT. Good quality"