Clinical question.

In patients with ST-elevation myocardial infarction identified by emergency medical services personnel in the prehospital setting (P), does the use of direct transport to a PCI centre for primary PCI (I), compared with standard management strategies initially involving transportation to the closest hospital (C), improve outcomes (eg. Infarct size, LV function, reinfarction, cardiogenic shock, survival to discharge, 30/60/1year mortality) (O)?

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

State if this is a proposed new topic or revision of existing worksheet: Revision of existing worksheet.

Conflict of interest specific to this question

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet?  No potential financial/commercial/industrial conflicts of interest.  Potential intellectual conflict of interest: Author Steven Brooks previously authored systematic review on this topic and co-authored a position statement on the prehospital management of STEMI for the National Association of EMS Physicians in the United States.

Search strategy (including electronic databases searched).

These search strategies were initially conducted from 2004 to May 7 2008 to update the C2005 worksheet by Dr. M. Welsford (236A).

OVID Cochrane Controlled Trials register (CENTRAL) and Database of Systematic Reviews

1. exp Emergency Medical Services/
2. exp Emergency Medical Technicians/
3. exp Emergency Medicine/
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62. 49 and 43 and 61

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32 exp Coronary Disease/
33 exp Angina, Unstable/
34 myocardial infarct$.mp.
35 AML.mp.
36 MI.mp.
37 STEMI.mp.
38 acute coronary syndrome$.mp.
State inclusion and exclusion criteria

Inclusion criteria
- Reports of patients with acute ST-elevation myocardial infarction (STEMI) with chest pain <12 hours who were identified by emergency medical services (EMS) personnel in the prehospital environment. Reports describing a treatment group intervention where 12-lead prehospital electrocardiography was used by prehospital personnel to identify STEMI followed by direct transportation from the scene to an interventional centre for primary percutaneous intervention (pPCI).

Exclusion criteria
- Abstract-only publications
- Reports of patients diagnosed by non-EMS personnel in the prehospital setting (e.g. general practitioners offices/medical clinics)
- Narrative reviews
- Commentaries and editorials

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

#### Evidence Supporting Clinical Question

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**Level of evidence**

A = Infarct size  
B = LV function  
C = re-infarction  
D = in-hospital mortality  
E = 30 day mortality  
F = long term mortality  
G = Death/reinfarction/stroke at 30 d  
H = Other composite outcome (see citation list for description (>30 days))  
I = Medical contact-to-intervention time (PCI or fibrinolysis)  
J = 911 call-to-intervention time (PCI or fibrinolysis)  
K = Door-to-intervention time (PCI or fibrinolysis)  
L = Symptom-onset-to-intervention (PCI or fibrinolysis)  
M = Hospital stay  
N = Cardiogenic shock
### Evidence Neutral to Clinical question

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### Evidence Opposing Clinical Question

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L=symptom-onset-to-intervention (PCI or fibrinolysis)
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N=cardiogenic shock
Approximately 40% of patients with myocardial infarction (MI) are initially cared for and transported by emergency medical services (EMS). Controversy exists about how EMS systems should facilitate timely coronary reperfusion in ST-segment elevation myocardial infarction (STEMI) patients and significant practice variation is evident.

Primary percutaneous coronary intervention (PCI) appears to be superior to in-hospital fibrinolysis for most patients with STEMI. However, traditionally, EMS protocols for chest pain involve transportation of patients to the closest hospital, most of which do not have PCI facilities. As defined in the 2004 STEMI guidelines by the American Heart Association and by the American College of Cardiology, skilled PCI facilities include interventional cardiologist operators who perform more than 75 primary PCI cases per year, and catheterization lab support team members who experience more than 36 primary PCI cases per year. Patient outcomes have been found to be associated with operator and facility volume.

Urgent transfer of patients from community hospitals to primary PCI facilities is one potential method of improving access to primary PCI. However, data from the National Registry of Myocardial Infarction in the United States suggest that interhospital transfer delays are excessive and may limit the feasibility of this strategy in many North American communities. This registry has demonstrated a median time from presentation at the first hospital to PCI at the second hospital of 180 minutes, which greatly exceeds the current American Heart Association recommendations for a medical contact-to-balloon interval of less than 90 minutes. Data from European studies such as the DANAMI and PRAGUE studies suggest that this strategy may be more feasible in European communities with higher population density and shorter interhospital transport times.

Triage of STEMI patients by EMS personnel and direct transport to PCI-capable centres, bypassing closer non-PCI centres as necessary is an alternative strategy which aims to increase access to primary PCI. The American Heart Association, based on the 2005 ILCOR CoSTAR process found inadequate evidence to support a strong recommendation for this practice. At the conclusion of the 2005 evidence review, the ideal strategy for patients who are diagnosed with STEMI by emergency care providers in the prehospital setting remained unclear.

With this review, we set out to update the 2005 literature search to present day and reconsider the consensus on science and treatment recommendations. Again, we have found that the data derived from direct comparisons of strategies for patients diagnosed with STEMI by EMS personnel are sparse. The most important update to the data was a before-after study reported by LeMay and colleagues (LeMay, 2006, 1329) from Ottawa, Canada. The study involved the implementation of a regional STEMI protocol in which paramedics were trained in 12-lead ECG interpretation and bypassed the nearest emergency room and referred patients with suspected STEMI directly to a designated primary PCI center. Outcomes of these patients were compared with a retrospective cohort of 225 consecutive patients with STEMI transported by ambulance to the nearest hospital. Most patients in the control group (80.4%) received in-hospital fibrinolysis. In the bypass group, 93% received primary PCI. The inhospital mortality was 1.9% in the bypass group versus 8.9% in the historical controls. Although impressive, the conclusions of this study are limited by it’s before-after design, specifically it’s inability to control for the Hawthorne effect and secular trends over time.

The bulk of supportive data for this strategy must be extrapolated from comparisons involving STEMI patients assessed and initially diagnosed in the emergency department. Within the studies listed as LOE 5 in the evidence table above, there are two types of comparisons:

1. Immediate in-hospital fibrinolysis versus interhospital transfer for pPCI in STEMI patients diagnosed in an emergency department and,
2. STEMI patients diagnosed in the prehospital setting and taken directly to PCI centres for pPCI versus STEMI patients diagnosed in an emergency room who are transferred for primary PCI.

Although reasonable extrapolations and hypotheses can be developed on these data as they pertain to the optimal strategy for the STEMI patient diagnosed in the EMS prehospital setting, there are several reasons why this may be misleading. Compared with patients who self-transport to the ED, patients who call EMS with acute coronary syndrome tend to have had a shorter duration of symptoms before seeking medical care, and are more likely to have a previous history of cardiac disease. They are older, more likely to be female and receive more aggressive management when they reach the hospital. There are many feasibility and safety issues that are unique to the management of STEMI patients in the prehospital setting. These include the diagnostic ability of prehospital providers, the ability to safely administer prehospital fibrinolysis, potential transport delays associated with diversion to a PCI centre, and the ability of a system to effectively activate PCI resources from the prehospital setting.

The strength of any treatment recommendation on this topic needs to be attenuated because of these concerns. The primary limitation being that there is only one before-after comparison providing direct supportive evidence for this strategy.
Because of the nature of prehospital care, the relative benefit of diversion to primary PCI versus transportation to the closest hospital is very likely to be dependent on a host of particular local variables, such as geography, the relative distribution of hospitals within a region, EMS system configuration and the quality of STEMI management at each of the local hospitals. The results from any investigation exploring this issue need to be considered carefully in the context of local conditions. The decision analysis by Wang et al. (Wang, 2009, 233), demonstrates this with sensitivity analyses showing that the relative benefit of one strategy over another changes depending on best or worst case scenarios for fibrinolysis and PCI quality of care.

Future research needs to provide direct comparisons of direct transport for pPCI with alternative strategies including including prehospital fibrinolysis and pharmaco-invasive strategies. Future trial design should incorporate specific analyses of patients who present within 2-3 hours of symptom onset, because there is some evidence that these “early presenters” may have more relative benefit from fibrinolysis. The impact of other clinical characteristics on the relative benefit of one strategy over another needs to be explored to determine whether the approach needs to be tailored on a patient by patient basis.

Acknowledgements:

### Citation List


**LOE 5, Good quality, Supportive.**

**DANAMI-2 Study from Denmark**

- fibrinolysis in-hospital (tPA) versus transfer for PCI ;
- 1129 patients recruited in referral hospitals (also included arm of fibrinolysis vs PCI in PCI hospital)
- long 50 minute delay to transportation time (even though randomized on ambulance stretcher and used same crew)
- 30-day composite outcome
- statistical improvement with PCI (study stopped early because reached end-point): 8.5 versus 14.2 composite endpoint (p=0.002)
- difference driven by rate of reinfarction: 1.6 percent in the angioplasty group vs. 6.3 percent in the fibrinolysis group, p<0.001)
- non-significant difference in mortality; 6.6 percent vs. 7.8 percent, P=0.35
- up to 3 hours transfer but 96% were within 2 hours; so can only generalize for up to 2 hours transfer time.
- MD went with patient
- failed fibrinolysis treated with second dose
- 4% were deemed unable to tolerate being transported
- transport: a fib 14, AVB 13, VF 8; no deaths, 1 death soon after arrival at receiving facility 1 of 559, and 8 more not transferred;


**LOE 5, Quality fair, Neutral**
Outcomes reported: Primary outcome is a composite outcome of death, refractory ischaemia, congestive heart failure, cardiogenic shock and major ventricular arrhythmia (no difference). Medical contact-to-first study drug, Medical contact-to-PCI (exact time point undefined).

Difficulty with this study for interpreting results as it applies to this question because clinical outcomes (e.g. composite endpoint) are reported for the entire group which includes patients randomized in both the prehospital and in-hospital settings. For the combined prehospital and inhospital randomization groups - no difference between group A (fibrinolysis) and group C (primary PCI).


LOE 1, Good quality, Neutral

CAPTIM
Outcomes reported: composite outcome of death, re-infarction, or disabling stroke within 30 days, secondary outcomes
- France; Lyon
- mobile ICUs with MDs on board
- prehospital fibrinolysis (tPA) versus primary PCI; all transported to PCI centres;
- fibrinolysis group - 26% had rescue angioplasty (very high)
- excluded if transfer greater than an hour
- stopped early; recruited 840 of 1200 planned; poor recruitment & financial
- nonsignificant improvement in 30 day composite with PCI; 8.2% in the prehospital-fibrinolysis group and 6.2% in the primary-angioplasty group (risk difference 1.96, 95% CI -1.53 to 5.46);
- nonsignificant decrease in mortality in fibrinolysis (even greater strong trend in those treated in first 2 hours of symptoms - almost significant (30 day mortality 2.2% versus 5.7%, p equals 0.058).
-Problem with generalization - all patients were transported to PCI centres as "standard care" -- i.e. all patients bypassed closer non-PCI hospitals


LOE 1, quality good, Neutral
Trend towards better outcomes with PCI among diabetics, but not statistically significant
Outcomes reported: Composite death, non-fatal MI, re-infarction, and non-fatal disabling stroke within 30 days

LOE 5 (bypass to PCI is intervention, but comparison group is patients transported by EMS to PCI centre and had diagnosis made in ED i.e. NOT STEMI patient in the prehospital setting, same issue as with Clemmensen series), Quality good, Supportive - shortened symptom onset to first balloon inflation, door to balloon time, neutral for in-hospital mortality re-infarction, cardiac arrest, stroke


LOE 5, quality poor, supportive outcomes hospital arrival to procedure start

Implementation study from Copenhagen where all ECGs recorded in the field transmitted to cardiologist hand-held computer and decision on whether to bypass closer hospitals for PCI made. 408 ECGs transmitted - 113 diverted for PCI. Compared in-hospital treatment times to a poorly defined group of "DANAMI-2 controls" not otherwise described. We assume this means the group diagnosed in hospital and transferred for pPCI in the DANAMI study. For the purposes of this worksheet then, this is considered an extrapolation because the comparison is made with STEMIs diagnosed in-hospital, not prehospital -- different population. Bottom line - diversion to pPCI was shown to be feasible in this study using transmission of pECG to cardiologists handheld and showed improved door to reperfusion times compared to a group of patients diagnosed in the hospital in another study.


LOE 5, good quality, Supportive, Outcomes combined death, re-infarction and stroke, as well as these outcomes reported individually

metaanalysis of trials comparing transfer for pPCI vs. immediate lysis
• transfer of STEMI patients for PCI (from non-PCI facilities) versus immediate fibrinolysis.
• heterogeneity and funnel plot analysis done; overall sound statistical analysis
• Outcomes of the trials were not uniform. 30 day composite was primary in 4, secondary in 1, and the last used a 42 day different composite score. However, the analysis was able to tease the three different outcomes (although 30 and 42 day considered the same).
• Some arms of the studies which weren't directly related were removed (and both analyses were done to compare)
  • CAPTIM was a prehospital fibrinolysis and was included (little different from other 5 articles)
  • different agents used for fibrinolysis: SK and tPA
  • significant reduction in composite endpoint; and reinfarction;
  • nonsignificant reduction in mortality


LOE 5, quality good, outcomes 30 day mortality (supportive), re-infarction (supportive), stroke (supportive).
This is a methodologically sound systematic review of RCTs comparing immediate on-site fibrinolysis with interhospital transfer for pPCI. Therefore, this is LOE 5 for the purposes of this review.


LOE 4, Quality good, Supportive, Outcomes door-to-ballon time, 30 day mortality, major bleed, revascularization, reinfarction, stroke


LOE 5, Good quality, Supportive for Outcomes hospital length of stay, re-infarction, neutral for combined 30 day death, re-infarction, stroke at 30 days

Air-PAMI
- NA & Europe
- stopped early due to poor recruitment; therefore not enough power to show difference
- tPA(NA) or SK(europe) versus transfer for PCI
- transport by land and air of high risk STEMI patients; (age > 70, HR > 100, SBP 80-100, Ant AMI, ECG with LBBB, Killip class II/III
- no significant adverse events during transfer
- non-significant (under powered) reduction in combined 30 day endpoint with transfer for PCI
- time delay in initiating transfer was long; mean 52 minutes (median 38)
- did not indicate level of training of transfer personnel eg: EMT-P or MD on board


LOE 5, Quality fair, Supportive re feasibility and supportive by extrapolation of a strategy of direct transportation to PCI center vs. transportation to closest hospital for subsequent transfer, supportive for outcomes including initial hospital arrival to open artery, supportive for in-hospital mortality

Designated LOE 5 for this question because comparison groups are patients diagnosed in the hospital setting. It is known that prehospital diagnosis improves treatment times and therefore the comparison here does not allow examination of whether the diversion directly to PCI is likely to be the active factor in causing the observed benefit.


LOE 3, Quality good, Supportive, Outcomes in-hospital mortality (supportive), hospital arrival to first balloon inflation (supportive), median hospital length of stay (supportive)

LOE 5, quality good, outcomes door-to-balloon time interval (supportive), in-hospital mortality (neutral), re-infarction (neutral), stroke (neutral), cardiogenic shock (neutral), major bleeding (neutral).

LOE5 because comparison is for ACPs with prehospital 12 lead ECGs and direct transfer to pPCI versus referred in from ED to pPCI (no prehospital diagnosis in most cases).


LOE 5, Quality good, Supportive for treatment delay (sx onset to PCI start), neutral for in-hospital mortality benefit

LOE 5 because this cohort study compares prehospital ambulance triage and diversion to PCI with walk-in and ambulance patients diagnosed at referral hospitals and then transferred and those diagnosed in the PCI hospital ED.

Shock sub-group (reported separately in Ortolani 2007) supportive for all-cause mortality benefit


LOE 5, Quality good, Supportive for all Outcomes LV ejection fraction, all-cause mortality in-hospital and at one year

Study involving STEMI patients with cardiogenic shock on first assessment. Also similar to Clemmensen series of articles, control group was not diagnosed in prehospital setting. Cohort study comparing prehospital triage and diversion to PCI vs. "conventional triage" which included walk-ins and EMS arrivals to PCI hospital and spoke hospitals with first ECG in the ED.


LOE 5, fair quality, supportive for primary 911 call to PCI, door to balloon, neutral for in-hospital mortality

Cohort study with retrospective controls from DANAMI-2. Comparison between a group of patients who have prehospital 12-lead ECG transmitted to cardiologist and are transferred directly to pPCI vs. historic controls in DANAMI-2 who have there first ECG and dx of STEMI in an emergency department and are then transferred for pPCI.

LOE 5, Quality poor, Supportive, Outcomes door-to-PCI,

Pilot data which matches data from the same implementation system as Clemmensen and Sejersten


CAPTIM subgroup analysis
• LOE 1? (subgroup analysis of CAPTIM RCT -- this needs to be clarified what to do with subgroup analyses), Good quality, opposing for cardiogenic shock/neutral for combined death, re-infarction, stroke and mortality alone (trend towards lower mort and cardiogenic shock in those with sx <2 hours who get lysis vs PCI
• posthoc analysis
• looking at < 2 hours from symptoms versus > 2 hours
• no significant difference but trend of less mortality with thrombolysis in < 2 hours


LOE 2, Quality poor, neutral regarding outcomes symptom onset to balloon inflation, door to balloon time, In-hospital deaths, deaths within six months

Quality judged as poor because: unable to determine if all eligible patients included in study (great possibility of selection bias for entry into study), unclear on nature of "prehospital diagnosis" -- may have included diagnosis at non-EMS GPs office. Important patient characteristics not reported or controlled for. Comparison of interest for this project was "Group B" which was a group of patients with prehospital diagnosis and initial admission to local hospital with subsequent transfer and "Group C", patients with prehospital STEMI diagnosis and direct transportation for pPCI from prehospital setting. Unfortunately, hypothesis testing between these two groups not performed and therefore the statistical significance of observed differences cannot be determined by reading the paper (this is why this paper is listed as being "neutral" as opposed to supportive).


LOE 2, quality poor, outcomes reported 30 day and 1-year mortality (neutral), re-infarction (neutral), stroke (neutral).

LOE 5, Quality good, outcomes LVEF (neutral), % of patients with LVEF <40% (supportive), 30 day mortality (neutral), 1-year mortality (supportive)


LOE 5, Good quality, neutral for efficacy

MAASTRICHT
Netherlands
• randomized; three arms (approx 224 patients)
• thrombolysis (tPA); thrombolysis and transfer +/- rescue tPA; transfer for primary PCI
• primary outcome: death or recurrent infarction in 42 days
• small study showed feasible and safe; non significant reduction in outcome with primary PCI - precursor to doing larger studies
• adverse events during transfer: no deaths, 2 defib for ventricular arrhythmias, 2 atropine for brady; 6 had iv nitro turned down because of hypotension; 3 didn't undergo transport
• transport times up to 1 hour only


LOE 5, quality fair
This is a decision analysis using data from previous studies to model outcomes for STEMI patients identified in the prehospital setting if they were to undergo transportation to the closest hospital for fibrinolytic versus diverting to further hospitals for PCI. Based on a number of assumptions not based on actual data including the distances of PCI centres, lack of complications en route with longer transport times, that the local hospitals will provide fibrinolysis instead of transferring for PCI. Primary outcome 30-day survival. The analysis shows "small but uncertain" benefit with diversion for pPCI. This results was sensitive to whether or not the fibrinolysis process was assumed to be standard or "best-case scenario" (e.g. very rapid with best outcomes). My interpretation of this is that the benefit of one strategy over another may be region-specific and needs to be examined in each case -- better strategy will depend on best achievable time to reperfusion for each modality of care.


LOE 5, Good quality, supportive for efficacy

PRAGUE
• Czech
• randomized three arms - community hospital thrombolysis, thrombolysis and then transport (during) for PCI; transport to PCI without thrombolysis
• SK used
• 300 patients
• no complications during transfer in transfer only arm
• 2% in SK and then transfer
• combined endpoint significant reduction in PCI only PCI 8% vs TL 23% (p <0.02)


• LOE 5, Good quality, supportive for efficacy

PRAGUE-2
• Czech
• SK versus transfer for PCI; randomized
• 850 patients; stopped early (planned 1200) due to meeting criteria in > 3hour patients and reluctance of sites to continue to thrombolys
• primary outcome: 30 day mortality; secondary: 30 day composite
• 1.2 % complication rate during transfer
• overall significant reduction in composite
• in > 3 hours from symptom onset; significant decrease in mortality with PCI; mortality 6% PCI vs 15.3% TL (p<0.02);
• combined endpoint significant difference 8.4% PCI vs 15.2%TL (p<0.003)
• in < 3 hours, no difference in mortality;
• intention to treat analysis (also post-hoc actual treatment analysis - ignore this part)