Can a pre-hospital ECG significantly improve the 'call-to-needle' time for patients suffering an acute myocardial infarction?

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1.0 Project Summary.

Thrombolysis has been proven to be a valuable intervention in the management of Acute Myocardial Infarction (AMI). However it is a time critical process - a one hour reduction in the delay to thrombolysis has been estimated to save up to 28 lives per 1000 treated[1]. Current NHS guidelines[2] call for thrombolysis to be administered within 60 minutes of an initial call for help (the call-to-needle time).

Currently paramedics inform the receiving Accident and Emergency (A&E) department in advance of patients with suspected myocardial infarction to facilitate prompt assessment of the need for thrombolytic therapy. At present only some 5% of these cases require thrombolysis. As a result this “fast-tracking” is often overwhelmed, and the majority of patients do not receive rapid treatment.

Incorporation of a 12-lead electrocardiogram (ECG) into pre-hospital triage would be expected to further refine the process leading to a reduction in delays in identifying patients requiring thrombolysis.

We aim to determine, by means of a randomised controlled trial, the impact of a pre-hospital diagnostic ECG on the call-needle time of patients requiring thrombolysis for AMI. In addition we aim to define the sensitivity and specificity of trained paramedic interpretation of an ECG in acute chest pain.

2.0 Introduction

2.1 Background

The National Service Framework for Coronary Artery Disease[2] has set tough targets for the emergency management of acute coronary syndromes. In particular, individuals suffering from acute myocardial infarction (AMI) should receive thrombolysis within 60 minutes of their initial call for help, and within 30 minutes of arrival at hospital (door-to-needle time). At present few hospitals can claim to meet these goals. Previous work from our unit has shown that only 35% of patients currently receive treatment within such a time frame[3] despite regular quality improvement strategies.

A variety of other means to achieve these aims have been proposed ranging from dedicated thrombolysis nurses[4], mobile coronary care units[5] as well as sophisticated telemetric links to ECG recorders in paramedic ambulances[6]. In the long term, one of the aims of the NHS Plan[7] includes a pledge to develop prehospital thrombolysis.

A number of pathways have been used to evaluate how rapid thrombolysis from the initial time of call for help can be achieved[5,6,9-11]. However, none of the studies thus far have evaluated the role of introducing an ECG as a pre-hospital intervention and assessing its impact on the 'call-to-needle' time in a large urban setting with thrombolysis being provided in the A&E department. Successful use of this strategy would potentially have a significant positive effect in meeting the NSF standards for 'call to needle' times in these patients.

2.2 Target group

Acute chest pain is a common presentation to A&E. At present Leeds General Infirmary A&E Department thrombolyses over 250 patients per year and St James' 200. This accounts for approximately 5% of all attendances with chest pain of a possibly cardiac origin.

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2.3 Current practice

On being called to a patient with cardiac sounding chest pain paramedics inform the receiving A&E department of the patient's estimated time of arrival and initiate cardiac rhythm monitoring. On arrival at A&E the patient is assessed by a triage nurse who arranges for a 12-lead ECG to be performed. The patient is then assessed by a doctor who initiates treatment, including thrombolysis, as required. At present 35% of patients receive thrombolysis within 30 minutes of arrival. The median call to needle time being 90 minutes.

A major source of delay is believed to be due to the fact that 95% of patients assessed in this manner do not require thrombolysis. Inevitably this creates inertia. In addition the triage nurse also assesses all other patients brought to A&E by ambulance, thus at peak times delays occur. By using a 12 lead ECG to identify patients with AMI in the pre-hospital stage, it should be possible to initiate treatment with a greater degree of urgency.

2.4 Potential health gains

Thrombolysis is a time critical intervention. If received within an hour of the onset of pain 65 lives can be saved per 1000 patients. This figure falls rapidly to 37 at 2 hours and 26 at up to 6 hours[1]. By enabling the earlier delivery of thrombolysis within Leeds we hope to achieve a worthwhile reduction in mortality for our patients.

2.0 Research evidence

The Myocardial Infarction Triage and Intervention Trial[6] looked at pre-hospital initiation of thrombolysis in 360 patients. A 12-lead ECG was transmitted to the receiving Emergency Room where a interpretation was performed by a physician. The control group had an AMI diagnosed in the prehospital phase but did not receive thrombolysis until arrival at the emergency department. Comparison of this arm of the trial to patients treated concurrently but not within the trial itself showed a reduction in mean door-needle time of 40 minutes (from 60 to 20). These patients, however, had either been excluded from the trial for other reasons, or had chosen not to use the ambulance system. Acquisition of the ECG added a mean of 7 minutes to the prehospital phase[8].

Studies in rural areas have shown the benefits and safety of prehospital thrombolysis when initiated by a General Practitioner, particularly in the context of extended transit times[9]. More *et al*[10] consistently obtained 'door to needle' times of 25 minutes (median) and 'call to needle' times of an hour by using a prehospital ECG in 274 patients over an eighteen-month period. Paramedics performed and interpreted ECGs in patients whom they suspected had suffered an AMI. Eligibility for thrombolysis was assessed by means of a check list. The A&E department was then informed of potential thrombolysis patients. ECG acquisition and interpretation was reported as taking an average of 10 minutes. Unfortunately this was a case series review rather than a true trial and no details of sensitivity and specificity were given.

Other studies[11] have examined the accuracy of paramedic interpretation of a prehospital ECG, and the benefits of prehospital triage of such patients directly to the

Coronary Care Unit. The authors found that 84% of prehospital ECGs were of adequate diagnostic quality. Paramedic interpretation was reported as being 92% accurate. A reduction in call to needle time from 154 to 93 minutes was found, largely due to a reduction in the door to needle time from 97 to 37 minutes. This study was prospective but not randomised, historical controls being used.

4.0 Aims and objectives

This study aims to evaluate the potential for improvement in the delivery of rapid thrombolysis for patients suffering AMI in a large urban setting to meet the NSF standards.

The specific hypothesis to be tested is: In patients with AMI does prehospital diagnosis by means of a 12-lead ECG significantly reduce the delay to administration of thrombolytic therapy?

5.0 Plan of investigation

Each paramedic ambulance serving Leeds will shortly be issued with a 12-lead ECG recorder (Lifepack 12, Physiocontrol). Paramedic crews will undergo a short training course in ECG interpretation, specifically to train them in recognition of the changes suggestive of acute myocardial infarction (AMI). This consists of a 3-day lecture and workshop based programme together with a day of practical experience in hospital.

At present, upon reaching a patient with probable cardiac chest pain, the Ambulance Control rings the receiving A&E department to warn of the patients arrival, allowing space for the assessment of that patient to be created. This system will be modified for the purpose of the study.

5.1 The protocol

Upon arrival to a 999 call for chest pain, the ambulance crew will assess whether the pain may be of cardiac origin, and initiate supportive care as necessary. The patient

will be assessed for inclusion criteria (all of which are currently part of routine paramedic assessment):

- Chest pain of probable (in the paramedic's opinion) cardiac origin
- Duration of between 15 minutes and 6 hours
- Pulse rate of between 40 and 120
- Glasgow coma score 15
- Age >18

Should all these criteria be met the patient will be eligible to participate in the trial. Ineligible patients will be treated in accordance with current guidelines.

Group A Experimental Group

A 12 lead ECG will be performed by paramedics (prior to transport). Should this ECG show changes diagnostic of AMI a call will be placed to ambulance control stating "definite MI". Should there be no changes, or the ECG be of insufficient quality for analysis the call will state "chest pain possibly cardiac". Ambulance control will pass this on to the receiving hospital in the usual fashion.

Upon receipt of a call using the term "definite MI" the nurse co-ordinating A&E will assemble a team consisting of a nurse and doctor, in an appropriate area (e.g. the resuscitation room). As the patient arrives a focused assessment including a further ECG, will be made. The paramedic ECG will be part of the assessment. Thrombolysis will be at the discretion of the doctor and nurse in consultation with other staff if required. The patient will be given the standard treatment for AMI in the A&E department and referred onto the admitting medical team as usual. The paramedics will note their interpretation of the ECG on a proforma 'sticker' attached to either the prehospital ECG or the WYMAS chest pain form. All other documentation should be completed as usual. Photocopies will be placed in a box in the resuscitation room, all original documentation going with the patient.

Patients who, in the opinion of the paramedics, do not have ECG changes diagnostic of AMI will be treated according to current guidelines. A call will be placed to ambulance control stating "Chest pain possibly cardiac". On arrival at the receiving hospital the triage nurse will assign a triage category and assess the need for an ECG

(the nurse may use the paramedic ECG but its apparent normality should not be used to justify the omission of a hospital ECG). Patients will then be seen by a doctor in time order, and further management (including thrombolysis if required) initiated at the discretion of the staff of the A&E department. Again paramedics should complete the prehospital ECG sticker and attach it to the ECG. Copies of the A&E record, WYMAS chart and any ECGs will be retained in the A&E department, all original documentation staying with the patient.

Group B Control Group

No prehospital ECG will be recorded. Treatment will be carried out according to current guidelines, including rhythm monitoring. The call to WYMAS control will simply state “chest pain possibly cardiac”. This will then be forwarded to the receiving A&E which will respond as outlined above. The prehospital ECG sticker will be completed as saying simply “omitted” and attached to the WYMAS form. Copies of any documentation and ECGs will again be retained.

5.2 Randomisation strategy

Randomisation will take place on the basis of a rolling rota. Alternate days of the week will be allocated to be either “pre-hospital ECG days” or “control days”, each A&E department will be aware of this in advance.
Other strategies considered included:

- Randomisation of each patient by radio call to a distant centre. Although felt to be more scientifically robust this was rejected as being too time consuming for this study.
- Randomisation by sealed opaque envelopes carried in each ambulance. Again this was felt to be advantageous from the pure research point of view, but inappropriate for use in the pre-hospital arena.
- Randomisation of individual ambulance crews on a permanent basis. This was felt to be inappropriate as the “control” crews may become deskilled.

- Randomisation of each crew at the start of a shift. This was felt to offer no real advantage over the chosen method but would introduce the potential for confusion.

5.3 Sample size calculation

To detect a reduction in the call to needle time of 20% (from 90 minutes mean to 78, a conservative estimate) with a type I error of 0.05 and a power of 80% would require 80 patients per arm. Both A&E departments see approximately 200 MIs per year, therefore the study is anticipated to take approximately 6 months. Approximately 5% of chest pain calls are actually thrombolysed, it will thus be necessary to recruit about 3200 patients with chest pain in total.

5.4 Study evaluation

Study type: prospective randomised controlled trial

Data set: See Appendix 2

Data Collection: Copies of patients records will be held in a box in the resuscitation areas of the two A&E Departments. This will be collected on a daily basis by the study investigators. Data will be transferred to a data collection sheet and copies of original notes shredded.

Data Storage: Data will be held in a single Microsoft Access database. This will be on a password protected workstation in the offices of the LGI A&E department. Data will be anonymous.

Data Review: Analysis will occur on a monthly basis and be presented to the project team.

6.0 Project management

A project team will be set up and chaired by the lead co-ordinator for the study (TBH) who is experienced in the development and management of randomised studies in the pre-hospital setting.

The team will meet at monthly intervals to review progress of the project under the following headings :

a) Patient throughput
b) Data quality assurance issues
c) Feedback to relevant personnel
d) Meeting interim milestones

7.0 Evaluation

7.1 Clinical efficacy of pre-hospital ECGs on 'call to needle' time.

For each arm of the study, results will be expressed in terms of:

- Mean and median call to needle time.
- Mean and median door to needle times.
- Cumulative call and door to needle times in 10 minute blocks.
- Proportion of patients meeting NSF guidelines.
- Proportion of cases in which ECG changes have evolved between the pre-hospital and hospital ECG.

This data will be further subdivided by hospital site and type of infarct.

7.2 Accuracy of pre-hospital personnel in diagnosing acute MI.

A comparison of paramedic and doctor interpretation of ECGs will be made, the doctor's interpretation acting as a "gold standard" for the purposes of the study. Cases of disagreement will be reviewed by the project team. A random sample will also be reviewed by the project team as a further quality assurance measure.
Results will be expressed in terms of sensitivity and specificity.

8.0 Potential application and dissemination of results.

8.1 Potential application

Pre-hospital ECGs have been used in a number of systems, predominantly in rural setting. They have not been evaluated in an urban setting. If this study is successful and improves call to needle times it has the potential for wider dissemination and adoption. In addition it would act as a potential step towards delivery of pre-hospital thrombolysis in certain patient groups (e.g. obvious MI and haemodynamically stable).

8.2 Dissemination of results

Results from the study will be made available in the form of a report to WYMAS and the board of the Leeds Teaching Hospital Trust. In addition we anticipate that the results will be presented at national and international meetings and be submitted to a peer-reviewed journal.

Appendix 1 : Project milestones

Month	Milestone
1	Application to the LREC
2-3	Training and communication exercise to pre-hospital and in-hospital personnel
3	Pilot study
4-12	Study period
13-16	Data analysis and write-up
17-18	Presentation to national and international meetings and submission to international journal

Appendix 2 : Data collection

Data will be collected on:

Basic Demographic: Age, sex, postal area (first part only)

Initial point of contact: GP, NHS-Direct ,999

Time of Call

Time of Arrival

Time of prehospital ECG **Interpretation (paramedic)** into St elevation (anterior, inferior), Left Bundle Branch Block, posterior MI, other abnormal, normal

Prehospital treatments: Aspirin, GTN

Complication en route: VF/pulseless VT, VT(pulse), other arrhythmia, asystole, EMD

Time of arrival at A&E

Triage category

Time of Hospital ECG **Interpretation (doctor)** into St elevation (anterior, inferior), LBBB, posterior MI, other abnormal and normal

Thrombolytic therapy Given, contraindicated, not indicated

Time of Thrombolysis

Disposal CCU, Died In Department, Dead on Arrival, admitted (other ward), Clinical Decision Unit, discharged

A&E Diagnosis MI, Unstable coronary artery disease, Stable coronary artery disease, Other

Final Diagnosis (according to discharge summary)

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