CASE REPORT

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Pilot of Prehospital Thrombolysis in ST Elevation Myocardial Infarction

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THE CASE

Mr B was a 59-year-old male who had a history of chronic obstructive pulmonary disease and a positive family history of heart disease. He experienced chest pain at 10am, and contacted the ambulance service approximately 45 minutes later following no resolution of his pain.

On arrival of the Bendigo Mobile Intensive Care Ambulance [MICA] crew, Mr B was complaining of chest pain, was hypotensive [systolic blood pressure = 80 mmHg] and his 12 lead ECG revealed a junctional rhythm [56 bpm], with ST-segment changes consistent with an inferior ST-elevation myocardial infarction [STEMI].

He was administered Aspirin, Morphine and Glyceryl Trinitrate. A 12 lead ECG was transmitted to Bendigo Healthcare [BH] Emergency Department [ED] for validation. STEMI was confirmed.

r-PA 10 units and heparin 5000 units were administered at 11.30am. The patient was loaded into the vehicle and transported to BH ED. A further dose of r-PA was administered 30 minutes following the initial dose. No adverse events occurred.

On arrival to the ED, Mr B. was pain-free, and there was complete resolution of ECG changes with absence of Q waves, as shown in Figure 1. His systolic blood pressure had improved to 110 mmHg. He made a full recovery to hospital discharge.

Abstract

Based on data from overseas and local case modelling, Rural Ambulance Victoria [RAV] implemented a pilot study of prehospital thrombolysis [PHT] for patients with ST Elevation Myocardial Infarction [STEMI] in the Bendigo region. The purpose of this report is to provide the background to the pilot, describe the PHT model, report the outcome of the single enrolled case and discuss various barriers to PHT implementation.

Keywords:

Emergency medical services; myocardial infarction; paramedic, prehospital; thrombolytic therapy

Author(s): Kerr D, Jennings P, Kelly A-M, Walker T, Edington J.

Background

Timely coronary reperfusion reduces mortality and morbidity from STEMI. While emergency angioplasty is preferred to fibrinolysis if it can be delivered within defined time intervals,¹ access to angioplasty is largely limited to major centres. Thus fibrinolysis is the mainstay for reperfusion in most rural and remote areas of Australia, and has been shown to improve outcome.²⁻⁶ Moreover, mortality and infarct size directly relate to the time between onset of symptoms and commencement of treatment.⁶⁻⁹ The British Heart Foundation¹⁰ has recommended that patients with STEMI should receive thrombolysis within 90 minutes of calling for medical assistance. Similarly, the National Heart Foundation of Australia [NHF]¹¹ has recommended out-of-hospital treatment for patients unable to reach a hospital with facilities to deliver thrombolysis within 90 minutes of contacting health services. Local Victorian data¹² has reported that less than 61% of eligible STEMI patients received thrombolysis within 90 minutes of calling for an ambulance and that the proportion of patients in rural areas treated within the benchmark was as low as 42% in some centres.¹² Transfer times longer than 20 minutes were found to be a risk factor for failure to achieve in-hospital fibrinolysis within the 90-minute benchmark.

The case for PHT for selected patients has already been established. A meta-analysis of 6 randomised controlled trials of prehospital versus in-hospital thrombolysis concluded that prehospital treatment significantly decreases the time to thrombolysis [58 minute reduction for prehospital groups] and all-cause mortality.¹³ That work was however conducted overseas and is dominated by some studies with long transport times and poor hospital performance. Generalisability to the Australian context, with its usually shorter transfer times, could not be assumed. Fibrinolysis is particularly effective when it is delivered within 2 hours of symptom onset.^{14,15}

The pilot project was undertaken with the aim of evaluating the feasibility, safety and efficacy of paramedic-administered PHT for patients with STEMI.

PREHOSPITAL THROMBOLYSIS PILOT

Setting

The project was based in the provincial city of Bendigo, Victoria, approximately 150km from Melbourne. BH is a multi-campus regional health care facility providing health services to residents of the Loddon Mallee region. The approximate population of Bendigo is 94,000, with 14.5% aged over 65 years. Bendigo is the third largest urban centre in the State outside Melbourne, and the major regional centre for north central Victoria.

The Bendigo area is serviced by a two-tiered system comprising Advanced Life Support [ALS] paramedics and MICA paramedics. While both levels have defibrillation capability, the latter are authorised to perform endotracheal intubation and administer a range of cardiac drugs. Bendigo has one dedicated MICA paramedic crew and a number of ALS ambulance crews to service the catchment.

The Bendigo region was chosen as previous data suggested that it was an area where a higher proportion of patients had longer transfer times which threatened the systems ability to provide in-hospital fibrinolysis within the 90-minute benchmark.

Consultation

Recognising that delivery of paramedic PHT would involve several health-care services, a steering committee was established that included members from RAV, the Joseph Epstein

Centre for Emergency Medicine Research, and staff of BH including emergency physicians, registered nurses, a critical care physician and a cardiologist. This committee oversaw all aspects of the pilot project including development of the PHT protocol, ethics approval, individual organisational issues, training and competency requirements, and study evaluation.

PHT Model

Eligible patients were defined as those with: symptoms of ischaemia / infarction of duration >20 minutes, transport time to BH ED >30 minutes, symptom onset <6 hours, ECG changes [>1 mm ST elevation in two contiguous limb leads (I-III, aVR, aVL, aVF), >2 mm in 2 contiguous chest leads (V1-V6)] and willingness to give verbal consent to participate in the project.

Paramedics transmitted the ECG [obtained from a Zoll™ M Series monitor defibrillator] via mobile phone, to BH ED for confirmation of STEMI by an approved medical practitioner. In addition, the 'Prehospital Thrombolysis Assessment Document' [Figure 2] was completed. Eligibility for paramedic-administered thrombolysis required that all criteria on that form were met.

Given the potential risks associated with the use of thrombolytic therapy, informed verbal consent was obtained from patients prior to thrombolysis administration. Patients were verbally informed of the benefits and risks of treatment using an approved script, as detailed in Figure 2. MICA paramedics provided initial assessment and management at the scene following usual RAV Clinical Practice Guidelines [CPG].

The protocol detailed that Aspirin 300mg orally and Heparin 5000 units intravenous [IV] bolus be administered prior to thrombolysis. r-PA [10U] was then to be administered as a slow IV bolus over 2 minutes, followed by a 2nd 10U bolus dose 30 minutes later. For prolonged transport, an infusion of heparin 1000 units per hour was commenced 1 hour after the first heparin bolus. Choice of thrombolytic agent was determined on the basis that the majority of rural Victorian hospitals used one agent at the time of the study, including BH. The study was approved by the BH Human Research Ethics Committee.

Training and project evaluation

MICA Paramedics receive training in 12-lead ECG interpretation as part of their primary training program. Prior to project commencement, MICA paramedics of the Bendigo crew participated in a 4-hour, competency-based training program that included 12 Lead ECG acquisition, recognition and transmission, prehospital and hospital thrombolysis and review of the RAV Thrombolysis CPG. The interim CPG for prehospital thrombolysis was approved by the RAV Medical Standards Committee prior to study commencement. This training culminated with a competency-based assessment conducted by the Area Medical Officer.

Projected and actual caseload

It was projected that approximately 11 patients in the Bendigo region would be suitable for PHT in a 12-month period. As detailed, a single patient received paramedic-administered PHT in the 12-month period of the pilot project.

Focus Group

An informal focus group, consisting of Bendigo MICA paramedics and researchers who were involved in the project, was conducted after the pilot project had been completed [mid-2007].

The aim of this forum was to explore some of the perceived barriers and enablers to implementation of a PHT strategy in a provincial environment. The focus group was audio taped and the tapes later transcribed by an experienced researcher [PJ] to allow for thematic analysis.

There was voluntary involvement. All participants were provided with questions likely to be asked prior to the session, in order to collect information related to participant's involvement in the project, adequacy of training, and perceived reasons for low enrolments.

Seven people participated in the focus group: 5 MICA Paramedics and two of the research team [DK, PJ]. Two core themes emerged; perceived barriers to recruitment of participants, and technical issues with implementation of the project.

The key issues identified as barriers to recruitment were the 30-minute transport inclusion requirement, thrombolysis administration by smaller hospitals within the catchment, and education and ambulance dispatch practices.

MICA paramedics considered that the 30-minute transport time from retrieval to BH ED restricted potential enrolments. They also described the introduction of thrombolysis administration in smaller hospitals around the same time as the commencement of the trial, which resulted in lower than expected recruitment into the trial. According to one MICA paramedic, nearly all outlying hospitals were administering thrombolysis to STEMI patients soon after commencement of the project.

Members of the focus group felt that inconsistent dispatch practices of the RAV Communications Centre contributed to reduced enrolment of potential participants. Sending single ALS crews [who did not have the ability to administer thrombolytic therapy] rather than the Bendigo MICA crew to potential thrombolytic candidates was believed to reduce recruitment. Members of the focus group also indicated that ALS crews and the communication centre may have had an insufficient understanding of the project, or the importance of early thrombolysis in the setting of STEMI.

There were also technical issues with ECG transmission. Incidents were described where the location of patient retrieval was out of transmission range, and ECGs could not be transmitted to BH ED. Rates of failed ECG transmissions were not collected.

In general, paramedics were satisfied with the level of training provided prior to initiation of the study.

The future

An operational decision was made not to continue this initiative in this region due to the low caseload. The results of the project will help inform decisions about implementation of PHT in other regions.

Discussion

This is an account of an attempt by an Australian ambulance service to provide early aggressive management of STEMI in a rural environment. While it has the obvious limitation of recruitment of only a single patient, it has demonstrated that it is possible to safely implement thrombolysis outside of hospital within a rural Australian context. Other local quality improvement practices, in particular initiation of thrombolysis by small hospitals within the region, have improved care for STEMI patients in this region, albeit in competition with [and potentially catalysed by] this initiative. This is not a bad thing and should not be

seen as a failure of the pilot project. Rather it is a demonstration of the various arms of health care implementing a system to ensure that eligible patients receive reperfusion therapy with the shortest possible delay.

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Figure 1: 12 lead ECG

**FIGURE 2: PREHOSPITAL THROMBOLYSIS ASSESSMENT DOCUMENT
(ADAPTED FROM JRCALC PROFORMA)**

Patient Name: _____ **Date:** _____ **Case No:** _____

Primary Assessment (Inclusion Criteria)	Yes	No	Unsure
Is the patient conscious, coherent, and able to understand that clot dissolving drugs will be used?			
Can you confirm that the patient is aged between 18 and 75 years of age?			
Can you confirm that the patient has had symptoms characteristic of a heart attack (i.e. pain in a typical distribution and of 30 minutes duration or longer)?			
Can you confirm that the pain built up over seconds and minutes rather than starting totally abruptly?			
Can you confirm that symptoms started less than 6 hours ago?			
Can you confirm that breathing does not influence the severity of the pain?			
Can you confirm that the heart rate is between 40 and 140?			
Can you confirm that the systolic BP is more than 80 mmHg and less than 160 mmHg and that the diastolic BP is below 110 mmHg?			
Can you confirm that the ECG shows ST Elevation ≥ 1 mm in 2 contiguous limb leads (I, II, III, aVR, aVL, AVF) or ST Elevation ≥ 2 mm in 2 contiguous chest leads (V1, V2, V3, V4, V5, V6)?			
Can you confirm QRS width 0.14 seconds or less, and that bundle branch block is absent from the ECG?			
Can you confirm that there is no atrioventricular block greater than 1st degree? (If necessary after treatment with IV Atropine)?			
Can you confirm that the above ECG findings have been validated by an approved emergency physician at Bendigo Health Care Emergency Department?			

Secondary Assessment (Contraindications) (Exclusion Criteria)	Yes	No	Unsure
Can you confirm that the patient is not likely to be pregnant, nor has delivered within the last 2 weeks?			
Can you confirm that the patient has not had a peptic ulcer within the last 6 months?			
Can you confirm that the patient has not had a stroke of any sort within the last 12 months and no permanent disability from a previous stroke?			
Can you confirm that the patient has not been treated for any serious brain conditions? (This is intended to exclude patients with cerebral tumours)			
Can you confirm that the patient has no diagnosed bleeding disorder, has had no blood loss within the last eight weeks (except for normal menstruation) and is not on ANY anticoagulant therapy (i.e. heparin, warfarin, clopidogrel etc.) except aspirin?			
Can you confirm the patient has not had any surgical operation, tooth extractions, significant trauma or head injury in the last month?			
Can you confirm that the patient is not being treated for liver failure, renal failure or any other severe systemic illness?			
Can you confirm that the patient does not have suspected aortic dissection [sudden onset of pain radiating to back +/- abdomen (possibly tearing pain), neurological symptoms (pins and needles, weakness) in any limb, neurological symptoms centrally (visual disturbances or dysphasia), unequal BPs (right vs left), loss of peripheral pulses?			

CONSENT STATEMENT

If you have answered yes to all indications and contraindications, read this statement to the patient

'It is likely that you have suffered a heart attack, and the best treatment is a clot dissolving drug called Reteplase. The quicker you receive this drug, the lower the risk from the heart attack - which is why doctors recommend the treatment is started as soon as possible. This treatment is given by way of 2 injections in the cannula in the vein, 30 minutes apart. Reteplase carries a small risk of causing internal and external bleeding – the most serious being a stroke. From the answers you have given, however, the risk appears to be outweighed by the likely benefit of administering Reteplase and the recommendation is that you start treatment for your heart attack as soon as possible. Do you wish to receive Reteplase?'

If the answer is yes, proceed with the following request for consent to participate in a study.

"We are conducting a study to find out if paramedics can administer Reteplase in a safe and effective way. We have had significant training in giving this drug. If you decide to not take part in this study it is highly likely you will receive Reteplase when we take you to Bendigo Hospital. We have received approval from the ED doctors at Bendigo Hospital to give you Reteplase based on your symptoms and ECG changes. We are asking you now if you would like to take part in our study, and receive Reteplase by paramedics."

If the answer is yes indicate patients agreement to the treatment on the patient Care Record

Confirmation of ST segment elevation of more than 2mm in at least two standard leads or at least two adjacent precordial leads on the 12 lead ECG

Doctor Name: _____

Hospital

Paramedic Name _____

Signature

Date: _____

Time: