

**Optimal treatment of patients with
Acute Coronary Syndrome and the evolutionary
role of nurses and allied health professionals**

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Dedication

Composing a PhD thesis is an onerous, time-consuming and all-encompassing piece of work. For their patience, inspiration and fortitude I dedicate this thesis, and the success of my working life in general, to Fiona, Ryan and Jake McLean. They give me the inspiration to succeed in all that I do.

Declaration

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification at this or any other university or institute of learning.

Signed:



Date:

1st March 2011

Acknowledgements

More than acknowledgement I wish to express my eternal gratitude to Professor Morag Gray and Dr. Michael Brown. They have, in their own dynamic yet passive, challenging yet supportive, and humorous yet focussed way, steered me through this journey to the point where I feel able to stand firmly behind my work. I am truly grateful for their counsel.

I would also like to pay personal tribute to Dr. Andrew Flapan. A brilliant Cardiologist and a thoroughly unique character, he without doubt helped bring me to a place where I am submitting work for doctoral examination. Without his support, trust and motivation I would not have achieved this.

It would also be remiss of me not to acknowledge the clinicians I have worked alongside over the last 15-years caring for patients with stable and unstable coronary disease. I have learned much, and have much more to learn. They reassure me that the people of the United Kingdom receive ambulance service, medical and nursing care which is second to none, and perhaps most amazingly of all, remains free at the point of use. It is their work and the direct impact it has on patient outcome which has motivated me to share with the wider audience.

Abstract

Heart disease is a serious problem for both the individual and society at large. It takes many lives. As an acute cardiac nurse I have spent the bulk of my clinical and research career striving to provide acute cardiac care outwith the historical boundaries of the doctor-led, specialty-based, inpatient setting. The barometer of this work however must be the additive knowledge and consequent impact on practice it has provided to the cardiovascular community through peer-reviewed publications. This thesis presents an analysis of the evidence base for contemporary developments in acute cardiac care, including 6 core peer-reviewed publications, and 11 supporting publications where I am either primary or secondary author. These publications demonstrate the feasibility, safety and efficacy of programmes of cardiac care which depend on complex clinical decision-making and teamwork by nurses, paramedics and doctors. Critical appraisal of the publications is conducted and the research methodologies and theoretical underpinnings analysed. Strengths and limitations are identified and the implications and impact on clinical practice debated. One of the primary aims of this work is to identify a logical and programmatic approach to the body of work, concordant with and focussing in detail on the patient journey. Potential areas, and plans, for future research are detailed.

Key themes such as moving the site of thrombolytic treatment to the Emergency Department (ED), streamlining care for patients presenting to the ED with Acute Coronary Syndromes (ACS), establishing and evolving communication networks between Coronary Care Unit nurses and ambulance paramedics, moving the site of thrombolytic treatment to the ambulance, developing an optimal reperfusion programme including pre-hospital thrombolysis, primary percutaneous coronary intervention and in-hospital thrombolysis, analysis and synthesis of treatment timelines as they are distributed across treatment groups are presented.

In totality this work supports the direction of travel towards pre-hospital treatment of ACS. Although this may sound somewhat straightforward it is, and has been, a significant paradigm shift for multidisciplinary clinicians in the United Kingdom. These works in their totality have contributed to defining the optimal contribution of multidisciplinary experts to ACS treatment in the United Kingdom, and in a Scottish context have contributed to national policy and service provision.

Finally this thesis does not sit specifically within the confines of “nursing research.” Rather it is defined by healthcare research by a nurse with multidisciplinary colleagues. The practice and research described herein is not confined within artificial boundaries within one discipline. Rather the study is of patient outcomes, systems of care and the contribution of nurses and paramedics to the care of patients with ACS.

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Researcher's notes

1. For reasons of ease of presentation, brevity, reflexivity and academic style, the writing throughout this thesis will be the first person.
2. By nature of the specialty to which this relates there are a number of abbreviations throughout this thesis. A glossary of terms appears as Appendix 1 (p117).

Chapter One - Introduction

1.1 Introduction

“Heart disease is a serious malady. It takes many lives and cripples many more. An intelligent physician can make a diagnosis with sufficient accuracy of any heart disease, can give good treatment, good advice and can arrive at the cause of the trouble with a fair degree of accuracy – no-one else can.

Any physician can do any and all of these things in his office, the patient’s home or elsewhere. He does not need any elaborate or special equipment. What he does need, what the patient needs, and what the patient cannot get in any other way, is the personal service of a physician.”

Anon, California and Western Medicine (1926: 372)

Although at first-sight this statement might challenge the contemporary cardiovascular nurse, there are significant messages within it which are still resonant some 84 years after its publication. Heart disease is a serious problem for both the individual and society at large. It does indeed take many lives. Care for patients experiencing cardiovascular disease, can take place in a multitude of settings including both health-care institutions or in the patient’s home. There are many aspects of clinical cardiology which require knowledge, experience, reasoned judgement and sound decision-making rather than elaborate or special equipment.

The evidence presented in this thesis, which relates to work published over a ten year period, will provoke the reader to ask whether or not the patient with heart disease in 2011 needs the “*personal services of a physician,*” or perhaps more importantly whether or not “*no-one else can.*”

As an acute cardiology nurse I have spent the bulk of my clinical and research career, striving, like a number of others to provide acute cardiac care outwith the historical boundaries of the doctor-led, specialty-based, inpatient setting.

I have striven, in a pragmatic and programmed way, to gradually move the acute care of the cardiovascular patient to the place or places where it confers the greatest benefits. The barometer of this work however must be the additive knowledge and consequent impact on practice it has provided to the cardiovascular community through peer-reviewed publications. Davies and Rolfe (2009) postulate that a doctoral student being assessed by published works must already have a successful track record of publications in an established field, before submitting their thesis and defending their work in an oral examination.

This thesis presents an analysis of the evidence base for contemporary developments in acute cardiac care, including eighteen peer-reviewed publications where I am either primary or secondary author. Six of these publications will be explored as my “core” pieces of published work. The remaining twelve publications, which include abstracts and reports, will be used as supporting material, as described in section 1.5 (p6).

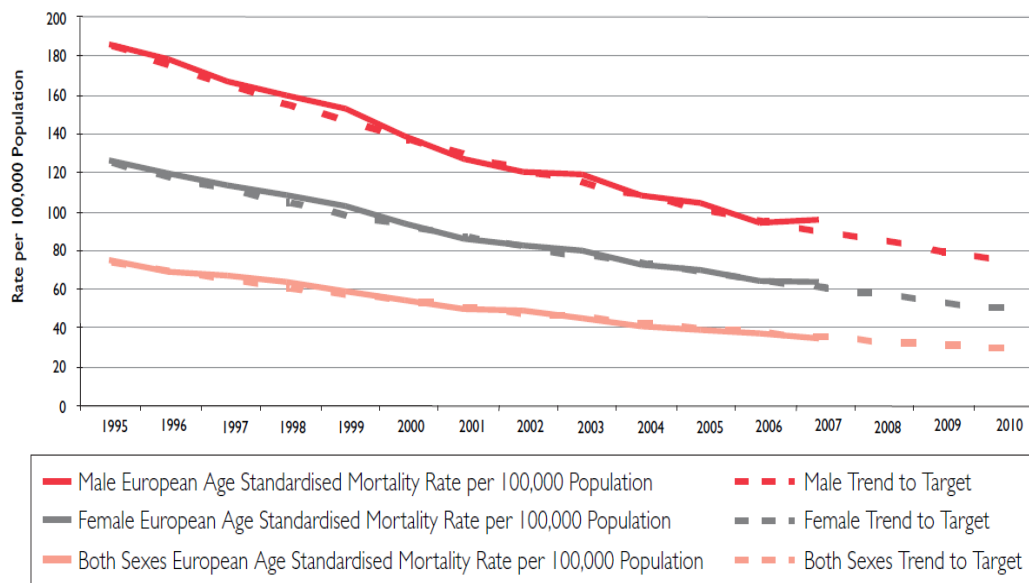
Based on a track record of success in investigating the subject area, colleagues and I were commissioned by the Chief Scientist Office (CSO)/Scottish Government Health Department (SGHD) to investigate the feasibility of implementing a programme of care based around guidelines of the Scottish Intercollegiate Guidelines Network (SIGN). This work was seen as being key to informing national policy and strategic direction.

As one might expect these pieces of work when viewed collectively are multifactorial and multifaceted. This body of evidence demonstrates the feasibility, safety and efficacy of novel programmes of cardiac care which depend on complex clinical decision-making and teamwork by nurses and paramedics facilitated by telemedicine. It also further confirms the benefits in bringing healthcare to the patient, rather than the patient to healthcare.

1.2 Background

Diseases of the heart and circulatory system (cardiovascular disease (CVD)) are the main cause of death in the United Kingdom (UK) and account for approximately 200,000 deaths per annum. More than one in three UK deaths are as a result of CVD and almost half (48%) of deaths from CVD are as a result of its most common manifestation – Coronary Heart Disease (CHD). CHD caused almost 94,000 deaths, of which 31,000 were premature deaths in the UK in 2006 (Allender *et al.*, 2008). Since this body of work is contextualised in Scotland, the latest Scottish mortality data are presented in Figure 1:

Figure 1: Coronary Heart Disease in ages <75. European Age Standardised Rate of Mortality per 100,000 population in Scotland.



Scottish Government (2009)

Mortality rates from CHD have declined significantly in Scotland over the last twelve years. Ministers may attribute these improvements to policy guidance including the CHD and Stroke Strategy for Scotland (Scottish Executive, 2002) and updated in 2004 (Scottish Executive, 2004).

These policy initiatives have helped shape cardiovascular practice over the last ten years, in addition to advances in medical and surgical management of CVD, improvements in primary and secondary screening, improvements in access to CVD services, reductions in major risk factors, and major public health initiatives such as smoke-free legislation (Pell *et al.*, 2008).

Nevertheless, despite recent improvements, the death rate from CHD in Scotland remains disproportionately high when compared to European neighbours, with only Ireland and Finland ranking above Scotland.

1.3 Aims of this thesis

This thesis will outline the aims, drivers, context and questions which resulted in the published works presented. Critical appraisal of the publications will be conducted and the research methodologies and theoretical underpinnings analysed. Strengths and limitations will be identified and the implications and impact on clinical practice debated.

One of the primary aims of this work is to identify a logical and programmatic approach to the body of work, concordant with and focussing in detail on the patient journey. Potential areas (and plans) for future research will also be detailed.

1.4 Research Questions

The primary research question for this work is:

1.4.1 - What constitutes the optimal treatment model for patients presenting with Acute Coronary Syndromes?

Secondary questions are:

1.4.2 - What is the optimal contribution of multidisciplinary experts to Acute Coronary Syndromes treatment?

1.4.3 - Based on this work, what areas require a research focus in the future?

These research questions were addressed through the peer-reviewed publications making up this body of work. A summary of published works can be found in section 1.5 (p6).

1.5 Published works

Core published works	
1	McLean, S. , Wild, S., Connor, P. & Flapan, A.D. (2010b) Treating ST Elevation Myocardial Infarction by Primary Percutaneous Coronary Intervention, In-hospital thrombolysis and Pre-hospital thrombolysis. An observational study of timelines and outcomes in 625 patients. <i>Emergency Medicine Journal</i> doi:10.1136/emj.2009. 086066.
2	McLean, S. , Phillips, A., Carruthers, K. & Fox, K.A.A. (2010a) Use of the GRACE score by cardiology nurse specialists in the emergency department. <i>British Journal of Cardiac Nursing</i> 5 91-95.
3	McLean, S. , Egan, G., Connor, P. & Flapan, A.D. (2008a) Collaborative decision making between Paramedics and CCU nurses based on 12 lead ECG telemetry expedites the delivery of thrombolysis in ST Elevation Myocardial Infarction. <i>Emergency Medicine Journal</i> 25 370-374.
4	McLean, S. & Timmins, F. (2007) An exploration of the information needs of spouse/partner following acute myocardial infarction using focus group methodology. <i>Nursing in Critical Care</i> 12 141-150.
5	McLean, S. , O'Reilly, M., Doyle, M. & Rathaille, M.O. (2004) Improving door-to-drug time and ST segment resolution in AMI by moving thrombolysis administration to the emergency department. <i>Accident and Emergency Nursing</i> 12 2-9.
6	Robb, C. & McLean, S. (2000) Using pressure dressings after femoral artery sheath removal. <i>Professional Nurse</i> 15 371-374.
Supporting published works	
7	Fox, K.A.A. & McLean, S. (2010) NICE Guidance on Chest Pain. <i>Heart</i> 96 903-906. (Editorial)
8	Fitzpatrick, D. & McLean, S. (2010) Reperfusion of the old or the new: Left Bundle Branch Block? <i>Journal of Paramedic Practice</i> 2 50–55. (Original paper)
9	McLean, S. (2009a) Clinical history versus the exercise ECG in assessment of stable coronary artery disease. <i>British Journal of Cardiac Nursing</i> 4 363-366. (Original paper)
10	McLean, S. , Preston, J. & Flapan, A.D. (2008b) Belching: An unusual clinical presentation of Coronary Ischaemia. <i>Scottish Medical Journal</i> 53 10. (Case report)
11	McLean, S. , Mondoia, C. & Divers, F. (2007) The Cardiology Nurse Consultant in Scotland. <i>British Journal of Cardiac Nursing</i> 2 589-591. (Narrative/Opinion piece)
12	McLean, S. (2006) Chest Pain: Providing an integrated service for patients. <i>Emergency Nurse</i> 13 12-14. (Narrative/Opinion piece)
Published abstracts	
13	Maccioca, P., Cruden, N., McLean, S. , Flapan, A.D. & Newby, D.E. (2010) Effect of smoking status on angiographic outcomes and 12-month mortality following primary percutaneous coronary intervention for acute myocardial infarction. <i>Heart</i> 96 (Suppl 1):A27.
14	McLean, S. & Flapan, A.D. (2009) Decision-making between nurses and paramedics in reperfusion of ST elevation myocardial infarction. <i>Heart</i> 95 (Suppl 1):A35.

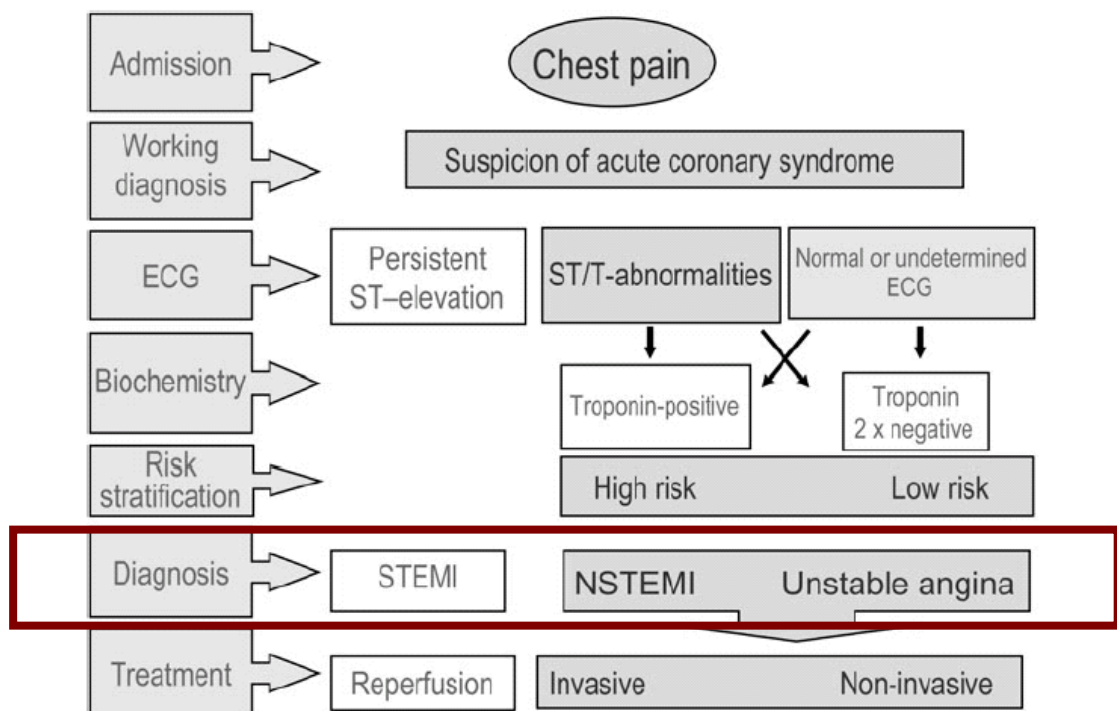
15	McLean, S. (2009b) Decision-making between nurses and paramedics in reperfusion of ST elevation myocardial infarction. <i>European Journal of Cardiovascular Nursing</i> 8 (Suppl 1):S23.
Commissioned reports	
16	McLean, S. , Wild, S., Connor, P. & Flapan, A.D. (2009) Strategies for optimal reperfusion in ST segment elevation myocardial infarction. A feasibility study for provision of primary percutaneous coronary intervention and pre-hospital thrombolytic therapy in Scotland: A report of one-year follow-up. <i>A report to the Chief Scientist Office re. grant no. CZB/4/413. (Grade – Excellent).</i>
17	McLean. S. , Wild, S., Connor, P. & Flapan, A.D. (2008c) Strategies for optimal reperfusion in ST segment elevation myocardial infarction. A feasibility study for provision of primary percutaneous coronary intervention and pre-hospital thrombolytic therapy in Scotland. <i>A report to the Chief Scientist Office re. grant no. CZB/4/413. (Grade – Excellent).</i>

Chapter Two – Review of the literature

2.1 Acute Coronary Syndrome (ACS)

The term ACS is essentially an “umbrella” term which encompasses a range of definitive diagnoses of acute Coronary Artery Disease (CAD) along a spectrum of outcome-based severity. It is well established that ACS, in their different clinical presentations share a common pathophysiological substrate (Bassand *et al.*, 2007). Detailed studies have demonstrated that atherosclerotic plaque rupture within the coronary artery results in superimposed thrombosis and embolisation. The resulting hypoperfusion of the myocardium represents the basic pathophysiological mechanism of ACS (Bassand *et al.*, 2007). Careful assessment using clinical acumen, diagnostic tools and quantitative risk-stratification are key to the optimal management of ACS.

Figure 2: The spectrum of acute coronary syndromes.



Bassand *et al.* (2007)

While there are published data on many thousands of patients describing the optimal management of ACS in the cardiology inpatient setting, there are significantly fewer data describing the identification and management of these patients in settings where patients present with undifferentiated chest pain (Lyon *et al.*, 2007). Differentiating patients with ACS from patients with chest pain not due to plaque rupture within a coronary artery is a major diagnostic challenge (Carruthers *et al.*, 2005). This is important given Deakin *et al.*'s report (2006) that only one of every eighteen calls to 999 ambulance services with chest pain result in an in-hospital diagnosis of ACS.

While cardiovascular clinicians are familiar with the risk stratification of patients presenting with ACS, there is a dearth of evidence describing the application of this skill in an undifferentiated population (de Araújo Gonçalves *et al.*, 2005), and no evidence reporting risk stratification by cardiovascular nurses in undifferentiated populations (McLean *et al.*, 2010a).

Pottle (2005) reported the non-inferiority of services provided by cardiovascular nurses in 454 patients attending her Rapid Access Chest Pain Clinic between 2001 and 2003. There are also reports of staff perceptions of "front-door" chest pain nurses (Dunkley *et al.*, 2006; McLean, 2006; MacIntosh, 2010), and advantages and disadvantages of chest pain nurses in expediting patient flow through the care system (Mullan *et al.*, 2007; O'Neill and Currie, 2007; MacIntosh, 2010). There are however few, if any, reports of the quantifying benefits of cardiovascular risk-stratification performed by cardiovascular nurses in the acute setting.

Previous investigators have commented that one of the disadvantages of quantitative risk-stratification tools is that they are constructed from data pertaining to patients with confirmed ACS, rather than patients with undifferentiated chest pain (Lyon *et al.*, 2007). The risk-scoring matrixes tend to be validated amongst patients admitted to specialist cardiology services, a group who are likely to be at higher risk of significant cardiac events than those presenting to an ED (Conway-Morris *et al.*, 2006).

The Global Registry of Acute Coronary Events (GRACE) risk prediction tool provides a method of calculating the risk of in-hospital death, 6-month death and MI (Fox *et al.*, 2006). The tool is designed to reflect a broad population of patients with ACS and has enrolled 102,341 patients in 247 hospitals over 30 countries (GRACE, 2009). Portuguese investigators have reported that the GRACE score was superior to other available scores in predicting the risk of death or MI at one-year following hospital admission (de Araújo Gonçalves *et al.*, 2005). Siebens *et al.* (2007) highlighted that risk scores such as GRACE, and others, are available to help nurses as they triage patients with chest pain in designated chest pain units. They cite evidence of patients with chest pain being safely triaged by nurses (Smith, 2000), while Quinn *et al.* (2000) concluded that CCU nurses were more likely to identify suitability for transfer to a general ward as compared with a physician-devised algorithm, in patients with chest pain.

In spite of this however there are few reports in the nursing literature detailing the training in, quality of, or assessment of clinical history taking (and risk-stratification) by nurses (McLean, 2009a). This is a worrying phenomenon, given Ramani's assertion (2004) that quality patient history taking leads to the final diagnosis in approximately 75% of cases.

2.2 ST segment elevation myocardial infarction

2.2.1 Evolution of treatment strategies in ST segment elevation myocardial infarction

Along a spectrum of chronic and acute CAD, the condition resulting in the highest early mortality is ST Segment Elevation Myocardial Infarction (STEMI). The treatment of STEMI has developed significantly over the last 40-years (Hanson and Williamson, 2006). One of the earliest developments was to establish specialist Coronary Care Units (CCU's) to monitor cardiac rhythm and allow prompt treatment of ventricular arrhythmia by cardioversion using defibrillators (Quinn and Thompson, 1999). Professor Desmond Julian established one of the world's first CCU's in the Royal Infirmary of Edinburgh in the early 1960's (Julian, 1961).

While the focus of community-based resuscitation by lay responders remains on the application of basic life support techniques, the use of defibrillation has moved over time from the CCU (Julian, 1961), to the ambulance (Pantridge and Geddes, 1967) and finally into the community by trained lay-responders (Hallstrom *et al.*, 2004) and to 'public access' schemes (Davies *et al.*, 2002). This demonstrates the journey of a treatment originally conceived in and for the CCU, out to its application in people's homes, shops, airports and other community settings.

In 1980 de Wood and colleagues demonstrated the role of occlusive coronary artery thrombus in acute myocardial infarction (de Wood *et al.*, 1980). The use of thrombolytic drugs to restore coronary artery patency in myocardial infarction (MI) was then widely adopted following the major clinical trials of the 1980's (GISSI, 1986; ISIS-2, 1988). Like defibrillation, the use of thrombolytic therapy has moved from the CCU (Quinn and Thompson, 1999), to the Emergency Department (ED) (Pell *et al.*, 1992; Quinn *et al.*, 2005), then finally to the community (Schofer *et al.*, 1990; Barbash *et al.*, 1990; Weaver *et al.*, 1993; Rawles, 1994).

This very brief synopsis describes the evolution of two key advances in the treatment of cardiac arrest and myocardial infarction. There are in addition important historical milestones to acknowledge in the nursing contribution to the care of these patients. Quinn and Thompson (1999) cite 1964 as the year in which Dr. Meltzer (1964) published the first report of nurses formally being taught rhythm recognition and the application of defibrillation to patients in cardiac arrest. Killip and Kimball (1967) then made the very important statement in *The American Journal of Cardiology* that: *"In our opinion, optimal treatment ... cannot be attained unless certain prerogatives hitherto reserve for the physician are delegated to the nurse."* (1967:463). These were crucial formative years for the pioneers of coronary care units and coronary care nursing. Quinn and Thompson (1999:135) pay tribute to Dr. Meltzer and his nursing colleague Rose Pinneo for what is widely regarded as one of the first and most widely used books on coronary care nursing (Meltzer *et al.*, 1965), stating that they deserve credit as the *"true pioneers of coronary care nursing."*

While the chronology may seem almost intuitive, significant debate remains in some parts of the clinical community regarding the scientific justification, evidence base and safety of developing what have become 'modern' programmes of STEMI care. While evolving evidence reported the benefits (or otherwise) of new generation drugs or interventional technologies, there was little evidence reporting how these technologies could be applied in a contemporary healthcare model, with its historical professional boundaries and intricate inter-professional relationships and governance arrangements.

2.2.2 The critical importance of time-to-treatment

The now ubiquitous phrase imparted upon every new recruit to cardiovascular units across the world of "minutes mean muscle," has probably been in existence since the beginning of treatment of STEMI with thrombolytic ("clot-busting") drugs.

Following de Wood et al.'s discovery (1980), cardiovascular scientists and clinical trialists embarked on a series of now seminal trials describing the treatment of myocardial infarction. There were pre-dated by a number of key exploratory trials attempting to assess the benefits of coronary artery recanalisation (reopening of the occluded coronary artery) by means of intravenous and intracoronary thrombolytic treatment. In an early meta-analysis Yusuf *et al.* (1985) concluded that an overview of some 6,000 patients in 25 randomised trials indicated that intravenous treatment with streptokinase produced a significant reduction ($p < 0.001$) in the odds of death, and an even larger reduction in the odds of reinfarction (both at index admission and up to 6-months following hospital discharge), with an absolute frequency of serious adverse effects to set against this that was much smaller than the absolute mortality reduction (Yusuf *et al.*, 1985). They stated that "*because of the irreducibly large effects of the play of chance on individual trial results, the disadvantages of doing meta-analyses pale into insignificance compared with the disadvantages of not doing them, and of basing inference instead on whichever few trial results one happens to find the most attractive*" (1985: 582), and concluded that future trials should obviously be much larger than previous trials.

ISIS-2 (1988) tested streptokinase, aspirin, both or neither in 17,187 patients with MI. There were significant mortality reductions when treating MI patients with aspirin versus placebo ($p < 0.0001$) and streptokinase versus placebo ($p < 0.00001$). Furthermore there was an additive effect, with patients receiving both agents having a superior outcome versus patients receiving neither agent or either agent alone (both $p < 0.00001$). This came at a cost of increased cerebral haemorrhage ($p < 0.05$), and an excess of non-fatal reinfarction was reported when streptokinase was used alone, but this appeared to be avoided by the addition of aspirin.

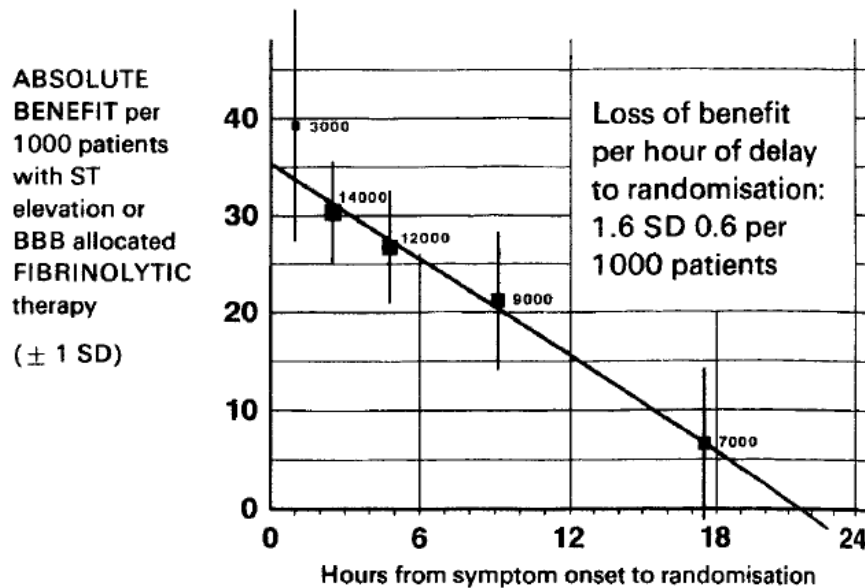
ISIS-3 (1992) then compared two treatment modalities. MI patients receiving unfractionated Heparin in addition to oral aspirin, over aspirin alone experienced slightly less reinfarction and mortality, though neither of these findings were statistically significant, and came with a cost of significant increases in cerebral and non-cerebral bleeding in the Heparin group ($p < 0.01$ and $p < 0.05$ respectively). Perhaps more importantly this study found that (i) treatment with anistreplase was not superior to streptokinase, with no significant difference in mortality or reinfarction and at a cost of increased cerebral haemorrhage ($p < 0.0001$), and (ii) treatment with tissue-plasminogen-activator was superior to streptokinase in terms of significantly reducing reinfarction ($p < 0.02$), but again at a cost of increased cerebral haemorrhage ($p < 0.00001$) and with no significant mortality benefit.

In these trials patients were eligible if they were thought to be within 24-hours of the onset of the symptoms of suspected or definite MI (with or without ECG changes), with randomisation occurring at a median of 4-hours after the symptom onset (ISIS-2, 1988), and 9.6-hours in Yusuf *et al.*'s meta analysis (1985). The site of randomisation or treatment in both ISIS-2 (1988) and Yusuf *et al.* (1995) is not clear, although it is clear that no patients received treatment in the pre-hospital setting.

Lau *et al.* (1992) then published a cumulative meta-analysis of 36,974 patients enrolled in 33 STEMI trials between 1959 and 1988. They suggested that the technique of cumulative meta-analysis allows practitioners and policy-makers to study trends in 'good' and 'bad' effects and "*pinpoint the first time a difference in outcome between treatment and control groups becomes statistically significant*" (Lau *et al.*, 1992:248). They purported that a consistent, statistically significant reduction in total mortality was achieved in trials published by 1973, after only eight trials including 2,432 patients had been completed. The results of the 25 subsequent trials, which enrolled an additional 34,542 patients had little or no effect on the odds ratio establishing efficacy, but did narrow the 95% confidence interval. While the authors did not suggest it explicitly, there may be an argument to be made from Lau *et al.* that the benefits of thrombolytic therapy in clinical practice could have been realised earlier.

In 1994 the Fibrinolytic Trialists Collaboration (FTT, 1994) published an important meta-analysis of 58,600 patients in nine randomised trials conducted between 1982 and 1992. They concluded that in the 45,000 patients presenting with ST segment elevation or Bundle Branch Block the relation between benefit and delay from symptom onset indicated highly significant absolute 35-day mortality reductions of about 30 per 1,000 for those presenting within 0-6 hours of symptom onset, around 20 per 1,000 for those presenting from 7-12 hours, and a statistically uncertain benefit of about 10 per 1,000 for those presenting between 13-18 hours (with more randomised evidence needed in this latter group to assess reliably the net effects of treatment). This overview concluded that thrombolytic therapy was beneficial in a much wider range of patients than was given routinely in clinical practice, using Figure 3 to present the linear time-based reductions in treatment benefit.

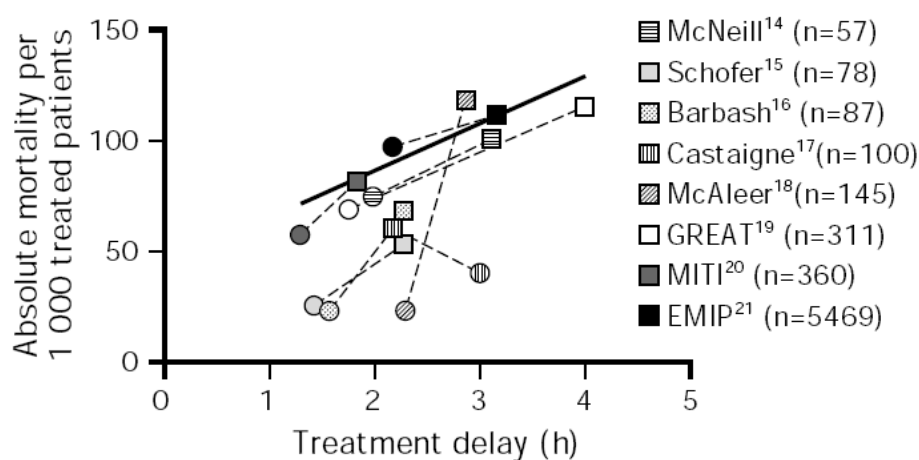
Figure 3: Absolute reduction in 35-day mortality versus delay from symptom onset to randomisation among 45,000 patients with ST segment elevation or Bundle Branch Block (BBB).



FTT (1994)

In 1996 Boersma and colleagues in Rotterdam published what became a seminal meta-analysis of 22 trials including 50,246 patients, of whom 16,197 (21%) were randomised to thrombolytic therapy within 3-hours of symptom onset. Boersma and colleagues accepted that the 'first golden hour' of maximal benefit of thrombolytic therapy was supported by both experimental studies and randomised trials, however sought to explore whether or not a substantial additional reduction of mortality could be achieved with treatment within 2–3 hours of symptom onset. As demonstrated in Figure 4 (overleaf) they cited the first randomised studies of pre-hospital thrombolytic therapy in the meta-analysis, for example EMIP (1993).

Figure 4: Mortality at 35-days in randomised studies comparing pre-hospital (circles) with in-hospital (squares) thrombolytic treatment.



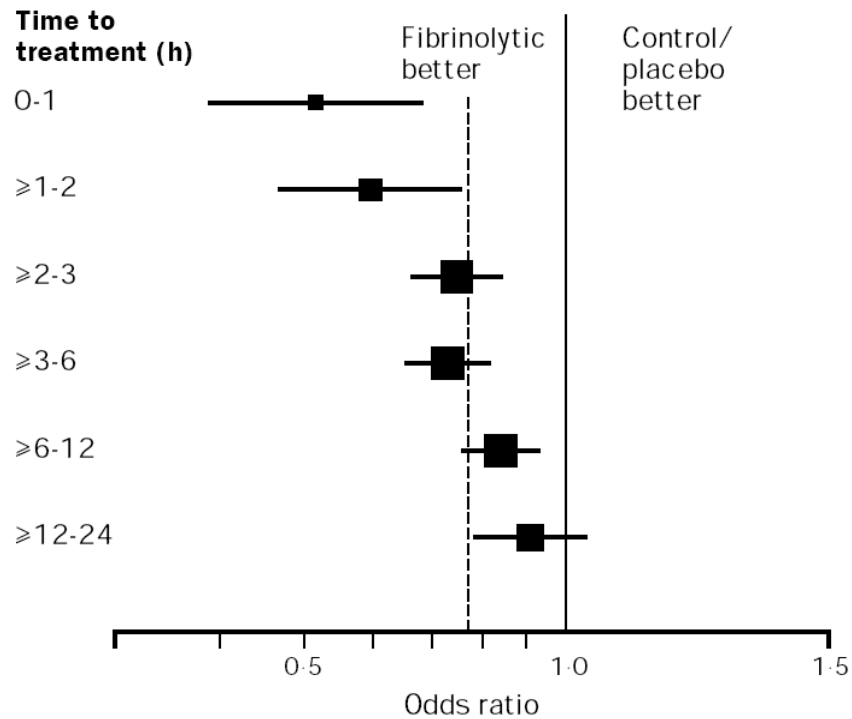
Boersma *et al.* (1996)

Boersma *et al.* (1996) postulated that the FTT investigators (1994) concluded from these data a gradually increasing benefit with earlier treatment, without significant additional treatment effect at 0–1 hours, and that according to this analysis little would be gained by extra efforts to achieve very early, pre-hospital thrombolytic therapy. Boersma *et al.* (1996) criticised the FTT decision to exclude small trials (which FTT arbitrarily defined as less than 1,000 patients), particularly as a significant proportion of these trials included patients treated in the pre-hospital setting, and therefore treated very early. Boersma *et al.* also commented that the FTT statistical analysis was based on subdivision of patients according to delay from symptom onset with only two benefit estimations in the first 3-hours. Boersma *et al.* suggested that in this way, part of a potential large effect in the first 2-hours may be obscured by a relatively small effect in the third hour. The findings of Boersma *et al.* (1996) challenged the findings of FTT (1994) that there was linear benefit when reducing time-to-treatment in STEMI.

Boersma *et al.* (1996) suggest that the absolute benefits of thrombolytic therapy in mortality reduction were greatest within 1-hour of symptom onset with 65 lives saved per 1,000 patients treated (Figure 5).

Lives saved per 1,000 patients treated were 37 from 1-2 hours of symptom onset and 26 per 1,000 patients from 2-3 hours. These estimations were significantly higher than those published by the FTT investigators (1994).

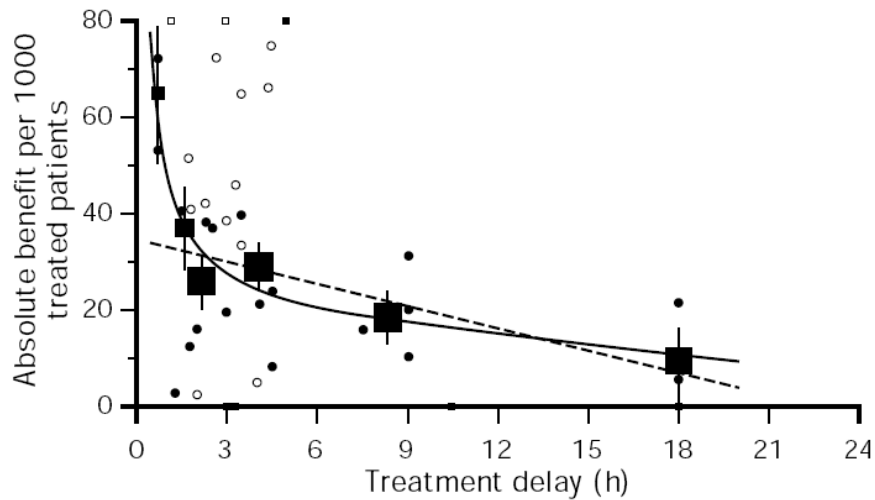
Figure 5: Proportional effect of thrombolytic therapy on 35-day mortality according to treatment delay (Odds ratios, plotted with 95% CI on a log scale, are significantly different over the six groups (Breslow-Day test, $p=0.001$)).



Boersma *et al.* (1996)

The investigators stated that while they agreed with the concept of the ‘first golden hour,’ their alternative analysis supported a non-linear relation which was in-line with the experimental and pre-hospital trial data. As shown in Figure 6, they graphically presented their data to show the non-linear relationship, versus the linear findings of the FTT investigators (1994) (Figure 3).

Figure 6: Absolute 35-day mortality reduction versus treatment delay.



Boersma *et al.* (1996)

Boersma *et al.* (1996) concluded that: “from a clinical standpoint, the challenge is to initiate thrombolytic treatment within the first 2 to 3 hours after symptom onset. A first important step will be to increase public awareness of the need to reduce delay in seeking medical help for cardiac symptoms. Second, as an aid to rapid diagnosis when there is chest pain suggestive of infarction, the general practitioner or ambulance team should obtain, preferably on-site, a computer-interpreted standard 12-lead ECG” (1996: 774).

Stating that many North American EMS systems had implemented PHT programmes despite the fact that most were situated in urban areas with rapid transit times and short door-to-needle times, Morrison *et al.* (2000) performed a meta-analysis of 6 RCTs including 6,434 patients. The primary objective of this meta-analysis was to critically appraise all RCTs of PHT versus IHT. The primary outcome measure was all-cause hospital mortality; secondary outcome measures were EMS scene times, time to thrombolytic treatment, infarction size, and adverse events, including ventricular fibrillation, cardiogenic shock, hypotension, bradycardia, bleeding, and stroke.

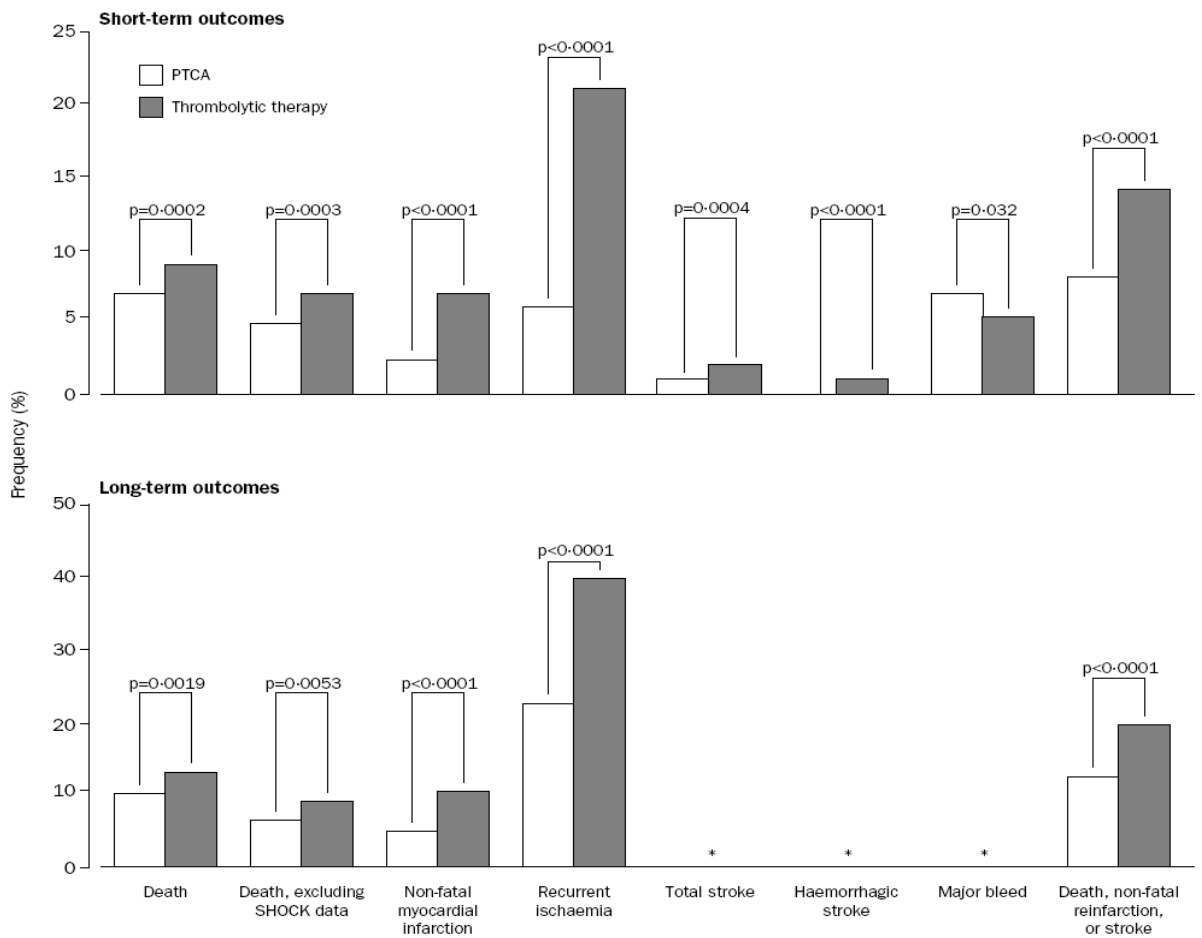
The results of the 6 RCTs were pooled and indicated significantly decreased all-cause hospital mortality among patients treated with PHT compared with IHT (odds ratio, 0.83; 95% confidence interval, 0.70-0.98). Median time to thrombolysis was 104-minutes for the PHT group and 162-minutes for the IHT group ($p=0.007$). Results were similar regardless of trial quality or training and experience of the provider, which in the trials studied included general practitioners, intensivists, hospital physicians and EMS paramedics (Morrison *et al.*, 2000).

At around the same time as Boersma *et al.*'s meta-analysis, key trials began to emerge reporting the outcomes of performing Primary Percutaneous Coronary Intervention (PPCI) in STEMI. One of the first was published by Zijlstra *et al.* (1993). 152 patients were randomised to PPCI and 149 patients to streptokinase thrombolysis with median times to treatment of 62-minutes for PPCI and 30-minutes for thrombolytic therapy. There were no adjunctive therapies common to modern practice such as intracoronary stents or intravenous glycoprotein inhibitors used in the PPCI group. The study found that there were statistically significant reductions in death (1% vs 7%), non-fatal reinfarction (1% vs 12%) and stroke (0.7% vs 2%) in patients receiving PPCI.

As with many new technologies, initial trials were small and single-centred. 14 of the 23 trials cited in Keeley *et al.*'s meta-analysis (2003) for example had less than 100 patients in each treatment arm.

Keeley *et al.* (2003) included 7,739 patients from 23 trials conducted between 1993 and 2002 in their meta-analysis. Crucially they distinguished between patients receiving fibrin-specific (standard tPA, accelerated tPA and alteplase), versus non-fibrin specific (streptokinase 1.2mU and 1.5mU) thrombolytic therapy and demonstrated the superiority of PPCI over both fibrin specific and non-specific thrombolytic agents. Figure 7 displays the benefits in short and long term outcome:

Figure 7: Short and long-term clinical outcomes in patients treated with PPCI or thrombolytic therapy.



Keeley *et al.* (2003)

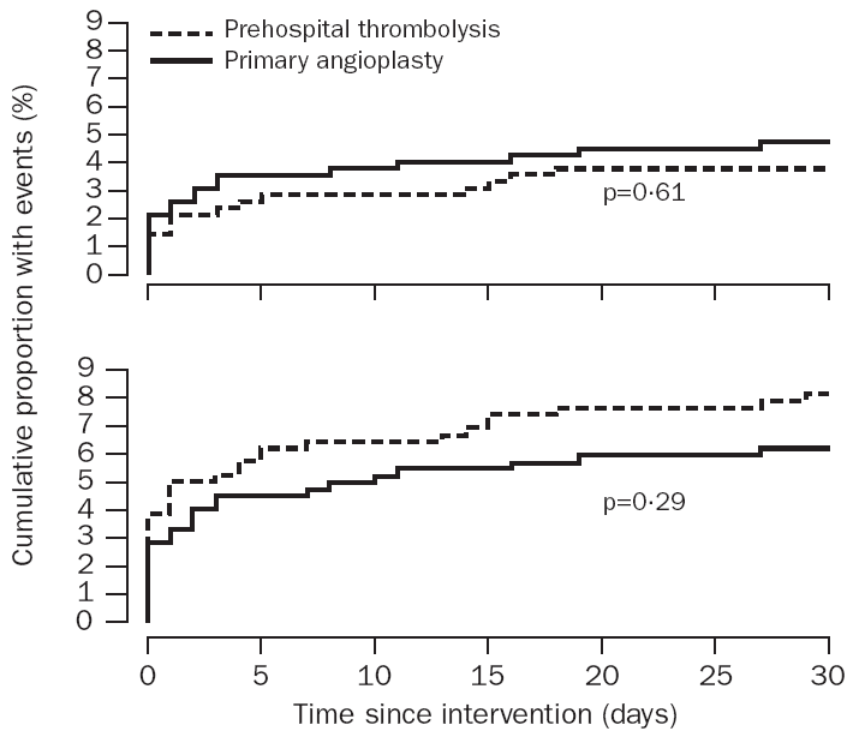
Keeley *et al.* (2003) acknowledged that a number of the trials included in their meta-analysis did not reflect current and evolving practice at the time of publication (use of streptokinase, low or no use of intracoronary stents/intravenous glycoprotein inhibitors). Conversely the analysis is strengthened by the authors efforts to separate fibrin specific/non-fibrin specific agents, inclusion of multi-centre (and therefore multi-operator and multi-volume) PPCI programmes, and inclusion of long-term follow-up data. Like Boersma *et al.* (1996), and unlike FTT (1994), Keeley *et al.* (2003) do mention pre-hospital treatment. While focussing primarily on PPCI Keeley *et al.* (2003) cite and discuss Bonnefoy *et al.* (2002), and stated that Bonnefoy *et al.* (2002) concluded that PPCI was no better than pre-hospital thrombolytic therapy in patients who presented within six hours of STEMI.

In the following year Bogaty and Brophy (2004) published criticism of Keeley et al. (2003), concluding “*that reasonable health care professionals may still find considerable uncertainty about the superiority of primary angioplasty for all situations. The magnitude of benefit for primary angioplasty over thrombolysis is probably less than 1 to 2 lives saved/100 patients treated and largely depends on the choice of thrombolytic agent, time to treatment, place of treatment, and adjunctive therapy*” (Bogaty and Brophy, 2004:292). They stated that there was scarce evidence that systematically transferring patients for primary angioplasty in routine practice would provide benefits over thrombolysis, and that consequently it may be most useful to view these treatments as complementary rather than competitive. Thrombolysis, they stated, remains a clinically and economically attractive option for the treatment of acute myocardial infarction that does not require the radical restructuring of health care systems (Bogaty and Brophy, 2004).

Bonnefoy *et al.* (2002) cited the findings of the 1993 EMIP analysis, a 17% lower relative mortality in patients receiving prehospital thrombolysis (PHT) versus in-hospital thrombolysis (IHT), stating that thrombolysis had since evolved from a stand-alone strategy to a strategy where it had become combined with PCI. Their French study of 840 patients in 27 tertiary hospitals aimed to compare PHT followed by transfer to a centre with interventional facilities, versus PPCI. The methodology of and recruitment to Bonnefoy *et al.*'s CAPTIM trial (2002) was criticised subsequently by Boersma *et al.* (2006) and Terkelsen *et al.* (2009). Firstly although 1,200 patients were needed to demonstrate a foreseen 44% relative reduction in the composite endpoint of death, non-fatal reinfarction and non-fatal stroke, only 67% of the target sample size was achieved (n=840) due to cessation of research funding. Thereafter coronary angiography and subsequent revascularisation were allowed in the thrombolysis group at the discretion of the responsible physician. This resulted in the significant majority of thrombolysis patients (358/419, 85%) having angiography within 30-days of treatment, and 70% (n=295/419) having angioplasty. Conversely only 86% (n=364/421) of patients assigned to PPCI underwent the procedure.

Commentators (Boersma et al., 2006; Terkelsen et al., 2009) have since criticised this and claim that this was the reason for the similarities in death and in the composite endpoint (Figure 8).

Figure 8: Kaplan-Meier curves for death (upper panel) and composite endpoint (lower panel) within 30-days after randomisation according to treatment group.



Bonnefoy *et al.* (2002)

CAPTIM therefore showed that PHT followed by PCI within 30-days of admission in 70% of cases, yielded a statistically similar outcome to PPCI. The authors do however comment that, although not a pre-specified outcome, an exponential mortality reduction was noted when thrombolytic therapy was initiated within 3-hours of symptom onset, and that mortality reduction was highest in patients treated within 2-hours of symptom onset than those treated later (44% vs 20%, $p=0.001$).

Boersma and colleagues then revisited the issue of time-to-treatment in a second analysis in 2006.

The aim of their pooled analysis of 6,763 patients in 22 trials reported since 1990 was to assess whether the clinical benefit of PPCI compared with IHT was modulated by time-to-treatment in a pooled analysis of Randomised Controlled Trials (RCTs) reported since 1990.

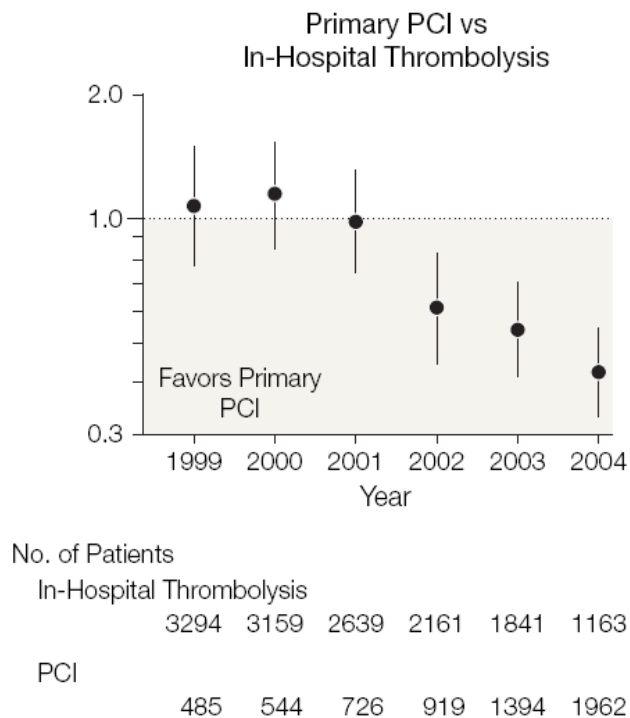
Despite the study analysing time-to-treatment rather than logistics of treatment, the authors elected to exclude the CAPTIM trial (2002) from their analysis on the basis that it was a pre-hospital study. The median time to thrombolysis in the pooled analysis was significantly shorter than that of the beginning of PPCI (19-minutes vs 76-minutes respectively, giving an overall PPCI-related delay of 55-minutes ($p < 0.001$)). In patients randomised to IHT 30-day mortality increased two-fold as the presentation delay increased from less than 1-hour to over 6-hours ($p < 0.001$), yet the trend to similar in PPCI patients was not significant ($p = 0.06$). The combined endpoint of 30-day death and reinfarction occurred in 13.5% of IHT and 7.3% of PPCI patients ($p < 0.001$), although it should be noted that a significant number of patients received streptokinase thrombolysis. According to presentation delay the treatment effect consistently favoured PPCI in all subgroups. The absolute mortality reduction by PPCI increased from 1.3% in patients randomised in the first hour after symptom onset to 4.2% in those randomised after 6-hours. Consequently with increasing delay, the number needed to treat to prevent a death decreased from 77 to 24 patients. Finally, Boersma and colleagues (2006) stated that the logistical and economic challenges which make 'PPCI-for-all' unlikely, do not negate the importance of developing comprehensive and unified approaches to the delivery of acute cardiac care. They concluded that while PPCI-related-delays remain as high as 93-minutes (as they were in some population-based studies), thrombolysis would remain a viable treatment strategy when timely PPCI is not available: "*one treatment does not fit all: time matters*" (2006: 775).

The real-world setting of STEMI reperfusion was described by the Swedish RIKS-HIA registry (Stenstrand *et al.*, 2006). While acknowledging that RCTs are "*rightly at the top of the evidence hierarchy*" (2010:908), McNamara highlights that registry research has gained increasing visibility within cardiovascular medicine.

He purports that while RCTs “*may be able to provide the basis for the most ‘beautiful’ management strategies, determining how these strategies work in the ‘real-world’ is critical*” (McNamara, 2010:908). Stenestrand *et al.* (2006) compared the outcomes of PPCI with PHT and IHT in 26,205 STEMI patients admitted between 1999 and 2004. Figures 9, 10 and 11 summarise these data.

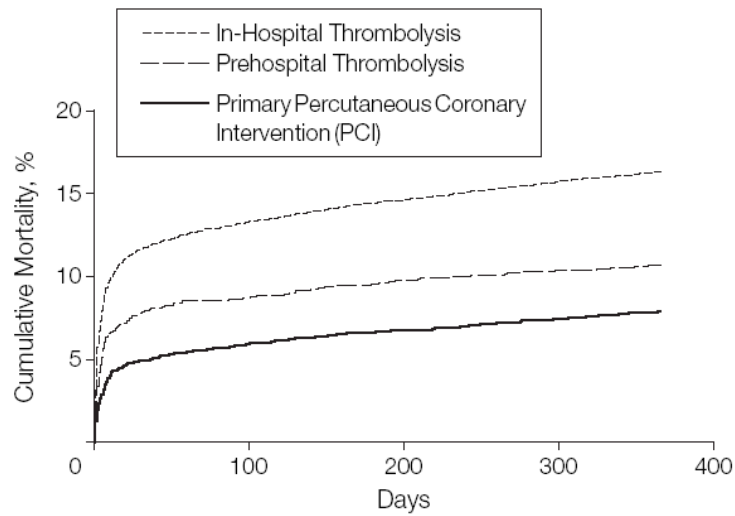
Figure 9 describes temporal trends in PPCI and IHT and the continually widening gap between IHT and PPCI mortality favouring PPCI, perhaps due to an increase in the use of PPCI in 8.3% of STEMI patients in 1999 to 37.2% in 2004. Median delay was 47-minutes shorter for PHT and 43-minutes longer for PPCI against a reference point of patients receiving IHT. PPCI was associated with lower mortality than IHT at 7-days, 30-days, and 1-year. Also PHT predicted a lower adjusted mortality than IHT at 30-days and 1-year. Finally, PPCI predicted lower mortality than PHT at 30-days (4.9% vs 7.6%) and at 1-year (7.6% vs 10.3%) (Figure 10).

Figure 9: Temporal trends in 1-year mortality in IHT and PPCI patients in RIKS-HIA.



Stenestrand *et al.* (2006)

Figure 10: Unadjusted cumulative mortality during the first year after the STEMI admission in RIKS-HIA.

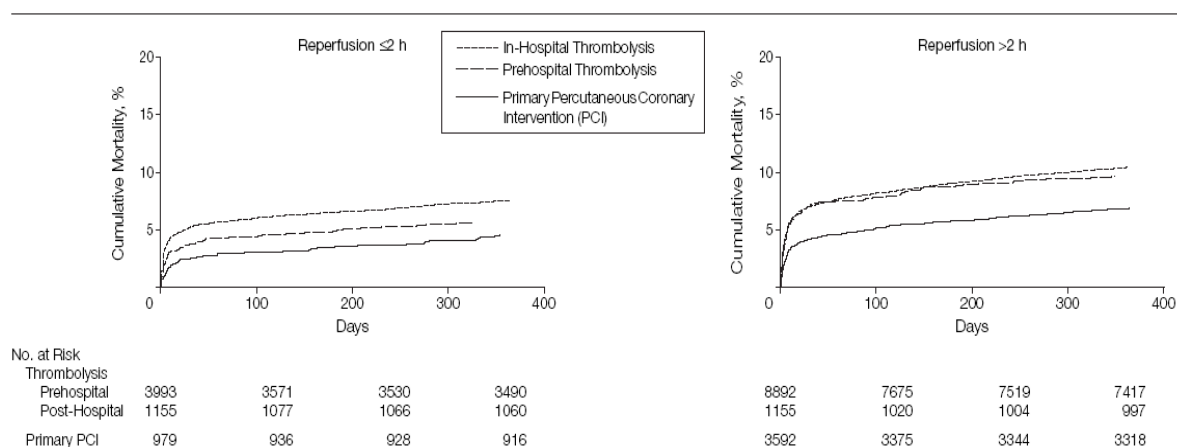


No. at Risk				
Thrombolysis				
In-Hospital	14 260	12 322	12 100	11 931
Prehospital	2 736	2 491	2 460	2 442
Primary PCI	6 030	5 661	5 607	5 555

Stenestrand *et al.* (2006)

Arguably the most powerful data to emerge from Stenestrand *et al.* (2006) related to differences in mortality when treatment was received early. During the first 2-hours of infarction, there was an approximate 2% absolute difference in mortality favouring PPCI, which rose to about 6% to 7% after 6 to 7 hours. Not until after 7-hours' delay did the age-adjusted 1-year mortality for PPCI reach the same mortality as thrombolysis given within 2-hours (Figure 11). While acknowledging the advantages and deficiencies of registry data, the authors concluded that the relative mortality benefits with PPCI might amount to approximately 20% during the first hours but increase to 35% after 4 to 7 hours. They stated that this was concordant with Boersma's meta-analysis (2006) and contradicts Bonnefoy *et al.*'s CAPTIM trial (2002) which claimed that PPCI was not superior (and indeed may be inferior) to PHT within 2-hours of symptom onset.

Figure 11: Estimate cumulative mortality for patients receiving reperfusion treatment within 2-hours or after 2-hours after symptom onset.



Stenestrand *et al.* (2006)

2004 saw the publication of updated STEMI guidelines of the American College of Cardiology (ACC)/American Heart Association (AHA). The publication (Antman *et al.*, 2007) and the position statement of the European Society of Cardiology (Bassand *et al.*, 2005) was, according to Terkelsen *et al.* (2009), based around findings in the meta-analysis of Nallamothu & Bates (2003). Terkelsen *et al.* (2009) are scathing in their criticism of Nallamothu & Bates' work. They claim that Nallamothu & Bates inaccurately extracted tabulated data and used incorrect PPCI-related-delay times, thus underestimating the maximal accepted PPCI-related-delay.

Nallamothu and Bates (2003) used data from the 3 primary sources of Keeley *et al.* (2003) and extracted (i) 4-6 week incidence of death, reinfarction and stroke in patients who received PPCI or thrombolytic therapy, and (ii) the PPCI-related time delay. After excluding 2 of the 23 studies they performed variance-weighted linear regression analysis to assess the impact of PPCI-related time delay on treatment differences for death in 21 studies, and the combined end point of death, reinfarction, or stroke in 13 studies reporting this end point. As PPCI-related time delay increased, the absolute mortality reduction favouring PPCI decreased significantly (0.94% decrease for every additional 10-minute delay; $p=0.006$). Overall, the two reperfusion strategies appeared to become equivalent with regard to mortality after a PPCI-related time delay of 62-minutes.

The impact of PPCI-related time delay on the composite end point of death, reinfarction, or stroke was also significant (absolute 1.17% decrease for every 10-minute delay; $p=0.016$). The time to equivalence for the composite end point, however, was longer at 93 minutes.

Terkelsen *et al.* (2009) repeated the regression analysis performed by Nallamothu and Bates (2003). They found that the acceptable PPCI-related-delay was in fact 119-minutes (as opposed to Nallamothu and Bates' 62-minutes) when compared to all-comer thrombolysis, and 86-minutes when compared to fibrin-specific thrombolysis. The authors acknowledge however that their findings are based on summary statistics at trial level rather than individual patient data and thus should be interpreted with caution. Nevertheless they concluded that while the maximal PPCI-related-delay may be an issue unsettled, it is likely to be around 80-120 minutes.

They state that the importance of reducing treatment delay in STEMI is logical, but can only be demonstrated properly in studies deliberately delaying treatment in one patient cohort – which they state would be unethical in the context of STEMI reperfusion.

In the UK context at this time, work was underway to synthesise the findings of these data, and recommendations of international guidelines, into national policy. SIGN 93 for Acute Coronary Syndromes (2007) clearly stated that where PPCI could not be provided within 90-minutes of diagnosis in Scotland, patients with STEMI should receive immediate thrombolytic therapy. Scotland at this time had a well established PHT programme with 89% of patients receiving PHT within 60-minutes of EMS call in one study (McLean *et al.*, 2008). In England an observational study was funded by the Department of Health in collaboration with the British Cardiovascular Society (BCS) and British Cardiovascular Intervention Society (BCIS) to test the feasibility of developing PPCI services as the initial treatment for STEMI across England (Department of Health, 2008). Data from seven pilots (ten centres) were collected between April 2005 to March 2006. Patients recruited to the study in that year were then followed up for a further year to March 2007.

This study, which has led to little in the way of peer-reviewed evidence, reported that the development of PPCI services was feasible in a variety of geographical settings. The data to support this argument was that in the pilot centres studied the median EMS call-to-balloon times ranged from 86-minutes to 159-minutes. In the 2,245 patients audited there was a mortality benefit in those receiving PPCI at both 30-days (5.6% PPCI vs. 7.9% thrombolysis), and at 12-months (9.9% PPCI vs. 14.8% thrombolysis) although the authors are clear that pre-specified analysis of mortality was not the objective of the study. While data are presented describing the increase in mortality resulting from increasing EMS call-to-balloon times, there are no data describing comparison with thrombolysis. Nor are data presented describing incremental benefits of PPCI and thrombolysis (which is not separated as IHT and PHT) over 1-2 hour gradations.

A subsequent economic analysis of the report (Goodacre *et al.*, 2008) concluded that an English PPCI service was more expensive than thrombolysis care but was likely (about a 90% probability) to be a cost-effective use of NHS resources by NICE criteria. It also suggested that systems based on direct access to the catheter laboratory were almost certain (95% probability) to be cost-effective, whereas systems based on access via emergency departments, coronary care units or other wards were less certain (about a 75% probability) to be cost-effective. Finally it warned that transfer of patients from a non-PPCI hospital to a PPCI hospital with the time delays seen in the NIAP was unlikely to be cost-effective (about a 38% probability). Although (in my opinion) there are many and significant flaws in the NIAP report, the drive in England to establish 'Heart Attack Networks' was further enhanced by its publication. The position paper of the English National Director for Heart Disease and Stroke (Department of Health, 2006) and the wide-ranging NHS England review (Darzi, 2008) set out the arguments for creating specialist centres for STEMI to deliver improved service.

The theme of heart attack networks is expanded in the narrative review of Fox and Huber (2008). They state that the delivery of STEMI care has lagged behind establishing the evidence for effectiveness.

Citing the GRACE registry (Fox, 2004) they state that approximately a quarter of all patients with STEMI still fail to receive reperfusion therapy. Additionally, for most patients delays substantially exceed guideline recommendations and secondary prevention is incomplete. They suggest that Cardiologists need to take the lead in improving systems of care, with the integration of pre-hospital care within “heart attack networks” involving intervention centres, non-intervention hospitals, primary care, and paramedic ambulance care. The authors provided several examples to show that such systems were feasible, namely the Vienna network (Kalla *et al.*, 2008) where 1,053 patients admitted to one of five major interventional centres across Vienna were studied before and after formation of a heart attack network.

Although acknowledging the potential bias of a single centre study based on comparison with retrospective data, the authors state that the implementation of guidelines for the treatment of STEMI in a metropolitan area by means of a ‘heart attack network’ led to a significant reduction in in-hospital mortality from 16% prior to the network to 9.5% after its creation. While it must be highlighted that this paper is a report of their local clinical experience, the authors attribute the mortality reductions to a system whereby patients received the most appropriate reperfusion treatment (PHT, PPCI or IHT) based on time from symptom onset and geographical location. When patients were treated in the early phase of STEMI (defined as within 2 to 3 hours), in-hospital mortality did not differ between PPCI and thrombolysis. However, if reperfusion therapy was initiated later than 3-hours after onset of symptoms, PPCI appeared to be the treatment of choice. Besides offering the fastest available reperfusion method to patients with STEMI of short duration, the reduction in the number of patients not receiving reperfusion at all might have had the strongest influence on the results. The authors concluded that these results serve as a reinforcement of the guidelines themselves and as a benchmark for the benefits of their implementation.

Given the continuing challenge in delivering timely and effective PPCI for STEMI, and their view that compelling evidence that delay to PPCI is associated with lesser myocardial salvage and worse outcomes, Armstrong *et al.* (2010) have designed a trial to evaluate “*whether a strategy of prompt thrombolysis coupled with contemporary antiplatelet and antithrombotic therapy at the time of first medical contact, followed by timely catheterization or rescue coronary intervention in STEMI patients presenting within 3 hours of symptom onset, represents an appropriate alternative strategy to PPCI*” (Armstrong *et al.*, 2010:31). Recruitment to this international multi-centre trial is currently underway with patients being randomised to thrombolysis combined with modern adjunctive pharmacological treatments, and cardiac catheterisation within 6-24 hours or rescue PCI if reperfusion fails within 90-minutes of fibrinolysis, versus PPCI performed according to local guidelines. Composite efficacy end points at 30-days include death, shock, heart failure, and reinfarction. Safety end points include ischaemic stroke, intracranial hemorrhage, and major non-intracranial bleeding. Follow-up is extended to 1-year and includes all-cause mortality. The Strategic Reperfusion Early After Myocardial Infarction (STREAM) study (Armstrong *et al.*, 2010) may fill a gap in the evidence by providing information on whether prompt thrombolysis at first medical contact, followed by timely catheterisation or rescue PCI in STEMI patients presenting within 3 hours of symptom onset, represents an appropriate alternative strategy to PPCI.

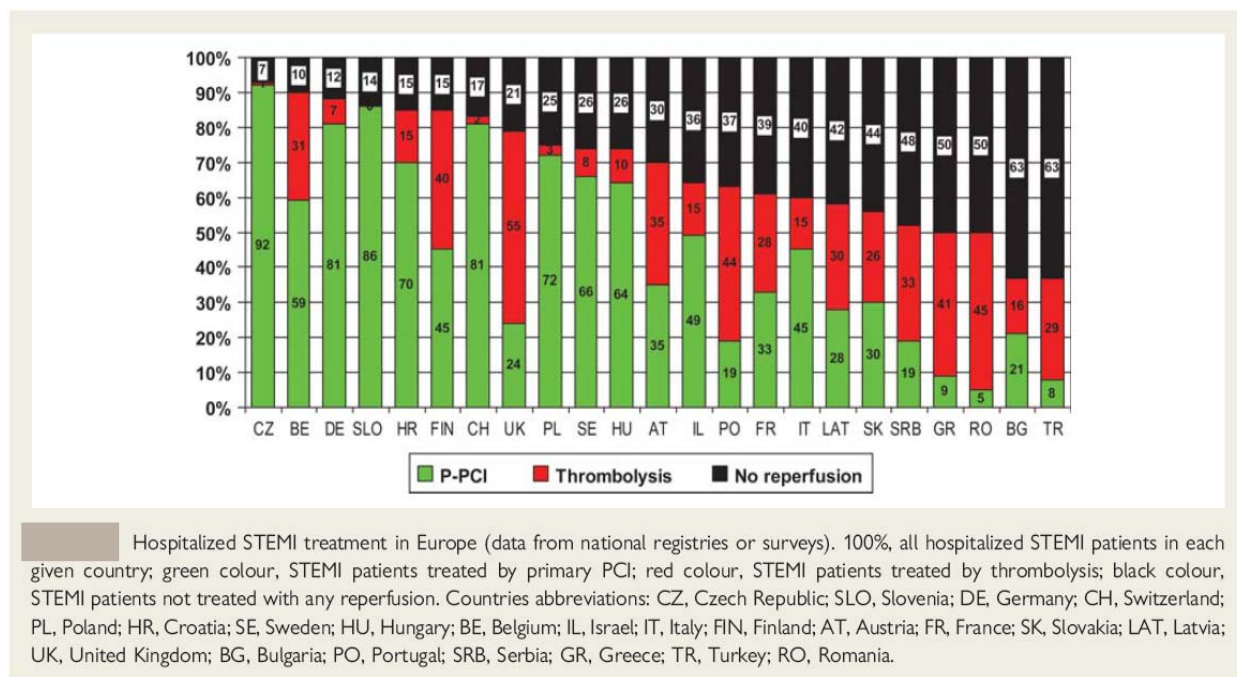
Guidelines of the European Resuscitation Council (Nolan *et al.*, 2010), although not explicitly, do suggest a system of care akin to the heart attack network described by Kalla *et al.* (2008). They state that PPCI is the preferred reperfusion strategy provided it is performed in a timely manner by an experienced team with an ‘acceptable’ delay between start of thrombolysis and first balloon inflation of between about 45 and 180-minutes depending on infarct localisation, age of the patient, and duration of symptoms. The guidelines state that a nearby hospital may be bypassed by the EMS provided PPCI can be achieved without too much delay, and that patients with successful thrombolysis but not in a PCI-capable hospital should be transferred for angiography and eventual PCI, performed optimally 6–24 hours after thrombolysis (the ‘pharmaco-invasive’ approach).

The guidelines also raised the spectre of “cardiac arrest centres.” They state that there is wide variability in patient survival among hospitals caring for patients after resuscitation from cardiac arrest. There is what the authors describe as some ‘low-level’ evidence cited that Intensive Care Units admitting more than 50 post-cardiac arrest patients per year produce better survival rates than those admitting less than 20 cases per year. They also cite ‘indirect evidence’ that regional cardiac resuscitation systems of care improve outcome in STEMI. The implication from these data is that specialist cardiac arrest centres and systems of care may be effective but, as yet, there is no direct evidence to support this hypothesis (Nolan *et al.*, 2010).

Huynh and colleagues (2009) undertook complex hierarchical Bayesian random-effect meta-analyses of 23 RCTs (n=8,140 patients) and 32 observational studies (n=185,900 patients). Their motivation to include patients treated in observational studies stemmed from their belief that RCTs do not reflect the practice of STEMI care in the ‘real-world,’ giving examples where patients enrolled in STEMI RCTs are generally younger, have fewer co-morbidities, less renal disease and less cardiogenic shock than in real-world practice (Huynh *et al.*, 2009). They found that PPCI was associated with a 34% reduction in short-term mortality in RCTs and 23% lower mortality in observational studies when compared with thrombolysis. Interestingly they report that there was no conclusive difference in mortality in the meta-analysis of observational studies that used PHT, and that an estimate of difference in mortality between PPCI and PHT could not be done with confidence in RCTs as only two RCTs studied used PHT. Reductions in short-term reinfarction of 65% and 53% were realized by the use of PPCI in RCTs and observational studies respectively. As one would expect in a meta-analysis the authors provide an extensive list of study limitations. They acknowledge that the greater use of thienopyridines in PPCI versus thrombolysis may have confounded results. They also acknowledge that the efficacy and safety of PHT compared with PPCI may be better evaluated in future large studies (Huynh *et al.*, 2009).

It is evident from the literature presented thus far there is a significant heterogeneity of views and conflicting evidence from meta-analyses/pooled-analyses, RCTs, observational studies, cohort studies, expert opinion and clinical guidelines regarding the optimal mode of treatment in STEMI. In an effort to describe the application of these data and guidelines in a contemporary European context Widimsky *et al.* (2010) published data from the national MI registries of 30 countries. The annual incidence of hospital admission for STEMI ranged from between 44 to 142 per 100,000 inhabitants per year. PPCI was the dominant reperfusion strategy in twenty-two countries, thrombolysis in eight countries. The use of PPCI varied from 5% to 92% of all STEMI patients (Figure 12), and thrombolysis from 0% to 55%.

Figure 12: Hospitalised STEMI treatment in Europe.

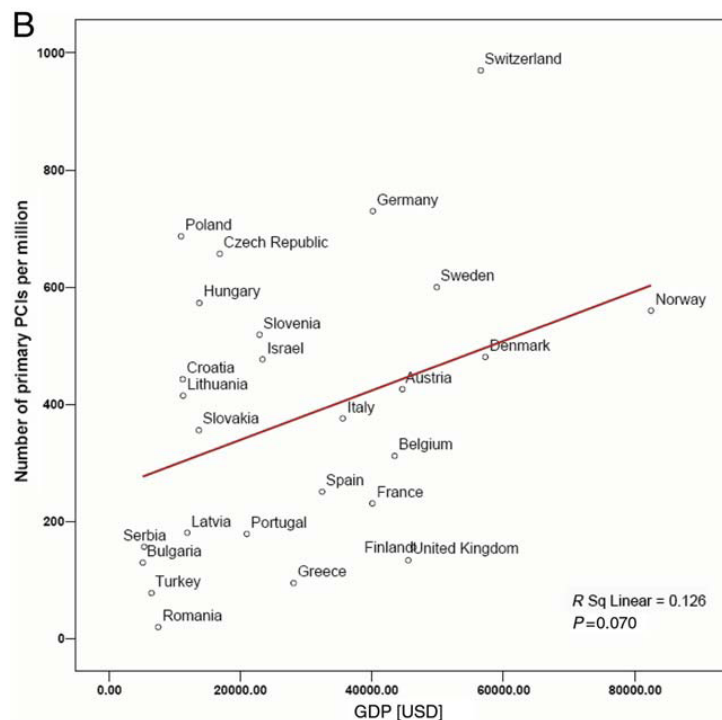


Widimsky *et al.* (2010)

The authors highlight the significant disparities in data quality and timing across the 30 countries studied.

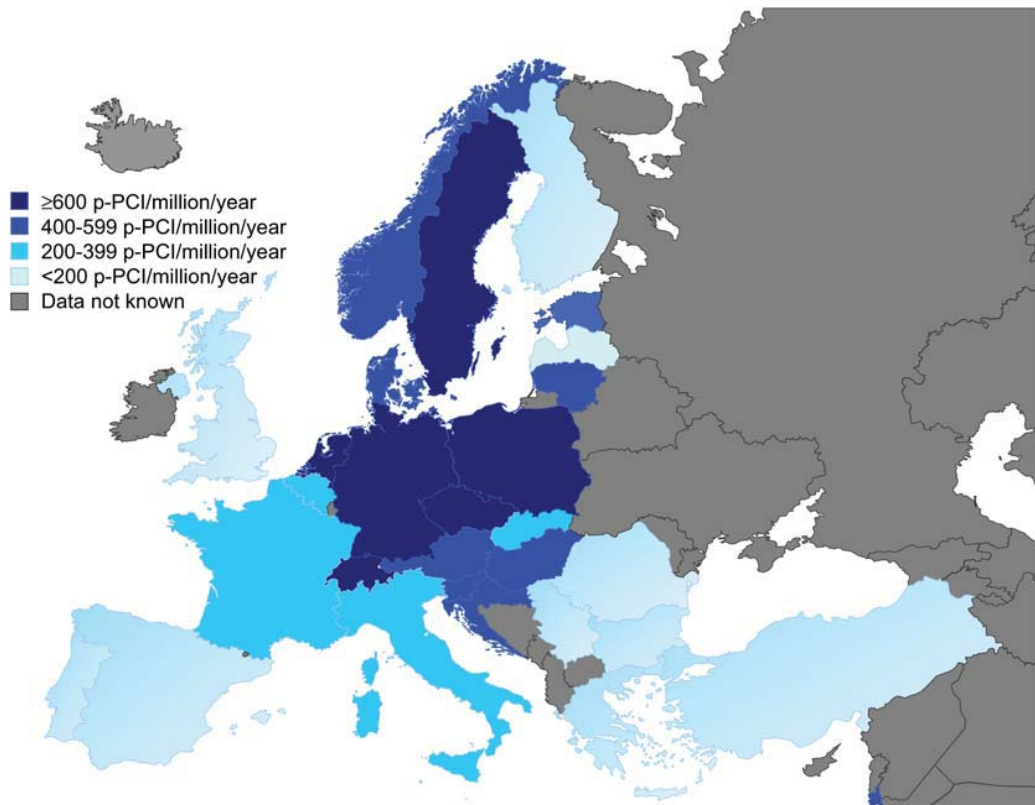
They make reference to the NIAP study (Department of Health, 2008) stating that patients treated with PPCI were younger than those treated with thrombolysis, suggesting a tendency to use PPCI in fitter patients who have a lower predicted mortality regardless of treatment strategy (Widimsky *et al.*, 2010). PPCI provision varied greatly across Europe, and did not correlate with either population size or economic status (as measured by Gross Domestic Product (GDP)). England and Wales for example had a catchment population of 2,642,445 per 24-hour PPCI centre. This compares with 354,559 in Italy, 312,245 in France and 265,000 in Germany – a ten-fold greater service provision (Figures 13 and 14).

Figure 13: Correlation between the annual number of PPCI per million population and GDP per capita.



Widimsky *et al.* (2010)

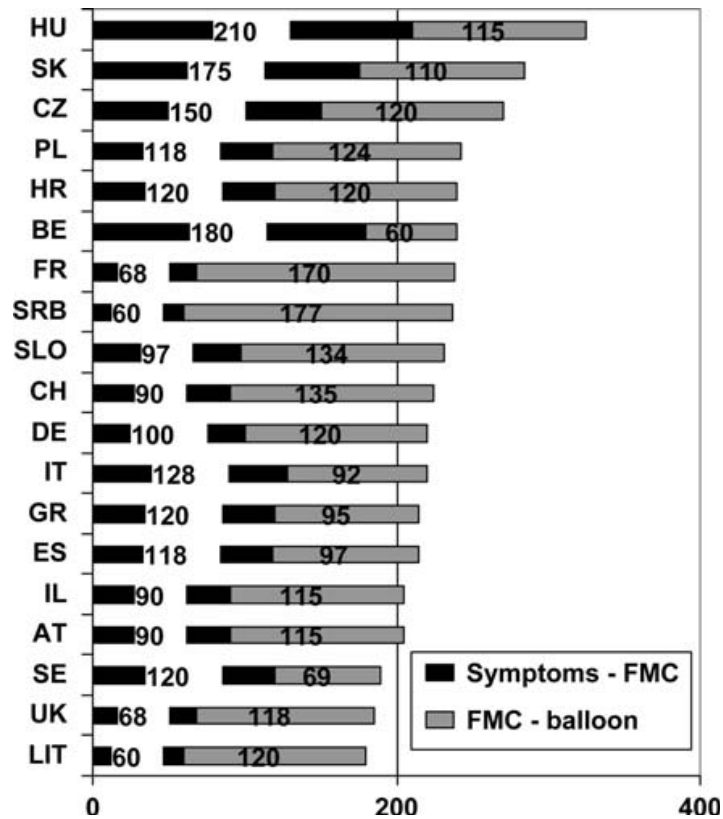
Figure 14: Primary PCIs per year per million inhabitants in European countries. (Grey colour, no data available; blue colour, countries participating in this study).



Widimsky *et al.* (2010)

Finally, Widimsky *et al.*'s study gave a valuable insight into the logistics of care and use of EMS. As shown in Figure 15, despite ranking 27th of 30 countries for PPCI provision per population, the UK ranks 2nd of 30 in having the shortest time delays in patients treated by PPCI.

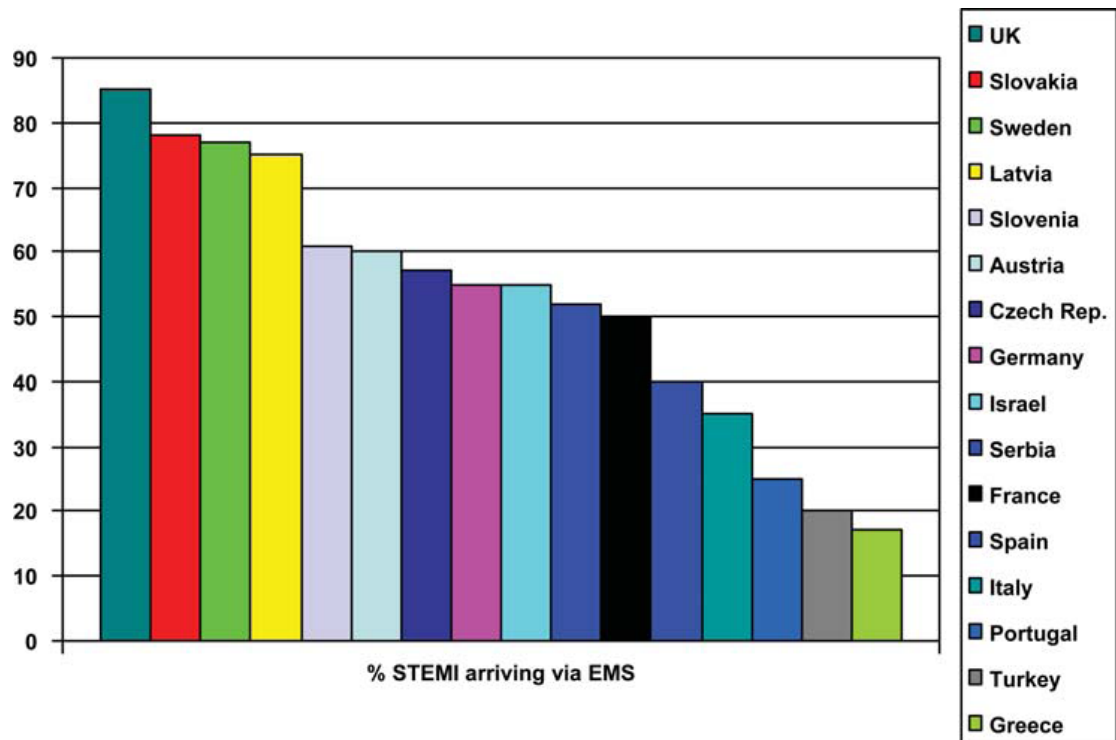
Figure 15: Time delays in patients treated by PPCI (FMC = First Medical Contact).



Widimsky *et al.* (2010)

In proposing how countries may overcome system delays the authors state that some of the problems may be overcome by organising ‘cooperating networks’ of PPCI hospitals in close vicinity and organized by the local EMS, citing the Vienna STEMI network (Kalla *et al.*, 2006) as one such model. While the authors do not allude to it explicitly, it may be the case that the data presented in Figure 16 (overleaf) is key to this, and that minimising treatment delay in STEMI is less about organising “cooperating networks of PPCI hospitals in close vicinity,” but rather is about having an EMS care system where as many patients as possible arrive at the first hospital by EMS.

Figure 16: Percentage of STEMI patients arriving to the first hospital via EMS.



Widimsky *et al.* (2010)

2.2.3 Care delivery systems

Evolving evidence and a gradual paradigm shift in cardiovascular, emergency and pre-hospital care, has seen an increasing emphasis on both pre-hospital diagnosis (Terkelsen *et al.*, 2005) and pre-hospital treatment (Bonney *et al.*, 2002) of STEMI. These reports however came from health-care systems in continental Europe where services, particularly ambulance services, are differently configured when compared to services in the UK. Some French emergency medical services for example are characterised by the presence of a physician on the ambulance. There are arguably few limits to the practices and procedures performed in the pre-hospital arena and Ranner (2009) states that the patient will receive the same standard of medical care as they would in the hospital ED.

Bøtker *et al.* (2010) however in a systematic review found no compelling evidence to support this, other than perhaps in trauma.

The paucity of evidence supporting ambulance-based physicians in the treatment of ACS therefore decreases the UK applicability of Terkelsen *et al.* (2005) and Bonnefoy *et al.* (2002) in the sense that UK ambulances do not, nor are likely to have in the immediate future, the widespread and routine presence of a physician on-board. This gap in the evidence base relative to the UK health system is important to acknowledge.

In a UK context Quinn *et al.*'s publication in 1998 was key in the evolution of thrombolytic treatment being administered by nurses/paramedics. Following a 1995 publication assessing the safety of nurses assessing suitability of patients for thrombolytic therapy (Quinn, 1995), Quinn and colleagues (Quinn *et al.*, 1998) reported that 95% of CCU nurse respondents (n=37) were found to reach a standard of STEMI ECG interpretation deemed as "gold standard" by a panel of cardiologists. Wilmhurst *et al.*'s interrupted time-series (2000) and Qasim *et al.* (2002) then reported the safety, efficacy and benefits of nurse-initiated thrombolytic treatment. There was a significant increase in the number of UK centres adopting nurse administered thrombolysis following publication of this work 8-12 years ago. In contrast there are few reports in the contemporary cardiovascular literature of nurses/paramedics in other European countries either administering, or being engaged in autonomous decision-making regarding the administration, of these drugs. There are some reports from Australasia (Kucia *et al.*, 2001; Kremser and Lyneham, 2007) which support the role of nurses in this domain, however McDermott *et al.* (2008) concluded from their review of 42 papers that although the array of quality improvement processes they studied were associated with significant improvements in door to reperfusion time, suboptimal study designs and inadequate information about implementation limit the usefulness of this literature (McDermott *et al.*, 2008).

Chapter Three – Research Process

3.1 Introduction

It has been stated the ultimate goal of nursing is to provide evidence-based care that promotes quality outcomes for patients, families, health care providers and the health care system (LoBiondo-Wood and Haber, 2010). It seems reasonable therefore to define nursing research as a scientific process that validates and refines existing knowledge and generates new knowledge that directly and indirectly influences nursing practice (Burns and Grove, 2009).

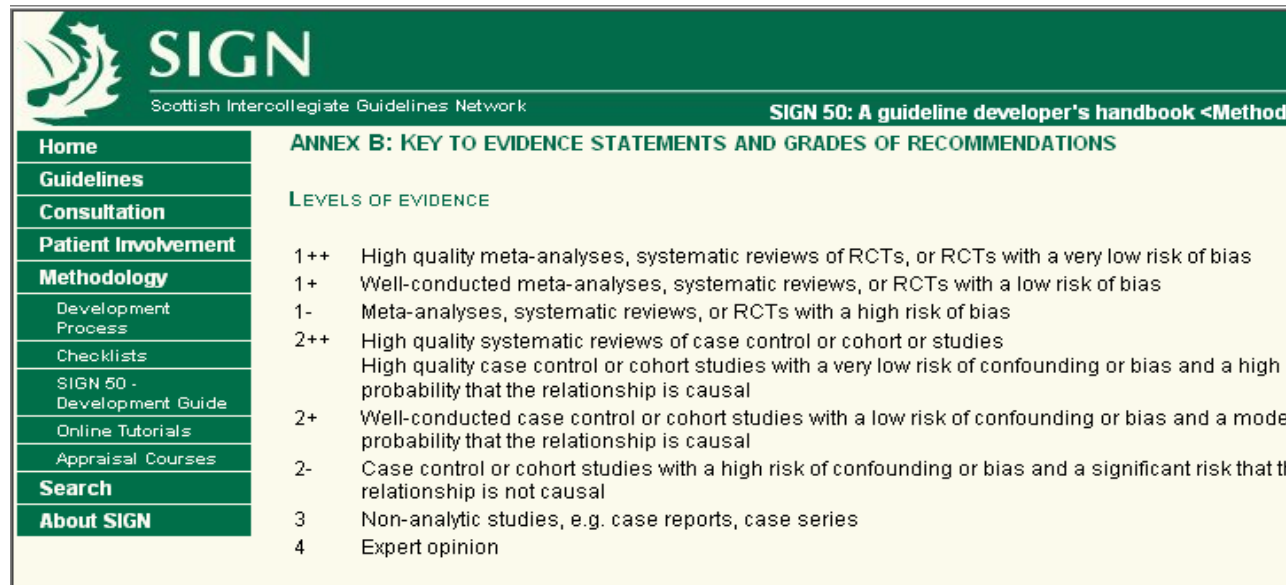
Many volumes of work have been written debating realms of nursing knowledge, definitions of nursing, nursing's position in the broader health-care environment, and the theoretical constructs underpinning nursing practice, education and research (Risjord, 2010). While a proportion of the academic research community encourage continuation and expansion of this debate (Erickson, 2009) others have encouraged a cessation. Tillman (2009: 458) suggests that this debate "*never seems to go anywhere...seeming never to amount to much more than "interesting conversation."*" Howe (2009: 466) suggests that the debate is "*tiresome*" and urges "*getting over this conversation and resisting the formation of "paradigm cliques."*"

3.2 Evidence-based practice

Evidence-based practice aims to apply the best available evidence gained from the scientific method to clinical decision making (Timmermans and Mauck, 2005). It seeks to assess the strength of evidence of the risks and benefits of interventions (including lack of intervention). Evidence quality can range from meta-analyses and systematic reviews of double-blind, placebo-controlled clinical trials at the top of the evidence pyramid (Figure 18), down to personal opinion at the bottom. As an example the Centre for Evidence-Based Medicine (2010) suggests levels of evidence according to the study designs and critical appraisal of prevention, diagnosis, prognosis, therapy, and harm studies (<http://www.cebm.net/index.aspx?o=1025>).

These principles are used commonly by guideline groups. Figure 17 displays the hierarchy of evidence as described by SIGN (2008). Figure 18 displays a synthesis of the hierarchy of evidence as I understand and utilise it.

Figure 17: Levels of evidence, SIGN 50.

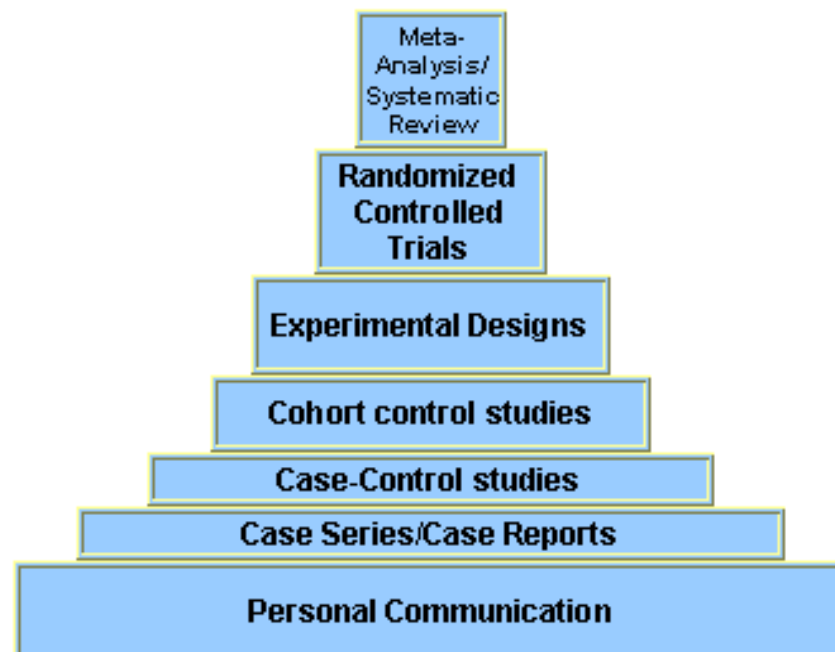


The screenshot shows the SIGN 50 website interface. On the left is a navigation menu with items: Home, Guidelines, Consultation, Patient Involvement, Methodology (highlighted), Development Process, Checklists, SIGN 50 - Development Guide, Online Tutorials, Appraisal Courses, Search, and About SIGN. The main content area is titled 'ANNEX B: KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS' and 'LEVELS OF EVIDENCE'. It lists seven levels of evidence from 1++ to 4, each with a brief description of the study types included.

Level	Description
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

SIGN (2008)

Figure 18: Hierarchy of evidence.



The Evidence-Based Practice and certainly the Evidence-Based Medicine hierarchies are of course positively skewed towards empirical research, namely within medicine. It is unlikely that qualitative researchers would wish their work to be situated within this hierarchy. Perhaps more usefully the NHS Health Development Agency produced in 2004 a document describing “Integrative approaches to qualitative and quantitative evidence.” This document was commissioned to assist those looking to synthesise qualitative and quantitative evidence. It suggests specific approaches to assessing and synthesising the quality of qualitative evidence, but perhaps most importantly states as follows:

“Are there hierarchies of evidence within the different types of qualitative investigation?: The short answer is ‘probably not – or at least, not any that everyone would agree on’. Mays et al. (2001) argue that the epistemological diversity of the field renders any single hierarchy of evidence inappropriate for qualitative research. Barbour (1998) also cautions against the development of hierarchies of evidence, referring for example to the dangers of using interview data as the yardstick against which to measure the validity of focus group data. Few other commentators have even approached the question of a hierarchy of evidence within qualitative inquiry.”

Health Development Agency (2004: 10)

A contributory factor to this statement may lie in the philosophical bases of the research paradigms.

3.3 Philosophical bases of qualitative and quantitative research, and moves to post-positivism

Although some distinction between methods is well placed, it is increasingly acknowledged that the qualitative and quantitative paradigms are not as philosophically diverse or mutually incompatible as is often conveyed (Watson *et al.*, 2008). Staunch identification of methods within particular paradigms may not be as accurate, or even as useful an endeavour as past trends would indicate.

This tendency may lead to over-simplification of methods in relation to paradigms, or worse, confusion over the philosophies and assumptions that underpin particular methods (Polit and Beck, 2008). Qualitative research offers a reliable, credible, and useful approach to research, particularly in the world of nursing. It evolved from behavioural and social sciences as a method of understanding the unique, dynamic nature of human beings (Burns and Grove, 2009). Qualitative researchers believe that truth is both complex and dynamic and can be found only by studying people as they interact (Hardy *et al.*, 2009).

The quantitative approach to scientific enquiry emerged from the *logical positivism* branch of philosophy, which revolves around rules of logic, truth and predictions (Polit and Beck, 2010). Quantitative researchers believe that truth is absolute and that human behaviour is objective, purposeful and measurable (Bryman, 2008). While logical positivism forms the foundation for a significant proportion of research papers, the philosophy is inappropriately deemed synonymous with empirical method, with some commentators suggesting that labeling quantitative researchers as 'positivists' is in effect limiting rather than opening thoughtful discussion (Howe, 2009).

Johnson (2009) suggests that researchers have increasingly grounded their quantitative work in more of a *post-positivist* philosophy. Post-positivism includes a much broader range of views, including explicitly anti-positivist views such as pragmatism (Phillips, 2006), where pragmatic researchers link the choice of approach directly to the purpose of and the nature of the research questions posed (Creswell, 2003). Bredo (2009) postulates a 'fault-line' along which post-positivist thoughts about reductionism and holism in research exist, and suggests that dogmatic subscription to either of these approaches is deleterious. Many nursing researchers continue to base their arguments on a positivistic view of science, and although some acknowledgement of post-positivism has occurred in the nursing literature, this has yet to permeate into mainstream nursing research (Burns and Grove, 2009).

From the mid-1980's the philosophy of post-positivism has increasingly been noted as that which underpins contemporary empirical research activity (Burns and Grove, 2009). Key influences in promoting post-positivist philosophies include the works of Karl Popper (1959) and Thomas Kuhn (1970). Essentially an alternative conceptualisation of truth was proposed by the post-positivists. Like positivism, metaphysical considerations were still deemed to be outwith the sphere of science. However, in contrast, a realist perspective of science was advocated, with unobservables deemed to have existence and the capability of explaining the functioning of observable phenomena (Phillips, 2006). Like the positivists, science was still deemed to require precision, logical reasoning and attention to evidence (the approach still focusses on rendering complex aspects of human beings researchable, seeking causation, prediction and explanation in the patterns and regularities of life), but was not confined to that which could be directly perceived. Phillips (2006) concluded that achievement of a better understanding of post-positivism and greater focus on the philosophical assumptions underpinning research methods, may help ameliorate the distinctions perceived to exist between qualitative and quantitative methodologies, with the unhelpful debate being confined to the past.

Groat and Wang (2002) assert that the philosophy of post-positivism is that truth can be discovered only in a probabilistic sense. This is in contrast to the positivistic ideal of establishing cause-and-effect explanations of immutable facts. They suggest that research methods should be selected, and their philosophical underpinnings discussed, solely on the phenomenon to be researched and nature of the research questions.

3.4 Research paradigms and this body of work

3.4.1 Qualitative research

Quantitative research approaches used in specific cohorts of patients following MI have been criticised by some in favour of qualitative methodologies (Scott and Thompson, 2003).

This was particularly relevant in the research exploring the information needs of spouses/partners of patients suffering acute MI (McLean and Timmins, 2007). It was clear that (i) the research objective (to explore the spouse/partner experiences of information received and required following acute MI), and (ii) philosophical criticisms of quantitative methodologies previously employed during published work conducted with this group, would be best addressed by a framework and design lending itself to maximal exploration of the spouse/partner experience. To this end a focus group methodology was employed.

The work describing focus group methodology was primarily conducted and published in the mid-late 1990's. There is little in the contemporary nursing research literature describing or defending focus groups as a methodology (as opposed to a data collection tool). Morgan and Bottorff (2010) make the point that of 50 articles reviewed in an American journal, only six advanced focus groups as a method. They do however reinforce the value of the focus group "method" in qualitative research. Kitzinger (1995: 105) defined the focus group approach as "*group discussions organised to explore a specific set of issues.*" Such discussion takes place in a social setting, moderated by a group leader, so as to generate descriptive or explanatory information (Lane *et al.*, 1999). Focus group methodology has been used in health service research to examine people's experiences of the health service, health education and the attitudes and needs of communities (Sloan, 1998). Twinn (1998) however, submitted that the time consuming nature of the process, supports the view of Kreuger (1995) that focus groups do not provide a quick and cheap method of undertaking qualitative research.

Rudolph and Hill (1994) reported the application of the methodology in assessing the effectiveness of educational programmes on health behaviours. Both of these points were particularly relevant in the context of McLean and Timmins (2007), where the research aim was to explore perceived need and support. There are favourable reports of focus group methodology being used in studying perceived needs.

Robinson (2001) reported that as a result of using focus group methodology, researchers felt the incongruence between perceived and actual needs as stated by clients was clarified. Lane *et al.* (1999) support this and suggested that the focus group approach is an effective means of ascertaining perceived needs. The philosophical underpinnings of the methodology are commensurate with the principal advantage of focus groups, namely the ability to use participant interaction to gain in-depth understanding and rich data that would not be obtained through other techniques (Webb and Kevern, 2001). Sim and Wright (2000) suggested that focus groups are unique, in that they combine elements of group process theory with qualitative research methods, highlighting the importance of the interaction of the group in determining the quality of the data. The researcher serves as an instrument in validating, enriching and explaining the data. The analysis process relies heavily upon the conceptual and creative perceptions of the researcher in assigning interrelatedness and determining meaning across data sets (Sim and Wright, 2000). Kvale (2007: 5) situates the focus group alongside the seminal 'qualitative interview' works of Freud (1963), Piaget (1960), and Jung (1964) but suggests that it is more aligned to the "depth interview" work of Dichter (1964) or "non-directive interview" work of Rogers (1967). Webb and Kevern (2001) make a broad criticism of the literature describing focus group research in its superficial discussion of the methodology without specific analysis or critique. They further criticise a tendency towards an unsophisticated application of the method and non-rigorous method mixing. Pivotaly they conclude that researchers must pay greater attention to marrying the underlying methodological assumptions, with the methods used to analyse and report the data generated. They fail however to acknowledge the positive benefits of focus groups in hypothesis generation for future studies.

3.4.2 Quantitative research

As postulated earlier, research methods should be selected, and their philosophical underpinnings discussed, solely on the nature of research questions.

Although related to similar cohorts of patients (those with STEMI who have received reperfusion treatment), the key publications which comprise this body of work and ongoing work in the same subject area, addressed different research problems, had different research questions, made different assumptions and required different research designs (with their different philosophical underpinnings).

This resulted in selection of a qualitative research method for the single paper specifically exploring perceived needs of spouses (McLean and Timmins, 2007), and quantitative method for the papers assessing optimal models of care in ACS (McLean *et al.*, 2004; McLean *et al.*, 2008a; McLean *et al.*, 2008c; McLean *et al.*, 2009; McLean *et al.*, 2009b; McLean and Flapan, 2009; McLean *et al.*, 2010b). Bryman (2008) states that a quantitative research strategy has a deductive orientation towards the role of theory in relation to research, a positivistic epistemological orientation, and an ontological orientation towards objectivism. He also however states that the connection between research strategy on the one-hand, and epistemological and ontological commitments on the other is not deterministic, and that positivism by definition entails elements of both a deductive approach and an inductive strategy.

3.4.3 Rigour

The rigorous quantitative researcher striving for excellence will be disciplined, scrupulously adhere to detail, be strictly accurate, and strive for ever more precise measurement methods, representative samples and study designs (Burns and Grove, 2009). This is the focus of the seminal work of the Chalmers Research Group (<http://www.chalmersresearch.com/home.html>) who strive for fair and free-from-bias conduct and assessment of research.

The specific steps which comprise the research process will be critically examined and re-examined for errors and weaknesses. Reducing these errors and weaknesses is key to ensuring that the research findings postulated are an accurate reflection of reality (Gerrish and Lacey, 2010).

To come to a conclusion about whether or not the research findings are representative of “real world truth,” each aspect of the study must be subjected to critical scrutiny (Polit and Beck, 2010).

3.5 Randomised Controlled Trials

The methodology for a RCT uses strategies from medical and pharmacological research, with Phase I to Phase IV trial categories developed specifically for testing experimental drug therapy (Watson *et al.*, 2008). RCTs are frequently referred to, either implicitly or explicitly, as the “gold standard” of quantitative research design. LoBiondo-Wood and Haber (2010) state importantly however that the RCT does not necessarily fit the “knowledge-building” needs of nursing and that criteria for defining a study as a clinical trial as opposed to defining it as an experimental study have not been teased out in the nursing literature.

Strengths

Conceptually the term *clinical trial* as it is used in the literature seems to be closely aligned to the design of a Phase III pharmaceutical trial (Burns and Grove, 2009). Clearly defined interventions constructed from evidence from previous studies are definitively tested against hypotheses and effects measured (Bryman, 2008). The study is conducted in a clinical (rather than a laboratory) setting and has high internal validity (Polit and Beck, 2010). The random allocation of patients with equivalent distribution of known and unknown prognostic factors is such that differences in outcome at the end of the study should only be explained by differences in treatment effect (Isley, 2006). When researchers organise large RCTs the number of subjects enrolled mostly allows for more precise findings with broader applicability and are generally better at dealing with confounding variables and bias (Isley, 2006). Clinical trials have played a crucial role in the development of treatment strategies for cardiovascular disease since the earliest trials were conducted in the 1950s, but it was not until the 1970-80s that the results of clinical trials had a major impact on the choice of cardiovascular treatments (Yusuf, 1999).

Weaknesses

As the RCT moves from the explanatory to the pragmatic, it becomes more difficult to isolate the effect of the treatment from the other aspects of delivering the intervention (Isley, 2006). Thus mechanistic inferences become weaker while the applicability of the findings becomes more secure (Isley, 2006), resulting in a reduced ability to generalise and infer with confidence. The modern “mega” RCTs are especially criticised for issues around faulty/incorrect comparators, post-hoc analyses, exclusion criteria, subgroup analyses, small treatment effects and formation of composite endpoints (Montori, 2006). Isley (2006: 161) is especially critical of composite endpoints which he refers to as “*a smorgasbord of events that may be possibly affected by the treatment in question.*”

The answers in the RCT environment are much less clear because of the potential sources of influence on trial results, as well as the possibility that the prevailing hypothesis is incorrect (Bryman, 2008). Reviews of RCTs performed in general surgery have reported that more than 90% of trials reviewed had inadequate sample sizing, powering, exclusion criteria, standard of interventions in apposite arms of the trial and justification of conclusions (Burns and Grove, 2009). The Cochrane Collaboration (2002) also caution against ‘publication bias,’ citing that many researchers have shown that those studies with significant, positive, results are easier to find than those with non-significant or ‘negative’ results. The subsequent over-representation of positive studies in systematic reviews may mean that they are biased toward a positive result. Further, Ioannidis (2005) showed that of forty-nine RCTs published in three major journals and cited over one-thousand times, the effectiveness claims of around one-third appeared to be exaggerated or contradicted by subsequent research.

Linde *et al.* (2001) heavily criticised the reporting of drop-outs and withdrawals in sufficient detail in RCTs, which have less generalisability, are slower to conduct, are more expensive, and cannot answer as broad a range of questions as observational studies (Katz, 2006). In addition, many commentators express concern regarding inherent ethical issues in RCTs.

There are perhaps the obvious issues of intervention versus placebo arms of studies where either has a patently harmful or positive effect. For example randomising patients to smoking or non-smoking in order to assess the impact on the dependent variable would not be ethical due to the known deleterious effects of smoking on health, and therefore on patients randomised to the smoking arm of the study (Levin, 2007). Indeed this would be contrary to the principles of the Nuremberg code (1986) and this research question may perhaps be better, or more ethically, answered by the use of a comparative descriptive design (as per my work in Maccioca *et al*, 2010). Hutton *et al*. (2008) on the other hand suggest that rarely, if ever, are the principles of informed consent applied in their entirety in RCTs, and that as a result it could be argued that the majority of RCTs do not comply with the ethical standards expected at the time of ethics committee approval.

In an attempt to define contemporary standards the European Union, Japan, United States, Australia, Canada, the Nordic countries and the World Health Organisation subscribe to the International Conference on Harmonisation (ICH) / WHO Good Clinical Practice (GCP) standards (<http://www.ich.org/LOB/media/MEDIA482.pdf>). This provides a unified standard for the conduct of clinical studies. thus any country that adopts this guideline should follow the same robust standard.

The “true experiment”

Fawcett *et al*. (1994) stated some fifteen years ago that the previous technique of testing interventions, the “true experiment,” was being seriously questioned by a growing number of scholars due to modifications to the original experimental design having decreased the validity. They reported that a revolutionary new approach was evolving which held great promise for testing interventions. Watson *et al*. (2008) also highlighted that the “true experiment” is based on the atheoretical logical-positivist approach to research, which is not consistent with the theory-based approach through which nursing constructs their body of knowledge.

Bryman (2008), when quoting the rigid rules of the true experiment as initially defined by Fisher (1935) states that the method is much easier to apply when studying corn (as Fisher did), than when studying human-beings (as nurses do). Studying human-beings requires modifications in the true experiment which weaken the power of the design and threaten the validity. Commentators have suggested that subjects in clinical trials are increasingly unlike the target population (Burns and Grove, 2009).

3.5.1 Randomised Controlled Trials and this body of work

These criticisms were especially relevant when considering the RCT (the “*true experiment*”) as a methodology for this body of work. Cardiology, and in-particular ACS is often heralded as an area famous for its “mega” RCTs, with many hundreds of thousands of patients having being randomised since the seminal thrombolysis trials of the 1980’s. There are few areas of cardiology practice which have not been studied by means of an RCT. This is the case in the areas relevant to this work (STEMI, thrombolytic therapy and risk assessment in ACS).

When planning the research presented in this body of work, one may argue that it would have been reasonable to replicate major RCTs of investigators like Bonnefoy *et al.* (2002), and Terkelsen *et al.* (2005). This may have been all the more appropriate, and additive to the body of knowledge, given the significant differences in the provision of pre-hospital (EMS) care in both France (Bonnefoy *et al.*, 2002) and Denmark (Terkelsen *et al.*, 2005) where these studies were conducted. Other researchers have designed studies aiming to do precisely this and conduct studies which are necessary to both (i) contribute to a gap in the evidence, and (ii) provide evidence relevant to the particular healthcare context. An example of this is the STREAM study (Armstrong *et al.*, 2010), where providing adequate numbers of patients recruited are within a UK context, the study interventions are equally as deliverable in the UK health context as in the North American and Continental European contexts.

The findings from STREAM (Armstrong *et al.*, 2010) will therefore have a significantly greater weight of applicability in the UK as opposed to, for example, the findings of the ON-TIME II study (van't Hof *et al.*, 2008), which due to the fact that the study intervention required an ambulance-based physician, are not immediately applicable in a UK model.

3.6 Intervention studies

The term *applied research* has been defined as a scientific investigation conducted to generate knowledge that will directly influence or improve clinical practice (Gerrish and Lacey, 2010). The purpose of applied research is to solve problems, to make decisions, or to predict or control outcomes in real-world practice situations (Hardy *et al.*, 2009).

An increasing number of intervention studies are being conducted by nurse researchers in an effort to further develop and refine an evidence-based practice (Bryman, 2008). Burns and Grove (2005) state that 87% of research ideas originate from clinical practice, with many fewer arising from the theoretical literature, interactions with colleagues or funding priorities. One may argue that methods used by nurses to answer their questions need to reflect this. Like the experimental/RCT design the quasi-experimental research design involves an *intervention*; however quasi-experimental designs lack randomisation, the signature of a true experiment. The definition of a quasi-experimental design therefore is an intervention in the absence of randomisation (Polit and Beck, 2010). LoBiondo-Wood and Haber (2010) highlight that the quasi-experiment is conducted to examine the effect of an intervention on an outcome. They propose three facets of a study intervention in such a research design, and state that a study intervention must be:

1. Clearly and precisely developed
2. Consistently implemented with protocol
3. Examined for effectiveness through quality measurement of dependent variables or outcomes (Burns and Grove, 2009).

The strength of quasi-experiments is that they are practical and are aligned to nursing research which, by definition, occurs in natural settings where it can be difficult, impractical or indeed unethical to deliver interventions to some people and not to others (Polit and Beck, 2010). This would certainly have been the case with my research, particularly that studying reperfusion treatment in STEMI. Quasi-experimental designs are unlikely to either exclude as many patients, or suffer refusal to participate in the study as evidenced in experimental trials (Bryman, 2008).

This creates somewhat of a paradox for the researcher where it results in a broader generalisability of the results, however at the risk of results which are both less conclusive and have less validity (Polit and Beck, 2008). The most commonly used quasi-experimental design, particularly by nurse researchers, is the *non-equivalent control group before-after design* (Bryman, 2008). This design involves two or more groups of subjects observed before and after implementation of an intervention. The design is similar to the before-after design in experimental research however subjects are not randomly assigned to groups, and hence the 'inferiority' of this design in the evidence hierarchy described in section 3.2 (p38). While without randomisation the researcher cannot assume that the experimental and control groups are equivalent at the outset of the study, this design remains strong because the collection of pre-test/pre-intervention data allows the researcher to determine the level of dependent variable before the change/intervention was made (Polit and Beck, 2010). Where the comparison and experimental groups are similar at baseline, the researcher can be relatively confident when inferring that any post-test differences are the result of the study intervention (Munro, 2005).

3.6.1 Intervention studies and this body of work

My body of work relates to the real-world, contemporary, pragmatic provision of acute cardiac care by multidisciplinary clinicians, with a particular emphasis on the reperfusion treatment of STEMI. It does not seek to demonstrate efficacy (or otherwise) of one specific intervention over another. If exploring the superiority of treatment A over treatment B had been the purpose of this work, then one may have argued that:

- (i) it was atheoretical, logical-positivist approach to research, which is not consistent with the theory-based approach through which nursing constructs its body of knowledge, and
- (ii) it was direct (or indirect) replication of work already conducted and therefore not additive to the existing body of knowledge in this subject area.

Rather, this body of work seeks to add to the existing body of knowledge by scientific investigation conducted to generate knowledge that will directly influence or improve clinical practice. When planning and conducting this applied research, with the aim of directly influencing clinical practice and affecting outcomes in real-world practice situations, it became clear that intervention studies using quasi-experimental research methodology were the natural evolution of the research purpose, framework, and assumptions, and would best answer the research questions.

Chapter Four – Critical analysis of published works

4.1 Introduction

The submission for a PhD by publication must demonstrate evidence of an original and significant contribution to knowledge within the discipline, in peer-reviewed published works (Davies and Rolfe, 2009). The multiple project format of the PhD by publication allows for a closer relationship with practice than is often possible with the traditional monolithic thesis (Courtney *et al.*, 2005). What is key however to rigorous examination of PhD by publication is the candidate's critical self-assessment, which is the most important and difficult skill for academics to master, and the best indication of doctoral level work (Davies and Rolfe, 2009).

4.2 Framework for self-assessment

There are in existence a plethora of tools, structures and models which serve to either evaluate, or strengthen the reporting, of research studies (Watson *et al.*, 2008; LoBiondo-Wood and Haber, 2010; Risjord, 2010). The research design detailed in Chapter 3 and selected for the core pieces of work comprising this thesis (McLean *et al.*, 2004; McLean *et al.*, 2008a; McLean and Flapan, 2009; McLean, 2009b; McLean *et al.*, 2010) was a quasi-experimental design: the non-equivalent control group before-after design. Bryman (2008) suggested that where nurse researchers choose a quasi-experimental research design, the non-equivalent control group before-after design is the one most commonly used (Bryman, 2008), and involves two or more groups of subjects observed before and after implementation of an intervention (Polit and Beck, 2010).

The Public Health Resource Unit (2009) provide researchers with a useful toolkit (<http://www.phru.nhs.uk/Pages/PHD/resources.htm>) designed to guide the researcher through the research project. Following some consideration I have elected to use these tools as a framework to evaluate my studies and the strength of the research reports.

It is important to recognise that other than a single patient case-study describing an unusual presentation of coronary ischaemia (McLean *et al.*, 2008b) and a paper translating previous work and evidence into contemporary practice by describing the a trio of services which comprise a “gold standard” chest pain service (McLean, 2006), each of the papers comprising this body of works has undergone peer-review, critical to establishing a reliable body of research and knowledge (Burns and Grove, 2009).

“Hindsight is an exact science”

(Bellamy, 1996: 13)

While Bellamy, an author of popular fiction may indeed have a point, it is important that this thesis provides recognition of deficiencies in single papers, the series of papers, or the programme detailed herein as a whole. Efforts will then be made to evidence how recognition of these deficiencies has aided learning, quality of work, addition to knowledge and the future direction of research. This section of the thesis will therefore dissect the body of works, using the Public Health Resource Unit checklists (2009) to aid the process.

4.3 The “thread”

Programmatic research is typically large-scale research conducted over the medium to long term, and is designed to impact on problems of priority interest (Watson *et al.*, 2008). A research programme comprises planned, purposeful, and substantively and/or theoretically linked studies with demonstrable public benefit (LoBiondo-Wood and Haber, 2010) and involves a substantive line of enquiry in which researchers seek to advance and apply knowledge in line with local, national and international initiatives. A research programme is underpinned by a vigorous research culture. Programmatic research has been used effectively across a wide range of disciplines and research issues (Polit and Beck, 2008) and is the defining characteristic of scholarship (Boyer, 1997).

This thesis does not purport that the published works represent or stem from a programme of research. Rather one of the key aims of this thesis, submitted in support of published works, is to demonstrate a deliberate and programmed approach to the body of evidence. Table 1 (p56) presents a summary of the publications comprising this thesis, while Figure 19 (p58) presents research themes tabulated chronologically against the published works. Figure 20 (p59) then describes research foci, hypotheses, issues following analysis and conclusions as they evolved over this programme of work.

Table 1: Methods vs. aims of the published works

No.	Aim	Type of Work	Sample size	Outcome measures	Main findings
1	To describe the effects of implementing of a PPCI service and compare the distribution of reperfusion therapies 12-months pre and post introduction of PPCI	Quasi-experimental study using a non-equivalent control group before-after design	625 pts	Type of Rx, mode of presentation, length-of-stay, 30-day readmission and death, time indicators and time distributions across Rx groups were reported	Diagnosis-to-Rx and door-to-Rx times were impressive when compared with other international data. In patients receiving PPCI mortality appeared to be reduced and length of stay was significantly reduced
2	To investigate whether application of the GRACE risk-score by Cardiology Nurse Specialists in the Emergency Department, identifies patients at increased risk of death and prolonged hospitalisation	Retrospective analysis of cardiac risk scores prospectively collected by chest pain nurses in the emergency department seeing patients with undifferentiated chest pain	504 pts	Death at follow-up	Statistically significant differences ($p < 0.05$) in the likelihood of death, prolonged length of hospital stay, acute coronary syndrome, and cardiac catheterisation over low, moderate and high-risk groups as assessed by the chest pain nurse
3	To assess the benefits of moving heart attack treatment from the A&E department to the ambulance	Quasi-experimental study using a non-equivalent control group before-after design	812 pts	Call-to-Drug time, Door-to-Drug time and Pain-to-Drug time. Treatment failure and time to presentation were also recorded and in-hospital adverse clinical events	Statistically significant reductions ($p < 0.05$) in on-scene time, travel time, Call-to-Drug time, Door-to-Drug time and Pain-to-Drug time when Rx given in the ambulance

4	To explore the self-perceived information needs of spouses/partners following acute myocardial infarction	Qualitative study using focus group methodology with spouses of STEMI patients	15 spouses/partners Two focus groups facilitated and transcribed by me, and enriched by personal notes	Thematic analysis used. Detailed description of credibility, dependability, confirmability and transferability. 157 words and statements 'reduced' to 4 key themes: emotional reactions, the need for information, pulling-apart and pulling-together, and feeling like a burden	Recommends specific, tailored, menu-based cardiac rehabilitation which directly involves spouses from the beginning of the patient journey
5	To assess the benefits of moving heart attack treatment from the CCU to the A&E department	Quasi-experimental study using a non-equivalent control group before-after design	74 pts	Door-to-Treatment time, time to ECG resolution, use of IV beta-blockers and in-hospital adverse clinical events	Statistically significant reductions ($p < 0.05$) in Door-to-Treatment time, Pain-to-Treatment time, proportion of Rx given in A&E, proportion receiving beta-blocker, time to receiving beta-blocker, ECG resolution and combined adverse clinical endpoints in the year post-intervention
6	To assess the superiority of application of pressure bandages (vs. no pressure bandage application) to puncture sites following femoral artery sheath removal	Randomised control study with a non-inferiority hypothesis	654 pts	Rebleed, pseudoaneurysm, surgical/radiology referral or a composite of all. Presence of and size of haematoma and bruising were recorded in both groups by staff and patient completed diagrams	No statistically significant difference in individual or combined sequelae with an odds ratio confidence interval of 0.74 to 3.89. Trend towards more complications in the pressure bandage group (4.7% vs 2.8%)

Figure 19: Research themes tabulated against published works

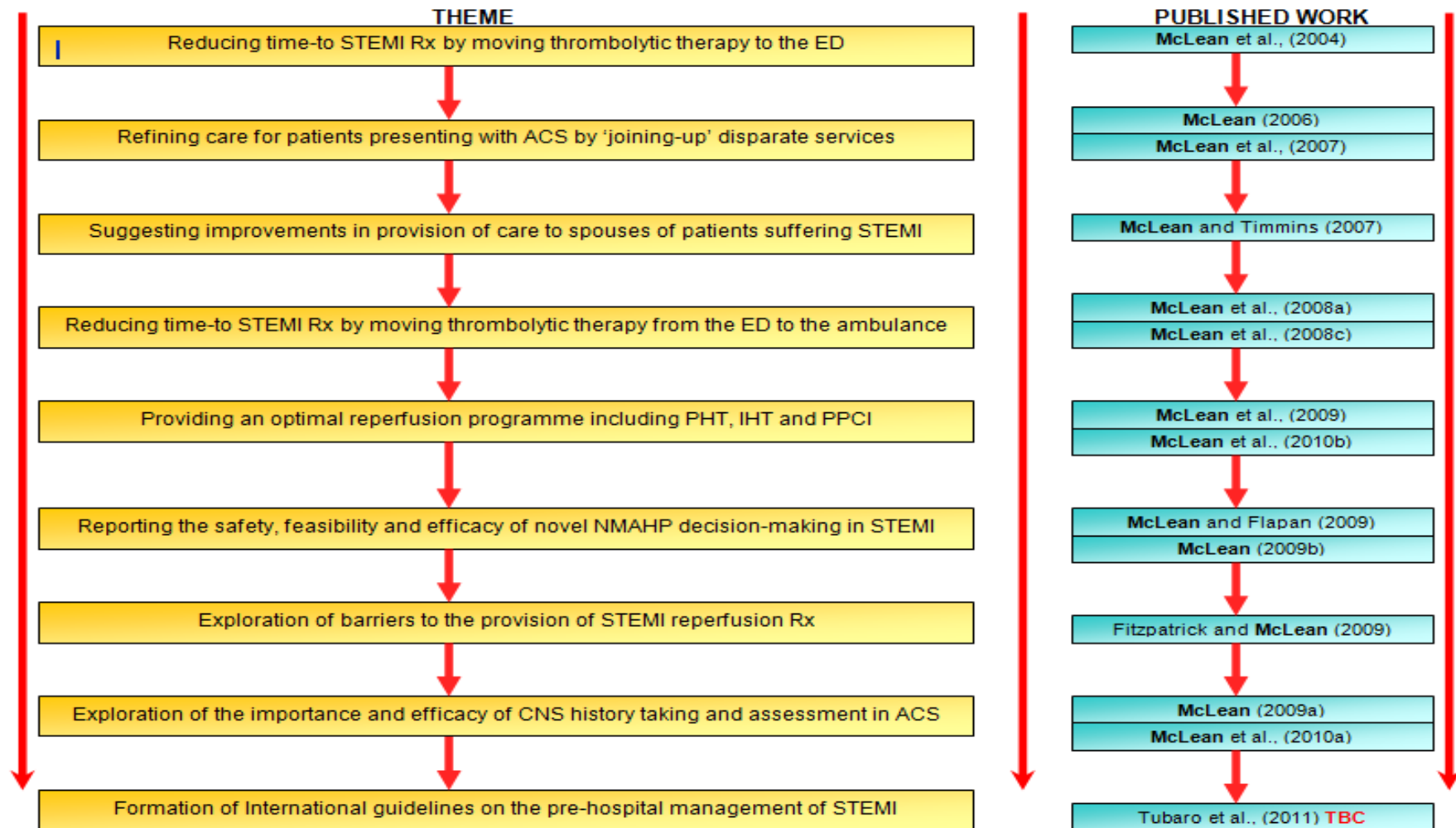


Figure 20: Research Foci, hypotheses, issues following analysis and conclusions



The purpose in presenting these figures is to demonstrate that the body of work comprises a logical and coherent set of interlinked publications that build up a body of evidence. The resulting overarching themes are:

- Moving thrombolytic therapy to the ED
- Refining care for patients presenting with ACS
- Establishing and evolving communication networks between CCU nurses and EMS paramedics
- Moving thrombolytic therapy to the ambulance
- Developing an optimal reperfusion programme PHT, PPCI and IHT
- Analysis and synthesis of treatment timelines as they are distributed across treatment groups
- Using these data to postulate optimal models of reperfusion treatment
- Seeking novel ways of improving the proportion of STEMI patients who arrive at the catheter lab with some degree of flow down the coronary artery by exploring how evidence from different EMS settings might be applied in the UK using paramedics and CCU nurses as the primary decision-makers.

4.4 Research framework

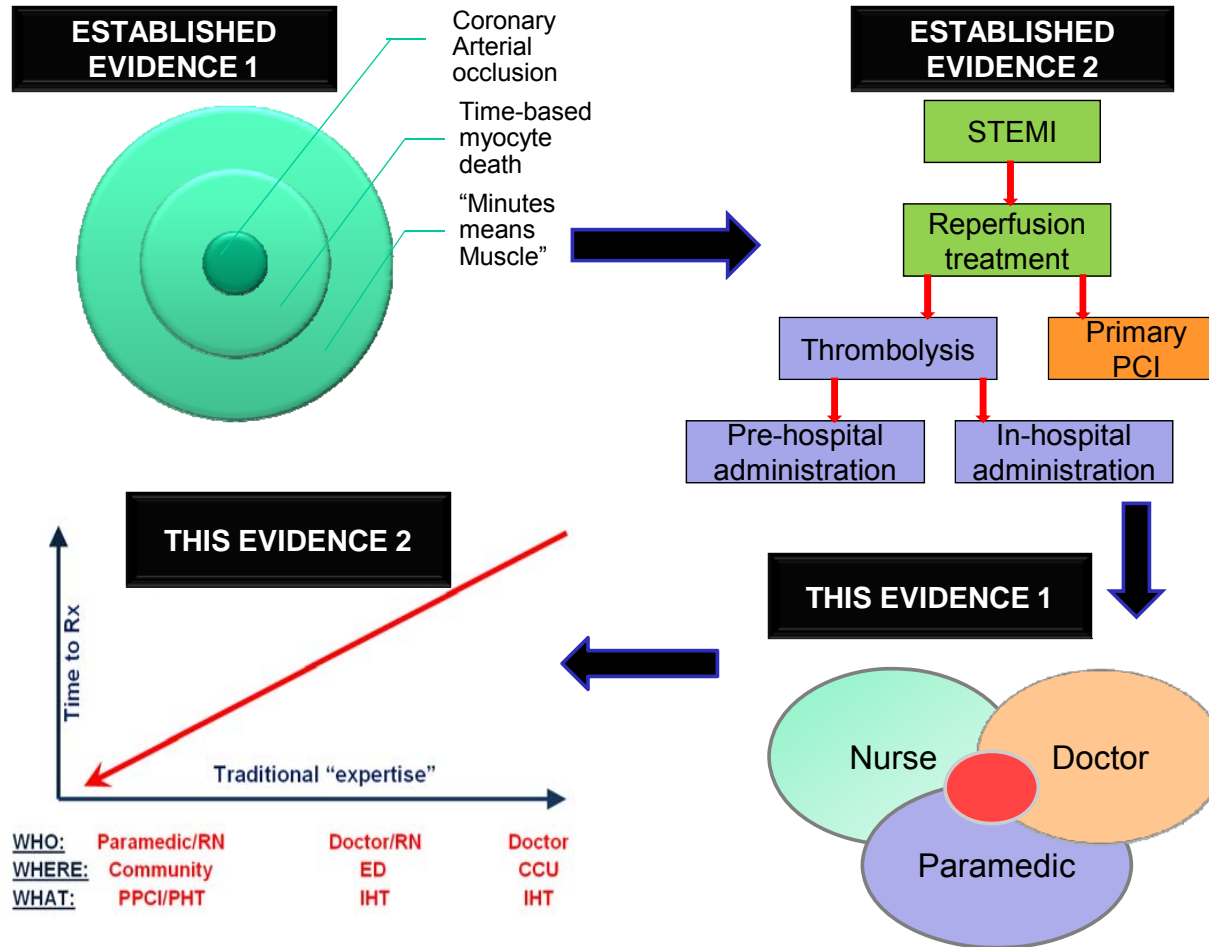
The research framework is the important, abstract, logical structure of meaning which guides the development of the study, or studies, and provides the researcher with the tool by which he/she can relate their findings to a body of knowledge (Bryman, 2008). In quantitative research the framework may either emerge deductively from a conceptual model, or inductively from the clinical observations of the researcher (Polit and Beck, 2010). Nursing research has been heavily criticised in the past for either unclear or entirely absent theoretical perspectives (Watson *et al.*, 2008).

4.4.1 Conceptual map

One strategy for expressing a framework is a conceptual map, which diagrammatically illustrates the interrelationships of the concepts and statements in either a single study or a series of studies (Burns and Grove, 2009). Figure 21 (p62) describes the interrelationships of concepts inherent to this body of work.

The final diagram on the map (labeled as 'this evidence 2') is the final distillation of the research programme and is intended to assist in grasping the gestalt of the phenomenon detailed in this thesis:

Figure 21: Concept map.



Bryman (2008) states that conceptual maps are useful beyond the study (or studies) for which they were developed, and that they may suggest hypotheses that can be tested in future studies. This is the intention of the conceptual map underpinning this work. The next logical inclusion in the map will be focussed around the future direction of the work and will report ways of improving the proportion of STEMI patients who arrive at the catheter lab with some degree of flow down the coronary artery. This is explained further in section 5.3 (p97).

4.5 Ethical issues

In any discipline that involves research with human beings, researchers must address ethical issues. Ethical considerations are especially prominent because the line of demarcation between what constitutes expected practice and the conduct of research can be blurred (Polit and Beck, 2010). While the phenomenon of ethically conducted research defies precise delineation (Burns and Grove, 2009), there are a plethora of historical events, codes of conduct, regulations, statutory mechanisms and guidelines pertaining to research involving human beings. From the atrocities of the Nazi medical experiments (Steinfels and Levine, 1976), through the Nuremberg code (1986) and Declaration of Helsinki (1986), attempts have been made to ensure a minimum of non-maleficence, with detailed guidance around self-determination, autonomy, competence and consent, privacy, confidentiality, fairness, discomfort, risks, benefits, conflict of interests and harm (LoBiondo-Wood and Haber, 2010; Watson *et al.*, 2008; Polit and Beck, 2010; Gerrish and Lacey, 2010). These principles are captured more contemporaneously in the ICH-GCP standards (<http://www.ich.org/LOB/media/MEDIA482.pdf>) and Caldicott regulations (Department of Health, 2010).

While acknowledging the potential inadequacies, Hutton *et al.* (2008) provide an argument which resonates in relation to my research. My published works are not “implementation research” as defined by Eccles *et al.* (2009).

Nevertheless the core work undertaken around the multidisciplinary provision of STEMI reperfusion treatment, and moving the site of treatment from the CCU to the ED, and the ED to the ambulance, does contain elements that are pertinent to the science of implementation research. Hutton *et al.* (2008) argue that the distinction between implementation research and service development is blurred, often small, and that the requirement for formal ethics approval may deleteriously affect the development of evidence-based clinically-effective interventions. They argue that the “natural experiment” conducted by the professional or group of professionals (who have a core ethical duty to “do the best” for their patient, including implementation of evidence-based clinically-effective interventions) should be catered for in the complex world of institutional ethics committees. They describe ethics committees as being “confused” about this, but also make clear that research involving developments of service provision should not be maverick, and that one might argue that “service developments” should also be subject to some form of ethical review, given that they potentially pose similar risks to research studies.

This is an argument that has resonance, particularly in McLean *et al.* (2004), McLean *et al.* (2008a), McLean *et al.* (2008c), McLean and Flapan (2009), McLean *et al.* (2009), McLean (2009b), and McLean *et al.* (2010b). In each of these pieces of work, and as a “thread” throughout these works, there was a prospective decision to study the effects of moving the site of, and/or personnel delivering, STEMI reperfusion treatment. This concurs with the definition of the quasi-experiment (LoBiondo-Wood and Haber, 2010) as one which is conducted to examine the effect of an intervention on an outcome.

It also aligns with Burns and Grove’s (2009) definition of study interventions in quasi-experimental research design, where the study intervention must be:

1. Clearly and precisely developed
2. Consistently implemented with protocol
3. Examined for effectiveness through quality measurement of dependent variables or outcomes.

One may argue however that the distinction between the work done in these studies, and what could be described as “service development” is small. Although not to downplay the design and process of my research, it could also be suggested that had this work not been designed in the way it was, then it may simply have been implemented as an evidence-based, clinically effective change in service provision. To this end the extraction of data from medical records following the intervention (or service development) need not always be governed by formal approval by the institutional ethics committee (MRC, 2003). Indeed some have advocated that not asking for formal consent to access medical records, in appropriate instances, minimises impact on patients in terms of time and unnecessary inconvenience (Tu *et al.*, 2004). It might also be suggested that adherence to the Caldicott principles of: justifying the purpose of the proposed use of data, not using data unless necessary, using the minimum amount of data, ensuring that access to data is on a ‘need-to-know’ basis, ensuring that those with access to data are aware of their responsibilities and understand and comply with the law, (Department of Health, 2010) is acceptable practice in this type of research.

Hutton *et al.* (2008) relate this argument to ethical theories. They argue that a consequentialist ethic would balance the implication of the informed consent requirement (that if the research cannot provide valid results then opportunities to improve people’s health will be lost), with the consequences of not requiring informed consent.

The informed consent duty based around a Kantian philosophy (Kant, 1781) on the other hand would mean that the researcher’s duty to seek informed consent was absolute, and takes priority over any duty to act so that knowledge may be gained and health improved (Hutton *et al.*, 2008).

Eccles *et al.* (2009) explore the principle of non-maleficence, suggesting that while it is typically understood as the principle of doing no harm through direct or harmful actions, there may be an argument that the principle applies to omission, regardless of motivation.

The synthesis of their argument is that where the professional fails to engage, or is prohibited from engaging in, activities which will clearly afford benefit based on evidence-based and clinically effective interventions, then perhaps the principle of non-maleficence has been breached. They cite evidence that the public do appear to understand that formal informed consent raises significant problems, and that public concern about confidentiality and protection of patient rights might be addressed by other means (Robling *et al.*, 2004). Assurance may be sought from the Royal College of Nursing (2009) who state that in some instances it is not always practical or a requirement to secure a formal/signed consent, and this assurance is helpful in the context of the research underpinning my published works. Nevertheless Ethics Committee advice was gained for McLean *et al.* (2008c), and McLean and Timmins (2007). Ethics Committee advice was also sought for McLean *et al.* (2008a) and McLean *et al.* (2010b).

4.6 Limitations

An important part of any research process is to examine, weigh-up and set out weaknesses and limitations of the study (Hardy *et al.*, 2009). This is the mark of the mature researcher and of mature research (Watson *et al.*, 2008), and concords with Weber's (1988) aspiration of 'value-free research' (Turner, 2000). In acknowledging limitations, an opportunity is created to suggest areas for future research (LoBiondo-Wood and Haber, 2010). Theoretical limitations restrict the abstract generalisability of the study findings and are reflected in the study framework and conceptual and operational definitions (Polit and Beck, 2010).

Methodological limitations restrict the credibility of the study findings and limit the population to which the findings can be generalised (Risjord, 2010). Limitations result from factors such as unrepresentative samples, weak study design, single setting, limited control over treatment, instruments with limited reliability, limited control over data collection, and improper use of statistical analyses (Burns and Grove, 2009). As stated previously the recognition of assumptions by the researcher is a strength rather than a weakness (Burns and Grove, 2009).

While specific limitations of individual studies will be discussed in section 4.7 there are some generic assumptions worthy of presentation at this point. These are characterised in Table 2:

Table 2: Assumptions of research framework, design and interpretation.

Assumption of...	
Research Framework	Calculating increased risk of an event confers an absolute increase in likelihood of that event occurring
	Comparable (no statistically significant differences in) baseline characteristics suggest homogeneity across two or more groups
	Changes in the dependent variable are the direct result of the study intervention
	“Disease” and “Symptoms” are two distinct concepts
	The sample studied is representative of the population
	Time is a continuous variable which is recorded in a standard way by the multiple individuals involved in care delivery
Study Design	EMS paramedics have a level of training which is sufficient for them to identify STEMI
	Consistent and homogenous decision-making in the care of patients with ACS is desirable
	Provision of information about an event results in increased knowledge about the event
	Spouses wish to help and aid the recovery of their partner following STEMI
Interpretation of Findings	100% of patients experiencing ACS wish the most timely treatment possible
	Reducing time-to-treatment in STEMI is beneficial
	The risks of treatment in ACS are (i) explained to patients, (ii) are understood by patients, and (iii) are outweighed by the benefits
	Findings are transferable across differing geographical contexts

4.6.1 Limitations of research framework

Limitations of the research framework generally pertain to the philosophical underpinnings of both the research paradigm and particular framework employed (Risjord, 2010), with complex, abstract phenomena involved. For example, while there will be proponents of statistical analysis who claim that the absence of difference in two or more groups (as calculated by statistical testing) makes a valid claim for homogeneity, there will be those from naturalistic paradigm who believe that statistical significance is too crude a measure upon which to make this claim, or indeed that attempting to make this claim at all is by definition anathema to nursing research (LoBiondo-Wood and Haber, 2010).

Similar principles apply to the assumption that changes in the dependent variable are the direct result of the study intervention.

There exists a growing body of literature critiquing the phenomena, semantics and implications of what are generally described as “diseases” and “symptoms.” Modern healthcare appears to find it increasingly difficult to disentangle these concepts, and is in my opinion (as per Fox and McLean, 2010) primarily responsible for blurring these concepts. Studies failing to carefully identify the research purpose (for example is the aim to identify presence or absence of CAD, or presence or absence of angina pectoris) will be significantly limited.

4.6.2 Limitations of study design

Decisions taken at the study design stage have the potential to limit the reliability and generalisability of the study (Gerrish and Lacey, 2010).

Apparently straightforward assumptions such as spouses’ wish to help and aid the recovery of their partner following STEMI, or provision of information about an event results in increased knowledge about the event (as studied in McLean and Timmins, 2007), must be deliberately and carefully considered. This makes the job of the researcher difficult and identifying these apparently straightforward issues is often overlooked, occasionally with a negative impact of the study findings (LoBiondo-Wood and Haber, 2010). For studies receiving funding, the associated peer-review process may help identify these issues at an early stage (LoBiondo-Wood and Haber, 2010).

There are in addition operational and logistical issues in study design which if not carefully considered have the potential to limit the study results. As an example from this body of works there was an assumption that EMS paramedics have a level of training which is sufficient for them to identify STEMI.

This assumption was carefully considered and as a clinician experienced in this field I know while the mandatory training of this staff group is sufficient and consistent (due to the fact it is a national programme, co-ordinated from the national training school) there is an anecdotal geographical disparity across the UK in the retention, refreshing and implementation of these skills. One may argue that this heterogeneity is a limitation of the generalisability of my study findings. My belief however was that correcting the results for the skill and knowledge level of the individual paramedic would potentially render the work unfeasible, not to mention the difficulties in reliably measuring knowledge retention *per se*. Furthermore my work is applied research looking at the pragmatic and real-world provision of STEMI care. I would therefore contest that, even if it were possible, correcting my results for differing skills/knowledge levels of individual paramedics would have been in conflict with the aims of my research, which was to study this cohort of patients in a real-world service provision setting. The logical step however having acknowledged this limitation would have been to document it in my report and suggest that others may wish to consider it as an area for future research, which on reflection I did not do and should have done.

4.6.3 Limitations of interpretation of findings

Coming from a clinical practice perspective Hallberg (2006) claims that a significant proportion of nursing studies do not lend themselves to implementation in clinical practice because they are descriptive and do not attempt to test new strategies or determine the effects of interventions. In a later paper she states that this is also true for theoretical and interpretive research which needs to be tested for applicability (Hallberg, 2009). She concludes that nurse researchers must be aware of the kind of knowledge they produce, how findings are interpreted and generalised or applied, what further studies are needed, and the implications for clinical practice.

There is an example of how one might advise caution in the interpretation of findings in this body of works. As stated previously the expression “minutes mean muscle” is one widely used across the cardiovascular multidisciplinary community.

The majority of clinicians working in cardiovascular care will have been schooled in this way and will strive to minimise treatment delays as much as possible in STEMI. There are even dedicated professional and lay internet resources promoting exactly this concept (<http://minutesmeanmuscle.com>), and it is a concept I subscribe to. There are however those who believe that this argument is not without caveats. Investigators have suggested that in fact this concept remains valid only within the first 2-3 hours of infarction and that at time points beyond this the concept does not stand and delays to treatment are much less relevant (Boersma *et al.*, 2006). Some investigators suggest that clinicians could consider withholding thrombolytic treatment for some considerable time in patients presenting greater than 2-3 hours after symptoms onset (particularly in patients aged over 65 years with infarction of the inferior surface of the heart), in favour of PPCI (Pinto, 2006). As a concept this appears to be contrary to the 'minutes mean muscle' concept detailed above. What this example demonstrates is that interpreting findings in the context of what may appear a well established concept, may in fact require further consideration of alternative and evolving concepts.

Concluding for example that clinical performance based on the results of study X (symptoms-to-PHT time of 115-minutes) was superior to clinical performance based on the results of study Y (symptoms-to-PHT time of 125-minutes), is perhaps not quite so intuitive as one might expect and interpretation of the findings of these studies should be performed with caution. While EMS care systems in continental Europe are differently configured when compared to services in the UK, comparison of the pre-hospital care of patients with ACS is difficult across the ESC countries. Moreover this makes the formulation of guidelines applicable to member countries of the ESC even more difficult.

Researchers and readers of research papers must bear these complex geographical and logistical heterogeneities in mind when formulating and interpreting research findings.

4.7 Presentation of the core published works

My first ever study was undertaken while I was a junior staff nurse on a Cardiology ward. My cath-lab colleague and I perceived that the application of pressure dressings to the femoral artery puncture site following cardiac catheterisation was done with varying degrees of quality, based on weak evidence of efficacy and at the cost of significant distress to patients, particularly men. We therefore undertook a study (Robb and McLean, 2000) randomising 654 patients to an intervention (a pressure bandage or usual care) following femoral artery sheath removal. The results, showing no statistically significant difference in individual or combined sequelae, and a trend towards more complications in the pressure bandage group (4.7% vs 2.8%), initiated a change in practice in our institution such that this practice was stopped. Following peer-review the resulting manuscript became my first publication.

My second core publication resulted from work assessing the benefits of moving heart attack treatment from the CCU to the ED. This quasi-experimental study (McLean *et al.*, 2004) used a non-equivalent control group before-after design and showed statistically significant reductions in door-to-treatment time, pain-to-treatment time, proportion of treatment given in the ED, proportion of patients receiving beta-blocker, time to receiving beta-blocker, ST segment resolution and combined adverse clinical endpoints in the year following the study intervention. This was to become the first of my three quasi-experimental studies assessing the benefits of changing either the site or mode of reperfusion treatment in STEMI (McLean *et al.*, 2004; McLean *et al.*, 2008a; McLean *et al.*, 2010b), and my first of six publications relating to delivery of cardiovascular care outwith the confines of the CCU (McLean *et al.*, 2004; McLean, 2006; McLean *et al.*, 2008a; Fitzpatrick and McLean, 2010; McLean *et al.*, 2010a; McLean *et al.*, 2010b).

In 2007 I published my first and only qualitative study exploring the self-perceived information needs of spouses/partners following AMI (McLean and Timmins, 2007).

Two focus groups involving spouses/ partners were facilitated and transcribed by me, and enriched by personal notes. 157 words and statements were 'reduced' to 4 key themes: emotional reactions, the need for information, pulling-apart and pulling-together, and feeling like a burden. Recommendations of the study were that cardiac rehabilitation should be specific, tailored and menu-based, directly involving spouses from the beginning of the patient journey.

Following this I embarked upon my largest study to date. Including 812 patients in a quasi-experimental study using a non-equivalent control group before-after design, it assessed the benefits of moving thrombolysis treatment from the ED to the ambulance (McLean *et al.*, 2008a). We reported statistically significant reductions in EMS on-scene time, travel time, EMS call-to-drug time, hospital door-to-drug time and symptom onset-to-drug time when thrombolytic treatment was given in the ambulance by EMS paramedics. This preparation of the manuscript resulting from this study took some time, with a particularly detailed presentation and analysis of data. Following an iterative process of peer-review, the manuscript became my first work to be published in a predominantly medical journal, the Emergency Medicine Journal, an international journal with an impact factor of 1.347.

These successes then led to the commission by the Chief Scientist Office / Scottish Government Health Department (CSO/SGHD) to undertake a study assessing the feasibility of providing a hybrid reperfusion programme including PPCI and thrombolysis in Scotland, as recommended in national guidance (SIGN, 2007). The study was designed as a quasi-experimental study using a non-equivalent control group before-after design and included 854 patients over a two year period. The conclusions of the study were that the SIGN recommended hybrid programme was safe and effective, and the report to CSO/SGHD included a series of recommendations described as prerequisites to a successful STEMI reperfusion service. The report (McLean *et al.*, 2008c) and the one-year follow-up report (McLean *et al.*, 2009) were graded as excellent by the CSO/SGHD Health Services Research Committee (Appendix 3: 121).

I returned to the familiar field of cardiovascular care outwith the confines of the CCU in my next publication (McLean *et al.*, 2010a). This was a retrospective analysis of cardiovascular risk scores, prospectively applied by cardiovascular nurse specialists in the ED. This study included my first use of Kaplan-Meier survival analyses and showed, with a strong statistical significance, differences in the likelihood of death, prolonged length of hospital stay, ACS, and cardiac catheterisation over low, moderate and high-risk groups as assessed by the chest pain nurse.

Finally my most recent paper (McLean *et al.*, 2010b) describes the effects of implementing of a PPCI service and compares the distribution of reperfusion therapies 12-months pre and post introduction of PPCI. Diagnosis-to-treatment and door-to-treatment times were impressive when compared with other international data. In patients receiving PPCI mortality appeared to be reduced and length of stay was significantly reduced. Temporal trends in a real-world reperfusion programme were described and we reported, for the first time in any of my publications to date, data relating to the concept of total-ischaemic time.

Confirmation of my unique contributions to these papers is provided in Table 1 (p56) and in Appendices 4 (p122), 5 (p123) and 6 (p125).

4.8 Self-assessment of my publications

4.8.1 Introduction sections

The introduction section should describe why the study was done and what questions and hypotheses it addresses. It should allow others to understand the study's context and judge its potential contribution to knowledge (NIHR, 2009; Burns and Grove, 2009).

On analysing the publications comprising this body of work the introductions do appear to set an appropriate context for the study which follows. There is also evidence of learning.

The introduction to McLean *et al.* (2004) was perhaps somewhat overdetailed and elements may have been best placed in the discussion section of the paper and cross-referenced with the results. Watson *et al.* (2008) and Burns and Grove (2009) describe this process of 'revisiting' the literature following formation of the results as a key stage of the research process and one which enriches the validity and rigour. The work of McLean *et al.* (2008a), McLean *et al.* (2010a) and McLean *et al.* (2010b) however present a more focussed and concise introduction to the study, with a corresponding increase in the breadth and depth of literature cited in the discussion section of the papers. This change in practice came about as a direct result of the peer-review process and demonstrates the influence it has in improving the practice of the novice researcher and author.

Nevertheless the body of work does suffer from not having clear, explicit and unambiguous statements of what questions and hypotheses the studies sought to address. There are general statements informing the reader that the paper will describe the intervention and comparison, but there is an absence of explicitly stated aims/objectives/questions/hypotheses which in retrospect are necessary to inform the reader and would have enhanced the body of work.

On reflection these points have been raised by peer-reviewers and as the complexity of my research increases are points which I must learn from and develop, particularly given Vandembroucke *et al.*'s assertion (2007) that substandard statement of objectives hinder the reader from formulating their own conclusions regarding pre-specified versus post-hoc analyses, and assessing any deviations from the original study plan.

4.8.2 Methods

4.8.2.1 Study design

Key elements of the study design should be presented early in the methods section so that the reader can understand the basics of the study (Watson *et al.*, 2008). "*Authors should refrain from calling a study 'prospective' or 'retrospective' because these terms are ill-defined and papers rarely define what they mean*" (Vandembroucke *et al.*, 2007: 809). As a result of critical reflection, there are now apparent deficiencies in some of the earlier works comprising this thesis.

As shown in Table 3a there are papers where despite the study being quasi-experimental with a non-equivalent control group before-after design, the statement describing the design is unclear and tends towards a descriptive nature. Further, in the early work of Robb and McLean (2000), there is no explicit statement presenting the reader with the study design, despite the fact that it is a randomised control trial. This prevents the reader from making a full and objective evaluation of the findings and their relevance.

Table 3a: Unclear statements of study design.

<p>"This paper reports the introduction and application of a combination of measures in the ED aimed at reducing..."</p>	<p>McLean <i>et al.</i>, (2004: 3)</p>
<p>"We report our experience of working with the SAS in ..."</p>	<p>McLean <i>et al.</i>, (2008a: 370)</p>

As the work progressed developments in the more recent publications have taken place such that that the aim of the study is explicitly stated, prefixed by the words "The aim of this study..."

While the two examples listed in Table 3b (p76) are from quantitative papers, the paper of McLean and Timmins (2007: 142) also states “*The study aimed to explore spouse/partner experiences of information received and required following AMI.*” Although this statement is not quite as explicit as the statements presented in Table 3b, it should be borne in mind that McLean and Timmins (2007) was the sole qualitative work comprising this thesis and therefore had a broad and more open-ended research aim.

Table 3b: Clear statements of study design.

<p>“The aim of this article is to determine whether systematic application of the GRACE risk-score by cardiology nurse specialists predicts long term outcome among unselected patients with chest pain.”</p>	<p>McLean <i>et al.</i>, (2010a: 91)</p>
<p>“The aim of this study was to describe the effects of implementing of a PPCI service and compare the distribution of reperfusion therapies 12-months pre and post introduction of PPCI.”</p>	<p>McLean <i>et al.</i>, (2010b: 2)</p>

In terms of the recommendation that the words ‘prospective’ and ‘retrospective’ should be avoided, I would suggest that my work has employed the terms usefully and with appropriate and transparent definition. The following excerpt from McLean *et al.* (2010a: 92) is evidence of this:

“The GRACE score was systematically and prospectively applied to all patients with undifferentiated chest pain in the ED assessed by chest pain nurses between September 2005 and April 2008. A random sample of 504 of the first 7000 patients was analysed retrospectively to determine the relationship between risk score and outcomes”

This statement makes very clear what the prospective and retrospective elements of the design are and allows the reader to come to their own conclusions on the appropriateness, or otherwise, of the study design.

4.8.2.2 Setting

Readers of research papers require information on setting and locations of studies to allow them to assess the context and generalisability of a study's results (Polit and Beck, 2010). From the early work of Robb and McLean (2000) to the more recent work of McLean *et al.* (2010b) there is a thread of clear and transparent descriptions of the study setting, locations, dates, periods of recruitment and follow-up.

From recollection, issues have never been raised by peer reviewers regarding ill-defined study settings. Table 4 provides examples of this:

Table 4: Descriptions of study setting.

"Of the 739 patients undergoing diagnostic or interventional catheterisation at The Royal Infirmary of Edinburgh between October 1998 and February 1999, 654 (88.5%) were studied. Those included met the inclusion criteria of a procedure being performed through a 7-French gauge sheath (11cm) and complete data being available. The data set collected for each patient included..."	Robb and McLean (2000: 372)
"NHS Lothian is South-East Scotland's largest health board area, has a population of 810,000 people of whom 79% live in urban areas, and includes 3 acute receiving hospitals, one of which, the Royal Infirmary of Edinburgh contains three cardiac catheterisation laboratories (cath-labs). The establishment of the 12-lead electrocardiography (ECG) telemedicine and PHT programmes in this population has been described previously."	McLean <i>et al.</i> , (2010b: 2)

4.8.2.3 Participants

Stating the eligibility criteria, sources and methods of selection of participants, and providing a rationale for the selection of the study group or groups is crucial, regardless of the study design (Polit and Beck, 2010). Detailed description of the study participants helps the reader understand the applicability of the results (Watson *et al.*, 2008). As detailed in the previous section on study setting (4.8.2.2, p77) there is a thread throughout these works stating the sources, methods and rationale for selection of the study participants. On reflection however there are papers where description of what in essence is 'sampling' has not been adequately performed.

A good description of sampling is provided by McLean and Timmins (2007: 142) who state that *“Purposive sampling was used. The study population included spouses/partners of patients who had attended (with at least 50% completion) a cardiac rehabilitation programme over a 5-month period at the hospital.”*

McLean *et al.* (2004) on the other hand provides the reader with detail as to the attrition from the selection of the study sample (n=74 patients discharged with a diagnosis of STEMI, who received thrombolytic therapy and had a full data set available) from the study population (n=3,060). This paper does not however make an explicit statement that the non-probability convenience sampling method was used, or perhaps more importantly, why (ease, expense, ready access, representative of ‘real-world’ practice). This is an important issue as described by Gerrish and Lacey (2010) who state that sampling is central to quantitative research designs and decisions regarding sampling have a major impact on the meaning and generalisability of the research findings (Risjord, 2010).

4.8.2.4 Variables, data sources and measurement

A common deficiency in published research reports is an absent or insufficient definition of variables (Gerrish and Lacey, 2010). The way in which data items are measured affects the reliability and validity of a study and make it difficult to detect, analyse or claim relationships (LoBiondo-Wood and Haber, 2010).

From a baseline of good quality work in defining variables, data sources and diagnostic criteria, the quality of my work has improved again as time, and the publications comprising this thesis, have evolved. Details of all variables explicitly defined in the manuscripts are presented in Table 5 (p79) and demonstrate this evolution:

Table 5: Explicit definition of variables.

Robb and McLean (2000)	McLean <i>et al.</i> (2008a)	McLean <i>et al.</i> (2010)
Data collection information sheets	Application of the GRACE score	Year 1 of the reperfusion programme
Pressure dressing application technique	GRACE score recording	Year 2 of the reperfusion programme
Post procedural mobilisation	Data sources	12-lead ECG programme
Post procedural observations	Killip class	PHT programme
Haematoma	Blood result availability	Time of diagnosis
Bruising	Death	Diagnostic electrocardiographic criteria
Clinical sequelae	Follow-up period	Protocol for ECG acquisition
Confounding variables	Length of hospital stay	Total number of STEMIs
Mechanical device use	Cardiac catheterisation	Self-presentation
	GRACE score categories	Exclusion criteria
	Duration of follow-up	Primary PCI
	Time from admission to death	Rescue PCI
		ST segment resolution
		Admission protocol
		Measurement of infarct related artery flow
		Readmission
		Mortality
		Time of EMS call
		Time of EMS scene arrival
		EMS scene time
		EMS drive time
		Time of reperfusion treatment
		Time of reperfusion assessment
		PPCI-related delay
		Data sources

Furthermore where it is not mentioned in Robb and McLean (2000) (and should have been), McLean *et al.* (2010a) clearly state that a potential limitation of the study is inter-observer reliability.

The paper states that *“One possible limitation of this study would be if there were variations in scoring between the various CPNs. This was not analysed in the study, but could be an area for future research.”* (McLean *et al.*, 2010: 95). This shows an evolution and maturity of research quality. Robb and McLean (2000) involved staff and patients sketching around areas of (self-perceived) haematoma and bruising and in retrospect was clearly at risk of diverse inter-observer reliability, which should have been made clear in the research report.

4.8.2.5 Bias

Biased studies produce results that differ systematically from the truth and therefore readers must be aware of what measures, if any, were taken during the course of the study to reduce the potential of bias (Burns and Grove, 2009).

Dependability of data in most qualitative work is closely related to confirmability, and to the level of transparency created by the researcher. McLean and Timmins (2007) for example informs the reader:

- The researcher (SMcL) acted as moderator
- The length of the focus groups
- The data collection media: tape recordings and researcher notes
- Timelines
- The researcher’s engagement (SMcL) with and immersion in the data (replaying tapes, making further notes, recording the researcher’s thoughts and feelings)
- Data transcription
- Data analysis techniques
- The thematic framework
- The data reduction technique and logistics (three phases)
- The process of returning back to the literature
- Rationale for claiming credibility, dependability, confirmability and transferability
- A clear description of the study audit trail

In doing so there was an explicit effort to not only minimise any potential bias, but also an effort to present a sufficiently rich account to allow the reader to form their own judgements. In contrast there was no effort in that study to present the draft findings back to the participants and provide them with an opportunity to confirm or refute any of the content. On reflection this was a missed opportunity to (a) further enrich the paper, and (b) improve the confirmability and potential impact.

4.8.2.6 Study size

A quantitative research study should be large enough to obtain an estimate, with a sufficiently narrow confidence interval, to meaningfully answer a research question (Munro, 2005). Small studies which show ‘interesting’ or ‘statistically significant’ associations are published more frequently than small studies that do not have ‘significant’ findings (Watson *et al.*, 2008).

On reviewing the papers comprising this thesis none of them have explicit statements regarding power calculations, or indeed information regarding how the study size was arrived at. It is however implicit in several of the papers (McLean *et al.*, 2004; McLean *et al.*, 2008a, McLean *et al.*, 2010), and explicitly stated in McLean *et al.* (2010b) that the purpose of the study was not to prospectively test the effect of an independent variable on a dependent variable. There may be an argument to suggest that sample size calculations as they are known in the world of the RCT are not strictly relevant in non-equivalent control group before-after design.

4.8.2.7 Statistical methods

In general terms there is no one ‘correct’ statistical analysis, but rather several possibilities which may serve to address the same question, but make different assumptions (Munro, 2005). Nevertheless, even though the distinction between pre-specified and exploratory analyses may sometimes be blurred, authors should clarify reasons for particular analyses so as to enable the reader to objectively assess their applicability (Watson *et al.*, 2008).

While it is acknowledged in the previous section that explicit calculation of sample size was not performed in the works comprising this thesis, there is evidence of the appropriate use, one a case-by-case basis, of statistical tests. In Robb and McLean (2000), McLean *et al.* (2004), McLean *et al.* (2008a) and McLean *et al.* (2010a), statistical tests were used, all through the prospective involvement of a statistician. Table 6 presents the range of tests used:

Table 6: Statistical methods.

Robb and McLean (2000: 373)	McLean <i>et al.</i> (2004: 4)	McLean <i>et al.</i> (2008a: 371)	McLean <i>et al.</i> (2010a: 92)
Chi-squared test for categorised variables	Two sample t-tests for differences between means from independent samples	Two sample t-tests in normally distributed groups	Kaplan-Meier analysis of survival
Mann-Whitney test for quantitative variables	Two sample tests for differences between proportions	Mann-Whitney test where the distribution did not appear normal and there were two groups	Log rank tests
	Mann-Whitney test for differences between medians	Kruskal-Wallis test where the distribution did not appear normal and there were more than two groups	Chi-squared tests
			Kruskal-Wallis test

On reflection there was no feedback from reviewers that any of the tests applied were unreasonable, or that unreasonable assumptions were made during their application.

This acceptance that the statistical tests used in the papers was reasonable is likely testament to my prospective use of a statistician which according to LoBiondo-Wood and Haber (2010) is a crucial decision for not only the de novo researcher, but also for the experienced researcher who may not be exposed to the range of statistical analyses options and limitations on a regular basis.

4.8.3 Results

4.8.3.1 Descriptive and outcome data

Readers of research papers need information about variables which may potentially confound the study results including whether and how they were measured, in order to make judgments about study validity (LoBiondo-Wood and Haber, 2010). Authors should also report sufficiently rich descriptive data before addressing the possible association between variables and outcomes, (Polit and Beck, 2008).

While there is some evidence of efforts to document potentially confounding factors throughout this body of work, there are unfortunate inconsistencies. Robb and McLean (2000), McLean *et al.* (2004) and McLean *et al.* (2008a) clearly document (as continuous, mean, median and range values):

- Male versus Female gender
- Age
- Height
- Weight
- Body Mass Index
- Systolic blood pressure
- Diastolic blood pressure
- Presence of aortic valve disease
- Previous cardiac catheterisation
- Consultant versus Registrar procedures
- Use of mechanical devices
- Use of anti-coagulant or anti-platelet drugs
- Presence of diabetes mellitus
- Cigarette smoking versus non-cigarette smoking
- Location of myocardial infarction

- Territory of myocardial infarction
- Previous cardiovascular history (myocardial infarction, coronary angiography, PCI, coronary artery bypass grafting)
- Concomitant medications
- Time from onset of symptoms to arrival at hospital

McLean *et al.* (2010a) however makes no mention of any confounding variables, despite being a study describing long term outcome following attendance to the ED with chest pain. In addition McLean *et al.* (2010b), while describing gender, age and territory of infarction, may have benefited from a more comprehensive and detailed presentation of confounding factors, particularly as it describes outcome (logistical and clinical) between before and after groups.

4.8.4 Discussion

4.8.4.1 Key results

The discussion section of the paper addresses the central issues of validity and the meaning of the study (Polit and Beck, 2010). Surveys however have found that the discussion section of papers are often dominated by incomplete or biased assessments of the study's results and their implications, and rhetoric supporting the authors' stance (Horton, 2002).

There is evidence in this body of works of evolution in the quality of the discussion section. In McLean *et al.* (2004) the discussion section is to a large extent a more expansive results section, with use of repetition. Results are restated with a broader discussion suggesting possible reasons, and there are only 4 attempts to place the results in the context of other studies. McLean *et al.* (2008a) on the other hand situates the results in the context of previous literature on 13 occasions, and McLean *et al.* (2010b) on 11 occasions.

This improvement in presentation of results is more in keeping with the style of presentation of applied research in peer reviewed journals.

4.8.4.2 Limitations

The identification and discussion of the limitations of a study are an essential part of scientific reporting (Burns and Grove, 2009). While many of the papers comprising this thesis have limitations acknowledged (McLean *et al.*, 2004; McLean *et al.*, 2008a; McLean *et al.*, 2010a, McLean *et al.*, 2010b), there are others which do not (Robb and McLean, 2000; McLean and Timmins, 2007). The studies where limitations are not explicitly acknowledged may be argued to be weaker as a result. In addition to the limitations of singular pieces of work, it is important to discuss limitations in the body of work *per se*. Each of the studies has been performed in either a single hospital (Robb and McLean, 2000; McLean *et al.*, 2004; McLean and Timmins, 2007; McLean *et al.*, 2010a) or single health board area with three receiving hospitals (McLean *et al.*, 2008a; McLean and Flapan, 2009; McLean, 2009b; McLean *et al.*, 2010b). There are some concerns that single centre studies have a generalisability which is inferior to studies performed in a multi-centre environment (Burns and Grove, 2009), and as discussed in Chapter 5 this is an area for future development of my research.

LoBiondo-Wood and Haber (2010) do point out however that the 'tension' between acknowledging limitations of study, versus the fear of the implications of a very negative critique on professional reputation and responsibility, is a tension which as yet is unresolved.

4.8.4.3 Interpretation

The heart of the discussion section is the interpretation of a study's results (Watson *et al.*, 2008). Over-interpretation is common and human: even when the researcher tries hard to provide an objective assessment, reviewers often rightly point out that he/she went too far in some respects (LoBiondo-Wood and Haber, 2010). In fact no study is generalisable *per se* (Risjord, 2010), the term being meaningful only with regard to clearly specified conditions.

The question of the degree to which the results of a study are generalisable is often a matter of judgment that depends on the study setting, characteristics of participants, variables examined and outcomes and relationships assessed (Polit and Beck, 2010).

Robb and McLean (2000) shows the immaturity of the de novo researcher, when there is a move directly from the results section to the conclusion section of the study without any intervening discussion or attempt to interpret the results in the context of the study objectives, limitations or results from previous studies.

McLean *et al.* (2004) does in retrospect present statements which require a 'leap of faith' and are perhaps driven by the opinion and local context of the authors rather than an objective and rigorous examination of the study results. An example is "*The higher incidence of a second dose of thrombolytic agent for failure-to-reperfuse in Year 2, is probably due to combination of increased awareness of the phenomenon in CCU...*" (McLean *et al.*, 2004: 7). While memory serves this to be a reasonable statement for practice at that time in that hospital, it does not stand up to robust external scrutiny and has almost certainly gone "too far" as suggested by LoBiondo-Wood and Haber (2010), where the hypothetical obverse of the statement may in fact be that the higher incidence of failure-to-reperfuse was a negative outcome of the study intervention.

McLean *et al.* (2010a) and McLean *et al.* (2010b) are examples of perhaps a more restrained and mature approach where statements made in the interpretative phase of the paper are more objective and are based on the results presented in the study. As an example of this, Table 7 presents the statements made in the discussion of McLean *et al.*, (2010a), and how they relate to the results of the study:

Table 7: Interpretation versus supporting data; McLean *et al.* (2010a).

Interpretation	Supporting data
This study demonstrates the feasibility of determining the GRACE score during the assessment of patients presenting to the ED	GRACE score data was collected on over 7000 patients over a 32-month period by chest pain nurses in the ED seeing this patient group, and thus by definition its determination must be feasible
The GRACE score as predicted by the chest pain nurse in the ED powerfully predicts outcome	There were statistically significant differences ($p < 0.0001$) in (i) survival to follow-up, (ii) length of hospital stay, (iii) cardiac catheterization on index admission, and (iv) confirmed ACS, over the 3 GRACE strata as assessed by the chest pain nurse
Nurses assessing patients with chest pain can play an important role in the diagnostic process	As above

4.8.5 Target journals

Although there are no definitive regulations (nor evidence base) to stipulate, it is generally recommended that the “beginning researcher” submits work to journals which focusses on their core domain of practice (LoBiondo-Wood and Haber, 2010). Concentrating on their specific area of expertise will facilitate a simpler and more rewarding process for the novice writer (Burns and Grove, 2009). Once writing experience is achieved however, a seasoned writer will be more proficient and confident with researching and presenting new and challenging topics, and will likely have developed the confidence, ability and expertise to submit to journals of higher standing (larger audience, multidisciplinary, impact factor, increasingly robust peer-review, widely known reputation) (Polit and Beck, 2010).

Because journals vary in content and style, it is crucial that researchers familiarise themselves with the targeted publication. It is most important to recognise the goal of the publication and who makes up their readership - *their audience* (Burns and Grove, 2009). This is critical in ensuring that the findings and the implications reach the intended audience.

The work comprising this thesis has been published in range of nursing, medical and paramedical journals. Publications have been deliberately targeted at journals with the readership to whom the paper would be most relevant. Robb and McLean (2000) was published in the *Professional Nurse* at a time when that journal had a wide readership and a policy of publishing both generalist and specialist papers. McLean *et al.* (2008a) was published in the *Emergency Medicine Journal*, a respected journal aimed at clinicians (doctors, paramedics and nurses) working in pre-hospital care and ED's. McLean (2006) on the other hand was a paper describing my views on an optimal model for delivering emergency cardiovascular care. This paper translated my clinical experience and the empirical data of McLean *et al.* (2004) and what would become McLean *et al.* (2008a), to present a recommendation of what could be a contemporary practice model.

There is also a demonstrable evolution of quality in the status of the journals over time. The last two publications comprising this body of works are in renowned peer-review journals with registered impact factors. One of the publications is an invited joint-editorial in *Heart*, the UK's and one of Europe's leading cardiovascular journals with an impact factor (May 2010) of 4.964, demonstrating my progression as an author.

4.8.5.1 Citations

From January 2011 searches of the citation engines of the ISI Web of Knowledge (<http://wok.mimas.ac.uk>) and Publish or Perish, (<http://www.harzing.com/pop.htm>) the papers comprising this thesis have been cited in 64 other publications, of which only 6 were self-citations. This figure however may be misleading for two reasons. The first is that McLean *et al.* (2009a), McLean *et al.* (2010a), Fitzpatrick and McLean (2010), Fox and McLean (2010), Maccioca *et al.* (2010) and McLean *et al.* (2010b) have all been published within the last 6-months and therefore the likelihood of them being cited in papers which have gone to press is limited. The second reason is that some of the journals in which the papers were published do not belong to publishing groups whose products feature on the seminal searching databases (PubMed, Medline, Cinahl). This makes citation of these works, or recording of citation of these works very difficult.

There may also be an argument that journal citations are not a surrogate for impact on clinical practice, and that clinical practice can be influenced in ways other than citation. It is noteworthy that McLean *et al.* (2004) was cited in the SIGN 93 guidance for ACS (2007). Publication in national guidelines is high accolade and one that is difficult to capture simply by citation searching. Journal of publication, peer-review status, impact factor and citations of the core papers comprising this body of works are tabulated in Table 8. It is difficult to postulate why these papers were cited in the proportions they were, and at the time they were. As an example nurse researchers in Singapore in 2011 submitted a manuscript to a national nursing journal in which they reference the work of Robb and McLean (2000) some eleven years ago.

Table 8: Journal, peer-review status and impact factor (January 2011).

No	Cited	Journal	Peer review	Impact factor
1	7	Emergency Medicine Journal	Yes	1.347
2	7	British Journal of Cardiac Nursing	Yes	
3	11	Emergency Medicine Journal	Yes	1.347
4	15	Nursing in Critical Care	Yes	
5	18	Accident and Emergency Nursing	Yes	
6	6	Professional Nurse	Yes	

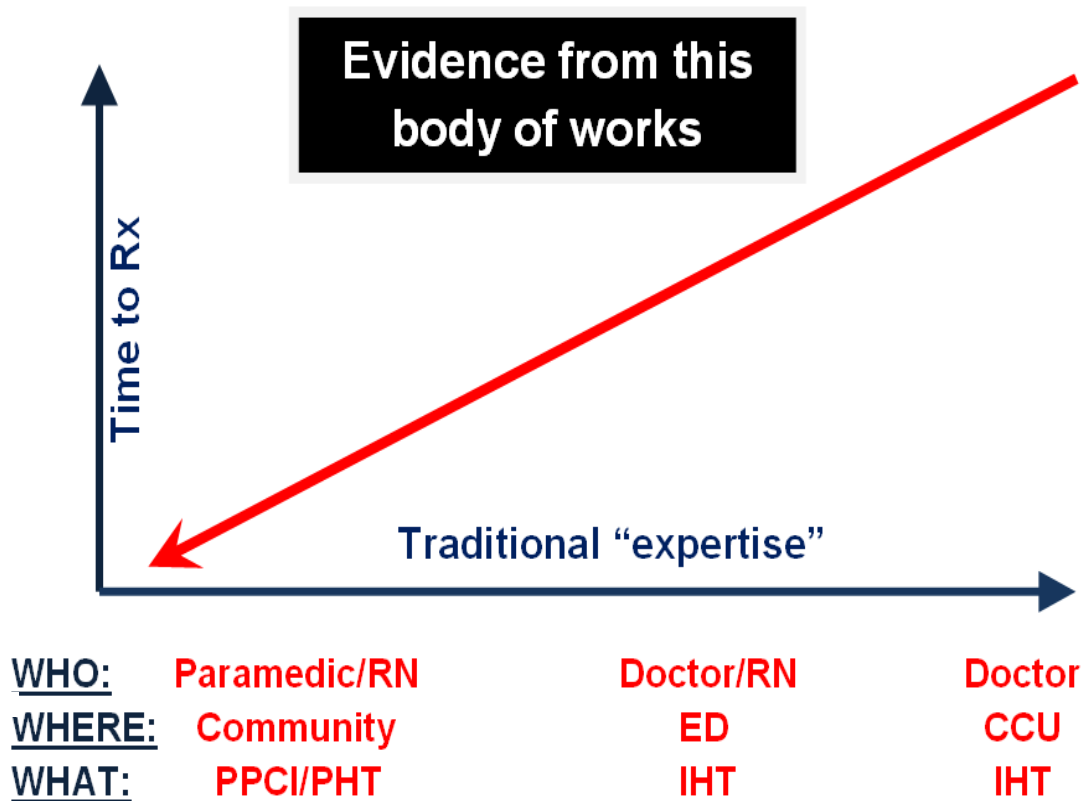
4.8.6 The “thread” and contribution to knowledge

Figures 19 (p58) and 20 (p59) present the body of works comprising this thesis as a complete and coherent programme of interlinked publications, culminating in the conceptual map presented in Figure 21 (p62). Figure 19 clearly demonstrates progression through themes of moving thrombolytic therapy to the ED, refining care for patients presenting with ACS, establishing and evolving communication networks between CCU nurses and EMS paramedics, moving thrombolytic therapy to the ambulance, developing an optimal reperfusion program including PHT, PPCI and IHT, analysis and synthesis of treatment timelines as they are distributed across treatment groups, and using these data to postulate optimal models of reperfusion treatment.

Davies and Rolfe (2009) argue that the sequential and developmental nature of the individual projects within the PhD by Published Works encourages both integration and flexibility. They say that the PhD by this route can, and should, grow and change as it develops. I believe that the progression of themes described in the previous paragraph are evidence of an integrated flow of ideas, and an intuitively sequential ordering of research topics.

In taking a 'wide-angled' view of this body of works, its independent contribution to knowledge, and significance, is graphically presented in the conceptual map (Figure 21, p62). The "established evidence" (1 and 2) as presented in the map is indeed established evidence. The role of occlusive thrombus in STEMI, the time dependent risks of mortality and morbidity, and, the benefits of reopening the occluded coronary artery (either by chemical or mechanical means) have been well established since the 1980's (De Wood *et al.*, 1980; ISIS-2, 1988). The contribution of this body of work, in its totality, is summarised in "this evidence" (1 and 2) of Figure 21, and in Figure 22 (p91):

Figure 22: The contribution of this body of works to knowledge.



In totality the work of McLean *et al.* (2004), McLean *et al.* (2008a), McLean *et al.*, (2008c), McLean *et al.*, (2009), McLean and Flapan (2009), McLean (2009b), Fitzpatrick and McLean (2010) and McLean *et al.*, (2010b) recommends travelling in the leftwards direction along the horizontal axis of Figure 22, as represented by the red arrow. Although this may sound somewhat straightforward it is, and has been, a significant paradigm shift for multidisciplinary clinicians in the United Kingdom. While this thesis by no means seeks to claim sole or primary responsibility for this shift, the works have contributed to the body of knowledge informing it, and I would postulate have answered the primary research in terms of what constitutes the optimal treatment model for patients presenting with Acute Coronary Syndromes.

In terms of the second research question the work of McLean (2006), McLean *et al.* (2008a), McLean *et al.*, (2008c), McLean and Flapan (2009), McLean (2009b), Fitzpatrick and McLean (2010), Mclean *et al.*, (2010a), and McLean *et al.*, (2010b) have in my view defined the optimal contribution of multidisciplinary experts to what is bespoke and robust ACS treatment in the United Kingdom, and in a Scottish context have contributed to national policy and service provision.

Chapter Five – Reflexivity

5.1 Introduction

Reflexivity is defined as a critical approach to professional practice that questions how knowledge is generated (D’Cruz *et al.*, 2007). The reflexive practitioner understands the cognitive processes by which knowledge is created and that knowledge is not simply a resource to ‘deploy’ in practice (Taylor and White, 2000).

Researcher reflexivity requires an awareness of the researcher's contribution to the construction of meanings throughout the research process, and an acknowledgment of the impossibility of remaining 'outside of' one's subject matter while conducting research (Risjord, 2010). Reflexivity then, urges researchers to explore the ways in which their involvement with a particular study influences, acts upon and informs the research (Nightingale and Cromby, 1999). There are two types of reflexivity: personal reflexivity and epistemological reflexivity. ‘Personal reflexivity’ involves reflecting upon the ways in which values, experiences, interests, beliefs, political commitments, wider aims in life and social identities have shaped the research (Willig, 2001). It also involves thinking about how the research may have affected and possibly changed the researcher. ‘Epistemological reflexivity’ requires engagement with questions such as: How has the research question defined and limited what can be ‘found?’, How has the design of the study and the method of analysis ‘constructed’ the data and the findings?, How could the research question have been investigated differently?, To what extent would this have given rise to a different understanding of the phenomenon under investigation? (Willig, 2001). Thus, epistemological reflexivity encourages researchers to reflect upon the assumptions that have been made in the course of the research, and encourages researchers to think about the implications of such assumptions for the research and its findings (Willig, 2001).

In simple terms, the starting point for my research was based on observations from practice and a curiosity as to why interventions are done in a certain way.

This then developed into generating evidence and moving it on to influence practice. People who deliver care are the audience at whom the papers are aimed, and an impact on the delivery of, decision-making in, and settings for cardiovascular care is the desired goal. Challenges for the future and opportunities to develop evidence remain foremost.

The reason for describing my journey in these terms relates to Risjord's (2010), Nightingale and Cromby's (1999) and Willig's (2001) assertions around personal reflexivity and the fallacy of claiming to remain 'outside of one's subject matter while conducting research. From attempting to deliver an RCT as a very junior staff nurse, through to being cited in national guidelines, my journey has been informed and influenced by key relationships, clinical practice, the peer-review process, and the impact of and response to my last paper. While by its very nature the process may not have been quite as forensically sequenced as described in this thesis, the sequential and logical flow of my works has been as a result of not being 'outside of one's subject matter' (Risjord, 2010), and rather have been as a result of enjoying the bulk of my career deeply immersed in the evolving evidence and practice of caring for patients with ACS.

5.2 Personal reflections

The process of constructing this thesis has been an enjoyable and truly rewarding experience. The chronology and progress of my career from new staff nurse, to charge nurse, to nurse specialist and then to nurse consultant has played a significant part in shaping my published works. Paradoxically the published works have undoubtedly shaped my career, where the gravitas, professional respect and currency which publishing in national and international peer-review journals brings, has afforded me opportunities which would not have arisen were it not for the reputation I have garnered through these works.

I recognise that the opportunities I have had in being awarded Nurse Fellowship of the ESC, membership of the ESC Working Group on Acute Cardiac Care, and a commissioned editorial in one of Europe's leading heart journals (Fox and McLean, 2010), would not have arisen were it not for my body of published work. Although a personal and perhaps subjective view, and therefore not included in the body of this thesis, it has been overwhelmingly gratifying to see, feel and hear of the improvements in the standard of care for patients with ACS in the centres where this work has been conducted. That the work was conducted in a major hospital environment has meant that there have been, relatively minor, disputes and disagreements along the way. These have required time, effort and resolve to address, yet act as an opportunity and have been part of my developmental process and research learning.

Particularly pleasing is the response to the programmes described by these works, not by colleagues who have believed in them since their inception, but by those colleagues who have not. I have had positive interactions with colleagues who initially were sceptical of a programme where nurses and paramedics are the primary decision-makers in the treatment of STEMI, or in nurses being responsible for the primary risk-stratification of patients presenting to the ED with undifferentiated chest pain. Perhaps most gratifying of all is the fact that these colleagues have been convinced through carefully constructed, coherent and programmed quasi-experimental and observational research, with the data used to inform publications on the issue.

Similarly it has been a privilege and a pleasure to watch, and to be a key part in, the evolution of nurses and paramedics in this domain. For no additional financial reward, and therefore for no other reason than a sense of professional duty and desire to improve patient outcome, these practitioners have revolutionised the care of patients with ACS. I believe that the care of these patients will never recede to where it was even as recently as 10 years ago (to the right of the horizontal axis of Figure 22, p91). These groups have changed the face of ACS care forever.

While it makes me proud to have worked alongside them, I do not believe that many of them understand just how seismic either the shift in practice, or their contribution to it has been. Figure 22 does not do justice to this and I again would emphasise the enormity of what has been achieved across the United Kingdom.

Of course at the beginning of this journey with my first paper (Robb and McLean, 2000) I had no thoughts of composing a body of work which would be submitted for doctoral examination. While the PhD by a traditional route has some clear advantages in terms of research training that focusses on a single issue, it has been criticised for producing a low yield of publications, with some successful candidates failing to publish their work at all (Davies and Rolfe, 2009). The PhD by Published Works has clear advantages in terms of adding to the body of literature.

The challenge in composing a thesis to support the body of published works has been in identifying and feeling comfortable with frameworks which furnish the evaluation of the body of work in totality. Through describing the background, context, aims, philosophical basis of post-positivism, principles of causality and rigour, underpinning principles of interventional studies, ethical issues, limitations, use of the NIHR toolkit (2009) and the conceptual map I am personally assured that I have constructed a framework by which my work can be assessed in objectivity. This has significantly increased my understanding of my own work and perhaps more importantly has informed my learning. I am convinced that I have and will become a “better” researcher as a result.

Contrary to my preconceptions I did not find this process a lonely or isolated experience. In fact I found it both comforting and rewarding. I found that it helped me, through deep and honest introspection, to self-define my place within my specialty world, within the research world, and within the nursing world. It has, beyond doubt, energised me and given me focus, enthusiasm and new skills to take forward into my post-doctoral research.

In terms of the nursing world, this work has further compounded my determination to move nursing away from the 'naval-gazing' which I believe it to be guilty of. Professor John Paley from the University of Stirling has published several times criticising the "destructive naval-gazing of nursing," and in-particular in nursing academia (Paley, 1996). I do not subscribe to the term "nursing research." Rather I subscribe to healthcare research by nurses. As a clinician and a researcher working in a health-care environment I do not confine my practice or research within artificial boundaries within one discipline. I believe this to be a positive feature of my work. I justify this by stating that I study patient outcomes, systems of care and the contribution of multidisciplinary clinicians to the care of patients with ACS. Collectively these outputs contribute to healthcare research.

Post-procedural complications, effectiveness of interventions, reducing time-to-treatment in heart attack, "extended" nursing and paramedical roles involving telemedicine, synergies of "nurse-led" services when combined, exploration of information and support needs, analysis of contemporary patient journeys, and exploration of specialist nurse assessment of cardiovascular-risk are to my opinion at the heart of healthcare research by nurses. For those who believe these to be "medical" rather than "nursing" issues I would cite the following who state that 'nursing' relates to: developing person-centred systems (Risjord, 2010), improving health and health outcomes of clients (Polit *et al.*, 2010), evaluating practice (Watson *et al.*, 2008), study and assessment of patient outcomes (Schmidt and Brown, 2009) and generation of an evidence-base (LoBiondo-Wood and Haber, 2010).

I believe these statements to define the gestalt of my research.

5.3 Future research

As a body of work I believe that it must now evolve further, perhaps bi-directionally. This of course will not be possible without the collaboration of others. I think the first direction will be similar to the one described in this thesis.

As empirical research testing the efficacy of novel pharmacological agents for use in ACS evolves, so does the opportunity to conduct applied research testing their utility in real-world clinical practice (as opposed to the RCT environment). van't Hof *et al.* (2008) reported the benefits of administering the glycoprotein inhibitor Tirofiban in the pre-hospital setting. They undertook a double-blind, randomised, placebo-controlled trial including 984 patients where 491 were assigned to receiving the drug in the ambulance. They concluded that there were benefits in clinical outcome as a result.

The van't Hof *et al.* (2008) study was performed in ambulances in Belgium, Holland and Germany. As highlighted in the first chapter of this thesis, health-care systems across continental Europe, particularly ambulance services, are configured differently when compared to services in the UK, with some emergency medical services being characterised by the systematic presence on-board the ambulance of a physician. This was a characteristic of van't Hof *et al.*'s (2008) study where all ambulances had an on-board physician. There is therefore an opportunity to study the clinical utility of this regime in a UK context. While the UK cardiology community is engaged in debate regarding optimal models of STEMI reperfusion treatment, understanding the pre-hospital utility of a drug which is arguably the most useful adjunctive treatment in patients undergoing PPCI would be a useful addition to knowledge. The framework for such a piece of work would be similar to the work comprising this thesis with a few notable exceptions. As acknowledged in the limitation section of this thesis, the generalisability of this body of work is less strong than it might be due to the single-centre nature of the publications. Whether as part of the study proposed above, or another study, I will endeavour to undertake multi-centre research in the future, with gaining clinical trial experience and expanding my collaborative links being key objectives. I believe that this will be key to my development as a clinical researcher.

A further area for research might be in understanding more about the treatment of patients with ACS from the perspective of the paramedics and nurses engaged in it.

Quinn *et al.* (2009) performed a survey of paramedics perceptions of their role when considering thrombolytic therapy for patients with STEMI. They found that paramedics hold a range of views and perceptions of their role in administering the treatment, some of which appear to be related to age and length of service.

While many paramedics view thrombolytic therapy as a positive step in patient care, the authors concluded that further work is required to elicit paramedics views on alternative reperfusion strategies such as PPCI. As yet there are no UK publications reporting this, nor the views of CCU nurses and a carefully designed study would undoubtedly add to knowledge.

Finally I have over the course of my research and clinical career formed the view that the pre-hospital 12-lead ECG is the pivotal component of the assessment of patients presenting to EMS with suspected ACS, particularly STEMI. Use of pre-hospital ECG is however suboptimal in some countries with only around 10% of STEMI patients receiving one in the analysis of the United States National Registry of Myocardial Infarction (Curtis *et al.*, 2004). I am currently involved in discussions with colleagues in England planning a study which will assess the clinical benefits of the pre-hospital ECG, and the predictors for patients having/not having one performed, which will hopefully contribute to the evidence-base in this domain.

5.4 Conclusion

On page one of this thesis, referencing the California and Western Medicine Editorial (1926) I set a challenge that the evidence presented in this thesis would provoke the reader to ask whether or not the patient with heart disease in 2011 needs the “*personal services of a physician,*” or perhaps more importantly whether or not “*no-one else can.*” It is my contention that this has been achieved and that the great work of the men and women who deliver world-class care to these patients has been made clear. It is gratifying that we have come far; and fascinating that we have even further to go.

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Appendix 1

Glossary of terms

ACS	Acute Coronary Syndrome
AMI	Acute Myocardial Infarction
ASR	Age Standardised Rate
CAD	Coronary Artery Disease
Cath Lab	Cardiac Catheterisation Laboratory
CCNAP	Council on Cardiovascular Nursing and Allied Professions
CCU	Coronary Care Unit
CHD	Coronary Heart Disease
CNS	Clinical Nurse Specialist
CPNs	Chest Pain Nurses
CSO	Chief Scientist Office
CVD	Cardiovascular Disease
ECG	Electrocardiogram
ED	Emergency Department
EMS	Emergency Medical (Ambulance) Services
ESC	European Society of Cardiology
GRACE	Global Registry of Acute Coronary Events
IHT	In-Hospital Thrombolysis
MI	Myocardial Infarction
n	number (sample size)
NFESC	Nurse Fellow of the European Society of Cardiology
NHS	National Health Service
NIHR	National Institute for Health Research
PCI	Percutaneous Coronary Intervention
PhD	Doctor of Philosophy
PHT	Pre-Hospital Thrombolysis
PHRU	Public Health Research Unit
PPCI	Primary Percutaneous Coronary Intervention
RCT	Randomised Controlled Trial
RN	Registered Nurse

Rx	Treatment
SAS	Scottish Ambulance Service
SGHD	Scottish Government Health Department
SIGN	Scottish Intercollegiate Guidelines Network
STEMI	ST segment elevation myocardial infarction
UK	United Kingdom

Appendix 2

Curriculum Vitae

Mr. Scott McLean RN, MSc., NFESC

Current post

- Divisional Nurse, Circulatory, Respiratory & Metabolic Sciences Division, Barts and The London NHS Trust

Awards/Memberships

- Awarded British Heart Foundation Excellence Award for Cardiac Nursing in 2006
- Awarded Nurse Fellowship of The European Society of Cardiology in 2008
- Voted President Elect of The British Association for Nursing in Cardiovascular Care in 2009
- Professional memberships:
 - British Association for Nursing in Cardiovascular Care
 - European Society of Cardiology Working Group on Acute Cardiac Care
 - European Society of Cardiology Working Group on Acute Cardiac Care Pre-Hospital Care study group
 - European Society of Cardiology Council on Cardiovascular Nursing and Allied Professions
 - European Society of Cardiology Expert Consensus Group on the Pre-Hospital Care of ST Elevation Myocardial Infarction

Research/Educational

- Currently undertaking PhD by Published Works, Edinburgh Napier University
- First-class Masters degree in Nursing
- Peer reviewer for:
 - The Emergency Medicine Journal
 - International Journal of Therapy and Rehabilitation
 - Malaysian Journal of Medical Sciences
 - The British Journal of Cardiac Nursing
- Abstract marker for British Cardiovascular Society and European Society of Cardiology Council on Cardiovascular Nursing and Allied Professions
- Zero-hours Lecturer, Edinburgh Napier University (Faculty of Health, Life & Social Sciences)
- Honorary Senior Lecturer, City University, London (School of Community and Health Sciences)

Educational Qualifications

- 2002 to 2004 - The Royal College of Surgeons in Ireland, Dublin, Ireland
Master of Science Degree in Nursing (First Class)
- 1998 to 2000 - Edinburgh Napier University, Edinburgh
Bachelor of Science Degree in Nursing Studies
- 1992 to 1995 - University of Abertay, Kirkcaldy, Fife
Diploma of Higher Education in Nursing Studies - Adult Branch

Employment History

Date	Post
Apr 10 - Currently	Divisional Nurse, Circulatory, Respiratory & Metabolic Sciences Division, Barts and The London NHS Trust
Sep 07 – Apr 10	Consultant Nurse in Acute Cardiology, The Edinburgh Heart Centre (Band 8b)
Sep 06 – Sep 07	<ul style="list-style-type: none"> • Clinical Nurse Specialist, Rapid Access Chest Pain Service, The Edinburgh Heart Centre (Grade H), and • A/Clinical Nurse Manager, Cardiology Directorate, The Royal Infirmary of Edinburgh (Grade H)
Sep 05 - Sep 06	<ul style="list-style-type: none"> • Clinical Nurse Specialist, Rapid Access Chest Pain Service, The Edinburgh Heart Centre (Grade G)
Mar 04 – Sep 05	Clinical Nurse Specialist, Acute Chest Pain Service, The Edinburgh Heart Centre (Grade F)
Mar 03 – Mar 04	Deputy Charge Nurse, Coronary Care Unit, The Edinburgh Heart Centre (Grade F)
Sep 02 - Mar 03	Cardiology flow manager, The Mater Private Hospital, Dublin, Ireland ('Grade G')
Mar 01 - Sep 02	Clinical Nurse Specialist, Chest Pain Service, Waterford Regional Hospital, Ireland ('Grade G')
Jan 98 – Mar 01	Staff Nurse, Coronary Care Unit, The Royal Infirmary of Edinburgh (Grade E)
Mar 97 – Jan 98	Staff Nurse, Cardiac Catheterisation Suite, The Western General Hospital, Edinburgh (Grade D)
Sep 95 – Mar 97	Staff Nurse, Coronary Care Unit, The Victoria Hospital, Fife (Grade D)

Appendix 3

Chief Medical Officer Directorate

αβγδεφγηιφκλμνοπθρστ

Chief Scientist Office

T: 0131-244 2248 F: 0131-244 2285
roma.armstrong@scotland.gsi.gov.uk

Dr Andrew D Flapan
Department of Cardiology
Royal Infirmary of Edinburgh
Little France Crescent
EDINBURGH
EH16 4SA

Our ref: CZB/4/413
2 March 2010

Dear Dr Flapan

FINAL REPORT

STRATEGIES FOR OPTIMAL REPERFUSION IN ST SEGMENT ELEVATION MYOCARDIAL INFARCTION. A FEASIBILITY STUDY FOR PROVISION OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION AND PRE-HOSPITAL THROMBOLYTIC THERAPY IN SCOTLAND

The Biomedical and Therapeutic Research Committee considered the Final Report on this project.

The Committee graded the report as Excellent.

Please share this information with your co-applicants: S McLean, P Connor and S Wild.

Yours sincerely



DR ROMA ARMSTRONG

Biomedical and Therapeutic Research Committee

CSO has moved to electronic working so unless requested otherwise, please respond by e-mail.

St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.scotland.gov.uk

CSO 22 Rev

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Appendix 4



SCHOOL OF CLINICAL SCIENCES AND
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11 October 2010

Dear Sir/Madam

PhD Thesis: Scott McLean

I am pleased to provide this letter to define the contributions of Scott Mclean in relation to the following two publications:

Fox, K.A.A. & McLean, S. (2010) NICE Guidance on Chest Pain. Heart 96 903-906.

Scott McLean made an equal contribution to the design, drafting and revisions of this manuscript and he was entirely responsible for the data analysis (exploring the application of the NICE Guidance in relation to the Edinburgh dataset).

McLean, S., Phillips, A., Carruthers, K. & Fox, K.A.A. (2010a) Use of the GRACE score by cardiology nurse specialists in the emergency department. British Journal of Cardiac Nursing 5 91-95.

Scott McLean was responsible for the development of a highly innovative programme of chest pain evaluation by cardiology nurse specialists. He was the lead on the analysis of the data, the interpretations and the drafting and revisions of the manuscript.

Yours faithfully

Keith A A Fox
Professor of Cardiology

Appendix 5



Dr. Andrew D Flapan
Clinical Director - CTR Directorate
The Royal Infirmary of Edinburgh
Little France Crescent
Edinburgh
EH16 4SA

20th November 2010

Dear Sir/Madam

PhD Thesis: Scott McLean

I am pleased to provide this letter to define the contributions of Scott Mclean in relation to the following publications:

McLean, S., Wild, S., Connor, P. & Flapan, A.D. (2010) Treating ST Elevation Myocardial Infarction by Primary Percutaneous Coronary Intervention, In-hospital thrombolysis and Pre-hospital thrombolysis. An observational study of timelines and outcomes in 625 patients. *Emergency Medicine Journal* doi:10.1136/emj.2009. 086066.

Scott McLean and I were jointly responsible for formation of the idea that we could perform this study. He was responsible for designing the data collection and data analysis strategies, leading the study, and, with added input from Sarah Wild and I, primarily authoring the final submission.

Maccioca, P., Cruden, N., McLean, S., Flapan, A.D. & Newby, D.E. (2010) Effect of smoking status on angiographic outcomes and 12-month mortality following primary percutaneous coronary intervention for acute myocardial infarction. *Heart* 96 (Suppl 1):A27.

Nicholas Cruden and I were responsible for the idea for this study. Paul Maccioca was responsible for the data collection and authoring of the final submission. Scott McLean and Paul Maccioca were responsible for analysis the pre/post intervention data.

McLean, S. & Flapan, A.D. (2009) Decision-making between nurses and paramedics in reperfusion of ST elevation myocardial infarction. *Heart* 95 (Suppl 1):A35.

Scott McLean and I were jointly responsible for formation of the idea that we could perform this study. He was responsible for designing the data collection and data analysis strategies, leading the study, and authoring the final submission.

McLean, S., Wild, S., Connor, P. & Flapan, A.D. (2009) Strategies for optimal reperfusion in ST segment elevation myocardial infarction. A feasibility study for provision of primary percutaneous coronary intervention and pre-hospital thrombolytic therapy in Scotland: A report of one-year follow-up. A report to the Chief Scientist Office re. grant no. CZB/4/413.

Scott McLean and I were jointly responsible for formation of the idea that we could perform this study. He was primarily responsible, with added input from Sarah Wild and I, for authoring the final report to the Chief Scientist Office.

McLean, S., Egan, G., Connor, P. & Flapan, A.D. (2008) Collaborative decision making between Paramedics and CCU nurses based on 12 lead ECG telemetry expedites the delivery of thrombolysis in ST Elevation Myocardial Infarction. *Emergency Medicine Journal* 25 370-374.

Scott McLean and I were jointly responsible for formation of the idea that we could perform this study. He was responsible for designing the data collection and data analysis strategies, leading the study, authoring the final manuscript and steering it through the iterative peer-review process to publication.

McLean, S., Wild, S., Connor, P. & Flapan, A.D. (2008) Strategies for optimal reperfusion in ST segment elevation myocardial infarction. A feasibility study for provision of primary percutaneous coronary intervention and pre-hospital thrombolytic therapy in Scotland. A report to the Chief Scientist Office re. grant no. CZB/4/413.

Scott McLean and I were jointly responsible for formation of the idea that we could perform this study. He was responsible for writing the grant application to the Chief Scientist Office and leading the study. He, with some input from co-applicants was responsible for framing the research questions, designing the data collection and data analysis strategies, leading the study and research nurse, and, with added input from Sarah Wild and I, primarily authoring the final report to the Chief Scientist Office.

McLean, S., Preston, J. & Flapan, A.D. (2008) Belching: An unusual clinical presentation of Coronary Ischaemia. *Scottish Medical Journal* 53 10.

Scott McLean was responsible for the diagnosis and initial treatment plan of the patient described in the case study. He initiated drafting, writing and submission of the manuscript.

Yours sincerely



Dr. Andrew D Flapan

Clinical Director – CTR Directorate

Appendix 6

Authors contribution to core publications

No.	Core Paper	% contribution		Letter of support
1	McLean, S., Wild, S., Connor, P. & Flapan, A.D. (2010b) Treating ST Elevation Myocardial Infarction by Primary Percutaneous Coronary Intervention, In-hospital thrombolysis and Pre-hospital thrombolysis. An observational study of timelines and outcomes in 625 patients. <i>Emergency Medicine Journal</i> doi:10.1136/emj.2009. 086066.	Preparing research proposal / grant application [includes research design]	90%	Appendix 5
		Gaining ethical / management approval	100%	
		Developing and testing data collection instruments	75%	
		Data collection	10%	
		Data analysis	90%	
		Writing up report	80%	
		Preparing manuscript for publication	80%	
2	McLean, S., Phillips, A., Carruthers, K. & Fox, K.A.A. (2010a) Use of the GRACE score by cardiology nurse specialists in the emergency department. <i>British Journal of Cardiac Nursing</i> 5 91-95.	Preparing research proposal / grant application [includes research design]	85%	Appendix 4
		Gaining ethical / management approval	100%	
		Developing and testing data collection instruments	80%	
		Data collection	30%	
		Data analysis	90%	
		Writing up report	75%	
		Preparing manuscript for publication	75%	
3	McLean, S., Egan, G., Connor, P. & Flapan, A.D. (2008a) Collaborative decision making between Paramedics and CCU nurses based on 12 lead ECG telemetry expedites the delivery of thrombolysis in ST Elevation Myocardial Infarction. <i>Emergency Medicine Journal</i> 25 370-374.	Preparing research proposal / grant application [includes research design]	100%	Appendix 5
		Gaining ethical / management approval	100%	
		Developing and testing data collection instruments	100%	
		Data collection	30%	
		Data analysis	90%	
		Writing up report	90%	
		Preparing manuscript for publication	90%	

4	McLean, S. & Timmins, F. (2007) An exploration of the information needs of spouse/partner following acute myocardial infarction using focus group methodology. <i>Nursing in Critical Care</i> 512 141-150.	Preparing research proposal / grant application [includes research design]	100%	None
		Gaining ethical / management approval	100%	
		Developing and testing data collection instruments	100%	
		Data collection	100%	
		Data analysis	100%	
		Writing up report	100%	
		Preparing manuscript for publication	50%	
5	McLean, S. , O'Reilly, M., Doyle, M. & Rathaille, M.O. (2004) Improving door-to-drug time and ST segment resolution in AMI by moving thrombolysis administration to the emergency department. <i>Accident and Emergency Nursing</i> 12 2-9.	Preparing research proposal / grant application [includes research design]	100%	None
		Gaining ethical / management approval	85%	
		Developing and testing data collection instruments	90%	
		Data collection	80%	
		Data analysis	80%	
		Writing up report	80%	
		Preparing manuscript for publication	75%	
6	Robb, C. & McLean, S. (2000) Using pressure dressings after femoral artery sheath removal. <i>Professional Nurse</i> 15 371-374.	Preparing research proposal / grant application [includes research design]	40%	None
		Gaining ethical / management approval	25%	
		Developing and testing data collection instruments	75%	
		Data collection	50%	
		Data analysis	50%	
		Writing up report	60%	
		Preparing manuscript for publication	50%	

Published works

Core published works	
1	McLean, S. , Wild, S., Connor, P. & Flapan, A.D. (2010b) Treating ST Elevation Myocardial Infarction by Primary Percutaneous Coronary Intervention, In-hospital thrombolysis and Pre-hospital thrombolysis. An observational study of timelines and outcomes in 625 patients. <i>Emergency Medicine Journal</i> doi:10.1136/emj.2009.086066.
2	McLean, S. , Phillips, A., Carruthers, K. & Fox, K.A.A. (2010a) Use of the GRACE score by cardiology nurse specialists in the emergency department. <i>British Journal of Cardiac Nursing</i> 5 91-95.
3	McLean, S. , Egan, G., Connor, P. & Flapan, A.D. (2008a) Collaborative decision making between Paramedics and CCU nurses based on 12 lead ECG telemetry expedites the delivery of thrombolysis in ST Elevation Myocardial Infarction. <i>Emergency Medicine Journal</i> 25 370-374.
4	McLean, S. & Timmins, F. (2007) An exploration of the information needs of spouse/partner following acute myocardial infarction using focus group methodology. <i>Nursing in Critical Care</i> 12 141-150.
5	McLean, S. , O'Reilly, M., Doyle, M. & Rathaille, M.O. (2004) Improving door-to-drug time and ST segment resolution in AMI by moving thrombolysis administration to the emergency department. <i>Accident and Emergency Nursing</i> 12 2-9.
6	Robb, C. & McLean, S. (2000) Using pressure dressings after femoral artery sheath removal. <i>Professional Nurse</i> 15 371-374.
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7	Fox, K.A.A. & McLean, S. (2010) NICE Guidance on Chest Pain. <i>Heart</i> 96 903-906.
8	Fitzpatrick, D. & McLean, S. (2010) Reperfusion of the old or the new: Left Bundle Branch Block? <i>Journal of Paramedic Practice</i> 2 50-55.
9	McLean, S. (2009a) Clinical history versus the exercise ECG in assessment of stable coronary artery disease. <i>British Journal of Cardiac Nursing</i> 4 363-366.
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11	McLean, S. , Mondo, C. & Divers, F. (2007) The Cardiology Nurse Consultant in Scotland. <i>British Journal of Cardiac Nursing</i> 2 589-591.
12	McLean, S. (2006) Chest Pain: Providing an integrated service for patients. <i>Emergency Nurse</i> 13 12-14.
Published abstracts	
13	Maccioca, P., Cruden, N., McLean, S. , Flapan, A.D. & Newby, D.E. (2010) Effect of smoking status on angiographic outcomes and 12-month mortality following primary percutaneous coronary intervention for acute myocardial infarction. <i>Heart</i> 96 (Suppl 1):A27.
14	McLean, S. & Flapan, A.D. (2009) Decision-making between nurses and paramedics in reperfusion of ST elevation myocardial infarction. <i>Heart</i> 95 (Suppl 1):A35.
15	McLean, S. (2009b) Decision-making between nurses and paramedics in reperfusion of ST elevation myocardial infarction. <i>European Journal of Cardiovascular Nursing</i> 8 (Suppl 1):S23.



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Treating ST elevation myocardial infarction by primary percutaneous coronary intervention, in-hospital thrombolysis and prehospital thrombolysis. An observational study of timelines and outcomes in 625 patients

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ABSTRACT

Objective To describe the effects of implementing of a percutaneous coronary intervention (PPCI) service and compare the distribution of reperfusion therapies 12 months pre and post introduction of PPCI.

Design Observational study with data collected 12 months pre and post-availability of Primary PCI as routine treatment.

Setting Lothian region in South-East Scotland.

Patients 625 Patients who received reperfusion treatment between December 2005 and November 2007.

Results PHT was given to 96/328 patients (29%) prior to availability of PPCI as routine treatment. Following routine availability, PPCI was delivered to 248/297 patients who received reperfusion treatment (84%). Median diagnosis-to-PCI balloon inflation time and hospital door-to-balloon time were 84 and 54 min, respectively. Patients received PPCI balloon inflation within 90 min of diagnosis in 60% of cases. PPCI-related delay was 74 min compared with prehospital thrombolysis (PHT). PHT (152 min) and PPCI (166 min) had shorter symptom onset-to-assessment of reperfusion times than in-hospital thrombolysis (IHT) (226 min).

Conclusions More than two-thirds of the total-ischaemic-time in (ST-segment elevation myocardial infarction) STEMI occurs before the patient reaches hospital, with less than one-third being accounted for by door-to-needle (IHT) or door-to-balloon (PPCI) time. The magnitude of difference in the time between symptom onset-and-assessment of reperfusion treatment efficacy is short and should be considered, particularly in patients treated with thrombolysis in hospitals without cath-lab facilities. Optimal reperfusion treatment including a combination of PHT, IHT and PPCI, as recommended in international guidelines, is feasible in the UK although the balance between the use of different treatments will differ between urban and rural areas.

Individual randomised trials and pooled analyses^{1–3} have reported the importance of minimising delays in the treatment of ST-segment elevation myocardial infarction (STEMI), however few systems of care presented in the literature have successfully demonstrated shortening of prehospital and in-hospital time delays. Optimal treatment for STEMI has been defined as a reperfusion strategy which includes both primary percutaneous coronary

intervention (PPCI) and thrombolytic therapy.⁴ This strategy will dramatically improve clinical outcome compared with conservative treatment strategies, if the most appropriate treatment is offered within the shortest possible time delay from symptom onset.⁴ Unfortunately, 25–30% of patients across Europe with STEMI do not receive reperfusion treatment¹ and there are unacceptably long-time delays to treatment reported in real-world registries,² so that only a minority of patients receive all guideline-indicated therapies within desirable timescales.⁵

This situation may be improved by building systems of care in which Emergency Medical Systems (EMS), hospitals with PCI facilities and non-PCI-capable hospitals work together to reduce the time from symptom onset-to-administration of reperfusion treatment, or ‘total-ischaemic-time (TIT).’⁶ These ‘STEMI networks’ may not only reduce TIT but should also increase the proportion of patients receiving reperfusion therapy, with resultant decreases in short and long-term mortality.⁷

While the majority of treatment delay in STEMI occurs prior to arrival at the interventional hospital, with door-to-PPCI balloon time accounting for around only one-third of the delay between symptom onset and reperfusion treatment,⁶ many of the reported initiatives have focused only on care in the final interventional hospital.^{8–9} Defining the optimal time interval between a patient presenting to emergency healthcare services and receiving reperfusion therapy in STEMI has generated significant debate. Guidelines from the American Heart Association/American College of Cardiology¹⁰ use conflicting terminology by suggesting that both hospital door-to-PPCI balloon inflation, and first medical contact-to-balloon inflation intervals should be less than 90 min. European Society of Cardiology guidelines⁴ recommend that the time between first medical contact and PPCI balloon inflation should be less than 90 min in patients within 2 h of symptom onset, and less than 120 min in patients presenting more than 2 h after symptom onset.

A recent report describing PPCI in England¹¹ suggests that a desirable call-to-balloon time should be within 120–150 min, however guidelines in Scotland¹² state that patients with STEMI should be treated with PPCI where the diagnosis-to-balloon

time does not exceed 90 min. These guidelines also state that where PPCI cannot be provided within 90 min of diagnosis, patients should receive immediate fibrin-specific thrombolytic therapy.¹²

The interchangeable use of these four terms (call, first medical contact, door and diagnosis) as the starting point for desirable treatment intervals further complicate the logistical challenges presented by delivering PPCI.

This paper describes the introduction of a programme of optimal reperfusion based around a 90 min diagnosis-to-PPCI balloon time, involving prehospital decision-making by ambulance paramedics and coronary care unit (CCU) nurses. Following the release of Scottish Intercollegiate Guidelines Network (SIGN) guidelines on management of acute coronary syndromes, the Chief Scientist Office provided funding to assess the feasibility of an optimal reperfusion programme (ORP), based around these guidelines¹²:

1. Patients with an ST elevation acute coronary syndrome should be treated immediately with primary percutaneous coronary intervention.
2. Where primary percutaneous coronary intervention cannot be provided within 90 min of diagnosis, patients with ST elevation acute coronary syndromes should receive immediate thrombolytic therapy.

Data were collected on patients receiving reperfusion therapy over 24 months from December 2005 to November 2007. The reperfusion programme during the first 12 months of this period (year 1) consisted of prehospital thrombolysis (PHT) and in-hospital thrombolysis (IHT), with PPCI reserved for patients who had contraindications to thrombolytic therapy. The second 12 months of data collection were on commencement of the ORP (year 2), when treatment options were PPCI, PHT and IHT (for patients self-presenting to a hospital without cath-lab facilities).

METHODS

NHS Lothian is South-East Scotland's largest health board area, has a population of 810 000 people of whom 79% live in urban areas, and includes three acute receiving hospitals, one of which, the Royal Infirmary of Edinburgh contains three cardiac catheterisation laboratories (cath-labs). The establishment of the 12 lead electrocardiography (ECG) telemedicine and PHT programmes in this population has been described previously.¹³

The aim of this study was to describe the effects of implementing of a PPCI service and compare the distribution of reperfusion therapies 12 months preintroduction and post-introduction of PPCI.

Data items were defined/collected as follows.

General

Time of diagnosis was taken from the time of the first diagnostic ECG whether this was performed in the prehospital or in-hospital setting. This is supported by the position statement of the European Society of Cardiology which emphasises the importance of the exact time of STEMI diagnosis being established by the ECG, whether it is in the prehospital setting, Emergency Department (ED) or CCU.¹⁴ Prehospital ECG recordings taken by EMS paramedics were transmitted to the ECG receiving station based in the CCU. Criteria for the electrocardiographic diagnosis of STEMI were identical to those in many of the reperfusion studies^{15 16}: >0.1 mV of ST segment elevation in >2 limb leads, or >0.2 mV in >2 precordial leads. Legislation in the United Kingdom (UK) allows EMS paramedics to autonomously administer treatment to patients suffering

acute coronary syndromes including oxygen, aspirin, glyceryl trinitrate, morphine, clopidogrel and tenecteplase within nationally agreed inclusion/exclusion criteria.¹⁷ Where the first EMS ECG did not meet electrocardiographic criteria for STEMI, the acquisition of further ECG recordings were symptom-driven (worsening or return of chest discomfort). Where the first in-hospital ECG did not meet criteria for STEMI, local policy was to repeat the ECG within 60 min. Total number of STEMIs was defined as the number of patients with a discharge summary coded for STEMI, regardless of disposal (discharge, transfer or in-hospital death). Self-presentation was defined as patients who arrived at hospital by means other than an ambulance. Variables of interest from ambulance report forms, medical records, the cath-lab database and discharge summaries were entered in to a Microsoft Access database by a research nurse.

Exclusion criteria

Exclusion criteria for year 2 were: initial 12 lead ECG not diagnostic of STEMI, out-of-hospital cardiac arrest and patients to whom no reperfusion treatment was administered. The same exclusion criteria applied in year 1, with the addition of patients who received PPCI due to contra-indications to thrombolysis.

PPCI definitions and service

PPCI was defined as PCI performed on a patient with no exclusion criteria, who presented with an initial ECG showing diagnostic ST-segment elevation. Rescue PCI was defined as PCI performed due to inadequate resolution of ST-segment elevation following the administration of thrombolytic therapy, as assessed by 12 lead ECG recording 60 min following the administration of PHT/IHT. During office hours (Monday–Friday, 08:00–18:00) patients were taken directly to the cath-lab for PPCI if the CCU nurse identified the ECG as suggestive of STEMI and the paramedic confirmed that it would be possible to be at the cath-lab within 60 min of the diagnostic ECG. At other times, patients were taken by EMS to the ED to wait while the on-call cath-lab team were en-route to hospital. For patients with a STEMI ECG who could not arrive at the cath-lab within 60 min of diagnosis, the CCU nurse advised the paramedic to consider PHT and transport the patient to the nearest hospital. Patients self-presenting to one of the non-cath-lab hospitals were treated with IHT and with subsequent transfer to the cath-lab hospital for rescue PCI if necessary. Degree of flow down the infarct-related coronary artery was measured using the thrombolysis in myocardial infarction trial (TIMI) scoring system. The TIMI-flow grading system classifies successful reperfusion as either grade II (partial) or grade III (complete) flow.¹⁸ Vessels with TIMI grade 0 or grade I flow are considered functionally occluded. TIMI grade II and grade III flows have been shown to result in superior clinical outcome following myocardial infarction.¹⁹

Outcome measures

Outcome measures: were defined prior to commencement of data collection. Readmission to hospital was defined as all-cause readmission to any of the three acute receiving hospitals within 12 months of STEMI admission. Mortality was recorded during index admission, within 30 days of admission and within 12 months of admission using records of deaths held by the General Register Office for Scotland. The time of EMS call was taken from the electronic EMS record accompanying the patient. EMS response time was calculated from the difference between the time of EMS call and the time of EMS scene arrival. EMS scene time was calculated by from the difference between the time of EMS scene arrival and the time of EMS scene departure.

Likewise, EMS drive time was calculated from the difference between time of EMS scene departure and the time of EMS arrival at hospital. Time of reperfusion treatment was recorded at the point where either intravenous injection of a thrombolytic drug or intra-coronary inflation of an angioplasty balloon took place.

Reperfusion assessment was defined as the time at which the clinician/team made an effort to assess the effect of the reperfusion treatment administered; either a 12 lead ECG 60 min after administration of PHT/IHT, or contrast dye injection immediately following first inflation of the angioplasty balloon. PPCI-related delay was calculated by subtracting the TIT for PHT from the TIT for PPCI.

Data analysis

The study was designed as an observational analysis of contemporary reperfusion of STEMI. It was not a trial designed to assess the effect of an intervention. Time-to-treatment is studied for the differing reperfusion therapies both as individual components and as TIT. Results are presented as number (n) and proportions of outcomes (%), ages as mean (SD) and times as medians (ranges).

Due to the nature of the study (an observational analysis of a change in service provision) formal ethics committee review was not sought. Patient data was encrypted, password protected, stored anonymously and complied with internal and external data protection procedures.

RESULTS

A total of 854 people had a coded discharge diagnosis of STEMI during the 24 months of data collection, giving a STEMI rate of 527 per-million-population-per-annum. Summary patient and presentation characteristics are given by treatment received in table 1. A total of 229 (27%) patients met exclusion criteria and were excluded from analysis, leaving a study group of 625 patients. The reasons for non-administration of reperfusion treatment included late or atypical clinical presentation, borderline 12 lead ECG changes and misdiagnosis.

The proportion of patients not receiving reperfusion treatment (18%) is in line with international reports of 29% of STEMI patients leaving hospital having not received acute reperfusion therapy.²⁰

Median length of hospital stay was shorter in PPCI patients (3.9 days) than in patients receiving either PHT (6.7 days) or

IHT (5.9 days) (table 2). During year 2 28% (n=69) of patients who received PPCI were admitted directly to the cath-lab, with similar proportions of patients receiving both PPCI and IHT being admitted to the ED (70% vs 76%). A total of 552 patients (88%) presented via EMS, with 93% of PPCI patients (n=231) presenting in this way.

Of the 73 patients (12%) who self-presented to hospital, 17 (23%) received PPCI and 56 (77%) received IHT, the majority of the IHT being administered in the non cath-lab hospitals. Of the 552 patients (88%) who presented to hospital by EMS, 231 (42%) received PPCI, 101 received PHT (18%) and 220 received IHT (40%). Patients who ultimately received IHT appeared to take longer to call for help (79 min) than those receiving PHT (49 min) or PPCI (54 min). In all 552 EMS patients, 283 (51%) called for help within 60 min of symptom onset. EMS scene time appeared to be shorter in patients receiving PPCI (29 min) when compared to those receiving PHT (41 min).

Call-to-reperfusion treatment times were shortest in patients receiving PHT who received reperfusion treatment within 43 min of calling EMS, compared with 87 min for IHT and 112 min for PPCI. Median EMS ECG-to-reperfusion treatment time was 84 min in patients receiving PPCI, with 60% (n=139) receiving PPCI within 90 min of the EMS ECG (table 3). Median hospital door-to-PPCI balloon time was 54 min in PPCI patients, compared with a hospital door-to-thrombolysis time of 31 min in patients receiving IHT.

Prehospital cardiac arrest occurred in the ambulance among 9 of the 231 EMS PPCI patients (3.9%). All nine survived to hospital discharge and 30-day follow-up, with eight surviving to 12-month follow-up. The on-call team were called for PPCI on three occasions when the patient did not undergo PPCI. All three of these patients had widespread coronary disease with no occlusive thrombus. None had normal coronary arteries.

TIMI II/III flow was present in 40% (n=119) of all PPCI patients during the first injection of contrast medium in the cath-lab. TIMI III flow was present in 88% (n=218) of patients immediately post-PPCI. Four cases had TIMI 0–I flow post-procedure, three had persistent thrombus and one had an acute dissection which could not be recanalised.

Figure 1 displays timelines generated from detailed mapping of all data for patients presenting via EMS over the 24 months studied (n=552). Median PPCI-related delay was calculated as 7 min against PHT and 0 min against IHT. Both PHT (152 min)

Table 1 Total STEMI, total patients excluded/included in analysis, and reperfusion treatment Dec 05 to Dec 07

	Year 1 (Dec 05 to Nov 06)	Year 2 (Dec 06 to Nov 07)	Total (Dec 05 to Nov 07)
Discharge diagnosis of STEMI	438	416	854
Excluded from analysis:	110 (25%)	119 (29%)	229 (27%)
'Normal' ECG on presentation	11 (2%)	20 (5%)	31 (4%)
Out-of-hospital-cardiac arrest	9 (2%)	13 (3%)	22 (3%)
No reperfusion treatment given	69 (16%)	86 (21%)	155 (18%)
Year 1 PPCI	21 (5%)	NA	21 (2%)
Included in analysis	328 (75%)	297 (71%)	625 (73%)
Reperfusion treatment			
Thrombolysis	328/328 (100%)	49/297 (16%)	377/625 (60%)
Prehospital thrombolysis	96/328 (29%)	5/297 (1%)	101/625 (16%)
In-hospital thrombolysis	232/328 (71%)	44/297 (15%)	276/625 (44%)
Primary PCI	NA	248/297 (84%)	248/625 (40%)

STEMI, ST elevation myocardial infarction; PCI, percutaneous coronary intervention.

Table 2 Baseline characteristics, length of hospital stay, hospital readmission, death, cardiac catheterisation and mode of presentation

	Total (n=625)	Primary PCI (n=248)	Thrombolysis (n=377)	
			PHT (n=101)	IHT (n=276)
Male sex n (%)	452 (72%)	184 (74%)	70 (70%)	198 (72%)
Mean age (+SD)	61 (+13)	63 (+12)	61 (+13)	63 (+13)
<60 years n (%)	280 (45%)	118 (48%)	45 (45%)	117 (42%)
Anterior infarction	174 (28%)	64 (26%)	28 (28%)	82 (30%)
Time from symptom onset to hospital arrival:				
< 2 h n (%)	276 (44%)	117 (47%)	38 (38%)	121 (44%)
< 6 h n (%)	539 (86%)	213 (86%)	91 (91%)	235 (85%)
Length of stay (days)				
Median	4.9	3.9	6.7	5.9
Range	0–65	0–47	0–65	0–42
Episodes of all-cause readmission within 12 months of STEMI n (%)	286 (46%)	114 (46%)	40 (40%)	132 (48%)
Cumulative mortality n (%)				
Inpatient	45 (7.2%)	9 (3.7%)	5 (5%)	31 (11.2%)
Within 30 days of admission	54 (8.6%)	14 (5.6%)	5 (5%)	35 (12.7%)
Within 12 months of admission	75 (12%)	19 (7.8%)	7 (7%)	49 (17.7%)
Cardiac catheterisation n (%):				
Primary PCI	248 (40%)	248 (100%)	NA	NA
Rescue PCI	84 (13%)	NA	27 (27%)	57 (21%)
During STEMI admission (excluding rescue and primary PCI)	100 (16%)	NA	32 (32%)	68 (25%)
Area of hospital admission:				
Emergency department	391 (63%)	173 (70%)	9 (9%)	209 (76%)
Coronary care unit	165 (26%)	6 (2%)	92 (91%)	67 (24%)
Cardiac catheterisation laboratory	69 (11%)	69 (28%)	0 (0%)	0 (0%)
Proportion presenting during 'office hours' (0800 to 1800, Monday–Friday)	269 (43%)	119 (48%)	41 (41%)	109 (39%)
EMS presentation	552 (88%)	231 (93%)	101 (100%)	220 (80%)

EMS, Emergency Medical Services; PCI, percutaneous coronary intervention; IHT, in-hospital thrombolysis; PHT, prehospital thrombolysis; STEMI, ST elevation myocardial infarction

and PPCI (166 min) had shorter time between symptom onset and reperfusion assessment than IHT (226 min).

DISCUSSION

A significant majority of STEMI patients in this population-based study presented via EMS. This is higher than in previous reports from our centre¹³ and from others in North America²¹ and Sweden.²² The finding that very few patients during year 2 of the programme received PHT (n=5) reflects the fact that NHS Lothian is largely an urban area with 74% of the population living within a 30-min drive time of the cath-lab and the remaining population being within easy reach of motorways or dual-carriageway roads.

The median door-to-balloon time of 54 min reported in this study remains favourable when compared with data from elsewhere. Median door-to-balloon times of 88–94 min in 241 hospitals in the USA,⁸ 70–93 min in 190 hospitals in continental Europe,¹ and 74 min in England¹¹ have been reported.

Nevertheless with evidence of mortality rates increasing as both door-to-balloon and symptom-onset-to-balloon times increase,²³ we have endeavoured to continually improve our programme and its performance. Figure 2 shows temporal trends in door and diagnostic ECG-to-balloon times, and proportions of patients receiving reperfusion treatment and being admitted

directly to the cath-lab over the 3 years of the programme to date, all of which have moved in a favourable direction.

Although purely observational the similarities in inpatient, 30 day and 12 month mortality between patients receiving PPCI and PHT are largely in line with European registry data. In the French USIC Registry (2000), the combination of PHT with a large proportion of patients undergoing PCI on index admission yielded favourable results²⁴: in-hospital mortality was 3.3% with PHT, 6.7% with PPCI, 8.0% with IHT and 12.2% in non-reperfused patients. The more recent French nationwide registry (FAST-MI) reported comparable mortality results in patients treated with either thrombolysis or PPCI.²⁵

The Swedish RIKS-HIA Registry showed similar mortality data for ambulance-administered PHT and PPCI,²⁶ while a further analysis confirmed superior results of PHT in comparison with IHT, but showed that patients who received PPCI had the lowest rates of mortality and reinfarction and the shortest in-hospital stay.²⁷

We believe prehospital decision-making to be key in facilitating (1) preparation of the cath-lab and alerting of the team while the patient is en-route to hospital during office-hours, (2) activation and simultaneous transport of the patient/on-call cath-lab team during out-of-hours, (3) bypassing of the ED (during office hours) which has been shown by other investigators to reduce treatment delay and improve outcome.²⁸ There may however be undesirable

Table 3 Timelines in patients presenting to hospital by EMS only

	Primary PCI (n=231)		Thrombolysis (n=321)			
Symptom onset-to-EMS call (mins)			PHT (n=101)		IHT (n=220)	
	Median	54	Median	49	Median	79
	Range	4–610	Range	7–505	Range	10–610
	<60 min	127 (55%)	<60 min	57 (57%)	<60 min	99 (45%)
EMS scene time (mins)			PHT (n=101)		IHT (n=220)	
	Median	29	Median	41	Median	25
	Range	8–60	Range	7–67	Range	2–66
	<30 min	132 (57%)	<30 min	40 (40%)	<30 min	145 (66%)
EMS drive time (mins)			PHT (n=101)		IHT (n=220)	
	Median	19	Median	29	Median	15
	Range	4–64	Range	4–54	Range	2–43
	<30 min	166 (72%)	<30 min	53 (53%)	<30 min	172 (78%)
EMS call-to-Rx (mins)			PHT (n=101)		IHT (n=220)	
	Median	112	Median	43	Median	87
	Range	59–395	Range	12–71	Range	39–168
	<120 min	176 (76%)	<60 min	84 (84%)	<60 min	
EMS ECG-to-Rx (mins)			PHT (n=101)		IHT (n=220)	
	Median	84	Median	34	Median	67
	Range	38–196	Range	7–59	Range	39–168
	<90 min	139 (60%)*	<90 min	101 (100%)	<90 min	37 (17%)
Hospital door-to-Rx (mins)			PHT (n=101)		IHT (n=220)	
	Median	54	Median	NA	Median	31
	Range	12–255	Range	NA	Range	7–69
	<60 min	164 (71%)	<60 min	NA	<60 min	205 (93%)
Symptom onset-to-Rx (mins)			PHT (n=101)		IHT (n=220)	
	Median	166	Median	92	Median	166
	Range	64–886	Range	49–634	Range	50–796
	<180 min	120 (52%)	<180 min	83 (83%)	<180 min	128 (58%)

*EMS-to-PPCI balloon inflation within 90-minutes achieved during office-hours (Monday-to-Friday 0800 to 1800), in 84% of cases and out-of-office-hours in 44% of cases. EMS, Emergency Medical Services; PCI, percutaneous coronary intervention; IHT, in-hospital thrombolysis; PHT, prehospital thrombolysis; Rx, treatment.

consequences in reducing the numbers of people with STEMI initially managed in the ED, with evidence from other specialities that decreased ED exposure to acute conditions (eg trauma) can result in a poorer standard of ED care.²⁹

Planners of ambulance services can be reassured that the median on-scene time for crews dealing with PPCI was 12 min less than those dealing with PHT (41 vs 29 min). This will partly compensate for the extra time that may be needed to avoid a nearby non cath-lab hospital and drive to a more distant hospital with a cath-lab for some patients. There may however still be local ambulance services that need to be convinced of the benefits of delivering patients to a hospital where definitive STEMI care can be provided, rather than the geographically nearest hospital. We found that a disproportionate number of patients who received IHT resided in the catchment area of a non cath-lab hospital. It appears that these patients may have been delivered to the local hospital and received IHT despite being within the potential timeline for PPCI.

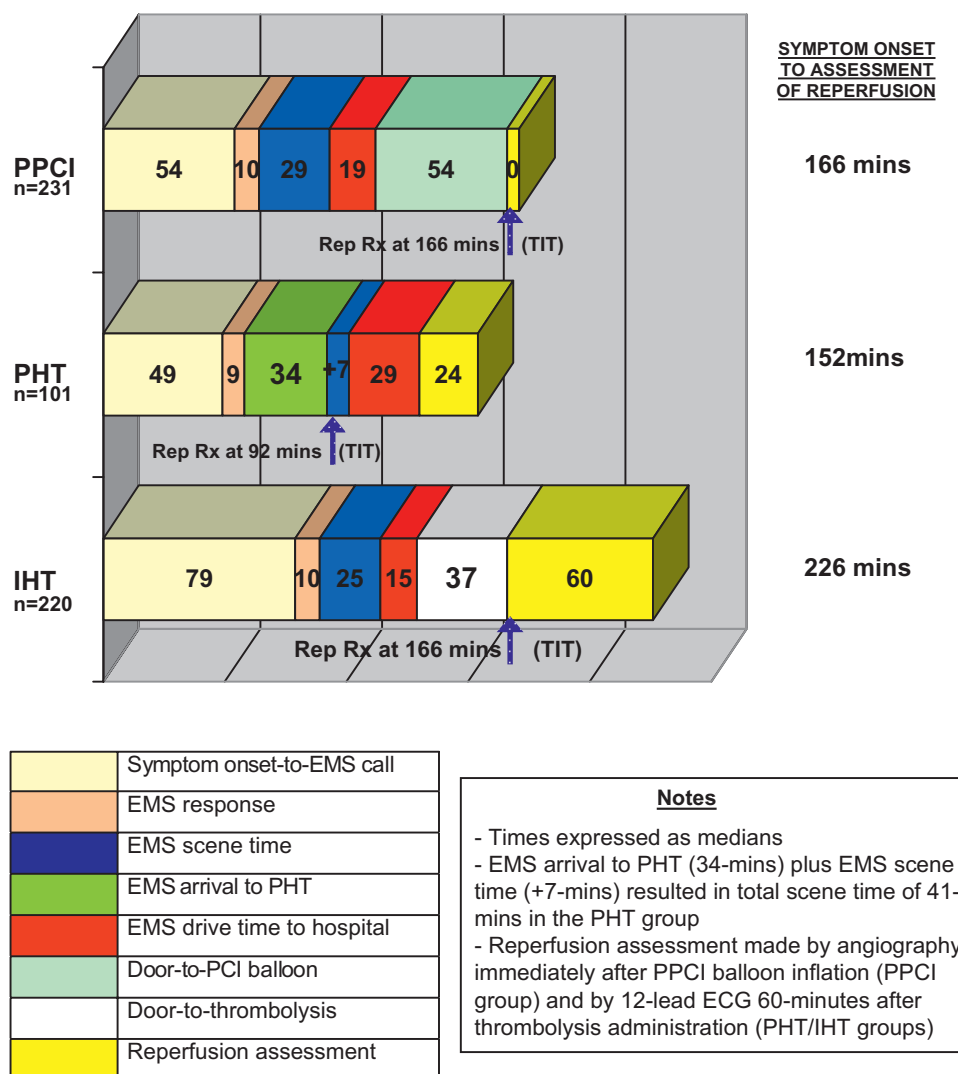
The finding that 40% of PPCI patients arrive at the cath-lab table with TIMI II/III flow is of interest, particularly in terms of adjunctive treatment in the prehospital management of STEMI. Ambulance services across the UK have recently introduced prehospital administration of Clopidogrel. Prehospital glycoprotein IIb/IIIa inhibitor treatment has been administered in some European ambulance services for several years, with recent

evidence supporting the benefits of their administration in the prehospital setting.³⁰ This may be a factor worth considering when planning PPCI services for the future, particularly if acceptable PPCI-related delay is extended and acceptable travel times becomes longer. The time-based nature of this treatment may support an argument for prehospital administration aimed at inhibition of the final pathway of platelet aggregation. This is an area worthy of further research and plans are being developed to test this concept in our centre.

The finding of a PPCI-related delay of 74 min (figure 1) is important. Experienced Danish investigators have highlighted the need for careful mapping of individual components of the patient journey in order to calculate PPCI-related delay and design the most appropriate programme of care based on geographical location and resources.³¹ They cite studies advocating maximum PPCI-related delays ranging from 60 to 171 min, reassuring us that a median delay of 74 min is within accepted limits. Furthermore while TIT is 74 min shorter in PHT patients than in PPCI patients (the PPCI-related-delay), the time from symptom onset to reperfusion assessment was only 14 min between the two groups. Patients receiving PHT spend a median of 7 min (from PHT-to-EMS scene departure) + 29 min (travel time to hospital) + 24 min (delay while waiting to perform a 12-lead ECG 60 min post-thrombolysis) between reperfusion and assessment of its efficacy, with thrombolysis failing to

Original article

Figure 1 Total ischaemic timelines for patients presenting to hospital by EMS (time from symptom onset to delivery and assessment of reperfusion therapy). (Abbreviations: EMS, emergency medical services; PPCI, primary percutaneous coronary intervention; IHT, in-hospital thrombolysis; PHT, prehospital thrombolysis; Rep, reperfusion; Rx, treatment; ORP, optimal reperfusion programme; TIT, total-ischaemic-time).



reperfuse the artery approximately 30% of the time. In PPCI however, balloon inflation is followed by an almost immediate contrast injection to assess TIMI flow, and therefore immediate assessment of treatment outcome.

Study limitations

This study reports a single-centre experience of an ORP. We suggest that, although other regions of the UK may have differing in-hospital logistics and EMS provision, the principles of our programme could apply in any setting. The patients were not randomised and this study reports real-life experience of an ORP through application of contemporary STEMI guidelines. This was not an attempt to replicate the multiple published studies, enrolling many thousands of patients, which have compared the differing treatment modalities of PHT, IHT and PPCI. We also acknowledge that we acknowledge that our pragmatic assessment of TIT and reperfusion assessment uses proxy measures of points in time throughout the patient journey, rather than scientific measurements of arterial recanalisation.

Ongoing developments

Patient pathways have been redesigned since year 1 of the ORP (year 2 of the study). Rather than be kept in the hospital nearest to the scene of their STEMI, patients receiving PHT anywhere in the region, or patients receiving IHT in one of the non cath-lab

hospitals are routinely transferred to the heart attack centre for either rescue PCI (in the event of inadequate resolution of ST-segment elevation), or inpatient PCI during their STEMI admission. This is line with national¹² and international guidance.⁴

Furthermore we have continually improved our programme and its performance in terms of door and diagnostic ECG-to-

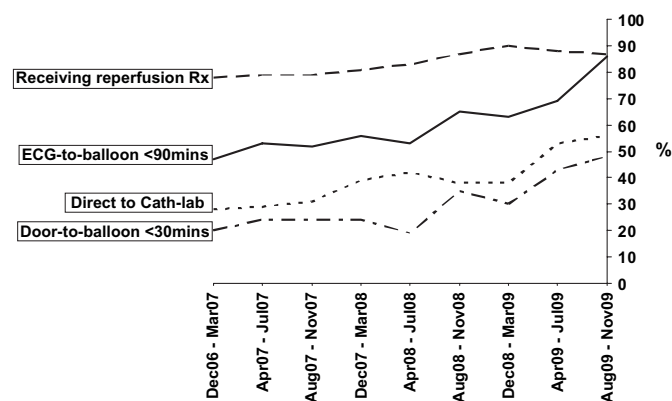


Figure 2 Temporal trends in direct admission to cath-lab, ECG-to-balloon and door-to-balloon times from Dec 2006 to Nov 2009. (Abbreviations: ECG, electrocardiogram).

balloon time, and proportions of patients receiving reperfusion treatment and being admitted directly to the cath-lab. This comes as a result of the small-scale process redesign suggested by other centres over the 3 years of the programme to date,^{32–34} and the benefits of these changes are made clear in figure 2.

CONCLUSION

Based on telemetric transmission of a prehospital 12-lead ECG and telephone conversation between ambulance paramedic and CCU nurse, it is possible to offer PPCI for the majority of patients with STEMI although it is challenging to meet current targets regarding time to treatment. This study, like others in the literature, demonstrated that more than two-thirds of the total-ischaemic-time in STEMI occurs before the patient reaches hospital, with less than one-third being accounted for by door-to-needle (IHT) or door-to-balloon (PPCI) time. We have also demonstrated that the difference in the time between symptom onset-and-assessment of reperfusion treatment efficacy is much shorter than total-ischaemic-time between PHT and PPCI patients, and should be considered, particularly in patients treated with thrombolysis in hospitals without cath-lab facilities. As reperfusion programmes evolve and measures are put in place to address system inefficiencies, it appears that door and diagnostic ECG-to-balloon time, and proportions of patients receiving reperfusion treatment and being admitted directly to the cath-lab improve. Optimal reperfusion treatment including PHT, IHT and PPCI, as recommended in international guidelines, is feasible in the UK, and allows evidence-based reperfusion treatment to be available for all patients with STEMI.

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Competing interests None.

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Use of the GRACE score by cardiology nurse specialists in the emergency department

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Chest pain suspected to be cardiac in origin is responsible for 6% of all emergency department (ED) attendances in the United Kingdom (Goodacre et al, 2005). It is the most common reason for 999 calls to ambulance services (Laird et al, 2004) and results in more than 149 000 admissions to hospital in Britain a year (Stewart et al, 2003).

Differentiating patients with acute coronary syndrome (ACS) from patients with chest pain not due to plaque rupture within a coronary artery is a major diagnostic challenge (Carruthers et al, 2005). There is an important paradox in that while Deakin et al (2006) reported only 0.6% of 999 calls to ambulance services resulting in an in-hospital diagnosis of ACS, Collinson et al (2000) stated that an estimated 6% of ED patients assessed solely on clinical and electrocardiographic findings, and as such discharged from hospital, could have experienced significant myocardial injury.

The GRACE (Global Registry for Acute Coronary Events) risk prediction tool provides a method of calculating the risk of in-hospital death, 6-month death and myocardial infarction (MI) (Fox et al, 2006). The tool is designed to reflect a broad population of patients with ACS and has enrolled 102 341 patients in 247 hospitals over 30 countries (Center for Outcomes Research, 2009). Portuguese investigators reported that the GRACE score was superior to both the TIMI (Thrombolysis In Myocardial Infarction) (Antman et al, 2000) and PURSUIT (Platelet glycoprotein IIb/IIIa in Unstable agina: Receptor Suppression Using Integrilin) (Boersma et al, 2000) scores in predicting the risk of death or MI at 1 year following hospital admission (de Araújo Gonçalves et al, 2005). Investigators in the authors' own institution have reported that the GRACE score stratifies risk in patients presenting to the ED with undifferentiated chest pain accurately (Lyon et al, 2007). There are however no reports in the literature of nurses assessing risk of death/MI by prospectively applying these risk scores.

Investigators have highlighted that risk scores such as TIMI, PURSUIT and GRACE are available to help nurses as they triage patients with chest pain in designated chest

pain units (Siebens et al, 2007). They cite evidence of patients with chest pain being safely triaged by nurses (Smith, 2000), while Quinn et al (2000) concluded that CCU nurses were more likely to identify suitability for transfer to a general ward, as compared with a physician-devised algorithm, in patients with chest pain.

Aims

The aim of this article is to determine whether systematic application of the GRACE risk-score by cardiology nurse specialists predicts long-term outcome among unselected

ABSTRACT

Suspected cardiac chest pain is responsible for a significant number of emergency department attendances and 999 calls to ambulance services in the UK. Differentiating patients with acute coronary syndrome (ACS) is a major diagnostic challenge. The GRACE risk prediction tool provides a validated method of calculating the risk of in-hospital death, 6-month death and myocardial infarction. This study aimed to determine whether systematic application of the GRACE risk-score by cardiology nurse specialists predicts long-term outcome in unselected patients with chest pain. Seven-thousand patients had a GRACE score recorded between September 2005 and April 2008. A random sample of 504 patients was extracted and their outcomes analysed. Incidence of death by April 2009 was recorded, with a follow-up period ranging from 31 to 44 months. Median length of hospital stay, confirmation of ACS and cardiac catheterization on index admission were recorded. There were significant differences in confirmation of ACS, length of hospital stay, inpatient cardiac catheterization and death at follow-up, over low, moderate and high-risk GRACE scores, with patients in the high-risk group suffering the worst outcomes. This study demonstrates the feasibility and the potential additional utility of objective risk scoring in a busy and challenging clinical environment.

KEY WORDS

- ◆ Chest pain
- ◆ Risk-stratification
- ◆ Acute coronary syndrome
- ◆ GRACE score

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Conflict of interest: None declared*

patients with chest pain. The setting for the study was the ED of a major teaching hospital with attendance over 100 000 patients per year. The chest pain service at this institution has been described previously (McLean, 2006).

Design

The GRACE risk score was systematically and prospectively applied to all patients with undifferentiated chest pain in the ED assessed by the chest pain nurses (CPNs) between September 2005 and April 2008. Clinical staff remained blinded to the risk score. A random sample of 504 of the first 7000 patients was analysed retrospectively to determine the relationship between risk score and outcomes.

The local ethical committee was consulted and ethical approval for this study was waived as it was a retrospective audit of data obtained in routine clinical practice.

Methods

As a routine part of their clinical work, the four CPNs recorded GRACE scores on patients presenting to the ED with undifferentiated chest pain. Scores were calculated on a handheld PDA device and entered into the weekly spreadsheet collected by the CPNs. The variables that make up the GRACE score are displayed in *Figure 1*.

All the information required for the GRACE score was readily available for all patients. Assessment of Killip class is a routine part of the CPN role. In the ED setting, creati-

nine blood level results are available within one hour for almost all patients, and there was no delay to treatment.

A total population of 7000 patients had a GRACE score recorded by the CPN in the 32 months between September 2005 and April 2008. A random sample of 504 patients (7% of the overall population) was extracted using a random number generator (<http://www.random.org>) and their outcomes analysed.

Details of the 504 patients were cross-referenced with records of deaths held by the General Register Office for Scotland. Incidence of death from all causes by April 2009 was recorded, resulting in a follow-up period ranging from 31 to 44 months. Median length of hospital stay and cardiac catheterization on index admission were recorded from electronic hospital records. From the 504 patients 181 were classified by the GRACE score as low-risk (0–15% likelihood of death), 166 as moderate-risk (16–30% likelihood of death), and 157 as high-risk (>30% likelihood of death).

Statistical analysis

Kaplan-Meier analysis of survival (*Figure 2*) and association between death and confirmation of ACS (*Figure 3*) were performed, with significance calculated by use of the log-rank test. Chi-square tests were used to calculate significance of associations between GRACE score and cardiac catheterization, and GRACE score and ACS. The

Figure 1. The GRACE score calculator. HR = heart rate; SBP = systolic blood pressure; Creat = serum creatinine levels; CHF = congestive heart failure

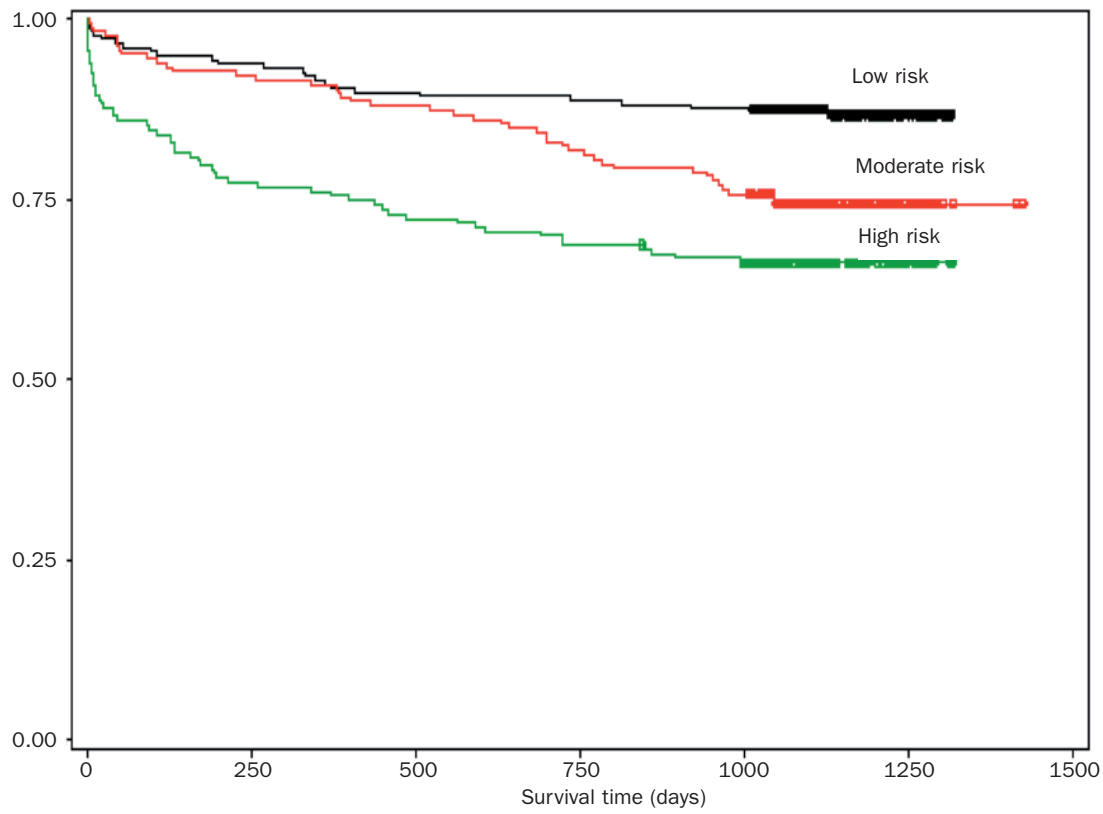
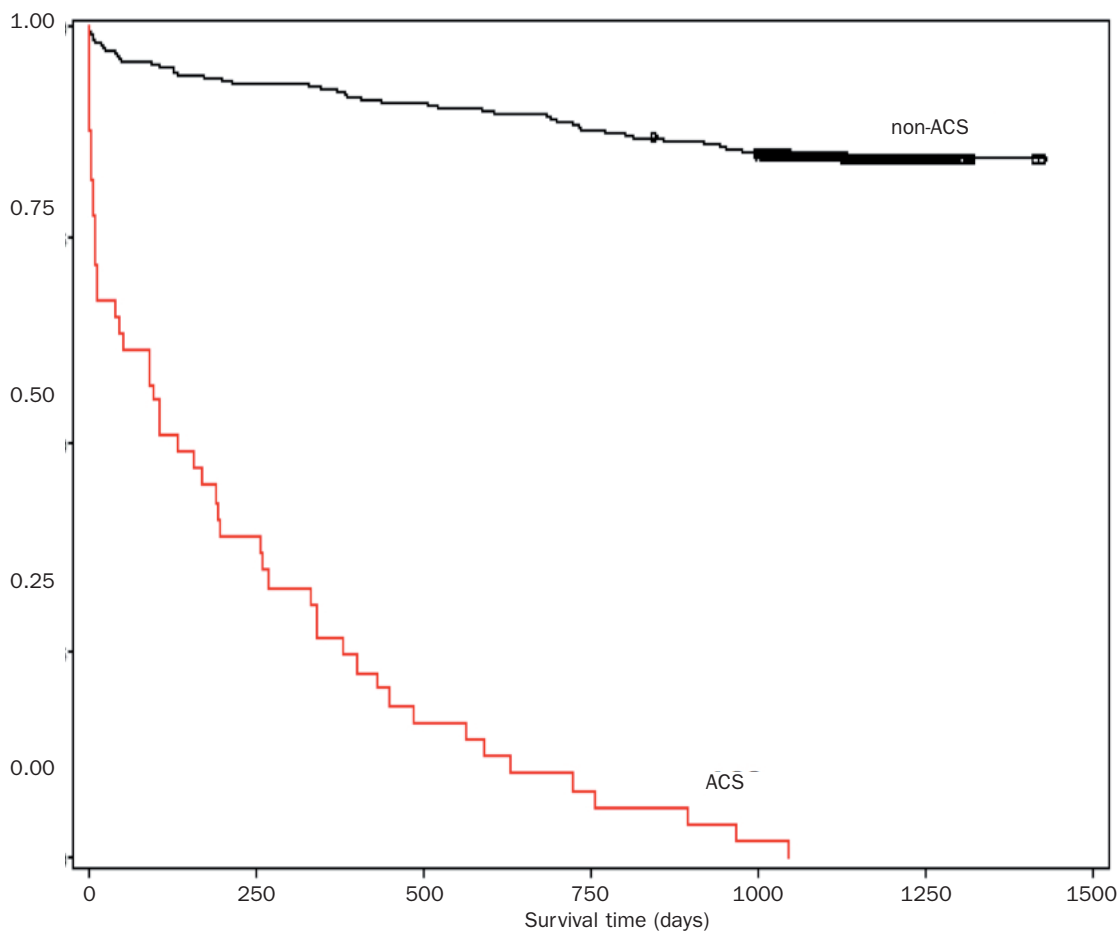


Figure 2: Kaplan-Meier analysis of survival to follow-up

Figure 3: Kaplan-Meier analysis of association between death and confirmation of acute coronary syndrome (ACS)



Kruskall-Wallis test was used for significance between GRACE score and length of hospital stay.

Results

For the 504 patients the median time between index admission and follow-up was 38 months. The duration of follow-up was determined by the time interval between presentation and the date of the study. 21% of patients ($n=105$) had a follow-up duration of 31–36 months and for 79% follow-up was 37–44 months. Survival status was checked against the national death registry. By April 2009 the overall number of deaths was 120/504 (24%) with a median time from admission to death of 219 days. These were deaths from all causes—it was not possible to track different causes of death and therefore single out cardiac deaths alone through the registry. There was a cumulative death rate of 14% within 12 months of admission, 19% within 24 months, and 24% within 36 months and 44 months of index admission.

Kaplan-Meier analysis demonstrated a difference between the survival of patients over the three GRACE score strata ($P<0.0001$).

There was an incremental rise in the likelihood of death over low ($n=23$, 13%), moderate ($n=42$, 25%) and high ($n=55$, 35%) risk groups. ACS was confirmed on index admission in 22% ($n=5$) of low-risk patients who were dead at follow-up, 33% ($n=14$) of moderate-risk and 54% ($n=30$) of high-risk patients. Survival to follow-up was significantly less in patients with confirmed ACS ($P<0.0001$) (Table 1).

Median length of stay for all patients during the index hospitalization was 4.2 days. Again there was an incremental rise in median length of stay over low (2.3 days), moderate (3.4 days) and high (6.5 days) risk groups ($P<0.0001$).

Cardiac catheterization was performed on index admission on 132/504 patients (26%). The procedure was per-

formed in 2% of low-risk ($n=4$), 21% of moderate-risk ($n=35$) and 59% of high-risk patients ($n=93$) ($P<0.0001$).

Discussion

The study first demonstrates the feasibility of systematically determining the GRACE risk score during the assessment of patients presenting to the ED with undifferentiated chest pain. The additional time required to determine the GRACE score using a handheld PDA device was approximately 30 seconds.

From this random sample of 504 patients the results demonstrate that the GRACE risk score calculated by the CPN in the ED powerfully predicts outcome in terms of deaths during follow-up and length of hospital stay and likelihood of cardiac catheterization during the index admission.

Although the sample size of 504 represents only 7% of the total number of patients for whom a GRACE score was calculated to April 2008, it was determined to be sufficient for the statistical analysis undertaken.

Siebens et al (2007) stated that nurses assessing patients with chest pain can play an important role in the diagnostic process by making it more efficient and cost-effective. They also stated that nurses in these roles are in a unique position to apply evidence-based practice published in guidelines and practice standards.

Treatment guidelines for nurse practitioners in the United States (Albert, 2007) suggest clinical assessment from the patient history (Braunwald et al, 2002), risk-scoring by using TIMI (Antman et al, 2000), or risk-scoring by using PURSUIT (Boersma et al, 2000). This study demonstrates that nurse practitioners in one centre in the UK can effectively use the GRACE score (Center for Outcomes Research, 2009) to accurately predict outcome, and in turn practice to a standard recommended in national (Scottish Intercollegiate Guidelines Network, 2007) and European guidelines (Bassand et al, 2007).

While other investigators have established that CPNs

Table 1.
Length of hospital stay, cardiac catheterization and confirmed ACS stratified by low/moderate/high risk GRACE score

	Low risk	Moderate risk	High risk	Total	P
Median length of hospital stay (days) (Inter-quartile range)	2.3 (1.7–3.9)	3.4 (2.1–5.4)	6.5 (5–7.9)	4.2	<0.0001
Cardiac catheterization on index admission	4/181 (2%)	35/166 (21%)	93/157 (59%)	132/504 (26%)	<0.0001
ACS confirmed on index admission in patients dead at follow-up	5/23 (22%)	14/42 (33%)	30/55 (54%)	49/120 (41%)	<0.0001

ACS = Acute coronary syndrome

may help address suboptimal care offered to patients presenting with chest pain (Mullan et al, 2007) this study demonstrates the utility of an objective tool in risk-assessing patients with undifferentiated chest pain. This is important given the findings of Hay et al (2001) who observed that nurses tended to over-estimate disease severity in patients presenting with chest pain.

There can be little argument that the clinical assessment of patients presenting to hospital with chest pain has been aided by the addition of troponin testing (Scirica and Morrow, 2004). However, it must be remembered that a negative troponin test is not a complete predictor of risk, and has had its appropriateness questioned in very low-risk subsets (Fox, 2005; Steg et al, 2009). The multifactorial nature of the GRACE score may therefore lend itself to a more complete evaluation in patients with undifferentiated chest pain.

One possible limitation of this study would be if there were variations in scoring between the various CPNs. This was not analysed in this study, but could be an area for future research.

Conclusions

Although this is a single-centre study, the catchment population in South East Scotland provides the full spectrum of patients with chest pain and the results of this study are likely to be applicable in other centres. This study has added to the paucity of work which exists reporting the application of cardiovascular risk scores by nurses in the acute setting. When the CPN risk stratified patients presenting to the ED with undifferentiated chest pain into low, moderate and high-risk strata, using the GRACE score, this predicted incrementally the likelihood of death during follow-up, length of hospital stay and inpatient cardiac catheterization.

The study demonstrates the feasibility of objective risk scoring and the potential additional utility of this information in a busy and challenging clinical environment.

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Figure 1 is reproduced by permission of the Global Registry of Acute Coronary Events. The authors are grateful to Ms Cat Graham who undertook statistical work for this study, and the chest pain nurse team who collected the data

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KEY POINTS

- ◆ Unscheduled presentation to hospital with chest pain places a significant burden on the National Health Service
- ◆ Early differentiation of cardiac versus non-cardiac chest pain is not straightforward
- ◆ Application of the GRACE risk prediction tool by cardiology nurses in the emergency department successfully predicted likelihood of death, length of hospital stay and inpatient cardiac catheterization

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Collaborative decision-making between paramedics and CCU nurses based on 12-lead ECG telemetry expedites the delivery of thrombolysis in ST elevation myocardial infarction

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ABSTRACT

Objectives: To describe a prehospital thrombolysis (PHT) and expedited in-hospital thrombolysis (IHT) programme in south-east Scotland using prehospital 12-lead ECG recordings transmitted by telemetry and autonomous paramedic-administered thrombolysis with decision support being provided by coronary care nurses.

Design: Retrospective observational study.

Setting: Three hospitals in south-east Scotland covering a population of 778 468 served by 54 ambulance vehicles.

Patients: 11 840 patients who telephoned the ambulance service with "chest pain" over 20 months, during which 812 patients were admitted with ST segment elevation myocardial infarction (STEMI).

Main outcome measures: All calls and cardiac/potential cardiac calls to the ambulance service, type/time of patient presentation, symptoms/call/door-to-thrombolysis times.

Results: Of the 11 840 calls to the ambulance service for chest pain over 20 months of the initiative, 60% were cardiac/potentially cardiac-related by Scottish Ambulance Service triage. ST segment elevation was present in 8% of the 5150 12-lead ECGs transmitted by paramedics to the ECG receiving station in the CCU. Over the 20 months, 812 patients were admitted to the three hospitals with STEMI and 71% received thrombolysis. Median symptom-to-thrombolysis times were 91, 148 and 184 min, respectively, in the PHT, telemetry-facilitated IHT and self-presenting IHT groups. Median call-to-needle time for the PHT group was 40 min. In 2/146 cases the cardiologists judged that the patient should not have been administered PHT.

Conclusions: Based on prehospital 12-lead ECG telemetry, it is possible for paramedics and CCU nurses to conduct live reperfusion decision-making in patients with STEMI, with resultant benefits in symptoms-to-thrombolysis time.

Clinical trials in the treatment of acute ST elevation myocardial infarction (STEMI) have consistently demonstrated the benefits of thrombolysis on mortality. These benefits are time-dependent and, in meta-analyses¹ as well as in clinical practice,² are consistently reported to result in significant reductions in left ventricular systolic impairment and mortality through early administration. It has been argued that very early thrombolysis, whether in the first 60 min,³ 70 min⁴ or 120 min¹ following symptom onset, offers the greatest benefit when compared with thrombolysis given more than 2 h after the onset of symptoms.

Various strategies have been designed to reduce delays between diagnosis and administration of treatment with thrombolysis.⁵ These range from GP diagnosis and administration without 12-lead ECG recording⁶ to autonomous paramedic administration following a 12-lead ECG recording in the community.⁷ To reduce in-hospital delay ("door-to-needle" time), early warning or pre-alert of the emergency department (ED) of incoming patients allows different models of thrombolysis to be delivered.⁸ In our own hospital a "fast track" response system was developed to reduce door-to-needle time in the ED.⁹

In 2002–3 the Scottish Ambulance Service (SAS) began moves towards prehospital thrombolysis (PHT). Paramedics were trained to a nationally accepted standard before being allowed to administer thrombolysis. Legislation has been in place since April 2004 approving both tenecteplase and reteplase under medicines provisions for paramedics. At the same time, the SAS became equipped with ECG machines capable of transmitting the 12-lead ECG by mobile telephone technology. We report our experience of working with the SAS in providing decision support from coronary care unit (CCU) nurses, facilitating PHT as well as expedited in-hospital thrombolysis (IHT).

METHODS

Prehospital 12-lead ECG recordings are performed on patients aged over 16 years presenting with non-traumatic chest pain or other symptoms which the paramedic suspects to be cardiac-related and potentially ischaemic (for brevity, the term "paramedic" has been used interchangeably to include either paramedics or ambulance technicians who perform and transmit 12-lead ECGs but are not licensed to administer thrombolysis). The ECG is transmitted to a receiving station in the CCU by mobile telephone technology.

A Lifenet RS 12-lead ECG receiving station (Medtronic Physio-Control, Basingstoke, UK) was installed in The Royal Infirmary of Edinburgh which is the tertiary referral centre for south-east Scotland, with a 10-bed CCU, 2 catheter laboratories, 24 hour/7 day ED and 24 hour/7 day CCU junior grade doctor. The population of 778 468 is served by 3 acute receiving hospitals, 7 ambulance stations, 54 vehicles, 160 paramedics and 200 technicians. In addition to standard equipment, the ambulance thrombolysis pack includes a 10 000 unit vial of tenecteplase and a 5000 unit

vial of heparin sodium. Responsibility for dealing with the 12-lead ECG arriving at the receiving station in the CCU is assigned either to the nurse in charge or a junior grade doctor.

Paramedics are instructed that if they receive no telephone call within 1 min of transmitting the 12-lead ECG, they can assume that the receiving nurse/doctor does not believe the ECG to show changes compatible with STEMI. The ECG receiving station alerts staff via very loud audio and visual alarms and is answered very promptly in every case. As an autonomous practitioner, the paramedic can ultimately choose to administer or not administer tenecteplase regardless of the advice given by the CCU.

Where there is a technical failure to transmit the ECG from the field, paramedics continue with their usual process of care and destination hospital. In the event of ST segment elevation, they are encouraged to telephone the CCU and describe the ECG changes over the telephone, giving PHT where they consider it appropriate. The paramedic is advised to admit the patient directly to the nearest appropriate CCU (with or without PHT) rather than to the ED.

Statistical methods

In order to compare the results between two normally distributed groups, two-sample *t* tests were used. In cases where the distribution did not appear normal (eg, symptom-to-call time), the Mann-Whitney test was used. In cases where the distribution did not appear normal and there were more than two groups (eg, symptoms-to-thrombolysis time and symptoms-to-hospital time), Kruskal-Wallis tests were used.

RESULTS

The initiative was implemented in October 2004. In the 20 months to May 2006 the SAS attended 11 840 calls within the catchment population where "chest pain" was the main presenting complaint. A total of 7060 calls (60%) were thought to be cardiac or potentially cardiac in nature by SAS triage. A 12-lead ECG was transmitted to the ECG receiving station in 5150 cases, 73% of calls with cardiac/potentially cardiac chest pain.

Table 1 shows the distribution of ECG findings. ST segment elevation of ≥ 0.1 mV in leads I–III, aVF, aVL, V4–V6 or ≥ 0.2 mV in leads V1–V3 was present in 412 (8%) of the ECGs. Horizontal or downsloping ST segment depression of ≥ 0.1 mV in two contiguous leads was present in 1030 (20%). Of the 412 ECGs classified as arrhythmias, 358 (87%) showed atrial

fibrillation with ventricular responses between 48 and 178 beats/min.

A total of 6179 patients had a 12-lead ECG recorded, 87% of cardiac/potentially cardiac-related chest pain calls. The 12-lead ECG failed to transmit to the receiving station due to technical problems in 144 cases (2%) and the paramedic did not attempt to transmit it in 885 cases (14%).

During the 20-month study period 812 patients were admitted to the three hospitals with STEMI. Thrombolysis was administered to 575 (71%). Patients presented via the ambulance service in 544 cases (67%), of whom 146 (27%) received PHT, 247 (45%) received IHT and 151 (28%) did not receive thrombolysis (table 2). Twenty patients (2%) with STEMI arrived at hospital within 1 h of the onset of symptoms, 3 were self-presentations and 17 from the SAS. A total of 222 patients presented between 1 and 2 h, 32 (12%) of which were self-presentations and 190 (35%) via the SAS. Fewer patients presented at >6 h via SAS than self-presentations (38 (7%) vs 43 (16%).

Of the patients transported by the SAS who received thrombolysis either before arriving at hospital or through telemetry-facilitated IHT (thrombolysis given in hospital following a pre-alert by 12-lead ECG transmission and direct admission to the CCU, $n = 393$), there were no significant differences in symptoms-to-call time ($p = 0.067$), SAS response time ($p = 0.492$) or time from symptoms-to-hospital arrival ($p = 0.893$). Patients in the PHT group had significantly reduced SAS call-to-thrombolysis times (40 vs 86 min, $p < 0.001$), symptoms-to-thrombolysis times (91 vs 148 min, $p < 0.001$) and proportion of patients given thrombolysis within 60 min of calling the SAS (130 (89%) vs 4 (2%)). The SAS spent more time on-scene (26 vs 22 min, $p < 0.001$) and travelling to hospital (47 vs 42 min, $p = 0.002$) when giving PHT than when transferring for telemetry-facilitated IHT (table 3).

When comparing those receiving IHT, the median door-to-thrombolysis time in patients receiving telemetry-facilitated IHT was 18 min (range 4–48) compared with 30 min (range 6–94) in patients receiving IHT who self-presented to hospital ($p < 0.001$). Median symptoms-to-thrombolysis times were significantly different between the three groups: 91 min (range 28–527) in the PHT group, 148 min (range 62–442) in the group given telemetry-facilitated IHT and 184 min (range 32–517) in the self-presenting group given IHT ($p < 0.001$).

Emergency percutaneous coronary intervention (PCI), either for failure to achieve $\geq 50\%$ ST segment resolution on the 90 min post-thrombolysis ECG or for acute reinfarction within 6 h following initially successful ECG evidence of reperfusion, was performed in 172/812 patients (30%). There were no significant differences between the three groups (32% for PHT, 30% for telemetry-facilitated IHT and 28% for self-presenting IHT).

DISCUSSION

We can find no previous reports of autonomous paramedic-administered thrombolysis with telemedicine decision support provided predominantly by nurses in a CCU. ST segment elevation was present on the ECGs of 3.5% of all calls for chest pain, which corresponds to previous observations.¹⁰ A study of advanced medical priority dispatch (AMPDS) codes used by ambulance services has shown that 5% of all calls with "chest pain" have a hospital diagnosis of acute coronary syndrome.¹¹

The observed rate of failure to transmit a prehospital 12-lead ECG due to technical problems of 2% was not unreasonable and is similar to the findings of previous Scottish investigators.¹²

Table 1 Calls to the ambulance service: distribution of successfully transmitted ECGs

Calls to the ambulance service with presenting complaint of chest pain	11840
Calls thought to be cardiac or potentially cardiac	7060
Presenting ECG successfully transmitted to CCU	5150
"Normal"	2678 (52%)
ST depression/T wave inversion	1030 (20%)
Bundle branch block/ventricular paced rhythm	412 (8%)
Arrhythmia	412 (8%)
ST segment elevation	412 (8%)
Other	206 (4%)
Cardiac/potentially cardiac patients with an ECG not transmitted to CCU	1910
ECG not performed	881
ECG performed, transmission attempted but transmission failure	144
ECG performed but no transmission attempted by paramedic	885
CCU, coronary care unit.	

Table 2 Baseline characteristics, site of thrombolysis and times to hospital arrival (20 months)

	Total STEMI (n = 812)	Self-presentation with STEMI (n = 268)	Ambulance presentation with STEMI (n = 544)
Baseline characteristics			
Male sex	511 (63%)	163 (61%)	348 (64%)
Anterior territory infarction	317 (39%)	110 (41%)	207 (38%)
Age >75 years	253 (31%)	86 (32%)	167 (31%)
Treatment and time to presentation			
Prehospital thrombolysis	146 (18%)	0 (0)	146 (27%)
Inhospital thrombolysis	429 (53%)	182 (68%)	247 (45%)
No thrombolysis	237 (29%)	86 (32%)	151 (28%)
Times from onset of symptoms to arrival at hospital			
0–1 h	20 (2%)	3 (1%)	17 (3%)
>1–2 h	222 (27%)	32 (12%)	190 (35%)
>2–6 h	489 (60%)	190 (71%)	299 (55%)
>6 h	81 (10%)	43 (16%)	38 (7%)

STEMI, ST elevation myocardial infarction.

Patients in this study were much more likely to use ambulance services than North American and Swedish patients,^{10 13 14} and those using the SAS were more likely to arrive at hospital within 0–2 h than self-presenting patients with STEMI. This may be particularly relevant to discussions surrounding optimal reperfusion strategies in patients presenting early after the onset of symptoms, with particular regard to the benefits of primary PCI or thrombolysis within 3 h of the onset of symptoms.¹⁵

Improved time to diagnosis,¹⁶ time to treatment¹⁷ and outcomes¹⁸ have been previously demonstrated by a strategy of prehospital diagnosis. This study shows a twofold increase in median symptoms-to-thrombolysis time from prehospital administration, through telemetry-facilitated in-hospital administration to in-hospital administration in self-presenting patients. MINAP data reported a PHT rate of 10% in England and Wales in 2005.¹⁹ In all cases of STEMI receiving thrombolysis, a prehospital administration rate of 25% in our

study appears reasonable given that up to 20% of patients with STEMI may have a contraindication to thrombolysis²⁰ and 10% presented >6 h after the onset of symptoms (and were thus precluded from PHT under the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines²¹ in place at the time).

Two previous studies^{22 23} have emphasised the constraints placed on PHT by the JRCALC guidance. Hanson and Williamson²³ recommended revision of the guidelines in order that they become more inclusive. It is encouraging that the JRCALC has made moves to extend the time window from 6 h to 12 h from symptom onset.

SAS response times were excellent and on average were better than the national performance indicator of 8 min. Although there was a statistically significant difference, the numerical difference of 4 min spent on-scene between PHT and non-PHT groups may be an encouraging finding for networks planning primary PCI as either part or all of a reperfusion service in STEMI. The extra 4 min spent delivering the intravenous

Table 3 Baseline characteristics, performance indicators (20 months) expressed as medians

	PHT (n = 146)	Telemetry-facilitated IHT (n = 247)	Self-presenting IHT (n = 182)	p Value* (95% CI)
Baseline characteristics				
Male sex	88 (60%)	153 (62%)	115 (63%)	
Anterior territory infarction	63 (43%)	99 (40%)	69 (38%)	
Age >75 years	45 (31%)	79 (32%)	53 (29%)	
Performance indicators				
Symptoms-to-SAS call (min)‡	45 (31–85)	42 (28–75)	NA	0.067 (0.00 to 10.99)
SAS response (min)§	8 (3.2)	8 (2.2)	NA	0.492 (–0.39 to 0.80)
SAS on-scene (min)§	27 (8.6)	23 (6.4)	NA	<0.001 (2.19 to 5.40)
SAS travel time to hospital (min)§	47 (16.5)	41 (16.0)	NA	0.002 (2.01 to 8.70)
SAS call-to-thrombolysis (min)‡	40 (29–51)	86 (72–126)	NA	<0.001 (–54.00 to –45.00)
Call-to-thrombolysis ≤60 min	130 (89%)	4 (2%)	NA	
Hospital door-to-thrombolysis (min)‡	NA	18 (9–25)	30 (21–45)	<0.001 (12.00 to 17.00)
Door-to-thrombolysis ≤30 min	NA	217 (88%)	126 (69%)	
Symptoms-to-thrombolysis (min)¶	91 (66–131)	148 (108–234)	184 (102–349)	<0.001
Symptoms-to-hospital arrival (min)¶	130 (96–232)	131 (96–215)	149 (79–432)	0.893
Emergency PCI within 6 h of thrombolysis	47 (32%)	74 (30%)	51 (28%)	

Data are presented as mean (SD) or median (interquartile range).

IHT, in-hospital thrombolysis; PCI, percutaneous coronary intervention; PHT, prehospital thrombolysis; SAS, Scottish Ambulance Service.

*Telemetry-facilitated IHT vs PHT.

†Self-presenting IHT vs telemetry-facilitated IHT.

‡Mann-Whitney test.

§Two-sample t test.

¶Kruskal-Wallis test.

heparin and thrombolytic agent suggests that, even with PHT, 85% of the ambulance on-scene time is spent reaching the patient, primary and secondary assessment, therapeutic intervention, 12-lead ECG, communication with CCU and decision-making regarding the most appropriate destination for the patient. This may influence those who believe that primary PCI will be a paradigm shift for ambulance services, given that the assessment, diagnosis and treatment processes remain the same, with only the 10 s bolus administration of tenecteplase being omitted.

While the paramedic can ultimately choose to administer or not administer tenecteplase regardless of the advice given by the CCU, this did not happen during the 20-month feedback. Feedback from both paramedics and CCU nurses was that the telephone discussion was mutually beneficial. Paramedics felt supported in the knowledge that they had a live link to experts in the care of STEMI, particularly in the context of cases which were outwith the rigid JRCALC guidance.

There are a number of potential areas for further study. The one-third of patients who continue to receive no thrombolysis regardless of how they present to healthcare services are arguably the most pressing of these. The finding of 29% in this study is similar to findings of the GRACE investigators. Their registry of 16 814 patients with STEMI across 113 hospitals in 14 countries reports that 29% of patients did not receive reperfusion therapy.²⁴

The 25% of patients who either had an ECG performed but not transmitted by the paramedic or who did not have an ECG performed require further investigation. This may simply reflect confidence among paramedics who feel secure in their interpretation of the ECG. With increased pressures on unscheduled/emergency medical services, the 20% of patients who had a prehospital 12-lead ECG showing ST segment depression or T wave inversion (60% of whom had a diagnostic rise in troponin I at 12 h) could perhaps be admitted directly to a cardiology unit for further assessment, thus reducing pressure on the emergency/medical assessment departments.

Although not prospectively measured, the CCU nurse in charge independently received and reported 85–95% of incoming 12-lead ECGs, with 5–15% involving the CCU junior grade doctor. In a study by Quinn *et al*,²⁵ 95% of CCU nurse respondents were found to reach a standard of 12-lead ECG interpretation in patients with ST segment elevation deemed as “gold standard” by a panel of cardiologists. There were six cases during the 20-month study period where there was not a subsequent rise in cardiac enzymes following thrombolysis administration by a paramedic. Four of these were thought by their cardiologist to have clinical myocardial infarction and ECG evidence deserving of PHT and two were thought not to have merited PHT.

The technique of prehospital 12-lead ECG transmission by cellular telephone was first described in 1987.²⁶ Before this, only single-lead rhythm strips could be transmitted to the ED. Previous investigators¹² found that 2% of attempts at prehospital 12-lead ECG telemetry were unsuccessful, identical to the failure-to-transmit rate in our study.

We found that 67% of the patients with STEMI presented to hospital via the SAS. In the 329 122 patients sub-studied in the large US NRMI-2 registry over 4 years in 1674 hospitals, 53% of patients were transported to hospital by ambulance.¹⁰ The non-users of emergency medical services (self-presentation or self-transport) were younger, had less previous history of cardiovascular disease, presented later after the onset of symptoms, were less likely to have anterior wall infarction or sustained

ventricular tachycardia/fibrillation and had a lower killip class, TIMI risk score and hospital mortality (5.5% vs 14.3%). The odds of ambulance use were reported to increase by 21% over each decade of life. Previous North American studies of patients with suspected or confirmed STEMI have reported varying ambulance use of between 33%¹³ and 59%.²⁷ Similar findings were reported in Sweden where the 34% of patients who used emergency medical services were older, had a greater likelihood of previous cardiovascular disease and were more likely to have a final diagnosis of myocardial infarction (69% vs 38% of patients not transported by ambulance).

Herlitz *et al*¹⁴ concluded that, after correcting for confounding factors, patients admitted to Swedish EDs with chest pain who were transported by ambulance had a much higher mortality during the subsequent 5 years than those not transported by ambulance.

Limitations of the study

Long term outcome data are not reported which may have been useful in determining the benefits (or otherwise) of prehospital 12-lead ECGs, particularly where 92% of patients did not have ST segment elevation. Although data are available to suggest the number of patients receiving PHT who perhaps should not have, there are no data reported on patients who could have received PHT but did not. In governance as well as research terms it is unfortunate that we made no prospective documentation of the decision-making discussion between paramedic and hospital nurse/doctor. This is something we will remedy as a result of this study. The statistically significant differences in SAS on-scene time and travel time may have been a type I error caused by the relatively small sample size.

CONCLUSIONS

Using cellular telephone technology, it is possible for paramedics and CCU nurses to conduct live decision-making based on a transmitted prehospital 12-lead ECG in patients with STEMI. This is an important finding and may create opportunities for reconfiguration of STEMI services. Prehospital administration of thrombolysis was associated with significantly reduced symptoms-to-thrombolysis times. Patients received IHT following direct CCU admission as a result of prehospital diagnosis more expeditiously than patients who self-presented to hospital.

A prehospital diagnosis of STEMI and decision-making process involving paramedics and CCU nurses may aid reductions, not only in symptoms-to-thrombolysis time, but also in the development of primary PCI services by reducing diagnosis to balloon time and creating a hybrid system for optimal reperfusion in STEMI.

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An exploration of the information needs of spouse/partner following acute myocardial infarction using focus group methodology

Scott McLean and Fiona Timmins

ABSTRACT

This study aimed to explore spouse/partners' experience of the information received and required in the acute myocardial infarction (AMI) in-hospital recovery period. A dearth of information exists that uncovers the information needs of spouse/partners following AMI. Although information needs, emotional reactions, support and information provision are prevalent themes within the literature, there are few studies that specifically address these issues in this population. While survey methods abound, with more recent qualitative interviews apparent, focus group methodology is underused. The study employed a qualitative descriptive design. Using focus group techniques, 15 partners were interviewed. Emerging themes included: reactions to the event, feeling like a burden on the health service, the need for information and pulling apart – pulling together. Spouse/partners play a critical role in helping patients recover from acute cardiac events thus information and support for the latter are crucial. While spouse/partners commonly seek information as a problem-solving coping strategy, in an effort to regain personal control, spouses often lack information. This study identifies spouse/partner isolation and suggests that additional supports need to be in place to adequately deal with the challenges that AMI brings to family life. Suggested support mechanisms to enhance current provision are inclusion of spouse/partner in cardiac rehabilitation programs and hospital-based care, self-help groups supported and attended by professionals and telephone support systems.

Key words: Cardiovascular • Acute care facility • Focus group • Nurses • Nursing • Qualitative

INTRODUCTION

Over the past 20 years there has been increasing emphasis on the provision of information to clients following acute myocardial infarction (AMI). Contemporary hospital- and community-based education programmes aim to deliver a service based on clients' perceived information needs. Despite an impetus towards promoting spousal involvement in education programmes, there has been a bias, with the exception of one seminal study (Turton, 1998), in developing information packages that concentrate on the needs of

the client (Gerard and Peterson, 1984; Karlik and Yarcheski, 1987; Chan, 1990; Wingate, 1990; Wang, 1994; Ashton, 1997; Czar and Engler, 1997; Hughes, 2000; Scott and Thompson 2003; Timmins and Kalisz, 2003).

Despite the small body of research, it is acknowledged that spouses of AMI victims experience, physical, psychological and economic difficulties. This includes the threatened loss of a partner, the trauma of separation, child and household care problems, financial strain, role change, self-esteem problems and an uncertain and unpredictable future (Nyamathi, 1987; Clarke *et al.*, 1996; Arefjord *et al.*, 1998). It may also involve physical and emotional symptoms such as sleep and appetite disturbances, headache, chest and stomach pains, anxiety, fatigue, depression, irritability and poor concentration (Bennet and Connell, 1998; Daly *et al.*, 1998). Additionally, the consequences of having an AMI are recognized to be stressful for both clients and their families (McGee *et al.*, 1994; Stewart *et al.*, 2001).

Differences in information provided to spouse and client have been shown to have a negative impact on

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overall outcome (Borkman, 1990; LaGaipa, 1990; Figueiras and Weinman, 2003). Data from other studies that have examined different cardiac groups reveal that spouse/partners often encounter difficulties in obtaining detailed information about the clients' condition (Albarran *et al.*, 2004) and were generally poorly informed (Thompson and Cordle, 1988; Theobald, 1997). Furthermore, the quantitative approaches used in studies that have examined both client and spouse (Turton, 1998) or client needs alone were later criticized in favour of qualitative methodologies (Scott and Thompson, 2003). Authors have suggested that due to the over reliance on the positivistic paradigm, a body of knowledge may have developed based on health care workers perception of what is considered important to learn, rather than the individuals themselves identifying learning needs (Theobald, 1997; Egan, 1999; Scott and Thompson, 2003).

There is a dearth of research evidence, therefore, that examines the perceived information needs and information received by spouse/partners. No qualitative studies were found in relation to spouse/partner experiences in this area. If emphasis on tailoring informational support to client need (Department of Health and Children 1999, Department of Health 2000, 2004), lay participation and moving from 'expert' provider to equal partner (Stewart *et al.*, 2000) be to be realised in practice it is imperative that these needs are addressed in a holistic manner that includes spouse/partner in the trajectory.

AIM

This study aimed to explore spouse/partner experiences of information received and required following AMI.

METHOD

In order to provide rich data, a qualitative descriptive design was chosen using focus group methodology. Focus groups are advantageous as a method of data collection as they provide the researcher with an in-depth understanding of the phenomenon, rich data may be gleaned through participant interaction, and they are useful for proving a user perspective of experiences or services (Webb and Kevern, 2001; McLafferty, 2004).

The study was conducted in one hospital in the Republic of Ireland in 2004, serving a mixed urban/rural community with a population of approximately 105 000. The hospital provides a variety of both in-patient and outpatient cardiology services. There is also a hospital-based cardiac rehabilitation service

comprised of an exercise/education programme that all clients may attend following hospitalization for AMI.

Sample

Purposive sampling was used. The population included spouse/partners of patients who had attended (with at least 50% completion) a cardiac rehabilitation programme over a 5-month period at the hospital. Using cardiac rehabilitation records for this period, a list of patients were identified who entered into cardiac rehabilitation programmes with the diagnosis of AMI. The records of these patients (and where necessary the hospital/medical records) were then reviewed to assess eligibility for inclusion in the study, as per the study criteria (Table 1).

An information pack was sent to the home address of each eligible couple ($n = 27$) containing:

- A cover letter explaining the study, and formally inviting the partner to take part in a focus group. The partner was asked to provide dates/times that would be suitable to attend a group.
- A consent form for the partner to complete.
- A copy of the topic guide.
- A stamped addressed envelope for return of consent form.

Couples who failed to reply were sent another pack 14 days later. Fifteen couples responded positively, and one partner from each couple attended ($n = 15$).

Table 1 Inclusion/exclusion criteria

Inclusion criteria

Ability to communicate by written/spoken English language
 Patient must have presented through the A&E Department, received thrombolytic therapy for their first ever ST elevation myocardial infarction and have been transferred to the coronary care unit
 Patient recently (<6 months) completed formal cardiac rehabilitation programme, or is currently more than 50% through a programme

Exclusion criteria

Patient had cardiac arrest during AMI admission
 Patient suffered cardiogenic shock which prolonged hospitalization
 Patient had cardiac surgery or percutaneous coronary revascularization during AMI admission
 Patient/partner has a current psychiatric illness receiving treatment
 Chronic disabling condition of either patient or partner
 Patient/partner is a health care professional
 Couple currently attending marriage/family counselling

A&E, accident and emergency.

Data collection

Two focus groups were conducted, containing seven and eight individuals, respectively. Before the focus groups participants were clearly informed as to the exact purpose and nature of the group. Participants were also provided with a written copy of the interview schedule (Table 2), which functioned as a topic guide for group discussion. A cardiac rehabilitation specialist was available to deal with any unexpected distress that some participants might have encountered. The researcher also acted as moderator, encouraging equal participation and refocusing the interview if necessary (Twinn, 1998).

The focus group interviews lasted between 45 and 58 min. The data were collected using tape recording. Notes were taken during the course of the interview which pertained to non-verbal communications, clarified issues when more than one participant was speaking, and miscellaneous notes on thoughts, feelings and emotions of the researcher. These notes were used to support the transcribing.

Data analysis

Immediately upon completion of the groups, the tapes were replayed. This entailed merely listening through the conversation and further notes were made on the main researchers' thoughts and feelings. Data were later transcribed verbatim and analysed using thematic analysis. A technique described by Reiskin (1992) and Morrison and Peoples (1999) was used to identify emerging themes. This involved summarizing and classifying data using a thematic framework (Lane *et al.*, 1999). Identification of 157 significant words and statements initially reduced the data from the transcripts and notes. Each significant statement was printed and cut into identically sized pieces of paper. These pieces of paper were placed in a receptacle and

pulled out one by one. Once drawn from the receptacle, the pieces of paper were placed along a desk on a horizontal axis until such times as a statement or word was drawn which was similar to another already present. When this was the case, the statement/word was placed on the vertical axis directly below the associate. This data-reduction process was repeated three times until the data were reduced in four final themes: reactions to the event, feeling like a burden on the health service, the need for information and pulling apart – pulling together. Three themes (reactions to the event, the need for information and pulling apart – pulling together) will be discussed in congruence with the overall aim of this paper.

Rigour

Four suggested criteria of rigour described by Lincoln and Guba (1985) were used as the basis for establishing the trustworthiness of the qualitative data: credibility, dependability, confirmability and transferability. Steps were taken to improve and data credibility, which refers to confidence in the truth of the data (LoBiondo-Wood and Haber, 1998). Firstly, by conducting the study in such a way that believability is enhanced and, secondly, by overtly demonstrating credibility (Polit *et al.*, 2001). Researcher credibility was assured, as main researcher in this study was a Clinical Nurse Specialist in Cardiology, certified in cardiac rehabilitation. Furthermore, there was no direct involvement, influence or relationship with the cardiac rehabilitation team involved with clients or any vested interest in client outcomes.

The dependability of the data in this study was closely married to factors pertaining to confirmability (Polit *et al.*, 2001). Confirmability, or auditability as it is otherwise known, places a responsibility on the researcher to report all decisions involved in the transformation of data to the theoretical schema (Burns and Grove, 2001). Decisions made while synthesizing the data were clearly detailed and described in an audit trail.

This audit trail comprised six types of crucial records (Polit *et al.*, 2001):

- raw data (interview transcripts),
- data reduction and analysis products (theoretical notes, notation sheets),
- process notes (methodological notes),
- materials relating to intentions and dispositions,
- instrument development and information,
- data reconstruction products (drafts).

In accordance with Lincoln and Guba (1985), the analysis aimed to provide sufficiently descriptive or 'thick' data in the report, so as to permit the reader to

Table 2 Question schedule

What new information (if any) do you feel you have learned since your partner's heart attack?
Has any information you received been helpful to you since your partner's discharge from hospital?
Are there things you did not receive information on that you think you should have?
What are the main things you believe partners of heart attack patients should be told about?
Do you feel you have received less than, more than, or similar amounts of information than your partner has?
How does this make you feel?
Do you feel that the hospital staff attempted to discover what information you would like to know?

evaluate the applicability or transferability of the data to other contexts.

Ethical considerations

The local Health Board Regional Ethics Committee granted ethical approval to conduct the study. Participants completed informed consent prior to the focus group interview. The right to withdraw from the study was stated, prior to the interviews. The nature of the focus group approach is such that true anonymity cannot be assured (Lane *et al.*, 1999), particularly in a reasonably small community such as the one from which the participants came. However, confidentiality was maintained by the ascription of codes assigned to participant data, and names were only known to the main researcher. On completion of the study the audiotapes were destroyed.

Findings

The group comprised three men and 12 women. Four emergent themes, only the following: reactions to the event, the need for information and pulling apart – pulling together, will be discussed in congruence with the overall aim of this paper. These themes relate more generally to participants' perception of information received, whereas the fourth theme, feeling like a burden on the health service was context specific and not necessarily related to information giving or receiving.

Reactions to the event

The participants reported emotional reactions to the event.

Emotional reactions

Spouse/partners found the event stressful and discussed the resultant reactions in emotive terms:

'Well I mean it's kind of a shock like, ye know? I mean one day your grand and then the next day your up at here at the hospital like with monitors and drugs and all that.' (R15, female partner)

They also reported the fear associated with witnessing the AMI:

'It's a wonder that partners actually... don't get heart attacks, you know? Cause it is an awful lot of stress. I mean ..[my husband]..was super-fit, he's only forty-four and he was in the military and went orienteering and everything and he had it at home he had it with me. It was an awful fright' (R8, female partner)

The need for information

Spouses identified the perceived benefits of information received, the support that information provided

and their views on the fact that spouses were not present at cardiac rehabilitation classes. There were also some views on the sequencing of information and criticisms of information received.

Perceived benefits of information received

The informants perceived benefits of having information and in particular it clarified aspects of information that their spouse/partners may have been previously told but not relayed to them effectively. Spouse/partners were also concerned with their perception of imposed limitations of the patients' condition:

'I think though ... you sort of want loads of information to start and ... cause my [husband] would just get on with things like nothing would happen ... I said that to the cardiac girl that he'd be back fishing and at the GAA next again day. I waited til he'd gone and I was asking the girl what he shouldn't be doing.' (R10, female partner)

'My husband still goes mad even now that I'm wrapping him up in cotton wool. We'd have a fight nearly every other day that he's says I'm minding him too much or I'm fussing.' (R13, female partner)

A common theme throughout was the self-expressed need for spouse/partners to be informed of the expected capabilities versus limitations of patients.

'So just how much they can do. What they're supposed to do.' (R5, female partner)

'I need that information cause I would....I think I may not have babied him if I thought he was capable of X Y and Z, and I'm doing X Y and Z for him ye know.' (R7, female partner)

This often resulted in over protectiveness:

'Cause you end up doing the wrong thing then. My husband still goes mad even now that I'm wrapping him up in cotton wool. We'd have a fight nearly every other day that he's says I'm minding him too much or I'm fussing.' (R5, female partner)

Information gave them confidence to act effectively in certain situations:

'I don't know though. I mean if you know a lot of the in's and out's of things then it makes it easier. I mean say six months ago if my wife had been going on about being tired and dizzy and that I would have probably have been giving out to here and telling her to liven up, d'ye know? Even last week though she was that way and I knew it was probably cause of the tablets being put up and' (R9, Male partner)

Indeed further information sources such as a nurse phone line were suggested to provide confidence and support after discharge:

'Definitely a contact number should anything ... I mean you're very raw in the early stages, you're very naïve, you don't know what's going on, and of course everybody has different symptoms, and you really don't know what to expect, and say hey love, this is happening, rather than have to ring the doctor ... in the middle of the night' (R8, female partner)

'That's what I often felt, that you were alone when you got home ... no contact number.' (R6 female partner)

Information as support

Many of the study participants also believed that the information they received helped them to cope with events:

'First in the admission I just needed someone to tell me ye know, not to panic, that he was in the right place and everything ye know ... I just needed somebody to say to me ye know your OK, he's OK ... that was the first stage anyway.' (R8, female partner)

'This information is to help you cope and know things after the heart attack.' (R10, female partner)

There were many other sources of support for spouse/partners identified received helpful information from sources other than health professionals:

'I definitely think that it helps ye if ye know somebody, like that lady was saying about her cousin.' (R15, female partner)

'Yes, yes ... he's not a cousin now I'd see a lot of but just ... well he's only forty-seven ... but it's just good like that ye can phone him up and ask how he was at a certain time and not be bothered.' (R11, female partner)

'Well ... a good pal of mine. He had an attack about four years ago. He'd be great and he'd tell you what kind of things to be looking for.' (R8, female partner)

Feeling left out

Sometimes the spouse/partners reported feeling left out of the information receiving process:

'But when we arrived here, I felt very very left out, and the worry of everything ... and I was actually not told it straight out, but I was literally told to shut up by a doctor in A&E.' (R9, Male partner)

'But when they brought him up to CCU then ... they were great, the care he was getting ... but still, I never saw a doctor who explained absolutely to me' (R8, female partner)

There were also explicit mentions of the issue of spouses not being present at cardiac rehabilitation classes and many felt excluded from the process:

'Definitely think it would have been better if we'd got to come.' (R10, female partner)

'Well, we waited while they did their exercises. Dropped them off and picked them up, but while we were outside ... discussions that were going on we were here for.' (R8, female partner)

'I think that maybe it would've been good if we could've had maybe one session, ye know, with our husbands, and then the rest maybe on our own ... I sat in the car. I would've loved to have joined him.' (R6, female partner)

Criticisms of information received

Many found the information received overwhelming:

'I think that maybe ye in the hospital think that we need things that we might not think we need ourselves ... the book, the biggest thick book that the girls give you ... well I mean that just scares ye, well it scared me anyway.' (R9, Male partner)

'Yeah, and I was thinking at the end of the day, your still a wife ... I mean you can support them and mind them without having to be a mini encyclopaedia and be able to know all of the information that there is about heart attacks.' (R13, female partner)

Others commented on the lack of individualized tailored information:

'Well like me and you and you would all have different things. Like if you're a young man who lives in the country like, so the driving would be ... the biggest thing ye'd want all the information on.' (R9, male partner)

'I mean for me, there's probably about a hundred pages in ... the book you were saying. I'd say there are about ten or twelve that actually really did be of help to me ... well us. What I'd like ... and I know they're busy ... if it was to be the gold standard (makes quotation signs with two fingers of both hands) then it'd be to concentrate on the things that would be really useful to each individual.' (R13, female partner)

'And the staff like, they even had a list of things. They were up in the ward above and they'd tell you a bit ...'

like I don't know, exercise so many times a week for so long, then they'd tick it on their sheet.' (R9, male partner)

Participants stated clearly that only a small proportion of the information given to them was helpful, and furthermore that they only utilized the information that they felt was useful. It is clear that these participants believed that the informational process involved staff working from a prescribed menu.

Sequencing of information

Much of the time in the group discussion focused the sequencing of information. One participant called her perceived 'stages' of the journey':

'First in the admission I just needed someone to tell me ye know, not to panic, that he was in the right place and everything ye know ... I just needed somebody to say to me ye know your OK, he's OK ... that was the first stage anyway.' (R9, female partner)

'I think it good, especially at the start that they don't tell you everything. I remember the nurse in the CCU part was a lovely fella, but he was going on about thromboses and breaking them down and arteries and things. Well I mean your just not able.' (R13, female partner)

'It is yeah but like you say all you want to hear, like you said the nurse in the Casualty said, is small chunks of information that you can say over and over in your head.' (R11, female partner)

'You probably don't think about it like that but ye definitely want the urgent kind of major things at the start and then the smaller things near the end ... mind they're still important but maybe's not so important as the start where ye'd be wondering are they going to die.' (R9, female partner)

These overt statements of spouses perceived needs changing over the course of time.

Pulling apart – pulling together

This theme outlined both the tension and in some cases harmony that became apparent within the relationship after the AMI.

Conflict

There were a significant number of mentions over both groups, of conflict, arguments, deceit and polarization between couples. One spouse/partner felt:

'One day she's alright, the next day she's like Jekyll and Hyde ... no matter what you do. I don't do it I'm wrong. And I say will I do this and then she'd say all

you keep saying to me is I'll do this, I'll do this ye know? I'm walking on eggshells ... and it's a complete change of our life.' (R2, male partner)

In some cases, the client appeared to wish to suffer alone; but spouse/partners felt that it that it was their illness too:

'Though they feel it's their heart attack and ... you're suffering too.' (R3, female partner)

The tension was evident from the group discussions. This tension appeared to be compounded by the spouse/partners' lack of information and compounded by the perception in some cases that the affected partner may be withholding information:

'... most of the time I find, my husband doesn't want me to come to the doctor with him, therefore I can speak for myself, so I really don't know what's going on.' (R3, female partner)

'... I mean I know my husband tells me stuff that there's no way they told him at the hospital, but then I wasn't there so I can't really argue the point.' (R14, female partner)

'I say to her, how are you this morning. Oh I'm alright. That's what they always say. I know you're alright. She doesn't. She doesn't tell me what's wrong half the time. And her tablets. She wont leave me go into the doctor with her.' (R2, female partner)

In some cases, the spouse/partner avoided sharing day-to-day information to spare the client stress:

'... you start keeping everything from them, you don't let them go out, you take most things on board yourself ... it is difficult.' (R6, female partner)

'Oh if you have a minor headache, you don't open your mouth.' (R5, female partner)

Harmony

Although there were no extensive dialogues involving a number of participants, there were brief mentions in the groups of harmony and togetherness.

'I've even started walking with mine and we'd never have been the type to walking just along the strand.' (R13, female partner)

'No though but ye have to be ... mature about something about this. I mean if he feels better doing those things and talking and that then.' (R2, male partner)

Limitations

Generalizing from the study findings is limited by the use of qualitative methodology, however, the rich

findings illuminate an area little explored in nursing. Congruent with qualitative methods, the study findings are contextualized within the specific location, although transferability of the data is possible. A small study sample further limits the application of findings. There are also limitations and resultant criticisms of the use of focus group methodology. Webb and Kevern (2001) suggest that focus group methodology provides a superficial discussion. They further criticise a tendency towards an unsophisticated application of the method. A rigorous approach to data collection and analysis was used in this study to address these issues.

DISCUSSION

Preference for individualized tailored information post-AMI echoes a predominant theme in the literature over the past 20 years (Scott and Thompson, 2003; Timmins, 2005). Furthermore, in keeping with the literature on the topic, spouse/partners were able to identify their readiness to receive information and their changing needs over time. Increasingly, UK and Irish cardiac rehabilitation processes are encouraged to adopt approaches that incorporate principles of adult learning such relevance (to patients' needs), individualization, feedback and facilitation (Department of Health and Children, 1999; Department of Health, 2000; SIGN, 2002). However, this current study indicates that an individualized approach to information provision to patients is not always provided, spouses very clearly perceived a 'tick box' approach. This mirrors recent findings from an Irish study that examined nurses' use of conceptual model-based documentation (Hyde *et al.*, 2005), whereby the authors noted that explicit conceptual use was not evident, but rather a medical model of care existed where tasks and routine were prioritized. Hyde *et al.* (2005) termed this 'impression management'. It is important for nursing staff to give a firm commitment to evidence-based principles, and embrace an individualized approach to cardiac patient education, rather than a token approach reflected within documentation only.

This study found that spouse/partners often felt isolated from the information process. They were left feeling suspicious if their partner knew more than they, often perceiving that they were receiving half-truths. This undermined their confidence and their relationship with the partner, and evoked a tendency to baby their partners if they were unsure of their limitations. Spouse/partners clearly indicated that information reduced this tendency assisted and with their confidence. Spouse/partner inclusion in the information-giving process is being increasingly rec-

ognized (Turton, 1998), however, there is a dearth of information about specific information needs of this group.

Spousal involvement in cardiac rehabilitation programmes is one way of addressing their information needs in the area, and many participants in this study voiced a desire to attend with their partner, and indeed felt excluded from the process. As early as 1994 in Ireland, McGee *et al.* recommended spousal involvement in cardiac rehabilitation programmes. However, in keeping with the situation in the UK (Department of Health, 2000), the priority focus in recent years has been increasing the number of and equitable access to such programmes (Department of Health and Children, 1999). Of interest to note that the most recent report of the Irish Cardiovascular Strategy Group (Department of Health and Children, 2003) recommended family involvement in the cardiac rehabilitation process, thus indicating a reoriented focus towards family centred care now that provision of basic services has been improved at national level. Although spousal or family involvement in these programmes has been reported in the USA (PS Friedman, Massachusetts School of Professional Psychology, Boston, unpublished PhD thesis; CC Winchester, Massachusetts School of Professional Psychology, Boston, unpublished PhD thesis; TB Hong, Wayne State University, Detroit, unpublished PhD thesis) with positive effects, the reporting of such innovations from within Ireland has yet to impact upon the published literature.

Spouse/partners in this study experienced emotional reactions consistent with international findings (Nyamathi, 1987; Clarke *et al.*, 1996; Arefjord *et al.*, 1998; Bennet and Connell, 1998; Daly *et al.*, 1998). Unlike Daly *et al.* (1998), specific cultural issues did not emerge with respect to this group. Information received by nurses evidently provided support to many of the respondents. Similarly, in the study of Ivarasson *et al.* (2005), family perceived positive support when they received attention and information and felt involved in the care. The concept of family involvement in care has recently been revisited by Rutledge *et al.* (2000a, 2000b) and this is an area that requires greater attention in the Irish context. While recent Irish national policy (Department of Health and Children, 2003) recommends family involvement in rehabilitation services, a cohesive framework for the delivery of such a service needs to be outlined. Furthermore, the concept of family centered care also needs to be integrated at hospital level.

Extending cardiac rehabilitation services into the home is another potential option that would ensure greater family/spouse/partner involvement. In the UK, Jolly *et al.* (2003) report positive findings following a randomized controlled trial of home-based intervention.

Similarly, J. Bell (University of London, London, unpublished PhD thesis) reports positive findings with a home-based program in Scotland. This finds significantly reduced hospital admissions compared with patients receiving usual care. Likewise in Canada, a home-based cardiac rehabilitation program reported a significantly improved quality of life (Arthur *et al.*, 2002). Home-based services could be developed in Ireland in conjunction with the growing impetus towards nurse-led services. Fallon and Ingram (2006) report on the benefits of evolving nurse-led services in cardiac rehabilitation in Ireland.

An adjunct to these developing services, or to current services is the proposed development of a telephone support service for patients and their families. This recommendation emerged from within the focus groups, whereby spouse/partners felt it would be useful to be able to summon assistance at odd hours, to answer simple questions and relieve anxiety about their partner's symptoms. The use of telephone services for patients following cardiac rehabilitation has been used in the USA for over 30 years (Miller, 1996). The literature reports a range of cardiac rehabilitation services being provided in this way, including provision of knowledge and support (Miller, 1996). From a number of US-based studies in cardiac rehabilitation, Miller (1996) is confident of their use within this setting. Mack (1997) later supported Miller's (1996) claim, in letter to the editor, suggesting that this 'showed great insight into the future of cardiac rehabilitation'. Telephone support systems area that requires research and development in both the UK and Ireland. In addition, to providing benefits to patients and families, these systems also hold the attraction of cost reduction, as the costs are more modest than other forms of home support (Miller, 1996).

In concurrence with Dickerson (1998), the information received from non-health professionals was identified by spouse/partners as a source of support. Similarly, Hentinen (1983) and Coyne and Smith (1991) found that spouse/partners turned to friends/family and neighbours for additional information and support. This support emanates from a natural interaction with a network of family/friends/peers and professionals. This support network communicates information, emotional alliance, practical aid and affirmation (Stewart, 1993). In keeping with the spouse/partners need for a supportive network, collaborative self-help support groups (between professionals and ex patients) may also be useful to provide emotional and social support for patients and spouse/partner during recovery. In Canada, Stewart *et al.* (2001) report that 12-week combined peer and professional support intervention to families provided emotional and information support as well as affirmation. A positive

effect on coping, confidence and spousal relationship was also noted. In Sweden, self-help groups for this patient group are well established (Hildingh *et al.*, 2000). Given the potential benefits of such an intervention, this establishment of self-help groups in cardiac rehabilitation settings in both UK and Ireland should be considered.

Both present and alternative support structures for both spouse/partner and patient following AMI need to consider relationship support as a part component of delivery. This particular aspect of an individual's life is not traditionally considered within rehabilitation programs, however, given the obvious strain experienced by some couples within the study its inclusion would be prudent. This marital disharmony revealed was reported elsewhere within the literature (Nelson *et al.*, 1998; Thompson and Cordle, 1988). As this study reports primarily upon the female spouse/partner greater consideration also needs to be given within future research to the needs of men.

CONCLUSION

There appears to be almost universal recognition that there is a need for families in the post-AMI period to be provided with cardiac education (Theobald, 1997). Increased spouse/partner involvement in information/education sessions, including cardiac rehabilitation, as suggested by Johnston *et al.* (1999) and Svedlund and Axelsson (2000) is imperative. Westmacott *et al.* (1999) suggest that the amount learned by spouses is unpredictable unless they are explicitly included in formal information/education sessions. Johnston *et al.* (1999) find that spouses benefited from the support, information and enhanced feelings of control experienced by being formally included in cardiac rehabilitation classes. Greater inclusion of spouse/partner in both formalized programs and hospital care may seek not only to address the latter's informational needs but provide a solid basis for relationship development and moving forward in the recovery period. Many spouse/partners live in fear of another fatal event and thus cosset their partner. They may also experience role change and increased household responsibility during the recovery period. They come to terms with events and with their new roles largely unaided, possibly with resultant tension in the relationship. Providing support through tailored in-hospital information and shared cardiac rehabilitation classes might lessen spouse/partner isolation and distress. Furthermore, additional support for the relationship could be included within the rehabilitation programs. Telephone support systems and self-help groups could further support these programs.

WHAT IS KNOWN ABOUT THIS TOPIC

- AMI is a stressful event for both patients and their families.
- Spouse/partners are presented with a number of challenges such as the threat of loss of a partner, separation from family and friends, child and household care problems, financial strain, change of role, change of self-esteem and an uncertain and unpredictable future.
- AMI can produce either a positive or a negative effect on the relationship.

WHAT THIS PAPER ADDS

- The use of focus group methodology illuminates the spouse/partners' perspective.
- Spouse/partners' isolation is identified and support groups are suggested for use in a UK and Ireland setting.
- The need for information and support for spouse/partners and greater inclusion in information/education programmes is revealed.
- Telephone support systems are also highlighted as a potential adjunct to current service provision in cardiac rehabilitation.

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Improving Door-to-Drug time and ST segment resolution in AMI by moving thrombolysis administration to the Emergency Department

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Summary Background. We describe a combination of measures to reduce Door-to-Drug (DTD) time and improve the Emergency Department (ED) management of ST elevation MI (STEMI): appointment of a Cardiology Nurse Specialist, application of the American College of Cardiology and the American Heart Association (ACC/AHA) guidelines, changing the site of thrombolysis from the CCU to the ED, the introduction of a single bolus thrombolytic agent.

Methods. The 12-month period before and after the introduction of the measures were retrospectively reviewed. One hundred and sixty patients were discharged from the CCU with the diagnosis of myocardial infarction confirmed by ECG and enzyme criteria. Eighty patients had STEMI and fulfilled criteria for thrombolytic therapy at the time of presentation to hospital. A full data set was available on 35/38 of patients in the 12 months prior to the measures (Year 1), and 39/42 in the 12 months subsequent (Year 2).

Results. Median DTD time fell from 80 to 22 min after institution of the measures. Median Pain-to-Drug time also fell from 270 to 140 min. Thrombolytic agent given in the ED rose from 3% in Year 1, to 72% in Year 2. IV β -blocker administered in the ED rose from 12% to 79%, resulting in median time to receiving IV β -blocker falling from 63 to 19 min. Elevated ST segments resolved by $\geq 70\%$ in < 2 h in 53% of Year 2 patients, compared with 23% of Year 1 patients. Combined major in-hospital adverse clinical events were reduced from 49% to 15%.

Conclusion. This combination of measures reduces DTD time, improves speed to delivery of important concomitant medications, and significantly improves the time to ST segment resolution and outcome in STEMI.

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Introduction

Since the first successful administration of thrombolytic therapy some 25 years ago, acute myocardial infarction (AMI) has been subject to the largest multicentre international trials ever performed

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(GISSI, 1986; ISIS-2, 1988; GUSTO, 1993; GISSI-2, 1990). The data show that thrombolytic agents have resulted in the greatest reduction in AMI mortality since the introduction of modern resuscitation in the 1960s; decreasing overall 30–35 day mortality by 18–25%, with increasing benefit as the time from onset of symptoms to thrombolysis is reduced (FTT Collaborative Group, 1994).

For every hour that thrombolytic treatment is delayed after the onset of symptoms, 1.6 lives are lost per 1000 patients treated (FTT Collaborative Group, 1994). In many institutions, the Door-to-Drug (DTD) time exceeds 1 h (White, 2000).

Symptom-to-drug delay consists of three distinct phases: time from onset of symptoms to calling for help, pre-hospital care and transportation, and hospital door-to-drug time. Of the three, hospital door-to-drug time is the most amenable to change (Bracken, 1997).

Reports indicate that thrombolysis administration in the Emergency Department (ED) is safe and effective in reducing DTD time (Sharkey et al., 1989; Birkhead, 1992; Gonzalez et al., 1992; Lambrew et al., 1997; Kendall and McCabe, 1996; Hourigan et al., 2000; Edhouse et al., 1999; Nee et al., 1994). Only 35% of EDs administer thrombolytic therapy, even though 58% of EDs believe that they should (Hood et al., 1998). Many EDs do not have policies or protocols for the management of AMI.

Previous studies detailing the most appropriate site for the in-hospital administration of thrombolytic therapy, have compared strategies between hospitals, reviewed registry data of hospitals using different pathways, or solely compared DTD time when moving the site of administration of thrombolytic therapy from the Coronary Care Unit (CCU) to the ED (Sharkey et al., 1989; Birkhead, 1992; Gonzalez et al., 1992; Lambrew et al., 1997; Kendall and McCabe, 1996; Hourigan et al., 2000; Edhouse et al., 1999; Nee et al., 1994). See Table 1.

Bolus thrombolytic therapy, is an attractive regimen which facilitates the rapid administration of reperfusion therapy in patients with acute myocardial infarction (ASSENT-2, 1999). Third generation single bolus thrombolytic agents with a longer

half-life than previous bolus drugs, are particularly suitable for use in the ED due to their ease of administration.

Subsequent to the availability of the single bolus thrombolytic agent Tenecteplase (TNK), the divisions of Emergency Medicine and Cardiology made a joint decision to move the location of the administration of thrombolysis from the CCU, to the ED. This decision was facilitated by the appointment of a Chest Pain Nurse Specialist (CPNS) based in the ED, and the promulgation of the American College of Cardiology and the American Heart Association (ACC/AHA) practice guidelines for the management of patients with acute coronary syndromes.

The aim of the change in practice to treating AMI immediately in the ED, as opposed to diagnosing in the ED then transferring patients to the CCU for thrombolysis, was to meet national (Horgan et al., 2000) and international (Ryan et al., 1996) targets of a DTD time of less than 30 min.

The time lines (adapted with permission from Hourigan et al., 2000) for ED vs. CCU patients are represented in Fig. 1.

This paper reports the introduction and application of a combination of measures in the ED, aimed at: reducing DTD time, raising awareness and speed of delivery of concomitant medications, reducing time to ST segment resolution, and improved clinical outcome.

Methods

Guidelines were adapted to promote standard early empirical therapies (oxygen, aspirin, sublingual nitroglycerine) for patients presenting with chest pain possibly attributable to myocardial ischaemia (Hazinski et al., 2000), as well as immediate essential therapies for ST elevation myocardial infarction (STEMI), namely thrombolytic agents, IV heparin, IV β -blocking agents and IV opiate analgesia using a simple algorithm. Copies of the algorithm, derived from and closely following ACC/AHA guidelines, were displayed prominently in patient care areas.

Table 1 Summary of median (Kendall and McCabe, 1996) and mean (Hourigan et al., 2000; Edhouse et al., 1999; Nee et al., 1994) DTD times (min) after changing site of drug delivery from the CCU to the ED.

		CCU	ED	<i>p</i>
Kendall and McCabe	(Median)	110	38	0.0006
Hourigan et al.	(Mean)	88	47	<0.0001
Edhouse et al.	(Mean)	59	44	0.004
Nee et al.	(Mean)	121	38	<0.0001

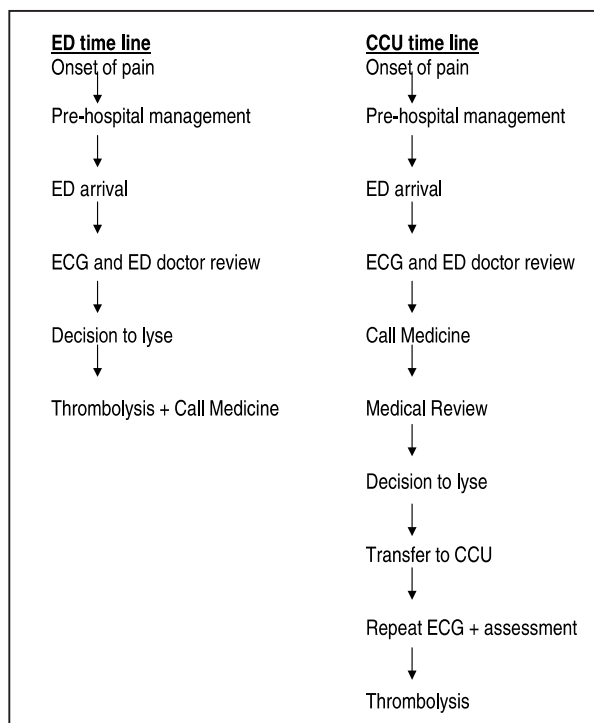


Figure 1 Emergency Department vs. Coronary Care Unit time lines for patients receiving thrombolytic therapy (adapted with permission from Hourigan et al., 2000).

Study design

The study was conducted in a Regional Hospital, serving a mixed urban/rural community with 40,000 ED visits a year. A new combination of measures designed to eliminate delay in the administration of thrombolytic therapy to patients suffering AMI was introduced on April 1st, 2001.

The measures included:

- Appointment of a Chest Pain Nurse Specialist (CPNS).
- Application of the ACC/AHA guidelines for acute coronary syndromes.
- Changing the site of administration of thrombolytic agents from the CCU to the ED.
- Introduction of a single bolus thrombolytic agent (TNK).

The management of STEMI patients treated with thrombolytic agents in the year before April 1st 2001 and the year following, were reviewed to compare:

- Door-to-Drug times.
- Time to ST segment resolution.
- Use of intravenous β -blocking agents.
- In-hospital adverse clinical events.

Sample selection

The 12-month period before and after the introduction of the changes (April 2000–April 2002) were retrospectively reviewed. During that time 3060 patients presented at the ED with chest pain, of whom 1960 were admitted to hospital. One hundred and sixty were discharged from the coronary care unit with the diagnosis of myocardial infarction, confirmed by ECG and enzyme criteria. Eighty patients who had STEMI, fulfilled criteria for thrombolytic therapy at the time of presentation to hospital. Thirty-eight of these were between 1st April 2000 and 31st March 2001 (Year 1), 42 between 1st April 2001 and 31st March 2002 (Year 2).

The data set was complete and available for analysis on 35 patients in Year 1 (92%), and 39 in Year 2 (95%).

Data

The demographic, ECG, treatment and outcome data for Years 1 and 2 were extracted from the hospital records, tabulated, analysed and statistically evaluated.

ST segment elevation was recorded using conventional methods previously described (Schroder et al., 1999; Fu et al., 2001), measured manually 20 mS after the J-point using a hand calliper; summing ST segment elevation in leads I, aVL and V₁ to V₆ for anterior myocardial infarction; and leads II, III, aVF, V₅ and V₆ for inferior myocardial infarction.

Statistical analysis

Statistical analysis was carried out using two-sample *t*-tests for differences between means from independent samples, two-sample tests for differences between proportions and the Mann–Whitney test for differences between medians, where appropriate.

Results

There were 35 patients in the Year 1 group with a median age of 64 years, 74% were male. The 39 Year 2 patients had a median age of 64 years, 79% were male. Baseline characteristics for both groups are compared in Table 2.

A thrombolytic agent was given in the ED to 3% of patients in Year 1, and 72% in Year 2 (Δ 69%, 95% CI 53% to 84%, $p \leq 0.0001$); with a DTD time of

Table 2 Baseline characteristics ($p \geq 0.05$ for all).

Characteristic	Year 1 ($n = 35$)	Year 2 ($n = 39$)
Median age (range)	64 (42–90)	64 (48–81)
Age >75 yr	6 (17%)	6 (15%)
Male gender	26 (74%)	31 (79%)
Diabetes	4 (11%)	4 (10%)
Current smoker	13 (37%)	19 (49%)
<i>Median blood pressure (mmHg)</i>		
Systolic (range)	147 (101–220)	150 (78–205)
Diastolic (range)	81 (52–126)	88 (50–114)
<i>Location of infarction</i>		
Anterior	19 (54%)	15 (38%)
Inferior	16 (46%)	23 (59%)
Other	0	1 (3%)
<i>Previous</i>		
Myocardial infarction	5 (14%)	2 (5%)
Coronary angiography	2 (6%)	1 (3%)
Percutaneous coronary intervention	3 (6%)	1 (3%)
Coronary artery bypass grafting	0	0

Table 3 Door and pain-to-drug time.

	Year 1 ($n = 35$)	Year 2 ($n = 39$)	p	95% CI
Median Door-to-Drug time ^a (range)	80 (20–235)	22 (9–80)	<0.0001	39–70
Median Pain-to-Drug time ^a (range)	270 (90–1155)	140 (54–1290)	0.0003	50–206
Door-to-Drug time ≤ 30 min	2 (6%)	25 (64%)	<0.0001	41–75%
Thrombolysis administered in ED	1 (3%)	28 (72%)	<0.0001	53–84%

^aMinutes.

≤ 30 min in 6% of Year 1, and 64% of Year 2 patients ($\Delta 58\%$, 95% CI 41% to 75%, $p \leq 0.0001$).

In the period after the introduction of the rapid thrombolysis package, median DTD time was reduced from 80 to 22 min (95% CI 39% to 70%, $p \leq 0.0001$) (Table 3). Median Pain-to-Drug time was reduced from 270 to 140 min (95% CI 50% to 206%, $p = 0.0003$).

Twenty-four (69%) patients received an IV β -blocking agent in Year 1, 28 in Year 2 (72%).

IV β -b was given to 12% of Year 1 patients in the ED, compared with 79% in Year 2 ($\Delta 67\%$, 95% CI 46% to 86%, $p \leq 0.0001$) (Table 4). There was a reduction in median time to receiving IV β -b from 63 to 19 min (95% CI 27% to 58%, $p \leq 0.0001$). No adverse reactions resulted from the use of intravenous β -blocker.

Twenty of the Year 2 patients (53%) achieved ST segment resolution $\geq 70\%$ in <2 h, and seven of the Year 1 (23%) ($\Delta 30\%$, 95% CI 8% to 52%, $p = 0.007$) (Table 5).

Individual and combined major in-hospital adverse clinical events of death, re-infarction, refractory ischaemia (requiring Rx) and new heart

failure (requiring Rx) fell from 17 (49%) in Year 1 to 6 (15%) in Year 2 ($\Delta 33\%$, 95% CI 13% to 53%, $p = 0.001$) (Table 6).

There were three deaths in Year 1, and two in Year 2. Year 2 saw two cerebrovascular events, compared to one in Year 1.

Discussion

The relationship between moving the site of administration of thrombolytic therapy from the CCU to the ED and reduced DTD time is clear. With an increase in the number of patients thrombolysed in the ED from 3% to 72%, median DTD time fell from 80 to 22 min.

The reduction in median Pain-to-Drug time from 270 to 140 min is a valuable sequelae.

The degree of ST segment resolution after reperfusion therapy, is an important prognostic indicator for patients with acute myocardial infarction and an accurate index of reperfusion (de Lemos et al., 2000; Dissmann et al., 1994; Schroder et al., 1994; Schroder et al., 1995). Many studies have

Table 4 Thrombolytic agents and concomitant medications.

	Year 1 (n = 35)	Year 2 (n = 39)
Aspirin	34 (97%)	39 (100%)
Sublingual nitroglycerine	24 (69%)	30 (77%)
Intravenous heparin	34 (97%)	39 (100%)
Intravenous opiate analgesia	21 (60%)	19 (49%)
Thrombolytic agent		
Streptokinase	1 (3%)	1 (3%)
Reteplase	23 (66%)	7 (18%)
ASSENT-3 trial drug	11 (31%)	0
Tenecteplase	0	31 (79%)
Intravenous β -blocking agent	24 (69%)	28 (72%)
β -Blocking agent given in ED ^b	3 (12%)	22 (79%)
Median time to β -blocking agent ^{a,c}	63	19

^a Minutes.

^b Δ 67%, 95% CI 46% to 86%, $p \leq 0.0001$.

^c 95% CI 27% to 58%, $p \leq 0.0001$.

Table 5 ST segment resolution of >70% distributed over time intervals.

	Year 1 (n = 31)	Year 2 (n = 38)
<2 h ^a	7 (23%)	20 (53%)
2–4 h	11 (35%)	5 (13%)
4–24 h	5 (16%)	7 (18%)
>24 h	8 (26%)	6 (16%)

^a Δ 30%, 95% CI 8% to 52%, $p = 0.007$.

Table 6 In-hospital major adverse events, 30 day sequelae.

	Year 1 (n = 35)	Year 2 (n = 39)
Death ⁱ	3 (9%)	1 (3%)
Re-infarction ⁱⁱ	5 (14%)	1 (3%)
Refractory ischaemia ⁱⁱⁱ	6 (17%)	3 (8%)
New heart failure ^{iv}	3 (9%)	1 (3%)
Combined ^{i-iv} ^a	17 (49%)	6 (15%)
Second thrombolytic agent for FTR ^b	1 (3%)	3 (8%)
Cerebrovascular event	1 (3%)	2 (5%)
Significant non-cerebral bleed	1 (3%)	0
Cardiac arrest	2 (6%)	2 (5%)
30 day		
Death	0	1 (3%)
Re-admission	2 (6%)	2 (5%)

^a Δ 33%, 95% CI 13% to 53%, $p = 0.001$.

^b Failure to reperfuse.

demonstrated that early complete resolution of the ST segment (classified by Schroder et al., 1999 as $\geq 70\%$) is associated with higher infarct-artery patency, smaller infarct size, better left ventricular function, and lower mortality rates (Schroder et al., 1994, 1995; Roberts et al., 1991; Owen, 1998).

Furthermore, $\geq 70\%$ ST segment resolution within 180 min of thrombolytic therapy confers

lower risk than resolution outwith this window (Schroder et al., 1995).

Measuring the extent of ST segment resolution in the context of ED administration of bolus thrombolytic agents is unreported in the literature.

Year 2 of the study saw an increase in the number of such patients from 23% to 53%. Five patients (7%) were excluded from ST segment

analysis because of either a (L) Bundle Branch Block; or because they received a thrombolytic agent in the context of having an absence of ST segment elevation, but a clinical history of typical chest pain with raised cardiac markers. Four of these patients were from the Year 1 group and one from the Year 2.

Despite evidence that early administration of an intravenous β -blocking agent reduces the incidence of ventricular fibrillation, non-fatal reinfarction and recurrent ischaemia in acute myocardial infarction (Ryan et al., 1996; Roberts et al., 1991), their use varies considerably between centres, with reports between 5% and 45% (Owen, 1998). In this study the frequency was 70% (69% Year 1 vs. 72% Year 2).

Intravenous metoprolol was administered 5 mg at 5-min intervals, over 15 min to a maximum dose of 15 mg. The reduction in median time from arrival at the ED, to administration of IV β -b from 63 min in Year 1 to 19 min in Year 2, is attributable to the increase in patients receiving IV β -blocker in the ED from 12% to 79%. The drive to reduce DTD time and the subsequent heightened awareness of acute coronary syndromes, encouraged the administration of concomitant medications indicated for the treatment of AMI.

The significant reduction in DTD time which followed the introduction of the combination of measures described, may have been responsible for the twofold increase in the number of patients achieving optimal resolution of elevated segments. The early administration of IV β -blocker may also have been beneficial.

While acknowledging the relatively small sample size, the reduction in combined major in-hospital adverse clinical events (death, re-infarction, refractory ischaemia, new heart failure) from 49% in Year 1, to 15% in Year 2 is encouraging.

The higher incidence of a second dose of thrombolytic agent for failure to reperfuse in Year 2, is probably due to combination of increased awareness of the phenomenon in the CCU, a greater emphasis on timely sequential post-thrombolysis 12 lead electrocardiograms, a formal protocol for treating this important subgroup of patients, and an increased confidence in the safety and efficacy of thrombolytic agents.

Of the five deaths over both years, four occurred in-hospital; three in Year 1, one in Year 2. A further Year 2 patient died of cardiogenic shock after re-admission.

Three cerebrovascular events were split between two in Year 2, and one in Year 1. All three were intracranial haemorrhages (ICH), confirmed on CT Scan. The patients were all males aged >75 years. The Year 1 patient, and one of the Year 2

patients received rPA, the remaining Year 2 patient received TNK.

One significant non-cerebral bleed (gastrointestinal) requiring blood transfusion occurred in the Year 1 group.

Thirty-day sequelae of hospital re-admission was evenly spread over both groups, with two re-admissions from each Year.

An essential component of the success of this programme is an emphasis on education, training and confidence building. This enables a team approach to improving the ED management of AMI. All medical and nursing staff in the ED attended at least one session, covering the physiology, clinical and electrocardiographic diagnosis and treatment of AMI. CD-ROMS, teaching packs, visual aids, sample ECGs and placebo demonstration single-bolus thrombolysis kits were used. Staff were generally very appreciative of this initiative. A heightened awareness and a competitive spirit to achieve a shorter DTD time than the previous regime was clearly evident.

Limitations

We recognise various potential limitations of this study.

The study was observational, using a relatively small sample size and retrospectively collected data.

There were some differences in the spread of baseline characteristics between Years 1 and 2, however these were not statistically significant (current smoker, $p = 0.311$; location of infarction, $p = 0.2$; previous MI, $p = 0.184$).

Although consistent throughout the two years studied, analysing time to ST segment resolution may be limited by the initial lack of standard timing in the performing of post-thrombolysis 12 lead ECGs. This has been resolved and ECGs are now routinely performed at 90 and 180 min post drug administration.

Thirty-one percent of the patients in Year 1 were involved in a clinical trial, which may potentially prolong DTD times due to the randomisation and enrolment process. In Year 1 however, the 31% of patients in the ASSENT-3 trial had a median DTD time of 78 min; while the 69% of patients not involved had a median DTD of 80 min.

Conclusions

Door-to-Drug time is a cardinal component in the successful treatment of STEMI which helps achieve

optimal outcome in mortality and morbidity, and is also an indicator of system efficiency. Reducing Door-to-Drug time has been a problem for many centres (Hourigan et al., 2000). Although achieving marked reductions, reported similar studies continued to have DTDs in excess of 30 min (Kendall and McCabe, 1996; Hourigan et al., 2000; Edhouse et al., 1999; Nee et al., 1994). A reduced DTD time leads to a reduced Pain-to-Drug time (Hourigan et al., 2000), a more accurate marker of the duration of ischaemia.

This comparative study, shows worthwhile improvement in the management of acute myocardial infarction, by the introduction of a package of measures directed at reducing DTD time and adherence to international guidelines.

Education and training, fostered by a dedicated Chest Pain Nurse Specialist, based in the ED, is essential in promoting the teamwork necessary to significantly improve the ED management of AMI. Promulgation of guidelines for the management of acute coronary syndromes has a major impact, particularly in a clinical area (the ED) previously unfamiliar with the routine urgent administration of thrombolytic agents and intravenous β -blocking drugs.

Changing the site of thrombolysis from the CCU to the ED was the primary contributor to the reduction in DTD time in this study.

The combination of measures used in this study, facilitated by a user-friendly single bolus thrombolytic agent, improved DTD time for acute MI patients, and significantly reduced the time to ST segment resolution.

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Using pressure dressings after femoral artery sheath removal

Patients undergoing cardiac catheterisation may experience haematoma, bruising and vascular sequelae after femoral artery sheath removal. A study in one centre investigated the routine use of pressure dressings to prevent such problems

Only one previous study has been performed to assess the efficacy of pressure dressings after removal of a femoral artery sheath.

The results of a 739-patient randomised study show there is no benefit in the routine application of pressure dressings after arterial sheath removal.

This practice can be abolished with no negative impact on patient safety.

FEMORAL ARTERY SHEATH REMOVAL, VASCULAR COMPLICATIONS, PRESSURE DRESSINGS, CARDIAC CATHETERISATION

Coronary angiography has evolved rapidly since its inception in the late 1950s, and percutaneous transluminal coronary angioplasty has revolutionised the management of coronary disease since first being described in 1977 (Uretsky, 1997). Advances in radiology, cardiac catheter, balloon and stent technologies are well documented in cardiology research (Uretsky, 1997; Grossman and Baim, 1996; Braunwald, 1996; Sigwart et al, 1987).

Documented complications of cardiac catheterisation as a result of femoral artery puncture include haematoma, bruising and vascular sequelae (De Bono, 1993).

Background

At the Royal Infirmary of Edinburgh, traditional practice dictated that pressure dressings were routinely applied to all patients after removal of a femoral artery sheath. An extensive literature review found few randomised studies outlining the most appropriate management of the arterial puncture site and only one (Christenson et al, 1976) studying the efficacy of pressure dressing application to the arterial puncture site. It is estimated that material and staff costs (three minutes of E-grade nurse time) within our centre are £1250 a year, mainly accounted for by the elasticated adhesive tape used. There is also evidence of patient discomfort and tape injuries (Blankenship et al, 1991).

Following correspondence, including completion of a questionnaire, with 20 of the UK's leading catheterisation laboratories it was discovered that 17 (85%) use either a Bandaid plaster or leave the puncture site uncovered. The other three centres (15%) routinely engage in the use of pressure dressings. The choice of dressing in these centres was decided by local policy and, although 50% of the centres audit complication rates, none had per-

formed a comparative study of the two options.

To facilitate the implementation of research-based practice, staff embarked on a six-month randomised study to determine if there was a statistically significant difference in haematoma, bruising and vascular sequelae in the pressure dressing and Bandaid groups. For the purposes of the study, a haematoma was defined as a swelling containing clotted blood. Bruising was defined as abnormal discoloration of skin around the puncture site. Vascular sequelae were understood to be complications arising in and around the femoral arterial vasculature as a result of arterial puncture, for example, pseudoaneurysm or a retroperitoneal bleed (Weller, 1997).

While conducting the study the researchers were mindful of the Department of Health's White Paper (DoH, 1998) describing direct patient involvement in changes in practice in health care. The DoH's aim was that 'surveys will give patients a voice, shaping practice in the NHS'. The DoH also stated that the experiences of people who use the NHS should form an important element of any assessment of its performance. The potential for improvement of patient experiences was of primary importance.

Improving the patient's experience was particularly relevant with respect to the documented evidence of patient discomfort and tape injuries mentioned by Blankenship et al (1991).

Current practice

The caseload of the catheterisation laboratory, a tertiary referral centre, consisted of elective and emergency, day-case and inpatient, diagnostic and interventional procedures. Sheaths from diagnostic catheterisation patients who had not received low-molecular-weight heparin (LMWH) were

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removed in the catheterisation laboratory recovery area immediately after the procedure by a nurse or doctor. Manual pressure would be exerted over the puncture site for 10 minutes before assessment of haemostasis. Patients receiving LMWH or intravenous heparin before diagnostic angiogram were returned to the cardiology wards, where the sheath was removed by medical or nursing staff in the same manner. Sheaths were removed from patients receiving LMWH eight hours after their last dose and from patients on intravenous (IV) heparin when the activated partial thromboplastin time (APTT), taken four hours after discontinuation of the infusion, was a ratio of 1.8 or less. Patients undergoing coronary intervention (such as balloon angioplasty or intracoronary stenting) were routinely given 10 000 units of IV heparin and their APTT was checked four hours later. Again, the sheath was removed if the APTT was 1.8 or lower. Patients undergoing interventional procedures had manual pressure applied for 15 minutes before assessment of stasis.

Study design

Of the 739 patients undergoing diagnostic catheterisation or interventional procedures at the Royal Infirmary of Edinburgh between October 1998 and February 1999, 654 (88.5%) were studied. Those included met the criteria of a procedure being performed through a 7 French gauge sheath (11cm) and complete data being available.

The data set collected for each patient included three information sheets:

- One from the cardiac catheterisation laboratory, containing demographic, clinical and procedural data
- One from the ward area to which the patient returned, containing sheath removal and immediate complication data
- One from the patient, recording bruising and haematoma information.

Patients were randomised into pressure dressing and no pressure dressing groups by using Yes/No cards. The health-care professional responsible for removing the arterial sheath and applying manual pressure was not permitted to view the card allocation until stasis was achieved, to prevent any possible bias. Only then did the patient receive either a pressure dressing or Bandaid.

Procedures

The following procedures were undertaken:

Dressing application To ensure uniformity of treatment, protocols detailing the desired application technique were distributed to all practitioners undertaking sheath removal. The dressing

consisted of two gauze swabs, folded and placed over the puncture site. A strip of 7.5cm elasticated adhesive tape was applied with the patient lying at 30-45 degrees on the left side (assuming right-sided puncture as the norm). The strip was placed in the lumbar area, right of the midline, and the tape was then smoothed down along the flank and over the folded gauze. With the patient now supine, the hip was flexed and abducted, and the tape advanced underneath and then over onto the anterior aspect of the mid-thigh. A second strip was then applied over the first. Haygood et al (1993) describe how pressure is then applied downwards onto the site by straightening the leg, offering pressures ranging from 10 to 60mmHg.

Post-procedural regimen After diagnostic catheterisation patients underwent bedrest at increasing degrees of elevation over three hours, then sat up in a chair for one hour before gently mobilising. After coronary intervention, patients underwent bedrest at increasing degrees of elevation after sheath removal for eight hours, sat up in a chair for one hour, and then gently mobilised.

During this period the after-care protocol stated that the puncture site, distal pulses and blood pressure be recorded every 30 minutes for two hours, then hourly for two hours in patients undergoing diagnostic catheterisation and hourly for four hours in patients undergoing intervention.

Data collection

Patients in the study were given a letter describing the project and instructing them to examine the femoral puncture site. A grid of 1cm squares was printed on an A4 sheet and the patient was asked to draw the outline of any bruising on this. A haematoma was described as a lump under the skin at the site, and this was to be drawn at its actual size and shaded in.

Whether at home or as an inpatient, it was thought that discoloration should be at its peak at around 72 hours after the procedure and patients were therefore instructed to make the assessment at this point.

A stamped addressed envelope was provided for the return of the form and any non-returns were followed up with a telephone call for a verbal description of the assessment. The total area of any bruise or haematoma was recorded in cm² on the study database.

Clinical sequelae such as rebleed, pseudoaneurysm, peripheral embolism, retroperitoneal bleed, subsequent radiology or surgical referral/procedure or blood transfusion were recorded from the medical notes. Possible confounding variables were recorded for each study group:

Table 1. Baseline characteristics in the two treatment groups

	Pressure dressing	
	Yes	No
Gender (male)	221 (67%)	223 (66%)
Age	62 (30-91)	62 (34-89)
Height (cm)	170 (140-186)	170 (115-196)
Weight (kg)	76 (46-116)	76 (42-131)
Body mass index	27 (18-40)	27 (16-42)
Systolic blood pressure	130 (80-220)	130 (78-225)
Diastolic blood pressure	70 (40-118)	70 (40-120)
● Aortic valve disease		
Stenosis	12 (4%)	18 (6%)
Incompetence	6 (2%)	4 (1%)
Both	8 (2%)	3 (1%)
None	312 (92%)	300 (92%)
Procedural factors		
Previous catheterisation	115 (36%)	127 (38%)
● Procedure		
Diagnostic	236 (75%)	249 (74%)
Angioplasty	39 (12%)	50 (15%)
Stent	40 (13%)	38 (11%)
Difficult access	25 (8%)	38 (11%)
● Operator		
Consultant	79 (25%)	85 (25%)
Registrar	237 (75%)	252 (75%)
Sheath removal factors		
● Puller		
Consultant	41 (13%)	57 (17%)
Registrar	108 (34%)	112 (33%)
House officer	81 (26%)	88 (26%)
Nurse	85 (27%)	82 (24%)
Haematoma (immediately after)	24 (8%)	26 (8%)
Haematoma size (cm ²)	7	15
● Manual pressure		
Used	311 (98%)	330 (98%)
Time (minutes)	10 (1-53)	11 (4-45)
Stasis	305 (96%)	326 (96%)
● Mechanical device		
Used	12 (4%)	19 (6%)
Time (minutes)	60 (30-120)	60 (30-120)
Sheath time (minutes)	538 (240-1570)	542 (185-1510)
Since heparin/enoxaparin (minutes)	510 (200-1430)	500 (285-1205)
Drugs given		
Heparin bolus	104 (33%)	109 (32%)
Protamine	23 (7%)	15 (4%)
Reopro	4 (1%)	8 (2%)
Enoxaparin	51 (16%)	47 (14%)
Heparin infusion	11 (3%)	19 (6%)
International normalised ratio (INR)	1.2 (1.0-1.9)	1.4 (1.3-1.9)
APTT	1.1 (0.6-1.7)	1.0 (0.8-1.7)

- Demographics (age, gender, body mass index)
- Clinical status (blood pressure, previous femoral artery puncture, aortic valve stenosis, incompetence or both)
- Procedural factors (diagnostic or intervention, duration, difficulty of access and operator status)
- Post-procedural factors:
 - sheath puller status (consultant, registrar, senior/junior house officer, nurse)
 - sheath *in situ* time
 - time to stasis
 - mechanical device use: a rigid plastic brace with a soft, plastic, hand-operated, air-inflated disc placed superior to the puncture site, held in place by a belt placed under the sacrum and inflated
 - use of anticoagulant and antiplatelet drugs.

These factors were compared between the two treatment groups using chi-squared tests for categorised variables and the Mann-Whitney test for quantitative variables. There were no significant differences between the groups in any of these factors, suggesting the informal method of randomisation had achieved satisfactory balance (Table 1).

Results

Of the 338 patients who received a pressure dressing, 201 (61%) reported bruising, median size 19cm², and 59 (19%) reported haematoma, median size 4cm².

Some 181 (59%) of the 316 patients who received no pressure dressing reported bruising of median size 30cm² and 45 (15%) recorded haematomas of median size 3cm². There was therefore no significant difference between the groups for either the incidence or the size of bruising or haematoma.

There was no reported incidence of peripheral embolism or retroperitoneal bleed; however, one patient from the study required a blood transfusion (pressure dressing group).

Of the patients who rebled after stasis had been achieved, seven (2.2%) were in the no pressure dressing group and 10 (3%) were in the pressure dressing group.

Pseudoaneurysm occurred in one patient (from the no-pressure dressing group) which was compressed under ultrasound guidance.

Of the three patients (0.9%) with pseudoaneurysms in the pressure dressing group, one had this compressed with ultrasound guidance and two underwent surgical repair.

The radiology department was asked to diagnose vascular complications in three (0.9%) of the no pressure dressing group and eight (2.4%) in the pressure dressing group.

Three (0.9) of the no pressure dressing group and eight (2.4%) of the pressure dressing group

Table 2. Outcomes in the two treatment groups

Outcome	Pressure dressing	
	No	Yes
Rebleed	7 (2.2%)	10 (3%)
Radiology (consultation only)	3 (0.9%)	8 (2.4%)
Radiology (procedure)	1 (0.3%)	1 (0.3%)
Surgery (consultation only)	1 (0.3%)	4 (1.2%)
Surgery (procedure)	0	2 (0.6%)
Pseudoaneurysm	1 (0.3)	3 (0.9%)
Embolism	0	0
Retroperitoneal bleed	0	0
Blood transfusion	0	1 (0.3%)
Any sequelae	9 (2.8%)	16 (4.7%)
Haematoma present	45 (15%)	59 (19%)
Haematoma size (cm ²)	3	4
Bruise present	181 (59%)	201 (61%)
Bruise size (cm ²)	30 (1-1370)	19 (1-501)

had haematomas which were the primary reason for an extended hospital stay.

There were no significant differences between the two groups for individual sequelae or with the total incidence of sequelae, which was nine (2.8%) of the no pressure dressing group versus 16 (4.7%) of the pressure dressing group (Table 2).

The power of the study has a confidence interval

for the odds ratio of any sequelae in the pressure dressing as compared with the no pressure dressing group of range 0.74 to 3.89.

Conclusion

Our results indicate clearly that there is no statistically significant difference in clinical sequelae, haematoma or bruising, when comparing pressure dressing with Bandid groups after removal of femoral artery sheaths. There would even appear to be a trend of problems occurring more frequently in the dressings group (2.8% vascular sequelae in the no dressing group as opposed to 4.7% in the dressing group), although there was no significant difference for any individual or combined sequelae. From this, we would submit that the routine use of pressure dressings in all patients after arterial sheath removal is unnecessary and that the practice affords no benefit to patients or staff.

After disseminating the study results to medical and nursing colleagues, it was decided to discontinue the use of pressure dressings on all patients undergoing cardiac catheterisation. In future, staff time, patient discomfort, tape injuries and £1250 a year will be saved in this and other hospitals. PN



Nice guidance on the investigation of chest pain

Keith A A Fox and Scott McLean

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Nice guidance on the investigation of chest pain

Keith A A Fox, Scott McLean

The NICE guidance on chest pain provides a structured and evidence-based approach to the diagnosis and triage of patients with chest pain and provides a series of improvements on the status quo.¹ However, the challenge is the high prevalence of occult vascular disease in our community, especially in older people and at younger ages in men than in women. There is also a high prevalence of chest pain (20%-40% of the population)²⁻⁴ but this is frequently non-cardiac in origin. Among those presenting to their primary care doctor with chest pain, the final diagnosis was not ischaemic heart disease in 83%.³ Nevertheless, because of the high prevalence of asymptomatic coronary disease *there may be an unintended consequence: detection of incidental non-obstructive coronary disease.* This non-obstructive coronary disease may not have been responsible for the symptoms and may "convert" an individual into a cardiac patient. Further, do we have good evidence that defining the anatomy with CT and angiography in those with non-obstructive disease will change the secondary prevention treatments that should be provided based on the patient's risk factors? From a professional and economic viewpoint we must also consider the implications for changes in clinical practice and the increased demands on finite human and economic resources.

Strengths of the guidance include the emphasis on establishing an early and accurate diagnosis based on clinical, electrocardiographic and biomarker assessments among those presenting with suspected cardiac chest pain (*see page 974*).⁵ Appropriately, there is emphasis on very early identification of ST elevation infarction and on the remainder of acute coronary syndromes (in one diagnostic pathway) and on managing those with stable angina (second diagnostic pathway). The subsequent management

of these conditions is dealt with in separate NICE guidance.^{6,7} The NICE guidance on chest pain also emphasises the importance of providing clear and accurate information to the patients and explanation of the diagnostic pathway.

WHAT IS THE PROBLEM WITH CURRENT MANAGEMENT OF CHEST PAIN?

As approximately a quarter of all emergency hospital admissions are for chest pain,⁴ robust triage pathways and accurate diagnostic tools are of major importance. International publications show that the diagnosis of acute myocardial infarction (MI) is missed and a patient discharged in approximately 2% of cases,^{8,9} and many patients are left with diagnostic uncertainty about whether the pain is of cardiac origin, even when infarction is "ruled out". Although ST elevation infarction can be identified with high diagnostic accuracy based on the ECG and clinical findings, non-ST elevation MI has less specific ECG changes and the threshold for differentiation from unstable angina is dependent on the sensitivity of the biomarker (troponin) assay. Further, troponin elevation does *not* equal infarction: several non-coronary causes of myocyte necrosis may precipitate troponin elevation (for example, arrhythmias, heart failure, myocarditis, pulmonary embolism).¹⁰ Hence, improved triage and diagnosis pathways are needed.

Without a systematic and evidence-based approach to differentiating chest pain and establishing a diagnosis, the patient and the patients' carers may be left in limbo. For example, a discharge statement, "chest pain MI excluded", is unhelpful as it does not establish a positive diagnosis and does not exclude prognostically important or other symptomatic coronary heart disease. Furthermore, inadvertent discharge of patients with acute coronary syndrome (ACS) or with MI is well documented.^{8,9} For example, in a study of patients presenting to emergency departments in 10 US hospitals (10 689 patients), 2.1% of those with acute infarction were mistakenly discharged home and 2.3% of those

with unstable angina were mistakenly discharged.⁹ The advent of more accurate and specific biomarkers of necrosis has improved diagnostic accuracy but currently requires a prolonged period of about 12 h of observation. However, even in the absence of biomarkers of necrosis the patient may have obstructive coronary disease with stress-induced ischaemia, and a further proportion have incidental non-obstructive coronary disease unrelated to the presenting symptoms.

The guideline emphasises clinical assessment and a resting 12-lead ECG in the initial investigation of any patient with suspected ACS.⁵ The ECG can be performed in the pre-hospital setting, facilitating early triage, provided that this does not significantly delay transfer to hospital. It is critically important to detect evolving ST elevation myocardial infarction and although the patient may not have diagnostic ST elevation at initial presentation, these signs can evolve over minutes or hours. The retrospective finding of evolved MI the following morning is a serious error and a missed opportunity to salvage myocardium.

DELAYS IN ESTABLISHING THE DIAGNOSIS

Once a patient arrives in hospital the NICE guidance recommends measuring troponin immediately in all patients with a recent episode of cardiac sounding chest pain, but it recognises that repeat sampling 10-12 h after the onset of symptoms is required to exclude MI. Newer very high-sensitivity troponin assays can identify patients earlier (within about 2 h)¹¹ but need testing in large unselected cohorts of patients with suspected cardiac pain. Importantly, the NICE guidance emphasises that troponin should not be interpreted in isolation, but in the context of the clinical history in ECG changes.

DOES THE PATIENT NEED RISK STRATIFICATION?

The NICE guidance on management of non-ST elevation ACS⁷ emphasises the spectrum of risk across the ACS syndrome. In the 12.5% of patients in the lowest eighth of risk the 6-month mortality is <2% (GRACE score <70), whereas in the half of patients with higher risk scores (GRACE score >112) the 6-month mortality is more than fivefold higher (>9.5%). This information will aid clinical decision making. In contrast, patients are currently transferred for

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Table 1 Percentage of people estimated to have coronary artery disease according to typicality of symptoms, age, sex and risk factors²

Age (years)	Non-anginal chest pain				Atypical angina				Typical angina			
	Men Lo	Hi	Women Lo	Hi	Men Lo	Hi	Women Lo	Hi	Men Lo	Hi	Women Lo	Hi
35	3	35	1	19	8	59	2	39	30	88	10	78
45	9	47	2	22	21	70	5	43	51	92	20	79
55	23	59	4	25	45	79	10	47	80	95	38	82
65	49	69	9	29	71	86	20	51	93	97	56	84

For men older than 70 with atypical or typical symptoms, assume an estimate >90%. For women older than 70, assume an estimate of 61–90% except women at high risk and with typical symptoms, where a risk of >90% should be assumed. Values are the percentage of people at each mid-decade age with significant coronary artery disease (CAD). Hi = High risk = diabetes, smoking and hyperlipidaemia (total cholesterol >6.47 mmol/l). Lo = Low risk = none of these three. The shaded area represents people with symptoms of non-anginal chest pain, who would not be investigated for stable angina routinely. **Note:** these results are likely to overestimate CAD in primary care populations. If there are resting ESG ST-T changes or Q waves, the likelihood of CAD is higher in each cell of the table.

Reproduced from NICE guideline: <http://www.nice.org.uk/guidance/CG95>. Adapted from Pryor DB, *et al*¹⁴

angiography largely on the basis of troponin elevation and without priority for the higher-risk patients. The short-comings have been defined of the “binary” approach to chest pain based only on elevated troponin.¹²

DEFINING OTHER CAUSES OF CHEST PAIN

A strength of the NICE guideline is the recommendation that simply excluding acute MI is not sufficient. Other causes of the chest pain need to be considered and managed and a pathway provided for investigation of patients with stable chest pain.

DIAGNOSIS OF ‘STABLE’ CHEST PAIN

The guideline has chosen a diagnostic probability, based on clinical assessment, of >90% likelihood of coronary artery disease (CAD) for diagnostic “rule in” and <10% likelihood of CAD for diagnostic “rule out”. These thresholds are arbitrary, but useful. The guideline has adopted the 1979 Diamond and Forrester criteria¹³ to stratify patients with chest pain into those with typical angina, atypical angina and non-anginal pain. This stratification then combines the clinical features of the symptoms with other factors including age, gender, cigarette smoking, diabetes mellitus, hyperlipidaemia and the presence of ECG changes.⁵ The guideline should be commended for re-emphasising the importance and positive predictive value of the clinical history, and for stating explicitly than the diagnosis of angina pectoris can be made on the basis of the clinical history alone.

TESTS FOR CARDIAC PAIN

Two forms of testing are advocated for investigating patients with stable angina thought to be due to CAD: anatomical testing to diagnose coronary arterial

narrowing, and non-invasive functional testing for myocardial ischaemia. The guideline has examined the sensitivity and specificity of tests against a ‘gold standard’ of angiographically demonstrated CAD, but this poses a number of problems because of the high prevalence of non-obstructive and functionally unimportant CAD.

Following clinical assessment the guideline recommends invasive angiography as the most cost-effective first test if the likelihood of CAD is 61–90%, and non-invasive functional testing with either myocardial perfusion scintigraphy with SPECT, stress echocardiography, first-pass contrast enhanced magnetic resonance (MR) perfusion or MR imaging for stress-induced wall motion abnormalities if the likelihood of CAD is 30–60%.¹ If the likelihood of CAD is 10–29% CT scanning is recommended (with 64 slices or above). The guidance suggests that patients with a low likelihood of CAD will not need further testing (<10% likelihood).

IMPLICATIONS OF THESE INVESTIGATION STRATEGIES

There are major implications associated with these recommendations. As can be seen from table 1 of the full guideline a man >65 years with atypical chest pain and no risk factors or a man >45 years with atypical chest pain and risk factors would exceed the 60% probability threshold for angiography. No women with atypical or non-anginal type pain would exceed this threshold. However, all men and women >35 years with atypical angina would exceed the 30% probability threshold for stress imaging if they have risk factors (table 1).¹ The NICE table is based on 1030 patients referred for non invasive testing in an observational study conducted from 1983 to 1985, and only 168 underwent angiography.¹⁴ Those authors acknowledge that severe disease

and left main disease were less reliably predicted than any coronary disease.¹⁴ The extent to which the findings are applicable to CT detection of coronary disease, or current higher-resolution radiological imaging is uncertain. Robust information is required as this formulaic approach to stress imaging and angiography has huge resource implications and may not be in the best interests of patients with atypical chest pain that is likely to be non-cardiac in origin.

THE “OBSOLETE” EXERCISE ECG

Despite its limitations, exercise ECG stress testing is currently widely used in chest pain and general cardiology clinics and although the sensitivity and the specificity are less good than the imaging techniques listed above, a positive test provides a rapid and cost-effective method of demonstrating myocardial ischaemia. Replacing all exercise ECG facilities with sufficient CT and imaging resources (staff and equipment) will be a significant challenge.

THE ROLE OF COMPUTED TOMOGRAPHY

There are important implications for radiation exposure, especially with the older slower 16-slice scanners. For these reasons the guidelines recommends calcium scoring initially, with no further testing if this is zero. The NICE guideline suggests a high degree of diagnostic accuracy with a sensitivity of 99%.¹ However, if the calcium score is >400 the guideline recommends proceeding directly to invasive coronary angiography. Unfortunately, the issues are not as straightforward as suggested by the guideline. For example, there is recent evidence from a multicentre trial using 64-slice CT that a zero calcium score was nevertheless associated with a 50% or greater coronary stenosis in 19% of the population and a 70% or greater coronary stenosis in 15% of the population.¹⁵ The probable explanation is that disrupted plaque may not contain sufficient calcium to be detected in the 64-slice CT. Unfortunately, there were not reliable multivariable predictors, using baseline characteristics, for the presence of coronary lesions, other than presentation to an emergency department (OR=4.7, CI 1.13 to 19.75, p value 0.03).¹⁵ The authors of this publication conclude that a zero calcium score should not be the gatekeeper for coronary angiography. Nevertheless, recent information indicates that among those with a zero calcium score there is a low rate of progression to an elevated calcium score within 4 years.¹⁶

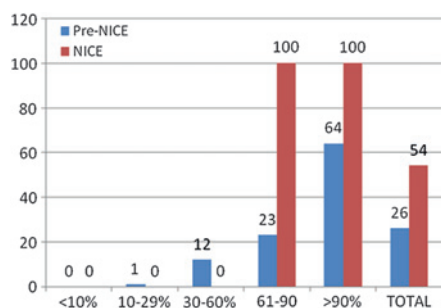


Figure 1 A cohort of 504 randomly selected patients (from 7000) attending the emergency department of the Royal Infirmary Edinburgh with non-traumatic chest pain.¹⁷ Distribution according to the GRACE risk score: 36% low risk (0–15% 6-month death/myocardial infarction (MI)), 33% moderate risk (16–30% 6-month death/MI) and 31% high risk (>30% 6-month death/MI). Pre-NICE, frequency of invasive coronary angiography in clinical practice in 2008; NICE, frequency of invasive coronary angiography proposed in the NICE guideline.¹

WHAT WILL BE THE IMPACT OF THE PROPOSED INVESTIGATIVE STRATEGIES?

The NICE guideline on chest pain, presented personal communications from two of the authors. These suggested that around 29% of patients were in the <10% likelihood of CAD category, 11–17% in the 10–29% likelihood of CAD category, 17–18% in the 30–60% likelihood of CAD category, about 15% in the 60–90% category and 6–9% in the >90% category. However, these figures are not in accord with a published cohort of 504 randomly selected patients from a complete cohort of 7000 consecutive patients presenting to the emergency department with undifferentiated chest pain.¹⁷ Only 3% were in the <10% likelihood of CAD category, 12% in 10–29% likelihood group, 31% in 30–60%

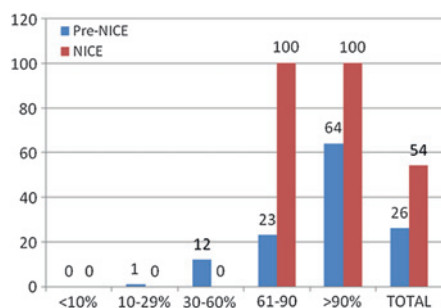


Figure 2 A second cohort of 500 consecutive patients attending the rapid access chest pain clinic of the Royal Infirmary Edinburgh in 2008 (see table 2) Pre-NICE, frequency of invasive coronary angiography in clinical practice in 2008; NICE, frequency of invasive coronary angiography proposed in the NICE guideline.¹

Table 2 A cohort of 500 consecutive patient attending the rapid access chest pain clinic of the Royal Infirmary of Edinburgh in 2009

Typicality of symptoms	n (%)	Investigation	
		Invasive angiography, n (%)	Non-invasive imaging, n (%)
Non-anginal chest pain	112 (22)	4 (4)	6 (5)
Atypical angina	245 (49)	29 (12)	19 (8)
Typical angina	143 (29)	88 (61)	4 (3)
Total	500 (100)	121 (24)	29 (6)

Total estimated to have CAD (%)	n (%)	Investigation Invasive angiography, n (%)	Non-invasive imaging, n (%)	Application of NICE criteria		Difference	
				Invasive angiography, n (%)	Non-invasive imaging, n (%)	Invasive angiography	Non-invasive imaging
<10	41 (8)	2 (5)	3 (7)	0 (0)	0 (0)	–2	–3
10–29	39 (8)	7 (18)	6 (15)	0 (0)	39 (100)	–7	+33
30–60	198 (40)	14 (7)	13 (7)	0	198 (100)	–14	+185
61–90	162 (32)	46 (28)	5 (3)	162 (100)	0 (0)	+116	–5
>90	60 (12)	52 (87)	2 (3)	60 (100)	0 (0)	+8	–2
Total, n (%)	500 (100)	121 (24)	29 (6)	222 (44)	237 (47)	+101 (+20)	+208 (+42)

Percentage increases in the lower table are absolute rather than relative.

likelihood group, 34% in the 61–90% likelihood group and 20% in the >90% likelihood group. The implications based on this published cohort are for a 28% increase in invasive angiography and a 43% increase in non-invasive imaging (figure 1). Likewise, in a second group of 500 consecutive patients attending the rapid access chest pain clinic in our own centre (McLean 2010, manuscript under review) the implications would be for a 20% increase in invasive angiography and a 42% increase in non-invasive imaging (figure 2, table 2).

CONCLUSIONS

The NICE guidance on chest pain provides a series of important advances over the current status of investigation and triage of chest pain and should be welcomed by the profession. The clearer triage pathways and use of more robust investigation tools will lead to improvements in clinical care. However, a serious concern needs to be addressed: the unintended consequence of investigating patients with stress imaging and/or invasive imaging on the basis of their pre-test probability of coronary disease. A high proportion of such disease may be incidental and non-obstructive (even though of prognostic importance) and evidence supports secondary prevention measures on the basis of vascular risk factors, alone. Thus, we must consider the benefits versus potential harm of investigating most men and many women with chest pain and vascular risk factors. We propose that, before widespread adoption, a prospective study is required to test the risk versus benefit of applying this approach.

Competing interests None.

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Diastolic stress testing: a new trick to evaluate the ageing heart

Zoran B Popović, Brian Griffin

Exertional shortness of breath in the absence of an obvious cardiac abnormality is a perplexing and relatively common clinical scenario especially in older patients. These patients often undergo multiple evaluations by different specialists and end up without a definitive diagnosis and, more importantly, without any specific therapeutic target to improve their symptoms. In some of these patients, exercise intolerance is attributed to respiratory disease, in others to deconditioning or obesity and in many diastolic abnormalities are claimed as the underlying problem without substantiating data. In their article in this edition of *Heart*, Tan *et al* describe a study of diastolic function on exercise in a group of patients with treated hypertension without significant diastolic dysfunction at rest whose functional capacity is significantly reduced (*see page 948*).¹ Their findings that these patients exhibit significant abnormalities of diastolic function on limited exercise and that these induced diastolic abnormalities relate to the degree of functional limitation are an important contribution to our understanding of the pathophysiology of functional impairment in older hypertensive patients. This paper also highlights the potential utility of diastolic stress testing as a diagnostic modality in this patient population.

It is not surprising that exercise stress will provoke diastolic abnormalities that are not apparent at rest. Indeed, diastolic abnormalities, as a rule, accompany systolic abnormalities during stress, and

demand ischaemia leads first to diastolic, and then to systolic abnormalities. One can roughly divide diastolic function parameters into ‘traditional’ or ‘hard’, and ‘contemporary’ or ‘soft’ indices. Traditional diastolic function indices are usually considered as measures of relaxation, diastolic stiffness and filling pressure (which results from the interaction of relaxation, stiffness and preload). Relaxation occurs first with mitral valve closure, followed by left ventricular (LV) filling along the pressure–volume curve that is defined by LV stiffness, and finally, results in LV end-diastolic pressure. By default, measuring traditional indices means measuring LV filling pressures invasively, which is impractical in routine clinical diagnostic assessment and is particularly difficult on exercise.

In clinical practice, we most often use ‘contemporary’ indices, almost exclusively obtained by echocardiography. These indices can be considered ‘soft’ as they often reflect factors other than ‘traditional’ indices.² However, ‘contemporary’ indices give us a slightly different description. Here, the diastolic process starts with LV untwisting. This represents the early relaxation of epicardial fibres, which in turn releases the elastic elements within the ventricle and leads to clockwise motion of the apex. This process starts in the second part of the systole, and reaches its maximum at the time of aortic valve opening, preceding the beginning of isovolumic relaxation as defined by ‘traditional’ indices. Next, the mitral valve opens owing to development of LV suction. Suction can be quantified by early diastolic intraventricular pressure gradient, or by its surrogate, colour-M mode flow propagation velocity. This is

followed by downward motion of the mitral annulus and outward motion of the LV wall, which results in the early filling flow through the mitral valve. Of note, all of the previous phenomena occur in this definite order both in sickness and disease, and show some correlation with ‘traditional’ parameters of relaxation. In contrast, the shape of the second half of the early mitral filling wave depends on LV stiffness: the greater the stiffness, the shorter the LV filling.

The biggest drawback of ‘contemporary’ indices is that their values are a result of mixed influences of relaxation, stiffness and filling pressures or even some other parameters, such as LV geometry. A potential strength is that in contrast to ‘traditional’ pressure-based parameters, echocardiography can provide regional estimates of both relaxation and stiffness indices obtained by measurement of regional deformation (strain and strain rate) and velocity. However, the comprehensive non-invasive assessment of diastolic dysfunction is complex and time consuming at rest and becomes more difficult with the effect of increased heart rate with exercise. Fusion of the early diastolic flow velocity and the atrial contraction velocity occurs at higher heart rates and makes their differentiation impossible. Furthermore, obtaining a technically adequate assessment is difficult in a patient who is fighting for breath while exercising.

Despite these difficulties, Tan and colleagues have shown that diastolic stress testing by Doppler echocardiography is both feasible and useful.¹ They compared patients with heart failure and normal ejection fraction (HFNEF) due to hypertension with healthy volunteers. Patients had a much lower exercise tolerance than healthy volunteers, despite being of similar age, gender, blood pressure and ejection fraction. Both groups underwent a challenging exercise protocol of supine symptom limited exercise testing, with the target heart rate of 100 bpm during which two-dimensional, pulsed and colour-M mode Doppler data were collected. The

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Reperfusion of old or new: left bundle branch block?

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Abstract

Reperfusion options for patients suffering ST-elevation myocardial infarction (STEMI) have developed significantly over recent years and now include both thrombolytic therapy and primary percutaneous coronary intervention (PPCI). This system of care means that patients presenting with STEMI can be transferred directly to a heart-attack centre to receive immediate PPCI. National guidelines state that pre-hospital thrombolysis (PHT) is a crucial part of STEMI reperfusion where PPCI cannot be delivered within 90 minutes of diagnosis. There is evidence describing rates of in-hospital thrombolysis in both MI with ST elevation and MI with LBBB. There is a knowledge gap however describing treatment of MI with LBBB based upon a pre-hospital 12-lead ECG. This paper describes the challenges around PHT in the context of LBBB and offers potential solutions that may provide assistance in making the decision to undertake PHT or not.

Key words

- Pre-hospital decision-making
- Primary percutaneous coronary intervention
- ST-elevation myocardial infarction
- Thrombolytic therapy
- 12-lead ECG

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Prevention and treatment of coronary heart disease (CHD) remains a significant challenge for the NHS across the UK. Data from 2006 suggests that CHD was the most common cause of premature death in the UK, with more than 31 000 premature deaths being attributed directly to heart disease. CHD accounts for around 19% of premature deaths in UK men and 10% in women (British Heart Foundation, 2006).

Although these figures are disturbing, in reality, many patients with CHD manage their condition well, with varying levels of support from relatives, friends and NHS services. However when these patients—or indeed patients with no history of CHD—have an acute episode of ischaemic chest discomfort, emergency care is generally sought.

Because of the time-critical nature of the condition, much effort has been placed on ensuring that these patients receive prompt evidence-based care both before they get to hospital and in the hospital itself.

Scotland historically has one of the highest incidences of CHD in Western Europe (Scottish Public Health Observatory, 2009). However, recent data has shown a 49% reduction in mortality rates for CHD between 1995 and 2007 (now at 61 per 100 000 population) and a 3% reduction in mortality rates from acute myocardial infarction (AMI) between 2006 and 2007 (now at 69 per 100 000) (Information Service Division Scotland, 2007).

Data from the Scottish Ambulance Service (SAS), one of the UK's largest ambulance services, showed that they responded to more than 27 000 emergency calls for chest pain during 2007–2008. 'Chest pain' was cited as the most common reason for category A (999) calls in Scotland during this period (Scottish Ambulance Service, 2008). Not all these calls, however, were directly related to coronary heart disease. Studies have shown that fewer than 60% of calls with 'chest pain' were triaged by emergency medical despatch centres (EMDC) to be cardiac or potentially cardiac related, and that only 0.6% of 999 calls to ambulance services result in an in-hospital diagnosis of acute coronary syndrome (Deakin et al, 2006).

Advances in pre-hospital emergency care of acute coronary syndrome

Pre-hospital emergency management of acute coronary syndrome (ACS) has developed significantly over recent years.

Such advances have occurred in paramedic practice via extended training/education packages and the development and introduction of national clinical guidelines by the Joint Royal College Ambulance Liaison Committee (JRCALC, 2006). Significant progress was made in Scotland during 2003–2004 when the SAS introduced pre-hospital thrombolytic therapy (PHT), supported by a national training and education programme. The combination of extended training, a robust clinical guideline and 12-lead electrocardiogram (ECG) telemetry allowing shared decision making with critical care unit (CCU) staff enabled paramedics to consider delivery of

thrombolytic agents to patients with ST elevation myocardial infarction (STEMI) and to symptomatic patients with new left bundle branch block (LBBB).

Both prior to and since its introduction, a strong evidence base has developed around PHT. Data has been published on paramedics' ability to recognise the ECG changes of STEMI (Pitt, 2002; Whitbread et al, 2002), the resultant reductions in 'door-to-needle' and 'call-to-needle' times (Weaver et al, 1993; McLean et al, 2008) and the positive impact on patient outcome (author not known, 1993). Meta-analysis has shown that patients given thrombolysis in a pre-hospital setting have a 17% lower mortality rate than those who receive it only when they get to hospital (Morrison et al, 2000).

As evidence and international guidelines have evolved, reperfusion options for patients suffering STEMI now include both thrombolytic therapy and primary percutaneous coronary intervention (PPCI) (Van de Werf et al, 2008). This system of care means that patients presenting with STEMI can be transferred directly to a heart-attack centre to receive either immediate PPCI or, in the event of failure to reperfuse adequately following PHT, 'rescue PCI'. This is defined as an emergency PCI procedure performed following administration of thrombolytic therapy which has failed to reduce ST-segment elevation by >50%. National guidelines state that PHT is a crucial part of STEMI reperfusion where PPCI cannot be delivered within 90 minutes of diagnosis (Scottish Intercollegiate Guidelines Network, 2007).

Although the important role of PHT has been stated, there are suggestions that pre-hospital guidelines produced by JRCALC actually restrict PHT rates for STEMI to around 14% (Castle et al, 2006). However, in a recent study undertaken in south-east Scotland, which involved collaborative decision-making between paramedics and CCU nurses, an impressive 27% of patients presenting with STEMI had received PHT (McLean et al, 2009). It was expected, however, that these rates would fall once PPCI was made available 24/7. Recent SAS audit data has shown that, in 2008–2009, of the 1 248 patients diagnosed with STEMI, only 7.2% ($n=177$) received PHT.

There is a lack of published evidence describing whether or not patients with a pre-hospital 12-lead ECG showing LBBB are as likely to be considered for reperfusion treatment with either PHT or PPCI, as patients presenting with MI with ST elevation. Anecdotal evidence in parts of Scotland, however, suggests that direct transportation to the heart-attack centre and/or administration of PHT depends very much on geographical location, with some patients presenting with LBBB still being transported to local emergency departments or critical care units.



Paramedic reading ECG: 12-lead ECG telemetry, allowing shared decision making with critical care unit staff, enables paramedics to consider thrombolysis before cardiac patients reach hospital.

In Scotland, during 2008–2009, only 2.5% ($n=61$) of patients with ACS were diagnosed with LBBB, with just 0.6% of these ($n=1$) receiving PHT (Monteath, personal communication, 2009). The apparently small number of patients presenting with LBBB and receiving PHT is concerning, particularly when this sub-group of patients is the most likely to benefit from prompt reperfusion therapy (Reuben and Mann, 2005).

Challenges of LBBB and STEMI reperfusion therapy

There are a number of challenges in delivering reperfusion therapy to patients with LBBB.

The first relates to difficulties in identifying LBBB changes on the 12-lead ECG. This is well documented in the literature (Brady and Aufderheide, 1997; Edhouse et al, 1999). There is some evidence, however, that suggests that paramedics perform as well as their emergency department colleagues when interpreting 12-lead ECGs (Whitbread et al, 2002). Although this evidence does not specifically relate to LBBB, it could be argued that the concept is transferable.

SAS paramedics have received training and education on the identification of both LBBB and STEMI, which aims to minimise uncertainty around diagnosis/recognition. However, as stated above, delivery of PHT by paramedics—and therefore use of these skills—has depended very much on geographical location, ranging from 40% of STEMI in some regions to <5% in others. This presents



Patient undergoing PPCI in the cath lab: direct transportation to such a centre can depend on location – many patients are taken to emergency departments or critical care units.

significant challenges for both training departments and operational managers.

Recognition of LBBB

Under normal circumstances, the heart's ventricles are depolarized rapidly through specialised conduction tissue. If one or other of the bundle branches fails to conduct, however, activation of the ventricle normally supplied by that bundle occurs by spread of depolarization from the other ventricle.

It is the delayed activation of that ventricle that results in the broadening of the QRS complex beyond the upper limit of normal (Colquhoun, 1998). In the normal heart, the time taken for the depolarization wave to spread from the interventricular septum to the furthest part of the ventricle is no more than 0.12 seconds, or three small squares on ECG paper (Hampton, 1996). Providing it is preceded by a P wave, a 'wide' QRS (>0.12 seconds) is indicative of a left bundle branch block (Hampton, 1996).

In LBBB, the initial small negative Q wave normally seen in the left ventricular leads (V_5 , V_6 , lead I and aVL), is replaced by a larger positive R wave (Bennett, 1993). The QRS complexes in these leads can show what has been described as a 'M-shaped' pattern (Colquhoun, 1998) as demonstrated in lead aVL of *Figure 1*. The

broad QS complex in lead V_1 is also characteristic of LBBB (*Figure 1*).

Comparison of presenting ECG with previous ECGs

Assuming the paramedic/clinician is competent in identifying LBBB on the 12-lead ECG, the next stage requires the clinician to determine whether the presenting changes of LBBB are new or old. This is incredibly difficult, particularly in patients who have pre-existing coronary heart disease, heart valve disease, cardiomyopathy or hypertension.

This decision, however, may be simplified in hospital (where patient records are often available) by comparing the presenting 12-lead ECG with an older one (Evans et al 2008). Unfortunately, previous ECGs are generally not available in pre-hospital settings and, on occasions, even in the emergency department, obtaining records containing ECGs can prove to be problematic, potentially resulting in delays in time-dependent treatments/interventions.

Consequently, when previous records are not available, both ambulance and hospital clinicians can be left with a decision-making dilemma, i.e. whether or not to consider the LBBB as a new finding and deliver reperfusion therapy.

This dilemma can be compounded by reduced confidence levels as a result of infrequent exposure to this group of patients (Rajabali et al, 2009). There are reports that the average UK paramedic sees fewer than one patient a year with STEMI who is suitable for PHT (Fairhurst, 2006).

It has previously been suggested that, when ambulance paramedics are faced with this dilemma, they often default towards the 'do no further harm' and 'risk averse' ethos of their training/education (Humphrey et al, 2005), which, in this case, results in patients with LBBB not receiving reperfusion treatment.

Anecdotal evidence from SAS ambulance paramedics suggests that symptomatic patients with LBBB are not receiving prompt reperfusion therapy because of difficulties in determining whether or not the ECG appearance is new or old (SAS, personal communication, 2009).

Available solutions

A potential solution to this information deficit has previously been described in recommendations made by the Scottish Intercollegiate Guidelines Network (2007). *Acute Coronary Syndromes* states that 'patients with persisting bundle branch block or ST segment change should be given a copy of their electrocardiogram to assist their future clinical management should they present with a suspected acute coronary syndrome'.

Although these recommendations were published in February 2007, audit data from one of Scotland's

main STEMI-receiving hospitals suggests that CHD patients continue to be discharged without copies of their 12-lead ECG (Scott, personal communication, 2009). The reasons for this may be multi-factorial and include shortening length of hospital stay, poor communication and lack of prioritization of this recommendation among the milieu of others. Furthermore, there is no published data reporting the retention and safekeeping of the ECG by patients discharged from cardiology units.

The second solution, which is freely available on the market, is digital ECG archiving. While there are a number of centres across the UK using this technology, there are few systems if any that have smooth communication links between pre-hospital ECG technology, in-hospital technology and digital archiving. The gold standard utilisation of this technology is described in *Figure 2*, shown overleaf, as observed on a visit to the STEMI reperfusion programme in southern Sweden (McLean, personal communication, 2009).

Conclusions

The pre-hospital environment has many challenges, particularly in relation to reperfusion of ST elevation myocardial infarction. With the increasing availability of PPCI, fewer patients presenting with STEMI appear to be receiving PHT. While this will inevitably result in reduced exposure to the bolus administration of thrombolysis for paramedics, it is vitally important to focus on the role of the paramedic in contemporary STEMI reperfusion.

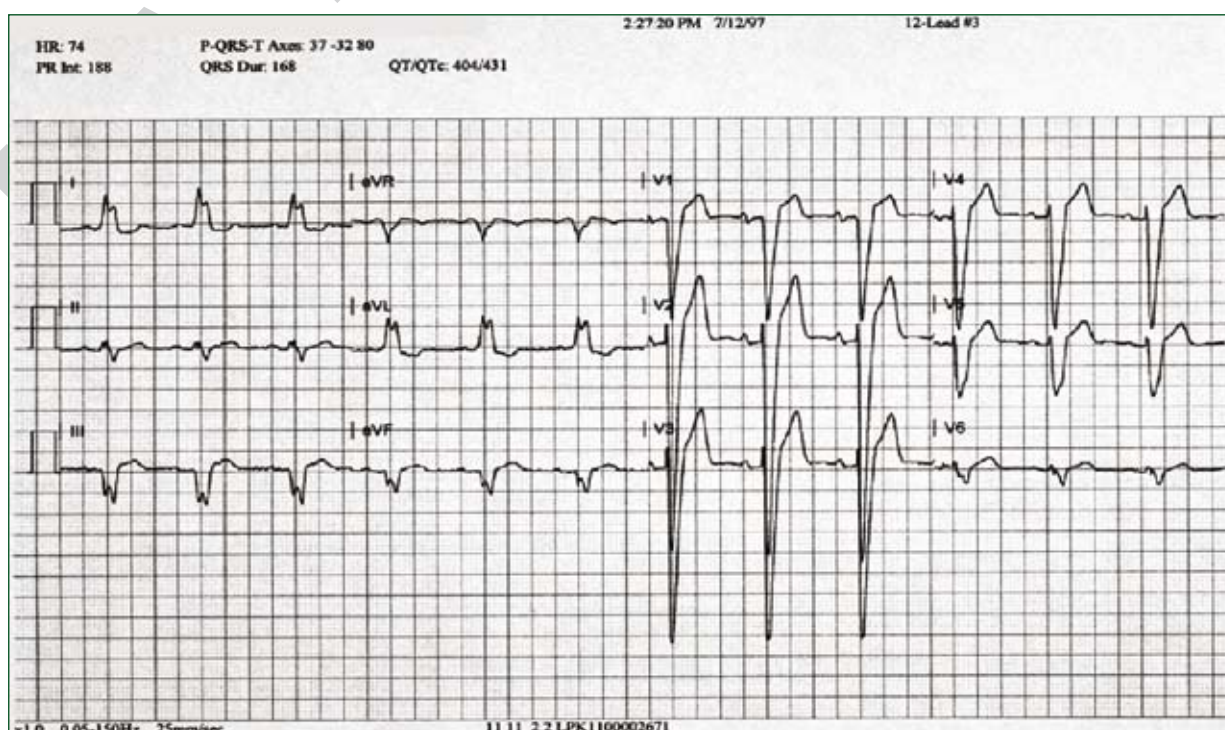


Figure 1. 12-lead ECG showing left bundle branch block.

Figure 2. Case study: Benefits of digital 12-lead ECG archiving in a patient with pre-existing left bundle branch block

Setting	Coronary Care Unit, University Teaching Hospital, Linköping, Sweden
Presenting scenario	Ambulance crew attend a 64-year-old male at home. He has telephoned emergency medical services with a one-hour history of crushing central chest pain. He has never experienced chest pain previously.
Previous medical history	Hypertension Right total hip replacement (one year previously) Gastro-oesophageal reflux disease.
Pre-hospital assessment	Ambulance crew assess patient as having 'likely acute coronary syndrome'. As part of assessment, the crew perform a 12-lead ECG which shows LBBB. The crew transmit the ECG via GPRS-based telemedicine to the critical care unit (CCU).
In-hospital assessment	Within 10–15 seconds of the pre-hospital ECG arriving on the CCU computer screen, and alert flashes on an adjacent screen showing a hard copy of the last ECG the patient had performed in that health board area. The ECG pulled-up from the orthopaedic clinic one year previously showed LBBB.
Decision making	The ambulance crew and CCU agree that reperfusion therapy is not indicated at this stage and organise direct transfer to the CCU. This decision is based on the fact that the LBBB appearance is old.
Discharge diagnosis	The patient was discharged from hospital six days later having been treated successfully for a pulmonary embolism. He was discharged on lifelong warfarin treatment.

While the 10-second intravenous bolus of tenecteplase may be given less often, the importance of timely and accurate assessment, diagnosis and communication with hospital-based colleagues is arguably even more important than in the era where PHT was the sole tool available to the paramedic. In essence, the paramedic will now begin the reperfusion cascade for over 80% of patients with STEMI, rather than for the <20% who received PHT. This can only be of benefit to patients.

As this article highlights, it is increasingly important that essential information is made available at the point of care, whether the home or the emergency department, which can directly assist with the decision to deliver reperfusion or not. In symptomatic LBBB, it is essential to know whether the 12-lead ECG changes are new or old. Having information immediately available will help ensure that patients with myocardial infarction receive appropriate life-saving treatment at the earliest opportunity. It is clear that improvements are required around the sharing of patient-specific information between professions and organizations.

To support and encourage future sharing of information it would seem sensible to implement the SIGN (2007) recommendation of the introducing of a robust, credit-card-sized 'LBBB alert' card (or, indeed, pocket-sized ECG print-out) for all CHD patients with known LBBB. This may help ensure

that patients with pre-existing LBBB are not exposed to either the haemorrhagic risks associated with PHT or unnecessary fear and worry that must surely be provoked by direct/emergency admission to the cardiac cath-lab at 2am for PPCI.

Future research

Given the difficulties involved in determining the electrocardiographic diagnosis of MI in patients with pre-existing or previously unknown LBBB, our group intends to explore this area further. We intend to investigate the predictive value of novel ECG scoring criteria designed for in-hospital use, and how this correlates with a hospital discharge diagnosis of myocardial infarction when applied to pre-hospital 12-lead ECGs.

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Key points

- Although chest pain is the most common reason for calling ambulance services, fewer than 1% of calls end in a diagnosis of acute coronary syndrome.
- The evidence for pre-hospital thrombolytic therapy is well established, but only a minority of patients with ST elevation myocardial infarction receive it.
- There is a lack of research describing or evidence on the reperfusion of patients presenting with a 12-lead ECG appearance of left bundle branch block.
- Healthcare professionals, particularly in pre-hospital settings, are challenged when trying to determine whether or not findings of left bundle branch block are new or old.
- In addition to in-hospital moves towards ECG archiving, there may be value in exploring alert cards for patients with pre-existing left bundle branch block to assist pre-hospital clinicians in decision-making.

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Clinical history versus the exercise ECG in assessment of stable coronary artery disease

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While it is disappointing to note that a trawl of the world-wide-web still yields results of peer-reviewed publications directly comparing the abilities and outcomes of nurses versus doctors (Munday et al, 2007), or more popular press such as 'Do you prefer doctors or nurses?' (BBC News website, 2002), it is slightly more reassuring that the majority of these pieces were published in the earlier rather than the latter part of this decade.

There are a host of publications from within our own specialty that demonstrate the benefits, non-inferiority or superiority of services provided by cardiovascular nurses (Pottle, 2005; Mullan et al, 2007; O'Neill and Currie, 2007). The majority of these reports highlight the key role of education and training in preparing nurses for these roles, hitherto the domain of medical colleagues.

Paradoxically, one may argue that the very difficult and important skill of clinical history-taking is not one covered in generic nursing courses. The teaching of this skill remains the domain of either undergraduate medical training or specialist postgraduate nursing training. Indeed while Ramani (2004) states that the patient history is a truly vital piece of the patient encounter and helps lead to the final diagnosis approximately 75% of the time, he also states that skilled history-taking is reported to be declining among medical trainees and that current educational methods do not emphasize these skills during medical school training. There are few reports in the nursing literature describing the training in, quality of, or assessment of clinical history-taking by nurses. Given the ever-increasing number of clinical services provided by nurses (Albarran and Tagney, 2007) some may find this worrying.

The emphasis on history-taking in coronary artery disease

It is therefore important to elicit relevant and specific information from the patient that will inform the differential diagnosis of their chest pain (Albarran and Tagney, 2007: 23).

While it is a definition the cardiovascular nurse may have heard many times, it is important that we remember

that angina pectoris is in fact 'the symptom of oppression, pain or tightness in the centre of the chest' (Youngson, 1992). Angina pectoris is the term applied to the symptoms of certain types of chest pain: it is not a diagnosis (Forfar and Firoozan, 1995).

Coronary artery disease (CAD) on the other hand could be defined as 'stenosis of the coronary arterial lumen caused by atheromatous plaque' (Timmis and Nathan, 1988). Significant confusion arises when the two terms ('angina' and 'CAD') are used interchangeably. The guideline development group responsible for the consultation version of the National Institute for Health and Clinical Excellence (NICE) guideline for chest pain of recent onset acknowledged this (National Clinical Guidelines Centre for Acute and Chronic Conditions (NCGC), 2009). They stated that the term angina is used to describe two different concepts. The first is the use of the term 'angina' as a symptom, and the second is the use of 'angina' as a description for CAD. They state that the reason for this

ABSTRACT

Reports highlighting the benefits of 'nurse-led' services invariably emphasize the importance of education and training. There is however a dearth of literature describing the training in or quality of clinical history-taking among cardiovascular nurses. Recent publications and forthcoming national guidance will re-emphasize the importance of clinical history-taking, and that the diagnosis of angina pectoris can be made solely on the basis of the presenting patient history. Furthermore, evolving guidance will discourage clinicians from using the exercise ECG as the primary diagnostic test for myocardial ischaemia. This will result in a significant shift in practice in the majority of centres across the United Kingdom, many of whom have chest pain assessment services led by cardiovascular nurses. If cardiovascular nurses are to claim the contemporaneous role of 'clinician', critical appraisal and preparation for these shifts in practice will be crucial.

KEY WORDS

◆ Nurse-led clinics ◆ Clinical history taking ◆ Angina
◆ Coronary artery disease ◆ Exercise ECG ◆ Non-invasive imaging

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may lie in the fact that angina is the most common consequence of symptomatic CAD in Western society, meaning that health professionals may often ignore the other causes of angina, for example aortic stenosis and hypertrophic cardiomyopathy.

Poor history-taking is largely responsible for the patient's symptoms being falsely attributed to CAD. The translation of the patient's symptoms to a diagnosis requires specific and detailed questioning to elicit the location, quality, duration, severity, frequency, radiation, relieving and provoking factors of the chest discomfort (Diamond and Forrester, 1979). The work of Diamond and Forrester (1979) was seminal and was followed by the work of Patterson and Horowitz (1989) who published simple criteria, which at the completion of history-taking would allow the clinician to classify the patient as having:

- (i) typical angina pectoris,
- (ii) atypical chest pain, or
- (iii) non-anginal chest pain (Table 1).

Investigators at Duke University in the United States (Pryor et al, 1989) then developed a nomogram (a graphical calculation aid) to determine pre-test probability of CAD based on classification of chest pain, previous myocardial infarction, ECG findings, presence of diabetes mellitus, age, smoking and serum lipids. While 20 years later we may find this pencil-and-ruler nomogram technique cumbersome and out-of-date, the principles of this method are absolutely key to contemporary practice.

The importance of determining pre-test probability of CAD has been re-emphasized in the draft NICE guidance (NCGC, 2009). This draft document suggests:

- ♦ 20-40% of patients will experience chest pain in their lives
- ♦ Up to 40% of emergency hospital admissions are due to chest pain
- ♦ The diagnosis of angina might be made from
 - ♦ A typical history alone, or

- ♦ The history in combination with functional testing demonstrating myocardial ischaemia, or
- ♦ The history in combination with the finding of significant obstructive CAD, or
- ♦ All three of the above
- ♦ Pre-test probability of CAD should be measured using the Diamond and Forrester (1979) algorithm
- ♦ Where pre-test probability is measured by clinical assessment alone as >90%, this may permit a diagnosis of angina caused by CAD
- ♦ Where pre-test probability is measured by clinical assessment alone as <10%, this may permit a diagnosis of non-anginal chest pain and alternative causes for chest pain should be explored.
- ♦ Where pre-test probability is intermediate (between 10% and 90%) either functional or anatomical testing may help confirm or exclude a diagnosis of CAD. The guideline development group make clear however that demonstrable myocardial ischaemia (functional testing) or demonstrable obstructive CAD (anatomical testing) is neither necessary nor sufficient for a diagnosis of angina. These suggestions are echoed in published guidance elsewhere in the United Kingdom (Scottish Intercollegiate Guidelines Network (SIGN), 2007), which state that diagnosis of angina caused by CAD can often be made on the basis of the clinical history alone. They reinforce that although a number of scoring systems are available to assess patients with chest pain and stable angina, an accurate clinical assessment is of key importance.

Where the guidelines do differ however (bearing in mind that the NICE document is a consultation version only) is in the area of diagnostic testing. SIGN (2007) recommends that:

Patients with suspected angina should usually be investigated by a baseline electrocardiogram and an exercise tolerance test

The draft NICE guidance (NCGC, 2009) on the other hand recommends that clinicians:

Do not use the exercise ECG as the primary diagnostic test for myocardial ischaemia in people without known CAD

This is a significant difference and requires further discussion.

Exercise ECG testing in the diagnosis of stable CAD

The exercise ECG has been widely used across the world as a screening procedure for the assessment of cardiac status since the 1960s (Curzen et al, 1996).

Even very early into its widespread use however it has been the subject of controversy, with investigators questioning its utility in women (Sketch et al, 1975), the elderly (Curzen et al, 1996), specific ethnic groups (Lear et al, 1994), patients with co-existing valvular heart disease

Table 1.
Categorization of chest pain

Chest pain is classified by the following criteria:

1. Precipitation by exercise
2. Brief duration
3. Prompt relief by rest or nitroglycerine
4. Substernal location
5. Radiation from chest to jaw, left arm or neck
6. Absence of other causes of pain

Typical angina pectoris	Criteria 1–3 positive Any four criteria positive
Atypical chest pain	Criteria 4–6 positive Any two criteria positive
Non-anginal chest pain	Only one criterion positive

Adapted from Patterson and Horowitz, 1989

(Aronow and Harris, 1975) and patients taking digoxin (Mooss et al, 1991).

The primary concern regarding exercise ECG testing lies in the sensitivity and specificity.

Sensitivity is a measure of the proportion of true positives which are correctly identified by the test (Altman and Bland, 1994) i.e. 100% sensitivity of the exercise ECG would mean that 100% of patients with CAD would have a positive test. In this ideal world, every patient with a negative ETT could be confidently 'ruled-out' for CAD.

Specificity is a measure of the proportion of true negatives which are correctly identified by the test i.e. 100% specificity of the exercise ECG would mean that 100% of patients without CAD would have a negative test.

Detrano et al (1989) performed a meta-analysis of 60 studies containing 12 030 patients and found reported sensitivities of 41–100% (mean 81%) and specificities of 17–100% (mean 66%) for the exercise ECG. As an example, extrapolation of Detrano et al's meta-analysis to the definitions above would result in 81/100 patients with CAD having a positive exercise ECG (19% 'false-negative'), and 66/100 patients without CAD having a negative ETT (34% 'false-positive').

In Curzen et al's study (1996) the exercise ECG was a misleading predictor of the presence or absence of CAD in 36% of women, with a sensitivity of only 56% and a specificity of 33% in women aged over 52 years with three or more risk factors for CAD. This would mean that the majority of exercise ECG results in this cohort of patients are misleading.

This is made all the more important by the findings of the more recent work of Sekhri et al in London (2007) who found that patients continue to be discharged from the RACPC with an incorrect diagnosis of 'non-cardiac chest pain' and that those diagnosed with non-cardiac chest pain account for up to a third of patients who subsequently die from cardiovascular disease or suffer an acute coronary syndrome over 5 years of follow-up.

What are the alternatives?

There have been large strides in the development of, evidence-base for, and application of non-invasive imaging techniques for the functional and anatomical assessment of CAD. Pooled analysis of over 800 patients (Schroeder et al, 2007) indicates a sensitivity of 89% and specificity of 96% for 64-multidetector computed tomography (CT) in comparison with the gold standard of invasive coronary angiography. According to Achenbach (2006) the most promising application of this technology is in the evaluation of stable patients with possible coronary artery disease.

The NCGC (2009) consultation document describes a plethora of non-invasive investigations including CT coronary calcium scoring, CT coronary angiography, myocardial perfusion scintigraphy, stress echocardiography, contrast-enhanced magnetic resonance perfusion imaging, and several more. While at first this list may seem overwhelming, the guidelines group provide an eloquent description of how these tests may be best used, based on

evidence-base, patient preference, resting ECG abnormalities, co-morbidity and, perhaps most importantly, assessment of pre-test probability of CAD based on the presenting clinical history.

There are many reports of cardiovascular nurses specialising in non-invasive cardiac imaging in the United Kingdom (Royal Brompton and Harefield NHS Foundation Trust, 2009) and further afield (Àvila et al, 2003).

'Nurse-led' cardiac perfusion imaging is now widespread across the UK, although there is little in the peer-review literature describing these services.

Translation to contemporary practice

The journey to today's position whereby there are many chest pain services (whether for acute or stable chest pain) led by cardiovascular nurses was not straightforward. The position of nursing in the multidisciplinary cardiovascular team, education and training, pay and conditions, credibility and validity, and inter-collegial relationships have all been tested en-route. Although not by explicit intent the role of nurses assessing patients with stable chest pain, generally in the rapid access chest pain clinic (RACPC), has in the majority of centres involved interpretation and application of the results of an exercise ECG. However even in one of the first published papers describing 'nurse-led' RACPCs, Pottle (2005) questioned the prognostic value of exercise ECG testing, and described a move to non-invasive anatomical testing.

If for evidence-based and valid reasons, the type of investigations performed on these patients is set to change significantly, it is crucial that nurses assessing these patients evolve accordingly. This will of course mean a critical appraisal and evaluation of the evidence and guidelines. It will also however mean maintaining a focus on the point made in this article—the diagnosis of angina caused by CAD can be made solely on the basis of the presenting history. This will be a test. However, if cardiovascular nurses wish to claim the role of 'clinician,' it is a test very much worth taking.

KEY POINTS

- ◆ There is a dearth of literature describing the training in or quality of clinical history-taking among cardiovascular nurses
- ◆ Recent publications and forthcoming national guidance will re-emphasize the importance of clinical history taking
- ◆ The diagnosis of angina pectoris can be made solely on the basis of the presenting patient history
- ◆ Evolving guidance will discourage clinicians from using the exercise ECG as the primary diagnostic test for myocardial ischaemia
- ◆ If cardiovascular nurses are to claim the role of 'clinician', critical appraisal and preparation for the resultant shifts in practice will be crucial.

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Belching: An unusual clinical presentation of Coronary Ischaemia

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Introduction

Belching is a symptom of myocardial ischaemia in a number of patients^{1,2}. Smith & Carley³ (2001) stated that "It should not be assumed that patients who have both chest pain and belching are more likely to be suffering from a non-cardiac cause." (p.467)

This case report describes a previously well 59-year-old man whose symptoms of coronary ischaemia manifested as eructation (belching), and were relieved by the deployment of intra-coronary stents to the Left Anterior Descending coronary artery.

Case History

The patient initially presented to the General Practitioner (GP) complaining of a week long history of severe belching. Over a five month period he had nine GP consultations and described frequent, forceful belching which interrupted normal speech and conversation. The symptoms began to disrupt sleep and make him reluctant to spend time in the company of others. There were no red flag gastrointestinal symptoms, but he did admit to four units of alcohol per day. He denied chest pain, but did describe a "pressure/bloated" feeling in the upper chest which was relieved by belching.

The patient tested positive and was treated for *Helicobacter Pylori* and stopped his non-steroidal anti-inflammatory drug. He was advised to reduce his alcohol intake and was prescribed Gaviscon/Ranitidine and then Lansoprazole (30mg once daily). Although there was some temporary improvement over for weeks severe symptoms returned and he was referred for upper gastrointestinal endoscopy.

While waiting for gastrointestinal investigations the patient again presented to the GP. Belching was still his main complaint, but on further questioning he admitted to a vague anterior chest discomfort which was worse on exertion and associated with a significant increase in the frequency of belching. Serum total cholesterol was found to be 7.2mmol (non-fasting).

The patient was referred to the Rapid Access Chest Pain Clinic (RACPC), where he was seen within

24 hours.

On arrival at the RACPC, a routine resting 12-lead ECG showed signs of a recent anterior wall myocardial infarction (Biphasic T wave inversion with 1mm ST segment elevation in precordial leads V₂ to V₄).

2D Echocardiography showed normal left ventricular size with hypokinesis of the apex and apical intraventricular septum. Overall left ventricular systolic function was preserved. Although the echocardiogram supported the diagnosis of recent anterior myocardial infarction, a functional assessment was thought necessary to assist with risk stratification.

The patient underwent a Bruce protocol exercise (treadmill) test. He managed 4 minutes 20 seconds before the test was discontinued due to ST segment elevation of 2-3mm in leads V₁ to V₃, with reciprocal ST segment depression in leads II, III and aVF. From 2 minutes 30 seconds onwards, the patient experienced very frequent belching. This abated in the recovery phase following the test.

Immediate admission to the cardiology ward was arranged. Within 2 hours the patient underwent coronary arteriography. This demonstrated mild diffuse 3-vessel coronary artery disease with a total occlusion of the Left Anterior Descending (LAD) artery from the mid-portion. Following angioplasty balloon inflation, one 3x32mm drug-eluting stent and one 3.5x18mm bare-metal stent were deployed with an excellent arteriographic result. The patient was returned to the ward, had an uncomplicated post-procedure recovery and was discharged home the following morning on Aspirin 75mg daily, Clopidogrel 75mg daily (12 months), Simvastatin 40mg daily, Bisoprolol 1.25mg daily, Ramipril 10mg daily and GTN spray.

At follow-up 3 weeks later the patient reported a significant reduction in symptoms of belching. He was able to report only 3-4 single episodes per day, in contrast with his description of 250-300 daily episodes previously. He was undertaking a daily 2 mile walk with neither symptoms of belching nor chest tightness.

Conclusion

Belching has been cited as being commonly associated with angina¹⁻³. The striking features of this case are the gradually evolving correlation of symptoms with exertion, the gravity of the findings of a recent anterior myocardial infarction/blocked LAD artery, and relief of symptoms following the deployment of intracoronary stents.

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Smith J, Carley S. Belching as a symptom of myocardial ischaemia. *Emerg Med J* 2001;18:467.

The cardiology nurse consultant in Scotland

Scott McLean, Catherine Mondo and Frances Divers describe their roles as nurse consultants working in cardiology in Scotland, against the background of the Scottish Executive's targets for increasing the number of such posts

In September 1999, Scotland's Health Minister announced 12 centrally-funded consultant posts for nurses and invited bids from individual boards (Anonymous, 1999). Twelve months later, with only three appointees in post, the minister reiterated the announcement (Anonymous, 2000) and detailed the specialties to which the remaining nine posts would be allocated: paediatrics, emergency receiving, cancer care, older people, mental health, sexual health, public health and epidemiology.

By 2004 the Royal College of Nursing, concerned at the lack of impetus, suggested that each of Scotland's 12 health boards should have at least one consultant nurse specialising in each of the areas of paediatrics, older people, primary care, mental health, cancer and 'heart care'. This was rejected by the Health Minister, on the grounds that 'statutory minimums is not the approach we are adopting...the next step is to evaluate the work the nurses are doing. There seems to be enough evidence that specialists are good for patients' (Anonymous, 2004).

Controversy erupted later in 2004 when the retiring Chief Nursing Officer heavily criticized the Scottish Executive Health Department (SEHD) over the lack of consultant nurses. At the time there were fewer than 30 posts across Scotland, compared with more than 800 posts in England and Wales. She told nurses at conference to 'Go and rattle some cages. Get more of them' (Trueland, 2004). The Scottish administration responded that creating more consultant nurse posts would be a priority for the incoming Chief Nursing Officer (Trueland, 2004).

Implementation

The most recent version of Scotland's nursing strategy—*Delivering care, Enabling Health* (SEHD, 2006a)—has a clear aim for consultant level nursing in Scotland: 'The

development of consultant nurse posts, each with defined leadership functions and responsibilities, marks a significant benchmark in progressing clinical leadership in Scotland.' At the time of writing, Scotland has 38 consultant nurses in post, 3 consultant midwives and 11 consultant allied health professionals (AHPs), with approximately 40 enrolled in a succession planning development pathway. This compares with a ministerial target of 54 posts by 2007 (O'Dowd, 2004).

Booth et al (2006) conducted a postal survey of all 16 consultant nurses and consultant midwives in Scotland at the time. Of the 13 responses, they found that the mean time from RN/RM qualification to consultant appointment was 19.6 years, with 5 of the 13 posts being joint clinical/academic posts. The mean salary was £40 000 (2003/4) and two-thirds of respondents continued to deliver direct patient care. Key emerging themes centred around role confusion 'manifesting as a lack of clarity and understanding of the role among colleagues within the organization and the consultant nurse/midwives themselves.' (Booth et al, 2006: 87). This view was reinforced by Graham's recent paper (2007) which concluded that the battle for consultant nurses to find achievement and acceptance will be made easier if the role is better understood.

Cardiology context

Scotland's Coronary Heart Disease Strategy states that 'The development of nurse and AHP consultant posts would support local initiatives and could be pivotal in developing the non-medical contribution to CHD service developments' (SEHD, 2002: 20). The subsequent National Advisory Committee for CHD report on cardiology services expands on this and makes a recommendation that 'The Scottish Executive Health Department should invest in the

expansion of nurse consultants, ensuring that the role of the nurse consultant in cardiology is developed.' (MacIntyre, March 2006, personal communication).

Scott McLean

The Royal Infirmary of Edinburgh is South-East Scotland's major tertiary cardiology centre, serving a potential tertiary population of 2.1 million people, and local emergency/acute receiving population of around 350 000–400 000. The state-of-the-art centre has an emergency department, 58-bed acute receiving unit, 10-bed coronary care unit (CCU), 49 inpatient cardiology beds, 33 day case cardiology beds, 3 cardiac catheterization laboratories, 10 cardiologists, 11 visiting regional cardiologists, around 100 cardiology nurses and 15 specialist nurses in chest pain, cardiac rehabilitation, heart failure and research.

The post of Nurse Consultant in Acute Cardiology was filled in July 2007 and is an NHS post with part funding from the local managed clinical network for coronary heart disease. Given the views of Graham (2007) I have strived to make this post as transparent as possible.

I have constructed a job plan based on 10 sessions per week, distributed as 40% expert clinical practice/caseload in the rapid access chest pain clinic (RACPC), 20% leadership and service development, 20% research, 10% education and training and 10% administration. From this I have developed a 12-month workplan detailing specific (measurable) objectives to achieve. This workplan has been widely distributed and can be easily accessed by colleagues of all grades, from a band 5 staff nurse in the

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CCU to the director of nursing at health board level.

I see this post as primarily focusing on the period between a patient being referred by (or self-referring from) primary care to the first 12 hours of hospitalization. This covers both scheduled and unscheduled care, ranging from GP referrals to RACPC, to primary percutaneous coronary intervention (PPCI) in ST-segment elevation myocardial infarction (STEMI). As the RACPC here is reasonably well-established, much of my time is spent developing reperfusion services for STEMI which have evolved from in-hospital thrombolysis, through pre-hospital thrombolysis to a hybrid strategy of time-based reperfusion decision-making, involving ambulance paramedics and coronary care nurses. This optimal reperfusion initiative centres around the Scottish Intercollegiate Guidelines Network recommendation that

**I SEE IT AS VITAL TO
FOCUS ON PATIENT CARE
IN THE FIRST FEW HOURS
OF THE PATIENT JOURNEY**

‘patients with ST elevation acute coronary syndrome should be treated as soon as possible with PPCI, however, where PPCI can not be provided within 90 minutes of diagnosis, patients should receive immediate thrombolytic therapy’ (SIGN, 2007: 13). The nurse consultant role has been to create a service allowing ambulance paramedics and CCU nurses to communicate in an effective manner, facilitating an optimal reperfusion service.

This clinical arena has given rise to a number of research interests. I am involved in several studies currently in progress (or at the planning stage) looking at pre-hospital thrombolysis in STEMI, decision-making by ambulance paramedics, analysis of pre-hospital 12-lead ECGs transmitted via telemedicine and pre-test/post-test probability scoring in the RACPC.

My educational activities include playing a key role in the division’s advanced nursing practice agenda. This involves being part of the core development group, writing the cardiology-specific part of the curriculum and delivering course content.

While this role is relatively new, it has a key part to play in the development of cardiology nursing and services in Scotland. I see it as vital to focus on patient care in

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the first few hours of the patient journey, and to develop transparency in critical appraisal of the role and its benefits.

Catherine Mondo

Serving a population of just less than 300 000, NHS Forth Valley is a single integrated system comprising acute hospital services and community-based services delivered through three community health partnerships. Although the local healthcare strategy has proposed the development of a new acute hospital, at present acute in-patient services are delivered in Stirling Royal Infirmary. Emergency services incorporate an emergency department and clinical assessment unit. In addition, there is a 36-bed acute medical receiving ward, 6-bed coronary care unit and medical ward designated for cardiology patients. Patients requiring coronary intervention are transferred to tertiary centres in both the East and West of Scotland.

Although my main focus is on developing cardiac rehabilitation and secondary prevention services for people affected by heart disease, primarily with a diagnosis of acute coronary syndrome or heart failure, I am able to exert an influence on the entire cardiac patient journey. The post involves working closely with the acute services team and cardiac managed clinical network. Collaboration across organizational boundaries is one of the key objectives in the SEHD consultation document *Better Care, Better Health* (SEHD, 2007).

I have been in post for just over a year and during this time I have received invaluable support from colleagues and the organization as a whole. The importance of organizational support and commitment in maximising the benefits of the nurse consultant’s position has been highlighted by the work of Woodward et al (2006).

My role, which incorporates expert clinical practice in the above specialities, also embraces a close working relationship with an enthusiastic multidisciplinary cardiac rehabilitation team that includes 15 specialist nurses. In a paper discussing the challenges facing consultant nurses Coady

(2003) advocates that consultant nurses should work as part of multidisciplinary teams if real improvements in patient outcomes are to be realized. Certainly working in a team provides an ideal opportunity to engage in the empowerment of others, another important goal which emerged from Woodward et al’s (2006) research, as well as elsewhere (Williams et al, 2001; Jarman, 2007).

Involvement in education and training is an important aspect of empowering colleagues. I have been a visiting university

**THIS POST PRESENTS AN
OPPORTUNITY TO TRULY
AFFECT LOCAL SERVICE
DEVELOPMENT AND
DELIVERY**

lecturer and I am currently engaged in the local promotion of post-registration education and continuous professional development. In order to fulfil the local strategic plan for coronary heart disease and cardiac services I am working alongside clinical colleagues from both acute and primary care, seeking to identify education and training needs of staff. In both care settings, competencies based on national frameworks are being introduced. Besides the benefit to the individual, investing in knowledge and skills is also key to improving services for patients.

This post presents an opportunity to truly affect local service development and delivery. It also maintains the link with research and evaluation. Involvement in strategic planning at local, regional and national levels also permits me to make a contribution towards the future shape of health services.

Frances Divers

St John’s Hospital in Livingston is a busy district general teaching hospital serving a population of approximately 170 000. Patients with chest pain are admitted to cardiology either through the emergency department or via GP referrals. There are 36 admission beds incorporating 6 high dependency/coronary care beds. Patients

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Livingston

requiring invasive intervention are transferred to the tertiary centre at the Royal Infirmary of Edinburgh.

The cardiology staff at St John's consists of one consultant cardiologist with visiting consultant cardiologist cover at weekends, one visiting consultant cardiologist for 1 session of clinic work per week, 1 cardiology nurse consultant, 3 chest pain/cardiac rehabilitation rotational nurses, 1 heart failure nurse and 2 part-time research nurses.

I have been in post since February 2005. My role is developing continuously but the primary aim remains constant: to provide expert care for patients with acute coronary syndromes and to give professional leadership and a consultancy function for cardiac services across the region.

Over the past two years I have maintained my clinical practice by carrying my own caseload through the RACPC, accepting referrals from GPs and areas within the hospital. This service allows GPs access to the RACPC for advice regarding potential patients with coronary heart disease. I have continued to develop the post-myocardial infarction clinic, expanding it to capture patients who have undergone PCI. Much of my clinical work is based in the acute admissions area where acute coronary syndrome patients are managed. Being based in the CCU gives me the opportunity to strengthen the nursing and medical contribution to patient care in the assessment and management of this population. The nurse consultant role has enabled me to exercise leadership, set standards and work towards best practice. A major part of my role has been to develop, adapt and implement protocols and guidelines in relation to a recent redesign of cardiac services across the region.

Much of my educational work is local multidisciplinary teaching of nurses, medical students and junior doctors. I am involved with the institutes of higher education, teaching on postgraduate and undergraduate cardiac courses and influencing curriculum content and course design. My special interests are in cardiac rehabilitation and the care of patients with chronic cardiology problems. I have been

responsible for leading and conducting a number of qualitative/quantitative studies within the field of cardiac rehabilitation

THE ROLE HAS ENABLED ME TO EXERCISE LEADERSHIP, SET STANDARDS AND WORK TOWARDS BEST PRACTICE

which have led to several service improvements, gaining three Government Charter Mark awards for excellence.

Liaison with clinical teams in primary and secondary care allows me to promote an integrated approach to care, and to explore joined-up ways of dealing with shared issues, e.g. addressing repeated readmissions in complex patients.

The introduction of nurse consultants has created much debate ranging from the title of the post to the roles and function. It is vital that we remain focused—arguably the important objective of this role is retaining experienced practitioners in clinical areas. With the growing number of nurse consultants across Scotland there is increased potential to influence the way healthcare is delivered.

The future

The three posts described here have differing expert practice, research, education, and service improvement components. Although not by design, this is advantageous. There should be no desire or mandate to make these posts generic. It should be left to the individuals to shape them as they see fit depending on the particular strategic and operational environment in which they practice.

What is key for patients, national colleagues and healthcare planners is to have a Nurse Consultant in Cardiology with a special interest in every component of patient journey, through specialist outpatient work to pre-hospital cardiology, front-door assessment of chest pain, STEMI and reperfusion, inpatient risk stratification and intervention, cardiac rehabilitation, follow-up clinics and back to specialist outpatient work.

The future of cardiology is set on two parallel paths. The first is towards improving the care of people with long-term conditions, with an increased focus on anticipatory care. Promoting self-care and empowerment through education and support is an intrinsic part of this. The second is the ever-narrowing 'super-specialization' of acute specialist inpatient services and regional programmes.

It is vital that cardiology nursing is represented at the discussion table when key strategic and service-delivery decisions are made. The cardiology nurse consultant, with an influential foot in all camps, is ideally placed to achieve this.

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Chest pain: providing an integrated service for patients

SCOTT McLEAN describes a trio of hospital based chest pain initiatives and how the appointment of a cardiology nurse specialist has led to the integration and expansion of patient care

Chest pain is one of the most common reasons for patients attending acute hospital services, and presents a great challenge to healthcare professionals because of its multifaceted nature (Antman *et al* 2004).

Although the number of specialist nurses, nurse practitioners and consultant nurses appointed to posts associated with chest pain continues to rise, there is little in the literature about how they have affected the shape or operation of what might loosely be termed 'chest pain services'.

Traditionally, patients with chest pain are first seen in A&E but the trio of patient centred chest pain initiatives at The Royal Infirmary of Edinburgh, which are described in this paper, can deliver these patients immediately to a specialist care area.

THE CHEST PAIN SERVICE

The Royal Infirmary of Edinburgh is an 870-bed teaching hospital serving a regional population of 405,000 and a tertiary referral population for cardiology of 2.1 million.

The first development in the evolution of its chest pain service was the appointment of a cardiology nurse specialist (CNS) in the field of chest pain to lead and transform the existing rapid access chest pain clinic (RACPC).

As well as the development of the RACPC however, there have been two other developments to improve the service: pre-hospital cardiology and the use of 'front door' chest pain nurses. Together, they form an integrated chest pain service.

PRE-HOSPITAL CARDIOLOGY

There are no accounts in the literature of clinical improvement initiatives based on care systems refined through direct co-operation between coronary care unit (CCU) nursing staff and members of the ambulance service.

However, following changes in drug legislation in 2003, which allow appropriately trained paramedics to administer thrombolytic therapy in pre-hospital settings, and advances in pre-hospital telemedicine technology, clinicians in the Scottish Ambulance Service proposed a national programme of pre-hospital thrombolysis (PHT) in ST segment elevation myocardial infarction (STEMI).

In our CCU, a receiving station was installed to receive 12-lead electrocardiograms (ECGs) transmitted from ambulances around south east Scotland. This provides nurses with high quality ECG readings and contact details for the paramedics involved.

If patients have ECGs showing changes consistent with STEMI, the CCU nurses call the paramedics to discuss the results and whether PHT is appropriate. They also advise the paramedics to admit the patients directly to the CCU whether or not PHT is required.

This initiative has resulted in significant improvements in care. For example, the median symptoms-to-needle time has fallen by 38 per cent, from 166 to 103 minutes.

This reduction is significant, particularly when placed in the context of Morrison *et al*'s (2000) meta-analysis showing a 17 per cent reduction in inpatient mortality when thrombolytic

therapy is administered in pre-hospital rather than hospital settings.

Audit results also show that the median call-to-needle time is 44 minutes, 27 per cent below the maximum recommended national standard of 60 minutes (Scottish Executive 2004).

Crucially, only 7 per cent of the 12-lead ECGs received through the receiving station show signs of STEMI and so demand action by the CCU nurses.

In patients with ECGs showing important changes consistent with other acute coronary syndromes, CCU nurses page the front door chest pain nurses to let them know that patients at high risk of acute cardiac event are about to arrive.

While this strand of the chest pain service was initially viewed in isolation, it has evolved to become a vital tool for cardiology clinicians in that it allows chest pain nurses working in the emergency department to be warned of incoming patients with acute coronary syndrome or arrhythmia for example, and to have hard copies of their 12-lead ECGs potentially showing ischaemia.

In addition to its primary function of supporting paramedics administer PHT to patients with STEMI, this telemetry service is integral to the future implementation of primary percutaneous coronary intervention (PCI) in STEMI.

It aids communication between departments and helps link otherwise disparate services, namely the ambulance service, the emergency department, the CCU and the cardiac catheterisation laboratory, and so helps them achieve common goals.

FRONT DOOR CHEST PAIN NURSES

At first, the CNS undertook the role of the front door chest pain nurse but, in order to expand and enhance the telemetry and RACPC aspects of the service, the CNS now supports two grade F cardiology nurses to perform this role.

The front door chest pain nurse role is crucial to patients and clinicians in the emergency and acute assessment departments because it expedites assessment, treatment and appropriate transfer of patients presenting with chest pain (Box 1).

The front door chest pain nurses are experienced members of the cardiology team based in A&E and provide a range of services that otherwise would be less easily accessed by non-cardiology clinicians.

For example, they have access to cardiac catheter laboratory reports, cardiology database information, senior cardiology clinicians, follow-up appointments at consultant clinics and to the RACPC.

They can also provide early access to acute cardiology beds, or interventional procedures such as PCI, for patients with acute coronary syndromes.

A qualitative audit was undertaken using questionnaires completed by multidisciplinary clinicians at the front door. Eighty eight per cent of the 24 people questioned had 'positive' or 'strongly positive' feelings about the front door chest pain nurse role, while 8 per cent had 'neutral' or 'non-committal' and 4 per cent 'negative' feelings. Box 2 shows some of the responses.

RAPID ACCESS CHEST PAIN CLINIC

Rapid access chest pain clinics provide one-stop services for patients needing rapid and early cardiovascular clinical assessment and investigations to confirm or exclude coronary heart disease (Scottish Executive 2004).

Until recently, referrals to The Royal Infirmary of Edinburgh from patients' GP surgeries were faxed to the hospital's secretary, without discussion between clinicians. On arrival, patients were seen by senior house officers



Cycle of activity: paramedics take patients' ECGs (1) and send them to coronary care nurses on duty (2) to enable pre-hospital thrombolysis (3)



Box 1. How front door chest pain nurses ensure prompt assessment

- > Taking patient history
- > Undertaking 12-lead ECGs
- > Checking vital signs
- > Organising and requesting chest X-rays
- > Starting oxygen therapy if necessary
- > Administering, as appropriate, aspirin, nitrolingual spray, intravenous analgesia, anticoagulation, and thrombolytic therapy

Box 2. Comments about the front door chest pain service

'A great support. I wish other specialties provided a similar service.'

'It has opened my eyes to what specialist nurses can offer. I feel my attitudes have positively changed.'

'It's fabulous to see patients crash in, be treated quickly, efficiently, and be transferred to an acute cardiology bed. The other side is that it makes you frustrated that it can't be like that for every patient all of the time.'

'Why do they finish at 5pm? Can't they be here 24/7?'

'Although it's a great service, I worry that it results in the cardiology registrar providing less of an input to our department, which is wrong.'

(SHOs), with consultant cardiologist supervision if required.

This service was established in 1996 and audit results from its first year of operation were published by Newby *et al* (1998). The system, as it evolved, presented several challenges (Box 3).

These challenges led to the appointment of the CNS as clinical lead for the service. The CNS now sees more than 80 per cent of the patients referred to the RACPC, and has implemented the changes described in Box 4.

The RACPC is truly 'nurse led' rather than 'nurse facilitated', in that the CNS:

- > Leads and develops the service and systems
- > Takes GP and emergency department referrals
- > Undertakes patient consultations
- > Takes full histories
- > Performs focused cardiorespiratory physical examinations, including heart and lung auscultation
- > Orders and interprets investigations
- > Creates management plans that may or may not involve cardiologists.

Box 3. Challenges associated with the RACPC

The lack of triage often resulted in inappropriate referrals. These included people who use wheelchairs, who would have been served better by referral to the routine consultant outpatient clinic, and acutely unwell patients with recent STEMI, who would have been served better by 999 calls and admission to A&E.

The SHOs worked in the clinic for perhaps three weeks of their four-month secondments to cardiology. While this provided a reasonable patient-by-patient service, the general benefit of the service were unclear because referrals were inappropriate and there was no formal audit. There was also no clinical lead to envisage, initiate or evaluate change.

Issues around junior doctors' hours and the European working time directive meant that SHOs were becoming increasingly scarce in clinic environments.

Box 4. How the CNS changed the RACPC

Introducing a mobile phone referral system requiring GPs to call the CNS to discuss referrals means that around 10 per cent of referrals can be directed to more appropriate services such as A&E. This benefits patients and clinicians, and gives GPs the opportunity to discuss patients and possible treatments.

Senior front door doctors, through use of the referral book and informal communications with the front door chest pain nurses, have access to the RACPC. Under the previous system, clinicians were forced to tell patients presenting to A&E with stable exertional angina to go home and make appointments to see their GPs, so that they could then be referred to the RACPC. Patients and front door clinicians now have quick and appropriate access.

More than 98 per cent of local GPs now have a weblink on their computers that gives comprehensive details of the service, including referral and treatment guidelines, referral forms and contact numbers. This allows them to download the form and refer patients during consultation so that patients can be given appointments before they leave.

The mean waiting time is now 25.8 hours, which compares favourably with the two weeks recommended in England and Wales (Department of Health 2005).

CONCLUSION

Although the three strands of the chest pain service are different, the common link of the CNS allows a flow of, for example, patients, paperwork, consistent evidence-based cardiology care and communication between services. This benefits patients, clinicians and managers.

Clinicians in both the A&E and CCU suggest that this model is a demonstration of the benefits of having specialist nurses based in, and contributing to the work of, the emergency department.

Senior nurses from in-hospital specialities can shape the services that are available to emergency department clinicians and their patients by restructuring admission and referral systems.

This, and the benefits of linking previously disparate services to enable smooth patient journeys after attendance at emergency departments, are the key reasons why colleagues in other centres might find the model of this integrated service useful in their organisations.

See also pages 25-36

Scott McLean is a cardiology nurse specialist at The Royal Infirmary of Edinburgh**References**

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044 EFFECT OF SMOKING STATUS ON ANGIOGRAPHIC OUTCOMES AND 12 MONTH MORTALITY FOLLOWING PRIMARY PERCUTANEOUS CORONARY INTERVENTION FOR ACUTE MYOCARDIAL INFARCTION

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Background Smokers treated with thrombolysis for acute ST elevation myocardial infarction (STEMI) have a higher frequency of reperfusion and lower in-hospital mortality when compared to non-smokers. We examined the effects of smoking status on angiographic outcome, in-hospital and 12-month mortality following primary percutaneous coronary intervention in patients presenting with STEMI.

Methods We examined the effect of smoking status on clinical and angiographic outcomes in 228 patients with STEMI undergoing primary percutaneous coronary intervention in South East Scotland over a 12-month-period.

Results The study population was predominantly male (66%) with a mean age of 61 years (range 29–93). Patients who smoked were younger than ex-smokers or non-smokers (57 ± 12 vs 66 ± 12 vs 65 ± 15 years respectively, $p < 0.0001$) and were less likely to have had prior coronary intervention (9% vs 13% vs 11% respectively, $p < 0.01$). The prevalence of traditional risk factors, culprit vessel, pre-procedural Thrombolysis in Myocardial Infarction (TIMI) flow grade, pain to balloon times, glycoprotein IIb/IIIa inhibitor use and procedural success rates were similar for smokers, ex- and non-smokers. Procedural success was achieved in 98% of patients and mortality at 12 months was 7%. There were no differences in post-procedure TIMI flow grade, corrected TIMI frame count, the proportion of patients with TIMI III flow in the infarct related artery, in-hospital or 12-month mortality between smokers, ex- and non-smokers.

Conclusions In patients presenting with STEMI, primary percutaneous coronary intervention is associated with high rates of reperfusion in the infarct-related artery and low 12-month mortality, irrespective of smoking status. The “smokers paradox” observed with thrombolytic therapy does not extend to patients treated with primary percutaneous coronary intervention for STEMI. These findings provide support for the hypothesis that the smokers paradox can be explained by a defect in endogenous fibrinolytic activity induced by smoking.

Outcomes following PPCI

Parameter	All patients	Smokers	Ex-smokers	Never-smoked	p
n	230	121	54	55	N/A
In-hospital mortality, n (%)	9 (3.9%)	4 (3.3%)	2 (3.7%)	3 (5.6%)	0.78
12-month mortality, n (%)	16 (7.0%)	9 (7.4%)	3 (5.6%)	4 (7.3%)	0.90
Procedural success, n (%)	223 (98%)	118 (98%)	51 (94%)	54 (100%)	0.12
End-procedure TIMI flow grade*	2.8 ± 0.6	2.8 ± 0.5	2.8 ± 0.7	2.9 ± 0.3	0.19
End-procedure TIMI III flow*, n (%)	206 (90%)	108 (90%)	48 (89%)	50 (93%)	0.79
End-procedure corrected TIMI frame count*	11 ± 5	11 ± 5	11 ± 5	11 ± 6	0.97

*TIMI data from infarct-related artery. Figures are presented as mean \pm SD unless otherwise stated.

045 CARDIOVASCULAR EFFECTS OF TUMOUR NECROSIS EFFECTS OF TUMOUR NECROSIS FACTOR IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

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Background Although not specifically targeted in the treatment of atherothrombotic syndromes, inflammation initiates, potentiates and destabilises atherosclerotic plaques. The inflammatory cytokine tumour necrosis factor α (TNF- α) is over expressed in unstable coronary plaques and is a potential therapeutic target in acute coronary syndromes.

Methods In a double-blind parallel group randomised controlled trial, 26 patients with acute myocardial infarction received an intravenous infusion of Etanercept (10 mg) or saline placebo. Differential leukocyte count, plasma cytokine concentrations, flow cytometric measures of platelet activation and peripheral resistance vessel vasomotor and fibrinolytic function were determined at before and 24 h after study infusion.

Results Treatment groups were well matched and similar at baseline. Placebo saline infusion did not alter any of the measurements at 24 h ($p > 0.1$ for all). Consistent with effective antagonism of the TNF- α receptor, plasma TNF- α concentration increased in all patients following Etanercept infusion (254.3 ± 14.7 vs 0.12 ± 0.02 pg/ml, $p < 0.0001$). At 24 h, Etanercept treatment reduced neutrophil counts (7.4 ± 0.6 vs 8.8 ± 0.6 cells $10^9/l$, $p = 0.03$) and plasma interleukin-6 concentrations (10.6 ± 4 vs 5.8 ± 2 pg/ml, $p = 0.012$) whilst increasing platelet-monocyte aggregate formation (30.2 ± 5.2 vs $20.3 \pm 2.9\%$, $p = 0.02$); a marker of platelet activation. Vasodilatation in response to substance-P, acetylcholine and sodium nitroprusside, and tissue plasminogen activator release in response to substance P, were unaffected by either treatment ($p > 0.1$ for all).

Conclusions In patients with acute myocardial infarction, Etanercept causes a modest anti-inflammatory effect, however this does not improve peripheral vasomotor or fibrinolytic function. Of concern, Etanercept caused an early increase in platelet activation suggesting potential adverse consequences of TNF- α antagonism in patients with acute coronary syndromes.

046 AGE-QRST ANGLE SCORE DIFFERENTIATES SURVIVAL AND PREDICTS EARLY AND LATE MORTALITY IN 1843 ACS PATIENTS

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Introduction Accurate and rapid risk assessment is central to the management of patients presenting with acute coronary syndromes (ACS). Simple data from the resting 12-lead electrocardiogram (ECG) is immediately available at first medical contact and may help predict mortality.

Methods We regressed 30-day and 2-year mortality on simple ECG variables and clinical characteristics available during admission in 1843 patients with ACS in the EMMACE 2 cohort to generate a parsimonious model that was validated in 550 ACS patients from the EMMACE 1 cohort. The absolute difference between the frontal QRS and frontal T wave axis was calculated as (T wave axis – QRS axis) and if greater than 180 degrees was subtracted from 360, to give a continuous variable between 0 and 180 degrees. Association between mortality and potential predictor factors were quantified by ORs with 95% CIs. An age-QRST angle score was developed and



Decision making between nurses and paramedics in reperfusion of ST elevation myocardial infarction

SM Mclean and ADF Flapan

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An audit was conducted by Greater Manchester and Cheshire Cardiac and Stroke Network in 29 GP practices, on ECG received between November 2006 and November 2007, to document the level of satisfaction and the number of avoided referrals to secondary care with using this service.

Results: Out of the 24 541 12-lead ECG, 15 698 patients were symptomatic. The recommended plans of action were GP assessment: 87.5%, cardiology referral: 6.5%, and emergency department referral: 6%. In the 8843 asymptomatic cases, GP assessment was recommended in 96.3%. The one-lead ECG was performed in 805 cases, GP assessment was advised in 96% of symptomatic patients and 99% of asymptomatic patients. In the satisfaction audit, 60% of the forms were returned (20 practices). Of the 29 GP practices, 17 had their ECG previously reported by their local NHS Trust, which resulted in significant delay in receiving the reports of 1–60 days. With the adoption of the telemedicine service, all ECG were reported within 2 h of their receipt. Satisfaction level questionnaires were filled by 20 GP practices. All were either “very satisfied” or “satisfied” with the service (including the accuracy and speed of ECG interpretation). Secondary care referrals were prevented in up to 65.8% of the total cases (95% CI 61.6% to 65.8%). The extrapolated gross savings derived was in excess of £300 000.

Conclusions: Telemedicine and wireless ECG interpretation can enhance the practice by extending the medical consultation from GP practices to a specialist ECG centre. This can ultimately broaden the overall standard of patient care and potentially save time and money.

056 DECISION MAKING BETWEEN NURSES AND PARAMEDICS IN REPERFUSION OF ST ELEVATION MYOCARDIAL INFARCTION

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Introduction: To describe a reperfusion programme in ST elevation myocardial infarction (STEMI) based around prehospital decision-making between coronary care unit (CCU) nurses and ambulance paramedics.

Methods: Experience began in 2004 with nurses and paramedics discussing 12-lead electrocardiograms (ECG) transmitted from the ambulance to the CCU. This programme involved CCU nurses providing support to paramedics considering prehospital thrombolysis (PHT). The programme evolved in 2006 to include primary percutaneous coronary intervention (PCI). Based on a 90-minute diagnosis-to-PCI balloon time, nurses and paramedics now make a joint decision on whether patients with STEMI should receive either PHT or primary PCI, based on clinical history, ECG findings, travel time from hospital and availability of PCI facilities.

Results: Between 1 December 2006 and 31 August 2008 primary PCI was the treatment for 70% of patients (526/751), with PHT administered to 1.5% (11/751) and in-hospital thrombolysis to 5.9% (44/751). The mean length of hospital stay was 3.5 days for primary PCI patients and 5.9 days for all comers. Although non-randomised data, in-hospital and 30-day mortality are significantly reduced in the primary PCI group at 3.2% and 4.7%, respectively. The 90-minute diagnosis-to-PCI balloon inflation was achieved in 64% of primary PCI cases (77% in in-hours cases and 45% out-of-hours). The median door-to-PCI balloon time was 53 minutes. No reperfusion therapy was administered to 14.2% of patients (107/751) with a discharge diagnosis of STEMI over the 21 months of the optimal reperfusion programme. This compares favourably with 141/487 (29%) in the first 12 months of the PHT programme, 89/438 (20%) in the second 12 months of the PHT programme and with the GRACE registry, which reported sustained rates of no-reperfusion in up to 29% of patients with STEMI. The on-call team were called for primary PCI on three occasions in which the patient did not undergo primary PCI. All three of these patients had widespread coronary disease with no occlusive thrombus. None had normal coronary arteries.

Conclusions: Using prehospital 12-lead ECG transmission, CCU nurses and ambulance paramedics can safely and effectively decide on the most appropriate reperfusion therapy for patients with STEMI. There are no other reported data of nurses and paramedics operating in this way and despite the single-centre observational nature of the data, this system of care appears to have a positive predictive value worth further exploration.

057 6-MONTH HEALTH-RELATED QUALITY OF LIFE IN ST ELEVATION MYOCARDIAL INFARCTION PATIENTS FOLLOWING THROMBOLYSIS OR PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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Introduction: Difficulty with psychological adjustment post ST elevation myocardial infarction (STEMI) has been reported in as many as 40% of patients. The process of rehabilitation, recovery and the time taken to return to work can be adversely affected. Treatment such as primary percutaneous coronary intervention (PPCI) or thrombolysis (lysis), can also influence post-STEMI rehabilitation and recovery. At present few published data are available evaluating the health-related quality of life (HR-QoL) for lysis and PPCI patients. The purpose of this cohort study is to ascertain predictors of physical health status in STEMI patients receiving lysis or PPCI for future service provision and adaptations.

Methods: A total of 430 STEMI patients will be recruited (200 lysis and 230 PPCI) across the Manchester conurbation; the study is in the recruitment phase at present. Four self-report questionnaires including the ENRICH social support instrument (ESSI), the hospital anxiety and depression scale (HADS), the medical outcomes study Short Form 36 (SF-36) and the brief illness perception questionnaire will be collected at baseline, 6 and 12 months. Further data including demographics, relevant medical history and index treatment details are also recorded.

Results: Six-month interim data are available for 179 patients (94 lysis and 85 PPCI). Participant demographics are: lysis group 80% male, mean age 61 years (38–90; SD 12.5) and PPCI group 72% male, mean age 60 years (37–83; SD 11.2). Baseline data analysis showed no differences on the ESSI, HADS and aspects of the SF-36 between the two groups. Physical component scores of the SF-36, 6-month data were analysed using regression analyses and showed baseline levels of anxiety, depression, education level and several quality of life indicators significantly predicted physical components of HR-QoL.

Conclusions/Implications: Analyses for interim data show no significant difference between treatment groups on a range of psychosocial variables at baseline. However, patients' own self-rating of their physical HR-QoL at 6 months was predicted by quality of life and levels of psychological distress measured at baseline. The findings show that a subgroup of patients post-STEMI may benefit from targeted psychosocial interventions in order to maintain their quality of life and aid recovery over time.

058 A QUALITATIVE STUDY OF THE EXPERIENCES OF MYOCARDIAL INFARCTION PATIENTS WHO REPRESENT POST-PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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Introduction: The current gold standard treatment for ST elevation myocardial infarction (STEMI) is primary percutaneous

($r=0.474$, $p=0.010$) and the Payen scales ($r=0.562$, $p=0.004$). Significant differences were detected in SP levels in AMI patients compared to controls ($\Delta M=-199.97$ pg/ml, $p=0.04$). In the coronary patients' group, average serum substance P levels while in pain were 195.27 ± 181.1 pg/ml, and those in controls were 113.52 ± 76.32 pg/ml. Serum SP levels were significantly different among patients with different primary diagnoses (ANOVA, $df=3$, $F=4.615$, $p=0.013$).

Conclusions: The observation of elevated SP serum levels in coronary critical care patients and of associations with subjective pain perception and pain scale scores may have important clinical implications. Further study is needed to elucidate the merits and feasibility of SP measurements as a biochemical "pain detector" in critical care

FP35

Use of behavioral pain scales in coronary and critical care patients. A comparative validation study

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Purpose: Pain management is a complex problem in critical care, due to limitations in pain assessment. Behavioral pain scales are employed in non-communicating critically ill patients, but their validity is difficult to be assessed, whereas they have not been applied in patients with coronary pain. Concomitant pain ratings in communicating and non-communicating critically ill patients may elucidate the metric properties of behavioral pain scales.

This study explored and compared the applicability, reliability and validity of the Greek version of two behavioral pain scales (Payen 2001, Puntillo 1997) in coronary and trauma critical care patients.

Methods: The scales were translated, back-translated and validated by an expert panel. A convenience sample of 24 coronary critical care patients and of 36 intubated trauma patients was followed up for 3 days. Validity was explored through associations with the numeric visual analogue scale (VAS), administered to both groups of patients, when able to self-report pain, and nurses. Test-retest reliability and inter-rater reliability were assessed ($n=10$ nurses).

Results: In both patients' groups, a strong positive correlation was detected between nurses' ratings at the Puntillo (1997) scale and patients' ($r=0.6-0.92$, $p<0.002$), as well as nurses' ($r=0.57-0.66$, $p<0.003$) VAS ratings. A consistent association was observed with nurses' ratings at the Payen (2001) scale ($r=0.57-0.85$, $p<0.004$). In coronary care patients, there was a strong positive association between the Payen score and patients' VAS ratings ($r=0.67$, $p<0.0001$), as well as nurses' VAS ratings ($r=0.67$, $p=0.000$). In intubated patients, a strong positive association was found only between the Payen score and nurses' VAS ratings ($r=0.85$, $p<0.0001$). Test-retest reliability ($r=0.93$) and inter-rater reliability ($r=0.81$, McNemar test $p>0.1$) were adequate.

Conclusion: Behavioral pain scales may be useful for pain assessment in coronary patients, as well as in non-communicating critical care patients. The Greek versions of these tools appear reliable and valid.

FP36

Decision making between nurses and paramedics in reperfusion of ST elevation myocardial infarction

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Purpose: To describe a reperfusion programme in ST Elevation Myocardial Infarction (STEMI) based around pre-hospital decision-making between Coronary Care Unit (CCU) Nurses and ambulance paramedics.

Methods: Experience began in 2004 with nurses and paramedics discussing 12-lead electrocardiogram's (ECG's) transmitted from the ambulance to

the CCU. This programme involved CCU nurses providing support to paramedics considering pre-hospital thrombolysis (PHT). The programme evolved in 2006 to include Primary Percutaneous Coronary Intervention (PPCI). Based on a 90-minute diagnosis-to-PCI balloon time, nurses and paramedics now make a joint decision on whether or not patients with STEMI should receive either PHT or PPCI, based on clinical history, ECG findings, travel time from hospital and availability of PCI facilities.

Results: Between 1st December 2006 and 31st August 2008 PPCI was the treatment for 70% of patients (526/751), with PHT administered to 1.5% (11/751) and in-hospital thrombolysis to 5.9% (44/751). Mean length of hospital stay was 3.5 days for PPCI patients and 5.9 days for all-comers. Although non-randomised data, in-hospital and 30-day mortality are significantly reduced in the PPCI group at 3.2% and 4.7% respectively. The 90-minute diagnosis-to-PCI balloon inflation was achieved in 64% of PPCI cases (77% in in-hours cases and 45% out-of-hours). Median door-to-PCI balloon time was 53 minutes. No reperfusion therapy was administered to 14.2% of patients (107/751) with a discharge diagnosis of STEMI over the twenty-one months of the optimal reperfusion programme. This compares favourably to 141/487 (29%) in the first twelve months of the PHT programme, 89/438 (20%) in the second twelve months of the PHT programme, and with the GRACE registry which reported sustained rates of no-reperfusion in up to 29% of patients with STEMI. The on-call team were called for PPCI on 3 occasions where the patient did not undergo PPCI. All 3 of these patients had widespread coronary disease with no occlusive thrombus. None had normal coronary arteries.

Conclusions: Using pre-hospital 12-lead ECG transmission CCU nurses and ambulance paramedics can safely and effectively decide on the most appropriate reperfusion therapy for patients suffering STEMI. There are no other reported data of nurses and paramedics operating in this way and despite the single-centre observational nature of the data, this system of care appears to have a positive predictive value worth further exploration.

FP37

Gender differences in symptoms of myocardial ischaemia

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Background and Purpose: Better understanding of acute coronary syndrome (ACS) symptoms by all health professionals is needed to improve diagnosis and timeliness of treatment. Nurses are often first to assess symptoms of ischaemia, and are usually responsible for educating patients about the nature of symptoms and appropriate actions to take, so this understanding is particularly important for nursing. Prior research has suggested there are gender differences in ACS symptoms, but has been plagued by methodological flaws. This study therefore sought to determine if gender differences exist in reported symptoms of ACS, using PCI balloon inflation as a model of myocardial ischaemia.

Methods: Consecutive patients having non-emergent PCI were prospectively recruited. Exclusions were diabetes, haemodynamic instability, left bundle branch block and total occlusion. Prior to PCI subjects answered open-ended questions about symptoms that had led to PCI referral. Inflation was maintained for 2 minutes or until a clinical reason to deflate occurred. During inflation, subjects were questioned about current symptoms. ECG data were collected prior to inflation and at deflation.

Findings: The final sample was 305 (mean age 63.9 (± 10.6); 39.7% women). 83% had ECG-evident ischaemia during inflation. There were no gender differences in rates of chest pain or typical ACS symptoms, regardless of ischaemic status, but women reported significantly more symptoms (though the statistical significance of this difference did not persist in the ischaemic subset).

Conclusions: This prospective study with ECG-affirmation of ischaemia suggests women and men have similar symptoms during ACS. However, women, perhaps due to psychosocial factors, report more symptoms. Nurses have a pivotal role to play in crafting educational messages for women (both those with clinical disease and those at risk), so that they recognize that