HEALTH-RELATED QUALITY OF LIFE OUTCOMES FOLLOWING PRIMARY PERCUTANEOUS CORONARY INTERVENTION FOR ST-ELEVATION MYOCARDIAL INFARCTION (HOOP-PCI STUDY)

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Doctor of Philosophy (Nursing)

This thesis is presented in fulfilment of the Degree of Doctor of Philosophy

University of Technology Sydney

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CERTIFICATE OF ORIGINAL AUTHORSHIP

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

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28th August 2016

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STATEMENT OF CONTRIBUTIONS TO JOINTLY AUTHORED WORKS IN THE THESIS

The results of studies contained in this thesis have been published in peer-reviewed journal as four discreet manuscripts from Chapters three to six inclusive. For each study, as the first author (50% contribution), I have been responsible for creating and finalising the research questions, conducting the analysis and writing and completing the manuscripts. I have received enormous support, guidance and supervision with all aspects of manuscript drafting and revisions (25% contribution each) by Professors Robyn Gallagher and Doug Elliott. I accept responsibility for the results reported in the publications and the accuracy of the research in this thesis.

RECORD OF PEER REVIEWED PUBLICATIONS (DATA BASED STUDIES) RELATED TO THIS THESIS

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2. Soo Hoo Soon Yeng , Gallagher R, Elliott, D. (2016), 'Factors influencing health-related quality of life after primary percutaneous coronary intervention for ST-elevation myocardial infarction', *Applied Nursing Research*, vol.30, pp. 237-244. **(Impact factor 0.73)**

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LIST OF ABBREVIATIONS

ACS	Acute coronary syndrome (umbrella term encompassing STEMI, NSTEMI, NSTEACS and angina
AMI	Acute myocardial infarction
BMI	Body mass index
CABG	Coronary Artery Bypass Graft
CAL	Chronic Airway Limitation
CASP	Critical Appraisal Skills Program
CHD	Coronary heart disease
CKMB	Creatine Kinase-MB
CR	Cardiac rehabilitation
CVD	Cardiovascular disease
ECG	Electrocardiogram
ED	Emergency department
HRQOL	Health-related quality of life
LOS	Length of stay
MACE	Major adverse cardiovascular events
MCID	Minimal clinically important difference
NSTEMI	Non-ST elevation myocardial infarction
SAQ	Seattle Angina Questionnaire
SF-12	Medical Outcomes Short Form 12
STEMI	ST-elevation myocardial infarction
PCI	Percutaneous coronary intervention (umbrella term which includes PTCA and or coronary artery stenting)
PPCI	Primary percutaneous coronary intervention

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTCA	Percutaneous transluminal coronary angioplasty
PVD	Peripheral Vascular Disease
QOL	Quality of life
RCT	Randomised controlled trial
WHO	World Health Organisation

THESIS ABSTRACT

Background

Health-related quality of life (HRQOL) is an important measure of patient outcome following primary percutaneous coronary intervention (PPCI) for an ST-Elevation myocardial infarction (STEMI). The assessment of HRQOL quantifies patient perceptions of the impact of an acute, unanticipated cardiac event on their survival and normal function. Despite international recognition and recommendations supporting HRQOL as a vital measure of cardiovascular health status, HRQOL remains under-reported and not routinely implemented in PPCI care. Field triage patients who are fast-tracked to PPCI have less ischaemic time delays than routine Emergency Department (ED) admissions but their HRQOL and cardiac rehabilitation (CR) attendance patterns have not been investigated.

Aims

This study aims to examine HRQOL outcomes of STEMI patients and to identify the key factors that influence recovery and CR attendance at 4 weeks and 6 months after PPCI.

Method

Clinical and HRQOL data was collected and compared for age categories, divided at 60 and 70 years separately; the cut-off age of 70 years used for this thesis. The cut-off for older age at 60 years was used for the systematic review based on the global standard set by the World Health Organisation (World Health Organization, 2002). The age cut-off was changed to 70 years for the

thesis study as it is more representative of older people in developed countries such as Australia. The timing of follow-up at 4 weeks and 6 months was chosen based on published evidence that improvements in HRQOL post-PPCI reached a plateau at 6 months, after which, no significant differences occurred. A prospective cohort study was conducted with repeated measures for all consecutive STEMI patients (n=246) comprised of 194 males and 52 females. All were treated by PPCI after ED or Field Triage admissions in two metropolitan hospitals, the Royal North Shore and North Shore Private Hospitals. Additional analyses included HRQOL in the subgroup of Field Triage patients and determination of CR participation at 4 weeks and 6 months.

Results

Age, length of hospitalisation, gender, partnership status and number of stents deployed were independent predictors of HRQOL after STEMI and PPCI. Participants aged ≥ 70 years achieved better cardiac-related HRQOL and mental health from angina relief despite physical limitations. Older age, longer hospitalization, hypertension and recurrent angina were associated with poorer HRQOL for field triage patients. Despite a high referral rate (96%, n=233), CR attendance was sub-optimal (36-54%, n=89-132). A total of 221 patients attended CR; men and patients who received post-discharge support were more likely to attend.

Recommendations

There is a need to integrate HRQOL measurement into PPCI care to ensure post-discharge support is directed at those who need it most. Older people and women were identified in this research as having lower HRQOL and attendance at CR. Important factors that negatively impact on HRQOL such as recurrent angina and longer hospitalization need to be considered in cardiovascular health-care delivery and risk management of acute STEMI cohorts.

Conclusion

The HRQOL for all ages improves from 4 weeks to 6 months after PPCI including field triage patients. Older age, longer hospitalization and female gender are common predictors of poorer HRQOL and lower CR attendance, constituting areas requiring future research focus.

CHAPTER 1: INTRODUCTION

Chapter Preface

This thesis explores health-related quality of life (HRQOL) of patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PPCI) for coronary reperfusion. This chapter introduces and outlines this program of doctoral research within the context of the broader published literature. It provides a description of the rationale and scope of this study, including the background, in order to introduce all subsequent chapters presented in the thesis. The chapter concludes with identification of existing gaps in research on PPCI outcomes after a critical cardiac event such as STEMI and the rationale for the current research, the research aims and design, including an outline of the thesis content.

Background to the problem and research gaps

Recommendations from key organisations such as the American Heart Association support HRQOL assessment as an important cardiovascular health outcome other than the common clinical measures of mortality and morbidity (Rumsfeld et al. 2013). These recommendations were introduced in 2013 but to date, there remains an existing gap in both clinical and research practice on the implementation of HRQOL assessment as part of routine post-procedural PCI /PPCI nursing care for all presentations of acute coronary syndrome (ACS). In Australia, there is no state or national practice framework or policy guidelines mandating the measurement of HRQOL. As a consequence, there is a substantial knowledge deficit regarding HRQOL outcomes of STEMI patients as the sickest group of ACS presentations who are treated by PPCI, including those admitted by field triage for rapid PPCI. From this aspect of cardiovascular care, it may mean that subgroups of patients experiencing poor outcomes are neither identified nor their needs addressed. International studies have identified the elderly as an important subgroup that is potentially disadvantaged (Bauer et al. 2011; Dauerman et al. 2003; Graham et al. 2006; Guagliumi et al. 2004; Kvakkestad et al. 2015); whose clinical health outcomes have been proven to be marginal after an acute cardiac event. Further research and post-treatment strategies are required to support this subgroup as a basis to ensuring equitable recovery to mainstream PCI/PPCI patients. The research described in this thesis provided a comprehensive exploration into a unique, specific cohort of older patients with myocardial infarction (AMI) and comparison to younger people to determine whether health status outcomes differ significantly in multiple domains of health.

Rationale for Study

The study undertaken in this thesis aimed to generate new findings which could potentially support HRQOL as a key clinical outcome measure for the comprehensive assessment of all STEMI cohorts after PPCI. There is evidence from published literature that older people aged >70 years, including octogenarians achieve good quality of life outcomes, mainly from angina relief after PCI/PPCI resulting in improved physical functioning (Agarwal, Schechter & Zaman 2009; Johnman et al. 2013; Li et al. 2012). Mortality is a major clinical outcome but HRQOL and CR during recovery is of equal importance. There is also competing evidence as above that age has no effect on HRQOL. This thesis explicitly addressed the limitations of past and existing research and provided important information that could broaden clinicians' understanding of older STEMI patients and the predictors which influence HRQOL outcomes after PPCI.

Full recovery of the patient post-PPCI for an acute STEMI event extends beyond a singular aspect of physical recovery. Therefore HRQOL was assessed from a global perspective, integrating some important domains of health described in the conceptual framework of Wilson and Cleary in order to provide a broader perspective of health status outcomes after PPCI for STEMI cohorts (Wilson & Cleary 1995).

Aims of the research

The main study aims were to:

1. Systematically review and synthesise relevant literature to appraise the evidence and to establish a platform for research enquiry.
2. Examine HRQOL and predictors of HRQOL in STEMI patients after PPCI at 4 weeks and 6 months of recovery and to compare for differences in health status outcomes by age ≥70 years and <70 years.
3. Examine attendance at cardiac rehabilitation and the factors that predict attendance after PPCI.
4. Examine HRQOL, clinical outcomes and determine the predictors of HRQOL for the field triage STEMI group specifically, comparing for differences between ≥70 years and <70 years.

Research design and rationale for application

A descriptive, comparative repeated measures design was used to address the research aims. The use of quantitative methodology enabled the systematic examination and comparative analysis of important measurable variables incorporating the sociodemographic and clinical characteristics of the sample and sub-groups. Due to the complexity of coronary heart disease and the change in cardiovascular health state with treatment, assessment of HRQOL should incorporate both generic and disease-specific instruments for a comprehensive measure of health status and treatment outcomes (Cepeda-Valery et al. 2010). In this research, HRQOL was assessed using a combination of validated generic and disease-specific instruments to provide measurable and quantifiable outcomes as reported by patients and including multiple dimensions of their health status. The comparative, repeated measures design permitted a comprehensive analysis of HRQOL to reflect both early (4 weeks) and late (6 months) changes after PPCI with statistical differentiation for health outcomes by age categories.

Thesis structure

This is a thesis by publication, comprising a series of linked sub-analyses focusing on STEMI patients treated by PPCI in order to address all research aims. Each individual publication addresses a specific research aim, related to existing gaps in the literature and in clinical practice, with information provided on the background, aims, methods, analysis, results, and concluding with a concise discussion of the findings and implications for practice. Each sub-study builds on the previous research, filling in the gaps of knowledge deficit for the topic by re-analysing relevant data for each new enquiry. This ensures clarity and completeness of the research process in addressing a contemporary but complex area of STEMI treatment by urgent primary treatment and the factors which could impact on health status and rehabilitation of patients during recovery. Figure 1.1 illustrates the structure of this thesis and how each sub-study and separate analyses link up to complete the research program. This section outlines the thesis by chapter and content.

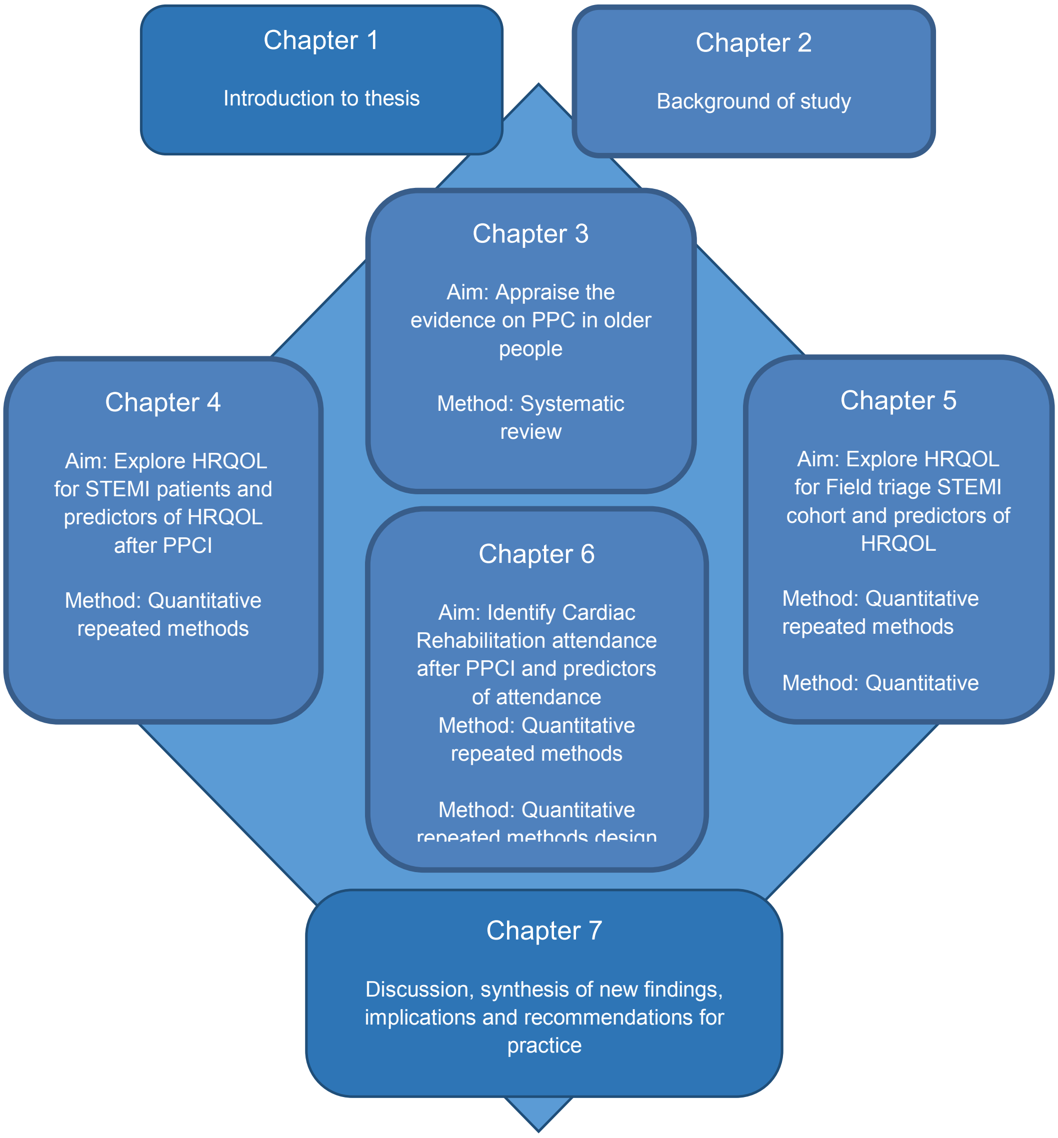

Figure 1.1. Thesis Structure: Linkage of study components in thesis

As noted earlier, **Chapter One** is an introduction to the research and describes the rationale and aims of the research, an outline of the complete thesis contents and peer-review publications and presentations as components of the whole thesis.

Chapter Two describes the background to cardiovascular disease, acute coronary syndrome and its major presentation of STEMI, PPCI pathways, HRQOL and patient-centred health outcomes including post-hospitalisation support such as CR. There is added focus on ageing and older people with STEMI and a description of the conceptual framework of Wilson and Cleary which provides guidance on exploring the important aspects of HRQOL for the STEMI cohort treated by PPCI (Wilson & Cleary 1995).

Chapter Three presents a systematic review of the existing literature base, exploring the research question; What is the effect of age on HRQOL following elective or emergency PPCI for acute coronary syndromes and stable angina? The chapter examined and synthesised published findings from 1999 - 2012, on the effect of age >60 years on HRQOL following elective PCI and PPCI. With an ageing global population, the impact of age on HRQOL outcomes is important and the incorporation of HRQOL assessment following PCI would help identify areas of clinical practice deficit in the care of older people with acute coronary occlusion. This paper was published in *Nursing and Health Sciences* in 2014.

Chapter Four presents HRQOL and assessment of health status outcomes for the PPCI cohort, using the generic instruments, the Medical Outcomes Short

Form 12 (SF-12) (Ware et al. 2009) and the cardiac-specific Seattle Angina Questionnaire (SAQ) (Spertus et al. 1995) and guided by the conceptual framework of Wilson and Cleary (1995). This chapter details participant recruitment, inclusion/exclusion criteria, sample size and setting, ethics, data collection and data analysis. Comparison of HRQOL was conducted for two age classifications (≥60 and <60 years) and (≥70 and <70 years). Based on the global definition of "older" (World Health Organization 2002), the age categories ≥60 and <60 years was used for the initial systematic review and analysis to determine HRQOL outcomes with PCI in an international population. The older age classification of ≥70 and <70 years reflects more accurately the changing perspectives on aging in developed countries such as Australia, where the average age of older people is rapidly increasing. The analysis includes a report on the predictors of HRQOL including age at 4 weeks and 6 months after PPCI. Results were published as two separate papers; an abstract citation in *Heart, Lung and Circulation* in 2012 and as a full research paper in *Applied Nursing Research* in 2016.

Chapter Five presents HRQOL and assessment of health status outcomes specifically for the STEMI Field Triage cohort. This chapter reports the sub-analysis for the select group of patients who received PPCI by a fast-track field triage pathway. The study provides unique information on clinical outcomes and predictors of HRQOL for field triage STEMI cohorts at 4 weeks and 6 months of recovery, comparing for differences between ≥70 years and <70 years. This paper was published in *Heart & Lung* in 2016.

Chapter Six presents a sub-analysis on the rates of CR attendance at 4 weeks and 6 months following PPCI and includes a comparison for ages ≥70 years and <70 years and identification of the independent predictors of CR attendance. As an integral part of cardiac care with PPCI, active participation in a CR programme confers recovery benefits in health and this chapter presents findings which inform CR referral and service practices. This paper was published in *Nursing and Health Sciences* in 2016.

Chapter Seven presents a summary discussion and synthesis of the complete findings emanating from the doctoral research program, including implications for nursing practice and recommendations for future research.

The appendices attached at the end of this thesis include copies of Human Research Ethics Committees approvals, participant information and consent forms, the generic SAQ and SF-12 questionnaires, patient follow-up data collection forms, publication copyright agreements and copies of all published studies and abstracts.

Chapter Summary

This chapter provides an introduction to the components of the thesis, list of publications emanating from the study and the rationale for conducting this research. The next chapter describes the background of cardiovascular disease and STEMI, the processes of treatment and the resultant HRQOL outcomes upon which this research and thesis is created.

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CHAPTER 2: INTRODUCTION TO CARDIOVASCULAR DISEASE

Chapter Preface

Chapter 1 provided the introduction, outline and structure of the thesis. This chapter describes the background context to the research undertaken including the prevalence, pathophysiology and presentation of cardiovascular disease (CVD), coronary heart disease (CHD) and the acute coronary syndromes (ACS), including its most severe presentation; ST-elevation myocardial infarction (STEMI). The contents of this chapter will also describe primary percutaneous coronary interventions (PPCI). The pathways to PPCI, including contemporary field triage and treatment outcomes of PPCI such as mortality, morbidity and patient-centred outcomes will be presented. Health issues specific to older people will be briefly discussed including the ageing process. Patient-related outcomes in terms of health-related quality of life (HRQOL) and the guiding conceptual framework of Wilson and Cleary (1995) will be introduced as well as cardiac rehabilitation (CR) for post-discharge support of patients after PPCI. This chapter concludes with the identification of existing gaps in cardiovascular research focussing on STEMI and PPCI outcomes in an older population and the rationale for the current research.

Cardiovascular Disease (CVD)

Cardiovascular disease (CVD) is described collectively as diseases of the heart and blood vessels and incorporates coronary heart disease (CHD), heart failure, cardiomyopathy, congenital heart disease, peripheral vascular disease and strokes. On a worldwide scale, CVD accounts for 17.3 million deaths per annum, with a projected rise to 23.6 million deaths by the year 2030 (Mozaffarian et al. 2016). Arguably, CVD adds an enormous burden to global health systems with the increased morbidity as people live with decreased functional levels from CVD diseases and with ageing. Of the conditions grouped within the CVD classification, CHD or ischaemic heart disease is the leading cause of mortality in Australia, accounting for 49% of all CVD deaths; 78% of which occur in people older than 75 years (Australian Institute of Health and Welfare 2015). The rise in mortality and morbidity with age may be attributed to the cumulative disease process of CHD, which is now described.

Pathophysiology of Coronary Heart Disease (CHD)

The main mechanism of pathophysiology in CHD is atherosclerosis. The development of atherosclerosis is linked to common risk factors such as hypertension, hypercholesterolaemia, diabetes and obesity (Libby, Ridker & Maseri 2002) as described in their seminal work. These risk factors contribute to the processes of oxidation and inflammation in coronary artery walls, which over time give rise to fatty-fibrous lesions or plaques. These plaques can rupture, due to degradation of the endothelium and inflammation, causing thrombus formation, embolisation and obstruction of blood flow through the artery (atherothrombosis) as shown in early and original studies in this area (Ambrose & Martinez 2002; Libby & Theroux 2005; Schoenhagen, McErlean & Nissen 2000). In contrast to the slow process of arterial narrowing which causes anginal symptoms, the consequence of atherothrombosis is rapid obstruction of coronary blood flow leading to acute events such as acute myocardial infarction

(AMI). Eventually both processes contribute to heart failure over time (Scott 2004). The disruption of plaques can also cause a coagulation cascade of other “high-risk” plaques, due to changes in circulating mediators in the blood such as prothrombotic and anti-fibrinolytic agents, ultimately extending the size and dispersion of the obstructions from the original site (Libby & Theroux 2005; Makki, Brennan & Girotra 2015). Ultimately ACS will result, with areas of the myocardium developing ischaemia and infarction.

Acute Coronary Syndrome (ACS)

There are three different clinical presentations of ACS namely, unstable angina, acute STEMI and non-ST-segment myocardial infarction (NSTEMI) (Chew et al. 2016; O’Gara et al. 2013; Roffi et al. 2015). The type with the most serious consequences in terms of mortality and morbidity is STEMI. Time is one of the most important factors in terms of outcome from STEMI because longer time delays to reperfusion treatment results in greater myocardial injury and higher mortality (De Luca, van 't Hof, et al. 2004; Terkelsen et al. 2010). Therefore, to limit mortality early revascularisation is recommended and this is recommended to be achieved by either percutaneous coronary intervention (PCI) or by administering thrombolytic drugs (thrombolysis) (O’Gara et al. 2013).

ST-Elevation Myocardial Infarction (STEMI)

A STEMI occurs when there is complete occlusion of a coronary artery resulting in cessation of blood flow to affected parts of the myocardium (Makki, Brennan & Girotra 2015). Acute cell ischaemia and necrosis of the myocardium invariably results from such an occlusion (Gallagher & Dennis 2007; Thygesen et al. 2012). One of the most serious outcomes of STEMI is the high potential for life-threatening arrhythmias such as ventricular fibrillation, ventricular tachycardia and in some instances, heart blocks and even cardiac rupture as a fatal event (Steg et al. 2012). These adverse events, as well as sudden late cardiac death can occur even after hospital discharge (Shimada & Scirica 2015).

The clinical diagnosis and treatment of STEMI is guided by the presence and extent of dynamic ischaemic electrocardiogram (ECG) changes and specific biochemical markers in the blood released by damaged and necrotised myocardial cells (Thygesen et al. 2012). Troponin T, Troponin I and Creatine Kinase-MB (CKMB) are time-sensitive, specific biochemical markers reflecting myocardial injury; recently use of high-sensitivity troponin has enabled detection of minor damage to heart muscle (Agewall et al. 2011; Reichlin et al. 2009). Each of these cardiac enzymes are released into the blood circulation following cellular death from myocardial necrosis and are detected from approximately three hours after the AMI (Fenton 2007; Garas 2006). Increased levels of serum biomarkers are therefore diagnostic and as conduction is altered through the ischaemic myocardium or must divert around infarcted tissue, there are visible changes in the ECG. Elevation of the ST segment of the ECG in two or more contiguous leads of ≥ 0.2 mV in the precordial leads V1 to V3 and ≥0.1 mV in other leads is diagnostic of myocardial infarction (Hamm et al. 2006; O’Gara et al. 2013). The extent of this ST segment elevation provides a quantitative measurement of the degree of myocardial ischaemia and hence, the size of the infarction.

Mortality in STEMI and Treatment Guidelines

Mortality associated with STEMI is high; up to 10% in the first year after the index AMI (Fenton, 2007) and therefore early treatment is necessary to improve survival. More than half of STEMI-related deaths occur prior to hospital admission; mainly from lethal ventricular arrhythmias (Steg et al. 2012). Fortunately, STEMI rates in Australia have decreased 30% in the period from 1993 to 2010 (Wong et al. 2013), which has been primarily attributed to better cardiovascular risk control through promotion of healthy lifestyle, as well as rapid treatment systems. However, the risk of death associated with STEMI remains high and it is crucial that patients are diagnosed and treated early. Therefore urgent PPCI and stent insertion is often recommended as first-line intervention for STEMI. International guidelines from both the American Heart Association (O'Gara et al. 2013) and the European Society of Cardiology have been developed for clinical practice (Steg et al. 2012) to prioritise and streamline the management of acute presentations of STEMI.

The aim of treatment is to rapidly restore coronary blood flow and to optimise oxygenation of cardiac myocyte cells so that the extent of the infarction is minimised. The two recommended reperfusion therapies for STEMI are PCI or thrombolysis (O'Gara et al. 2013). Clinical practice guidelines for STEMI have recently been updated to include the latest recommendations for multi-vessel PCI (Levine et al. 2015) where primary PCI (PPCI) is also performed for multiple blocked coronary vessels. This is based on the recognition that almost 40-50% of STEMI patients have multi-vessel disease, which when treated by PCI, demonstrated improved clinical outcomes with lower adverse complications due to the complete revascularisation and reperfusion of the myocardium (Banning & Gershlick 2015; Park et al. 2014; Sorajja et al. 2007).

Percutaneous Coronary Intervention (PCI)

A PCI is a direct, minimally invasive reperfusion strategy to treat coronary artery occlusion by using percutaneous coronary angioplasty (PTCA) to unblock the affected artery followed by intra-arterial stent placement to maintain patency (Meier 2006). The precise location and extent of the occlusion is determined by coronary angiogram and a balloon-tipped catheter is then used to dilate the lumen of a blocked vessel. A metallic stent is inserted to scaffold the newly dilated coronary artery wall and thus maintain patency of the vessel and to optimise myocardial blood flow (Dangas & Kuepper 2002; Fischman et al. 1994). Figure 2.1 illustrates coronary occlusion and PCI with a metallic stent insertion.

Since the advent of metallic stents, there has been rapid developments in stent technology. As each new stent type is tested clinically, further developments occur. In particular there is now widespread use of first generation and second generation polymer drug-eluting stents including biodegradable, bioresorbable stents which are associated with lower risk of in-thrombosis and restenosis, recurrent angina, myocardial infarctions and end-point cardiac mortality (Kedhi et al. 2010; Serruys et al. 2010; Stone et al. 2011).

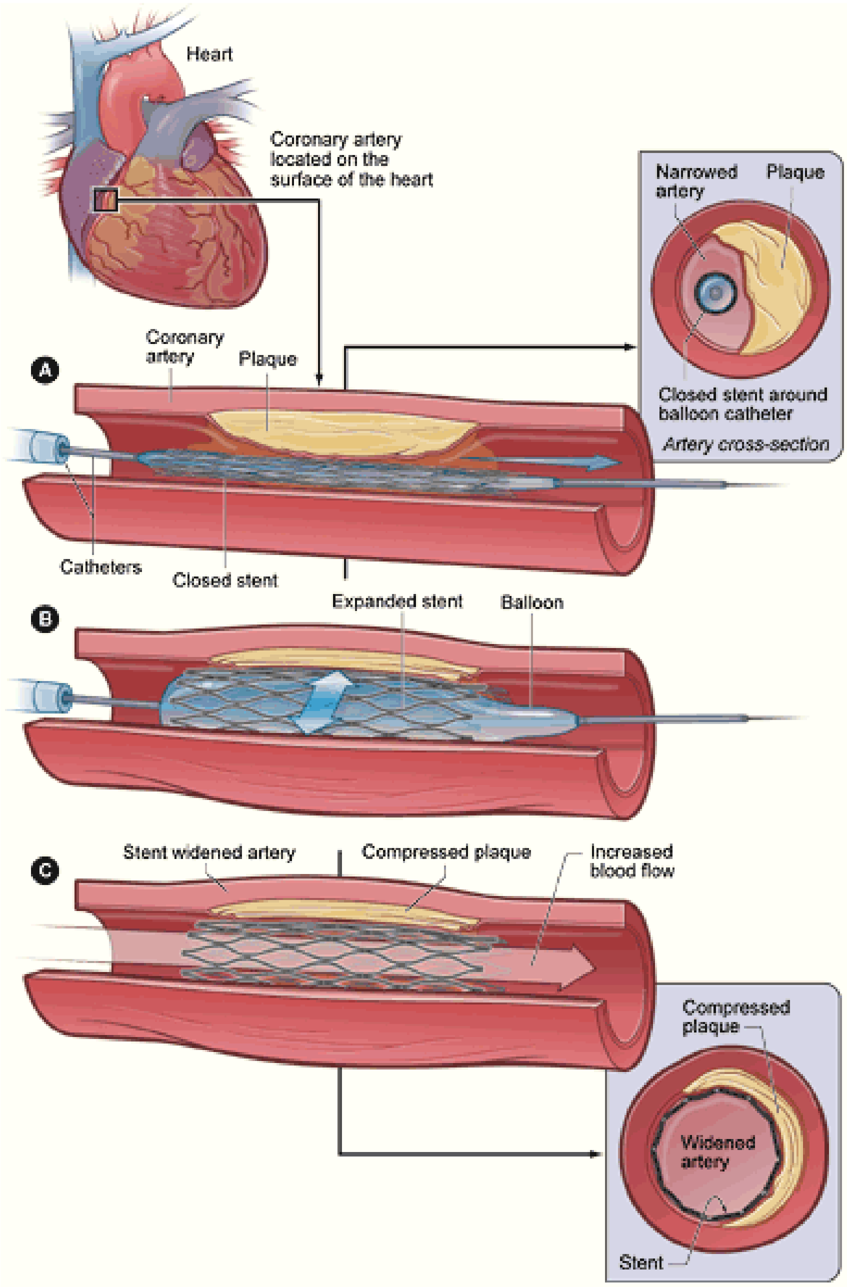

Figure 2.1. Plaque formation in a coronary artery and PCI with stent insertion (Retrieved: 1st November, 2015)
https://upload.wikimedia.org/wikipedia/commons/3/39/PTCA_stent_NIH.gif

Primary Percutaneous Coronary Intervention (PPCI) as treatment for STEMI

The term PPCI refers to a PCI procedure conducted as the first-line reperfusion strategy and therefore, without previous revascularisation intervention. PPCI is the routine treatment for STEMI at most health care institutions that are capable of providing a PCI team at short notice, which requires catheter laboratories to be operational on a 24 hour, 7-day service. Time-frames have been developed based on research evidence (Chan et al. 2012; Fosbol et al. 2013). The target time of ≤90 minutes to PPCI is recommended from the first medical contact or earlier; ≤ 60 minutes if the patient presents directly to a PCI centre and symptom onset is <120 minutes (O'Gara et al. 2013; Steg et al. 2012). Thrombolysis by contrast, is the treatment used to breakdown or dissolve (lysis) blood clots by intravenous infusion of drugs such as tissue plasminogen activator (tPA) resulting in specific lysis of fibrin (or fibrinolysis). Thrombolysis for STEMI is recommended within 30 minutes of hospital arrival and can be delivered at hospitals without PCI services and if PPCI is not immediately available.

PPCI outcomes compared to Thrombolysis

The outcomes for PPCI are superior in comparison to thrombolysis. Unlike thrombolysis, PPCI results in sustained reperfusion of the blocked artery with less of the major complications associated with thrombolysis, such as bleeding and stroke (Aversano et.al; 2002; Gersshlick et.al 2013; Grines et al. 1993; Svensson et al. 2006; Zijlstra et al. 1993); a reduction of re-infarction rate by 30-40%, shorter hospitalisation and overall lower 30 day and one year mortality have been reported (Senestrand, Lindback & Walletin 2006). The addition of coronary stenting is associated with better results such as less re-stenosis or re-narrowing than with balloon PTCA alone (Al Suwaidi, Berger & Holmes 2000; Fischman et al. 1994; Hannan et al. 2008; Serruys et al. 1994). Building on this early work, PPCI is now the treatment of choice if it can be initiated within 60 minutes as “door to balloon time” in a PCI-capable hospital or <90 minutes of the first medical contact (O’Gara et al. 2013; Steg et al. 2012). The following sections discuss the treatment pathways to PPCI and the impact of ageing on health outcomes of older patients who present with a STEMI event.

Processes and treatment pathways to PPCI for STEMI

Currently there are two main pathways to PPCI for STEMI; by routine emergency department (ED) admission and by pre-hospital field triage using ambulance ECG diagnosis prior to the patient’s arrival at hospital. Figure 2.2 illustrates these two pathways.

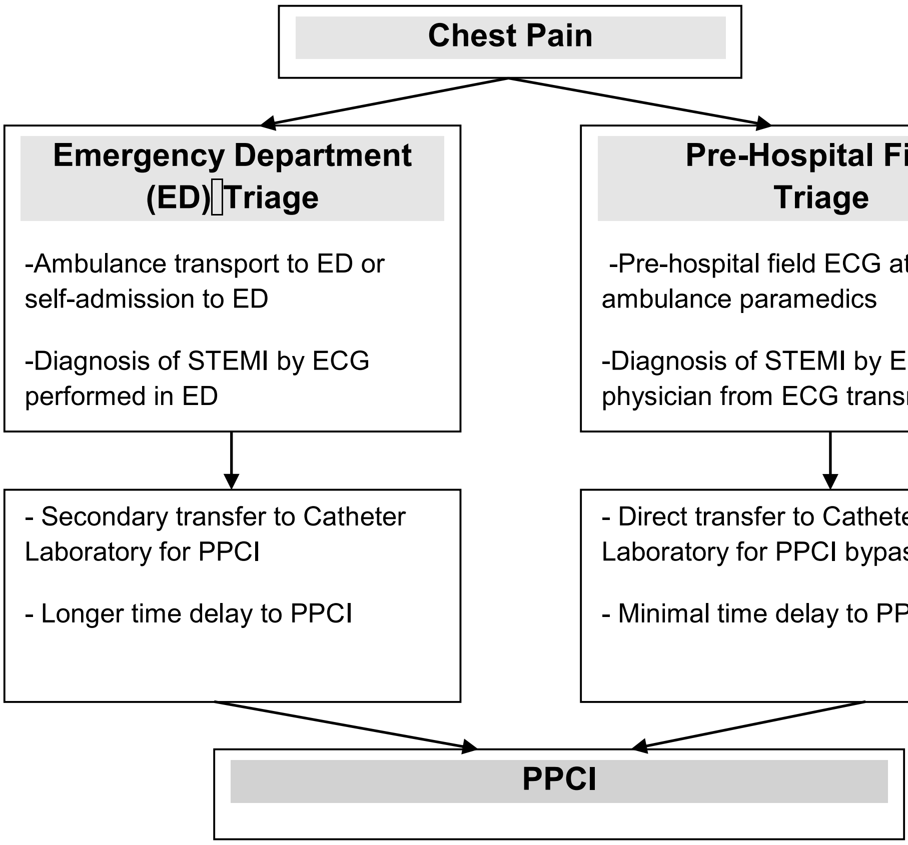

Figure 2.2. Treatment Pathways to PPCI for STEMI

Emergency Department admission for PPCI (Routine Pathway)

Emergency department admission or ED triage is the routine admission portal for patients with chest pain symptoms suggestive of AMI. Patients are either self-presenters or are transported by ambulance to the ED of the closest hospital for medical assessment. Diagnosis of STEMI is made by ED doctors using ECG and blood enzyme results, which is usually followed by transfer of the patient for treatment to a major regional heart centre with PPCI services or direct admission if presenting to the heart centre. Delays are frequent and can be prolonged in a busy ED location as ECGs and other assessments are undertaken and the catheter laboratory staff activated, and for smaller regional hospitals, if necessary, transfer for PPCI can only occur when there is final acceptance by the major regional heart centre. These delays have an important impact as mortality increases if “door-to-balloon” time (arrival time to PPCI) exceeds 120 minutes (Cannon et al. 2000). The impact of delays are most notable in high-risk patients such as the elderly (Vermeulen et al. 2008) and those with complications of cardiogenic shock (De Luca, Arnoud, et al. 2004). Therefore, an admission pathway than can reduce delays to PPCI is necessary for optimal clinical outcomes.

Field triage to PPCI (Fast-Track Pathway)

In contrast, a faster treatment pathway based on the concept of using ambulance-based (pre-hospital) field ECG diagnosis and early triage of AMI has been adopted internationally as best practice for STEMI (Levine et al. 2015; Steg et al. 2012). Field triage relies on ambulance paramedics performing an ECG on the patient at the scene of the AMI. This ECG is then transmitted to the ED of a major heart centre where STEMI is confirmed by ED physicians. The ambulance personnel are then directed to transport the patient straight to the PCI centre and the cardiac interventional team is simultaneously mobilised ready for urgent PPCI.

The concept of field triage has minimised delays to PPCI with resultant higher survival benefits (Carstensen et al. 2007; Ortolani et al. 2006; Terkelsen et al. 2009; Vermeulen et al. 2008; Zanini et al. 2008). A large European registry study on 5128 STEMI patients reported shorter time to treatment (OR 2.45, 95% CI 2.13-2.83), a smaller infarct size (OR 1.19, 95% CI 1.04-1.36) and including a lower 1-year mortality (OR 0.67, 95% CI 0.50-0.91) for patients who received field triage to PPCI (Postma et al. 2011). Recent research on PPCI for STEMI has also confirmed that pre-hospital triage is associated with lower four week (5.4% vs 13.3%, p=0.006) and 12 month mortality (6.6% vs 17.5%, p=0.019) and is an independent predictor of survival (Chan et al. 2012).

Field triage was first initiated in Australia in 2004 by two major metropolitan health regions in Sydney; the Northern Sydney and Western Sydney Health Networks (Carstensen et al. 2007) which provided urgent PPCI services on a 24 hour basis for STEMI patients. Following the initial success of the field triage program conducted at both Royal North Shore and Westmead Hospitals in reducing mortality and MACE, New South Wales became the first Australian health jurisdiction to roll-out the State Cardiac Reperfusion Strategy. This state-wide health project initiated mandatory pre-hospital assessment and field triage PPCI for patients with STEMI at all major metropolitan public hospitals. This model of acute cardiology care was a component of the NSW Health Clinical Services Redesign Programme (CSRP) started by New South Wales Health in collaboration with the NSW Ambulance Service for STEMI cardiac care and subsequently known as Pre-hospital Assessment of Primary Angioplasty (PAPA) (ACI NSW Agency for Clinical Innovation 2013).

Field triage has enabled the rapid assessment and equitable treatment of all STEMI patients unrestricted by age or co-morbid health barriers and 1522 patients have benefitted from field triage under NSW Ambulance STEMI cardiac care (NSW Ambulance 2015). In the full model, pre-hospital assessment includes clinical management of STEMI at the scene by paramedics who acquire the diagnostic ECG on the patient followed by a prescribed care protocol involving monitoring, defibrillation, oxygenation and initiation of Aspirin, Nitrates and a narcotic analgesia. Current Australian guidelines for STEMI management, endorsed by the National Heart Foundation and the Cardiac Society of Australia and New Zealand, highlight early PPCI as best cardiac reperfusion practice (Australian Commission on Safety and Quality in Health Care 2014; Chew et al. 2011).

Following PPCI, patients are faced with the reality that there are new changes in their routine activities and lifestyle as they recover. Adherence to medications, lifestyle modifications in diet and exercise activity and secondary prevention strategies in cardiac rehabilitation, resumption of work and routine activities are all vital facets of recovery after a STEMI (O'Gara et al. 2013). During hospitalisation, PPCI patients often receive educational information pertaining to their recovery, availability of post-discharge support services and cardiac rehabilitation. An important challenge for PPCI patients is the process of adjustment and compliance with new and long-term medications such as, dual and triple antiplatelet therapy which reduce the risk of in-stent thrombosis associated with the pathological increase in platelet activity with STEMI and the deployment of drug-eluting stents.

However, the degree of patient interest, compliance and engagement with education, new medication regimes and life changes may not be apparent until post-discharge follow-up. Results of a systematic review indicated that initial compliance with anti-platelet medication was high at 4 weeks but declined to sub-optimal levels by 12 months influenced by factors such as bleeding, lower educational and migrant status and poor understanding of anti-platelet medication (Czarny et al. 2014). Concurrent research have also reported adverse outcomes such as stent thrombosis and re-infarction, further PCI, strokes and increased cardiovascular mortality with inadequate antiplatelet medication regimes (Giustino et al. 2015; Mauri et al. 2014; Navarese et al. 2015). Therefore the engagement of PPCI patients in adopting new strategies and changes to their healthcare as well as rehabilitation participation during the recovery period is paramount for achieving event-free survival after PPCI and participation at cardiac rehabilitation.

Treatment outcomes of PPCI and clinical status (Mortality and Morbidity) in older patients

In Australia, the number of PCI procedures have increased steadily over the years, in part due to an ageing population as CHD rates increase with age; between 2000-2001 and 2007-2008 PCI rates rose by 57% (Australian Institute of Health and Welfare 2015). Mortality is commonly reported as the priority indicator of PPCI outcomes and there is evidence that mortality increases with age. Results of a study on older STEMI patients showed mortality to increase with age regardless of PPCI success in restoring good myocardial blood flow. The 90-day mortality rates were 2.3%, 4.8%, and 13.1% for patients <65 years, 65 to 74 years old, and >75 years correspondingly, with age identified as the strongest predictor of death (OR 2.07, 95% CI, 1.84-2.33) (Gharacholou et al. 2011). Similar findings were observed in a recent comparative study conducted on PCI patients aged >75 years to <85 years recruited from a German STEMI registry. There was increased one year mortality, more bleeding complications and higher rates of PCI failure associated with advancing age, despite revascularisation success (Fach et al. 2015). Recent research reported that octogenarians had 2.6 times higher risk of in-hospital death and 4.1 times the risk of not surviving at 3 years follow-up after a STEMI by comparison to younger patients <80 years (Kvakkestad et al. 2015).

Patient clinical outcomes on discharge

Following PPCI for STEMI, clinical outcomes are routinely monitored during their hospitalisation as described above. Additional outcomes which are assessed include major adverse cardiovascular events (MACE), such as access site complications, recurrent angina, stroke, arrhythmias, re-occlusion, recurrent-AMI, death, coronary artery bypass graft (CABG), repeat PCI, and repeat angiogram, as an overall indicator of PPCI success. On discharge, complications can include acute stent thrombosis, re-admissions, recurrent chest pain and ischaemia, arrhythmias and access site infection or bleeding including retroperitoneal bleeds and heart failure symptoms (Wong et al. 2006). However, patient-centred outcomes receive far less attention.

Patient-centred outcomes such as quality of life are very important to all patients as they reflect the patient's responses to illness, symptoms and their individual experiences of changes in normal function (Carr & Higginson 2001; Spertus 2008). An example of a patient-centred outcome is psychosocial adjustment. With STEMI, normal ageing adjustment is disrupted by a life-threatening acute cardiac event with the associated urgent, invasive and often unprecedented treatment such as PPCI. Older patients are unable to receive pre-procedural and psychological preparation due to the rapid nature of urgent triage and intervention. Despite this and other physical issues associated with aging there are no established national nursing practice guidelines for PPCI care specific to older people. Therefore older people receive the same post-procedural care as younger patients which extends to the post-discharge recovery period where additional support for older AMI patients is needed but may be overlooked.

Past studies have indicated that low social support and other patient-centred outcomes such as angina and depressive symptoms are important factors to assess after an AMI as these are associated with higher mortality, decreased health status and increased morbidity after an AMI (Barth, Schneider & von Kanel 2010; Dickens et al. 2004; Leifheit-Limson et al. 2012). An expectation during recovery from PPCI is the adjustment to new modifications in daily lifestyle for secondary prevention of further cardiac-related complications as STEMI patients remain at risk. This aspect of healthcare may need additional attention particularly for the elderly and those with low social support in the community due to changes in cognition and resources limitations. The next section introduces ageing and the impact of older age on cardiovascular health outcomes.

The “Older” Person and CVD

According to the World Health Organization’s (WHO) policy for the promotion of active ageing in the global population, “older” has been defined as age 60 years. This age delineation is used for the systematic review included in this study, as stated in Chapter 1. However, different classifications for ‘older’ exist, in part determined by the population being assessed. For example the WHO addresses global populations and therefore includes low income countries where the average life span is much younger than high income countries, such as Australia. By 2025, approximately 1.2 billion or one third of the world’s population will comprise of people aged 60 years or over (World Health Organization 2002). Alongside this ageing demographic, it is projected that many of these older people will also develop cardiovascular disease. In Australia, overall cardiovascular deaths and hospital admission rates for AMI have been declining. Cardiovascular mortality rates have dropped by two-thirds; largely attributed to improved management of risk factors such as cessation of smoking and more stringent control of hyperlipidemia and hypertension (Australian Institute of Health and Welfare 2011). However, the slowest rate of decline is in the oldest patient cohort from 75-90 years old (Mathur 2002). National health statistics (Australian Institute of Health and Welfare 2010) also demonstrated that 60% of hospitalizations for CHD were for people aged 65 years and older. The main reasons for admissions were angina, which accounted for nearly half (44%) and AMI (35%) of all cardiovascular hospitalizations in Australia (Australian Institute of Health and Welfare 2011). Therefore there is an urgent need to have insight into older people’s needs for optimal recovery. The following section will describe the physiological changes associated with ageing.

The Cardiovascular System and Ageing

The process of ageing is complex, with alterations in multiple physiological systems including those which impact on normal cardiovascular function. Ageing is a process of progressive physiological and functional decline (Lopez-Otin et al. 2013). Chronological ageing predisposes to structural and physiological age-related changes in the entire cardiovascular system. Arteries undergo structural changes with lower levels of elastine for elastic recoil and vascular compliance, and arterial-cardiac interactions causing endothelial dysfunction and isolated systolic hypertension in the elderly (Lakatta 2003; Maruyama 2012). Compensatory mechanisms such as increased blood velocity predisposes to raised afterload, left ventricular hypertrophy and myocardial ischaemia (Lakatta 2003). This is often compounded by aortic valve sclerosis, which occurs in 25% of people aged >65 years. Together these effects result in a 50% increase in risk of cardiovascular death, in addition to more AMI, angina, heart failure and strokes in patients without pre-existing cardiovascular problems (Otto 2004). Ageing is also associated with suppression of the renin-angiotensin-aldosterone system, increasing sodium and fluid retention and more cellular oxidative stress affecting endothelial cell function, glomerulosclerosis, increased hypertension and atherosclerosis (Barton 2005; Weinstein & Anderson 2010).

Other ageing effects and impact on health status outcomes

Age-related cognitive decline is prevalent and often associated with functional, mobility and gait impairments which predispose to higher risk of falls and general deconditioning. Ultimately these effects can also result in a progressive loss of independence, impaired self-care, poor decision-making capabilities and decreased quality of life (Davis et al. 2015; Segev-Jacubovski et al. 2011). Altogether these effects mean that older people, particularly the frail elderly, have more potential for higher health risks and poorer health status outcomes. This is compounded by the presence of other co-morbid conditions such as diabetes, hypertension or chronic airway limitation (CAL) when a major CVD event, such as STEMI occurs. Therefore, it can be concluded that older people have the potential for developing multiple age-related physiological and cardiovascular conditions which are not prevalent in younger people. These conditions can contribute to functional loss and increased disability and they need to be considered in the care of the elderly after PPCI, as complete recovery is not dependent solely on coronary reperfusion.

There is substantial research evidence that PCI in older people is associated with good quality of life outcomes, primarily from the relief of angina symptoms resulting in improved physical function (Agarwal, Schechter & Zaman 2009; Gunal et al. 2008; Ho et al. 2008; Li et al. 2012; Shan, Saxena & McMahon 2014; Zhang et al. 2006). However, these results are in reference to their existing assessment of their quality of life. This assessment can be complex as a common issue associated with ageing and changes in reported health related quality of life is the response shift phenomena (Schwartz 2010). With illness and sudden changes in health state, patients may re-prioritise or reconceptualise their responses to health status assessments. Congruent with the principles of adaptation theory, older people may have an inflated perception of their physical and functional limitations and tend to under-rate their progress when confronted with new or sudden changes in their social and health state with a resultant negative impact on their health outcomes (Blazer 2008). The next section discusses HRQOL after PPCI as the main focus of this study.

HRQOL as an outcome of PPCI for STEMI

Health-related quality of life (HRQOL) is not routinely assessed in PPCI patients but it remains an important aspect of healthcare and associated patient outcomes. HRQOL is described as a state of health perceived and reported by an individual impacting on their functioning, and it therefore reflects a patient's physical, social and emotional health (Pedersen et al. 2007b). The assessment of HRQOL in patients undergoing cardiac treatments is increasingly recognised as an important outcome measure and patient-reported health status is strongly recommended by peak organisations including the American Heart Association (Rumsfeld et al. 2013). Importantly, while older people form a high proportion of patients undergoing PPCI, few studies have focused on the potential differences in HRQOL that occur with age and treatment. While older people may consider mortality and longevity as a priority, they may place increasing emphasis on outcomes related to their independence and psychosocial and financial impact on their families (Jackson & Wenger 2011).

Two validated tools were utilized for measuring HRQOL. The Short Form-12 (SF-12) is a generic HRQOL survey and a shorter version of the SF-36. The SF-12 measures eight general health domains and has been determined to be valid in cardiovascular populations (Dempster and Donnelly 2001, Muller-Nordhorn, Roll and Willich 2004), including after PCI (Biering, Frydenberg and Hjollund 2014, deSmedt et al. 2013, Moore et al. 2006) for both physical and mental components of health. The cardiac-specific Seattle Angina Questionnaire (SAQ) measures five domains of cardiac-related HRQOL. The SAQ is reported to be valid for measuring functional improvements and anginal relief after PCI (Agarwal et al. 2009, Graham et al. 2006, Spertus et al. 2004). It is sensitive to cardiac-specific changes and often used in conjunction with a generic tool such the SF-12, to provide a more precise measure of all dimensions of HRQOL. In this thesis it is understood that biophysiological and psychosocial changes are common in heart disease and are very likely to impact on global HRQOL. For instance symptoms such as recurrent angina commonly impact on patients' perception of their health following PPCI for STEMI. The Wilson and Cleary HRQOL (1995) framework, which emphasizes the importance of biophysical changes and symptoms, therefore, is an ideal match. Wilson and Cleary also include multiple other factors, such as age and gender, which are important factors in cardiac recovery. By applying this framework to guide the study and the selection of appropriate measures, such as the SF-12 and the SAQ, it is possible to obtain a more accurate understanding and a deeper insight into multiple aspects of HRQOL experienced by PPCI patients. This is important for understanding and addressing deficits in current PPCI care for STEMI.

Therefore surveillance of quality of life, not only clinical and recovery events, are important following discharge. It is evident that PPCI can affect multiple physiological and psychosocial dimensions of a person's life. These aspects of STEMI treatment outcomes are not routinely assessed post-PPCI. The following section will discuss the conceptual framework that defines the relationship between these global aspects of HRQOL and guides research on HRQOL in older people as a major component of this thesis.

Conceptual framework of HRQOL

The framework guiding my understanding of patient reported outcomes in this thesis is Wilson and Cleary's conceptual model of HRQOL (Wilson & Cleary 1995). This model integrates five different levels of human function namely, physiological factors, symptom status, functional health, general health perceptions and overall quality of life. Within this linear model there is no direct link or effect between non-adjacent concepts but instead, a continuum and distinct measurement of causal associations. In addition, there are mediating variables such as individual characteristics and environmental characteristics which impact on these causal relationships (See Figure 2.3). This model has been widely used to explore HRQOL in various populations effected by chronic illness, including patients with cancer (Rodríguez, Mayo & Gagnon 2013), diabetes (Shiu et al. 2014), human immunovirus (HIV) (Henderson et al. 2012) and heart failure (Bennett et al. 2001; Krethong et al. 2008), to explain causal relationships among bio-physiological status, symptoms, functional status, general health perception and HRQOL. In order to explicitly understand the relationship between symptoms of angina which can occur preceding and during an acute STEMI event and the causal and adjunct factors which impact on HRQOL, Wilson and Cleary's framework has been selected as the most suitable for this research (Wilson and Cleary, 1995). To date, this is the first study that utilized this conceptual framework for addressing HRQOL in a STEMI cohort after PPCI and in particular for the less investigated field triage cohort.

The development of the model originates from the researchers' observations that despite the variety of conceptual models used for HRQOL, there remains little focus on causal variables that mediate or compound clinical interventions which directly affect patient outcomes. Wilson and Cleary's framework has been used to underpin HRQOL assessment and related causal elements in the research conducted for this thesis for the effects of STEMI, which may influence all aspects of a person's health status.

While Wilson and Cleary was finally selected as an appropriate framework, other frameworks were considered, including the Symptom Interactional Framework (Parker 2005). This framework explores physiological, psychological, behavioural, and sociocultural factors as symptom clusters in predicting HRQOL. While the Symptom Interactional Framework has been used in chronic stable angina patients to identify interactive mechanisms and symptoms such as fatigue and dyspnea which impact on HRQOL (Kimble et al. 2011), a STEMI event is life threatening and a process of adjustment is required subsequent to PPCI. It was considered that the framework of Wilson and Cleary is better in this scenario as it integrates all concepts of function and symptoms relevant to cardiac patients.

Moreover, by incorporating the Wilson and Cleary framework into cardiovascular research, it enables clinicians to evaluate the processes and health outcomes of a specific treatment. This will link into any deficits identified by the HRQOL tools used and may bridge the gap between clinical practice and research.

There is however limited research on HRQOL for PPCI STEMI cohorts, and even less which utilises a conceptual model of HRQOL that incorporates multiple aspects of bio-psychosocial and bio-physiological health. Some patient needs post-discharge are well understood, such as the need to address CVD risk factors and patients are often routinely referred to cardiac rehabilitation or may have post-discharge care early in recovery. However, the assessment of HRQOL after PPCI represents an important and novel approach to understanding what may be needed for appropriate healthcare provision, particularly for older ACS patients with complex co-morbidities and needs.

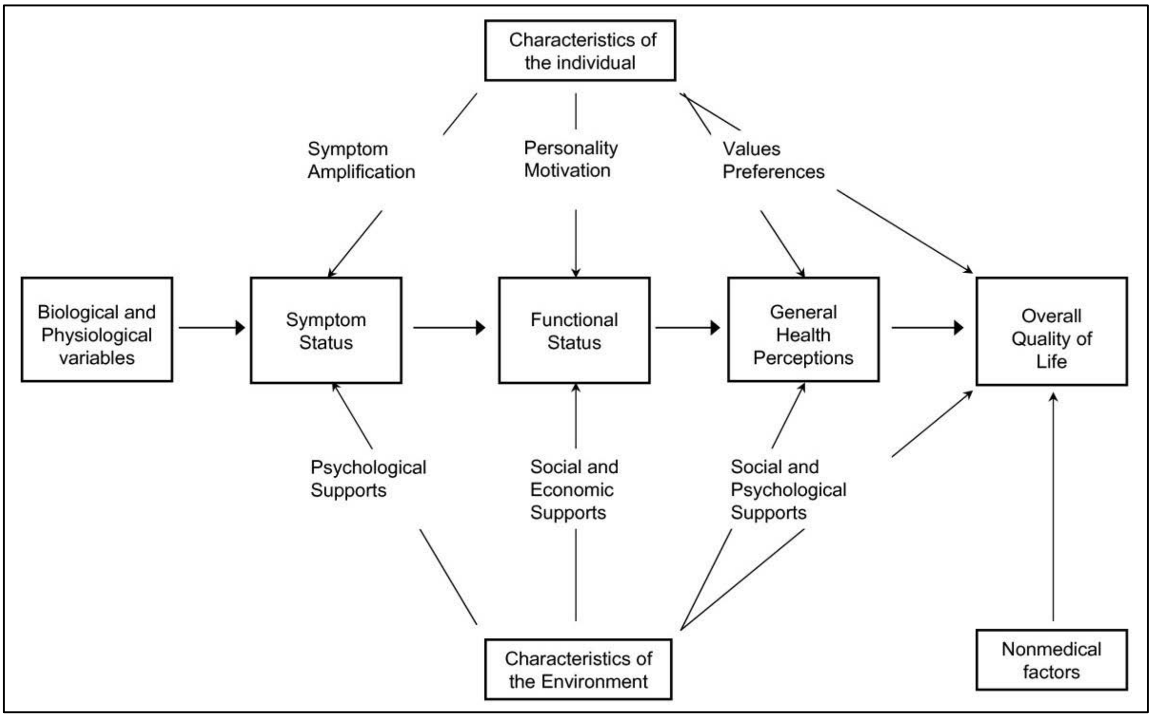

Figure 2.3. Conceptual Model of Health-Related Quality of Life

Adapted from Wilson, I.B. & Cleary, P.D. 1995, 'Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes', *Journal of the American Medical Association, JAMA*, vol. 273, no. 1, pp. 59-65.

Post-discharge support after PPCI: Cardiac Rehabilitation

In recognition of the issues raised previously, on discharge from hospital, support services such as cardiac rehabilitation (CR) and home visits by outreach and/or community nurses are often provided to PPCI patients to facilitate their recovery (Goel et al. 2011). These are important aspects of extended care in the community, particularly for older people who are residing alone or have multiple comorbidities that adversely impact on their active daily living.

Cardiac rehabilitation is defined by the World Health Organization as:

"the sum of activities required to influence favourably the underlying cause of the disease, as well as to ensure the patient the best possible physical, mental and social conditions, so that they may, by their own efforts, preserve or resume when lost, as normal a place as possible in the life of the community. Rehabilitation cannot be regarded as an isolated form or stage of therapy but must be integrated within secondary prevention services of which it forms only one facet" (World Health Organization 1993, p.1).

The objectives of CR are to assist patients to regain independence and improve physical function, control modifiable risk factors for lifestyle change, manage psychosocial problems and to provide therapeutic teaching for self-management of cardiac health outcomes (Mampuya 2012; Steg et al. 2012). A CR program is mainly comprised of three phases: Phase1 is initiated during hospitalisation for early mobility and adjustment processes; Phase 2 focuses on post-discharge community and outpatient support in supervised exercises and risk factor reduction; and Phase 3 is aimed at maintaining lifelong physical fitness and prevention of recurrent cardiovascular disease (Mampuya 2012).

Attendance at CR is associated with improved cardiovascular, physical and psychological function by reducing coronary risk factors (Higgins, Hayes & McKenna 2001; Taylor et al. 2004) resulting in fewer hospital readmissions and better HRQOL for patients with coronary artery disease (Shepherd & While 2012) and acute myocardial infarction (AMI) (Dunlay et al. 2014; West, Jones & Henderson 2012). Findings from a large clinical trial on ACS cohorts ≥ 60 years, comprising PCI patients, indicated that behavioural modification adherence with diet, exercise and smoking at 1 month follow-up was strongly associated with less AMI, stroke and cardiac death (Chow et al. 2010). Other studies that investigated CR participation in PCI patients also reported less MACE (Dendale et al. 2005; Izawa et al. 2011), although no study has investigated effects on PPCI cohorts treated by fast-track field triage for STEMI. International guidelines from the American College of Cardiology recommend CR for moderate to high risk patients after cardiac procedures such as PCI (Levine et al. 2011). These recommendations emphasize the importance of CR attendance as a vital component of recovery after coronary revascularization.

Past research has also noted that despite the benefits conferred by CR programs and often high referral rates, attendance remains suboptimal and is often influenced by multiple and complex factors. Reported barriers to CR participation and under-representation occurs for as women (Gallagher, McKinley & Dracup 2003), the socially disadvantaged (Nielsen, Meillier & Larsen 2013) and people aged over 62 years with higher risk of functional disability (Suaya et al. 2009; Williams, Fleg & Ades 2002). Results of an Australian population study (Clark et al. 2014) indicated that CR attendance was not affected by geographical distance to health and rehabilitation services but rather, other factors such as gender and socio-psychological issues of motivation and patients' perceptions of CR. Data on CR participation and its effects on PCI populations are limited. Males and older people aged >70 years were less likely to be referred and had lower CR attendance rates (Worcester et al. 2004). From these reports, it is clear that a gap exists in research on CR attendance for the older PPCI cohort whose psychosocial and functional needs are complex and have not been fully investigated from a rehabilitation perspective after a STEMI event.

The timeframe context for this thesis aligns with Phase 2 of CR; attendance and participation by PPCI patients in a supervised out-patient program of physical exercise, lifestyle and risk reduction counselling and patient education during recovery at 4 weeks and 6 months after the index PPCI. This phase was selected to determine the pattern of participation by all STEMI patients at both points of recovery and to determine what key factors predict patients' participation and the benefits of post-discharge support that could impact on recovery in the community following PPCI.

Chapter Summary

This chapter describes CVD and its components of CHD and ACS, STEMI and pathways to PPCI in older people, the ageing process, HRQOL, the conceptual framework and CR participation after PPCI with evidence from past research. The next chapter describes the first of the four linked studies upon which this research and thesis is created.

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CHAPTER 3: SYSTEMATIC REVIEW OF HEALTH RELATED QUALITY OF LIFE IN OLDER PEOPLE AFTER PERCUTANEOUS CORONARY INTERVENTION.

Chapter Preface

Publication reference

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Chapter 2 provided a background to cardiovascular disease, acute coronary syndrome and STEMI, pathways to PPCI, HRQOL and post-discharge support such as CR, with additional focus on ageing and older people with STEMI. The conceptual framework of Wilson and Cleary was introduced to guide exploration of important aspects of HRQOL for the STEMI cohort treated by PPCI.

This chapter will present a systematic review of the literature in its original form, pertaining to PCI and the impact of age on HRQOL with publication details listed above. The article in its published form is provided in the appendix. A brief background in this chapter preface expands the abstract and rationale for conducting this study with a summary of findings and its relevance to clinical practice.

Background

People aged over 60 years represent an increasingly high proportion of the population undergoing PCI. While risks are greater for older people in terms of major adverse cardiovascular events and higher mortality for this treatment, it is unclear if the benefits of health-related quality of life outcomes may outweigh risks. This review was undertaken to provide nurses and health professionals a pooled summary of published literature by systemically identifying, appraising, and synthesizing all related studies examining HRQOL in people treated with PCI. This chapter provides a comprehensive synthesis of published studies between years 1999 to 2012 examining the effect of age >60 years on HRQOL after elective and primary PCI. A total of 18 studies on PCI were examined and synthesized using the PRISMA approach, the CASP guide for appraisal of study quality and risk of bias was assessed by using the Cochrane Collaboration criteria.

Summary of results

Findings revealed that all people, regardless of age, reported better HRQOL, primarily from the relief of angina and improved physical and mental function. Most studies reported improvements in symptomatic angina occurring within 1 month of hospital discharge and continuing to 12 months after PCI. Similarly, HRQOL improved over time to both 6 months and I year with the biggest gains in physical functioning followed by angina frequency and cardiac-related QOL regardless of age. Conclusively, age itself did not have an independent predictive effect on HRQOL outcomes when other factors such as comorbid conditions were taken into account. The results expand the current limited pool of information and resources available for evidence-based healthcare for this cohort.

Recommendations for practice

From this review, gaps are identified in published literature on the management of older people aged >60 years with acute coronary occlusion. The findings could provide a guide to future enquiry and quality improvements in cardiac healthcare delivery. Recommendations for the incorporation of HRQOL assessment into routine PCI care could expand the limited research focussing on the needs of older PPCI patients. Assessment of older peoples' health status by nurses and other health professionals is important for a rapidly expanding population of retired and older people with ACS. This group undergoes similar PPCI treatment as younger cohorts, but their needs and health status outcomes may differ significantly during recovery.

The following section presents the study article in its original form, including the text content.

Abstract

People aged over 60 years represent an increasingly high proportion of the population undergoing percutaneous coronary intervention. While risks are greater for older people in terms of major adverse cardiovascular events and higher mortality for this treatment, it is unclear if the benefits of health-related quality of life outcomes may outweigh risks. A search of the PubMed, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Excerpta

Medica, and Cochrane databases was conducted for the period from January 1999 to June 2012 using key words “percutaneous coronary intervention”/”angioplasty”, “older”, “elderly” and “quality of life”/“health-related quality of life”. Using a systematic review approach data from 18 studies were extracted for description and synthesis. Findings revealed that all people regardless of age reported better health-related quality of life, primarily from the relief of angina and improved physical and mental function. Age itself did not have an independent predictive effect when other factors such as comorbid conditions were taken into account. Assessment of older peoples’ health status after percutaneous coronary intervention by nurses and other health professionals is therefore important for the provision of quality care.

Keywords: angioplasty transluminal, health-related quality of life, percutaneous coronary intervention, person, quality of life.

Introduction

The number of older people undergoing percutaneous coronary intervention (PCI) for coronary artery disease is increasing, partly due to an ageing population. While there is evidence that older people have more major adverse cardiovascular events (MACE) following PCI, it is less clear if age has an impact on other important health outcomes such as health-related quality of life (HRQOL).

By 2025, it is projected that approximately 1.2 billion people will be aged over 60 years (World Health Organization 2002). As age increases so does the risk of cardiovascular disease and therefore the use of treatments such as PCI. The goal of PCI is to relieve angina, decrease morbidity/mortality and improve HRQOL. Emergency or primary PCI for ST-elevation myocardial infarction (STEMI) is associated with higher survival rates (Carstensen et al. 2007; Terkelsen et al. 2009; Vermeulen et al. 2008; Zanini et al. 2008), better left ventricular function (Sivagangabalan et al. 2009) and smaller infarction size (Postma et al. 2011). Percutaneous coronary intervention can also be performed as an elective procedure for stable angina patients with symptomatic activity limitations despite optimal medical therapy.

Higher morbidity is reported for older people after PCI in comparison to younger groups, with more incidences of strokes, major bleeding, re-infarction, recurrent angina (Sakai et al. 2002) and longer hospitalization (Batchelor et al. 2000; Sukiennik 2007). While age-related co-morbidities are likely contributors, advanced age itself is an independent predictor of death and worse clinical outcomes for PCI (Batchelor et al. 2000; Chauhan et al. 2001; Floyd et al. 2006; Wenaweser et al. 2007). However, it is not clear if the benefits of improved symptoms and HRQOL outweigh these risks.

The main factors affecting HRQOL after PCI are predominantly age (Bengtsson, Hagman & Wedel 2001; Dias et al. 2005) and anginal frequency (Longmore et al. 2011). Controversy remains however over the degree of anginal benefit for patients older than 60 years. While earlier studies reported substantial anginal relief with PCI (Boden et al. 2007; Weintraub et al. 2008), a recent meta-analysis (Wijeysundera et al. 2010) comparing PCI with medical therapy for stable angina found little angina benefit (Teo et al. 2009). Older patients experience more recurrent angina resulting in repeat PCI (Spertus et al. 2005).

The impact of PCI on HRQOL is an important indicator of treatment effectiveness from the patient perspective and incorporation of measurements of HRQOL are recommended by key organisations including the American Heart Association (Rumsfeld et al. 2013). Treatments can affect multiple areas such as physical, mental, and social health of a person's life differently, therefore measurements of global health dimensions are important for an ageing population (World Health Organization 2002). As many patients with cardiovascular disease have co-morbidities, assessment may be best achieved by using both generic and disease specific HRQOL measures. Disease specific measures are more likely to capture the effects of specific symptoms attributable to the condition, such as the frequency and intensity of angina in PCI (Spertus et al. 2004). While PCI rates and use of improved stent technology have increased over the last decade, assessment of HRQOL in relation to age remains under-researched.

Aims

The aim of this systematic review was to examine and synthesize study findings on the effect of age on HRQOL following elective and primary PCI, framed by the question: What is the effect of age on HRQOL following elective or emergency primary PCI for acute coronary syndromes and stable angina?

Methods

A systematic review was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) approach (Liberati et al. 2009; Moher et al. 2009) to provide a comprehensive appraisal of studies examining the effect of age on HRQOL in people treated with PCI. The PRISMA checklist identifies the type of review, rationale and objectives including risk of bias within each study and limitations or strengths in the summation of findings. Different phases of the review process from identification of studies, screening, eligibility and inclusion of studies was illustrated by the PRISMA flow diagram (Figure 1). This framework highlights a systematic process for searching and selecting relevant studies, extracting and synthesizing data, and critically appraising their methodological quality.

Literature search

The bibliographic databases PubMed, Cumulative Index to Nursing and Allied Health Literature, Cochrane Database of Systematic Reviews, PsycINFO and Excerpta Medica were searched using the terms ‘percutaneous coronary intervention’, ‘angioplasty transluminal’, ‘quality of life’ and ‘health-related quality of life’ both separately and in combination with related keywords such as ‘older, ‘elderly’ and then the terms ‘psychological’, ‘anxiety’, ‘emotions’ and ‘depression’ were added. The publication period was limited to January 1999 to June 2012 and only English language papers were included. The publication period was chosen to focus on contemporary systems and methods of PCI, including primary and early triage processes and minimal length of stay, processes which began in the late 1990’s and potentially could impact on HRQOL.

Abstracts of identified studies from the search were initially assessed for content, then full-text versions were retrieved for detailed assessment. Reference lists of published studies were also examined for relevant studies. Following assessment of abstracts and exclusion of studies that did not meet the inclusion criteria, including the removal of duplicate papers, 41 full-text papers were identified and independently assessed by two authors (SH and RG). Eighteen relevant studies were finally retained for review (Figure 3.1) with justification for excluding studies.

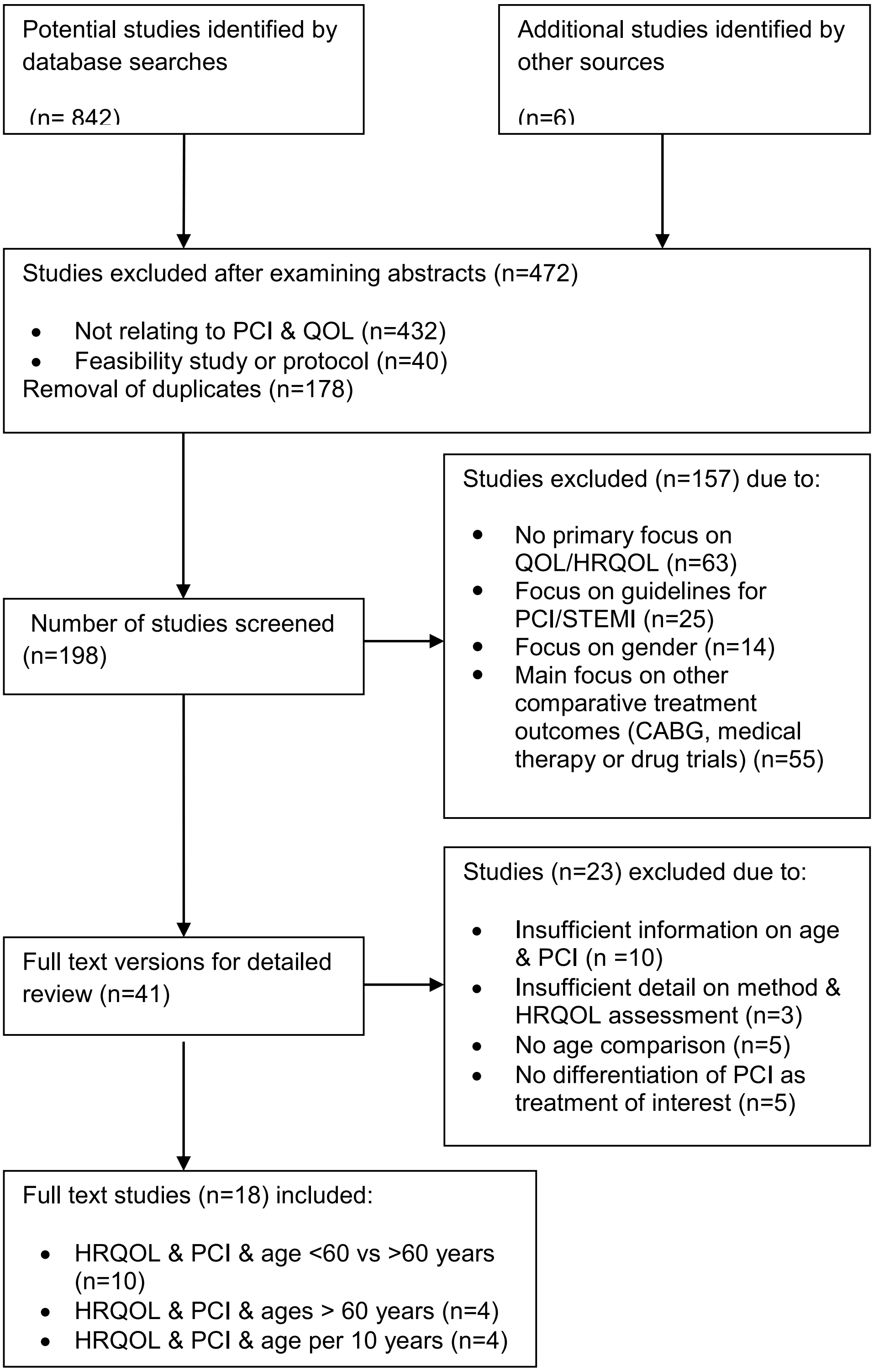

Figure 3.1: PRISMA Flow diagram of selection process

Inclusion and exclusion criteria

All studies on PCI (elective and primary PCI) based on a quantitative descriptive or randomized controlled trial design with follow-up to 12 months and using a validated instrument for measuring HRQOL in older people (aged 60 plus years) were included. The exclusion criteria was studies not published in English, research dissertations, gender studies, conference proceedings and brief reports which did not distinguish PCI results for older people.

Quality appraisal

Quality appraisal reflected the Clinical Appraisal Skills Program (CASP) guide for critically appraising the literature (Critical Appraisal Skills Program 2010). The CASP tool utilizes 10 questions to screen for validity, quality, design, precision of results, benefits and relevance to different clinical settings in studies and systematic reviews (Oxman, Cook & Guyatt 1994). For judging risk of bias the Cochrane Collaboration criteria were applied (Table 1). Each study was then independently reviewed by two authors (SH and RG). Review opinion from a third author (DE) was sought for final verification.

Data evaluation, extraction and synthesis

Data were extracted by the principal reviewer and validated by a co-reviewer using a data extraction form. Data elements were sample size and characteristics, study method, setting, country in which study was conducted, age categories, treatment comparison with PCI, HRQOL follow-up time, method and drop-out rate. Each study was systemically examined for score differences between baseline HRQOL and post-PCI using age >60 years to differentiate “older”. This corresponds to the classification of “older “ people described by the World Health Organization in their Active Ageing Policy Framework (World Health Organization 2002). Age groupings and classifications varied across studies so the classifications used by the study were reported but older people’s HRQOL outcomes were examined for better or worse scores and whether age was identified as an independent predictor of HRQOL. While recovery trajectories may differ, emergency (including urgent and acute) and elective PCI admissions were treated as one homogenous PCI group for HRQOL comparisons by age. Individual studies were not designed and therefore lack power to evaluate pooled HRQOL differences after PCI by time and age criteria. Extracted data and study characteristics are shown in Table 2 and synthesized summary results in Table 3.

Results

The search process is illustrated by a flow diagram for clarity (Figure 1). Eighteen studies were reviewed – six randomized controlled trials (RCTs), four of which were secondary analyses and twelve descriptive studies. Study characteristics are summarized and synthesized in Table 2. Studies were conducted primarily in North America (USA n=8, Canada n= 1, USA and Canada n=1) the UK (n = 3), Europe (one each for Netherlands, Germany and Norway), China (n=1), and UK, Europe and Canada (n=1). The total sample size of studies reviewed was 29917 with PCI-specific samples varying considerably from 68 to 3726.

Participant characteristics

Participant ages were provided as either mean or medians; mean participant ages ranged from 43.2 to 83 years (SD 2.8-3.0) while four studies only cited median ages which ranged from 58.4 to 88 years (IQR 51.6-67.0). Four studies purposefully recruited octogenarians (Agarwal, Schechter & Zaman 2009; Gunal et al. 2008; Kahler et al. 1999; Shah et al. 2009). The proportion of males in the studies varied from 38-99% and the mean proportion was 66.7% (SD 14.6) for fifteen studies. Three studies did not describe gender composition (Ho et al. 2008; Seto et al. 2000; Weintraub et al. 2008).

Table 1. Risk of bias assessment summary

Studies	Design	Adequate Sequence generation	Allocation concealment	Blinding	Incomplete Outcome Data addressed	Free of Selective Outcome reporting	Free of Other biases	Non-RCTs Measures taken to minimize bias
Nash et.al.,1999	Descriptive cohort	NA	NA	NA	✓	✓	✓	x
Kahler et.al.,1999	Descriptive cohort	NA	NA	NA	x	x	x	x
Seto et.al.,2000	RCT sub-study	?	?	x	✓	x	x	NA
Pocock et.al.,2000	RCT sub-study	✓	?	x	✓	✓	x	NA
Jamieson et.al.,2002	Descriptive cohort	NA	NA	NA	x	x	?	x
Rumsfeld et.al.,2003	RCT	x	x	x	x	x	x	NA
Spertus et.al.,2004	Descriptive cohort	NA	NA	NA	✓	✓	✓	✓
Zhang et.al.,2006	RCT sub-study	x	x	x	x	x	x	NA
Graham et.al., 2006	Descriptive cohort	NA	NA	NA	x	x	x	✓
Moore et.al., 2006	Descriptive cohort	NA	NA	NA	x	x	x	x
Gunal et.al., 2008	Descriptive cohort	NA	NA	NA	x	x	x	x
Ho et.al., 2008	Descriptive cohort	NA	NA	NA	✓	✓	x	✓
Agarwal et.al., 2009	Descriptive cohort	NA	NA	NA	x	x	x	x
Shah et.al., 2009	Descriptive cohort	NA	NA	NA	x	x	x	x
Melberg et.al., 2010	RCT	✓	✓	x	✓	✓	?	NA
Weintraub et.al., 2008	RCT substudy	✓	x	x	✓	✓	x	NA
Li et.al., 2012	Descriptive cohort	NA	NA	NA	✓	✓	?	✓
Gharacholou et.al.,2012	Descriptive cohort	NA	NA	NA	x	✓	x	✓

✓= Low risk of bias; x=high risk of bias; ? =unclear; NA=not applicable (for descriptive studies)

Table 2. Studies on HRQOL following PCI for age comparison

Author / Year *Country	Design Aim	Sample size n PCI (%) and Type Age Gender Attrition rate	HRQOL Instrument Timing Administration Type of follow-up Analyses	Results Mean (SD) for all scores unless otherwise stated Significant predictors of improved or worsened HRQOL change.
Nash et al. (1999) USA	Descriptive Cohort Comparison of HRQOL (physical and mental health components) after PCI	n=1182 PCI: 100% (PTCA) Elective PCI Age: mean (62-63 years) Males: 68-72% Attrition: NR	Measures: SF-36 Timing: Baseline and 6 months Administration: Self administered admission survey (baseline) and follow-up surveys by mail Analysis: Multiple regression	Comparison between baseline and 6 months for physical and mental health status *Baseline:* SF-36: PCS (36.6), MCS (48.5) *6 months:* SF-36: PCS (43 vs 36.6), MCS (50 vs 48.5) $p<0.0001$ *Significant predictors*: Age not a predictor.
Kahler et al. (1999) Germany	Descriptive cohort Comparison of quality of life and costs after coronary angioplasty for octogenarians (>80 vs <80 years)	n=68 PCI: 100% (PTCA) Elective PCI (50%> 80 years) Age: mean 83 years (range 80-89) 62 years (range 52-79) Males: 71% Attrition: NR	Measures: SF-36 Timing: Baseline and 6 months Administration: Face-to-face interviews post PCI Analysis: Descriptive statistics	*Comparison for <80 vs ≥80 years* Baseline SF-36: PCS (NR) MCS (NR) SF-36: PF (42 vs 59, p=NR), RP (29 vs 26, p=NR), BP (44 vs 40, p=NR), GH (45 vs 50, p=NR), VT (50 vs 45, p=NR), SF (78 vs 70, p=NR), RE (90 vs 70, p=NR), MH (73 vs 69, p= NR) 6 months: SF-36: PF (2 vs 4), RP (112 vs 70, p=0.045), BP (71 vs 42, $p<0.05$),GH (-6 vs -8, p=NR), VT (2 vs 4, p=NR), SF (-3 vs 18, p=NR), RE (-12 vs 18, p=NR), MH (-vs 69, p=NR *Significant predictors*: NA
Seto et al.	RCT (BOAT and ASCENT Trial	n=1445	Measures: SF-36 (MCID PCS >3.8 points,	*Comparison for <70 vs ≥70 years* *Baseline:*

(2000) USA	Substudy) Comparison of HRQOL and angina symptoms after PCI for age (<70 vs ≥70 years)	PCI: 100% Elective PCI (20%> 70 years) Age: median (range): <70 -57 years (38-69) >70 -74 years,(70-89) Males: NR Attrition: 20% (at 6 months)	MCS >7.2 points) SAQ (MCID >10 points) Timing: Baseline, 6 months, 1year Administration: Self administered in-hospital (baseline), mail and telephone interview at follow-up Analysis: Multiple regression	SF-36: PCS (40.1 vs 36.0), MCS (49.0 vs 50.6) SAQ: PF (66.7vs 61.1), AF (60.0 vs 60.0), DB (41.7 vs 41.7) NS differences between age group. *6 months:* SF-36: PCS (50.6 vs 44.6), MCS (53.1 vs 54.9) p=NR SAQ: PF, (91.7 vs 81.9), AF (100 vs100), DB (75.0 vs 83.3), p=NR. Significant improvements in all domains from baseline, NS for age group. *1 year:* SF-36: PCS (51.4 vs 45.0), MCS (54.3 vs 54.8) SAQ: PF (91.7 vs 81.9), AF (100 vs 100), DB (83.3 vs 83.3) *Significant predictors*: Age not a predictor.
Pocock et al. (2000) UK	RCT (RITA-2 Trial) substudy Comparison of PTCA with medical treatment on HRQOL in stable angina (age per 10 years)	n=504 PCI: 49.5% (PTCA) Elective PCI Age: (per 10 yrs-groups= NR) Males: NR Attrition: 2% (at 1 year) 33% (by 3 years)	Measures: SF-36 (scores from 0-100) Timing: Baseline, 3 mths, 1 year and 3 years (NR) Administration: Telephone interview at baseline and at follow-up Analysis: Multiple regression	*Comparison between treatments* *Baseline:* SF-36: PF 68, V 54, GH 61, RP 45, RE 63, MH 69, BP 62, SF 74 *3 month:** SF-36: PF 75, V 59, GH 64, RP 58, RE 70, MH 74, BP 69, SF 78 *1 year: ** SF-36: PF 75, V 59, GH 64, RP 65, RE 75 MG 75, BP 70, SF 81 *Significant predictors: variable (Beta value)* *Baseline:* PF: Breathlessness (-5.53), angina (-3.53), exercise capacity (2.11), number of antianginal drugs (-1.62), female (-7.99), **age per 10 years (1.57)**

				V: Breathlessness (-4.2), angina (-2.8), exercise capacity (0.58), number of antianginal drugs (-1.73), female (-5.72) GH: Breathlessness (-3.65), angina (-3.15), exercise capacity (1.23), number of antianginal drugs (-1.54), female (3.32), **age per 10 years (4.24**) *One year:* PF: Breathlessness (-3.87), angina (-3.05), exercise capacity (1.62), number of antianginal drugs (-3.4), baseline score (0.35) V: Breathlessness (-2.8), angina (-3.14), exercise capacity (0.87), **age per 10 years (2.13),** baseline score (0.47) GH: Breathlessness (-2.10), angina (-2.59), exercise capacity (0.97), number of antianginal drugs (-2.55), **age per 10 years (1.38),** baseline score (0.55)
Jamieson et al. (2002) USA	Descriptive cohort Evaluation of effects of age, gender, type of procedure, risk stratification and co-morbidity on HRQOL following cardiac rehabilitation for CABG and PTCA patients with angina and AMI (<65 and ≥65 years)	n=301 PCI: 37.9% (PTCA) Elective PCI Age: mean (SD): 63.3 (11) years Males:72% Attrition: NR	Measures: SF-36 (compared with USA population norms) Timing: Baseline and 3 months Administration: Self-administered pre-and post-intervention Analysis: Linear regression	*Comparison for* <65 vs >65 years *Baseline: (pre-cardiac rehabilitation)* SF-36: PF (50.7 vs 44.5,p<0.001), RP (12.6 vs 13.0, p<0.001), BP (53.4 vs72.3,p<0.001), GH (64.1 vs 62.5, P=NR), V (42.0 vs 37.0, p<0.001), SF (58.5 vs50.3), RE (46.8 vs 45.8, p<0.05), MH (69.2 vs 69.6, p>0.05) *3 months: (post-cardiac rehabilitation compared by age)* SF-36: PF (74.3 vs 69.5,p=NR), RP (52.5 vs 47.7, p<0.001), BP (70.2 vs 71.0, p=NR), GH (66.5 vs 64.1, p=NR), V (60.0 vs 54.5, p<0.05), SF (82.1 vs 80.8, p=NR), RE (72.1 vs 73.3, p<0.05), MH (76.4 vs 77.8, p=NR) *Significant predictors*: (Beta value) **PF Age > 65 yrs** (-0.4), RP Age > 65 yrs (-0.5), baseline PF score (44.5) and RP (13.0). No age effect on other sub-scales.

Rumsfeld et.al (2003) USA	RCT (AWESOME Study) Comparison of HRQOL between PCI and CABG for stable angina in Veteran Affairs patients (<70 vs >70 years)	n=389 PCI: 49.6% Elective PCI Age PCI only, mean (SD): 67.6 (9.3) years Males PCI only: 99% Attrition: 8% (at 6 months)	Measures: SF-36 (PCS and MCS: MCID > 4-7 points change) Timing: 6 months Administration: Mail and telephone back-up Analysis: Linear regression	*Comparison between treatments* *Baseline: NR* *6 months:* SF-36: PCS 38.7, MCS 45.5. (mean) *Significant predictors*: Co-morbidity, COPD, diabetes, smoking, elevated creatinine and hypertension. Age not a predictor. Beta values NR
Spertus et.al (2004) USA	Descriptive cohort Investigation of predictors of QOL benefit with PCI for symptomatic angina. (age per 10 years)	n=1518 PCI: 100% Elective PCI Age:mean (SD): 66 (11) years Males: 69% Attrition: 31% (at 1 year)	Measures: SAQ (MCID ≥10 points change) Timing: Baseline, 1year Administration: Telephone interview Analysis: Logistic regression	*Comparisons for all ages* *Baseline:* SAQ: PL 69, AF 68, QOL 56 *1 year: (compared to baseline by* ±SE *points*) SAQ: AF (monthly, weekly and daily angina) improved (20.0±2.4, 28.3±2.5 and 32.0±3.2, p<0.001) PF (mild, moderate and severe) improved with PCI (7.8±2.0, 12.8±2.2 and 4.7±3.6, p<0.001), *Overall PL* 18±25, AF 24±28, QOL 30±26, p<0.001 *Significant predictors*: Age, physical function and baseline angina frequency. **Age a predictor by 10 year increments** (2.0±0.7, p<0.01)
Zhang et al. (2006) UK, Europe, Canada	RCT(SoS Trial, substudy) Comparison of age-related differences in HRQOL between PCI and CABG for	n=988 PCI: 49.3% Elective PCI Age: mean (SD) : 55.5 (6.6) to 70.4 years, mean	Measures: SAQ (MCID 5-8 points) Timing: Baseline, 6 and 1 year Administration: NR Analysis: multivariable analysis	*Comparisons for <65 vs >65 years* *Baseline: ** SAQ: PL (48.8 vs 45.1,NR), AS (46.6 vs 46.1,NR), AF (50.6 vs 49.1,NR), TS (83.7 vs 83.8,NR),QOL (34.5 vs 39.1, p = 0.001) *6 months *(compared to baseline by age groups)*

	symptomatic angina (including ACS) (<65 vs >65 years)	(SD 3.8) Males PCI only overall range: 71.6% -85.2% Attrition: 1.6% (at 1 year) Missing data (up to 11.3%) of sample		SAQ:PL (4.3 vs 6.8, p<0.001), AS NR AF (21.4 vs 26.8, p< 0.001),TS NR,QOL (19.9 vs 25.5, p< 0.001) *1 year *(compared to baseline by age)* SAQ:PL (4.5 vs 7.5, p<0.001), AS NR, AF (24.1 vs 29.7, p<0.001), TS NR, QOL (23.5 vs 30.7, p< 0.001) *Significant predictors:* Age not a predictor.
Graham et.al (2006) Canada	Descriptive (APPROACH Registry) Comparison of QOL after PCI or CABG with medical therapy in stable and unstable angina and AMI (<70 vs 70-79 vs ≥ 80 years)	n=16,525 PCI: 22.1% Elective and Emergency PCI Age PCI group <70 years, 70-90 and ≥80 years, mean: 59.1, 73.9, 82.1 Males PCI group overall range: 56-78% Attrition: 32% (at 1 year)	Measures: SAQ Timing: 1 year, 3 and 5 years Administration: Mail and telephone follow-up Analysis: Linear regression Note: 3 year and 5 year follow-up results not cited in this review	*Comparisons for <70 vs 70-79 vs ≥80 years* *Baseline: NR* *1 year:* SAQ: EC (74.9 vs 63.2 vs 51.9), AS (76.7 vs 78.2 vs 74.7, p<0.001), AF (85.4 vs 84.0 vs 79.3), QOL (72.5 vs 75.8 vs 72.9), TS (85.5 vs 87.1 vs 88.0) *Significant predictors:* Age not a predictor.
Moore et al. (2006) UK	Descriptive cohort Comparison of effect of age on HRQOL after PCI for stable coronary artery disease (<60 vs 60-70 vs >70 years)	n=105 PCI: 100% Elective PCI Age:mean (SD): 76 (5) years Males:73% Attrition: 5% (at 1 year)	Measures: SF-12 and SAQ (SF-12 PCS and MCS: score of 50 represent UK population norm; 10 point change=1 SD) Timing: 1 year Administration: NR Analysis: multiple regression	*Comparisons for ages <60 vs 60-70 vs >70 years* *Baseline: NR* 1 year: SF-12: PCS (7.8 p0.023 vs 4.0 ,p0.0435 vs 4.9, ,p0.047), MCS (6.2 p0.002 vs 3.9 p0.026 vs 4.1, p0.001) SAQ: PL (19.7 p0.001 vs 12.0,p0.003 vs 10.0, p0.004), AS (29.8 p0.001 vs 12.5,NS vs 16.1, p0.001), AF(22.3 p0.001 vs 10.5 p 0.049, vs 16.3 p<0.001), TS (10.9 vs 4.3 vs 4.1 NR),QOL (35.8 p<0.001vs 5.7p<0.001vs 24.4, p<0.001)

				Significant predictors: Age not a predictor.
Gunal et al. (2008) Netherlands	Descriptive cohort Investigation of QOL after PCI for octogenarians with coronary artery disease and AMI (≥80 years)	n=98 PCI: 100% 36% Acute PCI, 64% Elective PCI Age mean (SD) : 82.7 (2.9) years Males: 40% Attrition: 9% (at 1 year)	Measures: RAND-36 (SF-36) Dutch version Timing: 1 year Administration: Questionnaire survey plus additional questions (process NR) Analysis: Descriptive methods	*Comparison with Dutch population norm for* ≥80 *years* *Baseline: NR* *1 year: (compared to population norm)* RAND-36: PF 41,(28) vs 43(29) NR , RP 32,(37) vs 39(41) NR, BP 69,(28) vs 60(29) NR, GH 50,(18) vs 53(22) NR, V (55,(20) vs 53(27) NR, SF (67 (26) vs 66 (32) NR, RE (66 (42) vs 63 (44) NR, MH (70 (21) vs 67(24) NR *Significant predictors:* NR
Ho et al. (2008) USA	Descriptive cohort (PREMIER Study) Comparison of the effect of age on HRQOL after AMI for the groups <50, 50-<65, 65-<75, ≥75 yrs	n=2498 PCI: 56-66.4% Acute PCI Age: mean (SD) overall: 43.2 to 80.5 years, (2.8-5.2) Males range:53-76% Attrition: 1.8% for ≥75 years to 22.9% for <50 years (at 1 year)	Measures: SAQ (MCID >5 points score change) Timing; Baseline, 1, 6 and 12 mths Administration: Telephone Analysis: multivariable/repeated measures Note: scores derived from graph illustration	*Comparisons for ages <50 vs 50-<60 vs 65- <75 vs ≥75 years* *Baseline:* SAQ: QOL 58.8 vs 60.5 vs 64.3 vs 67 (p<0.0001, when adjusted for baseline differences) *1 year:* SAQ: QOL 80 vs 82.5 vs 88.1 vs 89.1 (p<.001 when adjusted for baseline differences). Change in QOL between baseline and 1 year significantly different for age group. *Significant predictors:* Increasing age associated with better HRQOL at 1 year. Beta values NR
Weintraub et al. (2008) USA, Canada	RCT (COURAGE Trial) sub-study Comparison of effect of PCI (with optimal medical	n=2, 287 PCI (plus optimal medical group): 50% Elective PCI	Measures: SAQ (MCID> 8 points) and RAND-36 (MCID >10 points) Timing: Baseline, 1,3, 6 and 1 year, 2 and 3 years	*Comparison for ages* <65 vs ≥65 year *Baseline:* SAQ: PL 66, (25), AS 54,(33),AF 68,(26),TS 88,(15), QOL 51,(25), RAND-36: PF (58), PL (38), EL (58),V (48), E (70),SF (70), BP (62), GH (58)

	therapy) to optimal medical therapy on QOL in stable angina (<65 vs ≥65 years)	Age: NR Males: NR Attrition: NR	Administration: Self-administered Analysis: Linear regression/repeated measures ANOVA Scores: Derived from graph illustration	*1 month: (compared to baseline by treatment groups)* SAQ : PL 73 (24), p 0.003, AS 81(26), p<0.001, AF 82 (23), p<0.001, TS 92 (12), p 0.001, QOL 68 (24), p0.00, RAND-36: PF 66, PL 62, EL 62 , V 52, E 72, SF 75, BP 68, GH 62,p< 0.01. For all subscales; P<0.001 *3 months: (compared to baseline by treatment groups)* SAQ : PL 76 (24), p 0.004, AS 77 (28), p<0.002, AF 85 (22), TS 92 (12), p 0.001, QOL 73(22), RAND-36: PF 76, p PL 62 , E 62 , V 52, E 72, SF 75, BP 72,, GH 63. For all subscales; P<0.001 6 *months: (compared with baseline by treatment groups)* SAQ: PL 77(23),p<0.001, AS 76, (28),p0.02, AF 87 (27) (26), p0.001, TS 92 (13), p 0.007, QOL 5 (22), p0.001 RAND-36: PF 70, PL 63, E 62, V 5, E 71, SF 75, BP 71, GH 62,p<0.001 For all subscales; P<0.001 *1 year: (compared baseline by treatment groups)* SAQ: PL 75 (24),p<0.21, AS 74 (27), p0.02, AF 87 (20) p< 0.003, TS 92 (12), p0.002), QOL 76 (21), p0.008 RAND-36: PF 70, PL 64, EL 72, V 50, E 71, SF 75, BP 72, GH 62, p<0.001. For all subscales, p<0.001. *Significant predictors:* Age not a predictor. Other predictors are physical limitation and anginal frequency.
Agarwal et al. (2009) UK	Descriptive cohort Assessment of functional status and QOL after PCI in octogenarians with ACS (≥80 years)	n=74 PCI: 100% Emergency and Elective PCI Age =mean 82.5 years (SD 2.1) Males: 68%	Measures: SF-36 and SAQ (SF-36 compared with USA population norms; sub-scales with UK normative data) Timing: Baseline, 6 months and 1 year Administration: NR	*Comparison with USA population norm for* ≥80 years *Baseline:* SF-36: PCS 31, MCS 44.6, PF 32.3, RP 7.9, BP 40.1, GH 49.2, V 34, SF 53.1, RE 35.8, MH 67.1 SAQ: PL 24.4, AS 50.0 , AF 45.8, TS 74.3, DP/QOL 38.8 *6 months: (compared to baseline)* SF-36: PCS (47.0 p<0.05), MCS (58.0 p<0.05) PF 44.5, RP 33.8, BP 61.6, GH 50.1, V42.7, SF

		Attrition: NR	Analysis: NR	72.0 RE 57.3, MH 71.0 SAQ: PL 42.3, AS 72.4, AF 76.5, TS 83.7, DP/QOL 66.7 *1 year: (compared to baseline)* SF-36: PCS 46.2,p<0.05, MCS 57.6,p<0.05 PF 42.3, RP 38.7, BP 58.4, GH 47.7, V 40.1, SF 68.0, RE 62.3, MH 70.1 SAQ: PL 41.4, AS 66.3, AF 73.5, TS 83.7, DB 62.3 *Significant predictors*: Age not a predictor.
Shah et al. (2009) USA	Descriptive cohort Evaluation of QOL and health outcomes of primary PCI for STEMI's ≥85 years (≥85 years)	n=73 PCI: 70% Emergency and Elective PCI Age =88 years, median Range 85-94 years Males: 38% Attrition: 43.8% (at 1.1 years)	Measures: EQ-5D EQ-VAS (compared with US population-based survey of elderly ≥85 years) Timing: median 429 days (1.1 years) Administration: Telephone and mail Analysis: Logistic regression	*Comparison with US population-based survey of elderly* *Baseline: NR* *1 year :* EQ-5D: 0.78 (0.04) vs 0.72 (0.01) EQ-VAS: 70.5 (4.5) vs 64.6 (1.4) *Significant predictors:* Age not a predictor.
Melberg et al. (2010) Norway	RCT Comparison of HRQOL after PCI at a hospital with and without on-site surgical back-up for stable coronary artery disease and ACS (age per 10 years)	n=609 PCI: 98.2% Elective PCI Age, 58.4 years, median(51.6-67) Males: 79.7% Attrition: 38-24% (at 6 months)	Measures: SF-36 (Norwegian version) Timing: Baseline and 6 months Administration: Self-administered Analyses: Linear regression	*Comparison between treatment sites* *Baseline:* SF-36: PCS 37.0 (9.0), MCS 45.1(10.9) PF 62.8, RP 63.8, RE 40.9, BP 59.0,SF 72.7, MH 73, V 47.7, GH 64.3 *6 months: (compared to baseline by treatment groups)* SF-36: PCS 44.5 vs 43.5 NR, MCS 48.5 vs 48.0 NR PF 79.7 vs 77.4 NR, RP 76.6 vs 81.8 NR, RE 63.3 vs 64.7 NR, BP 74.6 vs 71.4 NR, SF 72.7 vs 81.1 NR, MH 75.5 vs 76.3 NR, V 57.1 vs 57.1 NS, GH 66.6 vs 63.1 NR

				Significant predictors: Age not a predictor. *Baseline: (beta values)* PF: angina grade (-3.7), anginal drugs (-3.1), prior AMI (5.8), BMI (-0.8), RP: None BP: Anginal drugs (-3.4), prior AMI (9.5) *6 month: (beta values)* PF: Gender (-6.8), angina grade (-3.8), BMI (1.0), Exercise capacity (2.5), Baseline score (0.3), RP: angina grade (-7.7), BP: Gender (-7.2), BMI (-4.0), exercise capacity (2.1), baseline score (0.2)
Li et al. (2012) China	Descriptive cohort Comparison of HRQOLoutcomes for PCI and medical therapy in ACS (<60 vs 60-79 vs ≥ 80 years)	n=624 PCI: 45.9% Elective PCI Age =64 years, mean (SD 11) Males: 73.8% Attrition: 20% (at 6 months)	Measures: SF-36 (Chinese version) Timing: Baseline and 6 months Administration: Questionnaire and telephone interviews Analysis: Logistic regression	*Comparisons for ages <60 years, 60-70 and ≥80 years* *Baseline:* SF-36: PCS 39 (13) vs 29(15) NS 80 vs 22 (9) p=all NR, , MCS 50 (12) NS vs 52(12) NS vs 51(12) p=all NR, PF 78 vs 64 vs 51 NR, BP 51 vs 45 vs 37, p< 0.06, RP 58 vs 44 vs 43 NR, GH 47 vs 48 vs 46 NR *6 months: (compared to baseline and between age groups)* SF-36 PCS 46(11) vs 41 (14) vs 40 , p0.01(11), p<0.02 vs, 17(9), p<0.01 unadjusted MCS 51 (10) vs 54 (10) vs 55(13) p= NR, PF 86 vs 73 vs 65, p<0.01, BP 75 vs 76 vs 84,p=NR, RP 72 vs 72 vs 66,p= NR, GH 52 vs 65 vs 63, p= NR, RE 75 vs 80 vs 85, p=NR, SF 83 vs 81 vs 79, p=NR, MH 75 vs 73 vs 78,p=NR Vitality 66 vs 66 vs 60, p=NR PCI (OR=1.79, 95% CI: 1.01-4.15) , Age per 10 years increase (OR=1.27, 95% CI: 1.02-1.57) *Significant predictors:* **Age a predictor (per 10 years increase)**. Other predictor is PCI.

Gharacholou et.al (2012) USA	Descriptive cohort Comparison of health status outcomes for frail and non-frail patients >65 years after PCI (age per 10 years)	n=629 PCI: 100% Elective PCI: 35 % Emergency PCI:18% Urgent PCI:47% Age: Frail (mean 77 years) Intermediate frail (mean 75 years) Not frail (mean73 years) Males: 69% Attrition: 13% (at 30 days)	Measures: SF-36 and SAQ (SF-36 scores compared with USA population norms; SAQ:MCID>5 points) Timing: Baseline and 30 days Administration: NR Analysis: Linear regression	*Comparison between frail and non-frail stratification* *Baseline:* *SF-36: PCS: 29.0 vs 37.0 vs 42.9, p<0.001, MCS: 48.8 vs52.3 vs 55.6, p<0.001* *SAQ: PL 59.5 vs 70.2 vs 77.6, p<0.001* *QOL 55.1 vs 59.7 vs 63.0, p<0.001* *3 months* SF-36: PCS-11.9, 95% CI -14.4,vs -9.6, p<0.001 MCS -8.2, 95% CI -10.6 vs 5.8, p<0.001 SAQ: PL-18.0 95% CI 23.1 vs-12.9, p< 0.001 QOL -9.0, 95% CI vs-15.5 vs -2.6, p<0.001, *Significant predictors:* Age not a predictor.

NR: Not reported; NA: Not assessed *Country where study was conducted

Table 3. Summary table of HRQOL score changes for PCI studies at 6 months and 1 year using SAQ and SF36/SF-12

Study	**HRQOL Follow-up**		**SF-36/SF12**		**SAQ**					**Age a predictor**	**Compared to baseline**
First Author	**6 months**	**1 year**	**PCS**	**MCS**	**Physical function (%)**	**Angina frequency (%)**	**Angina stability (%)**	**Disease burden/QOL (%)**	**↑= Better ↓= Worse**	**yes/no (y/n)**	**↑= Better ↓= Worse**
Nash	✓		↑6.4	↑1.5	-	-	-	-	-	n	↑
Kahler	✓		↑32	-	-	-	-	-	-	n	↑
Seto	✓		↑7	↑1	↑4	↑1	-	↑6	-	n	↑
		✓	↑9	↑4	↑21	↑40	-	↑42	-		
Pocock		✓	-	-	-	-	-	-	-	y	↑
Jamieson	✓ **3**		↑25	↑8	-	-	-	-	-	y	↑
Rumsfeld	✓		-	-	-	-	-	-	-	n	↑
Spertus		✓	-	-	NS	↑18	↑24	-	↑30	y	↑
Zhang	✓	✓	-	-	↑58	↑25	-	↑28	-	n	↑
					↑67	↑23	-	↑31	-		
*Shah		✓	-	-	-	-	-	-	-	n	↑
Graham		✓	-	-	-	↓12	↓1	↑3	↑2	n	↑
Moore		✓	*↑4	*↑4	*↑12	*↑12	*↑10	*↑26	*↑4	n	↑
Gunal		✓	*↑9	*↑3	-	-	-	-	-	n	↑
Ho		✓	-	-	-	-	-	↑13	-	n	↑
Weintraub	✓		-	-	↑11	↑19	↑22	↑24	↑4	n	↑
		✓			↑9	↑19	↑20	↑41	↑4		
Agarwal	✓		↑16	↑13	↑18	↑31	↑20	↑28	↑9	n	↑
		✓	↑11	↑13	↑17	↑28	↑16	↑24	↑9		
Melberg	✓		↑7	↑3	-	-	-	-	-	n	↑
Li	✓	✓	↑4	↓1	-	-	-	-	-	y	↑
Gharacholou	✓**3 months**		↓2	↓2	↓5	-	-	↓7	-	n	↓

* mean difference in scores at 1 year for >60 years; - HRQOL domains not assessed or not stated; EQ-5D and EQ-VAS used.

Risk of bias assessment

Half of the RCT's and sub-studies contained adequate sequence allocation (Table 1). Five descriptive cohort studies (28%) adopted measures such as repeated measures analysis, propensity scoring for selection bias and sensitivity analysis for comparison of HRQOL scores in order to minimize bias (Gharacholou et al. 2012; Graham et al. 2006; Ho et al. 2008; Li et al. 2012; Spertus et al. 2004). Eight studies (44%) addressed incomplete outcome data with an equivalent number free of selective outcome reporting.

Sampling bias is a common problem associated with RCTs and sub-studies. One-third (33%) of studies (Melberg, Nordrehaug & Nilsen 2010; Pocock et al. 2000; Rumsfeld et al. 2003; Seto et al. 2000; Weintraub et al. 2008; Zhang et al. 2006) were in this category. Generally, participants in clinical trials tend to have less comorbidities and are therefore not representative of the cohort of interest. Elderly populations are often excluded from invasive treatment based on age, risk factors and potential complications (Alexander et al. 2006). Other studies showed potential gender bias, with more males comprising the majority of samples (Agarwal, Schechter & Zaman 2009; Graham et al. 2006; Li et al. 2012; Moore et al. 2006; Rumsfeld et al. 2003; Spertus et al. 2004). Only two studies (Gunal et al. 2008; Shah et al. 2009) had 60 and 62% females. Four studies (Agarwal, Schechter & Zaman 2009; Gunal et al. 2008; Kahler et al. 1999; Shah et al. 2009) on octogenarians comprised the smallest samples (68-98 participants). One possible explanation may be age inclusion criteria resulting in less participants available for recruitment. Higher sample losses of 23-44% were reported by four studies (Graham et al. 2006; Melberg, Nordrehaug & Nilsen 2010; Shah et al. 2009; Spertus et al. 2004) whilst others (Agarwal, Schechter & Zaman 2009; Jamieson et al. 2002; Kahler et al. 1999; Nash, Curtis & Rubin 1999; Weintraub et al. 2008) did not describe participant drop-out rates.

Study designs and comparison of HRQOL with PCI by age

All studies used quantitative designs, of which most were prospective observational studies with two RCT's (Melberg, Nordrehaug & Nilsen 2010; Rumsfeld et al. 2003) and four RCT sub-studies (Pocock et al. 2000; Seto et al. 2000; Weintraub et al. 2008; Zhang et al. 2006). PCI was conducted as an elective procedure for stable and unstable angina and emergency or acute primary PCI for AMI. The timing of data collection included baseline in 72% of studies with HRQOL assessed in-hospital before or at time of PCI (Table 3). Only one study (Li et al. 2012) included PCI as baseline within 30 days. Five studies (28%) did not include baseline HRQOL assessment. Follow-up occurred at one year for 61% and six months for 56% (Agarwal, Schechter & Zaman 2009; Ho et al. 2008; Kahler et al. 1999; Li et al. 2012; Melberg, Nordrehaug & Nilsen 2010; Nash, Curtis & Rubin 1999; Rumsfeld et al. 2003; Seto et al. 2000; Weintraub et al. 2008; Zhang et al. 2006). Five studies did not compare follow-up to baseline (Graham et al. 2006; Gunal et al. 2008; Moore et al. 2006; Rumsfeld et al. 2003; Shah et al. 2009) and another five used population norms for comparison (Agarwal, Schechter & Zaman 2009; Gunal et al. 2008; Jamieson et al. 2002; Melberg, Nordrehaug & Nilsen 2010; Moore et al. 2006). Attrition in the studies over time was reported by the majority, thirteen studies which varied from 8 – 38% at 6 months and at one year, 2 – 44%. Five studies did not report attrition rates (Agarwal, Schechter & Zaman 2009; Jamieson et al. 2002; Kahler et al. 1999; Nash, Curtis & Rubin 1999; Weintraub et al. 2008).

All studies used repeated measures for comparing changes in HRQOL over time with the exception of three (Gunal et al. 2008; Rumsfeld et al. 2003; Shah et al. 2009) when HRQOL was measured only once. Regression analyses were used by 83% of studies to determine the independent predictors of HRQOL.

HRQOL measures

The Short-Form 36 and 12 (SF-36 including RAND-36, SF-12) (Ware & Kosinski 2001) and the Seattle Angina Questionnaire(SAQ) (Spertus et al. 1995) were the most common HRQOL instruments used (8 and 4 respectively) with five studies (28%) using both. The EuroQol (EQ-5D) and EuroQol Visual Analog Scale (EQ-VAS) was used in one study (Shah et al. 2009). These instruments were self-administered (n = 6) or combined with telephone interviews (n=5). Two studies used only telephone interviews (Ho et al. 2008; Pocock et al. 2000); one by face-to-face interview (Kahler et al. 1999) while four studies did not report administration method (Agarwal, Schechter & Zaman 2009; Gharacholou et al. 2012; Moore et al. 2006; Zhang et al. 2006).

The SF-12 measures eight general health domains reflecting physical functioning, physical role limitations, emotional role limitations, vitality, social functioning, bodily pain, general health and mental health (Ware & Kosinski 2001). The SF-12 is a shorter version of the SF-36 comprising twelve items and the same domains. SF instrument scores range from 0 (lowest and worst score) to 100 (highest). While domain scores were collected, most studies reported only the two summary measures: physical component summary (PCS) and mental component summary (MCS), with population-standardized transformations (mean of 50; 10 SD).

Studies using the SF-36 presented scores as points of difference between age groups. The MCID was cited by four studies (Rumsfeld et al. 2003; Seto et al. 2000; Weintraub et al. 2008) within the range of 4-7 points for PCS and >10 points for MCS, for detecting meaningful changes in HRQOL (Ware & Kosinski 2001). Five studies (28%) compared scores with national population norms for different age groups (Agarwal, Schechter & Zaman 2009; Gunal et al. 2008; Jamieson et al. 2002; Melberg, Nordrehaug & Nilsen 2010; Moore et al. 2006). Median scores cited by these studies varied from 29-51 for the PCS, and 46-54 for the MCS. Lower values were reported by one study (Moore et al. 2006) which used the SF-12 version, with mean differences ranging from 4.0 to 7.8 (PCS) and 3.9 to 6.2 (MCS). Another study (Shah et al. 2009) reported higher mean EQ-5D scores of 0.78 and EQ-VAS score of 70.5 obtained on a rating scale from 0 (poor) to 100 (best health state); comparable with a similar US population-based survey of the elderly ≥80 years.

The SAQ measures five dimensions of health status specific to coronary artery disease in the domains of physical limitations, angina stability, angina frequency, treatment satisfaction and the impact on quality of life (Spertus et al. 1995). Angina stability is measured by the prevalence of chest pain with strenuous activity whilst angina frequency reflects the number of times the person experiences chest pain and treats symptoms with Nitroglycerine. SAQ scores range from 0 (representing the worst QOL score) to 100. For comparisons of SAQ scores across time, the minimal clinically important difference (MCID) indicating change in HRQOL status was 5-10 points (6 studies). Scores ranged from 4 to 100% change for all SAQ domains across the reviewed studies. Results indicating differences from baseline for HRQOL comparisons across time are presented in Table 2.

HRQOL Results

Summary results indicated that HRQOL improves over time to six months and one year in seventeen studies after PCI. HRQOL improvements ranged from 1-67% increase, with the largest gains in physical functioning of 4-67% (SAQ). This was followed closely by anginal frequency and QOL (disease burden) gains of 1-40% and 6-42% respectively. For studies using the SF-36, improvements in physical and mental health component scores ranged from 7-25 points and 1-13 points respectively; achieving the acceptable MCID ranges. Only one study (Moore et al. 2006) demonstrated no significant differences between most HRQOL domains for ages <60, 60-70 and >70 years; the mean differences for physical limitation reflected better recovery in younger people (7.8 vs 4.0 vs 4.9, p=0.047) one year after PCI.

Influence of age on HRQOL

For studies showing multiple age groups, score differences for ages >60 years across time were used for comparison (Graham et al. 2006; Ho et al. 2008; Li et al. 2012; Moore et al. 2006). Summarized results including age as a predictor of HRQOL changes are displayed in Table 3. The majority of studies (72%) showed that there were no changes in overall HRQOL as age increased.

(Jamieson et al. 2002; Li et al. 2012; Nash, Curtis & Rubin 1999; Pocock et al. 2000; Spertus et al. 2004). The study by Seto *et al*. (2000) for example, showed that the probability of MCID gains following PCI was not significantly associated with age (Table 2). Two studies (Li et al. 2012; Spertus et al. 2004) showed that advancing age by 10 year increments was associated with better HRQOL in physical health at 6 months follow-up. Li (2012) identified age and PCI as independent predictors of improved HRQOL with significant improvements from baseline physical component scores of the SF-36. The earlier study using the SAQ revealed similar findings with age, physical function and baseline angina as important predictors of quality of life benefits from PCI (Spertus *et al.,* 2004). However, in specific domains, older people had fewer physical limitations, higher vitality and better anginal relief (Ho et al. 2008; Jamieson et al. 2002; Li et al. 2012; Melberg, Nordrehaug & Nilsen 2010; Pocock et al. 2000; Spertus et al. 2004) and better function with less symptom burden (Agarwal, Schechter & Zaman 2009; Graham et al. 2006; Gunal et al. 2008; Zhang et al. 2006). As time passed, HRQOL improved with all ages but patients aged ≥80 years by comparison, experienced more benefits from better physical functioning.

Baseline HRQOL was an important predictor regardless of age. Anginal frequency prior to PCI was a strong predictor of HRQOL improvements (Pocock et al. 2000; Spertus et al. 2004), with those with more anginal severity at baseline demonstrating the most benefit. Even for patients experiencing monthly, weekly and daily angina episodes, significant HRQOL corresponding improvements were achieved with PCI (21.4, 30.7 and 34.6, $p<0.001$) from baseline (Spertus et al. 2004). Most improvements in symptomatic angina occurred within 1 month of hospital discharge and continued until 12 months after which no differences were evident between age groups. One study examined frailty in adults >65 years with evidence that progressive frailty alongside increasing age was also associated with poorer physical HRQOL despite similar SAQ scores for angina frequency and treatment satisfaction (Gharacholou et al. 2012). Factors which may be associated with older age were assessed in one study (Rumsfeld et al. 2003) which identified that chronic co-morbidities such as chronic obstructive airways disease, diabetes, elevated creatinine, smoking and hypertension were predictive of HRQOL on their own. However, the sample of 389 patients comprised select Veterans Affairs patients, with 99% majority males.

Discussion

Limitations

We note limitations for this review. Despite stringent search and selection criteria culminating in detailed data extraction and summation of findings, some potentially relevant publications may have been omitted. Baseline HRQOL was not measured in 33% of studies, limiting capacity for effective pre and post-PCI comparisons. In addition, there was little focus on pre-PCI angina, an important predictor of HRQOL outcomes. Some studies (Ho et al. 2008; Seto et al. 2000; Zhang et al. 2006) did not provide scores for angina stability, focusing instead on anginal frequency to measure HRQOL. This did not enable a complete interpretation of the total HRQOL benefits associated with relief from angina, and underscores the importance of symptomatic angina both at baseline and after PCI. Past studies demonstrated that the accurate assessment of angina is critical as residual angina and symptom burden after PCI are major determinants of lower health status over time (Permanyer-Miralda et al. 1999; Spertus 2008; Spertus et al. 2005).

Our results involved health status assessments for both stable angina and acute coronary syndromes. Six studies reviewed (Agarwal, Schechter & Zaman 2009; Gharacholou et al. 2012; Graham et al. 2006; Gunal et al. 2008; Ho et al. 2008; Shah et al. 2009) included these patients but did not show elective or emergency PCI comparisons making it difficult to assess HRQOL results by age comparison for each specific treatment group. There was a mix of PCI and other treatment groups such as medical or CABG for comparisons which may affect results due solely to PCI. Mental health domains were measured by 50% of studies in this review with mean differences of scores ranging from 1-13 by comparison to physical component scores of 2-25 and results may not be generalizable to all older PCI cohorts.

Only a narrative summary was possible due to the heterogeneity between studies. Despite applying the Cochrane guide for comprehensive risk assessment, only six RCT's and sub-studies could be fully assessed; the majority being descriptive cohort designs and accurate cross-comparison was difficult. This was partially attributed to the different approaches adopted by various studies in using HRQOL instruments; each instrument with different emphasis on its main psychometric properties and not all components of HRQOL measurements were fully reported.

Major findings

This systematic review presents an integrated report of age on HRQOL changes following PCI over time at 1 year. HRQOL improved across all age-groups following PCI, with important improvements in angina and physical function for all recipients. Although there were less gains for anginal stability (10-24%) in comparison to anginal frequency, this synthesis of eighteen studies complements previous findings from other published literature showing the benefits of overall anginal relief and better HRQOL for PCI patients regardless of age (Kahler et al. 1999; Kamiya et al. 2007; Pfisterer 2004). PCI as treatment for is associated with improved HRQOL attributed to anginal relief and better physical and mental functioning and age is not an important predictor of better HRQOL gains. In fact, only a limited proportion (22%) of studies reviewed identified age to have an independent predictive effect on HRQOL following PCI. Furthermore, the oldest group studied, octogenarians, showed similar improvements to younger people in physical and mental scores across time. This is supported by a recent systematic review on quality of life for octogenarians which showed improved physical functioning and angina status comparable to that of younger people, particularly in the first 6 months after PCI (Johnman et al. 2013).

The evidence so far suggests that higher HRQOL is achievable by older people after PCI but other explanations may also need to be considered. It could be that older people may have lower expectations of recovery from PCI which influence their perceptions of health as far better than expected (Zhang et al. 2006). This systematic review identified predictors of HRQOL improvement in

18 studies on PCI in older people and most studies focused on physical gain and angina relief as the two most common domains for assessment of improved health status. However, the greatest deficits in HRQOL assessment were the domains where older did not perform so well in. These relate to mental health and recovery strategies such as cardiac rehabilitation and risk modification. Only one study (Jamieson et al. 2002) included cardiac rehabilitation in HRQOL assessment and another included frailty (Gharacholou et al. 2012); both studies also identified higher baseline co-morbidities and risks in older PCI patients to influence their HRQOL outcomes. With increased PCI for an ageing population and higher quality of life expectancy, investigating HRQOL along with monitoring clinical outcomes for older people from a starting retirement age of 60 years forms an integral part of health status assessment. This justifies our systematic review which enriches the limited information on PCI and HRQOL in published literature where age 60 years plus is selected for older PCI cohorts.

The review did not discriminate between the results for elective and primary PCI because the majority of studies did not report results separately although differences in HRQOL might be expected. The trajectory of symptoms preceeding and/or accompanying PCI in an emergency situation such as acute coronary syndromes would likely differ to those of an elective procedure (Gharacholou et al. 2012; Wijeysundera & Ko 2009), so it would be important that future reviews address these differences where possible.

Implications for practice

Our results have important relevance for nursing practice. HRQOL measurement reflects a holistic approach to physiological and psychological aspects of recovery and current care of PCI patients often does not address all of these aspects. The focus of nursing care often rests on PCI-procedural complications and institution-standardized, protocol-driven practices, irrespective of age and treatment pathways. HRQOL is rarely assessed or addressed, which may impact on older people who are disadvantaged by inequitable PCI access (Alexander et al. 2006) and higher comorbidity risks (Moore et al. 2006). Therefore, to adequately evaluate PCI-related outcomes, there is a need to extend beyond the conventional assessment of MACE and age-related risks. Other than costing and symptom management, nursing-sensitive PCI care should include HRQOL assessment (Leeper 2004) and monitoring, regulating and improving standards of PCI nursing practice (Rolley et al. 2009). Recent research has identified other factors which also influence HRQOL, such as frailty, poor health status, and gender but are these not routinely investigated with PCI (Gharacholou et al. 2012; Schenkeveld et al. 2010; Singh, Rihal, Lennon, Spertus, Sreekumaran Nair, et al. 2011). There is limited data on cardiac rehabilitation attendance patterns post-emergency PCI for older people despite the potential impact on mortality, morbidity, HRQOL outcomes and major cardiac events such as restenosis after PCI (Dendale et al. 2005; Goel et al. 2011; Jamieson et al. 2002) and these wider aspects of care delivery remain under-researched. In addition, future research should also differentiate results of primary and elective PCI.

Conclusion

This review demonstrated that age is not an influencing factor for HRQOL benefits following PCI. All people showed benefits after PCI related to improved physical function, angina frequency, disease burden and treatment satisfaction. Further research is however needed to evaluate the broader physical and emotional needs of older patients during the PCI recovery process, particularly the impact on HRQOL with ageing and frailty in the setting of fast-paced PCI pathways such as pre-hospital diagnosis for STEMI and early field-triage to PCI. Integrating HRQOL assessment with good clinical practice would help identify patient-specific care for older people who comprise an expanding proportion of the global population requiring primary PCI for coronary artery disease.

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Contributions

Study Design: SH, RG, DG.

Data Collection and Analysis: SH.

Manuscript Writing: SH, RG, DG.

Declaration of Conflicting Interests

No conflicting interests have been identified by any of the authors.

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CHAPTER 4: FACTORS INFLUENCING HEALTH-RELATED QUALITY OF LIFE AFTER PRIMARY PERCUTANEOUS CORONARY INTERVENTION FOR ST-ELEVATION MYOCARDIAL INFARCTION.

Chapter Preface

Publication reference

Soo Hoo Soon Yeng, RN, MN, Robyn Gallagher R, MN, PhD, Doug Elliott, MAppSc (Nur), PhD. 2016, 'Factors influencing health-related quality of life after primary percutaneous coronary intervention for ST-elevation myocardial infarction', *Applied Nursing Research*, vol. 30, pp. 237-244.

Chapter 3 provided a systematic review and synthesis of published studies on the effect of age >60 years on HRQOL following elective or emergency PPCI for acute coronary syndromes and stable angina. The age of 60 years used to define older by the World Health Organisation as "older", was selected for the systematic review which deliberately focussed on older PCI cohorts internationally. This chapter presents a study in its original form, pertaining to HRQOL after PPCI and the factors which influence HRQOL with publication details as above. A brief background adds to the abstract content and rationale for this study with summary of findings that have implications for current practice. The published PDF version is provided as an appendix.

Background

Health-related quality of life is an important patient outcome following PPCI for STEMI admissions including patients who are admitted by fast field-triage to PPCI. With international guidelines mandating PPCI for STEMI and an ageing worldwide population, HRQOL constitutes a major outcome of recovery and health. Research into the factors which are associated with improved HRQOL in older people undergoing PPCI is important but lacking This study examines HRQOL and its predictors, compared between older patients aged ≥70 and younger patients <70 years at four weeks and six months during PPCI recovery. By comparison, age 70 years was used as the cut-point for older age for the thesis study as it more accurately represents the concept of older people in developed countries like Australia. Four weeks after discharge from hospitalisation was a time when many patients have resumed their normal activities and by six months it is anticipated that the majority of PPCI patients would have achieved fully recovery. Residual symptoms such as angina may influence function and other HRQOL outcomes and these are the strategic points during the recovery process for measuring HRQOL.

This study is guided by what is already known in published literature, that is:

- HRQOL is increasingly recognised as an important measure of health outcomes after a critical cardiac event such as STEMI.
- Older age is one of many significant predictors of worse HRQOL including more MACE, such as higher mortality after PCI.
- Older people by comparison to younger patients derive greater HRQOL benefits from PCI, mainly due to improved angina.

- This research is also based on conflicting evidence and limited information on PPCI for STEMI patients to date, that is:
    - Age is inconsistently a significant predictor of better HRQOL after PPCI for STEMI.
    - Older people with STEMI presentation have poor functional and mental recovery despite PPCI when compared with younger STEMI patients.

The study compared HRQOL outcomes between STEMI patients aged ≥70 years and <70 years at 4 weeks and 6 months of recovery by using the SF-12 and the SAQ for patient interviews.

Summary of results

People ≥70 years by comparison to people <70 years had worse physical limitations but reported better angina relief and improved mental function during the recovery process after PPCI. Despite higher co-morbidities, people ≥70 years have improved HRQOL after PPCI over time. Age, length of hospital stay, gender, partnership status and number of stents deployed were the independent predictors of HRQOL across time.

Implications for practice

Key insights gained form this study extend our understanding of outcomes for PPCI for STEMI, including the factors which govern older patients' HRQOL over time. There is a need for further research focusing on HRQOL for older STEMI cohorts with the current international trends advocating rapid PPCI in order to reduce mortality and more importantly, to achieve more favourable STEMI outcomes such as improved HRQOL which is not routinely assessed after PPCI.

The following sections present the study in its original form.

Highlights

• Health-related quality of life is an important discriminating measure of health status.

• Older age is a predictor of lower health status with PPCI for STEMI.

• People ≥70 years have poorer physical health but better mental and cardiac outcomes than people <70 years.

• Angina stability improved with PPCI in older people.

Abstract

Aims: This study compared health-related quality of life (HRQOL) between patients aged ≥70 and <70 years at 4 weeks and 6 months after primary percutaneous coronary intervention (PPCI) and examined predictors of HRQOL.

Background: HRQOL is an important patient outcome following PPCI for ST-elevation myocardial infarction (STEMI) including pre-hospital field triage.

Methods: A comparative cohort design was conducted on STEMI patients undergoing PPCI. HRQOL was measured using the Medical Outcomes Short Form-12 (SF-12) and the Seattle Angina Questionnaire (SAQ) at 4 weeks and 6 months post-PPCI.

Results: HRQOL improved significantly from 4 weeks to 6 months in all aspects measured except anginal frequency and mental health. Patients aged ≥70 years

had poorer physical HRQOL (SF-12) and physical limitations (SAQ), but better mental HRQOL (SF-12), angina frequency and QOL (SAQ) at both time points. Age, length of hospital stay, gender, partnership status and number of stents deployed are independent predictors of HRQOL improvement over time.
Conclusion: People ≥70 years reported better cardiac-specific quality of life, primarily from angina relief and improved mental function, despite worse physical limitations. HRQOL assessment is an important gauge of health status after PPCI for STEMI.

Keywords: Elderly, Health-related quality of life, Older, Percutaneous coronary intervention, Quality of life, ST-elevation myocardial infarction

Introduction

Health-related quality of life (HRQOL) assessment for patients undergoing cardiac treatments is recommended by key organisations including the American Heart Association (Rumsfeld *et al.*, 2013). One of these treatments, primary percutaneous coronary intervention (PPCI) is the optimal first-line reperfusion treatment for ST-elevation myocardial infarction (STEMI) which is a serious form of the acute coronary syndromes with high mortality and long-term morbidity. Primary percutaneous coronary intervention is initiated preferably within 60 minutes from the first medical contact andutilises pre-hospital ambulance field triage to bypass Emergency Department (ED) delays (Steg *et al.*,2012). Although PPCI is known to improve outcomes for STEMI, the impact on HRQOL is not as well described. Furthermore, older people aged ≥70 years form a high proportion of patients undergoing this procedure, yet few studies focus on the potential differences in HRQOL that occur with age. It isprojected that by 2025 approximately 1.2 billion people globally will be aged over 60 years, the age defined as “older" (World Health Organisation, 2002) with increased risk of cardiovascular disease and coronary occlusion. Primary percutaneous coronary intervention affects multiple dimensions of a person’s life including physical, mental and social health as they develop across the life-span.

Researchers have investigated percutaneous coronary intervention (PCI), which includes elective procedures but limited studies explored health status outcomes for older STEMI patients.Older STEMI patients with acute symptoms may also derive the most clinical benefit from PPCI with fast field triage because of higher baseline risks and increased frailty. Indeed. changes to HRQOL in this population are known to impact on long-term recovery, physical function and mortality(Gharacholou *et al.*, 2012b, Panasewicz *et al.*, 2013).

Older people have more co-morbidities and constitute a higher risk cohort for PPCI as reflected by more major adverse cardiovascular events (MACE) including death in comparison to younger people (Bauer *et al.*, 2011, Claessen *et al.*, 2010). Clinical trials such as the Apex-AMI (Gharacholou *et al.*, 2011) reported age as the strongest predictor of 90 day mortality in STEMI patients >75 years after PPCI, but HRQOL was not investigated. When HRQOL was investigated in older people there was often better HRQOL outcome (Graham *et al.*, 2006, Li *et al.*, 2012, Seto *et al.*, 2000), mainly from angina relief (Agarwal *et al.*, 2009, Gunal *et al.*, 2008). A recent systematic review reported improved angina status and physical functioning in octogenarians after PCI, equivalent to younger peoples’ outcomes in the first 6 months (Johnman *et al.*, 2013). Some studies have also indicated age as a predictor of quality of life gains following PCI (Li *et al.*, 2012, Pocock *et al.*, 2000, Spertus *et al.*, 2004). However, there is a lack of consistency in outcomes and results of another recent systematic review (Soo Hoo *et al.*, 2014) did not find that age was a predictor of HRQOL after PCI.

An appropriate model of care for these complex groups examines the broader concepts of HRQOL and the theoretical framework guiding this study is the linear relationship model because it clearly includes health and physical symptoms. In this model Wilson and Cleary provided a conceptual model that links both the biophysiological and psychosocial concepts of health as causal variables which impact on global HRQOL (Wilson and Cleary, 1995). There are five health concepts in the model including physiological factors, symptoms, functional health, general health perceptions and overall quality of life interacting on a continuum. In addition, there are mediating variables such as individual and environmental characteristics which impact on these causal relationships. The model has been tested and widely used to examine the relationships among clinical, physiological outcomes and subjective psychosocial outcomes in patients with heart failure and cardiovascular diseases (Masterson Creber *et al.*, 2013, Pettersen *et al.*, 2008). Key concepts in this model that apply to our study on HRQOL after PCI include symptom status, which is particularly relevant because patients would expect relief from angina and that these symptoms would then likely influence their capacity to function both physically and mentally. Other nonmedical influences such as age are also considered to be influential and important in the current study. Previous studies on PPCI have inadequately examined this continuum of health complexities affecting HRQOL and this study's results will expand on the existing knowledge pool for STEMI/PPCI patients. Clarity is needed in whether there are differences and changes in HRQOL for older patients compared across time in order to improve care and recovery support.

Therefore this study aims to determine if:

i) Health related quality of life differs between people ≥70 years and <70 years old at 4 weeks and 6 months after PPCI,

ii) age has an independent effect on HRQOL, and

iii) to identify predictors of HRQOL.

Methods

Setting and Sample

Consecutive STEMI patients treated with PPCI were recruited between April 2010 and November 2011 from the PCI Registry of a tertiary-level, university affiliated public hospital and from a metropolitan private hospital. In these institutions, approximately 1070 PCI cases were performed annually for a population of 1.2 million. These hospitals have ambulance pre-hospital field triage for acute STEMI, with PPCI as first-line emergency treatment utilising 24-hour cardiac catheterisation services.

Sample inclusion criteria

Patients were considered eligible if they: 1) had STEMI confirmed by serum cardiac enzyme rise of Troponin I >0.14 ng/mL or Troponin T >14 ng/L and dynamic ST elevation on presenting ECG > 0.1 mV in 2 or more contiguous precordial leads or at least 2 adjacent limb leads (Antman *et al.*, 2007), 2) received PPCI (defined as urgent primary coronary reperfusion by using balloon inflation or stenting) following pre-hospital field triage or ED admission, 3) were able to write, read and comprehend English sufficient for consent and 4) were available for telephone contact after hospital discharge. Patients were excluded if they: 1) were diagnosed with dementia or any other severe neurocognitive disorder, 2) had severe hearing impairment which would prohibit telephone interviews, 3) required prolonged recovery with Intensive Care stay exceeding 5 days, or had cardiac arrest and or cardiogenic shock requiring intubation or inotropes, or 4) received thrombolysis as initial treatment.

Sample size was calculated for the multivariate regression analysis indicating that 258 participants with alpha level 0.05 and 11 predictors (age, admission pathway, marital status, smoking status, number of stents, hyperlipidaemia, previous acute myocardial infarction (AMI), length of hospital stay, ejection fraction, hypertension and gender) was required for a small effect size on HRQOL and a power of 0.8 at 4 weeks (Soper, 2010). A small effect for HRQOL was determined to be a minimal clinically important difference (MCID) of >5 points on the SAQ, based on previous similar studies (Ho *et al.*, 2008, Spertus *et al.*, 1995). The anticipated dropout rate at 4 weeks was 5%; therefore 270 participants were required to be recruited.

Ethics approval was obtained from the Human Research Ethics Committees of both study sites and the university. All ethical considerations were met, including informed and voluntary participant consent, privacy and confidentiality.

HRQOL measurement

Health-related quality of life is a state of health perceived and reported by the patient as impacting on their functioning and therefore, it reflects the patient's physical, social and emotional health (Pedersen *et al.*, 2007). It was measured using the Medical Outcomes Short Form (SF-12) and the Seattle Angina Questionnaire (SAQ) at 4 weeks and 6 months after PPCI. Both instruments are well-established, valid and reliable, commonly used in cardiac populations and are suitable for telephone administration (Summerhill and Taylor, 1992).

SF-12

The SF-12, a brief version of the SF-36 questionnaire measures eight general health domains: physical function, physical role limitations, emotional role limitations, vitality, social function bodily pain, general health and mental health (Ware and Kosinski, 2001). Responses are rated on a 3 to 6 point Likert scale and scores are transformed from a range of 0 to 100 (highest function). Two summary measures, the physical component summary (PCS) and mental component summary (MCS) have population-standardised norms for reference (mean of 50; 10 SD) (Ware et al. 2009).

The SF-12 has been validated in coronary disease patients (Muller-Nordhorn *et al.*, 2004) with high construct validity reported in international clinical and epidemiological settings (Gandek, 1998) including Australian population health surveys (Sanderson and Andrews, 2002) and for cardiovascular populations (Lim and Fisher, 1999). This instrument has high reliability for heart disease and stroke patients (Lim and Fisher, 1999) and the MCS was tested on older adults in community living (Resnick and Parker, 2001). The coefficient in this study for all eight domains demonstrated good internal consistency and reliability with Cronbach's alpha between 0.79 and 0.95 at both time points.

SAQ.

The SAQ measures five dimensions of health specific to coronary artery disease; physical limitations, angina stability, angina frequency, treatment satisfaction and impact on quality of life (Spertus *et al.*, 1995). Responses are rated on a 5 or 6 point Likert scale, with transformation of scores ranging from 0 (worst) to 100 (best). A MCID of 5-10 points indicates an important change in HRQOL status; many studies on PCI accepting a 5 point score difference as clinically significant and therefore this has been used for our study (Agarwal *et al.*, 2009, Graham *et al.*, 2006, Moore *et al.*,2006, Seto *et al.*, 2000, Spertus *et al.*, 1995, Weintraub *et al.*, 2008). Unlike generic measures, the SAQ measures unique dimensions of coronary artery disease and quantifies functional and angina improvements from PCI (Spertus *et al.*, 2004). As a disease specific instrument, it is able to detect small changes on HRQOL often missed by a general instrument (Borkon *et al.*, 2002). The SAQ was used to measure anginal relief after PCI (Ho *et al.*, 2008, Jamieson *et al.*, 2002, Li *et al.*, 2012, Melberg *et al.*, 2010, Pocock *et al.*, 2000, Spertus *et al.*, 2004) and symptom burden (Agarwal *et al.*, 2009, Zhang *et al.*, 2006, Graham *et al.*, 2006, Gunal *et al.*, 2008) which impact on HRQOL. Past PCI studies have also shown angina frequency to be a strong predictor of HRQOL (Pocock *et al.*, 2000, Spertus *et al.*, 2004). At 4 weeks and 6 months, the Cronbach alpha coefficients in our study for the SAQ were between 0.58 and 0.79.

Clinical and demographic data collection

Sociodemographic, baseline clinical and cardiovascular risk factors were collected for comparison. These risk factors included hypertension, hyperlipidaemia, angina, diabetes, renal impairment, family history of cardiovascular disease including prior AMI, stroke, PCI, obesity and current smoker (Table 1). Primary percutaneous coronary intervention procedural characteristics included MACE (represented by access site complications, recurrent angina, stroke, arrhythmias, reocclusion, recurrent-AMI, death, coronary artery bypass graft (CABG), repeat PCI and repeat angiogram). These were recorded during hospitalisation using a data collection form. Follow-up clinical information was recorded for 6 months. The Charlson Co-morbidity Index (Charlson *et al.*,1987), a validated measure was used to determine co-morbidity burden. The most common comorbidity components included congestive heart failure, myocardial infarction, peripheral vascular and cerebrovascular diseases, dementia, chronic obstructive pulmonary disease and diabetes in older participants.

Procedure

Eligible patients were identified from the hospital PCI registry. Consecutive patients with STEMI who received PPCI by either pre-hospital field triage or ED admission or urgent inter-hospital transfer were screened. Participants were approached whilst in hospital for informed, written consent, normally on the day after PPCI when they had recovered and appointment times for the telephone interview were arranged.

Participants were interviewed at home by telephone at 4 weeks and 6 months. Earlier studies had shown substantial HRQOL improvements for physical and mental health up to 6 months post PPCI, after which no significant differences occurred therefore this time was selected (Seto *et al.*,2000, Weintraub *et al.*, 2008). Interviews averaged 15 minutes to complete but could take from 10 to 25 minutes depending on interruptions.

Statistical Analyses

Data analyses were performed using the Statistical Package for the Social Sciences (SPSS version 21, IBM Corp., Armonk, New York). Data were described as frequencies and percentages or means and standard deviation based on the level of variables. Chi-square analysis or Fisher's exact test was used for categorical data (sociodemographic, baseline clinical, PPCI characteristics and MACE), while continuous variables (HRQOL) were compared using paired t-tests. Missing SAQ scores were individually adjusted by substituting missing values with the mean of each domain as stipulated by the scoring algorithms of the SAQ. All data for the SF-12 were complete. The impact of PPCI and patient characteristics on HRQOL over time and the interaction of age and time were analysed using repeated measures ANOVA. Paired t-tests were also conducted along with post-hoc tests to determine specific differences in HRQOL for ≥70 years and <70 years with Bonferroni correction $p=0.01$ to control for Type I error. All values were calculated by using two tailed t-test and a significant p-value was set at <0.05, twice that of a one-tailed test. All SAQ scores were adjusted values.

Multivariate linear regression analysis was used to determine the independent influence of various covariates, including age. Due to small numbers, variables such as prior CABG, diabetes and baseline angina, identified as predictors of HRQOL by previous studies (Nash *et al.*, 1999, Pocock *et al.*, 2000, Rumsfeld *et al.*, 2003, Spertus *et al.*, 2004) were not included in the current analysis. Variables selected for regression analyses were those that influenced HRQOL based on theoretical evidence and demonstrated statistical significance on univariate analyses.

Linear regression analyses on the SF physical domains were selected as the purpose of PPCI was to improve physical function and angina relief as measured by the SAQ. Separate models were created for both outcomes at 4 weeks and 6 months using backward stepwise elimination to examine the independent relationship of eleven predictors (age, admission pathway, partnered or unpartnered, smoking status, number of stents, hyperlipidaemia, previous AMI, length of hospital stay, ejection fraction, hypertension and gender) on HRQOL. The critical level was set at $P<0.05$. All assumptions of linearity, collinearity and homoscedasticity in our analyses were met. The predictive strength of the 2 main models of interest, the SF-PCS and SF-physical functioning was evaluated by accepting an adjusted R2 =0.10.

Results

Sample

A total of 268 participants were enrolled from 570 STEMI patients screened for eligibility (Figure 4.1). At 4 weeks 246 participants were interviewed and 212 participants completed the 6 month interview. Patients who withdrew were more likely to be ≥70 years and male (75%), whereas those lost to follow-up (47%) were males <70 years.

Demographic characteristics

The majority of participants (78.9%) were male with an overall mean age of 63.6 years (SD 13); ages ranged from 25 to 94 years, married/partnered (67.9%) and of Caucasian ethnicity (93.1%). Approximately half (48.4%) were employed and 66.3% had completed high school (12 years schooling) (Table 1). Statistically significant differences were noted between ≥70 years and <70 years, with older participants more likely to be female (38.3% versus 12.7%, p=0.01), retired (91.3% versus 23.6%, p =0.01) and without high school education level (45.7% versus 76.8%, p=0.01).

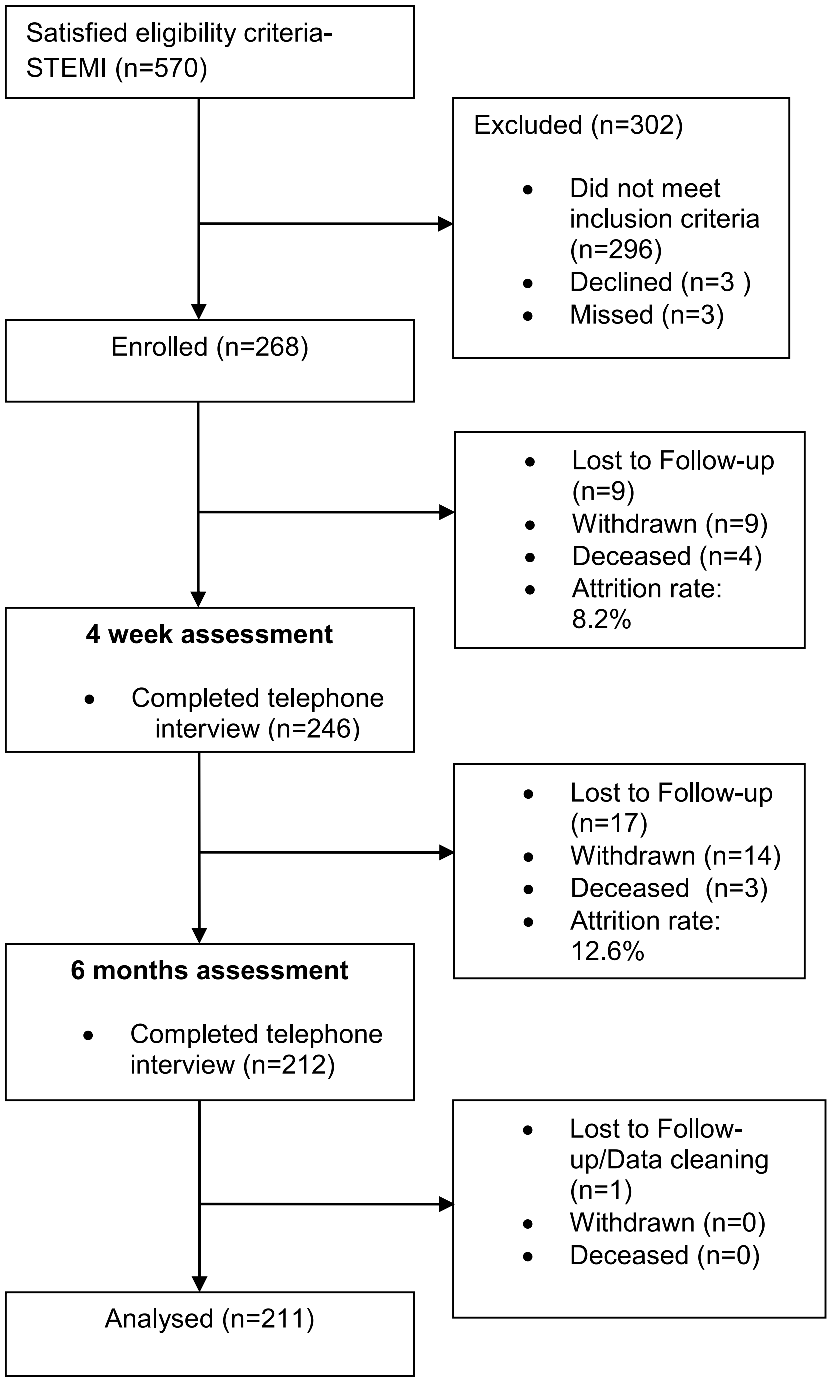

Figure 1: Flow diagram of STEMI participants from screening, identification, recruitment, withdrawal to completion at 4 weeks to 6 months post PCI

Table 1: Baseline characteristics

Characteristics	Overall sample n=246 n (%)		≥70 yrs n=81 n (%)		<70 yrs n=165 n (%)		p
Male	194	(78.9%)	50	(61.7%)	144	(87.3%)	0.01
Female	52	(21.1%)	31	(38.3%)	21	(12.7%)	0.01
Married/partnered	167	(67.9%)	52	(64.2%)	115	(69.7%)	0.38
Lives alone	44	(17.9%)	20	(24.7%)	24	(14.5%)	0.05
Caucasian	229	(93.1%)	80	(98.8%)	149	(90.3%)	0.14
Employed	119	(48.4%)	7	(8.6%)	112	(67.9%)	0.01
Retired	113	(45.9%)	74	(91.3%)	39	(23.6%)	0.01
Year 12 (completed high school)	163	(66.3%)	37	(45.7%)	126	(76.8%)	0.01
Hypertension	118	(48%)	50	(61.7%)	68	(41.2%)	0.02
Hyperlipidaemia	119	(48.4%)	42	(51.9%)	77	(46.7%)	0.44
Angina	25	(10.2%)	13	(16.0%)	12	(7.3%)	0.03
Diabetes	26	(10.6%)	7	(8.6%)	19	(11.5%)	0.49
Prior heart failure	2	(0.8%)	2	(2.5%)	0	(0%)	0.04
Family history	149	(60.6%)	44	(54.3%)	105	(63.6%)	0.16
PVD	5	(2%)	3	(3.8%)	2	(1.2%)	0.18
Renal Impairment	10	(4.1%)	5	(6.2%)	5	(3.0%)	0.24
PUD/GORD	10	(4.1%)	6	(7.4%)	4	(2.4%)	0.06
CAL	6	(2.4%)	3	(3.7%)	3	(1.8%)	0.36
Prior AMI	26	(10.6%)	9	(11.1%)	17	(10.2%)	□0.82
Prior Stroke	9	(3.7%)	7	(8.6%)	2	(1.2%)	0.01
Prior PCI	25	(10.1%)	9	(11.1%)	16	(9.7%)	0.73
Prior CABG	8	(3.2%)	5	(6.2%)	3	(1.8%)	0.07
BMI ≥25 kg/m²	160	(65.0%)	43	(53.1)	117	(70.9%)	0.06
Current smoker	69	(28.0%)	11	(13.6%)	58	(35.2%)	0.01
PCI Pathway							

Characteristics	Overall sample n=246 n (%)		≥70 yrs n=81 n (%)		<70 yrs n=165 n (%)		p
Pre-hospital field triage	77	(31.3%)	24	(29.6%)	53	(32.1%)	0.69
Non-field triage (ED/Inter-hospital)	169	(68.7%)	54	(70.4%)	112	(67.9%)	
Disease severity							
Single vessel	140	(56.9%)	44	(54.3%)	96	(58.2%)	0.76
Double vessel	80	(32.5%)	27	(33.3%)	53	(32.1%)	
Triple or more	26	(10.6%)	10	(12.3%)	16	(9.7%)	
Ejection fraction mean ± SD	47.6 ± 8.9		45.8 ± 9.5		48.5 ± 8.4		0.02
LOS (mean days) ± SD	4.2 ± 4.97		5.7 ± 7.1		3.4 ± 3.2		0.01

x^2 or Fisher's exact for categorical data, p≥0.05 significant

Clinical characteristics

Overall, cardiovascular risk factors were prevalent, with family history of heart disease (60.6%) the most common (Table 1). Nearly half the sample had hypertension (48%) and hyperlipidaemia (48.4%); almost two-thirds (65%) were overweight (mean BMI 26.9, SD 4.0) and 28% were current smokers. Participants ≥70 years were more likely to have hypertension (p=0.02), angina (p=0.03), be non-smokers (p=0.01) and to have had prior heart failure (p=0.04) and prior stroke (p=0.01) (Table 1). No differences were identified for other clinical characteristics. Co-morbidity risk (Charlson Comorbidity Index) was low with a mean of 0.86 (SD 0.9); the most common co-morbidities in our study population were diabetes, cerebrovascular and renal diseases.

PPCI characteristics and outcomes

Patients were admitted by inter-hospital transfer (45%), pre-hospital field triage (31%) or the ED (24%) for PPCI. The majority (57%) had single vessel disease, predominantly the left anterior descending coronary artery (LAD) and were treated with one stent (79%), mainly drug-eluting. The mean ejection fraction was 47.6 % (SD 8.9). Procedural complications were reported as composite MACE totalling 10%. Overall median CK value was 655 (IQR 200.5-1469.0) and troponin 1104 (IQR 145-4265) post- PPCI. Mean length of stay was 4.2 days (SD 4.9). Patients <70 years were more likely to have proximal coronary lesions treated (61% vs 44%, p=0.01) while older people were more likely to have distal lesions (12.7% vs 2.2%, p=0.01) and lower mean ejection fraction (45% vs 48%, p=0.02). The mean hospital stay days was significantly longer for older patients (5.7 vs 3.4, p=0.01).

HRQOL at 4 weeks and 6 months for entire cohort

At 4 weeks, mental health component scores (SF-12) were better than physical health (52.9 ± SD 9.9 vs 42.3 ± SD 8.8), with scores lowest for physical function, role physical and vitality and highest for bodily pain, social function and role emotional. For cardiac specific HRQOL, the highest scores at 4 weeks were for angina frequency (94.2 ± SD 13.7), treatment satisfaction (93.8 ± SD 10.4) and quality of life (75.1 ± SD20.1) but lowest for physical limitation and angina stability for the whole cohort. Over time, significant changes occurred for HRQOL in multiple areas. At 6 months, the SF-12 mental health scores were statistically better (54.6 ± SD 8.0 vs 52.9 ± SD 9.9, p<0.01) followed by the SF-12 physical limitation scores. For the SAQ, mean scores were highest for angina frequency (97.1 ± SD 12.4), physical limitation (94.2 ± SD12.7) and treatment satisfaction (96.8 ± SD 8.0). No deaths or strokes were reported. The greatest improvements were evident in the SAQ physical limitation and quality of life domains with score gains of 21.3 and 13.7 respectively. At 6 months angina stability was the sole domain with no improvement.

HRQOL compared between ≥70 years and <70 years at 4 weeks and 6 months.

Participants aged ≥70 years at 4 weeks had lower overall physical HRQOL (SF-PCS) (40.9 vs 43.1, p=0.03), physical function (SF-12) (47.2 vs 62.1, p<0.01) and social function (78.6 vs 82.0, p<0.01) but higher mental HRQOL (SF-MCS) (54.1 vs 52.3, p<0.01) (Table 2). For cardiac specific HRQOL (SAQ), participants ≥70 years experienced worse angina stability (52.4 vs 59.5, p<0.01) and quality of life (QOL) (72.8 vs 73.6, p=0.01).

At 6 months, participants ≥70 years had significantly better angina frequency scores (98.1 vs 96.6, $p<0.01$). Other significant differences were SAQ-QOL (91.8 vs 87.3, $p=0.02$) and SF-12 mental health (85.5 vs 79.6, $p<0.01$). The SAQ-QOL showed the highest and clinically significant improvement over time of 13.6 points for those ≥70 years, whilst angina frequency had the lowest score gain of 0.5 points. Older people had poorer SF-12 physical component scores (50.6 vs 52.6,$p<0.01$) including lower SAQ-physical limitation (91.5 vs 95.5, $p<0.01$) and angina stability (51.6 vs 50.9,$p<0.01$) scores over time. However, they scored better for SF-social functioning (93.5 vs 92.2, $p<0.01$) (Table 2).

Effect of age and time on HRQOL

There was only one interaction between age and time in one domain therefore these effects are reported separately. Age had an effect in less than half of all HRQOL domains, mainly the SF-12 domains of physical, MCS and social function. The PCS showed statistical improvement with both time ($p<0.01$) and age ($p=0.03$) showing separate effects. By 6 months, physical function scores had increased significantly for both older and younger people (47.2 and 62.1 vs 79.2 and 89.2, $F=99.0$, df=1, $p<0.01$). Therefore, people >70 years had improved physical function scores at 6 months of 32 and 27.1 independently for age and time, reflecting a variance in mean scores within and between age groups. However, the MCS showed significant differences only for age ($F=1.61$, df=1, $p<0.01$) but not time (Table 2). No interaction effects occurred for age and time with SF-12 subdomains.

For SAQ domains, participants ≥70 years had statistically significant higher scores for angina frequency ($F=2.35$, df=1, $p<0.01$) and QOL ($F=1.50$, df=1, p=0.02) and lower physical limitation (F=1.45, df=1, P=0.03) (Table 3). The remaining domains, angina stability and treatment satisfaction, demonstrated no differences for age whereas SAQ physical limitation (p<0.01) and QOL (p<0.01) showed statistical improvement with time and age (p=0.03 and p=0.02). Angina stability was the sole domain that showed a significantly large interaction effect (0.316) between age and time (F=1.54,df=1, p=0.02), result >0.14, indicating older people had better HRQOL over time whereas younger people had less improvements in HRQOL (Cohen, 1988).

Independent predictors of HRQOL

There were 8 predictors that independently predicted some aspects of HRQOL as measured by the SF12 over time. Model statistics for SF-12 PCS were statistically significant at 4 weeks (R2 =0.16, F=5.28, df=11, p=0.01) and 6 months (R2 =0.16, F=14.96, df=3, p=0.01) showing that 16% of the shared variance was explained by the predictors. Model statistics for SF-physical functioning was stronger for 4 weeks (R2 =0.19, F=15.43, df=4, p=0.01) compared to 6 months (R2 =0.14, F=13.70, df=3, p=0.01) (Tables 4, 5).

Age was a significant independent predictor of 4 week SF-physical functioning (ß=-0.33, CI:-0.64- -0.02, p=0.03), controlling for other factors entered into the model (Table 4). In addition, by 6 months age emerged as a predictor for both the SF-PCS (ß=-0.11, CI:-0.18- -0.03) and SF-physical functioning (ß=-0.50, CI:-0.77- -0.22). Overall, for each year increase in age, physical health decreased by 0.33 points at 4 weeks and 0.50 at 6 months for SF-physical functioning.

Length of hospital stay was also a significant predictor of worse SF-physical functioning (ß= -0.08, CI:-0.60- -0.18, p=0.01) at 4 weeks; more so at 6 months (ß=-1.60, CI:-2.34- -0.86, p=0.01) and SF-PCS (ß=-0.55, CI:-0.75- -0.34, p=0.01). This indicates HRQOL decreases with longer hospitalisation.

Other predictors included female gender which predicted substantially worse SF-physical functioning (ß=-16.31, CI: -26.0-6.5, p=0.01) and unpartnered status predicting worse SF-physical functioning (ß=-8.28, CI: -16.33—0.24) at 4 weeks. However by 6 months, number of stents was the only PPCI procedural covariate with positive predictive effect (ß=8.39, CI:2.12-14.6, p=0.01) on physical functioning.

Discussion

We examined HRQOL for STEMI patients aged ≥70 years versus <70 years after PPCI and age as a predictor of HRQOL, adjusting for other clinical factors at 4 weeks and 6 months during recovery. Health related quality of life improved at 6 months following PPCI across both age groups for physical and mental health. All aspects of cardiac-specific health status were better (physical limitation, anginal frequency, treatment satisfaction and QOL) except for angina stability. People ≥70 years had worse physical function than those <70 years even when adjusted for the presence of multiple factors. This may be explained by age-related conditions such as frailty limiting older peoples' physical activity and compounded by angina symptoms (Gharacholou *et al.*, 2012a). Our results parallel that of an earlier study conducted in UK using the SF-12 and SAQ (Moore *et al.*, 2006) which identified similar poorer physical function for people >60 years after PCI with improvements in other health domains. It is likely that comorbidities are reflected in functional status, which then ultimately affects HRQOL as explained in the Wilson and Cleary (1995) model. Numerous studies have also reported improved health status outcomes following PCI (Gunal *et al.*, 2008, Johnman *et al.*, 2013, Li *et al.*, 2012) with older people at risk from more MACE and higher mortality (Bauer *et al.*, 2011, Claessen *et al.*, 2010).

Our findings differ from results of a systematic review on octogenarians reporting better physical functioning and angina status compared to younger people after PCI and that quality of life improvements after PCI was not age-dependent (Johnman *et al.*, 2013). Angina stability was the sole domain in our study that reflected a large interaction effect between age and time but not a predictor of better or worse HRQOL. The paradoxical results of higher angina scores and good SAQ-QOL which persisted over time with increased age in our study supports previous published findings (Ho *et al.*, 2008, Spertus *et al.*, 2004). As expected, It is likely that physiological ageing, recurrent angina, different expectations of recovery and longer hospitalisation may account for differences in angina scoring and reporting between patients ≥70 and <70 years. These results support the relationships described in the Wilson and Cleary (1995) model which indicate that symptom load as well as nonmedical aspects such as age are important in HRQOL.

Age was an important independent predictor at 4 weeks of PPCI recovery for physical aspects of HRQOL with progressive improvement over time. By 6 months age remains an independent predictor of multiple aspects of HRQOL in our study, with a positive impact on physical health, mental health, quality of life and angina frequency. Few studies have examined this predictive effect of age on HRQOL following PPCI; most focused on the impact of MACE and mortality. Our study results expand on previous findings (Li *et al.*, 2012, Pocock *et al.*, 2000, Spertus *et al.*, 2004) showing age as a significant predictor of quality of life benefits at 6 month. Another study (Shah *et al.*, 2009) reported good quality of life for elderly STEMI patients ≥85 years with PPCI as an independent predictor of in-hospital mortality. This suggests that despite higher potential for MACE, people ≥70 years have improved HRQOL after PPCI over time. Age should not be an exclusion for PPCI in older STEMI patients irrespective of admission pathway. However, our cohort was unique as PPCI was conducted on acute STEMI patients, in particular older people receiving fast reperfusion by pre-hospital field triage and to date, there are no comparable published results.

Length of hospitalisation was another predictor of HRQOL correlating with physical domains of SF-PCS and SF-physical functioning across time. This is perhaps the most interesting finding. Despite no publications with similar results, a study (Chin *et al.*, 2011) showed that STEMI patients hospitalised >2 days were older and more likely to have MACE including cardiogenic shock after PPCI. Another study (Noman *et al.*, 2013) showed age and post-PCI complications to be predictive of longer hospitalisation for STEMI cohorts following PPCI although HRQOL was not assessed.

Gender and partnership status had a predictive effect on 4 week physical functioning after PPCI but not later. Two studies (Mortensen *et al.*, 2007, Pocock *et al.*, 2000) showed female gender to have worse HRQOL whilst unmarried females had the longest delays to PCI with higher mortality (Austin *et al.*, 2014). The role of gender independent of age and comorbidities needs further investigation.

Strengths and limitations

The strength of this study is the focus on the effect of age on HRQOL after urgent PPCI; recognising that measuring patient-reported health status is an important step towards improving quality of care for an ageing population. We used validated tools; the SF-12 and the cardiac-specific SAQ to comprehensively assess all domains of HRQOL and there was sufficient power to detect MCID between patients ≥70 and <70 years across time. An additional strength was the use of the SAQ scales because they are cardiac-specific complementing the SF-12 measurement for general health domains. Of patients screened, 47% met the study criteria and only 8.2% were lost to follow-up at 4 weeks with a further 12.6% lost by 6 months. This is another strength as high attrition rates are common with longitudinal studies on older participants (Newman, 2010).

We identified predictors of HRQOL by stepwise regression analysis; our multivariable models included a repeated measures analysis for all observations. We specifically focused on the SF-PCS and physical functioning models for comparison across time in order to support angina results as these are important indicators of recovery for older PPCI cohorts. Our findings compare favorably with previous studies. One study (Spertus *et al.*, 2004) reported models with R2 values from 0.7% to 25.3% for age and PCI as predictors of quality of life benefit after PCI. Another study (Melberg *et al.*, 2010) described 3 models (R2 =0.09, 0.20 and 0.42) comparing health status after PCI at different hospital sites. Given the complexity of HRQOL, it can be argued that HRQOL in cardiac patients has a cause and–effect relationship between symptoms (angina) and global HRQOL (physical, emotional and mental health, vitality and social function); supporting the theory of Wilson and Cleary. Our study captured all biophysical, psychological and social aspects of HRQOL as quantified by patient-rated life satisfaction responses during their recovery from PPCI for STEMI.

This study has several limitations. Participants were all STEMI patients recruited from two hospitals and therefore stringent recruitment criteria may restrict generalizability of results to other cardiac cohorts. The oldest patients with the most severe complications were excluded, hence the sample was comprised of non-complicated STEMI patients. More males aged >70 years withdrew from the study resulting in uneven comparison groups and study results may not adequately account for that group. In analysis, our strongest model explained only 19% of the variation in HRQOL status outcomes and there were limitations in the sensitivity of the SAQ, with a ceiling effect evident in some subscales. The data collected may potentially be limited by the length of interviews. There was no baseline HRQOL measurement pre-PPCI for comparison as urgent PPCI precluded this assessment.

Implications for practice

In clinical practice, nursing care is often protocol-based, focused on PCI procedural care such as access site and symptom management. Health related quality of life is not routinely assessed despite higher comorbidity risks and frailty in older people (Gharacholou *et al.*, 2012a, Moore *et al.*, 2006, Singh *et al.*, 2011) and they often lack equitable treatment also achievable by older people for physical health, mental health and anginal status comparable to younger people during PCI recovery (Ho *et al.*, 2008, Li *et al.*, 2012, Spertus *et al.*, 2004). Our results support a comprehensive approach to PPCI care incorporating physiological and psychological aspects of recovery, particularly with fast-track field triage pathways, where research is lacking for older people. Apart from measurable outcomes such as cost and MACE, there is a need for nursing-sensitive PCI care (Leeper, 2004) and improved monitoring standards for PCI nursing practice (Rolley *et al.*, 2009). Current clinical guidelines for post-PPCI care are inconsistent for in-hospital and discharge support aspects such as cardiac rehabilitation. Future research should include HRQOL evaluation in order to address specific needs identified by older STEMI patients whose expectations of recovery differ from younger cohorts.

Conclusion

Age is an important factor to consider in relation to physical function recovery following PPCI for STEMI. Length of hospitalization, age, number of stents, gender and partnership status are significant independent predictors of HRQOL outcomes over time. With increased PPCI in an ageing population and higher quality of life expectancy, HRQOL measurement constitutes an integral part of health status assessment and clinical care improvement. Further research should focus on enhancing physical activity, reducing hospitalization time and providing additional support particularly for older people following PPCI during the transition to full recovery.

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Table 2. HRQOL (SF-12) over time compared for over and under 70 year age groups by repeated measures ANOVA

HRQOL measurement	≥70 years Mean scores (SD)		<70 years Mean scores (SD)		Within subjects Time		Between subjects Age		Interaction effect Age * time	
	4 week	6 month	4 week	6 month	F[a]	p	F[a]	p	F[a]	p
PCS (SF-12)	40.9 (9.9)	49.3 (7.7)	43.1 (8.0)	52.3 (7.4)	139.621	<0.01	1.463	0.03	1.057	0.38
MCS (SF-12)	54.1 (9.3)	56.7 (5.9)	52.3 (10.2)	53.6 (8.7)	5.712	<0.01	1.612	<0.01	.809	0.81
Physical function	47.2 (34.0)	79.2 (32.0)	62.1 (31.2)	89.2 (24.7)	99.000	<0.01	1.723	<0.01	1.158	0.23
Role physical	50.3 (30.4)	81.0 (26.8)	45.3 (27.3)	82.1 (28.8)	130.682	<0.01	1.135	0.26	.760	0.88
General health	63.0 (21.7)	73.9 (20.4)	64.2 (23.7)	75.0 (21.5)	45.086	<0.01	1.123	0.28	.905	0.65
Bodily pain	92.6 (16.8)	98.3 (9.3)	89.8 (18.5)	96.9 (12.1)	18.906	<0.01	.868	0.72	.928	0.61
Vitality	48.1 (26.8)	62.6 (20.9)	55.9 (22.3)	65.0 (23.2)	14.932	<0.01	1.129	0.27	.944	0.58
Social function	78.6 (32.4)	94.1 (19.8)	82.0 (27.9)	92.6 (22.0)	22.870	<0.01	1.760	<0.01	1.205	0.18
Role emotional	86.1 (22.3)	92.6 (19.5)	79.0 (25.1)	91.4 (19.2)	12.930	<0.01	1.266	0.12	1.137	0.26
Mental health	80.7 (16.4)	85.5 (79.6)	75.7 (18.7)	79.6 (17.7)	13.769	<0.01	1.354	0.07	1.275	0.12

[a]repeated measures ANOVA, df =1

Table 3. Cardiac specific HRQOL (SAQ) at 4 weeks and 6 months compared for over and under and 70 years age groups

HRQOL measurement	≥70 years Mean scores (SD)		<70 years Mean scores (SD)		Within subjects Time		Between subjects Age		Interaction effect Age * time	
	4 week	6 month	4 week	6 month	F[a]	p	F[a]	p	F[a]	p
Physical limitation	70.7 (20.7)	91.5 (15.8)	73.9 (18.9)	95.5 (10.7)	114.680	<0.01	1.456	0.03	1.074	0.34
Angina stability	52.4 (12.7)	51.6 (10.2)	59.5 (22.6)	50.9 (10.2)	9.590	<0.01	1.025	0.44	1.541	0.02
Angina frequency	97.6 (10.0)	98.1 (9.8)	92.0 (15.0)	96.6 (13.5)	0.930	0.336	2.35	<0.01	1.311	0.09
Treatment satisfaction	96.6 (6.3)	99.1 (2.9)	92.4 (11.7)	95.7 (9.4)	13.084	<0.01	1.341	0.08	0.995	0.49
Quality of life	72.8 (19.3)	91.8 (10.3)	73.6 (20.4)	87.3 (14.3)	68.467	<0.01	1.501	0.02	0.849	0.75

[a]repeated measures ANOVA, df =1, SAQ scores are adjusted values

Table 4. Prediction model for HRQOL: SF-Physical Functioning and SF-PCS domains at 4 weeks

Predictor variables	SF-Physical Functioning			SF-PCS		
	Beta	95% CI	p	Beta	95% CI	p
Constant	116.62	95.56-137.68	0.01	46.76	36.27-57.25	0.01
Age	-0.33	-0.64- -0.02	0.03	-0.15	-0.10-0.07	0.73
Admission pathway	-4.61	-12.89-3.64	0.27	-0.05	-2.31-2.20	0.96
Partnered/unpartnered	-8.28	-16.33- -0.24	0.04	-1.25	-3.48-0.97	0.26
Smoking status	3.31	-1.19-7.83	0.14	0.59	-0.65-1.83	0.34
Number of stents	-0.20	-7.22-6.81	0.95	-0.18	-2.10-1.73	0.84
Hypercholestraemia	-5.74	-13.19-1.70	0.13	-1.02	-3.18-1.14	0.35
Previous AMI	2.58	-15.52-10.35	0.69	-2.25	-5.79-1.29	0.21
Length of stay (days)	-0.08	-0.60- -0.18	0.01	-0.55	-0.77- -0.34	0.01
Ejection fraction	0.29	-0.13-0.73	0.17	0.09	-0.03-0.21	0.14
Hypertension	0.97	-7.17-9.12	0.82	-2.09	-4.32-0.13	0.06
Gender	-16.31	-26.07- -6.54	0.01	-1.78	-4.53-0.96	0.96
Model statistics	(R^2 =0.19, F=15.43, df=4, p=0.01)			(R^2 =0.16, F=5.28, df=11, p=0.01)		

p-value <0.05 significant**.** The prediction models for remaining SF-12 domains including all SAQ domains with low R^2 <0.10 are not illustrated.

Table 5. Prediction model for physical HRQOL: SF Physical Functioning and SF-PCS at 6 months

Predictor variables	SF-Physical Functioning			SF-PCS		
	Beta	95% CI	p	Beta	95% CI	p
Constant	114.89	96.50-133.27	0.01	58.93	53.89-63.98	0.01
Age	-0.50	-0.77- -0.22	0.01	-0.11	-0.18- -0.03	0.01
Admission pathway	-4.47	-11.75-2.79	0.22	-0.34	-2.39-1.71	0.74
Partnered/unpartnered	-1.96	-9.29-5.37	0.59	-1.54	-3.53-0.45	0.12
Smoking status	1.74	-2.37-5.85	0.40	-0.51	-1.59-0.66	0.35
Number of stents	8.39	2.12-14.66	0.01	1.55	-0.17-3.27	0.07
Hypercholestraemia	-1.46	-8.63-5.69	0.68	-0.28	-2.23-1.67	0.77
Previous AMI	-6.75	17.61-4.09	0.22	-2.16	-5.16-0.82	0.15
Length of stay (days)	-1.60	-2.34- -0.86	0.01	-0.55	-0.75- -0.34	0.01
Ejection fraction	0.24	-0.63-0.15	0.22	-0.01	-0.11-0.10	0.91
Hypertension	0.92	-7.00-7.68	0.81	-0.64	-2.55-1.27	0.50
Gender	-7.92	-16.7-0.87	0.07	-1.65	-4.08-0.76	0.17
Model statistics	(R^2 =0.14, F=13.70, df=3, p=0.01)			(R^2 =0.16, F=14.96, df=3, p=0.01)		

p-value <0.05 significant. The prediction models for 6 month SF-12 and SAQ domains with low R^2 <0.10 are not shown

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CHAPTER 5: FIELD TRIAGE TO PRIMARY PERCUTANEOUS CORONARY INTERVENTION: FACTORS INFLUENCING HEALTH-RELATED QUALITY OF LIFE FOR PATIENTS AGED >70 AND <70 YEARS WITH NON-COMPLICATED ST-ELEVATION MYOCARDIAL INFARCTION.

Chapter Preface

Publication reference:

Soo Hoo S, Gallagher R, Elliott, D. (2016), 'Field triage for non-complicated ST-elevation myocardial infarction: Factors influencing health-related quality of life after primary percutaneous coronary intervention for patients aged ≥ 70 and < 70 years', *Heart & Lung,* vol. 45 no 1, pp.56-63.

Chapter four provided an exploration of the factors which impact on HRQOL outcomes after PPCI for STEMI according to age (≥ 70 and < 70 years). This chapter complements the previous study with an in-depth investigation of the predictors which impact on HRQOL for an important but smaller sub-set of STEMI patients who received PPCI by rapid field triage using a similar age group comparison. This study is presented in its original form in this chapter with publication details as above. A brief background expands the abstract content and rationale for conducting this study. The published form of this study is provided as an appendix at the end of the thesis.

Background

Field triage represents a rapid pathway to PPCI for STEMI patients and past research has shown that field triage results in with lower mortality and improved clinical outcomes such as better ejection fraction resulting from less myocardial ischaemia and cell damage.

This study is undertaken guided by what is already known, that is:

● Internationally, field triage to PPCI is recognised as best practice for the treatment of STEMI.

● Field triage to PPCI is associated with lower STEMI mortality.

● Field triage is associated with shorter time delays to coronary reperfusion and less MACE but this is not age-specific.

This research aims to investigate a field-triage STEMI subgroup to supplement the sparse information available for:

● Differences in HRQOL outcomes between older and younger patients who have STEMI after PPCI.

● Clinical and demographic variables that could significantly predict HRQOL outcomes after field triage for STEMI.

● The impact of age on HRQOL with rapid field triage.

Summary of results

This study identified 5 important clinical variables, namely age, length of hospitalization, recurrent angina and hypertension to have a predictive effect on HRQOL after field triage PPCI for STEMI. Age in particular predicted worse physical function at both 4 weeks and 6 months of recovery after field triage but by 6 months, age is a predictor of improved cardiac-related QOL. Other interesting findings indicate that longer hospitalisation in field triage cohorts is similarly associated with poorer physical function and cardiac QOL at both time points of recovery. Like age, recurrent angina was also identified as a significant predictor of poor physical function and lower cardiac QOL at both 4 weeks and 6 months after rapid PPCI, indicating the need for further research into this persistent symptom that dominates HRQOL outcomes.

Implications for practice

The implications of these similar findings in the field triage subgroup highlight a need for further good quality research into older people's recovery time, in-hospital MACE and the impact on HRQOL with equal access to rapid PPCI as younger patients. This has not been investigated to date. Recurrent angina remains a common reported symptom after PCI. Assessment of HRQOL combined with increased support for physical and emotional recovery is needed to improve clinical care for field triage PPCI patients. This study is the first to investigate HRQOL and the factors that impact on HRQOL in select field triage patients, particularly older people, hence creating a new knowledge base with novel information that could benefit future research for older STEMI patients. The following sections present the original study.

Abstract

Objective: To examine clinical and health-related quality of life (HRQOL) outcomes and predictors of HRQOL for uncomplicated field triage ST-elevation myocardial infarction (STEMI) patients aged ≥70 years and <70 years after primary percutaneous coronary intervention (PPCI).

Background: Pre-hospital field triage for PPCI is associated with lower mortality but the impact of age and other factors on HRQOL remains unknown.

Methods: 77 field triage STEMI patients were assessed for HRQOL using the Short Form-12 (SF-12) and the Seattle Angina Questionnaire (SAQ) at 4 weeks and 6 months after PPCI.

Results: Regression analysis showed improvements in SF-12 domains and angina stability. Age predicted lower physical function ($p=0.001$) and better SAQ QOL at 6 months ($p=0.003$).

Conclusion: Age, length of hospitalization, recurrent angina and hypertension were important predictors of HRQOL after field triage PPCI. Assessment of HRQOL combined with increased support for physical and emotional recovery is needed to improve clinical care for field triage PPCI patients.

Keywords: Field triage, pre-hospital ECG, percutaneous coronary intervention, ST-elevation myocardial infarction, health-related quality of life

Introduction

Field (pre-hospital) triage of patients with ST-elevation myocardial infarction (STEMI) represents a fast-track pathway to percutaneous coronary intervention (PCI). With STEMI, primary PCI (PPCI) is the urgent intervention for coronary reperfusion by comparison to routine or elective PCI. A pre-hospital ECG is performed by ambulance paramedics at the scene, and transmitted to the Emergency Department (ED) of a regional major heart centre. When a

STEMI is confirmed, the patient is transported directly to the heart centre for urgent PPCI. Unlike patients triaged through ED, who experience delays with routine assessment and admission processes, field triage directly to PPCI reduces myocardial ischemic time, resulting in better left ventricular function(Sivagangabalan et al. 2009) and lower mortality.(Carstensen et al. 2007; Ortolani et al. 2006; Pedersen et al. 2009; Terkelsen et al. 2009; Vermeulen et al. 2008; Zanini et al. 2008) For example, pre-hospital ECG STEMI diagnosis and field triage PPCI was associated with a 45-minute reduction in revascularisation delay (p= 0.001), and a two-thirds reduction for in-hospital mortality (p= 0.019)(Ortolani et al. 2006) including lower one month (5.4% vs 13.3%, p=0.006) and one year mortality (6.6% vs 17.5%, p=0.019).(Chan et al. 2012) While these effects on mortality are clear, influences on HRQOL for this patient cohort has not been investigated.

Rates of PCI in people over 70 years with STEMI have increased substantially in the United States with a 33.5% increase in PCI rates for those aged 65-79 years and 22% for ≥80 years between 2001 and 2010.(Khera et al. 2013) In Australia, PCI procedures increased with age until 75–84 years, but declined after 85 years.(Australian Institute of Health and Welfare 2010). Historically, older patients were excluded from PCI clinical trials(Alexander et al. 2006) due to frailty, poor coronary vasculature and multiple comorbidities which predisposed them to increased major adverse cardiovascular events (MACE) such as strokes or death.

Despite these limitations, older individuals appear to benefit from PCI.(Dauerman et al. 2003; Goldenberg et al. 2003) The Senior PAMI trial for example, demonstrated that STEMI patients aged ≥70 years treated with PCI had significantly reduced incidences of death, strokes and AMI.(Mortensen et al. 2007) Later studies comparing PCI with thrombolysis confirmed similar findings(Brooks et al. 2009; O'Gara et al. 2013) for patients with cardiogenic shock (Khera et al. 2013) and other forms of acute coronary syndromes (ACS) (Australian Institue of Health and Welfare 2014). However, a recent large cohort study on STEMI patients aged ≥75 years reported higher co-morbidities of hypertension, chronic airway disease, previous angina including prior revascularisation but patients had more PPCI-related MACE and that age was the strongest predictor of 90 day mortality after PPCI.(Gharacholou et al. 2011)

Few studies have however examined health-related quality of life (HRQOL) in older people after PCI. HRQOL assessment is included in the American Heart Association’s guidelines for PCI(Rumsfeld et al. 2013) to ensure all physical, mental, and social aspects of recovery are considered. However, with new technological advancements and increased emphasis on early coronary revascularisation, research is still lacking on HRQOL for field triage cohorts particularly for older people despite age being a strong predictor of mortality and MACE after STEMI.(Chin et al. 2011; Gharacholou et al. 2012) Results of a systematic review on octogenarians showed better physical functioning, angina status and quality of life improvements comparable to younger people and these outcomes were not age-dependent with PCI (Johnman et al. 2013). A more recent systematic review on HRQOL in PCI patients aged over 60 years also reported improved HRQOL, mainly from angina relief and better physical and mental function, with increasing age not demonstrating a predictive effect on HRQOL.(Soo Hoo, Gallagher & Elliott 2014). It is apparent therefore, that the most prevalent factors influencing HRQOL after PCI are likely to be age and angina symptoms, but it remains unclear if older people who have fast field triage PPCI experience similar HRQOL changes. Past studies have primarily reported improved mortality and better clinical outcomes associated with early reperfusion rather than evaluating the biopsychosocial aspects that HRQOL assessment confers in the setting of field triage PPCI. With projections for a global aging population (World Health Organization 2002) and increased risk of cardiovascular diseases, HRQOL assessment is crucial for strategic cardiac health care planning and improving clinical care for older people with acute coronary occlusion.

To date, there are no published studies examining HRQOL in field triage patients nor the independent effect of age in this population for potential comparison with other PCI cohorts during recovery. Similarly, the impact of socio-demographic and other potential coviarates on health status and clinical outcomes of field triage PPCI patients aged ≥70 years after a STEMI event also remain relatively unknown.

The objectives for conducting this study were to:

1. Compare socio-demographic and clinical characteristics between field triage STEMI patients aged ≥70 and <70 years.
2. Differentiate HRQOL outcomes at 4 weeks and 6 months after PPCI.
3. Determine any independent predictors of HRQOL after PPCI such as age and clinical factors including hypertension, recurrent angina, smoking status and length of hospital stay which impact on HRQOL outcomes.

Methods

Design, Setting and Sample

This study is a component of a larger study which examined multiple outcomes following PPCI including HRQOL, qualitative and clinical data. The current study included only the field triage cohort, which comprised 31.3% of all patients recruited and examined a contemporary issue that had not been previously reported. A prospective repeated measures cohort study design was developed to address the study objectives. All consecutive STEMI patients admitted by field triage and treated exclusively with PPCI between April 2010 and November 2011 were recruited from the PCI registry of a large university-affiliated public teaching hospital and a private hospital in Sydney, Australia. These hospitals provide 24-hour cardiac catheterisation services in collaboration with a state-wide ambulance program for pre-hospital field triage of STEMI patients.

Sample inclusion/exclusion criteria

The inclusion criteria for the field triage cohort were: 1) STEMI diagnosis characterised by dynamic ST-segment elevation on field triage ECG or new left bundle branch block 2) persistent chest pain and symptoms of myocardial ischemia 3) no initial thrombolysis 4) Serum Troponin T >14 ng/L or Troponin I >0.14ng/mL 5) able to provide informed consent in English and 6) has telephone for contact for follow-up. Exclusion criteria included a diagnosis of 1) dementia, 2) deafness, or 3) intensive care admission >5 days. The study was approved by the Human Research Ethics Committees of the two hospitals and all participants provided informed consent prior to data collection.

HRQOL measurement

Health-related quality of life was measured using the Medical Outcomes Short Form (SF-12) for general health and the Seattle Angina Questionnaire (SAQ) for cardiac-specific health. The SF-12 measures eight health domains:

physical function, physical role limitations, emotional role limitations, vitality, social function bodily pain, general health and mental health (Ware & Kosinski 2001). Patients rated their responses on a Likert scale from 3 to 6 and scores were transformed from the lowest 0 (worst health state) to the highest 100 (best health state). The SF-12 has two summary components; the physical component summary (PCS) and mental component summary (MCS) and all domains and summary scores can be compared with population-standardized norms.(Ware et al. 2009) The instrument has been validated internationally for cardiovascular populations,(Lim & Fisher 1999; Muller-Nordhorn, Roll & Willich 2004) epidemiological studies(Gandek 1998) and for Australian population health surveys,(Avery, Dal Grande & Taylor 2004; Sanderson & Andrews 2002) and also in smaller studies on HRQOL in cardiac patients, often combined with the SAQ(Moore et al. 2006) and is highly correlated and comparable with other HRQOL instruments.(Sansgiry et al. 2008) In this study, all domains showed high internal consistency (Cronbach's alpha 0.79 - 0.95) for the SF-12 at both measurement points.

The SAQ is a 19-item questionnaire for patients with coronary artery disease and measures domains of physical limitations, angina stability, angina frequency, treatment satisfaction, and quality of life (Spertus et al. 1995). Responses are measured on a 5 or 6 point Likert scale, with scores summed and transformed from 0 (worst health) to 100 (best health). SAQ scores for each domain are calculated creating a percentage of the total possible score – an adjusted score. Higher scores represent better function, fewer symptoms and higher HRQOL. As a disease-specific tool, the SAQ is sensitive and detects small changes in cardiac status not adequately captured by a general instrument(Borkon et al. 2002) hence its addition in this study. The SAQ has been demonstrated as valid in determining the impact of angina relief after PCI.(Ho et al. 2008; Jamieson et al. 2002; Li et al. 2012; Melberg, Nordrehaug & Nilsen 2010; Pocock et al. 2000; Spertus et al. 2004) A difference in scores of 5-10 points is considered a minimal clinically important difference (MCID) representing a significant change in HRQOL status.(Ho et al. 2008; Seto et al. 2000; Spertus 2002) In the current study internal consistency reliability for the SAQ was moderate (Cronbach alpha coefficients were 0.58 and 0.79 at 4 weeks and 6 months). Both instruments are brief and suitable for telephone interviews(Summerhill & Taylor 1992) with feasibility for our study initially confirmed by a pilot test.

Procedure

Consecutive field triage patients were identified from the hospital PCI registry and screened for eligibility. Post-PPCI, participants were visited by a research nurse who provided printed information and explanation of the study. A consent form for study participation was signed and follow-up telephone interview times arranged before hospital discharge. Socio-demographic, baseline clinical and cardiovascular risk factors, PPCI data and MACE were recorded during hospitalisation. Telephone interviews were conducted at 4 weeks and 6 months by a trained research nurse using an interview guide for uniformity of the interview process and HRQOL was assessed using the SF-12 and the SAQ. Each interview lasted approximately 15 minutes. These two interview times were selected as previous studies had reported improved physical and mental health up to 6 months post-PPCI, after which no significant differences occurred.(Seto et al. 2000; Weintraub et al. 2008) For age comparison, 70 years was chosen as it was more representative of older, retired people in Australia based on the national health statistics for 2014 which indicated a 3.6% population growth for people aged over 65 years.(Australian Institue of Health and Welfare 2014)

Statistical Analyses

Data analyses were conducted using the Statistical Package for the Social Sciences (SPSS version 22, IBM Corp., Armonk, New York). Data were reported as frequencies and percentages or means and standard deviations. Differences between patients ≥70 and <70 years were compared using chi-squared analysis for categorical data and t-test for continuous data (baseline socio-demographic, clinical and PPCI characteristics including MACE), with possible correlations examined using Spearman's; a $p<0.05$ was set as the level of significance. Due to uneven sample numbers, Levene's test for homogeneity was applied, accepting $p>0.05$.

Scores for HRQOL measures (SF-12 and SAQ) at 4 weeks and 6 months were compared between age groups using repeated measures ANOVA with testing of interaction effects for age and time. A Bonferroni correction of $p=0.01$ was used to control for Type I error. All SF-12 data were complete. Missing SAQ responses ($n = 4$) were adjusted and replaced by the average score for that scale of activity according to the SAQ scoring algorithms.(Spertus et al. 1995) This was calculated by subtracting the lowest crude score, dividing the range and multiplying by 100. As each SAQ scale had its own computation formula, adjusted SAQ scores were used for analysis. Multivariable linear regression analyses were then conducted on three HRQOL scores; SF PCS and physical functioning and SAQ QOL at 4 weeks and 6 months using 5 potential predictors (age, recurrent angina, current smoking, hypertension and length of hospital stay). These variables were selected based on findings from previous literature (Johnman et al. 2013; Li et al. 2012; Noman et al. 2013; Pocock et al. 2000; Rumsfeld et al. 2003; Spertus et al. 2004) and from statistically significant associations in the preliminary univariate analyses. Regression analysis was conducted on the physical and QOL domains, as the aims of PPCI are to relieve angina and improve QOL and physical function. Power calculation (A-priori) for two group comparisons of all STEMI patients receiving PPCI indicated that 45 participants were required for each group, with alpha level 0.05, medium effect size (Cohen's d 0.6), power level 0.8 using two-tailed t-test for 4 week analysis and an estimated 15% drop-out rate.

All predictor variables were entered into one block for analysis with separate regression models constructed, using a p-value of <0.05 as significant. Six models were created; one for each of the three HRQOL domains (SF-12 PCS, physical functioning and SAQ QOL) and for each time analysis (4 weeks and 6 months). Pearson's correlation was used to assess multicollinearity between the five independent covariates; results of collinearity statistics (VIF) did not exceed 10 for all models (range 1.016 to 1.190). Assumptions of linearity, collinearity and homoscedasticity in analyses were met and the predictive strength of all models were evaluated using an adjusted $R^2 \geq 0.10$ with 95% confidence intervals.(Katz 2011)

Results

Demographic and clinical characteristics

Patients who received PPCI by field triage (n=77) comprised 31.3% of all patients recruited in the larger cohort study (n=246) which included STEMI patients from ED (24%) and inter-hospital transfers (44.7%). Participants were mainly male (82%) with a mean age of 77.7 years (SD 5.8) and Caucasian (93%). At 6 months 71 patients had completed both interviews; 8% were lost to follow-up and one patient had deceased. Most participants were married/partnered (65%), employed (56%) and had completed year 12 education (70%). Participants aged ≥70 years (n=24) were less likely to have year 12 education (54% vs 79%, p=0.039) compared to younger patients <70 years (n=53) (Table 1). Risk factors for cardiovascular disease included hypertension (48%), hyperlipidaemia (48%), diabetes (10%), prior AMI (11%), prior PCI (10%), BMI≥25 kg/m^2 (65%) and current smoking (28%) (Table1).

Table 1. Characteristics of field triage patients – comparison across age categories

Characteristics	≥70 yrs n=24 (%)	<70 yrs n=53 (%)	p
Sociodemographics			
Male	18 (75)	46 (87)	0.231
Partnered	18 (75)	33 (62)	0.587
Employed	5 (21)	11 (21)	0.762
Year 12 (completed high school)	13 (54)	42 (79)	**0.039**
Lives alone	5 (21)	11 (21)	0.762
Clinical characteristics			
Hypertension	15 (63)	13 (25)	**0.001**
Hyperlipidaemia	7 (29)	26 (49)	0.095
Diabetes	2 (8)	3 (6)	0.335
Prior stroke	3 (13)	0 (0)	**0.031**
Prior AMI	4 (16)	6 (12)	0.605
Prior PCI	2 (8)	5 (9)	0.898
Angina	4 (16)	2 (4)	0.170
Renal impairment	1 (4)	0 (0)	0.227
Body Mass Index ≥25 kg/m²	13 (54)	37 (70)	0.299
Current smoker	5 (21)	22 (42)	**0.042**
Family history	14 (58)	32 (60)	0.879
Clinical outcomes			
Single vessel disease	16 (64)	27 (51)	0.287
Ejection fraction mean ± SD	48.0 ± 9.5	50.3 ± 7.3	0.251
LOS (mean days) ± SD	5.73 ± 7.1	3.48 ± 3.2	**0.008**
Re-admission at 4 weeks	0 (0)	2 (4)	0.527
Re-admission at 6 months	3 (13)	5 (9)	0.809
Recurrent angina at 4 weeks	0 (0)	12 (23)	**0.033**
Recurrent angina at 6 months	0 (0)	6 (12)	0.232

x^2 for categorical data comparison, continuous variables expressed as mean ± standard deviation, $p<0.05$. AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; LOS, length of stay.

Participants ≥70 years had more risk factors than those <70 years, including hypertension (63% vs 25%, p=0.001) and prior strokes (13% vs 0%, p=0.031), but were less likely to smoke (21% vs 42%, p=0.042), had longer hospitalization days (5.7 vs 3.4, F=14.50, df=1, p=0.008) and experienced less recurrent angina at 4 weeks (0% vs 23%, p=0.033). There were no significant differences for other risk factors. Over half (56%) of the cohort had single vessel disease, 39% had double vessel disease and 5% had triple vessel disease.

At 4 weeks, the highest scores and (therefore the best HRQOL) were for role emotional (91.8 ± SD 15.3), bodily pain (92.6 ± SD 15.2) and mental health (83.3 ± SD27.6) while the lowest scores (the worst HRQOL) were for PCS (40.2 ± SD10.7), role physical (50.7 ± SD 29.5) and vitality (56.8 ± SD 22.9) (Table 2). For cardiac specific HRQOL, higher scores at 4 weeks were for treatment satisfaction (95.3 ± SD 6.6), QOL (78.7 ± SD 16.9) and physical limitation (76.4 ± SD 21.8) while angina stability had the lowest score (50.0 ± SD 0.0).

At 6 months, scores were consistently high for bodily pain (100 ± SD 0.0) and role emotional (99.3 ± SD 2.7), while physical function had improved statistically (93.1 ± SD 15.8) and the PCS remained low (52.9 ± SD 5.6) (Table 2). For cardiac specific HRQOL, the higher scores were again for treatment satisfaction (98.7 ± SD 4.3), physical limitation (96.6 ± SD 7.4) and QOL (92.1 ± SD 10.2), with angina stability remaining low and with no improvement (48.4 ± SD 7.9).

Effects of time and age

The main effect on HRQOL outcomes was time; almost all SF-12 domains (except for MCS) improved significantly over time (Table 2). An independent effect of age was also noted for physical functioning ($F=3.554$, $df=2$, $p<0.030$) and role emotional ($F=3.68$, $df=2$, $p<0.036$), but no interaction effect of age and time. By 6 months, physical functioning scores had improved for both age categories (52.5 and 83.7 vs 64.7 and 93.1, $F=74.88$, $df=2$, $p<0.001$, respectively), with the older age category achieving greater improvements (12.2 and 9.4). Conversely, role emotional scores were better in older patients at 4 weeks (91.8 vs 81.6, $F=3.368$, $df=2$, $p<0.036$) but worsened with time ($p<0.001$), with 10.2 and 5.9 mean score differences, respectively. For the SAQ, time also had the greatest effect; with the exception of angina frequency, all domains improved significantly over time; QOL and physical limitation showing 13.4 and 18.7 score differences. One interaction effect (0.035) was observed between age and time ($F=4.112$, $df=2$, $p<0.018$) for angina stability; people over 70 years had no change in angina stability, while people aged <70 years had worse angina stability over time (Table 3).

Statistically significant differences were observed in age for two domains; participants aged ≥70 years had lower SF physical function scores (52.5 vs 64.7, F=3.554, df=2, p<0.030) but higher role emotional scores (91.8 vs 81.6, F=3.368, df=2, p<0.036) at 4 weeks (Table 2). No differences were noted for cardiac-specific (SAQ) HRQOL (Table 3). At 6 months, older people continued to have lower SF physical functioning (83.7 vs 93.1, F=74.88, df=2, p<0.001), vitality (61.2 vs 65.6, F=11.85, df=2, p< 0.001) but maintained higher role emotional scores (99.3 vs 93.8, F=15.81, df=2, p<0.001) reflecting 9.4, 4.4 and 5.5 score differences respectively. No effect for age was demonstrated for the SAQ.

The influence of age and covariates on HRQOL

At 4 weeks, the PCS showed negative associations with age (r=-.211, p=0.001), hypertension (r=-.223, p=0.001), length of stay (r=-.372, p=0.001) and recurrent angina (r=-.134, p=0.036). By 6 months, only age (r=-.234, p=0.001), length of stay (r=-.352, p=0.001) and recurrent angina (r=-.236, p=0.001) were significantly associated with SF PCS. The SAQ QOL domain at 4 weeks was positively associated with age (r=.126, p=0.048) and had a negative association with recurrent angina (r=-.216, p=0.001). By 6 months, only age (r=.210, p=0.001) and smoking (r=-.186, p=0.004) showed positive associations with SAQ QOL. Age was therefore correlated with HRQOL changes for both SF-PCS and SAQ QOL at both time periods.

Table 2: HRQOL (SF-12) in field triage patients compared for over and under 70 years age groups

HRQOL measurement	**≥70 years Mean scores (SD)**		**<70 years Mean scores (SD)**		**Within subjects Time**		**Between subjects Age**		**Interaction Age * time**	
	4 week	**6 month**	**4 week**	**6 month**	**F[a]**	**p**	**F[a]**	**p**	**F[a]**	**p**
PCS	40.2 (10.7)	49.3 (8.8)	43.8 (7.4)	52.9 (5.6)	99.20	**0.001**	2.567	0.079	0.018	0.982
MCS	57.0 (7.2)	57.7 (3.0)	52.8 (10.2)	55.3 (7.9)	2.693	0.102	2.729	0.067	0.264	0.768
Physical function	52.5 (34.3)	83.7 (28.4)	64.7 (24.5)	93.1 (15.8)	74.88	**0.001**	3.554	**0.030**	0.073	0.929
Role physical	50.7 (29.5)	83.7 (27.2)	67.0 (24.8)	86.2 (26.1)	105.0	**0.001**	0.759	0.469	0.663	0.516
General health	65.5 (25.1)	76.0 (18.0)	64.6 (23.1)	75.4 (21.5)	26.51	**0.001**	1.128	0.880	0.017	0.983
Bodily pain	88.7 (24.9)	100.0 (0.00)	92.6 (15.2)	96.5 (11.2)	19.74	**0.001**	0.106	0.899	1.358	0.259
Vitality	58.7 (26.0)	61.2 (17.1)	56.8 (22.9)	65.6 (19.2)	11.85	**0.001**	1.480	0.230	1.043	0.354
Social function	82.5 (29.3)	96.2 (16.7)	83.3 (27.6)	92.5 (15.8)	17.98	**0.001**	1.107	0.332	0.008	0.992
Role emotional	91.8 (15.3)	99.3 (2.7)	81.6 (24.7)	93.8 (18.2)	15.81	**0.001**	3.368	**0.036**	0.238	0.789
Mental health	81.2 (11.8)	88.1 (9.4)	77.2 (16.9)	88.3 (16.8)	11.37	**0.001**	0.492	0.227	0.544	0.581

[a]repeated measures ANOVA, df=2.; MCS: mental component summary; PCS: physical component summary.

Table 3. Cardiac-specific HRQOL (SAQ) in field triage patients compared for over and under 70 years age groups

HRQOL measurement	**≥70 years Mean scores (SD)**		**<70 years Mean scores (SD)**		**Within subjects Time**		**Between subjects Age**		**Interaction effect Age * time**	
	4 week	**6 month**	**4 week**	**6 month**	**F[a]**	**p**	**F[a]**	**p**	**F[a]**	**p**
Physical limitation	76.4 (21.8)	95.1 (11.7)	75.1 (15.3)	96.6 (7.4)	120.1	**0.001**	1.207	0.301	0.206	0.814
Angina stability	50.0 (0.0)	50.0 (0.0)	61.7 (21.1)	48.4 (7.9)	8.565	**0.004**	1.475	0.231	4.112	**0.018**
Angina frequency	100.0 (0.0)	100.0 (0.0)	94.31 (12.3)	95.49 (16.1)	1.417	0.235	1.666	0.191	0.880	0.416
Treatment satisfaction	95.3 (6.6)	98.7 (4.3)	94.9 (7.7)	96.4 (9.4)	7.223	**0.008**	0.746	0.475	0.606	0.547
Quality of life	78.7 (16.9)	92.1 (10.2)	74.5 (19.7)	89.1 (15.6)	67.30	**0.001**	0.778	0.461	0.034	0.966

Significant *p*-values are highlighted in bold

[a] Repeated measures ANOVA, df=2. All SAQ scores are adjusted values

Independent predictors

Five predictors (age, hypertension, smoking, LOS and recurrent angina) independently predicted different aspects of HRQOL (Tables 4 and 5). All models were statistically significant; however the variance explained was generally small and varied from 5% to 20% at 4 weeks and from 12% to 15% at 6 months. Four SF-12 model statistics including SF PCS were statistically significant at 4 weeks (R^2 =0.20, F=13.2, df=5, p<0.001) and 6 months (R^2 =0.15, F=13.9, df=5, p=0.001). The PCS models were strongest, reflecting 20% and 15% respectively of the shared variance explained by the predictors (Table 4).

Age was a significant independent predictor at both time points for all physical HRQOL outcomes, except overall cardiac HRQOL at 4 weeks, when other factors were controlled for in the models (Table 4). Older participants reported significantly worse HRQOL for SF physical functioning at both 4 weeks (ß=-0.294, 95% CI:-0.938- -0.316, p=0.001) and for PCS at 6 months (ß=-0.241, 95% CI:-0.804- -0.250, p=0.001) (Table 4). For each year increase in age, physical functioning decreased by 0.29 points at 4 weeks and 0.24 points at 6 months, while the PCS decreased by 0.13 points and 0.21 points, respectively. In contrast, age was a significant predictor at 6 months for improved SAQ QOL (ß=0.19, 95% CI: 0.07-0.34, p=0.003) (Table 5).

Similar to age, length of hospital stay (LOS) was a significant independent predictor at both time points for all HRQOL outcomes, explaining the highest variances for the SF-Physical Functioning (25%) and the PCS (32%) at 6 months. Participants with a longer length of stay had worse HRQOL for physical functioning and PCS (both p=0.001) (Table 4), and for SAQ QOL at both measurement points (p=0.049 and p=0.012) respectively (Table 5). For each additional day of hospitalisation, physical functioning and PCS decreased by 0.28 and 0.34 points at 4 weeks and by 0.25 and 0.32 points at 6 months. In addition, QOL also decreased by 0.12 points at 4 weeks and a further 0.15 points at 6 months. Hypertension had a negative impact on one domain, the SF-PCS at 4 weeks (p=0.010) (Table 4). Participants with hypertension had poorer SF PCS scores (0.15 points less) at 4 weeks while smoking was not a significant predictor of better or worse HRQOL.

Recurrent angina emerged as a predictor of lower SF physical functioning (p=0.003) and SF-PCS (p=0.001) at 4 weeks and 6 months (p=0.002 and p=0.001 respectively). Recurrent angina explained the highest variances for the SAQ QOL at both 4 weeks (20%) and 6 months (28%) but predicted lower SAQ QOL at both times (p=0.001) (Table 5). For people who had recurrent angina, their SAQ QOL score decreased by 0.20 points at 4 weeks and even more, by 0.28 points at 6 months of recovery.

Table 4. Predictors of HRQOL in patients for SF-Physical Functioning, SF-PCS and SAQ-QOL at 4 weeks

Predictor variables	SF-Physical Functioning			SF-PCS			SAQ-QOL		
	Beta	**95% CI**	**p**	**Beta**	**95% CI**	**p**	**Beta**	**95% CI**	**P**
Constant	105.6	85.4-125.9	0.001	52.0	46.7-57.4	0.001	65.3	52.1-78.6	0.001
Age	-0.29	-0.93- -0.31	**0.001**	-0.13	-0.17- -0.01	**0.035**	0.12	-0.01-0.40	0.057
Hypertension	0.03	-9.87-5.86	0.616	-0.15	-4.81- -0.66	**0.010**	-0.03	-6.44-3.86	0.622
Smoking status	-0.07	-1.53-7.42	0.197	-0.05	-0.61-1.75	0.342	0.07	-1.08-4.78	0.216
Length of stay (days)	-0.28	-2.65- -1.09	**0.001**	-0.34	-0.80- -0.39	**0.001**	-0.12	-1.02- -0.01	**0.049**
Recurrent angina	-0.17	-27.1- -5.64	**0.003**	-0.20	-7.76- -2.09	**0.001**	-0.20	-18.8- -4.75	**0.001**
Model statistics	(R^2 =0.17, F=11.2, df=5, p=0.001)			(R^2 =0.20, F=13.2, df=5, p=0.001)			(R^2 =0.05, F=3.88, df=5, p=0.002)		

p-value <0.05 significant**.** All SAQ scores are adjusted scores.
Significant *p*-values are in highlighted in bold

Table 5. Prediction models for SF-Physical Functioning, SF-PCS and SAQ-QOL at 6 months

Predictor variables	SF-Physical Functioning			SF-PCS			SAQ-QOL		
	Beta	**95% CI**	**p**	**Beta**	**95% CI**	**p**	**Beta**	**95% CI**	**p**
Constant	125.5	107.4-143.6	0.001	63.0	58.2-67.8	0.001	77.9	69.1-86.8	0.001
Age	-0.24	-0.80- -0.25	**0.001**	-0.21	-0.20- -0.05	**0.001**	0.19	0.07-0.34	**0.003**
Hypertension	0.01	-6.29-7.51	0.862	-0.01	-1.91-1.73	0.923	0.03	-2.40-4.33	0.573
Smoking status	-0.06	-1.76-6.08	0.278	-0.06	-1.61-0.46	0.274	0.02	-1.56-2.26	0.716
Length of stay (days)	-0.25	-2.26- -0.80	**0.001**	-0.32	-0.73- -0.34	**0.001**	-0.15	-0.81- -0.10	**0.012**
Recurrent angina	-0.18	-27.7- -6.04	**0.002**	-0.28	-9.90- -4.17	**0.001**	-0.28	-17.6- -7.02	**0.001**
Model statistics	(R^2 =0.15, F=9.35, df=5, p=0.001)			(R^2 =0.15, F=13.9, df=5, p=0.001)			(R^2 =0.12, F=7.74, df=5, p=0.001)		

p-value <0.05 significant**.** All SAQ scores are adjusted scores.
Significant *p*-values are in highlighted in bold

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Discussion

We examined the patterns of HRQOL during recovery from early triage PPCI and found that HRQOL was moderate to high. We also examined the effect of age, socio-demographic and clinical variables on HRQOL for field triage STEMI patients at 4 weeks and 6 months of recovery. Our results confirmed that patients aged ≥70 years can achieve significant improvements for physical functioning, angina stability, treatment satisfaction and quality of life domains over time. The high QOL and physical limitation scores for our sample showed differences of 13.4 and 18.7 which exceeded the MCID of 5-10 point differences as recommended for the SAQ. After accounting for hospital length of stay and recurrent angina, age had an important independent and negative effect on SF-12 physical and role emotional domains, which was not surprising, given the comorbidities older people commonly have (Jamieson et al. 2002). Age-related conditions such as frailty affecting physical activity may combine with angina symptoms to impact on HRQOL (Li et al. 2012). Despite poorer physical function, older people improved in cardiac QOL by 6 months, most likely from improved angina stability. Our results were comparable with an earlier study conducted in the UK using both the SF-12 and SAQ (Moore et al. 2006) which identified similar poorer physical function for people >60 years after PCI but with improvements in other health domains.

The effect of age on HRQOL is an important consideration in facilitating PPCI recovery from fast field triage; our results however, could not be compared unequivocally with any existing study. A previous study(Gharacholou et al. 2011) reported age to be a strong predictor of mortality and adverse health outcomes after PPCI for STEMI but results were not exclusive to field triage cohorts. From this perspective, our results provide beginning information for clinical research on older adults with early presentation of STEMI for PPCI, particularly for post-procedure and community approaches for managing people over 70 years recovering from fast-track pathways to PPCI, as their physical recovery patterns differ from general PCI cohorts.

We identified recurrent angina as a predictor of worse physical and cardiac health status after PPCI, supporting previous research on the prevalence of angina symptoms particularly during the first month of recovery (Johnman et al. 2013; Pocock et al. 2000; Spertus et al. 2004). Our results also indicated recurrent angina to be a predictor of worse physical function and QOL with a significant interaction effect between age and time. Therefore angina is an important symptom to detect and treat (Fosbol et al. 2013). This finding differed from previous systematic reviews where octogenarians reported better physical functioning and angina status after PCI (Johnman et al. 2013) and patients of all ages reported improved HRQOL after PCI, with age not a predictor of HRQOL outcomes (Soo Hoo, Gallagher & Elliott 2014). An earlier study reported residual recurrent angina following PCI as a major determinant of poorer 3-year quality of life (Permanyer-Miralda et al. 1999). In view of such differences, it is possible that recurrent angina had more impact on field triage patients who rated their physical recovery and QOL as poorer despite early PPCI. Further research into this phenomenon is indicated especially with field triage and PPCI as the recognized first-line treatment for STEMI without any age delineation.

Interestingly, the domains with least improvements were SF-12 vitality and mental health for both age groups. A recent study on HRQOL in ACS patients reported high anxiety and depression impacting on long-term HRQOL improvements at 36 months but not initially in the first week to 6 months, with age and gender as influencing factors (Uchmanowicz & Loboz-Grudzien 2015). This indicates that physical and mental aspects of support for patients after a cardiac event and PPCI may need to extend beyond the early phase of recovery.

An important finding from this study is that length of hospitalisation was a negative predictor of multiple aspects of HRQOL and consistent with past findings (Noman et al. 2013) which showed age and post-procedural complications as predictive of longer hospitalisation for STEMI patients after PPCI. HRQOL was not however assessed in those studies. Another randomised trial on low-risk PPCI STEMI patients indicated that early hospital discharge within 72 hours was safe and feasible (Kotowycz et al. 2010). Our study showed low-risk STEMI patients had longer hospitalisations with lower HRQOL and poorer physical function recovery. As there was no protocol governing discharge of low-risk STEMI patients at the study hospitals, our results has implications for early discharge planning with field triage PPCI.

Past studies demonstrated improved SAQ physical function for older patients after PCI (Moore et al. 2006; Seto et al. 2000) but not specifically for non-complicated STEMI patients treated by fast-track PPCI. Our study appears to be the first to identify the impact of age and other predictors on HRQOL within the context of rapid coronary revascularisation for a unique cohort of STEMI patients whose recovery outcomes differ from those treated by routine ED pathways. Field triage of STEMI is recognised as the superior pathway to PPCI but it is not universally implemented. Our research from an Australian context may not translate to other countries with different health systems such as Korea (Kim et al. 2013) where STEMI patients are routinely assessed in ED first. By contrast, field triage is well-established in countries such as Denmark (Pedersen et al. 2009; Terkelsen et al. 2009), the United States(Curtis et al. 2006; Fosbol et al. 2013) and Canada (Chan et al. 2012) with where PPCI can be performed expeditiously for STEMI patients. However, HRQOL is internationally recognised as a measure for health status outcomes. This study has provided insights into HRQOL as perceived by a select cohort of older STEMI patients and constituted first-time patient-reported recovery experiences following rapid coronary reperfusion.

Assessment of HRQOL is not routine practice for older patients receiving PCI despite higher comorbidity risks and frailty (Gharacholou et al. 2012; Moore et al. 2006; Singh, Rihal, Lennon, Spertus, Sreekumaran Nair, et al. 2011); and often lacking equity in treatment access (Alexander et al. 2006). In practice, older STEMI patients remain vulnerable to protocol-driven nursing care that is not age-sensitive. Our results confirmed that older people have HRQOL benefits with PPCI. A concise and age-inclusive approach to post-PPCI care is therefore needed, including nursing-sensitive care (Leeper 2004) and better monitoring standards (Rolley et al. 2009) particularly for patients who lacked routine pre-procedural information and preparation for urgent revascularization. With field triage, the prognosis for patient survival from a STEMI is enhanced but to date, this is the only identified study that has examined all HRQOL aspects during PPCI recovery in this unique cohort. Future research should focus on evaluating additional patient support, education and counseling for older STEMI patients in order to provide an optimal hospitalization period and to promote physical and emotional recovery after fast-track PPCI (Table 6). Larger scale studies including systematic assessments of HRQOL and factors which impact on health status outcomes for older patients treated by rapid pathways to PPCI is needed.

Methodological strengths and limitations

The strength of this study was its focus on field triage STEMI patients and our findings support the need for assessing HRQOL after fast-track PPCI. We also used validated tools, the generic SF-12 and the SAQ to comprehensively measure all aspects of general and cardiac-specific HRQOL. Our study participants met international guidelines for STEMI and PPCI management (O'Gara et al. 2013; Steg et al. 2012) (Steg et al. 2012) but generalizability of our findings may however, be limited by the relatively small sample number of "non-complicated" STEMI participants. Power estimation for study size was conducted for entire cohort of STEMI patients rather than for the smaller study group. We also lacked baseline HRQOL measurements for comparison, although the urgency of field triage to PPCI makes it impractical to assess HRQOL prior to rapid coronary reperfusion. Finally, the regression models had limited explanatory power (5-20%), therefore it is likely that other important variables not included in the current study may be essential to include in a study which has a larger sample size.

Table 6: Recommendations for nursing practice and research

- HRQOL measurement is important and needs to be integrated into the routine clinical care of patients after urgent PPCI.
- Follow-up health status assessment post-hospital discharge is vital for monitoring patient recovery after STEMI and for targeting specific health care needs.
- Future research should focus on evaluating the potential for additional patient support and education for an aging population in order to optimize physical and emotional recovery after fast-track PPCI.
- Nursing research is lacking for field triage PPCI cohorts and systematic assessments of factors which impact on health status outcomes of older patients are warranted.

Conclusion

HRQOL is an important measure of health status and recovery from PPCI by field triage. Age, length of hospitalization, recurrent angina and baseline hypertension are key predictors of HRQOL outcomes. This study is the first to report the impact of socio-demographic and clinical factors which influence and predict HRQOL in field triage STEMI patients, and expands the limited research evidence for this important cardiac subset. Further studies are required to determine the relationship between improved effectiveness of PPCI for STEMI by field triage, and other factors such as emotional, social and rehabilitative support that could potentially enhance health status outcomes for an aging global population.

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CHAPTER 6: PREDICTORS OF CARDIAC REHABILITATION ATTENDANCE FOLLOWING PRIMARY PERCUTANEOUS CORONARY INTEVENTION FOR ST-ELEVATION MYOCARDIAL INFARCTION IN AUSTRALIA

Chapter Preface

Publication reference

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Background

Cardiac rehabilitation (CR) is an important support for recovery and secondary prevention following any cardiac event, but perhaps more so for urgent PPCI. The benefits and importance of CR following AMI has been extensively researched and documented but there remains limited studies focusing on select groups such as older people after PPCI

This study is undertaken guided by what is already known in published literature, that is:

- CR after PCI is associated with lower mortality and better recovery.
- Attendance at CR, including referral to established programs remain suboptimal.

- CR attendance is poorer for female gender, the elderly, unemployed people, smokers and those with lower socio-economic and educational status but whether these factors apply to STEMI PPCI cohorts is unknown.

International practice guidelines for STEMI care recommend CR as an important component of secondary prevention in cardiovascular risk and lifestyle management after PCI. Despite this, attendance patterns and factors which predict participation by patients admitted with STEMI for urgent PPCI remain unclear. This study employed a descriptive, comparative design. Consecutive STEMI patients (n=246) were interviewed by telephone at 4 weeks and 6 months after PPCI. Open-ended questions were used to assess CR attendance, socio-demographics, modifiable risk factors, clinical outcomes and post-discharge health support. Results were compared for differences in attendance between ≥ 70 years and < 70 years.

Summary of results and implications for practice

Gender, employment status and post-discharge support were identified as independent predictors of CR attendance after PPCI. Attendance at CR was lower than desired and many PPCI patients were not accessing support such as post-discharge support that could assist with their recovery. The availability of post-discharge home visits at 4 weeks and at 6-months was associated with better cardiac rehabilitation attendance as was male gender and unemployed status. This study has implications for current practice whereby standardised, routine CR programs may need to be more diversified in content and flexible for younger patients resuming work. Importantly, key insights gained from this study provide new evidence that CR programs in the community also need to integrate post-discharge health support in the recovery period and encourage more female participation as these are the areas that predict the extent of CR attendance. The following sections present the study in its original form and text content.

Abstract

Cardiac rehabilitation is an important component of recovery and secondary prevention following urgent primary percutaneous coronary intervention. However, attendance and factors that predict participation by patients admitted with ST-elevation myocardial infarction remain unclear. This Australian study was conducted using a descriptive, comparative design. Consecutive patients (n=246) at two hospitals were interviewed by telephone at 4 weeks and 6 months. Open-ended questions were used to assess cardiac rehabilitation attendance, socio-demographics, modifiable risk factors, clinical outcomes and post-discharge health support. Post-discharge home visits at 4 weeks (odds ratio: 2.64, 95% confidence interval: 1.48-4.71) and at 6-months were associated with better cardiac rehabilitation attendance; more males participated at 4 weeks and at 6 months. The results suggest the need to integrate post-discharge health support with cardiac rehabilitation to facilitate recovery after primary percutaneous coronary intervention, particularly for females with ST-elevation myocardial infarction.

Keywords: attendance, cardiac rehabilitation, gender, percutaneous coronary intervention, ST-elevation myocardial infarction.

Introduction

Cardiac rehabilitation (CR) after acute myocardial infarction (AMI) has been associated with lower mortality and morbidity (Dunlay et al. 2014; West, Jones & Henderson 2012) and fewer clinical complications following percutaneous coronary intervention (PCI) for coronary occlusion (Dendale et al. 2005; Izawa et al. 2011). In Australia, coronary heart disease is a common cause of death, accounting for 49% of all cardiovascular deaths mainly in people older than 75 years and a corresponding increase in PCI procedures for ages 75–84 years (Australian Institute of Health and Welfare 2015). Within the acute coronary syndromes (ACS), ST-elevation myocardial infarction (STEMI) is the most serious form of AMI with poor survival outcomes if early treatment is not initiated. Consequently, guidelines from American Heart Association (O'Gara et al. 2013) and the European Society of Cardiology (Steg et al. 2012) recommend primary percutaneous coronary intervention (PPCI) as priority treatment for STEMI, followed by CR as secondary prevention for improving risk factors management and healthy lifestyle changes. However, a gap in enquiry exists relating to what predicts CR attendance specifically for STEMI patients after PPCI and these remains un-investigated and unclear.

Literature review

Cardiac rehabilitation is an important support program for recovery and secondary prevention for coronary heart disease and is aimed at improving cardiovascular risk management and promoting healthy lifestyle (Leon et al. 2005). Attendance at CR improves cardiovascular, physical and psychological function by reducing coronary risk factors (Higgins, Hayes & McKenna 2001;

Taylor et al. 2004) and results in less hospital readmissions and better health-related quality of life (HRQOL) for patients with coronary artery disease (Shepherd & While 2012), AMI (Dunlay et al. 2014; West, Jones & Henderson 2012) and after PCI. Not surprisingly, international guidelines, such as those from the American College of Cardiology, recommend referral to CR for moderate to high risk patients undergoing PCI (Levine et al. 2011). It is argued that during recovery following a PCI, CR participation is important to assist patients to increase their physical fitness, reduce cardiac-related symptoms, minimise the risk of future AMI events and to resume normal activity, using counseling, educational and psychological support.

Past studies have investigated the association between CR participation and major adverse cardiovascular events (MACE) with conclusive evidence of lower mortality, less recurrent angina, restenosis and consequently, revascularization rates among PCI participants (Bellardinelli et al. 2001; Dendale et al. 2005). A further study (Goel et al. 2011) using PCI registry data observed a 45% to 47% lower all-cause mortality in CR participants after PCI, although there was no effect on recurrent AMI and revascularization. However, the evidence for the effectiveness of CR is not as clear in primary percutaneous coronary intervention (PPCI) patients as in AMI patients. This is an important deficit, as PPCI rates have grown in response to international guidelines promoting early treatment of STEMI by expediting coronary reperfusion with stenting/angioplasty (O'Gara et al. 2013; Steg et al. 2012). Further contemporary PPCI treatments include fast field triage (pre-hospital triage) by utilising ambulance ECG transmissions to hospitals for early definitive diagnosis of STEMI and bypassing emergency department waiting time; therefore identifying a subgroup which may have different outcomes (Carstensen et al. 2007; Vermeulen et al. 2008; Zanini et al. 2008) and thus, different needs for CR.

Attendance at CR programs has been described as suboptimal internationally and is influenced by multiple factors. Recent studies have highlighted common disparities relating to the structure, objectives and lack of comprehensive CR programs with a shortfall in meeting patients' expected needs after ACS (Eshah 2011) and a lack of cultural considerations in the development of appropriate CR programs for coronary heart disease (Kim et al. 2014). Similarly, a recent Australian study (Clark et al. 2014) reported sub-optimal attendance by cardiac patients despite good geographical access in metropolitan areas to established CR services. However, with diverse cultural and language differences combined with an ageing population and poor rural services, disparities continue to exist for CR participation. This indicates that more complex factors, personal and service barriers will need to be considered when assessing patients' decisions for continual participation and perseverance with CR programs.

Reported barriers to CR participation and under-representation is present for vulnerable populations such as women (Gallagher, McKinley & Dracup 2003), the socially disadvantaged with AMI (Nielsen, Meillier & Larsen 2013) and people over 62 years with higher risk of functional disability (Suaya et al. 2009; Williams, Fleg & Ades 2002). One publication identified multiple factors including STEMI, younger age, male gender, non-diabetic, no prior AMI or prior CR attendance and psychosocial issues to be important predictors of increased attendance (Dunlay et al. 2009). Other studies identified depression and denial

(Ades et al. 1992) including anxiety, less exercise pre-AMI and thrombolysis as decreasing attendance (Lane et al. 2001). Past research showed some inconsistency as one Australian study identified older age and male PCI patients who were non-drivers as less likely to attend and predictors of program drop-out were males who smoked, diabetics, unemployed and females who were physically inactive on admission (Worcester et al. 2004). Older age and female gender were often reported, apart from high risk factors and multiple comorbidities which were associated with worse HRQOL and CR outcomes (Ades et al. 1992; Jamieson et al. 2002). Results of a large systematic review identified social and personal factors such as patient knowledge of CR, perceptions of heart disease, family, financial and occupational restraints to be predictors of attendance more than physician referral or clinical factors (Clark et al. 2012). Overall these studies described factors associated with increasing attendance at CR to be male gender, younger age and being employed whilst female gender, older age, lower socioeconomic and educational status, unemployment and lack of access or transport as decreasing attendance. However, these factors are relatively unknown in PPCI patients as past studies mainly focused on AMI cohorts (Farley, Wade & Birchmore 2003; French et al. 2005; McKee et al. 2013). CR referral and subsequent utilization of CR remains unclear between ACS cohorts as the urgency and lack of preparation could impact on patient attitudes to participation following PPCI. Therefore, the aims of this study were to examine the rates of CR attendance at 4 weeks and 6 months following PPCI for acute STEMI, and the independent predictors of CR for PPCI when adjusted for baseline characteristics, co-morbidities and risk factors.

Methods

Design, Setting and sample

This prospective cohort study was conducted as a separate study on STEMI patients who also participated in a HRQOL study comparing health outcomes after PPCI between age groups. Eligible STEMI patients treated with PPCI were consecutively enrolled from the PCI Registry of a large metropolitan university affiliated public hospital and a private hospital in Sydney, Australia. These institutions conduct approximately 1070 PCIs annually for a regional population of 1.2 million, including pre-hospital field triage admissions. Services for PPCI patients at these institutions includes post-discharge health visits to the home by a community nurse and comprehensive CR programs for the support and facilitation of recovery and secondary prevention after discharge. The CR programs included staged physical exercise, counselling support and education on nutrition, medications and maintenance of healthy life-style changes (Northern Sydney Local Health District 2012), provided in sessions over 6 consecutive weeks of two 1-hour duration per week or by fast-track half-day workshops and patients could commence from two weeks post-discharge. Most patients received CR referral from special CR nurses, including information on the benefits of participation in CR program. Patients were systemically enrolled in the current study if they were diagnosed with a STEMI (without thrombolysis), received PPCI, able to consent in English and contactable by telephone for interviews. Exclusion criteria were diagnosis of dementia or severe neurocognitive impairment, deafness and prolonged Intensive Care stay. Ethics approval was obtained from the Human Research Ethics Committees of both study sites and the university.

Data collection

Socio-demographic, baseline clinical and cardiovascular risk factors, PPCI data and MACE were recorded during hospitalisation. CR attendance at 4 weeks and 6 months post-PPCI were recorded during patient interviews using a data collection form, along with provision of post-discharge health visit. CR and post-discharge service data were collected by asking 3 simple questions: i) whether they were referred to CR, ii) if they had participated in CR and number of sessions attended and iii) whether they received post-discharge health visit after hospital discharge.

Procedure

All STEMI patients admitted by either pre-hospital field triage direct to the Catheter Laboratory, through the Emergency Department (ED) or urgent inter-hospital transfer for PPCI were screened for eligibility. Eligible participants were approached for informed consent in hospital, usually on the next day from the PPCI and follow-up appointments were arranged for telephone interviews. At 4 weeks and 6 months after the index PPCI, patients were interviewed at home by telephone contact; each interview lasted approximately 15 minutes.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS version 21, IBM Corp., Armonk, New York) was used for data analysis, with frequencies and percentages or means and standard deviation reported. Chi-square analysis or Fisher's exact test was used for categorical data analysis and for CR attendance or non-attendance at 4 weeks and 6 months. Multivariable logistic regression analysis was conducted on 9 potential predictors (age, gender, marital status, employment status, educational status, previous AMI, previous PCI, length of hospital stay, post-discharge health visit and total modifiable risk factors) for independent effects on CR attendance at 4 weeks and 6 months. For analysis purposes, total modifiable risk factors included hypertension, hyperlipidaemia, diabetes, obesity/BMI ≥25 kg/m^2 and smoking; common cardiovascular conditions which could be treated or improved with medications and lifestyle change. Potential variables were forced into one block for the analysis using all 9 variables each time as a full model, at 4 weeks and repeated for 6 months in order to examine which variables independently predicted CR attendance. Demographic and clinical variables were selected based on previous literature and a series of correlations to determine which variables were likely to be associated with or predictive of CR attendance. Two separate regression models were constructed, with variables set for inclusion at $p \leq 0.05$.

Results

Sample characteristics

The sample consisted of 268 participants enrolled from 570 STEMI patients screened for eligibility. Overall 246 participants were interviewed at 4 weeks and 233 participants completed the final 6-month interview. Those who withdrew before interview were more likely to be ≥70 years and male. The sample mean age was 63.6 years (SD 13), mainly male (79%), married or partnered (68%) and had completed year 12 high school education (66%) (Table 1).

Modifiable risk factors were common, 65% were obese (mean BMI 26.9, SD 4.0) with hyperlipidaemia (48%), hypertension (48%) and diabetes (10%) and 28% were current smokers (Table 1). Almost equivalent numbers had a previous AMI (11%) and PCI (10%).

PPCI characteristics and outcomes

Patients were admitted by inter-hospital transfer (45%), pre-hospital field triage (31%) or the ED (24%). The mean ejection fraction (EF) was 47.6 % (SD 8.9), recurrent angina (15%) occurred at 4 weeks and less (10%) at 6 months, while readmissions at 4 weeks and 6 months were 4% and 12%, respectively.

Table 1. Characteristics of study patients (n=246)

Characteristics	**n**	**(%)**
Male	194	(79)
Partnered	167	(68)
Employed	119	(48)
Year 12 (completed high school)	163	(66)
Risk Factors		
Hypertension	118	(48)
Hyperlipidaemia	119	(48)
Diabetes	26	(10)
Prior AMI	26	(11)
Prior PCI	25	(10)
BMI ≥25 kg/m²	160	(65)
Current smoker	69	(28)
PCI Pathway		
Field triage	77	(31)
Disease severity		
Single vessel	140	(57)
Ejection fraction mean ± SD	47.6 ± 8.9 (SD)	
LOS (mean days) ± SD	4.2 ± 4.97 (SD)	
Clinical outcomes		
Re-admission at 4 weeks	10	(4)
Re-admission at 6 months	29	(12)
Re-angina at 4 weeks	37	(15)
Re-angina at 6 months	25	(10)
Post-discharge health visit		
At 4 weeks	134	(54)
At 6 months	129	(52)

AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; LOS, length of stay; Re-angina, recurrent angina.

CR attendance rates at 4 weeks and 6 months

Almost all PPCI patients (96%) were referred to CR prior to discharge (Table 2). At 4 weeks, 36% of patients (n=89) had attended CR. The only factors that demonstrated a statistical difference for attendance were more males (p=0.013), currently employed (p=0.043), received a post-discharge health visit (p=0.002) and shorter length of hospital stay (p=0.027). Less than one-quarter (22%) of participants had completed 1-2 CR sessions by 4 weeks, and only 1% attended the maximum possible of 9-14 sessions.

At 6 months, CR participation had increased to 54% (n=132). Those who attended CR were more likely to be male (p=0.018), previously had an AMI (p=0.047) or PCI (p=0.008) and had received post-discharge health support (p=0.001). Post-discharge health support or acute post-acute care, was a free, home-based health program offered to patients who resided within the local health district, aimed at monitoring and facilitating recovery after hospitalization. Initially, a community nurse visited the patient within 24 hours of hospital discharge in order to assess home safety, medication regime, wound care, dietary goals and weight management and to organize social worker and physiotherapy support if required. Similar to CR, patients received information on discharge plans during hospitalization and participation in the post-discharge health program was voluntary with visits dependent on each patient's perceptions of self-progress and prioritization of recovery needs (Table 3).

No significant differences were observed for other clinical characteristics such as diabetes, hyperlipidaemia, hypertension, smoking, recurrent angina or readmissions at either time point.

Table 2. Comparison of characteristics for attendance and non-attendance at Cardiac Rehabilitation for 4 weeks and 6 months

Attendance		**4 weeks**					**6 months**				
		Yes n = 89 (36%)		**No** n = 155		**p**	**Yes** n =132 (54%)		**No** n = 101		**p**
Characteristics		n	(%)	n	(%)		n	(%)	n	(%)	
Age (years)	≥70	23	(26)	58	(37)	0.065	38	(29)	63	(62)	0.154
	<70	66	(74)	97	(63)		94	(71)	38	(38)	
Gender	male	78	(88)	115	(74)	0.013	111	(84)	72	(71)	0.018
	female	11	(12)	40	(26)		21	(16)	29	(29)	
Partnered	Yes	64	(72)	101	(65)	0.278	90	(68)	69	(68)	0.982
	No	25	(28)	54	(35)		42	(32)	32	(32)	
Employed	Yes	51	(57)	68	(44)	0.043	64	(48)	48	(48)	0.884
	No	38	(43)	87	(56)		68	(52)	53	(52)	
Year 12 education	Yes	67	(75)	95	(61)	0.030	89	(67)	64	(63)	0.518
	No	22	(25)	59	(38)		43	(32)	37	(37)	
Hypertension	Yes	37	(41)	81	(53)	0.108	63	(48)	48	(48)	0.976
	No	52	(58)	74	(47)		69	(52)	53	(52)	
Hyperlipidaemia	Yes	44	(49)	73	(47)	0.725	62	(46)	50	(50)	0.701
	No	45	(50)	82	(53)		70	(53)	51	(50)	
Diabetes	Yes	11	(12)	15	(10)	0.513	15	(11)	10	(10)	0.721
	No	78	(88)	140	(91)		117	(89)	91	(90)	
Previous AMI	Yes	6	(7)	20	(13)	0.133	10	(8)	16	(16)	0.047
	No	83	(93)	135	(87)		122	(92)	85	(84)	
Previous PCI	Yes	7	(8)	18	(12)	0.353	8	(6)	17	(17)	0.008
	No	82	(53)	137	(88)		124	(94)	84	(83)	
BMI	Mean ± SD	26.6	± 3	27.1	± 4.4	0.332	27.0	± 3.7	26.8	± 4.3	0.659
Smoker	Yes	26	(29)	42	(27)	0.723	35	(27)	29	(29)	0.710
	No	63	(71)	113	(73)		97	(73)	72	(71)	
Field triage	Yes	31	(35)	46	(30)	0.404	44	(33)	28	(28)	0.358
	No	58	(65)	109	(70)		88	(67)	73	(72)	

Attendance		4 weeks					6 months				
		Yes n = 89 (36%)		No n = 155		p	Yes n =132 (54%)		No n = 101		p
Characteristics		n	(%)	n	(%)		n	(%)	n	(%)	
Single vessel	Yes	57	(64)	81	(52)	0.074	80	(61)	52	(51)	0.123
	No	32	(36)	74	(48)		51	(39)	50	(49)	
Re-admission	Yes	2	(2)	8	(5)	□0.334	18	(14)	11	(11)	0.529
	No	87	(98)	147	(95)		114	(86)	90	(89)	
Re-angina	Yes	15	(17)	22	(14)	0.577	14	(11)	11	(11)	0.944
	No	74	(83)	133	(86)		118	(89)	90	(89)	
LOS	Mean ± SD	3.30	± 2.8	4.7	± 5.8	0.027	4.02	± 4.9	4.24	± 4.1	0.726
EF	Mean ± SD	48.6	± 8.5	46.8	± 9.0	0.135	47.9	± 9.0	47.5	± 8.7	0.750
Post-discharge health visit	Yes	60	(67)	73	(47)	0.002	88	(67)	41	(41)	0.001
	No	28	(31)	82	(53)		44	(33)	60	(59)	

AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; LOS, length of stay; BMI, body mass index; LOS, length of stay; EF, ejection fraction; Re-angina, recurrent angina; SD, standard deviation.

Table 3. Logistic regression model predicting factors associated with CR attendance for 4 weeks and 6 months

Predictor variables	4 week attendance				6 month attendance			
	Beta	Odds Ratio	95% CI	p-value	Beta	Odds Ratio	95% CI	p-value
Constant	-1.297	.273	NA	0.048	-.479	.619	NA	0.416
Age (years)	-.131	.877	.413-1.866	0.734	-.515	.598	.288-1.241	0.167
Gender	.811	2.251	1.002-5.057	*0.049	.931	2.538	1.213-5.313	*0.013
Employed	.053	1.055	.524-2.124	0.882	-.733	.481	.232-.997	*0.049
Year 12 Education	-.456	.634	.327-1.229	0.882	-.275	.760	.394-1.464	0.760
Pre-AMI	-1.116	.328	.084-1.276	0.108	-.535	.586	.168-2.041	0.401
Pre-PCI	.294	1.342	.353-5.111	0.666	-.891	.410	.114-1.477	0.173
Length of hospital stay	-.067	.935	.849-1.031	0.179	.009	1.009	.943-1.080	0.792
Post-discharge health visit	.972	2.643	1.481-4.716	*0.001	1.149	3.154	1.775-5.605	*0.001
Total modifiable risk factors	.003	1.003	.779-1.293	0.979	.048	1.049	.813-1.354	0.711

*p<0.05 significant . NA, not applicable; AMI, acute myocardial infarction; PCI, percutaneous coronary intervention

Predictors of CR attendance

Two independent models were developed for CR at 4 weeks and 6 months, and both were statistically significant (p=0.001). The model for CR attendance at 4 weeks included two significant independent predictors; receiving post-discharge health support and male gender (p=0.001). After controlling for all other factors those who had post-discharge health support (OR 2.64, CI 1.48-4.71, p=0.001) and males (OR 2.25, CI 1.00-5.05, p=0.001) and were more than twice as likely to attend CR. The model for 6 months included 3 independent predictors (male gender, post-discharge health visit and employed status). After controlling for all other factors, patients receiving post-discharge health visit were more than three times more likely to attend (OR 3.15, CI 1.77-5.60, p=0.001) and males more than twice as likely to attend (OR 2.53, CI 1.21-5.31, p=0.001), whereas employed people were less likely to attend CR (OR 0.48, CI 0.23-0.99, p=0.049). Therefore, male gender and receiving post-discharge health visit were positive predictors of CR participation during PPCI recovery.

Discussion

We examined CR attendance rates and predictors of attendance after PPCI for STEMI patients at 4 weeks and 6 months, as a gap in the literature was evident for this cohort. Despite a high referral rate (96%), attendance rates of 36%-54% in this study are consistent with 40%-55% attendance reported for international studies, (Cooper et al. 2002; Goel et al. 2011; Witt et al. 2004) reflecting a common finding that only half of patients referred actually attended a CR program to completion. Previous studies have identified multiple barriers to CR attendance including transport and cost constraints, personal embarrassment, cultural and linguistic barriers, poor understanding and lack of interest (Cooper et al. 2002; Daly et al. 2002; Lane et al. 2001; McKee et al. 2013; Neubeck et al. 2012). One study (Brown et al. 2009), showed that only 56% of patients post-AMI, PCI and cardiac surgery had CR referral and that younger age, STEMI, smoking and dyslipidaemia were associated with increased referral; the main reason cited for poor referral was due to lack of awareness of CR benefits by health professionals.

Our results demonstrated an important finding in that post-discharge health visit was a key predictor for both 4 weeks and 6 months CR attendance, with participants who received the discharge health program more likely to attend CR at both times. This indicates a need for more focus on discharge support that will facilitate physical recovery and return to routine activities after an unprecedented acute cardiac event with subsequent fast coronary revascularisation.

The influence of gender on CR attendance has been previously demonstrated. Women were less likely to attend CR (Farley, Wade & Birchmore 2003; Gallagher, McKinley & Dracup 2003; Witt et al. 2004) and reasons for poor participation were multifactorial. Various studies have described women having more difficulties with transport (Daly et al. 2002; King, Humen & Smith 2001; Marzolini, Brooks & Oh 2008), less referral to CR (Aragam et al. 2011; Caulin-Glaser et al. 2001; Colbert et al. 2014; Colella et al. 2014; Witt et al. 2004), lower enrolment rates (O'Farrell et al. 2000) and higher attendance dropout (Colbert et al. 2014; Worcester et al. 2004). Results of two recent meta-analyses examining CR publications over a decade on gender differences showed that CR referral remained consistently low for women diagnosed with cardiovascular disease (Colella et al. 2014) and they were 36% less likely to be enrolled in a CR program compared to men (Samayoa et al. 2014). Another recent study (Beckstead et al. 2014) found disparities in CR referrals in favour of men by doctors who were biased in their judgement of women as less likely to benefit from CR based on their own beliefs and lack of insight on patients' motivation levels. This bias may have a restrictive impact on the numbers of eligible females attending CR, particularly when participation is dependent on their physician's decision.

Another possible explanation for more men attending CR may be attributed to socioeconomic and psychological reasons; past studies have noted that psychological factors of perceived benefits of CR and self-efficacy for lifestyle change and exercise were determinants of CR attendance and program adherence (Kelly, Zyzanski & Alemagno 1991; King et al. 2001). Female patients often participate less in physical activity than men partially due to their perceptions of their physical limitations, particularly with ageing (Worcester et al. 2004) and women may not perceive CR as important for recovery (Daly et al. 2002). Our results confirmed that employed males were less likely to attend CR, possibly explained by a need to resume work early (De Vos, Xiao, et al. 2012) and a better knowledge of the benefits that CR attendance confers. Consequently, gender disparities occur for CR attendance, where men continue to dominate despite the fact that CR is beneficial for all participants.

Our study also showed that being employed had a small but negative significant impact on CR attendance at 6 months. Similarly, a recent study (McKee et al. 2013) reported employment, age and past AMI to be predictors of intention to attend CR whilst another study (De Vos, Xiao, et al. 2012), found lack of time such as work obligations to be one reason for non-attendance. Further research is indicated as the benefits of CR participation may be diluted when unemployment or late resumption of work after an invasive procedure (PPCI) is considered.

Whilst CR aims at maximising physical, social and psychological recovery with shortened recovery time, there remains no existing national Australian database on post-discharge CR participation and health status outcomes for comparison (Australian Institute of Health and Welfare 2015). A recent population study (Clark et al. 2014) indicated that CR attendance was not associated with distance to CR services but rather socioeconomic and socio-psychological factors. Therefore, attention should focus on developing patient motivation and self-efficacy to participate. It is clear that evaluation should incorporate multiple aspects such as gender, educational background, socioeconomic and psychosocial factors which could negatively impact on patients' decision to participate. Our results confirmed that female gender, being employed and not receiving post-discharge health visit were negative factors and barriers to CR attendance. Of note, age was not an independent predictor of CR attendance at either time.

Study Strengths

This study provided important information on CR attendance and its impact on a select cohort of acute STEMI and early field triage PPCI patients. To date there are no comparable findings on predictors of CR attendance analysed by both socio-demographic and clinical risk factors for specific field triage PPCI subjects in Australia. While a number of international studies have investigated predictors of CR attendance mostly for AMI cohorts, few have focussed on PCI subjects (Dendale et al. 2005; Goel et al. 2011; Izawa et al. 2011; Worcester et al. 2004) and none had included post-discharge support specifically for a PPCI cohort. Our results are therefore unique and expand on the current limited information on factors which govern CR participation and recovery in vulnerable populations. One post-discharge visit after PPCI is a significant positive factor for increased CR attendance. This suggests a need to augment health support services that will inform, reinforce and promote CR attendance for STEMI patients after rapid revascularisation. Despite a high referral rate (96%), the attendance rates of 36%-54% in this Australian study are consistent with 40%-55% attendance reported for international studies (Cooper et al. 2002; Goel et al. 2011; Witt et al. 2004) and supports a common finding that only half of patients referred actually attended a CR program to completion. Therefore future research is indicated to investigate factors for non-participation including review and standardization of CR referrals for PPCI patients.

Limitations

Study limitations are also noted in that the sample may not be representative of PPCI patients in general as recruitment was from one large metropolitan health service and comprised low risk STEMI patients. Furthermore, CR attendance pattern was based on individual self-report. We excluded covariates such as baseline angina or prior coronary artery bypass in the regression analysis due to small sample numbers. This was despite past studies (Rumsfeld et al. 2003; Spertus et al. 2004) identifying them as predictors of worse physical recovery and that the severity of coronary vessel occlusion may also impact on CR attendance. Our results have implications only for STEMI patients who agreed to CR participation with post-discharge visits during the recovery phase rather than reflect on the overall effectiveness of CR referral processes following PPCI.

Conclusion

Our study shows that despite high levels of referral, CR participation rates in PPCI patients are lower than ideal, with approximately half participating by 6 months follow-up. Participation was highest in men, the unemployed and those who had a post discharge health visit. These results add a new perspective not reported previously for an important sub-group of STEMI patients, by identifying that health visits post-discharge after PPCI are associated with improved CR attendance.

Implications for practice

Future research is recommended to investigate the impact of tailored CR programs suitable for women, the very elderly and the unemployed after fast track PPCI and highlighting the important relationship between community health support programs, CR participation patterns and patient health status outcomes. Standardised CR programs could be redefined and expanded in content and scope to incorporate the educational and emotional needs of recovering PPCI patients who did not receive routine pre-procedural preparation and care. With increased focus on PPCI as priority treatment for STEMI both in Australia and internationally and the advantages of CR participation for high risk cohorts, there is a need for comprehensive risk assessment with PPCI. Strategies to incorporate post-discharge health care and to promote active and sustained CR participation with vigilant follow-up of attendance are recommended for patients with acute presentations of STEMI as successful CR is an integral component of comprehensive PPCI recovery.

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Contributions

Study Design: SH, RG, DE.

Data Collection and Analysis: SH.

Manuscript writing: SH, RG, DE.

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CHAPTER 7: THESIS DISCUSSION AND CONCLUSION

Chapter Preface

This thesis provides a comprehensive exploration and description of HRQOL in STEMI patient cohorts during recovery from PPCI. The overall thesis aim was to understand HRQOL as a key patient outcome for STEMI/PPCI cohorts and the effect of age, if any, on HRQOL outcomes and the major predictors of HRQOL. Analyses (and related published studies) presented earlier highlighted the important factors that influenced HRQOL at 4 weeks and 6 months after PPCI (Chapter 4); the health status outcomes of patients admitted for PPCI by a fast field triage pathway (Chapter 5); and factors influencing patient participation in CR during PPCI (Chapter 6).

This chapter describes the key findings and synthesis of this original research in light of what is already known about HRQOL. The sub-optimal utilisation of CR for recovery and risk factor modification in this population is considered in view of existing services. The chapter concludes with implications for practice and future research directions.

Key findings in relation to the literature

The key study findings include:

- All STEMI patients irrespective of age and type of access to PPCI demonstrated improvements in HRQOL from 4 weeks to 6 months after PPCI, confirming the results of the systematic review (Chapter 3). Of note, the key predictors of HRQOL over time were age, length of hospitalisation, gender, partnership status and number of stents deployed.

- For the field triage PPCI STEMI patients, the key predictors of HRQOL were similar to the overall group in terms of age and length of hospitalisation but otherwise differed to include recurrent angina and baseline hypertension.
- People aged 70 years or older Improved over time similar to their younger counterparts but had worse physical HRQOL but better mental health, angina frequency and cardiac-specific QOL at 4 weeks and 6 months of recovery.
- Attendance at CR after PPCI for STEMI patients was poor and the main predictors of better attendance included male gender, unemployed status and receiving post-discharge home visits during recovery.

Improved HRQOL after PPCI

It is not surprising that HRQOL improved over time from 4 weeks to 6 months following PPCI for STEMI and should be considered a normal process of recovery from a stressful event. These improvements have been reported previously (Agarwal, Schechter & Zaman 2009; Ho et al. 2008; Rinfret et al. 2001; Shah et al. 2009) and are also noted in our systematic review (Soo Hoo, Gallagher & Elliott 2014). Improvements in physical scores (SF-12 PCS, Physical function and Role physical; SAQ physical limitation) by 6 months after PPCI ranged from 9-37 points. These had exceeded the 5 point difference cited by others (Agarwal, Schechter & Zaman 2009; Graham et al. 2006; Moore et al. 2006) and also in many domains, exceeding the 5-10 point minimally clinical difference (MCID) measured by the SF-12 (Ware et al. 2009). The greatest improvements were in the physical domains of both the SF-12 and SAQ. Complementing physical HRQOL was the role physical domain, with 36.8 as the highest score attained by 6 months. Older STEMI patients had the greatest improvements. The most likely explanation for improvements in the physical domain is that once patients had recovered from the initial acute STEMI event, PPCI had provided symptomatic relief of angina (angina frequency score gain of 5.7 points). Supporting this and consistent with past studies, older people also improved in bodily pain (5.7 points gain) (Kahler et al. 1999; Seto et al. 2000); vitality (14.5 points) (Jamieson et al. 2002; Li et al. 2012; Pocock et al. 2000) and more so for role physical (30.7 points gain) (Jamieson et al. 2002; Kahler et al. 1999; Li et al. 2012; Melberg, Nordrehaug & Nilsen 2010; Pocock et al. 2000) over time. These improvements are likely to collectively contribute to and enhance the physical aspects of HRQOL, where patients are able to be active and perform their normal activities in the absence of symptomatic angina.

Treatment satisfaction also demonstrated gains up to 6 months for all ages (2.5 and 3.3 points scores more) for the whole cohort and for the field triage group (3.4 and 1.5). This is clearly related and supports similar improvements in angina as shown by earlier studies (Aggarwal et al. 2009; Graham et al. 2006; Moore et al. 2006). Treatment satisfaction is important because it includes patient's perceptions that they have improved in their angina symptoms and coronary disease state after PPCI, which in turn, impacted on their quality of life.

This study reinforces the usefulness of measuring HRQOL and supports its definition (Pedersen et al. 2007a) in that, HRQOL reflects the impact of illness on functioning as perceived by the patient and therefore incorporates the broader dimensions of physical, social and emotional health. From this perspective, the study findings also contribute to the advantages of using the conceptual framework of Wilson and Cleary (1995) in this population because of the integration of five levels of health outcomes, attributed to biological and physiological factors, symptoms, functioning, general health perceptions and overall quality of life; all of which impact on global HRQOL. The over-arching conceptual focus of this study is HRQOL; the findings for all domains provide a contextual link to the linear relationship of biophysiological factors, the symptoms, physical functioning, general health and quality of life as advocated by Wilson and Cleary's (1995) model of HRQOL. These are aspects of the patient's well-being and more importantly, show the causal relationships between clinical health variables such as angina symptoms which impact on HRQOL and PPCI recovery. However, angina relief alone may not accurately quantify health status changes as it does not fully represent the patient's perception of physical, emotional and psychosocial well-being (Blankenship et al. 2013). This study, by utilising the SAQ, illustrated patients' responses to a detailed and more holistic capture of HRQOL in the setting of STEMI. Please note also that HRQOL in physical domains was still the lowest aspect of scores for HRQOL overall, indicating an area needing attention.

Mental health scores (SF-12 MCS) showed statistical differences by age comparison but did not improve over time. A likely explanation for this is that mental health scores may be already high initially, with limits for greater improvements. Past research reported higher levels of anxiety and depression for late HRQOL outcomes at 3 years follow-up but not in the first few months after an AMI (Uchmanowicz & Loboz-Grudzien 2015). As time progresses following treatment, older peoples' HRQOL continues to improve but not so with younger people. This finding is synonymous with the recurrence of angina reported by all patients; especially in the field triage cohort where 23% of patients aged <70 years had recurrent angina (p=0.03) compared to no angina experienced by older people at 4 weeks after PPCI. Interestingly, all domains of the SF-12 improved statistically over time except for mental health scores (SF-12 MCS). The reason for this is largely unknown as no prior research had been conducted for this unique cohort. It can only be postulated that field triage PPCI patients already had high mental health scores but were more focussed on the success of their rapid treatment as confirmed by their higher SAQ-treatment satisfaction and quality of life scores. This may possibly be a reflection of the relief felt after surviving an initial critical STEMI episode.

In summary, this study confirms that the lowest HRQOL scores for routine ED-admitted STEMI patients occurred for physical health, including angina stability in the early recovery stage of 4 weeks after treatment, with significant improvement by 6 months. Consistent with previous research, the best HRQOL results relate to bodily pain (Kahler et al. 1999; Seto et al. 2000), role emotional (Jamieson et al. 2002; Pocock et al. 2000), social function (Aggarwal et al. 2009; Pocock et al. 2000), angina frequency, treatment satisfaction and QOL (Spertus et al. 2004; Zhang et al. 2006). Our findings indicate that even for acute STEMI patients with pronounced coronary occlusion and ischaemia, HRQOL improved in other domains after PCI. This is not dissimilar to reported findings from the mixed cohorts of elective and urgent PCI patients in past studies and from the systematic review results of this thesis. This may indicate the procedural effectiveness of PCI/PPCI in reducing the frequency of ischaemic chest pain symptoms and that STEMI patients were satisfied with the end-results of PPCI, as validated by the SAQ responses.

For the rapidly-treated field triage cohort, the main domains of health where HRQOL was lower than normal at 4 weeks after PPCI were also physical function, role physical and vitality (SF-12) including (SAQ) angina stability and physical function. The highest HRQOL scores were for role emotional and bodily pain (SF-12), angina frequency and treatment satisfaction (SAQ) across all ages for this group. These scores were most likely attributed to the fast relief of angina pain from the acute STEMI event, similar to published findings (Pocock et al. 2000; Spertus et al. 2005; Wijeysundera et al. 2010). All remaining domains; general health, bodily pain, vitality, social function and role emotional were better over time with the exception of the SF-MCS which was not statistically significant. Exclusive to this study, the results reflect that despite fast field triage to primary treatment, recovery remains slow for physical functioning and angina stability affecting HRQOL after PPCI. These findings are important, supported by previous publications which indicate that the reduction of time delays to PPCI is vital for STEMI, but it does not always translate into better clinical or quality of life outcomes (de Boer & Zijlstra 2015; Swaminathan et al. 2013).

Apart from faster time to PPCI, other high-risk factors, such as previous AMI, diabetes, age, CCF, out of hospital cardiac arrest and infarct size are major determinants of survival, morbidity and recovery outcomes after PPCI for STEMI (Doost Hosseiny et al. 2016; Gharacholou et al. 2011; Sanidas et al. 2014; Swaminathan et al. 2013; Terkelsen et al. 2011) but are often over-looked and under-researched; representing the key areas where this enquiry is strongly indicated. The results of this study add to the limited research, highlighting the domains of health which did not improve with fast reperfusion treatment and where clinical outcomes need to link in with HRQOL outcomes for a clearer perspective on PPCI healthcare.

Older age and lower physical HRQOL after PPCI

While older people improved as much as younger people post-PPCI, the results illustrated some complexity. On one hand they had worse physical HRQOL at both 4 weeks and 6 months, and this would be expected as the literature strongly supports decreased physical function which occurs with aging (Manini 2013; Thomas 2001). However, functional decline is often accelerated by episodes of hospitalisation (de Vos, Asmus-Szepesi, et al. 2012) and urgent STEMI admission for PPCI is no exception. Of interest, age was not identified as a predictor of worse physical HRQOL for patients undergoing a PCI in the systematic review from this thesis, as all ages have better physical functioning, angina relief and quality of life (Soo Hoo, Gallagher & Elliott 2014). A possible explanation for this variation may be the mixed cohort of elective and primary PCI patients (age range of 43 to 83 years) in the 18 studies reviewed where symptoms of myocardial ischaemia and subsequent angina were probably, less pronounced when compared to a more acute STEMI cohort with severe myocardial damage requiring rapid PPCI. As such, those PCI patients differed in sociodemographic, cardiovascular characteristics and adverse clinical outcomes from the selective acute STEMI participants; aged from 25 to 94 years in this present study. Differences were apparent in the systematic review sample of “older “people who were classified by a younger age delineation of ≥60 years, had both stable and unstable angina and the resultant finding that age had no impact on HRQOL outcomes. This is contrary to the main study on all STEMI patients where older age predicted lower HRQOL, particularly physical HRQOL.

Despite people aged >65 years having increased risk of complications after PCI often attributed to multiple comorbidities and decreasing physical function (Gharacholou et al. 2011; Singh, Rihal, Lennon, Spertus, Nair, et al. 2011), it is also clear that older people also have comparable short-term clinical outcomes similar to younger PCI patients. In recognition of this, guidelines by the American College of Cardiology and the American Heart Association (ACC/AHA) did not have an exclusive category of PCI practice guidelines applicable to the elderly, apart from providing specific recommendations for treating cardiogenic shock where a PCI is contra-indicated (O’Gara et al. 2013).

A synthesis of the two sub-analyses in the thesis revealed similar findings that age was a common predictor of poorer physical HRQOL, but better angina stability, mental and emotional health after PPCI in people aged ≥70 years compared to those aged <70 years (Soo Hoo, Gallagher & Elliott 2016a, 2016b). This study's findings are consistent with past research (Li et al. 2012; Shah et al. 2009; Spertus et al. 2004) which also showed overall improved HRQOL after PCI in the elderly. Patients aged >70 years have worse physical HRQOL but better mental health and cardiac–specific QOL (primarily angina relief). However, angina stability remained the same for field triage patients over time but physical and emotional HRQOL improved. Similarly, for octogenarians after PPCI, results from a previous systematic review confirmed that older people improved just as much as younger patients, with the greatest gains in physical functioning and angina relief mainly in the first 6 months after PCI (Johnman et al. 2013).

This study did not include frailty being a common geriatric presentation, as a covariate in analysis, due to the difficulty of assessing frailty at baseline when urgent coronary reperfusion and angina relief were treatment priorities. Increasing age and LOS shown in this study cohort of PPCI patients may be indicators of frailty. Frailty is one of the most important geriatric syndromes and is described as a lowered physiological reserve and increased vulnerability to stressors (Afilalo et al. 2014; Chen, Mao & Leng 2014). It also incorporates the wider aspects of psychological, cognitive and social factors which contribute to poor adaptation to any type of stressor resulting in the elderly having a faster cognitive and physical decline and an untimely death (Fulop et al. 2010). Older patients in this study have longer hospitalisation after PPCI, and coupled with an acute stressor such as STEMI, more functional limitations and recurrent angina symptoms, it is anticipated that frailty to some degree, may impact on older peoples' recovery after PPCI. Older frail people are at high risk of developing treatment complications with subsequent prolonged recovery, poor functional outcomes and disability (Shamliyan et al. 2013) or death within one month of discharge and are more dependent on health services (Kahlon et al. 2015). However, it remains debatable as to what are the appropriate treatment options or interventions needed to combat this increasing problem in the elderly with cardiovascular disease (Afilalo et al. 2014) and this warrants future research.

Clinical outcomes impacting on HRQOL

The next paragraph will discuss recurrent angina and total stent deployment as clinical predictors of lower HRQOL.

Recurrent Angina and lower HRQOL

Recurrent angina after PCI is a common predictor of lower HRQOL, validated by multiple studies on PCI cohorts (Johnman et al. 2013; Permanyer-Miralda et al. 1999; Pocock et al. 2000; Spertus 2002). In this study, recurrent angina is the umbrella term for all reported angina episodes after the index PPCI. Angina frequency (as defined by the SAQ), is the number of angina episodes reported by the patient on a daily and weekly basis over the 4 weeks after the PPCI including the frequency of using anti-anginal medications such as Anginine or Nitrolingual oral spray. In contrast, angina stability quantifies angina frequency with the most strenuous activity compared to the prior 4 weeks. The ultimate goal of PPCI/PCI is to improve coronary blood flow and to provide angina relief but past research has described the persistence of angina symptoms, particularly in the first six month after intervention (Johnman et al. 2013; Spertus et al. 2004) which has an adverse effect on physical HRQOL outcomes.

This study identified recurrent angina as a common predictor of worse physical HRQOL and cardiac-QOL at both 4 weeks and 6 months after PPCI for field triage patients but not for the entire STEMI cohort. Angina stability was the sole domain with a large interaction effect >0.14 for both age and time. From this, it can be deduced that there is a link between symptomatic angina, older age and poorer physical health plus lower (SAQ) QOL, occurring after STEMI, despite early, rapid PPCI. This finding was in accordance with published literature that patients who experienced angina had worse HRQOL than those who were angina-free (Bengtsson, Hagman & Wedel 2001; Gravely-Witte et al. 2007; Spertus et al. 2004). Irrespective of this, field triage patients rated high treatment satisfaction and good QOL at both recovery times; possibly explained by an improvement over pre-existent angina and not entirely dependent on physical aspects of recovery from the PPCI. It was noted that 10.2% of the whole cohort and 7.7% of field triage patients had angina on admission.

At 4 weeks, angina frequency improved showing 5.6 mean score differences for older people but comparatively less1.5, for people <70 years ($p<0.01$). A total of 23% of younger field triage patients experienced recurrent angina ($p=0.03$) early at 4 weeks but no angina was reported by older people. Early angina may be partially explained by the phenomenon of “stretch pain” attributed to structural over-expansion of the vessel by the implanted stent, which is not considered serious or ischaemic (Izzo et al. 2012; Jeremias et al. 1998) and this may not have been easily recognised by participants in this study. At 6 months, for the whole STEMI cohort, angina stability showed no improvement, most likely due to a ceiling effect where no further gain was detected. Ceiling effects have been encountered in applying generic measures for HRQOL (Asadi-Lari, Tamburini & Gray 2004; Feeny DH et al. 2013), particularly in older people where there is uncertainty and fear of responding negatively. Persistent anginal symptoms have consequences as PPCI patients would have resumed their normal physical activities at this specific time-point but at 6 months, patients of all ages (11% each group aged >70 and <70 years), reported recurrent angina.

By linking this to the findings for angina stability in the field triage group, an emergent pattern of poorer angina stability across time becomes clearer. Comparisons for 4 weeks to 6 months showed that the field triage sub-group had much lower mean scores of 0 to 1.6 compared to 0.8 and 8.6, indicating that despite early field triage and minimal ischaemic time, recurrent angina remains problematic, particularly for younger patients at 6 months when full recovery is the general expectation. Past research had shown recurrent angina to be a persistent problem in younger patients <65 years and females up to one year later irrespective of PCI as a treatment option for angina-relief (Holubkov et al. 2002; Venkitachalam et al. 2009). Despite urgent triage to PPCI, older field-triage STEMI patients by comparison, appear to benefit more from rapid PPCI with early angina-free recovery. Again, this may be explained by the success of PPCI in relieving angina pain associated with the initial STEMI event and possibly due to the lower expectations of health outcomes by older people but it does not explain recurrent angina occurring at 6 months for younger patients who had less co-morbidities and risks. This is an interesting area of outstanding deficit in HRQOL research conducted across the lifespan where treatment pathways to PPCI did not make a difference in this study. This confirms that older people with longer recovery time, had in fact, achieved more improvements in HRQOL, irrespective of the timing of PPCI and the higher presenting cardiovascular risks. Therefore HRQOL and PPCI outcomes should include angina assessment; quantified by the use of the SAQ in this study. Further research utilising a qualitative longitudinal design is recommended for clarifying this unexplained phenomenon of recurrent angina in all STEMI patients after successful PPCI.

Physiologically, the underlying causes of recurrent angina are complex and as discussed, may range from simple stretch pain to incomplete revascularisation, stent occlusion, microvascular disease or progression of coronary artery atherosclerosis (Izzo et al. 2012). The study in this thesis produced results congruent with previous studies (Abbate et al. 2007; Arnold et al. 2015; Pocock et al. 2000; Spertus et al. 2004) reporting persistent recurrent angina as an important outcome of PCI/PPCI with significant negative predictive effects on HRQOL. However, the impact of angina after PPCI specifically on field triage STEMI cohorts remains under-researched. This thesis has provided the first steps in identifying recurrent angina as a predictor of both lower physical and cardiac HRQOL at 4 weeks and 6 months for this sub-group, despite technical success in rapid reperfusion. This information may be useful in gauging patient’s expectations of pain relief and evaluating physiological and psychological recovery with a STEMI event. Apart from mortality, angina is an important symptom to define and manage in future cardiovascular research.

More Stents deployed and poorer HRQOL outcomes

Another significant predictor for lower HRQOL in all STEMI patients was the number of stents deployed, reflecting the scope of coronary vessel disease. HRQOL improved least in people who had more stents. The majority of participants in the present research had single vessel disease amenable to stenting (56.9% of all STEMI's and 55.8% of field triage patients). The mean ejection fraction (EF) was 47.6 %, (SD 8.9) which was within normal range. More young people had single vessel disease with a single stent but higher proportions of older people had double and triple vessel diseases. In contrast, the reverse occurred in the field-triage sub-cohort where a greater number of older people had less disease and stents. This may explain the better physical function gained over time in the main cohort following minimal (single vessel) intervention and a normal ejection fraction.

At 6 months, the number of stents was the only procedural predictor of better physical functioning for all STEMI patients indicating that with time progression, patients may have felt better and experienced the benefit of the PPCI treatment for functional recovery. Past research did not identify this phenomenon by age differences; therefore there are no identical studies to support or to refute this new evidence. A recent registry study on AMI patients, using similar instruments, reported improved health status after PCI at 6 and 12 months; more so with drug-eluting stents resulting in better SAQ quality of life and functional limitation scores by 12 months (Chhatriwalla et al. 2015). As HRQOL was compared mainly by the number and type of stents; drug-eluting or bare metal stents, the results support this study’s findings that more stents deployed were associated with better physical HRQOL.

This current research appears to be the first publication, to identify the association between number of stents (stent load) and improved HRQOL for an exclusive acute STEMI cohort, without age discrimination. For the field triage sub-group, the number of stents was not a covariate in statistical analysis, hence no cross-comparison by treatment groups were made. The impact of higher stent load on recurrent angina and HRQOL is a potential fertile area for future research, particularly for female and older patients who are treated by fast reperfusion strategies such as field triage and will be discussed in the recommendations for future research.

In this study, hypertension predicted lower HRQOL. Nearly half (48%) of all STEMI patients had hypertension mainly those aged ≥ 70 years, including the field triage sub-group where 63% of older patients presented with baseline hypertension. This is consistent with Australian national figures where 31.6% of the adult population has hypertension (Australian Bureau of Statistics 2013). Hypertension remains one of the highest risk factors for cardiovascular disease, but is treatable and modifiable through measures such as diet, exercise, weight control, medications and stringent blood pressure monitoring (National Heart Foundation of Australia 2010). Globally, hypertension accounts for 9.4 million deaths per annum the World Health Organisation has developed the Global Brief on Hypertension to prevent and reduce the for early detection and treatment of hypertension (World Health Organization 2013). In view of both international and national interest in hypertension, this study has produced evidence to support risk management for this clinical outcome through CR attendance.

Other indicators of HRQOL

The following paragraph will discuss other factors such as LOS, gender, CR and post-discharge support which predict HRQOL outcomes.

Longer hospitalization and lower HRQOL

Long hospitalisation was a common predictor of low SF-12 physical functioning scores for all patients, but not for other general health domains, irrespective of admission pathway. For field triage patients, each extra day of hospitalization was associated with lower SF-12 physical function and PCS by 0.28 points to 0.34 points at 4 weeks compared to 0.08 and 0.55 points for the whole STEMI cohort. At 6 months, this difference was less for field triage patients; by 0.25 and 0.32 but increased markedly to 1.60 to 0.55 for the entire STEMI cohort. Longer hospitalization was also associated with worse SAQ-QOL (0.12 to 0.15) at both recovery times for field triage cohorts. This is not surprising as field triage is associated with shorter hospitalisation but recurrent angina being a predictor of worse SAQ-QOL at both times may influence field-triage patients' perceptions of their illness and enjoyment of life. Past studies have reported longer hospitalisations associated with older age, MACE and more procedural complications (Chin et al. 2011; Noman et al. 2013; Swaminathan et al. 2015). Conversely, short hospitalisation with early discharge at 2 days after PPCI was safe for STEMI patients and was shown to be linked to younger age, lower co-morbidities and less MACE (Jones et al. 2012), although any impact on HRQOL was not investigated. This has important implications for post-discharge support and CR particularly for the elderly and rising healthcare costs.

This study confirmed that longer hospitalisation after PPCI was associated with worse physical HRQOL and cardiac QOL (Soo Hoo, Gallagher & Elliott 2016a) taking into account the minimal incidence of in-hospital MACE. This finding may potentially support the concept of early discharge planning after PPCI. An early study of 1100 patients in the second Primary Angioplasty in Myocardial Infarction (PAMI-II) trial reported that early discharge at 3 days compared to longer standard discharge resulted in less health expenditure, lower mortality (0.8% versus 0.4%) and less complications (unstable angina, re-infarction, stroke, heart failure; 15.2% versus 17.5%) at 6 months (Grines et al. 1998). Traditionally, STEMI patients are deemed to be the sickest of all ACS patients requiring PPCI, particularly high-risk STEMI patients with cardiac arrest and cardiogenic shock resulting in high in-hospital mortality (Van Herck et al. 2015; Wayangankar et al. 2016; Wong & White 2009) hence ruling out the possibility of shorter hospitalisation. Other studies (Chin et al. 2011; Jones et al. 2012) compared early discharge (≤2 and >2 days) after PPCI and concluded that at least 40% of low-risk STEMI patients could be safely discharged early without complications. On the contrary, early hospital discharge after 48 hours for older STEMI patients was safe but very early discharge (1-2 days) was associated with higher 30 day-mortality and more MACE after PPCI (Swaminathan et al. 2015). All studies measured clinical outcomes as the major reasons for poor prognosis and longer hospitalisation but excluded health status outcomes and its important impact on LOS and health costs following PPCI. Currently, there are no national or state-wide guidelines governing LOS with PPCI practice; the duration of hospitalization routinely determined by physician decisions based on patient progress and procedural outcomes. This study has produced new and compelling evidence that irrespective of the proven benefits of rapid field triage to coronary reperfusion and compounded by age-associated risks and co-morbidities, LOS remains a contentious issue in PPCI care.

Receiving Post-discharge support and sub-optimal cardiac relhabiliation attendance after PPCI

Post-discharge health support was a key predictor of both 4 week and 6 month CR attendance, emphasising the value of health services reminders from staff in the community to PPCI patients after hospitalisation. Support services such as Acute post-acute Care (APAC); also known as Hospital in the Home, is a state healthcare initiative for facilitating post-discharge recovery by providing medication, wound and lifestyle education in order to minimise unprecedented hospital re-admissions (New South Wales Ministry of Health 2013). Patients who received post-discharge support and health visits in this study were three times more likely to participate in CR to completion (Soo Hoo, Gallagher & Elliott 2016b). Conversely, patients who did not receive post-discharge support, people returning to their normal employment and females, were less likely to participate.

Systematic reviews and meta-analyses of past trials on coronary heart disease have unanimously confirmed mainly mortality and morbidity benefits with CR participation (Lawler, Filion & Eisenberg 2011; Oldridge 2012) including better HRQOL in one or more domains of health (Anderson et al. 2016). Despite better survival rates after ACS attributed to advanced PCI techniques and pharmacological therapy, CR remains under-utilised as a secondary prevention strategy (Arthur et al. 2010; Corra et al. 2010). The advantages of CR in reducing morbidity and improving functional status for AMI patients are well-published (Anderson et al. 2016; Astley et al. 2016; Mampuya 2012; Martin et al. 2012; McKee et al. 2013; Shepherd & While 2012). Comparatively, there is less research focus on sub-groups such as PPCI/STEMI patients and how effectively these groups respond to CR remains relatively unclear. Limited studies have described improved HRQOL with CR attendance for PCI groups in general (Fell, Dale & Doherty 2016; Goel et al. 2011; Izawa et al. 2011; Sandesara et al. 2015) results were not PPCI specific. In this thesis, attendance at CR for the whole sample was generally low; 36% initially at 4 weeks, improving to 54% by 6 months; this was less than ideal given the high 96% referral rate. While no recent Australian data for PPCI/STEMI patients was available for comparison, earlier work estimated similarly low participation rates of 32% in Victoria (Bunker et al. 1999) and 23% in Queensland for a mixed study cohort of CABG, AMI and PTCA patients (Scott, Lindsay & Harden 2003). International research reflects wider variations of sub-optimal attendance from 21% to 49% (Evenson, Rosamond & Luepker 1998; Martin et al. 2012). The reasons for non-attendance are multi-factorial, ranging from lack of interest, time and employment constraints, cost, transport difficulties, linguistic barriers, gender, age, poor education, low socioeconomic and socio-psychological factors (Dunlay et al. 2009; Gallagher, McKinley & Dracup 2003; Lane et al. 2001; McKee et al. 2013). To date there is no research conducted for STEMI female cohorts after fast PPCI by field triage or those residing in isolated and rural communities and their attendance outcomes which constitute areas lacking vital research investigation and funding. However, access to CR may not always equate attendance (Clark et al. 2014) as more complex socioeconomic, sociological or psychological aspects to attendance need to be considered and these wider aspects are again poorly researched.

Comparatively, for all patients in this study, higher participation rates in CR at both recovery times was evident when they received post-discharge health support. When linking this to the existing analysis that 10% of patients still had recurrent angina at 6 months, and that physical HRQOL had improved with time, it is possible that PPCI patients were less motivated to educate themselves or to actively participate in health care improvement programs such as CR. Based on the severity of STEMI and the angina that STEMI patients experience, it is anticipated that they would be more likely to participate in order improve their health and quality of life even further, but this is not the case as CR attendance after PPCI remains sub-optimal.

Of note, women were less likely to attend CR supporting other work (Farley, Wade & Birchmore 2003; Gallagher, McKinley & Dracup 2003; Samayoa et al. 2014; Witt et al. 2004), including females who live alone (O'Connell 2014). Inconsistencies prevail with the influence of unemployment status unlikely to reflect what it is measuring. Some studies reported lower attendance by employed people (De Vos, Xiao, et al. 2012; McKee et al. 2013) whilst others indicated that unemployed status was associated with poorer CR attendance (Dunlay et al. 2014; Lane et al. 2001; Worcester et al. 2004). A retrospective study (Parashar et al. 2012) also identified that women as well as the elderly, the uninsured and patients with previous PCI were less likely to participate at both 1 and 6 months CR post-AMI. Data from this thesis has expanded the pool of information on CR attendance for STEMI cohorts, demonstrating the importance of post-discharge support as a catalyst for CR attendance after PPCI, a finding not previously reported.

This important link between CR attendance, recurrent angina and post-discharge health support with HRQOL outcomes after PPCI, highlights the vulnerability of STEMI groups. Older people >70 years (Gharacholou et al. 2011; Li et al. 2012), women (Gijsberts et al. 2015; Mortensen et al. 2007) and patients who were hospitalised longer (Chin et al. 2011; Swaminathan et al. 2015), may benefit from support post-PPCI for up to 6 months of recovery. As noted earlier, HRQOL after PCI is influenced by complex, multiple factors, with critical points of assessment being 6 months and up to 12 months, after which most studies showed no long-term significant differences in outcomes. Based on this argument, assessment of HRQOL should be integrated into routine patient assessment from the index PPCI and for up to 6 months during their recovery progress.

Female gender, unpartnered status and lower HRQOL

Female gender was an independent predictor for worse physical HRQOL at 4 weeks recovery but not at 6 months (Soo Hoo, Gallagher & Elliott 2016). Prior studies and clinical trials have also shown that women experienced more recurrent angina than men after PCI (Holubkov et al. 2002; Ladwig et al. 2000) resulting in negative impact on HRQOL outcomes. However, a recent study on

STEMI patients (Gijsberts et al. 2015) described lower SF-36 PCS and MCS scores for female PCI patients only at 6 months of recovery whilst other studies (Mortensen et al. 2007; Pocock et al. 2000) have confirmed similar worse clinical outcomes and diminished HRQOL for women compared to men. More attention and recognition of gender differences in HRQOL outcomes after PPCI will allow clinicians to target factors that impede recovery and to focus on strategies which will improve HRQOL in women. Therefore, further gender-focused research on females and their HRQOL is indicated in order to identify factors such as social support, particularly for the under-researched field triage STEMI cohort.

Un-partnered status was a predictor for worse HRQOL in the main STEMI cohort but not for field triage patients. It has a negative predictive effect only for 4 week SF-12 physical functioning in the whole STEMI group. There is a scarcity of research on this topic and none to date was conducted for field-triage patients. Past publications on AMI cohorts reported that single-living and un-partnered status is associated with very long-term mortality, even up to 16 years after an AMI (Nielsen & Mard 2010). Single unmarried patients were younger, had less in-hospital complications, lower 1 year mortality and shorter hospitalisation when compared to older and widowed females, mainly due to lack of social support and more psychological stress (Hadi Khafaji et al. 2012). Specific studies on PCI groups are limited. Results of a retrospective analysis (Moshe et al. 2013) indicated that male gender and unmarried status were independent predictors of lower 30-day MACE after PCI.

The current study complements past findings that un-partnered status was a negative predictor of SF-12 health status after PPCI. Partnership status was not a significant predictor for field triage cohorts; 20% of whom live alone. This has not been researched but is an important consideration for newer studies. An increased understanding of partnership status and its effects on HRQOL will lead to better management of the social aspects of recovery which is equally important as physical components. This highlights the need for better and more equitable community access to social and psychological support systems for PPCI patients in the current health care structure, to align with this deficit in health care provision.

Methodological strengths and limitations of study

Study strengths included the use of reliable and valid instruments to comprehensively measure a wide dimension of subjective responses that were translated as quantitative interpretations of HRQOL after PPCI in all domains of health status relevant for STEMI patients, and with sufficient power to detect changes across time. All aspects of HRQOL most likely to reflect age-related differences and patient burden after PPCI were captured in this study by the combined use of both generic and cardiac-specific questionnaires. Other strengths include the focus on a select cohort of STEMI patients and the effect of age on HRQOL for the most acute, highest-risk sub-sets of the ACS classifications of PCI patients. From this perspective, these findings have added valuable contribution to the limited research on HRQOL outcomes for a complex group of patients to whom, mortality, is not the sole important outcome.

Understanding HRQOL issues allows clinicians to collect relevant data, assess HRQOL changes over time and identify the necessary elements that can improve therapeutic care for PPCI patients. In fact, self-rated HRQOL predicts lower global and physical scores including 5-year mortality and hospital readmissions in IHD patients (Hansen et al. 2015) indicating that HRQOL measurement would be a useful approach for risk management of cardiovascular disease prior to the need for PCI/PPCI. This study has provided an accurate analysis for a homogenous sub-group treated by a similar procedure despite different pathways of admission. This synthesis, by linking the major findings for HRQOL has produced sufficient evidence that there are clear gaps in clinical practice and management of cardiovascular health across all ages.

Limitations were also noted. Despite their sound psychometric properties, the use of selective instruments may have limited capacity to assess all aspects of HRQOL of concern for patients with ischaemic heart disease. These instruments were not able to differentiate the host of symptoms which comprise the term “angina”. Different symptoms of chest discomfort may influence patient perceptions of what is considered as chest pain after PPCI, thus impacting on the accuracy of results using these HRQOL instruments. Population-based norms for the SF-12 (mean 50, SD 10) were not comparable for this study’s exclusive STEMI/PPCI sample, despite its validation in an early South Australian population study for a mixed cohort of heart disease patients (Avery, Dal Grande & Taylor 2004). The Cronbach alpha coefficient was below 0.7 and therefore the internal consistency and reliability of the SAQ may be questionable, indicating that further work needs to be done.

Baseline HRQOL was not assessed due to the acuity of patients and early PPCI, limiting any comparisons with pre-PPCI HRQOL. The study was conducted at two separate hospitals and despite a low attrition rate of 8.2% to 12.6%, only 212 STEMI patients completed the 6 month interview and results may not be representative for all STEMI/PPCI patients. The field-triage sub-group of 77 participants was relatively small. The study population comprises a select cohort of non-complicated STEMI patients and therefore, generalisation of findings is limited for other ACS cohorts such as NSTEMI groups who are similarly treated with PPCI. Unlike randomised controlled trials, the observational design used could not provide adequate scope and conclusive results on the causation and the breadth of HRQOL outcomes.

It can be concluded that older people have the ability to recover from PPCI and achieve good HRQOL, irrespective of treatment pathway but will require longer recovery time. This is validated by the higher scores in most HRQOL domains by 6 months, including a large interaction effect of age and time for angina stability after PPCI. This is not surprising as older peoples' physical function is governed by a physiological ageing process. Future healthcare focus should be aimed at promoting HRQOL and healthy lifestyle education across all ages and reducing global health disparities, prevention of modifiable risks and diseases, disability, and early mortality associated with cardiovascular disease. Further research efforts, including qualitative studies, should be directed to elucidate the factors which govern the low health status outcomes despite successful coronary reperfusion. This finding is vital for health status assessment of smaller sub-sets of the population such as the elderly and those with heart failure where HRQOL benefit and angina relief are inextricably linked.

Patient choices and preferences for treatment need to be considered for managing heart disease, developing clinical trials, health care reimbursement and practice/policy guidelines based on what QOL benefits are derived from the PPCI/PCI (Blankenship et al. 2013). The primary purpose of assessing patient-reported health status is to identify the major health deficits which impact on patients' illness and to integrate their views and perceptions about their HRQOL into clinical practice so as to improve health care standards. Overall, the concept of HRQOL remains complex in its description but nevertheless, it reflects a global picture of all physiological and psychological aspects of health (Wilson & Cleary 1995) and cannot be assessed in isolation as PPCI impacts on multiple domains of health. Results from this research have implications for existing nursing practice in a wider health care context.

Implications for practice

Currently in Australia, as discussed earlier, there remains no standardised state or national guidelines governing nursing practice for PCI (Rolley et al. 2009), and the assessment of HRQOL is not a criteria for compliance and inclusion in PPCI patient care protocols. Clinical practice guidelines mandating HRQOL measurement, the availability of a national database for discharge-level and patient-level data is lacking in the present Australian national health system for health outcomes research with PPCI. The implementation of HRQOL assessment outside the hospital setting will expand existing clinical practice in providing follow-up data in predicting the multifaceted aspects of PPCI recovery across time. Additionally, a national registry for Interventional Cardiology which prospectively pools data on the processes and clinical outcomes of PCI/PPCI is indicated for best practice, such as practised in the UK where the British Cardiovascular Intervention Society (BCIS) audits PCI/interventional procedures in collaboration with the National Institute for Cardiovascular Outcomes Research (NICOR). This collaboration effectively allows national data to be analysed, publicly reviewed and published (Banning et al. 2015). Other sources available for healthcare research include the United States Nationwide Inpatient Sample (NIS), which is the largest database of US hospital discharges and contain data on 20% of all community hospitals belonging to the Healthcare Cost and Utilization Project (HCUP) of databases (Agency for Healthcare Research and Quality 2016). However, deficits also prevail with large administrative datasets involving re-admission identification, data security management and compatibility with other smaller clinical research databases, making accurate procurement, retrieval and sharing of HRQOL data a continual challenge in healthcare reform.

In order to address deficits in PPCI care and the impact of the ageing process on HRQOL outcomes, there is a need for review and reform of the present routine PPCI care approaches, which are largely, protocol and institution-driven. There remains a lack of adequate support for sub-groups who are distinctly at most risk for poor HRQOL outcomes such as the elderly and women. Improved

PPCI technology and the increased longevity in the population have resulted in more chronic conditions such as cardiovascular diseases which influence HRQOL outcomes. Despite this, there is limited contemporary real world data in Australia on the efficacy, costs and success of PPCI that links with clinical health outcomes of the national cardiovascular population (Scott 2008). The first combined Australia and New Zealand audit of clinical services delivery and care for acute coronary syndromes was conducted in 2012 which identified clear variations for in-hospital clinical events and the application of evidence-based practice but the results were not specific to PCI populations (Chew et al. 2013). Assessment of HRQOL is recommended by the American Heart Association (Rumsfeld et al. 2013) and increasingly recognised as an important clinical measure of health status with a patient-centred focus for disease monitoring and improving cardiovascular health. It is clear that there is a rising trend towards early and mandatory PPCI for STEMI. Arguably, if early triage to PPCI could make a difference towards attaining better HRQOL across the lifespan, then, the target factors which impact on physical HRQOL for this under-researched cohort will need further investigation.

Recommendations for future practice and research

The updated 2015 STEMI guidelines for PPCI addresses multi-vessel disease and recommends new approaches for its management, including aspiration thrombectomy for better clinical outcomes (Levine et al. 2016). It is known that at least 40% of STEMI/PPCI patients may also have severe disease in various arteries (Goldstein et al. 2000), and up to now, past guidelines did not recommend PPCI for non-culprit vessels (Levine et al. 2011). In our study, there is a higher proportion of older people who had double and triple vessel diseases with a higher stent load. The evidence is clear that by linking PPCI conducted for only culprit vessels with early recurrent angina reported by patients aged ≥70 years, it can be presumed that older peoples' HRQOL could possibly be better if multi-vessel disease was treated concurrently. This is further supported by this study's finding that more stents is a significant predictor of HRQOL outcomes; representing another fertile area for conducting HRQOL and patient outcomes research.

In line with the changes in international medical guidelines for multi-vessel stenting, there needs to be progress and standardization of the existing nursing approaches. The clinical care for a complex cohort of STEMI patients treated with multiple stents may be more challenging as their health outcomes may differ from mainstream PPCI cohorts. Ultimately, the real indicators of successful reperfusion intervention are not solely dependent on measured clinical outcomes such as MACE, but are equally dependent on HRQOL outcomes as perceived by the patient during recovery. There remains a substantial gap in this under-researched aspect of health care despite evidence that clinicians would benefit from a greater understanding of HRQOL in the care and monitoring of patient recovery (Ho et al. 2008)

Based on these study findings, the following eleven recommendations are proposed to address deficits identified in PPCI practice for STEMI patients:
Recommendation 1

There is a need for adopting and standardising universal practice guidelines for HRQOL measurement as an integral component of cardiovascular nursing care protocols. This will facilitate the quality management of PPCI patients, and highlight potential deficits for targeted clinical practice interventions.

Recommendation 2

Current local and system-level models of STEMI healthcare needs reform in order to improve patient-centred care delivery, informed by acute gerontology concepts that will foster specific quality care and better HRQOL outcomes during recovery for older and elderly PPCI patients.

Recommendation 3

Developing a national ACS database for the capture of STEMI and NSTEMI admissions, PPCI treatment outcomes, major adverse episodes of care and baseline health status. This will provide a platform for guiding, streamlining and facilitating evidenced-based cardiac health care reform.

Recommendation 4

Providing support for governing bodies such as the Australian Cardiac Rehabilitation Association (ACRA) towards establishing a CR national database. This is essential for monitoring attendance trends, referral disparities, and as a quality performance measure for gauging the recovery outcomes of STEMI/ PPCI populations, notably the elderly, women and the unemployed.

Recommendation 5

Promoting small scale and pilot in-hospital target programs for PCI/PPCI admissions that focus on early and facilitated discharge with mandatory referrals to CR and to acute post-acute community support services, prior to hospital discharge.

Recommendation 6

Developing and conducting in-hospital and post-discharge educational programs for field-triage patients who lack pre-procedural education, targeting recovery rehabilitation and cardiovascular knowledge gaps.

Recommendation 7

Promoting research findings and knowledge sharing initiatives such as CR information seminars that target wider audiences including health care workers, general practice physicians, carer groups, women and the elderly and other stakeholders in the community health sector.

Recommendation 8

Expanding research in high-risk older people aged >70 years with added focus on frailty in view of an ageing population with complex cardiovascular and age-related changes that will invariably, impact on HRQOL outcomes.

Recommendation 9

Promoting Tele-health interventions and telemonitoring approaches as alternatives to centre-based CR for rural and isolated communities where transport and post-discharge support is scarce.

Recommendation 10

Reviewing and establishing return to work support networks for cardiovascular patients relating to appropriate time off work, recovery and resumption of employment after a STEMI and PPCI.

Recommendation 11

Developing focused projects that integrate HRQOL measurements into all facets of PPCI care, from initial patient contact to in-hospital assessment and follow-up in the community. A registry of these projects, patient profiles and quality of life data can be utilised for improvement of patient care and for streamlining the processes of health care delivery.

Our results provided new insight into HRQOL for field triage cohorts aged ≥70 years but the specific impact on HRQOL for the oldest old aged over 80 years was not determined in this thesis. The evidence so far indicates that good HRQOL is achievable by older STEMI patients aged 70 years or more after PPCI. Existential determinants such as older age, female gender, recurrent angina and prolonged hospitalisation have a significant impact on HRQOL outcomes but are From the recommendations above, it is clear that there are outstanding deficits and challenges in HRQOL research conducted across the lifespan where treatment pathways to PPCI did not make a difference.

New research initiatives are recommended such as, large population-based cohort studies and randomised trials which can provide much broader prospective, observational data for comparison of HRQOL outcomes in both non-complicated, low-risk and high-risk STEMI patients and other presentations of ACS. An analysis of the temporal trends in STEMI outcomes and utilization of

PCI for a large multi-institutional cohort study in the USA showed PCI utilization to increase despite a reduction for in-hospital mortality in older STEMI patients aged ≥ 65 years (Khera et al. 2013). Contemporary international healthcare programs such as the Active Ageing Framework (World Health Organization 2002) and the more recent Healthy People 2020 framework in USA (US Department of Health and Human Services 2016) support the broad inter-related bio-psychological, organisational and policy sectors of collaborative health care delivery in addition to individual-level interventions. With increased longevity and ongoing promotion of healthy ageing, further research could potentially expand the current limited knowledge base for PPCI and HRQOL outcomes. This in turn, could potentially shape future clinical practice, drive innovative policies and streamline cardiovascular disease management with HRQOL as a priority health outcome.

Conclusion

This thesis has provided an important pool of findings on HRQOL after PPCI for STEMI patients across all ages and collates the available evidence by comparing differences in patient outcomes for people aged 70 years or older and under 70 years. This has provided a deeper understanding on how patients perceive and rate their altered health status during STEMI and PPCI recovery. Analysis of patients' recovery responses are clear reflections of their health and well-being, where physiological measures, tests or clinician-reported health outcomes are unlikely to uncover the real impact of acute coronary occlusion and its primary treatment on HRQOL outcomes. Understanding HRQOL issues allows clinicians to collect relevant data, assess HRQOL changes over time and identify the necessary elements that can improve therapeutic care for PPCI patients, especially for older adults with complex chronic and age-related impairments. This will be a focus for future research in order to capture short- and long-term health outcomes which will reflect a holistic, global reflection of health status.

The interrelated analyses in this thesis identified that the people who were at most risk of not achieving good HRQOL were older people, females and patients who had long hospitalisations. The dilemma posed is what can be done to effectively address the needs of these disadvantaged sub-groups of PPCI patients so as to achieve better and more equitable health outcomes. The solutions are complex as there are a multitude of barriers to optimal recovery and rehabilitation following a STEMI and urgent PPCI. Based on these key findings, deficits in contemporary health services practice, such as lack of HRQOL assessment after PPCI, low CR participation and age and gender disparities will continue to prevail in post-PPCI care. It is hoped that findings from this thesis will inform and assist healthcare professionals and researchers in addressing deficits and improving the quality of care for STEMI/PPCI patients. Further research into the more salient factors, such as partnership status, gender and stent load may potentially provide evidence-based information that could fill the void in comprehensive clinical management of STEMI cohorts. It is essential that as health care providers, we have an in-depth understanding of the multifaceted dimensions of HRQOL affected by an acute STEMI event in order to support uncomplicated patient recovery. With rapid advances in coronary revascularisation and predictions for global population ageing, the assessment of HRQOL across all ages is pivotal for transforming clinical practice and optimising health care delivery to ensure event-free survival of STEMI patients after PPCI.

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LIST OF APPENDICES

Appendix 1: Study HREC Application and Approval – University of Technology

UNIVERSITY OF TECHNOLOGY SYDNEY

Research and Innovation Office
City Campus
Building 1 Level 14 Room 14.31
PO Box 123 Broadway
NSW 2007 Australia
T +61 2 9514 9681
F +61 2 9514 1244
www.uts.edu.au

23 March 2010

Associate Professor Robyn Gallagher
Nursing, Midwifery and Health
CB10.07.214
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Robyn,

UTS HREC 2010-055 – GALLAGHER, Associate Professor Robyn, ELLIOT, Professor Doug (for SOON YENG, Ms Soo Hoo, PhD student) – "Heath-related Outcomes for Older People following urgent Primary Percutaneous Coronary Intervention (HOOP-PCI Study)" *[External Ratification: Harbour HREC of Northern Sydney Central Coast Health (NSCH) Human Research Ethics Committee HREC approval – 1001-024M(LR) 01/01/10 to 31/12/12]*

At its meeting held on Tuesday 9 March 2010, the UTS Human Research Ethics Committee reviewed your application and I am pleased to inform you that your external ethics clearance has been ratified.

Your UTS clearance number is UTS HREC REF NO. 2010-055R

Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report. You must also provide evidence of continued approval from the Harbour HREC of Northern Sydney Central Coast Health (NSCH).

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9772.

Yours sincerely,

Professor Jane Stein-Parbury
Chairperson
UTS Human Research Ethics Committee

Eth: Receipt of Ethics Application - UTS HREC 2010-055

Ethics Secretariat <Research.Ethics@uts.edu.au>

Reply all

11/02/2010

A/Prof Robyn D Gallagher <Robyn.Gallagher@uts.edu.au>;

Soon Soo Hoo

Inbox

Dear Robyn and Soon,

This is a confirmation that we have received your ethics application entitled "Heath-related Outcomes for Older People following urgent Primary Percutaneous Coronary Intervention (HOOP-PCI Study)", and you have been allocated the ethics application number referred to in the subject header.

Your application will be considered at the next HREC meeting, which is to be held on 9/03/2010. You will be notified of the HREC's decision by email, within two weeks of the meeting date.

If you have any questions or concerns regarding your application or this email, please don't hesitate to contact me at the details below.

Kind regards,

Research Ethics Officer

Research & Innovation Office
University of Technology, Sydney
Level 14, Tower Building
Broadway NSW 2007
Ph: 02 9514 9772
Fax: 02 9514 1244
Web: http://www.research.uts.edu.au/policies/restricted/ethics.html

Appendix 2: Ethics Approval –Royal North Shore Hospital

NORTHERN SYDNEY
CENTRAL COAST
NSW HEALTH

29 January 2010

Ms SY Soo Hoo
Department of Cardiology
Level 6, Main Block, RNSH
St Leonards NSW 2065

Dear Ms Soo Hoo,

Re: **1001-024M(LR) - SY Soo Hoo, R Gallagher, D Elliott, G Nelson** [redacted] **Health-related Outcomes for Older People following urgent Primary Percutaneous Coronary Intervention.**

Thank you for sending the **HARBOUR** Research Ethics Committee (HREC) of Northern Sydney Central Coast Health (NSCCH) a proposal for **Low Risk application** for the above study.

Please be advised that he Chair has reviewed this study and has concluded that the project is qualified as a Low Risk research and therefore full ethics approval will not be required.

It is noted that this study is now approved. The decision to approve this study will be noted by the HREC at its meeting to be held on the 22 February 2010.

Yours sincerely,

Mrs Judy Wells
Ethics Officer
HARBOUR HREC
Northern Sydney
Central Coast Health

RESEARCH BUSINESS UNIT
Level 2, Building 51, Royal North Shore Hospital, Pacific Hwy, St Leonards NSW 2065
Telephone 02 9926 8106; Facsimile 02 9926 6179

Appendix 3: Final Report and Completion of Study

electronic MM ✓

RECEIVED
23 APR 2015
BY:

Northern Sydney Local Health District (NSLHD)
Human Research Ethics Committee (HREC)

Annual Progress Report and/or Final Report Form

1. Submission of Annual Reports is a condition of ongoing approval. Reports are due every year on 30 August until the study is complete.
2. For multi-centre studies with lead ethics approval by NSLHD HREC, one report (incorporating information relating to any sub-studies conducted under the same file number) should be submitted by the Coordinating Investigator (a separate report for NSLHD Research Governance Officer is not required)
3. This form should be filled in electronically, printed, and signed by the Principal/Coordinating Investigator. Handwritten forms are not accepted by the office.
4. Edit this form by typing in the GREY fields. Delete guidance text prior to submission.
5. FINAL STUDY REPORTS: all sections of this form, including SECTION D must be completed when the study is closed and completed at all sites.
6. Please submit both a hard copy and an electronic copy of the completed report

Hard copies of applications, with original signatures, are to be sent to:	
Mailing address: Research Office Level 13, Kolling Building Royal North Shore Hospital Pacific Highway St Leonards NSW 2065	IN PERSON – Call x61590 from building reception and a team member will come and collect submission from you Kolling Building - Level 4 (street level reception desk) Royal North Shore Hospital
In addition, an electronic copy of ALL documents submitted must be emailed to NSLHD-Research@health.nsw.gov.au	

A	PROJECT DETAILS	
1	NSLHD File Number eg. RESP/xx/xx or xxxx-xxxM	1001-024M (LR)
2	HREC Reference number eg. HREC/year/HAWKE/xxx	
3	Project title	Health-related outcomes for older people following urgent primary percutaneous coronary intervention (HOOP-PCI Study).
4	Approval date	22/02/2010
5	When does HREC approval expire? Refer to original HREC approval letter Is an extension required?	Date: 03/12/2012 YES☐ NO☒ If YES, please submit an amendment request form for consideration of extension to the study. If the study involves recruitment of patients, please contact the Research Office to discuss requirements for ongoing ethical approval, and possible re-submission.
6	Coordinating Investigator *This is synonymous with Principal Investigator for single site studies*	name: Soo Hoo Soon Yeng email:soon.soohoo@health.nsw.gov.au

Appendix 4: Consent from Health Informatics for data collection

NORTH SHORE
PRIVATE HOSPITAL

HEALTH INFORMATION DEPARTMENT
Ph: 02 8425 3085
Fax: 02 8425 3963

Consent to the release of information from the North Shore Private Medical Record.

I ______________________________________
(Patient's full name)

Date of Birth ______________________________

of ______________________________________
(Patient's address)

____

NSP MRN .... *(If Available)*

As a participant in clinical trial **"Research Study on health-related outcomes for older people following urgent primary percutaneous coronary intervention (PCI) – (HOOP-PCI Study)".**
I consent to the North Shore Private Hospital to release information from my medical record to the researchers involved in the clinical research unit.

______________________ (Patient Signature) ______________________ (Date)

** Please Phone 02 8425 3085 if you have any queries regarding this request.*

HI110c
Created on 27/05/2010 2:12:00 PM Review on 14/03/2008

Appendix 5: License for SF-12 Questionnaire

NON-COMMERCIAL LICENSE AGREEMENT
Office of Grants and Scholarly Research (OGSR)

License Number: CT122854 / OP005414

Effective Date: January 29, 2010

Licensee Name: Soo Hoo Soon Y

Licensee Address: University of Technology, Sydney
Pacific Highway
St. Leonards
Sydney, NSW 2065
Australia

Requested Administrations: 150

Approved Use: Non-commercial academic research - unfunded – "Evaluation of early primary PCI by pre- hospital field triage for acute STEMI in older people: Effect on HRQOL and MACE"

Term: Beginning on February 10, 2010 and ending on February 9, 2011

Licensed Surveys: As indicated in Appendix B attached

Manuals: Licensee must purchase (or have purchased) from QM a copy of the manuals indicated in Appendix B attached

Royalty Fee: None, because this License is granted in support of the non-commercial Approved Use below

Administrative Fee: $25.00 USD

Licensee accepts and agrees to the terms of this Non-Commercial License Agreement (the "Agreement") from the Office of Scholarly Grants and Research (OGSR) of QualityMetric Incorporated ("QM") as of the Effective Date.

Subject to the terms of this Agreement, including the QualityMetric Non-Commercial License Terms and Conditions attached as Appendix A: (a) QM grants to Licensee, and Licensee accepts, a non-exclusive, non-transferable, non-assignable, non-sublicensable worldwide license to use, solely for the Approved Use and during the License Term, the Licensed Surveys in the authorized Modes and Approved Languages indicated on Appendix B and to administer the Licensed Surveys only up to the Approved Administrations (and to make up to such number of exact reproductions of the Licensed Surveys necessary to support such administrations) in any combination of the specific Licensed Surveys and Approved Languages and Modes and to use any related software provided by QM and (b) Licensee agrees to pay the Administrative Fee and other applicable charges in accordance with the attached invoice.

Capitalized terms used in this Agreement and not otherwise defined herein shall have the meanings assigned to them in Appendix A. The appendices attached hereto are incorporated into and made a part of this Agreement for all purposes.

Soo Hoo Soon Y
University of Technology, Sydney
Pacific Highway
St. Leonards
Sydney, NSW 2065
Australia

Signature: ______________________

Name: ______________________

Title: ______________________

➢ For additional information about QM's OGSR , go to http://www.qualitymetric.com/advancing/ ≺

FileName: University of Technology, Sydney - Soo Hoo Soon - CT122854 OP005414 Page 1 of 4
Template - License Agreement (OGSR) - 09-2008

Appendix 6: SF-12 Questionnaire

Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

3. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix 7: Seattle Angina Questionnaire

The Seattle Angina Questionnaire

1. The following is a list of activities that people often do during a normal week. Although for some people with several medical problems it is difficult to determine what it is that limits them, please go over the activities listed below and indicate how much limitation you have had **due to chest pain, chest tightness, or anginal attacks** <u>**over the past 4 weeks:**</u>

Place an x in one box on each line

Activity	Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not Limited at all	Limited for other reasons or did not do the activity
Dressing yourself	☐	☐	☐	☐	☐	☐
Walking indoors on level ground	☐	☐	☐	☐	☐	☐
Showering	☐	☐	☐	☐	☐	☐
Climbing a hill or a flight of stairs without stopping	☐	☐	☐	☐	☐	☐
Gardening, vacuuming, or carrying groceries	☐	☐	☐	☐	☐	☐
Walking more than 100 m at a brisk pace	☐	☐	☐	☐	☐	☐
Running or jogging	☐	☐	☐	☐	☐	☐
Lifting or moving heavy objects like furniture or lifting children	☐	☐	☐	☐	☐	☐
Participating in strenuous sports (e.g. tennis, dancing)	☐	☐	☐	☐	☐	☐

2. Compared with 4 weeks ago, how often do you have **chest pain, chest tightness,** or **anginal attacks** when doing your **most strenuous** activities?

I have **chest pain, chest tightness,** or **anginal attacks...**

Much more often	**Slightly more** often	About **the same**	**Slightly less** often	**Much less** often	I have had **no chest pain** over the last 4 weeks
☐	☐	☐	☐	☐	☐

3. Over the past 4 weeks, on average, how many times have you had **chest pain, chest tightness,** or **anginal attacks**?

I have had **chest pain, chest tightness,** or **anginal attacks...**

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
☐	☐	☐	☐	☐	☐

4. Over the past 4 weeks, on average, how many times have you had to use nitrolingual spray, or put an anginine, or isordil tablet under the tongue, to relieve **chest pain, chest tightness,** or **anginal attacks?**

I have used them...

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once a week	None over the past 4 weeks
☐	☐	☐	☐	☐	☐

5. How bothersome is it for you to take your pills for **chest pain, chest tightness** or **anginal attacks** as prescribed?

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not** bothersome at all	My doctor has **not prescribed** pills
☐	☐	☐	☐	☐	☐

6. How satisfied are you that everything possible is being done to treat your **chest pain, chest tightness,** or **anginal attacks**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
☐	☐	☐	☐	☐

English (Australian) Translation.

7. How satisfied are you with the explanations your doctor has given you about your **chest pain, chest tightness**, or **anginal attacks**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
☐	☐	☐	☐	☐

8. Overall, how satisfied are you with the current treatment of your **chest pain, chest tightness**, or **anginal attacks**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
☐	☐	☐	☐	☐

9. Over the past 4 weeks, how much has your **chest pain, chest tightness**, or **anginal attacks** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not** limited my enjoyment of life at all
☐	☐	☐	☐	☐

10. If you had to spend the rest of your life with your **chest pain, chest tightness**, or **anginal attacks** the way it is at the moment, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
☐	☐	☐	☐	☐

11. How often do you think or worry that you may have a heart attack or die suddenly?

I think or worry about it **all the time**	I **often** think or worry about it	I **occasionally** think or worry about it	I **rarely** think or worry about it	I **never** think or worry about it
☐	☐	☐	☐	☐

Appendix 8: Participant Information Sheet

NSW HEALTH
NORTHERN SYDNEY
CENTRAL COAST
AREA HEALTH SERVICE

UNIVERSITY OF TECHNOLOGY SYDNEY

Royal North Shore Hospital

PARTICIPANT INFORMATION SHEET

Study Title: Health-related outcomes for older people following urgent primary percutaneous coronary intervention (Hoop-PCI Study)

Invitation

You are invited to participate in a research study into the effects of early treatment of acute heart attacks in older people after stents and dilatation of the blocked coronary artery (PCI) following field diagnosis by ambulance ECG.

The study is being conducted by Soo Hoo Soon Yeng, Registered Nurse, Clinical Nurse Specialist, Cardiology, Royal North Shore Hospital and PhD student, University of Technology, Sydney.

The supervisors for the research are Professor Robyn Gallagher, University of Technology, Sydney and Professor Doug Elliott, University of Technology, Sydney.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **'What is the purpose of this study?'**

   The purpose is to better understand the effects of early PCI on the health outcomes and quality of life of older people after heart attacks. More older people aged 60 years and over are now receiving this treatment urgently following ambulance ECG during the heart attack (pre-hospital field triage). This research will look at how older people respond to early PCI including their quality of life and what kind of complications, risks or gains are associated with it. It is hoped that this research will benefit older peoples' recovery and provide new information to doctors and health care workers to assist with improving health care for older people.

2. **'Why have I been invited to participate in this study?'**

   You are eligible to participate in this study because you have been treated with urgent PCI for your heart attack.

3. **'What if I don't want to take part in this study, or if I want to withdraw later?'**
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason and without any effect on your health care.

4. **'What are the alternatives to participating in this study?'**
If you decide not to participate in this study, you will still receive the standard treatment prescribed by your doctor for your condition.

5. **'What does this study involve?'**
This study will be conducted over 2 years at Royal North Shore Hospital.
If you agree to participate in this study, the following will happen:
    - A research nurse or investigator will visit you during your stay in hospital to explain this study and to seek your consent. You will be provided a copy of the Participant Information sheet with details of what the research is about.
    - You will be asked to sign the Participant Consent Form
    - You will need to answer 3 general questions about your own feelings and experience of your treatment. There will also be 2 short questionnaires at 4 weeks and at 6 months after your discharge home from hospital. These questionnaires will look at how older people feel about their angina and their physical recovery after PCI treatment for heart attack.
    - While in hospital, an appointment will then be made with you by the research nurse for a convenient time and day to telephone you. A sealed envelope containing the 2 questionnaires will be given to you to take home to refer to during the telephone interview.
    - After your discharge home, you will be contacted by the research nurse who will interview you by telephone to answer the questionnaires. This should take no more than 15 to 20 minutes of your time.
    - You will receive a reminder letter by mail about 1 week before the telephone interview.
    - Your records in the Cardiology Department may be looked at by the research team in order to obtain information for this study's purpose and all efforts will be made to protect your confidentiality.
    - No specific drugs, extra treatment or other restrictions are involved in this study.

6. **'How is this study being paid for?'**
   The study is not sponsored. It is a PhD project and there is no payment to the individual researcher or supervisors.

7. **'Are there risks to me in taking part in this study?'**
   No harm is anticipated. There might be a very small risk that some people may feel uneasy when recalling their heart attack event. This is not common and you may stop or decline to participate in the interview at any time.

8. **'What happens if I suffer injury or complications as a result of the study?'**
   If you suffer any injuries or complications as a result of this study, you should contact the study researcher as soon as possible, who will assist you in arranging appropriate medical treatment.

   You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

   If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

   You may also wish to contact your treating doctor and the Patient Representative in the hospital on Tel: 02-99267612 regarding your rights as a patient. The Research Office is appointed to receive complaints from research participants and can be contacted on Tel: 02 9926 8106.

9. **Will I benefit from the study?'**
   This study aims to further medical knowledge and may improve future treatment of acute myocardial infarction by PCI. However it may not directly benefit you but others may benefit from the new knowledge gained.

10. **'Will taking part in this study cost me anything, and will I be paid?**
    Participation in this study will not cost you anything. You will not be required to travel and there is no charge to you for any extra medical or hospital costs or research expenses. Participation is entirely voluntary and you will not receive money for taking part in the study.

11. **'How will my confidentiality be protected?'**
Of the people treating you, only the research team, your attending nurse and your doctor will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the research team named above will have access to your details and results that will be held securely in a locked office in the Department of Cardiology, Royal North Shore Hospital.

    It is possible that your personal health records and information may be disclosed to other agencies involved such as the University of Technology, regulatory bodies (including the Therapeutic Goods Administration) and Ethics Committees. This will only occur when necessary and the provisions of Australian privacy law will be complied with.

12. **'What happens with the results?'**
If you give us your permission by signing the consent document, we plan to present the results in health and peer-reviewed journal publications, at conferences, in a PhD thesis and in clinical practice evaluation forums. If the results of the research are published, information will be provided in such a way that you cannot be identified. A copy of the published results will be provided to you, if you wish.

13. **'What should I do if I want to discuss this study further before I decide?'**
When you have read this information, the researcher Soo Hoo Soon Yeng will discuss with you any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on Tel: 02- 95141336 or Tel: 02-99266526. Alternatively, you may also contact her supervisors on Tel: 02-95141336 or Tel: 02-95144833.

14. **'Who should I contact if I have concerns about the conduct of this study?'**
This study has been approved by the Harbour HREC of Northern Sydney Central Coast Health (NSCCH). Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on Tel: 02 9926 8106 and quote the study number.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Appendix 9: Participant Consent Form

NSW HEALTH
NORTHERN SYDNEY
CENTRAL COAST
AREA HEALTH SERVICE

UNIVERSITY OF
TECHNOLOGY SYDNEY

Royal North Shore Hospital
CONSENT FORM

Study Title: Health-related outcomes for older people following urgent primary percutaneous coronary intervention (Hoop-PCI Study)

1. I,..
   of..
   agree to participate as a subject in the study described in the attached participant information sheet.

2. I acknowledge that I have read the participant information sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the details has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Royal North Shore Hospital and the University of Technology.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Robyn Gallagher on Tel: 02- 95141336 or Dr. Gregory Nelson on Tel: 02-99267111 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may also be directed to the Patient Representative in the hospital by telephoning 02-99267612 or the Research Office on Tel: 02 9926 8106

Signature of subject	**Please PRINT name**	**Date**
Signature of investigator	**Please PRINT name**	**Date**

Hoop-PCI Study **Version 2.0 18th January 2010**
Study title

Patient Information Sheet & Consent Form [Version number] [date]

Page 5 of 6

Appendix 10: Participant Revocation Form

NSW HEALTH
NORTHERN SYDNEY
CENTRAL COAST
AREA HEALTH SERVICE

UNIVERSITY OF
TECHNOLOGY SYDNEY

Royal North Shore Hospital

Study Title: Health-related outcomes for older people following urgent primary percutaneous coronary intervention (Hoop-PCI Study)

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the University of Technology , *The Royal North Shore Hospital Hospital or my medical attendants*

Signature   Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:
Ms Soo Hoo Soon Yeng
Department of Cardiology
Level 6, Royal North Shore Hospital
St. Leonards. NSW 2065

Appendix 11: Participant Screening Log

Participant Screening Log
(HOOP-PCI Study)

Date Admited	Subject Name	Excluded	Age	Gender M/F	Consent Y/N	Admitted ED/FT/ IHT	Comments		
							Missed	Refused	Other

Hoop-PCI Study Version 3.1 / April 2010

Appendix 12: Participant Tracking Log

Participant Tracking Log
(HOOP-PCI Study)

				4 Week Follow-Up				6 Month Follow-up			
Code No.	Subject Name	Phone	Base-line Y/N	1st Follow-up (4 weeks due date)	Telephone Reminder date	No. of calls & dates	Comments & Completed Y/N	2nd Follow-up (6 mths due date)	Telephone Reminder date	No.of calls & Dates	Comments & Completed Y/N

Hoop-PCI Study Version 3.1 / April 2010

Appendix 13: Data Collection Form 1 (Baseline demographics)

DATA COLLECTION FORM 1- Baseline Demographics - Health-related outcomes for older people following urgent primary PCI (HOOP-PCI Study)

Participant Code: __________ **Date** _________ **Time:**______

Hospital transfers to Cath lab ☐ **Pre-hospital Field Triage** ☐
ED Admission ☐

1. Patient Details

Surname _______________ First name ________MRN _______

Age _________ Date of Birth: __________

Gender: male ☐ female ☐

Marital Status:
Single ☐ Married ☐ Divorced ☐ Widowed ☐ De facto ☐
Lives alone: Yes ☐ No ☐ Lives with:____________

Ethnicity:
Caucasian ☐ Asian ☐ Indigenous ☐ Other ☐ (specify)_______

Employment:
Employed ☐ Seeking work ☐ Not seeking work ☐ Retired ☐

Education Level:
≤ Year 10 ☐ Year 10 ☐ Year 12 ☐ Trade/TAFE ☐ University ☐

2. Cardiovascular History
Current Risk Factors:

Hypertension ☐ Hyperlipidaemia ☐
Angina ☐ Diabetes Mellitus ☐

Heart Failure/CCF ☐ Family History of Heart Disease ☐
PVD ☐ Renal Failure/Impairment ☐
PUD/GORD ☐ COPD/CAL ☐
BMI: _______

Others ☐ (specify) ______________________

Hoop-PCI Study Version 3.1 / April 2010

1

Smoking: Current ☐
Ex-smoker > 12 months ☐
Other substances: (specify) ☐__________________

Previous history :
AMI ☐ Cabg ☐ PCI ☐ Stroke ☐ CCF ☐ Others ☐

3. Presenting Clinical Diagnostic Data

Blood enzymes: CKMB _________ Troponin T ________

ECG: STEMI ☐
NSTEMI ☐
Others ☐ (specify)___________

4. PCI Data

Stents ☐ PTCA only ☐ No PCI ☐

Type of stent: Drug-eluting stent ☐ Bare stent ☐

Number of stents: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 or more ☐
None ☐

Infarct vessel treated: LAD ☐ RCA ☐ LCx ☐ Others ☐

Segment treated: Proximal ☐ Mid ☐ Distal ☐

Ejection Fraction (EF %) __________

Severity of coronary disease: Single ☐ Double ☐ Triple ☐
Normal ☐

Symptom onset to PCI (TIMI 3 time= _________)

Hospital arrival to TIMI 3:

Field Triage ECG to TIMI 3:

5. PCI Outcomes (MACE)

Access site complication (major bleed requiring transfusion or surgical treatment) ☐

Recurrent angina ☐

Stroke ☐

Arrhythmias (Lethal) ☐ Type of arrhythmia and date ____________________

Re-occlusion ☐ Cause, date and intervention ____________________

Re-infarction (AMI) ☐ Cause, date and intervention ____________________

Death ☐ Cause and date ____________________

Cabg ☐

Repeat PCI ☐

Repeat Angiogram ☐

Other complications: ☐ (specify) ____________________

6. PCI (TIMI 3) : Yes ☐
No ☐

7. Hospital Stay (LOS) : No. of days __________

8. Discharge Home: Yes ☐ No ☐ Other ☐ (specify)____________

Appendix 14: Data Collection Form 2 (Post-Discharge Data)

DATA COLLECTION FORM 2- Post-Discharge PCI Data and MACE (HOOP-PCI Study)

Participant Code: ___________ Date ___________ Time:______

4 weeks ☐ 6 months ☐

Hospital Transfers to Cath Lab ☐ Pre-hospital Field Triage ☐
ED Admission ☐

Surname ________________ First name ____________ MRN ________

1. PCI Outcomes (MACE)

Access site complication (major bleed requiring transfusion or surgical treatment) ☐

Recurrent angina ☐

Stroke ☐

Arrhythmias ☐ Type of arrhythmia and date ______________________

Re-occlusion ☐ Cause, date and intervention ______________________

Re-infarction (AMI) ☐ Cause, date and intervention ______________________

Death ☐ Cause and date ______________________

Cabg ☐

Repeat PCI ☐

Repeat Angiogram ☐

Re-admission ☐ Cause and date ____________________

Other complications:☐ (specify) ______________________________

Post discharge services: APAC __________ GP _______________
Cardiologist_______________ No of Visits ____________

Referred to Cardiac Rehabilitation : Yes ☐ No ☐

Attended Cardiac Rehabilitation: Yes ☐ No. of sessions___________
No ☐ Reason_________________

2. **Questions:**

1. What is the most important change in your life caused by your heart problem?

2. Has there been any major events in your life since we last spoke?

3. What did you find most beneficial to your recovery?

Comments:

____

____

____

____

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Appendix 17: Publication - Chapter 6

Nursing & Health Sciences

Nursing and Health Sciences (2016) **18**, 230–237

Research Article

Predictors of cardiac rehabilitation attendance following primary percutaneous coronary intervention for ST-elevation myocardial infarction in Australia

Soon Yeng Soo Hoo RN, MN,[1,2] Robyn Gallagher RN, BA, MN, PhD[3] and Doug Elliott BAppSc (Nurs), MAppSc (Nurs), PhD[2]

[1]*Department of Cardiology, Royal North Shore Hospital, Sydney, Australia,* [2]*Faculty of Health, University of Technology Sydney, Australia and* [3]*Charles Perkins Centre and Sydney Nursing School, University of Sydney, Sydney, New South Wales, Australia*

Abstract Cardiac rehabilitation is an important component of recovery and secondary prevention following urgent primary percutaneous coronary intervention. However, attendance and factors that predict participation by patients admitted with ST-elevation myocardial infarction remain unclear. This Australian study was conducted using a descriptive, comparative design. Consecutive patients ($n = 246$) at two hospitals were interviewed by telephone at four weeks and six months. Open-ended questions were used to assess cardiac rehabilitation attendance, sociodemographics, modifiable risk factors, clinical outcomes, and post-discharge health support. Post-discharge home visits at four weeks (odds ratio: 2.64, 95% confidence interval: 1.48-4.71) and at six months were associated with better cardiac rehabilitation attendance; more males participated at four weeks and at six months. The results suggest the need to integrate post-discharge health support with cardiac rehabilitation to facilitate recovery after primary percutaneous coronary intervention, particularly for females with ST-elevation myocardial infarction.

Key words attendance, cardiac rehabilitation, gender, percutaneous coronary intervention, ST-elevation, myocardial infarction.

INTRODUCTION

Cardiac rehabilitation (CR) after acute myocardial infarction (AMI) has been associated with lower mortality and morbidity (Dunlay *et al*., 2014; West *et al*., 2012) and fewer clinical complications following percutaneous coronary intervention (PCI) for coronary occlusion (Dendale *et al*., 2005; Izawa *et al*., 2011). In Australia, coronary heart disease is a common cause of death, accounting for 49% of all cardiovascular deaths, mainly in people older than 75 years, and a corresponding increase in PCI procedures for ages 75–84 years (Australian Institute of Health and Welfare, 2015). Within the acute coronary syndromes (ACS), ST-elevation myocardial infarction (STEMI) is the most serious form of AMI, with poor survival outcomes if early treatment is not initiated. Consequently, guidelines from the American Heart Association (O'Gara *et al*., 2013) and the European Society of Cardiology (Steg *et al*., 2012) recommend primary PCI (PPCI) as priority treatment for STEMI, followed by CR as secondary prevention for improving risk-factor management and healthy lifestyle changes. However, a gap in enquiry exists relating to what predicts CR attendance, specifically for STEMI patients after PPCI, and these remain uninvestigated and unclear.

Literature review

CR is an important support program for recovery and secondary prevention for coronary heart disease; it is aimed at improving cardiovascular risk management and promoting healthy lifestyle (Leon *et al*., 2005). Attendance at CR improves cardiovascular, physical, and psychological function by reducing coronary risk factors (Higgins *et al*., 2001; Taylor *et al*., 2004), and results in fewer hospital readmissions and better health-related quality of life (HRQOL) for patients with coronary artery disease (Shepherd & While, 2012), AMI (Dunlay *et al*., 2014; West *et al*., 2012), and after PCI. Not surprisingly, international guidelines, such as those from the American College of Cardiology, recommend referral to CR for moderate- to high-risk patients undergoing PCI (Levine *et al*., 2011). It is argued that during recovery following a PCI, CR participation is important to assist patients to increase their physical fitness, reduce cardiac-related symptoms, minimize the risk of future AMI events, and to resume normal activity, using counseling and educational and psychological support.

Past studies have investigated the association between CR participation and major adverse cardiovascular events (MACE), with conclusive evidence of lower mortality, less

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recurrent angina, restenosis, and consequently, revascularization rates among PCI participants (Bellardinelli *et al.*, 2001; Dendale *et al.*, 2005). A further study (Goel *et al.*, 2011) using PCI registry data observed a 45–47% lower all-cause mortality in CR participants after PCI, although there was no effect on recurrent AMI and revascularization. However, the evidence for the effectiveness of CR is not as clear in PPCI patients as it is for AMI patients. This is an important deficit, as PPCI rates have grown in response to international guidelines promoting early treatment of STEMI by expediting coronary reperfusion with stenting/angioplasty (Steg *et al.*, 2012; O'Gara *et al.*, 2013). Further contemporary PPCI treatments include fast field triage (pre-hospital triage) by utilizing ambulance electrocardiogram transmissions to hospitals for the early definitive diagnosis of STEMI and bypassing emergency department waiting time, therefore identifying a subgroup which might have different outcomes (Carstensen *et al.*, 2007; Vermeulen *et al.*, 2008; Zanini *et al.*, 2008), and thus, different needs for CR.

Attendance at CR programs has been described as suboptimal internationally and are influenced by multiple factors. Recent studies have highlighted common disparities relating to the structure, objectives, and lack of comprehensive CR programs with a shortfall in meeting patients' expected needs after ACS (Eshah, 2011), and a lack of cultural considerations in the development of appropriate CR programs for coronary heart disease (Kim *et al.*, 2014). Similarly, a recent Australian study (Clark *et al.*, 2014) reported suboptimal attendance by cardiac patients, despite good geographical access in metropolitan areas to established CR services. However, with diverse cultural and language differences, combined with an aging population and poor rural services, disparities continue to exist for CR participation. This indicates that more complex factors and personal and service barriers will need to be considered when assessing patients' decisions for continual participation and perseverance with CR programs.

Reported barriers to CR participation and underrepresentation are present for vulnerable populations, such as women (Gallagher *et al.*, 2003), the socially disadvantaged with AMI (Nielsen *et al.*, 2013), and people over 62 years with a higher risk of functional disability (Williams *et al.*, 2002; Suaya *et al.*, 2009). One publication identified multiple factors, including STEMI, younger age, male gender, non-diabetic, no prior AMI or prior CR attendance, and psychosocial issues to be important predictors of increased attendance (Dunlay *et al.*, 2009). Other studies identified depression and denial (Ades *et al.*, 1992), including anxiety, less exercise pre-AMI, and thrombolysis, as decreasing attendance (Lane *et al.*, 2001). Past research showed some inconsistencies, as one Australian study identified older age and male PCI patients who were non-drivers as less likely to attend, and predictors of program dropout were males who smoked, diabetics, people who were unemployed, and females who were physically inactive on admission (Worcester *et al.*, 2004). Older age and female gender were often reported, apart from high risk factors and multiple comorbidities, which were associated with worse HRQOL and CR outcomes (Ades *et al.*, 1992; Jamieson *et al.*, 2002). The results of a large systematic review identified social and personal factors, such as patient knowledge of CR, perceptions of heart disease, family, and financial and occupational restraints, to be predictors of attendance, more than physician referral or clinical factors (Clark *et al.*, 2012). Overall, these studies described factors associated with increasing attendance at CR to be male gender, younger age, and being employed, while female gender, older age, lower socioeconomic and educational status, unemployment, and lack of access or transport as decreasing attendance. However, these factors are relatively unknown in PPCI patients, as past studies mainly focused on AMI cohorts (Farley *et al.*, 2003; French *et al.*, 2005; McKee *et al.*, 2013). CR referral and subsequent utilization of CR remains unclear between ACS cohorts, as the urgency and lack of preparation could impact on patient attitudes to participation following PPCI. Therefore, the aim of the this study were to examine the rates of CR attendance at four weeks and six months following PPCI for acute STEMI, and the independent predictors of CR for PPCI when adjusted for baseline characteristics, comorbidities, and risk factors.

METHODS

Design, setting, and sample

This prospective cohort study was conducted as a separate study on STEMI patients who also participated in a HRQOL study comparing health outcomes after PPCI between age groups. Eligible STEMI patients treated with PPCI were consecutively enrolled from the PCI Registry of a large metropolitan university affiliated with a public hospital and a private hospital in Sydney, Australia. These institutions conduct approximately 1070 PCI annually for a regional population of 1.2 million, including pre-hospital field triage admissions. Services for PPCI patients at these institutions include post-discharge health visits to the home by a community nurse and comprehensive CR programs for the support and facilitation of recovery and secondary prevention after discharge. The CR programs included staged physical exercise, counselling support, and education on nutrition, medications, and maintenance of healthy lifestyle changes (Northern Sydney Local Health District, 2012), which were provided in sessions over six consecutive weeks of two 1-h duration per week or by fast-track, half-day workshops. Patients could commence from two weeks' post-discharge. Most patients received a CR referral from special CR nurses, including information on the benefits of participation in a CR program. Patients were systemically enrolled in the study if they were diagnosed with a STEMI (without thrombolysis), received PPCI, were able to consent in English, and were contactable by telephone for interviews. Exclusion criteria were the diagnosis of dementia or severe neurocognitive impairment, deafness, and prolonged intensive care stay. Ethics approval was obtained from the Harbour Human Research Ethics Committees (HREC) 100–024M (LR), of both study sites and the university.

Data collection

Sociodemographic, baseline clinical and cardiovascular risk factors, PPCI data, and MACE were recorded during hospitalization. CR attendance at 4 weeks and 6 months post-PPCI were recorded during patient interviews using a data-collection form, along with provision of a post-discharge health visit. CR and post-discharge service data were collected by asking three simple questions: (i) whether they were referred to CR; (ii) if they had participated in CR, and if so, the number of sessions attended; and (iii) whether they received a post-discharge health visit after hospital discharge.

Procedure

All STEMI patients admitted by either pre-hospital field triage direct to the catheter laboratory, through the emergency department (ED) or urgent inter-hospital transfer for PPCI were screened for eligibility. Eligible participants were approached for informed consent in hospital, usually the next day following the PPCI. Follow-up appointments were arranged for telephone interviews. At four weeks and six months after the index PPCI, patients were interviewed at home by telephone contact; each interview lasted approximately 15 min.

Statistical analysis

SPSS (version 21; IBM Corp, Armonk, NY, USA) was used for the data analysis, with frequencies and percentages or means and standard deviations (SD) reported. The χ^2-test or Fisher's exact test was used for categorical data analysis and for CR attendance or non-attendance at four weeks and six months. Multivariable logistic regression analysis was conducted on nine potential predictors (age, gender, marital status, employment status, educational status, previous AMI, previous PCI, length of hospital stay, post-discharge health visit, and total modifiable risk factors) for independent effects on CR attendance at four weeks and six months. For analysis purposes, total modifiable risk factors included hypertension, hyperlipidemia, diabetes, obesity/body mass index (BMI) $\geq 25\ kg/m^2$, and smoking; common cardiovascular conditions that could be treated or improved with medications and lifestyle change. Potential variables were forced into one block for the analysis using all nine variables each time as a full model at four weeks, and repeated for six months in order to examine which variables independently predicted CR attendance. Demographic and clinical variables were selected based on previous literature and a series of correlations to determine which variables were likely to be associated with or predictive of CR attendance. Two separate regression models were constructed, with variables set for inclusion at $P \leq 0.05$.

RESULTS

Sample characteristics

The sample consisted of 268 participants enrolled from 570 STEMI patients screened for eligibility. Overall, 246 participants were interviewed at four weeks, and 233 participants completed the final six month interview. Those who withdrew before the interview were more likely to be ≥70 years and male. The sample mean age was 63.6 years (SD: 13), mainly male (79%), married or partnered (68%), and had completed year 12 high school education (66%) (Table 1).

Modifiable risk factors were common; 65% were obese (mean BMI: 26.9, SD: 4.0) with hyperlipidemia (48%), hypertension (48%), and diabetes (10%), and 28% were current smokers (Table 1). Almost equivalent numbers had a previous AMI (11%) and PCI (10%).

PPCI characteristics and outcomes

Patients were admitted by inter-hospital transfer (45%), pre-hospital field triage (31%), or the ED (24%). The mean ejection fraction was 47.6% (SD: 8.9), recurrent angina (15%) occurred at four weeks and less (10%) at six months, while readmissions at four weeks and six months were 4% and 12%, respectively.

CR attendance rates at four weeks and six months

Almost all PPCI patients (96%) were referred to CR prior to discharge (Table 2). At four weeks, 36% of patients ($n=89$) had attended CR. The only factors that demonstrated a statistical difference for attendance were more males ($P=0.013$), currently employed ($P=0.043$), received a post-discharge health visit ($P=0.002$), and shorter length of hospital

Table 1. Characteristics of study patients ($n=246$)

Characteristics	N	(%)
Male	194	(79)
Partnered	167	(68)
Employed	119	(48)
Year 12 (completed high school)	163	(66)
Risk factors		
Hypertension	118	(48)
Hyperlipidemia	119	(48)
Diabetes	26	(10)
Prior AMI	26	(11)
Prior PCI	25	(10)
BMI $\geq 25\ kg/m^2$	160	(65)
Current smoker	69	(28)
PCI pathway		
Field triage	77	(31)
Disease severity		
Single vessel	140	(57)
Ejection fraction mean ± SD	47.6 ± 8.9 (SD)	
LOS (mean days) ± SD	4.2 ± 4.97 (SD)	
Clinical outcomes		
Readmission at 4 weeks	10	(4)
Readmission at 6 months	29	(12)
Re-angina at 4 weeks	37	(15)
Re-angina at 6 months	25	(10)
Post-discharge health visit		
At 4 weeks	134	(54)
At 6 months	129	(52)

AMI, acute myocardial infarction; BMI, body mass index; LOS, length of stay; PCI, percutaneous coronary intervention; Re-angina, recurrent angina; SD, standard deviation.

Table 2. Comparison of characteristics for attendance and non-attendance at cardiac rehabilitation for 4 weeks and 6 months

Attendance		4 weeks					6 months				
		Yes		No			Yes		No		
		N = 89 (36%)		N = 155			N =132 (54%)		N = 101		
Characteristics		N	(%)	M	(%)	*P*-value	N	(%)	N	(%)	*P*-value
Age (years)	≥70	23	(26)	58	(37)	0.065	38	(29)	63	(62)	0.154
	<70	66	(74)	97	(63)		94	(71)	38	(38)	
Gender	Male	78	(88)	115	(74)	0.013	111	(84)	72	(71)	0.018
	Female	11	(12)	40	(26)		21	(16)	29	(29)	
Partnered	Yes	64	(72)	101	(65)	0.278	90	(68)	69	(68)	0.982
	No	25	(28)	54	(35)		42	(32)	32	(32)	
Employed	Yes	51	(57)	68	(44)	0.043	64	(48)	48	(48)	0.884
	No	38	(43)	87	(56)		68	(52)	53	(52)	
Year 12 education	Yes	67	(75)	95	(61)	0.030	89	(67)	64	(63)	0.518
	No	22	(25)	59	(38)		43	(32)	37	(37)	
Hypertension	Yes	37	(41)	81	(53)	0.108	63	(48)	48	(48)	0.976
	No	52	(58)	74	(47)		69	(52)	53	(52)	
Hyperlipidemia	Yes	44	(49)	73	(47)	0.725	62	(46)	50	(50)	0.701
	No	45	(50)	82	(53)		70	(53)	51	(50)	
Diabetes	Yes	11	(12)	15	(10)	0.513	15	(11)	10	(10)	0.721
	No	78	(88)	140	(91)		117	(89)	91	(90)	0.047
Previous AMI	Yes	6	(7)	20	(13)	0.133	10	(8)	16	(16)	
	No	83	(93)	135	(87)		122	(92)	85	(84)	
Previous PCI	Yes	7	(8)	18	(12)	0.353	8	(6)	17	(17)	0.008
	No	82	(53)	137	(88)		124	(94)	84	(83)	
BMI	Mean ± SD	26.6	±3	27.1	±4.4	0.332	27.0	±3.7	26.8	±4.3	0.659
Smoker	Yes	26	(29)	42	(27)	0.723	35	(27)	29	(29)	0.710
	No	63	(71)	113	(73)		97	(73)	72	(71)	
Field triage	Yes	31	(35)	46	(30)	0.404	44	(33)	28	(28)	0.358
	No	58	(65)	109	(70)		88	(67)	73	(72)	
Single vessel	Yes	57	(64)	81	(52)	0.074	80	(61)	52	(51)	0.123
	No	32	(36)	74	(48)		51	(39)	50	(49)	
Readmission	Yes	2	(2)	8	(5)	0.334	18	(14)	11	(11)	0.529
	No	87	(98)	147	(95)		114	(86)	90	(89)	
Re-angina	Yes	15	(17)	22	(14)	0.577	14	(11)	11	(11)	0.944
	No	74	(83)	133	(86)		118	(89)	90	(89)	
LOS	Mean ± SD	3.30	±2.8	4.7	±5.8	0.027	4.02	±4.9	4.24	±4.1	0.726
Ejection fraction	Mean ± SD	48.6	±8.5	46.8	±9.0	0.135	47.9	±9.0	47.5	±8.7	0.750
Post-discharge health visit	Yes	60	(67)	73	(47)	0.002	88	(67)	41	(41)	0.001
	No	28	(31)	82	(53)		44	(33)	60	(59)	

AMI, acute myocardial infarction; BMI, body mass index; LOS, length of stay; PCI, percutaneous coronary intervention; Re-angina, recurrent angina; SD, standard deviation.

stay ($P = 0.027$). Less than one-quarter (22%) of participants had completed one-to-two CR sessions by 4 weeks, and only 1% attended the maximum possible of nine-to-14 sessions.

At 6 months, CR participation had increased to 54% ($n = 132$). Those who attended CR were more likely to be male ($P = 0.018$), previously had an AMI ($P = 0.047$) or PCI ($P = 0.008$), and had received post-discharge health support ($P = 0.001$). Post-discharge health support or acute post-acute care was a free, home-based health program offered to patients who resided within the local health district, aimed at monitoring and facilitating recovery after hospitalization. Initially, a community nurse visited the patient within 24 h of hospital discharge in order to assess home safety, medication regime, wound care, dietary goals, and weight management, and to organize social worker and physiotherapy support if required. Similar to CR, patients received information on discharge plans during hospitalization, and participation in the post-discharge health program was voluntary, with visits dependent on each patient's perceptions of self-progress and prioritization of recovery needs (Table 3).

No significant differences were observed for other clinical characteristics, such as diabetes, hyperlipidemia, hypertension, smoking, recurrent angina, or readmissions at either time point.

Predictors of CR attendance

Two independent models were developed for CR at 4 weeks and 6 months, and both were statistically

Table 3. Logistic regression model predicting factors associated with cardiac rehabilitation attendance for 4 weeks and 6 months

	4-week attendance				6-month attendance			
Predictor variables	β	Odds ratio	95% CI	*P*-value	Beta	Odds ratio	95% CI	*P*-value
Constant	−1.297	0.273	NA	0.048	−0.479	.619	NA	0.416
Age (years)	−0.131	0.877	0.413–1.866	0.734	−0.515	0.598	0.288–1.241	0.167
Gender	**0.811**	**2.251**	**1.002–5.057**	***0.049**	**0.931**	**2.538**	**1.213–5.313**	***0.013**
Employed	0.053	1.055	0.524–2.124	0.882	**−0.733**	**0.481**	**0.232–0.997**	***0.049**
Year 12 Education	−0.456	0.634	0.327–1.229	0.882	−0.275	0.760	0.394–1.464	0.760
Pre-AMI	−1.116	.328	0.084–1.276	0.108	−.535	.586	0.168–2.041	0.401
Pre-PCI	0.294	1.342	0.353–5.111	0.666	−0.891	0.410	0.114–1.477	0.173
Length of hospital stay	−0.067	0.935	0.849–1.031	0.179	0.009	1.009	0.943–1.080	0.792
Post-discharge health visit	**0.972**	**2.643**	**1.481–4.716**	***0.001**	**1.149**	**3.154**	**1.775–5.605**	***0.001**
Total modifiable risk factors	0.003	1.003	0.779–1.293	0.979	0.048	1.049	0.813–1.354	0.711

*$P < 0.05$ significant. AMI, acute myocardial infarction; CI, confidence interval; NA, not applicable; PCI, percutaneous coronary intervention.

significant ($P = 0.001$). The model for CR attendance at 4 weeks included two significant independent predictors: receiving post-discharge health support and male gender ($P = 0.001$). After controlling for all other factors, those who had post-discharge health support (odds ratio [OR]: 2.64, 95% confidence interval [CI]: 1.48–4.71, $P = 0.001$) and males (OR: 2.25, 95% CI: 1.00–5.05, $P = 0.001$), and were more than twice as likely to attend CR. The model for 6 months included three independent predictors (male gender, post-discharge health visit, and employed status). After controlling for all other factors, patients receiving post-discharge health visit were more than three times more likely to attend (OR: 3.15, 95% CI: 1.77–5.60, $P = 0.001$), and males were more than twice as likely to attend (OR: 2.53, 95% CI: 1.21–5.31, $P = 0.001$), whereas employed people were less likely to attend CR (OR: 0.48, CI: 0.23–0.99, $P = 0.049$). Therefore, male gender and receiving a post-discharge health visit were positive predictors of CR participation during PPCI recovery.

DISCUSSION

We examined CR attendance rates and predictors of attendance after PPCI for STEMI patients at 4 weeks and 6 months, as a gap in the literature was evident for this cohort. Despite a high referral rate (96%), attendance rates of 36–54% in this study are consistent with 40–55% attendance reported for international studies, (Cooper *et al*., 2002; Goel *et al*., 2011; Witt *et al*., 2004), reflecting a common finding that only half of patients referred actually attended a CR program to completion. Previous studies have identified multiple barriers to CR attendance, including transport and cost constraints, personal embarrassment, cultural and linguistic barriers, poor understanding, and lack of interest (Cooper *et al*., 2002; Daly *et al*., 2002; Lane *et al*., 2001; McKee *et al*., 2013; Neubeck *et al*., 2012). One study (Brown *et al*., 2009) showed that only 56% of patients post-AMI, PCI, and cardiac surgery had CR referral, and that younger age, STEMI, smoking, and dyslipidemia were associated with increased referral; the main reason cited for poor referral was due to lack of awareness of CR benefits by health professionals.

Our results demonstrated an important finding in that post-discharge health visit was a key predictor for both 4-week and 6-month CR attendance, with participants who received the discharge health program more likely to attend CR at both times. This indicates a need for more focus on discharge support that will facilitate physical recovery and return to routine activities after an unprecedented acute cardiac event, with subsequent fast coronary revascularization.

The influence of gender on CR attendance has been previously demonstrated. Women were less likely to attend CR (Farley *et al*., 2003; Gallagher *et al*., 2003; Witt *et al*., 2004), and reasons for poor participation were multifactorial. Various studies have described women as having more difficulties with transport (Daly *et al*., 2002; King *et al*., 2001a; Marzolini *et al*., 2008), less referral to CR (Aragam *et al*., 2011; Caulin-Glaser *et al*., 2001; Colbert *et al*., 2014; Colella *et al*., 2014; Witt *et al*., 2004), lower enrolment rates (O'Farrell *et al*., 2000), and higher attendance dropout (Colbert *et al*., 2014; Worcester *et al*., 2004). The results of two recent meta-analyses examining CR publications over a decade on gender differences showed that CR referral remained consistently low for women diagnosed with cardiovascular disease (Colella *et al*., 2014), and they were 36% less likely to be enrolled in a CR program compared to men (Samayoa *et al*., 2014). Another recent study (Beckstead *et al*., 2014) found disparities in CR referrals in favor of men by doctors who were biased in their judgement of women as less likely to benefit from CR based on their own beliefs and lack of insight on patients' motivation levels. This bias might have a restrictive impact on the number of eligible females attending CR, particularly when participation is dependent on their physician's decision.

Another possible explanation for more men attending CR might be attributed to socioeconomic and psychological reasons; past studies have noted that psychological factors of perceived benefits of CR and self-efficacy for lifestyle change and exercise were determinants of CR attendance and program adherence (Kelly *et al*., 1991; King *et al*., 2001b). Female patients often participate less in physical activity than men, partially due to their perceptions of their physical limitations, particularly with aging (Worcester *et al*., 2004), and women might not perceive CR as important for recovery (Daly *et al*., 2002). Our results confirmed that employed males were less likely to attend CR, possibly explained by a need to resume work early (De Vos *et al*., 2012) and a better knowledge of the benefits that CR attendance confers. Consequently, gender disparities occur for CR attendance, where men continue to dominate, despite the fact that CR is beneficial for all participants.

Our study also showed that being employed had a small but negative, significant impact on CR attendance at 6 months. Similarly, a recent study (McKee *et al*., 2013) reported employment, age, and past AMI to be predictors of intention to attend CR, while another study (De Vos *et al*., 2012) found lack of time, such as work obligations, to be one reason for non-attendance. Further research is warranted, as the benefits of CR participation might be diluted when unemployment or late resumption of work after an invasive procedure (PPCI) is considered.

While CR aims at maximizing physical, social, and psychological recovery with shortened recovery time, there remains no existing national Australian database on post-discharge CR participation and health status outcomes for comparison (Australian Institute of Health and Welfare, 2015). A recent population study (Clark *et al*., 2014) indicated that CR attendance was not associated with distance to CR services, but rather socioeconomic and sociopsychological factors. Therefore, attention should focus on developing patient motivation and self-efficacy to participate. It is clear that evaluation should incorporate multiple aspects, such as gender, educational background, and socioeconomic and psychosocial factors, which could negatively impact on patients' decision to participate. Our results confirmed that female gender, being employed, and not receiving a post-discharge health visit were negative factors and barriers to CR attendance. Of note, age was not an independent predictor of CR attendance at either time point.

Study strengths

This study provided important information on CR attendance and its impact on a select cohort of acute STEMI and early field triage PPCI patients. To date, there are no comparable findings on predictors of CR attendance analyzed by both sociodemographic and clinical risk factors for specific field triage PPCI patients in Australia. While a number of international studies have investigated predictors of CR attendance, mostly for AMI cohorts, few have focused on PCI patients (Dendale *et al*., 2005; Goel *et al*., 2011; Izawa *et al*., 2011; Worcester *et al*., 2004), and none had included post-discharge support specifically for a PPCI cohort. Our results are therefore unique and expand on the current limited information on factors that govern CR participation and recovery in vulnerable populations. One post-discharge visit after PPCI is a significant positive factor for increased CR attendance. This suggests a need to augment health support services that will inform, reinforce, and promote CR attendance for STEMI patients after rapid revascularization. Despite a high referral rate (96%), the attendance rates of 36–54% in this Australian study are consistent with the 40–55% attendance reported for international studies (Cooper *et al*., 2002; Goel *et al*., 2011; Witt *et al*., 2004), and supports a common finding that only half of patients referred actually attended a CR program to completion. Therefore, future research is should investigate factors for non-participation, including review and standardization of CR referrals for PPCI patients.

Limitations

Study limitations are also noted, in that the sample might not be representative of PPCI patients in general, as recruitment was from one large metropolitan health service and comprised low-risk STEMI patients. Furthermore, the CR attendance pattern was based on individual self-report. We excluded covariates, such as baseline angina or prior coronary artery bypass, in the regression analysis due to small sample numbers. This was despite past studies (Rumsfeld *et al*., 2003; Spertus *et al*., 2004) identifying them as predictors of worse physical recovery, and that the severity of coronary vessel occlusion might also impact on CR attendance. Our results have implications only for STEMI patients who agreed to CR participation with post-discharge visits during the recovery phase, rather than reflect on the overall effectiveness of CR referral processes following PPCI.

Conclusion

Our study shows that, despite high levels of referral, CR participation rates in PPCI patients are lower than ideal, with approximately half participating by 6 months follow up. Participation was highest in men, the employed, and those who had a post-discharge health visit. These results add a new perspective not reported previously for an important subgroup of STEMI patients, by identifying that health visits post-discharge after PPCI are associated with improved CR attendance.

Implications for practice

Future research is recommended to investigate the impact of tailored CR programs suitable for women, the very elderly, and the unemployed after fast-track PPCI, and highlighting the important relationship between community health support programs, CR participation patterns, and patient health status outcomes. Standardized CR programs could be redefined and expanded in content and scope to incorporate the educational and emotional needs of recovering PPCI patients who did not receive routine preprocedural preparation and care. With increased focus on PPCI as priority treatment for STEMI both in Australia and internationally, and the advantages of CR participation for high-risk cohorts, there is a need for comprehensive risk assessment with PPCI. Strategies to incorporate post-discharge health care and to promote active and sustained CR participation with vigilant follow up of attendance are recommended for patients with acute presentations of STEMI, as successful CR is an integral component of comprehensive PPCI recovery.

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CONTRIBUTIONS

Study Design: SH, RG, DE
Data Collection and Analysis: SH
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Appendix 19: Publication - Chapter 4

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Original Article

Factors influencing health-related quality of life after primary percutaneous coronary intervention for ST-elevation myocardial infarction

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ABSTRACT

Aims: This study compared health-related quality of life (HRQOL) between patients aged ≥70 and <70 years at 4 weeks and 6 months after primary percutaneous coronary intervention (PPCI) and examined predictors of HRQOL.

Background: HRQOL is an important patient outcome following PPCI for ST elevation myocardial infarction (STEMI) including pre-hospital field triage.

Methods: A comparative cohort design was conducted on STEMI patients undergoing PPCI. HRQOL was measured using the Medical Outcomes Short Form-12 (SF-12) and the Seattle Angina Questionnaire (SAQ) at 4 weeks and 6 months post-PPCI.

Results: HRQOL improved significantly from 4 weeks to 6 months in all aspects measured except anginal frequency and mental health. Patients aged ≥70 years had poorer physical HRQOL (SF-12) and physical limitations (SAQ), but better mental HRQOL (SF-12), angina frequency and QOL (SAQ) at both time points. Age, length of hospital stay, gender, partnership status and number of stents deployed are independent predictors of HRQOL improvement over time.

Conclusion: People ≥70 years reported better cardiac-specific quality of life, primarily from angina relief and improved mental function, despite worse physical limitations. HRQOL assessment is an important gauge of health status after PPCI for STEMI.

1. Introduction

Health-related quality of life (HRQOL) assessment for patients undergoing cardiac treatments is recommended by key organizations including the American Heart Association (Rumsfeld et al., 2013). One of these treatments, primary percutaneous coronary intervention (PPCI) is the optimal first-line reperfusion treatment for ST-elevation myocardial infarction (STEMI) which is a serious form of the acute coronary syndromes with high mortality and long-term morbidity. Primary percutaneous coronary intervention is initiated preferably within 60 minutes from the first medical contact and utilizes pre-hospital ambulance field triage to bypass emergency department (ED) delays (Steg et al., 2012). Although PPCI is known to improve outcomes for STEMI, the impact on HRQOL is not as well described. Furthermore, older people aged ≥70 years form a high proportion of patients undergoing this procedure, yet few studies focus on the potential differences in HRQOL that occur with age. It is projected that by 2025 approximately 1.2 billion people globally will be aged over 60 years, the age defined as "older" (World Health Organisation, 2002) with increased risk of cardiovascular disease and coronary occlusion. Primary percutaneous coronary intervention affects multiple dimensions of a person's life including physical, mental and social health as they develop across the life-span.

Researchers have investigated percutaneous coronary intervention (PCI), which includes elective procedures but limited studies explored health status outcomes for older STEMI patients. Older STEMI patients with acute symptoms may also derive the most clinical benefit from PPCI with fast field triage because of higher baseline risks and increased frailty. Indeed, changes to HRQOL in this population are known to impact on long-term recovery, physical function and mortality (Gharacholou et al., 2012b; Panasewicz et al., 2013).

Older people have more co-morbidities and constitute a higher risk cohort for PPCI as reflected by more major adverse cardiovascular

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events (MACE) including death in comparison to younger people (Bauer et al., 2011; Claessen et al., 2010). Clinical trials such as the Apex-AMI (Gharacholou et al., 2011) reported age as the strongest predictor of 90 day mortality in STEMI patients >75 years after PPCI, but HRQOL was not investigated. When HRQOL was investigated in older people there was often better HRQOL outcome (Graham, Norris, Galbraith, Knudtson, & Ghali, 2006; Li et al., 2012; Seto et al., 2000), mainly from angina relief (Agarwal, Schechter, & Zaman, 2009; Gunal et al., 2008). A recent systematic review reported improved angina status and physical functioning in octogenarians after PCI, equivalent to younger peoples' outcomes in the first 6 months (Johnman, Mackay, Oldroyd, & Pell, 2013). Some studies have also indicated age as a predictor of quality of life gains following PCI (Li et al., 2012; Pocock, Henderson, Clayton, Lyman, & Chamberlain, 2000; Spertus, Salisbury, Jones, Conaway, & Thompson, 2004). However, there is a lack of consistency in outcomes and results of another recent systematic review (Soo Hoo, Gallagher, & Elliott, 2014) did not find that age was a predictor of HRQOL after PCI.

An appropriate model of care for these complex groups examines the broader concepts of HRQOL and the theoretical framework guiding this study is the linear relationship model because it clearly includes health and physical symptoms. In this model Wilson and Cleary provided a conceptual model that links both the biophysiological and psychosocial concepts of health as causal variables which impact on global HRQOL (Wilson & Cleary, 1995). There are five health concepts in the model including physiological factors, symptoms, functional health, general health perceptions and overall quality of life interacting on a continuum. In addition, there are mediating variables such as individual and environmental characteristics which impact on these causal relationships. The model has been tested and widely used to examine the relationships among clinical, physiological outcomes and subjective psychosocial outcomes in patients with heart failure and cardiovascular diseases (Masterson Creber, Allison, & Riegel, 2013; Pettersen, Kvan, Rollag, Stavem, & Reikvam, 2008). Key concepts in this model that apply to our study on HRQOL after PCI include symptom status, which is particularly relevant because patients would expect relief from angina and that these symptoms would then likely influence their capacity to function both physically and mentally. Other nonmedical influences such as age are also considered to be influential and important in the current study. Previous studies on PPCI have inadequately examined this continuum of health complexities affecting HRQOL and this study's results will expand on the existing knowledge pool for STEMI/PPCI patients. Clarity is needed in whether there are differences and changes in HRQOL for older patients compared across time in order to improve care and recovery support.

Therefore this study aims to determine if:

i). Health related quality of life differs between people ≥70 years and <70 years old at 4 weeks and 6 months after PPCI,
ii). age has an independent effect on HRQOL, and
iii). to identify predictors of HRQOL.

2. Methods

2.1. Setting and sample

Consecutive STEMI patients treated with PPCI were recruited between April 2010 and November 2011 from the PCI Registry of a tertiary-level, university affiliated public hospital and from a metropolitan private hospital. In these institutions, approximately 1070 PCI cases were performed annually for a population of 1.2 million. These hospitals have ambulance pre-hospital field triage for acute STEMI, with PPCI as first-line emergency treatment utilizing 24-hour cardiac catheterization services.

2.1.1. Sample inclusion criteria

Patients were considered eligible if they: 1) had STEMI confirmed by serum cardiac enzyme rise of Troponin I >0.14 ng/mL or Troponin T >14 ng/L and dynamic ST elevation on presenting ECG > 0.1 mV in 2 or more contiguous precordial leads or at least 2 adjacent limb leads (Antman et al., 2007), 2) received PPCI (defined as urgent primary coronary reperfusion by using balloon inflation or stenting) following pre-hospital field triage or ED admission, 3) were able to write, read and comprehend English sufficient for consent and 4) were available for telephone contact after hospital discharge. Patients were excluded if they: 1) were diagnosed with dementia or any other severe neurocognitive disorder, 2) had severe hearing impairment which would prohibit telephone interviews, 3) required prolonged recovery with intensive care stay exceeding 5 days, or had cardiac arrest and or cardiogenic shock requiring intubation or inotropes, or 4) received thrombolysis as initial treatment.

Sample size was calculated for the multivariate regression analysis indicating that 258 participants with alpha level 0.05 and 11 predictors (age, admission pathway, marital status, smoking status, number of stents, hyperlipidemia, previous acute myocardial infarction (AMI), length of hospital stay, ejection fraction, hypertension and gender) was required for a small effect size on HRQOL and a power of 0.8 at 4 weeks (Soper, 2010). A small effect for HRQOL was determined to be a minimal clinically important difference (MCID) of >5 points on the SAQ, based on previous similar studies (Ho et al., 2008; Spertus et al., 1995). The anticipated dropout rate at 4 weeks was 5%; therefore 270 participants were required to be recruited.

Ethics approval was obtained from the Human Research Ethics Committees of both study sites and the university. All ethical considerations were met, including informed and voluntary participant consent, privacy and confidentiality.

2.2. HRQOL measurement

Health-related quality of life is a state of health perceived and reported by the patient as impacting on their functioning and therefore, it reflects the patient's physical, social and emotional health (Pedersen, Martens, Denollet, & Appels, 2007). It was measured using the Medical Outcomes Short Form (SF-12) and the Seattle Angina Questionnaire (SAQ) at 4 weeks and 6 months after PPCI. Both instruments are well-established, valid and reliable, commonly used in cardiac populations and are suitable for telephone administration (Summerhill & Taylor, 1992).

2.2.1. SF-12

The SF-12, a brief version of the SF-36 questionnaire measures eight general health domains: physical function, physical role limitations, emotional role limitations, vitality, social function bodily pain, general health and mental health (Ware & Kosinski, 2001). Responses are rated on a 3 to 6 point Likert scale and scores are transformed from a range of 0 to 100 (highest function). Two summary measures, the physical component summary (PCS) and mental component summary (MCS) have population-standardized norms for reference (mean of 50; 10 SD) (Ware, Kosinski, Turner-Bowker, & Gandek, 2009).

The SF-12 has been validated in coronary disease patients (Muller-Nordhorn, Roll, & Willich, 2004) with high construct validity reported in international clinical and epidemiological settings (Gandek, 1998) including Australian population health surveys (Sanderson & Andrews, 2002) and for cardiovascular populations (Lim & Fisher, 1999). This instrument has high reliability for heart disease and stroke patients (Lim & Fisher, 1999) and the MCS was tested on older adults in community living (Resnick & Parker, 2001). The coefficient in this study for all eight domains demonstrated good internal consistency and reliability with Cronbach's alpha between 0.79 and 0.95 at both time points.

2.2.2. SAQ

The SAQ measures five dimensions of health specific to coronary artery disease; physical limitations, angina stability, angina frequency, treatment satisfaction and impact on quality of life (Spertus et al., 1995). Responses are rated on a 5 or 6 point Likert scale, with transformation of scores ranging from 0 (worst) to 100 (best). An MCID of 5–10 points indicates an important small change in HRQOL status; many studies on PCI accepting a 5 point score difference as clinically significant and therefore this has been used for our study (Agarwal et al., 2009; Graham et al., 2006; Moore, Pedel, Lowe, & Perry, 2006; Seto et al., 2000; Spertus et al., 1995; Weintraub et al., 2008).

Unlike generic measures, the SAQ measures unique dimensions of coronary artery disease and quantifies functional and angina improvements from PCI (Spertus et al., 2004). As a disease-specific instrument, it is able to detect small changes on HRQOL often missed by a general instrument (Borkon, Muehlebach, House, Marso, & Spertus, 2002). The SAQ was used to measure anginal relief after PCI (Ho et al., 2008; Jamieson et al., 2002; Li et al., 2012; Melberg, Nordrehaug, & Nilsen, 2010; Pocock et al., 2000; Spertus et al., 2004) and symptom burden (Agarwal et al., 2009; Graham et al., 2006; Gunal et al., 2008; Zhang et al., 2006) which impact on HRQOL. Past PCI studies have also shown angina frequency to be a strong predictor of HRQOL (Pocock et al., 2000; Spertus et al., 2004). At 4 weeks and 6 months, the Cronbach alpha coefficients in our study for the SAQ were between 0.58 and 0.79.

2.3. Clinical and demographic data collection

Sociodemographic, baseline clinical and cardiovascular risk factors were collected for comparison. These risk factors included hypertension, hyperlipidemia, angina, diabetes, renal impairment, family history of cardiovascular disease including prior AMI, stroke, PCI, obesity and current smoker (Table 1). Primary percutaneous coronary intervention procedural characteristics included MACE (represented by access site complications, recurrent angina, stroke, arrhythmias, re-occlusion, recurrent-AMI, death, coronary artery bypass graft (CABG), repeat PCI and repeat angiogram). These were recorded during hospitalization using a data collection form. Follow-up clinical information was recorded for 6 months. The Charlson Co-morbidity Index (Charlson, Pompei, Ales, & Mackenzie, 1987), a validated measure was used to determine co-morbidity burden. The most common co-morbidity components included congestive heart failure, myocardial infarction, peripheral vascular and cerebrovascular diseases, dementia, chronic obstructive pulmonary disease and diabetes in older participants.

2.4. Procedure

Eligible patients were identified from the hospital PCI registry. Consecutive patients with STEMI who received PPCI by either pre-hospital field triage or ED admission or urgent inter-hospital transfer were screened. Participants were approached while in hospital for informed, written consent, normally on the day after PPCI when they had recovered and appointment times for the telephone interview were arranged.

Participants were interviewed at home by telephone at 4 weeks and 6 months. Earlier studies had shown substantial HRQOL improvements for physical and mental health up to 6 months post-PPCI, after which no significant differences occurred therefore this time was selected (Seto et al., 2000; Weintraub et al., 2008). Interviews averaged 15 minutes to complete but could take from 10 to 25 minutes depending on interruptions.

2.5. Statistical analyses

Data analyses were performed using the Statistical Package for the Social Sciences (SPSS version 21, IBM Corp., Armonk, New York). Data were described as frequencies and percentages or means and standard deviation based on the level of variables. Chi-square analysis or Fisher's exact test was used for categorical data (sociodemographic, baseline clinical, PPCI characteristics and MACE), while continuous variables (HRQOL) were compared using paired t-tests. Missing SAQ scores were individually adjusted by substituting missing values with the mean of each domain as stipulated by the scoring algorithms of the SAQ. All data for the SF-12 were complete. The impact of PPCI and patient characteristics on HRQOL over time and the interaction of age and time were analyzed using repeated measures ANOVA. Paired t-tests were also conducted along with post-hoc tests to determine specific differences in HRQOL for ≥70 years and <70 years with Bonferroni correction $p = 0.01$ to control for type I error. All values were calculated by using two tailed t-test and a significant p-value was set at <0.05, twice that of a one-tailed test. All SAQ scores were adjusted values.

Multivariate linear regression analysis was used to determine the independent influence of various covariates, including age. Due to small numbers, variables such as prior CABG, diabetes and baseline angina, identified as predictors of HRQOL by previous studies (Nash, Curtis, & Rubin, 1999; Pocock et al., 2000; Rumsfeld et al., 2003; Spertus et al., 2004) were not included in the current analysis. Variables selected for regression analyses were those that influenced HRQOL based on theoretical evidence and demonstrated statistical significance on univariate analyses.

Linear regression analyses on the SF physical domains were selected as the purpose of PPCI was to improve physical function and angina relief as measured by the SAQ. Separate models were created for both outcomes at 4 weeks and 6 months using backward stepwise elimination to examine the independent relationship of eleven predictors (age, admission pathway, partnered or unpartnered, smoking status, number of stents, hyperlipidemia, previous AMI, length of hospital stay, ejection fraction, hypertension and gender) on HRQOL. The critical level was set at $p < 0.05$. All assumptions of linearity, collinearity and homoscedasticity in our analyses were met. The predictive strength of the 2 main models of interest, the SF-PCS and SF-physical functioning was evaluated by accepting an adjusted $R^2 = 0.10$.

Table 1
Baseline characteristics.

Characteristics	Overall sample n = 246 n (%)		≥70 yrs n = 81 n (%)		<70 yrs n = 165 n (%)		*p*
Male	194	(78.9%)	50	(61.7%)	144	(87.3%)	0.01
Female	52	(21.1%)	31	(38.3%)	21	(12.7%)	0.01
Married/Partnered	167	(67.9%)	52	(64.2%)	115	(69.7%)	0.38
Lives alone	44	(17.9%)	20	(24.7%)	24	(14.5%)	0.05
Caucasian	229	(93.1%)	80	(98.8%)	149	(90.3%)	0.14
Employed	119	(48.4%)	7	(8.6%)	112	(67.9%)	0.01
Retired	113	(45.9%)	74	(91.3%)	39	(23.6%)	0.01
Year 12 (completed high school)	163	(66.3%)	37	(45.7%)	126	(76.8%)	0.01
Hypertension	118	(48%)	50	(61.7%)	68	(41.2%)	0.02
Hyperlipidemia	119	(48.4%)	42	(51.9%)	77	(46.7%)	0.44
Angina	25	(10.2%)	13	(16.0%)	12	(7.3%)	0.03
Diabetes	26	(10.6%)	7	(8.6%)	19	(11.5%)	0.49
Prior heart failure	2	(0.8%)	2	(2.5%)	0	(0%)	0.04
Family history	149	(60.6%)	44	(54.3%)	105	(63.6%)	0.16
PVD	5	(2%)	3	(3.8%)	2	(1.2%)	0.18
Renal impairment	10	(4.1%)	5	(6.2%)	5	(3.0%)	0.24
PUD/GORD	10	(4.1%)	6	(7.4%)	4	(2.4%)	0.06
CAL	6	(2.4%)	3	(3.7%)	3	(1.8%)	0.36
Prior AMI	26	(10.6%)	9	(11.1%)	17	(10.2%)	0.82
Prior stroke	9	(3.7%)	7	(8.6%)	2	(1.2%)	0.01
Prior PCI	25	(10.1%)	9	(11.1%)	16	(9.7%)	0.73
Prior CABG	8	(3.2%)	5	(6.2%)	3	(1.8%)	0.07
BMI ≥25 kg/m^2	160	(65.0%)	43	(53.1)	117	(70.9%)	0.06
Current smoker	69	(28.0%)	11	(13.6%)	58	(35.2%)	0.01
PCI pathway							
Pre-hospital field triage	77	(31.3%)	24	(29.6%)	53	(32.1%)	0.69
Non-field triage (ED/Inter-hospital)	169	(68.7%)	54	(70.4%)	112	(67.9%)	
Disease severity							
Single vessel	140	(56.9%)	44	(54.3%)	96	(58.2%)	0.76
Double vessel	80	(32.5%)	27	(33.3%)	53	(32.1%)	
Triple or more	26	(10.6%)	10	(12.3%)	16	(9.7%)	
Ejection fraction mean ± SD	47.6 ± 8.9		45.8 ± 9.5		48.5 ± 8.4		0.02
LOS (mean days) ± SD	4.2 ± 4.97		5.7 ± 7.1		3.4 ± 3.2		0.01

x^2 or Fisher's exact for categorical data, p ≥ 0.05 significant.

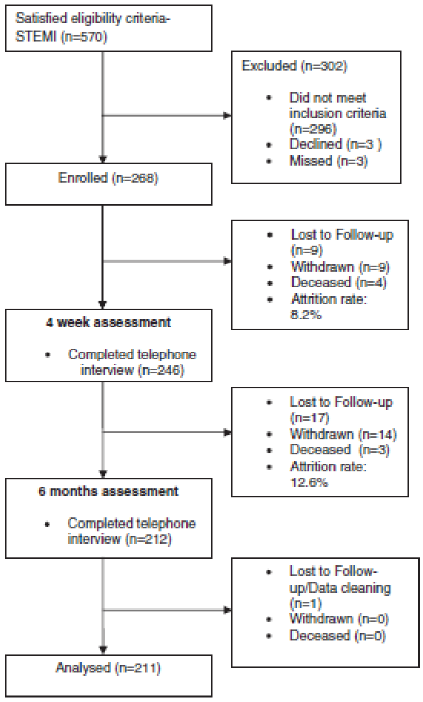

Fig. 1. Flow diagram of STEMI participants from screening, identification, recruitment, withdrawal to completion at 4 weeks to 6 months post-PCI.

3. Results

3.1. Sample

A total of 268 participants were enrolled from 570 STEMI patients screened for eligibility (Fig. 1). At 4 weeks 246 participants were interviewed and 212 participants completed the 6 month interview. Patients who withdrew were more likely to be ≥70 years and male (75%), whereas those lost to follow-up (47%) were males <70 years.

3.2. Demographic characteristics

The majority of participants (78.9%) were male with an overall mean age of 63.6 years (SD 13); ages ranged from 25 to 94 years, married/partnered (67.9%) and of Caucasian ethnicity (93.1%). Approximately half (48.4%) were employed and 66.3% had completed high school (12 years schooling) (Table 1). Statistically significant differences were noted between ≥70 years and <70 years, with older participants more likely to be female (38.3% versus 12.7%, $p = 0.01$), retired (91.3% versus 23.6%, $p = 0.01$) and without high school education level (45.7% versus 76.8%, $p = 0.01$).

3.3. Clinical characteristics

Overall, cardiovascular risk factors were prevalent, with family history of heart disease (60.6%) the most common (Table 1). Nearly half the sample had hypertension (48%) and hyperlipidemia (48.4%); almost two-thirds (65%) were overweight (mean BMI 26.9, SD 4.0) and 28% were current smokers. Participants ≥70 years were more likely to have hypertension ($p = 0.02$), angina ($p = 0.03$), be non-smokers ($p = 0.01$) and to have had prior heart failure ($p = 0.04$) and prior stroke ($p = 0.01$) (Table 1). No differences were identified for other clinical characteristics. Co-morbidity risk (Charlson Co-morbidity Index) was low with a mean of 0.86 (SD 0.9); the most common co-morbidities in our study population were diabetes, cerebrovascular and renal diseases.

3.4. PPCI characteristics and outcomes

Patients were admitted by inter-hospital transfer (45%), pre-hospital field triage (31%) or the ED (24%) for PPCI. The majority (57%) had single vessel disease, predominantly the left anterior descending coronary artery (LAD) and were treated with one stent (79%), mainly drug-eluting. The mean ejection fraction was 47.6 % (SD 8.9).

Procedural complications were reported as composite MACE totaling 10%. Overall median CK value was 655 (IQR 200.5–1469.0) and troponin 1104 (IQR 145–4265) post-PPCI. Mean length of stay was 4.2 days (SD 4.9). Patients <70 years were more likely to have proximal coronary lesions treated (61% vs. 44%, $p = 0.01$) while older people were more likely to have distal lesions (12.7% vs. 2.2%, $p = 0.01$) and lower mean ejection fraction (45% vs. 48%, $p = 0.02$). The mean hospital stay days were significantly longer for older patients (5.7 vs. 3.4, $p = 0.01$).

3.5. HRQOL at 4 weeks and 6 months for entire cohort

At 4 weeks, mental health component scores (SF-12) were better than physical health (52.9 ± SD 9.9 vs. 42.3 ± SD 8.8), with scores lowest for physical function, role physical and vitality and highest for bodily pain, social function and role emotional. For cardiac specific HRQOL, the highest scores at 4 weeks were for angina frequency (94.2 ± SD 13.7), treatment satisfaction (93.8 ± SD 10.4) and quality of life (75.1 ± SD 20.1) but lowest for physical limitation and angina stability for the whole cohort. Over time, significant changes occurred for HRQOL in multiple areas.

At 6 months, the SF-12 mental health scores were statistically better (54.6 ± SD 8.0 vs. 52.9 ± SD 9.9, $p < 0.01$) followed by the SF-12 physical limitation scores. For the SAQ, mean scores were highest for angina frequency (97.1 ± SD 12.4), physical limitation (94.2 ± SD 12.7) and treatment satisfaction (96.8 ± SD 8.0). No deaths or strokes were reported. The greatest improvements were evident in the SAQ physical limitation and quality of life domains with score gains of 21.3 and 13.7 respectively. At 6 months angina stability was the sole domain with no improvement.

3.6. HRQOL compared between ≥70 years and <70 years at 4 weeks and 6 months

Participants aged ≥70 years at 4 weeks had lower overall physical HRQOL (SF-PCS) (40.9 vs. 43.1, $p = 0.03$), physical function (SF-12) (47.2 vs. 62.1, $p < 0.01$) and social function (78.6 vs. 82.0, $p < 0.01$) but higher mental HRQOL (SF-MCS) (54.1 vs. 52.3, $p < 0.01$) (Table 2). For cardiac specific HRQOL (SAQ), participants ≥70 years experienced worse angina stability (52.4 vs. 59.5, $p < 0.01$) and quality of life (QOL) (72.8 vs. 73.6, $p = 0.01$).

At 6 months, participants ≥70 years had significantly better angina frequency scores (98.1 vs. 96.6, $p < 0.01$). Other significant differences were SAQ-QOL (91.8 vs. 87.3, $p = 0.02$) and SF-12 mental health (85.5 vs. 79.6, $p < 0.01$). The SAQ-QOL showed the highest and clinically significant improvement over time of 13.6 points for those ≥70 years, while angina frequency had the lowest score gain of 0.5 points. Older people had poorer SF-12 physical component scores (50.6 vs. 52.6, $p < 0.01$) including lower SAQ-physical limitation (91.5 vs. 95.5, $p < 0.01$) and angina stability (51.6 vs. 50.9, $p < 0.01$) scores over time.

Table 2
HRQOL (SF-12) over time compared for over and under 70 year age groups by repeated measures ANOVA.

HRQOL measurement	≥70 years mean scores (SD)		<70 years mean scores (SD)		Within subjects		Between subjects		Interaction effect	
					Time		Age		Age * time	
	4 week	6 month	4 week	6 month	F[a]	p	F[a]	p	F[a]	p
PCS (SF-12)	40.9 (9.9)	49.3 (7.7)	43.1 (8.0)	52.3 (7.4)	139.621	<0.01	1.463	0.03	1.057	0.38
MCS (SF-12)	54.1 (9.3)	56.7 (5.9)	52.3 (10.2)	53.6 (8.7)	5.712	<0.01	1.612	<0.01	.809	0.81
Physical function	47.2 (34.0)	79.2 (32.0)	62.1 (31.2)	89.2 (24.7)	99.000	<0.01	1.723	<0.01	1.158	0.23
Role physical	50.3 (30.4)	81.0 (26.8)	45.3 (27.3)	82.1 (28.8)	130.682	<0.01	1.135	0.26	.760	0.88
General health	63.0 (21.7)	73.9 (20.4)	64.2 (23.7)	75.0 (21.5)	45.086	<0.01	1.123	0.28	.905	0.65
Bodily pain	92.6 (16.8)	98.3 (9.3)	89.8 (18.5)	96.9 (12.1)	18.906	<0.01	.868	0.72	.928	0.61
Vitality	48.1 (26.8)	62.6 (20.9)	55.9 (22.3)	65.0 (23.2)	14.932	<0.01	1.129	0.27	.944	0.58
Social function	78.6 (32.4)	94.1 (19.8)	82.0 (27.9)	92.6 (22.0)	22.870	<0.01	1.760	<0.01	1.205	0.18
Role emotional	86.1 (22.3)	92.6 (19.5)	79.0 (25.1)	91.4 (19.2)	12.930	<0.01	1.266	0.12	1.137	0.26
Mental health	80.7 (16.4)	85.5 (79.6)	75.7 (18.7)	79.6 (17.7)	13.769	<0.01	1.354	0.07	1.275	0.12

[a] Repeated measures ANOVA, df = 1.

However, they scored better for SF-social functioning (93.5 vs. 92.2, $p < 0.01$) (Table 2).

3.7. Effect of age and time on HRQOL

There was only one interaction between age and time in one domain therefore these effects are reported separately. Age had an effect in less than half of all HRQOL domains, mainly the SF-12 domains of physical, MCS and social function. The PCS showed statistical improvement with both time ($p < 0.01$) and age ($p = 0.03$) showing separate effects. By 6 months, physical function scores had increased significantly for both older and younger people (47.2 and 62.1 vs. 79.2 and 89.2, $F = 99.0$, $df = 1$, $p < 0.01$). Therefore, people >70 years had improved physical function scores at 6 months of 32 and 27.1 independently for age and time, reflecting a variance in mean scores within and between age groups. However, the MCS showed significant differences only for age ($F = 1.61$, $df = 1$, $p < 0.01$) but not time (Table 2). No interaction effects occurred for age and time with SF-12 subdomains.

For SAQ domains, participants ≥70 years had statistically significant higher scores for angina frequency ($F = 2.35$, $df = 1$, $p < 0.01$) and QOL ($F = 1.50$, $df = 1$, $p = 0.02$) and lower physical limitation ($F = 1.45$, $df = 1$, $p = 0.03$) (Table 3). The remaining domains, angina stability and treatment satisfaction, demonstrated no differences for age whereas SAQ physical limitation ($p < 0.01$) and QOL ($p < 0.01$) showed statistical improvement with time and age ($p = 0.03$ and $p = 0.02$). Angina stability was the sole domain that showed a significantly large interaction effect (0.316) between age and time ($F = 1.54$, $df = 1$, $p = 0.02$), result >0.14, indicating older people had better HRQOL over time whereas younger people had less improvements in HRQOL (Cohen, 1988).

3.8. Independent predictors of HRQOL

There were 8 predictors that independently predicted some aspects of HRQOL as measured by the SF12 over time. Model statistics for SF-12 PCS were statistically significant at 4 weeks ($R^2 = 0.16$, $F = 5.28$, $df = 11$, $p = 0.01$) and 6 months ($R^2 = 0.16$, $F = 14.96$, $df = 3$, $p = 0.01$) showing that 16% of the shared variance was explained by the predictors. Model statistics for SF-physical functioning was stronger for 4 weeks ($R^2 = 0.19$, $F = 15.43$, $df = 4$, $p = 0.01$) compared to 6 months ($R^2 = 0.14$, $F = 13.70$, $df = 3$, $p = 0.01$) (Tables 4, 5).

Age was a significant independent predictor of 4 week SF-physical functioning (ß = −0.33, CI: −0.64 to −0.02, $p = 0.03$), controlling for other factors entered into the model (Table 4). In addition, by 6 months age emerged as a predictor for both the SF-PCS (ß = −0.11, CI: −0.18 to −0.03) and SF-physical functioning (ß = −0.50, CI: −0.77 to −0.22). Overall, for each year increase in age, physical health decreased by 0.33 points at 4 weeks and 0.50 at 6 months for SF-physical functioning.

Length of hospital stay was also a significant predictor of worse SF-physical functioning (ß = −0.08, CI: −0.60 to −0.18, $p = 0.01$) at 4 weeks; more so at 6 months (ß = −1.60, CI: −2.34 to −0.86, $p = 0.01$) and SF-PCS (ß = −0.55, CI: −0.75 to −0.34, $p = 0.01$). This indicates HRQOL decreases with longer hospitalization.

Other predictors included female gender which predicted substantially worse SF-physical functioning (ß = −16.31, CI: −26.0 to 6.5, $p = 0.01$) and unpartnered status predicting worse SF-physical functioning (ß = −8.28, CI: −16.33 to 0.24) at 4 weeks. However by 6 months, number of stents was the only PPCI procedural covariate with positive predictive effect (ß = 8.39, CI: 2.12–14.6, $p = 0.01$) on physical functioning.

Table 3
Cardiac specific HRQOL (SAQ) at 4 weeks and 6 months compared for over and under and 70 years age groups.

HRQOL measurement	≥70 years mean scores (SD)		<70 years mean scores (SD)		Within subjects		Between subjects		Interaction effect	
					Time		Age		Age * time	
	4 week	6 month	4 week	6 month	F[a]	p	F[a]	p	F[a]	p
Physical limitation	70.7 (20.7)	91.5 (15.8)	73.9 (18.9)	95.5 (10.7)	114.680	<0.01	1.456	0.03	1.074	0.34
Angina stability	52.4 (12.7)	51.6 (10.2)	59.5 (22.6)	50.9 (10.2)	9.590	<0.01	1.025	0.44	1.541	0.02
Angina frequency	97.6 (10.0)	98.1 (9.8)	92.0 (15.0)	96.6 (13.5)	0.930	0.336	2.35	<0.01	1.311	0.09
Treatment satisfaction	96.6 (6.3)	99.1 (2.9)	92.4 (11.7)	95.7 (9.4)	13.084	<0.01	1.341	0.08	0.995	0.49
Quality of life	72.8 (19.3)	91.8 (10.3)	73.6 (20.4)	87.3 (14.3)	68.467	<0.01	1.501	0.02	0.849	0.75

[a] Repeated measures ANOVA, df = 1, SAQ scores are adjusted values.

Table 4
Prediction model for HRQOL: SF-physical functioning and SF-PCS domains at 4 weeks.

Predictor variables	SF-physical functioning			SF-PCS		
	Beta	95% CI	p	Beta	95% CI	p
Constant	116.62	95.56 to 137.68	0.01	46.76	36.27 to 57.25	0.01
Age	−0.33	−0.64 to −0.02	0.03	−0.15	−0.10 to 0.07	0.73
Admission pathway	−4.61	−12.89 to 3.64	0.27	−0.05	−2.31 to 2.20	0.96
Partnered/Unpartnered	−8.28	−16.33 to −0.24	0.04	−1.25	−3.48 to 0.97	0.26
Smoking status	3.31	−1.19 to 7.83	0.14	0.59	−0.65 to 1.83	0.34
Number of stents	−0.20	−7.22 to 6.81	0.95	−0.18	−2.10 to 1.73	0.84
Hypercholestraemia	−5.74	−13.19 to 1.70	0.13	−1.02	−3.18 to 1.14	0.35
Previous AMI	2.58	−15.52 to 10.35	0.69	−2.25	−5.79 to 1.29	0.21
Length of stay (days)	−0.08	−0.60 to −0.18	0.01	−0.55	−0.77 to −0.34	0.01
Ejection fraction	0.29	−0.13 to 0.73	0.17	0.09	−0.03 to 0.21	0.14
Hypertension	0.97	−7.17 to 9.12	0.82	−2.09	−4.32 to 0.13	0.06
Gender	−16.31	−26.07 to −6.54	0.01	−1.78	−4.53 to 0.96	0.96
Model statistics	(R^2 = 0.19, F = 15.43, df = 4, p = 0.01)			(R^2 = 0.16, F = 5.28, df = 11, p = 0.01)		

p-value <0.05 significant. The prediction models for remaining SF-12 domains including all SAQ domains with low $R^2 < 0.10$ are not illustrated.

4. Discussion

We examined HRQOL for STEMI patients aged ≥70 years versus <70 years after PPCI and age as a predictor of HRQOL, adjusting for other clinical factors at 4 weeks and 6 months during recovery. Health related quality of life improved at 6 months following PPCI across both age groups for physical and mental health. All aspects of cardiac-specific health status were better (physical limitation, anginal frequency, treatment satisfaction and QOL) except for angina stability. People ≥70 years had worse physical function than those <70 years even when adjusted for the presence of multiple factors. This may be explained by age-related conditions such as frailty limiting older peoples' physical activity and compounded by angina symptoms (Gharacholou et al., 2012a). Our results parallel that of an earlier study conducted in UK using the SF-12 and SAQ (Moore et al., 2006) which identified similar poorer physical function for people >60 years after PCI with improvements in other health domains. It is likely that comorbidities are reflected in functional status, which then ultimately affects HRQOL as explained in the Wilson and Cleary (1995) model. Numerous studies have also reported improved health status outcomes following PCI (Gunal et al., 2008; Johnman et al., 2013; Li et al., 2012) with older people at risk from more MACE and higher mortality (Bauer et al., 2011; Claessen et al., 2010).

Our findings differ from results of a systematic review on octogenarians reporting better physical functioning and angina status compared to younger people after PCI and that quality of life improvements after PCI was not age-dependent (Johnman et al., 2013). Angina stability was the sole domain in our study that reflected a large interaction effect between age and time but not a predictor of better or worse HRQOL. The paradoxical results of higher angina scores and good SAQ-QOL which persisted over time with increased age in our study supports previous published findings (Ho et al., 2008; Spertus et al., 2004). As expected, It is likely that physiological ageing, recurrent angina, different expectations of recovery and longer hospitalization may account for differences in angina scoring and reporting between patients ≥70 and <70 years. These results support the relationships described in the Wilson and Cleary (1995) model which indicate that symptom load as well as non-medical aspects such as age are important in HRQOL.

Age was an important independent predictor at 4 weeks of PPCI recovery for physical aspects of HRQOL with progressive improvement over time. By 6 months age remains an independent predictor of multiple aspects of HRQOL in our study, with a positive impact on physical health, mental health, quality of life and angina frequency. Few studies have examined this predictive effect of age on HRQOL following PPCI; most focused on the impact of MACE and mortality. Our study results expand on previous findings (Li et al., 2012; Pocock et al., 2000; Spertus et al., 2004) showing age as a significant predictor of quality of life benefits at 6 months. Another study (Shah, Najafi, Panza, & Cooper, 2009) reported good quality of life for elderly STEMI patients ≥85 years with PPCI as an independent predictor of in-hospital mortality. This suggests that despite higher potential for MACE, people ≥70 years have improved HRQOL after PPCI over time. Age should not be an exclusion for PPCI in older STEMI patients irrespective of admission pathway. However, our cohort was unique as PPCI was conducted on acute STEMI patients, in particular older people receiving fast reperfusion by pre-hospital field triage and to date, there are no comparable published results.

Length of hospitalization was another predictor of HRQOL correlating with physical domains of SF-PCS and SF-physical functioning across time. This is perhaps the most interesting finding. Despite no publications with similar results, a study (Chin et al., 2011) showed that

Table 5
Prediction model for physical HRQOL: SF physical functioning and SF-PCS at 6 months.

Predictor variables	SF-physical functioning			SF-PCS		
	Beta	95% CI	p	Beta	95% CI	p
Constant	114.89	96.50 to 133.27	0.01	58.93	53.89 to 63.98	0.01
Age	−0.50	−0.77 to −0.22	0.01	−0.11	−0.18 to −0.03	0.01
Admission pathway	−4.47	−11.75 to 2.79	0.22	−0.34	−2.39 to 1.71	0.74
Partnered/Unpartnered	−1.96	−9.29 to 5.37	0.59	−1.54	−3.53 to 0.45	0.12
Smoking status	1.74	−2.37 to 5.85	0.40	−0.51	−1.59 to 0.66	0.35
Number of stents	8.39	2.12 to 14.66	0.01	1.55	−0.17 to 3.27	0.07
Hypercholestraemia	−1.46	−8.63 to 5.69	0.68	−0.28	−2.23 to 1.67	0.77
Previous AMI	−6.75	17.61 to 4.09	0.22	−2.16	−5.16 to 0.82	0.15
Length of stay (days)	−1.60	−2.34 to −0.86	0.01	−0.55	−0.75 to −0.34	0.01
Ejection fraction	0.24	−0.63 to 0.15	0.22	−0.01	−0.11 to 0.10	0.91
Hypertension	0.92	−7.00 to 7.68	0.81	−0.64	−2.55 to 1.27	0.50
Gender	−7.92	−16.7 to 0.87	0.07	−1.65	−4.08 to 0.76	0.17
Model statistics	(R^2 = 0.14, F = 13.70, df = 3, p = 0.01)			(R^2 = 0.16, F = 14.96, df = 3, p = 0.01)		

p-value <0.05 significant. The prediction models for 6 month SF-12 and SAQ domains with low $R^2 < 0.10$ are not shown.

STEMI patients hospitalized >2 days were older and more likely to have MACE including cardiogenic shock after PPCI. Another study (Noman, Zaman, Schechter, Balasubramaniam, & Das, 2013) showed age and post-PCI complications to be predictive of longer hospitalization for STEMI cohorts following PPCI although HRQOL was not assessed.

Gender and partnership status had a predictive effect on 4 week physical functioning after PPCI but not later. Two studies (Mortensen et al., 2007; Pocock et al., 2000) showed female gender to have worse HRQOL while unmarried females had the longest delays to PCI with higher mortality (Austin et al., 2014). The role of gender independent of age and comorbidities needs further investigation.

4.1. Strengths and limitations

The strength of this study is the focus on the effect of age on HRQOL after urgent PPCI; recognizing that measuring patient-reported health status is an important step toward improving quality of care for an ageing population. We used validated tools; the SF-12 and the cardiac-specific SAQ to comprehensively assess all domains of HRQOL and there was sufficient power to detect MCID between patients ≥70 and <70 years across time. An additional strength was the use of the SAQ scales because they are cardiac-specific complementing the SF-12 measurement for general health domains. Of patients screened, 47% met the study criteria and only 8.2% were lost to follow-up at 4 weeks with a further 12.6% lost by 6 months. This is another strength as high attrition rates are common with longitudinal studies on older participants (Newman, 2010).

We identified predictors of HRQOL by stepwise regression analysis; our multivariable models included a repeated measures analysis for all observations. We specifically focused on the SF-PCS and physical functioning models for comparison across time in order to support angina results as these are important indicators of recovery for older PPCI cohorts. Our findings compare favorably with previous studies. One study (Spertus et al., 2004) reported models with R^2 values from 0.7% to 25.3% for age and PCI as predictors of quality of life benefit after PCI. Another study (Melberg et al., 2010) described 3 models ($R^2 = 0.09$, 0.20 and 0.42) comparing health status after PCI at different hospital sites. Given the complexity of HRQOL, it can be argued that HRQOL in cardiac patients has a cause-and-effect relationship between symptoms (angina) and global HRQOL (physical, emotional and mental health, vitality and social function); supporting the theory of Wilson and Cleary. Our study captured all biophysical, psychological and social aspects of HRQOL as quantified by patient-rated life satisfaction responses during their recovery from PPCI for STEMI.

This study has several limitations. Participants were all STEMI patients recruited from two hospitals and therefore stringent recruitment criteria may restrict generalizability of results to other cardiac cohorts. The oldest patients with the most severe complications were excluded, hence the sample was comprised of "non-complicated" STEMI patients. More males aged >70 years withdrew from the study resulting in uneven comparison groups and study results may not adequately account for that group. In analysis, our strongest model explained only 19% of the variation in HRQOL status outcomes and there were limitations in the sensitivity of the SAQ, with a ceiling effect evident in some subscales. The data collected may potentially be limited by the length of interviews. There was no baseline HRQOL measurement pre-PPCI for comparison as urgent PPCI precluded this assessment.

4.2. Implications for practice

In clinical practice, nursing care is often protocol-based, focused on PCI procedural care such as access site and symptom management. Health related quality of life is not routinely assessed despite higher comorbidity risks and frailty in older people (Gharacholou et al., 2012a; Moore et al., 2006; Singh et al., 2011) and they often lack equitable treatment also achievable by older people for physical health, mental health and anginal status comparable to younger people during PCI recovery (Ho et al., 2008; Li et al., 2012; Spertus et al., 2004). Our results support a comprehensive approach to PPCI care incorporating physiological and psychological aspects of recovery, particularly with fast-track field triage pathways, where research is lacking for older people. Apart from measurable outcomes such as cost and MACE, there is a need for nursing-sensitive PCI care (Leeper, 2004) and improved monitoring standards for PCI nursing practice (Rolley, Davidson, Salamonson, Fernandez, & Dennison, 2009). Current clinical guidelines for post-PPCI care are inconsistent for in-hospital and discharge support aspects such as cardiac rehabilitation. Future research should include HRQOL evaluation in order to address specific needs identified by older STEMI patients whose expectations of recovery differ from younger cohorts.

5. Conclusion

Age is an important factor to consider in relation to physical function recovery following PPCI for STEMI. Length of hospitalization, age, number of stents, gender and partnership status are significant independent predictors of HRQOL outcomes over time. With increased PPCI in an ageing population and higher quality of life expectancy, HRQOL measurement constitutes an integral part of health status assessment and clinical care improvement. Further research should focus on enhancing physical activity, reducing hospitalization time and providing additional support particularly for older people following PPCI during the transition to full recovery.

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Appendix 20: Publication - Chapter 3

Nursing & Health Sciences

Nursing and Health Sciences (2014), **16**, 415–427

Review Article

Systematic review of health-related quality of life in older people following percutaneous coronary intervention

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Abstract People aged over 60 years represent an increasingly high proportion of the population undergoing percutaneous coronary intervention. While risks are greater for older people in terms of major adverse cardiovascular events and higher mortality for this treatment, it is unclear if the benefits of health-related quality of life outcomes may outweigh risks. A search of the PubMed, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Excerpta Medica, and Cochrane databases was conducted for the period from January 1999 to June 2012 using key words "percutaneous coronary intervention"/"angioplasty," "older," "elderly," and "quality of life"/"health-related quality of life." Using a systematic review approach, data from 18 studies were extracted for description and synthesis. Findings revealed that everyone regardless of age reported better health-related quality of life, primarily from the relief of angina and improved physical and mental function. Age itself did not have an independent predictive effect when other factors such as comorbid conditions were taken into account. Assessment of older peoples' health status following percutaneous coronary intervention by nurses and other health professionals is therefore important for the provision of quality care.

Key words angioplasty transluminal, health-related quality of life, percutaneous coronary intervention, person, quality of life.

INTRODUCTION

The number of older people undergoing percutaneous coronary intervention (PCI) for coronary artery disease is increasing, partly due to an aging population. While there is evidence that older people have more major adverse cardiovascular events (MACE) following PCI, it is less clear if age has an impact on other important health outcomes such as health-related quality of life (HRQOL).

By 2025, it is projected that approximately 1.2 billion people will be aged over 60 years (World Health Organization, 2002). As age increases so does the risk of cardiovascular disease and therefore the use of treatments such as PCI. The goal of PCI is to relieve angina, decrease morbidity/mortality, and improve HRQOL. Emergency or primary PCI for ST-elevation myocardial infarction (STEMI) is associated with higher survival rates (Carstensen *et al.*, 2007; Vermeulen *et al.*, 2008; Zanini *et al.*, 2008; Terkelsen *et al.*, 2009), better left ventricular function (Sivagangabalan *et al.*, 2009), and smaller infarction size (Postma *et al.*, 2011). Percutaneous coronary intervention can also be performed as an elective procedure for stable angina patients with symptomatic activity limitations despite optimal medical therapy.

Higher morbidity is reported for older people after PCI in comparison to younger groups, with more incidences of strokes, major bleeding, re-infarction, recurrent angina (Sakai *et al.*, 2002), and longer hospitalization (Batchelor *et al.*, 2000, Sukiennik *et al.*, 2007). While age-related comorbidities are likely contributors, advanced age itself is an independent predictor of death and worse clinical outcomes for PCI (Batchelor *et al.*, 2000; Chauhan *et al.*, 2001; Floyd *et al.*, 2006; Wenaweser *et al.*, 2007). However, it is not clear if the benefits of improved symptoms and HRQOL outweigh these risks.

The main factors affecting HRQOL after PCI are predominantly age (Bengtsson *et al.*, 2001; Dias *et al.*, 2005) and anginal frequency (Longmore *et al.*, 2011). Controversy remains, however, over the degree of anginal benefit for patients older than 60 years. While earlier studies reported substantial anginal relief with PCI (Boden *et al.*, 2007; Weintraub *et al.*, 2008), a recent meta-analysis (Wijeysundera *et al.*, 2010) comparing PCI with medical therapy for stable angina found little angina benefit (Teo *et al.*, 2009). Older patients experience more recurrent angina resulting in repeat PCI (Spertus *et al.*, 2005).

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The impact of PCI on HRQOL is an important indicator of treatment effectiveness from the patient perspective and incorporation of measurements of HRQOL are recommended by key organisations including the American Heart Association (Rumsfeld *et al*., 2013). Treatments can affect multiple areas such as physical, mental, and social health of a person's life differently, therefore measurements of global health dimensions are important for an aging population (World Health Organisation, 2002). As many patients with cardiovascular disease have comorbidities, assessment may be best achieved by using both generic and disease-specific HRQOL measures. Disease-specific measures are more likely to capture the effects of specific symptoms attributable to the condition, such as the frequency and intensity of angina in PCI (Spertus *et al*., 2004). While PCI rates and use of improved stent technology have increased over the past decade, assessment of HRQOL in relation to age remains underresearched.

AIMS AND METHODS

Aims

The aim of this systematic review was to examine and synthesize study findings on the effect of age on HRQOL following elective and primary PCI, framed by the question: What is the effect of age on HRQOL following elective or emergency primary PCI for acute coronary syndromes and stable angina?

Methods

A systematic review was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) approach (Liberati *et al*., 2009; Moher *et al*., 2009) to provide a comprehensive appraisal of studies examining the effect of age on HRQOL in people treated with PCI. The PRISMA checklist identifies the type of review, rationale, and objectives, including risk of bias within each study and limitations or strengths in the summation of findings. Different phases of the review process from identification of studies, screening, eligibility, and inclusion of studies was illustrated by the PRISMA flow diagram (Fig. 1). This framework highlights a systematic process for searching and selecting relevant studies, extracting and synthesizing data, and critically appraising their methodological quality.

Literature search

The bibliographic databases PubMed, Cumulative Index to Nursing and Allied Health Literature, Cochrane Database of Systematic Reviews, PsycINFO, and Excerpta Medica were searched using the terms "percutaneous coronary intervention," "angioplasty transluminal," "quality of life," and "health-related quality of life," both separately and in combination with related keywords such as "older," "elderly," and then the terms "psychological," "anxiety," "emotions," and "depression" were added. The publication period was limited to January 1999 to June 2012 and only English language papers were included. The publication period was chosen to focus on contemporary systems and methods of PCI, including primary and early triage processes and minimal length of stay, processes that began in the late 1990s and potentially could impact on HRQOL.

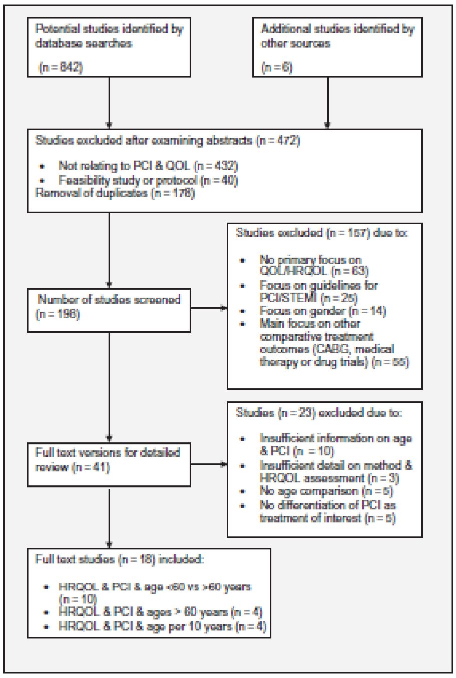

Figure 1. PRISMA Flow diagram of selection process.

Abstracts of identified studies from the search were initially assessed for content, then full-text versions were retrieved for detailed assessment. Reference lists of published studies were also examined for relevant studies. Following assessment of abstracts and exclusion of studies that did not meet the inclusion criteria, including the removal of duplicate papers, 41 full-text papers were identified and independently assessed by two authors (SH and RG). Eighteen relevant studies were finally retained for review (Fig. 1) with justification for excluding studies.

Inclusion and exclusion criteria

All studies on PCI (elective and primary PCI) based on a quantitative descriptive or randomized controlled trial design with follow-up to 12 months and using a validated

Table 1. Risk of bias assessment summary

Studies	Design	Adequate sequence generation	Allocation concealment	Blinding	Incomplete outcome data addressed	Free of selective outcome reporting	Free of other biases	Non-RCTs measures taken to minimize bias
Nash *et al.* (1999)	Descriptive cohort	NA	NA	NA	✓	✓	✓	x
Kahler *et al.* (1999)	Descriptive cohort	NA	NA	NA	x	x	x	x
Seto *et al.* (2000)	RCT substudy	?	?	x	✓	x	x	NA
Pocock *et al.* (2000)	RCT substudy	✓	?	x	✓	✓	x	NA
Jamieson *et al.* (2002)	Descriptive cohort	NA	NA	NA	x	x	?	x
Rumsfeld *et al.* (2003)	RCT	x	x	x	x	x	x	NA
Spertus *et al.* (2004)	Descriptive cohort	NA	NA	NA	✓	✓	✓	✓
Zhang *et al.* (2006)	RCT substudy	x	x	x	x	x	x	NA
Graham *et al.* (2006)	Descriptive cohort	NA	NA	NA	x	x	x	✓
Moore *et al.* (2006)	Descriptive cohort	NA	NA	NA	x	x	x	x
Gunal *et al.* (2008)	Descriptive cohort	NA	NA	NA	x	x	x	x
Ho *et al.* (2008)	Descriptive cohort	NA	NA	NA	✓	✓	x	✓
Agarwal *et al.* (2009)	Descriptive cohort	NA	NA	NA	x	x	x	x
Shah *et al.* (2009)	Descriptive cohort	NA	NA	NA	x	x	x	x
Melberg *et al.* (2010)	RCT	✓	✓	x	✓	✓	?	NA
Weintraub *et al.* (2008)	RCT substudy	✓	x	x	✓	✓	x	NA
Li *et al.* (2012)	Descriptive cohort	NA	NA	NA	✓	✓	?	✓
Gharacholou *et al.* (2012)	Descriptive cohort	NA	NA	NA	x	✓	x	✓

✓, Low risk of bias; ?, unclear; NA, not applicable (for descriptive studies); x, high risk of bias; RCT, randomized controlled trials.

instrument for measuring HRQOL in older people (aged 60 plus years) were included. The exclusion criteria was studies not published in English, research dissertations, gender studies, conference proceedings, and brief reports which did not distinguish PCI results for older people.

Quality appraisal

Quality appraisal reflected the Clinical Appraisal Skills Program (CASP) guide for critically appraising the literature (Critical Appraisal Skills Program, 2010). The CASP tool utilizes 10 questions to screen for validity, quality, design, precision of results, benefits, and relevance to different clinical settings in studies and systematic reviews (Oxman *et al.*, 1994). For judging risk of bias the Cochrane Collaboration criteria were applied (Table 1). Two authors (SH and RG) then reviewed each study independently. Review opinion from a third author (DE) was sought for final verification.

Data evaluation, extraction, and synthesis

Data were extracted by the principal reviewer and validated by a co-reviewer using a data extraction form. Data elements were sample size and characteristics, study method, setting, country in which study was conducted, age categories, treatment comparison with PCI, HRQOL follow-up time, method, and drop-out rate. Each study was systemically examined for score differences between baseline HRQOL and post-PCI using age > 60 years to differentiate "older." This corresponds to the classification of "older " people described by the World Health Organization in their Active Ageing Policy Framework (World Health Organisation, 2002). Age groupings and classifications varied across studies, so the classifications used by the study were reported but older people's HRQOL outcomes were examined for better or worse scores and whether age was identified as an independent predictor of HRQOL. While recovery trajectories may differ, emergency (including urgent and acute) and elective PCI admissions were treated as one homogeneous PCI group for HRQOL comparisons by age. Individual studies were not designed and therefore lack power to evaluate pooled HRQOL differences after PCI by time and age criteria. Extracted data and study characteristics are shown in Table 2 and synthesized summary results in Table 3.

RESULTS

The search process is illustrated by a flow diagram for clarity (Fig. 1). Eighteen studies were reviewed – six randomized controlled trials (RCTs), four of which were secondary analyses, and 12 descriptive studies. Study characteristics are summarized and synthesized in Table 2. Studies were conducted primarily in North America (USA $n = 8$, Canada $n = 1$, USA and Canada $n = 1$) the UK ($n = 3$), Europe (one each for The Netherlands, Germany, and Norway), China ($n = 1$), and UK, Europe, and Canada ($n = 1$). The total sample size of studies reviewed was 29 917 with PCI-specific samples varying considerably from 68 to 3726.

Participant characteristics

Participant ages were provided as either mean or medians; mean participant ages ranged from 43.2 to 83 years (SD 2.8–3.0), while four studies only cited median ages which ranged from 58.4 to 88 years (interquartile range 51.6–67.0). Four studies purposefully recruited octogenarians (Kahler *et al.*,

Table 2. Studies on HRQOL following PCI for age comparison

Reference and country of study	Design and aim	Sample characteristics	Survey characteristics	Results†
Nash *et al.* (1999) USA	Descriptive Cohort Comparison of HRQOL (physical and mental health components) after PCI	*n* = 1182 PCI: 100% (PTCA) Elective PCI Age: mean (62–63 years) Males: 68–72% Attrition: NR	Measures: SF-36 Timing: baseline and 6 months Administration: self-administered admission survey (baseline) and follow-up surveys by mail Analysis: multiple regression	Comparison between baseline and 6 months for physical and mental health status Baseline: SF-36: PCS (36.6), MCS (48.5) 6 months: SF-36 PCS (43 vs 36.6), MCS (50 vs 48.5) *P* < 0.0001 Significant predictors: age not a predictor.
Kahler *et al.* (1999) Germany	Descriptive Cohort Comparison of quality of life and costs after coronary angioplasty for octogenarians (> 80 *vs* < 80 years)	*n* = 68 PCI: 100% (PTCA) Elective PCI (50% > 80 years) Age: mean 83 years (range 80–89) 62 years (range 52–79) Males: 71% Attrition: NR	Measures: SF-36 Timing: baseline and 6 months Administration: face-to-face interviews post-PCI Analysis: descriptive statistics	Comparison for < 80 vs ≥ 80 years Baseline: SF-36: PCS (NR) MCS (NR); PF (42 vs 59, *P* = NR), RP (29 vs 26, *P* = NR), BP (44 vs 40, *P* = NR), GH (45 vs 50, *P* = NR), VT (50 vs 45, *P* = NR), SF (78 vs 70, *P* = NR), RE (90 vs 70, *P* = NR), MH (73 vs 69, *P* = NR) 6 months: SF-36 PF (2 vs 4), RP (112 vs 70, *P* = 0.045), BP (71 vs 42, *P* < 0.05), GH (−6 vs −8, *P* = NR), VT (2 vs 4, *P* = NR), SF (−3 vs 18, *P* = NR), RE (−12 vs 18, *P* = NR), MH (- vs 69, *P* = NR) Significant predictors: NA
Seto *et al.* (2000) USA	RCT (BOAT and ASCENT Trial Substudy) Comparison of HRQOL and angina symptoms after PCI for age (< 70 vs ≥ 70 years)	*n* = 1445 PCI: 100% Elective PCI (20% > 70 years) Age: median (range): < 70–57 years (38–69) > 70–74 years (70–89) Males: NR Attrition: 20% (at 6 months)	Measures: SF-36 (MCID PCS > 3.8 points, MCS > 7.2 points); SAQ (MCID > 10 points) Timing: baseline, 6 months, 1year Administration: self-administered in-hospital (baseline), mail and telephone interview at follow-up Analysis: multiple regression	Comparison for < 70 vs ≥ 70 years Baseline: SF-36: PCS (40.1 vs 36.0), MCS (49.0 vs 50.6); SAQ: PF (66.7 vs 61.1), AF (60.0 vs 60.0), DB (41.7 vs 41.7). No significant differences between age group 6 months: SF-36 PCS (50.6 vs 44.6), MCS (53.1 vs 54.9) *P* = NR; SAQ: PF (91.7 vs 81.9), AF (100 vs 100), DB (75.0 vs 83.3), *P* = NR. Significant improvements in all domains from baseline. No significant differences for age group 1 year: SF-36: PCS (51.4 vs 45.0), MCS (54.3 vs 54.8); SAQ: PF (91.7 vs 81.9), AF (100 vs 100), DB (83.3 vs 83.3) Significant predictors: age not a predictor.
Pocock *et al.* (2000) UK	RCT (RITA-2 Trial) substudy Comparison of PTCA with medical treatment on HRQOL in stable angina (age per 10 years)	*n* = 504 PCI: 49.5% (PTCA) Elective PCI Age: per 10 year groups = NR Males: NR Attrition: 2% (at 1 year); 33% (by 3 years)	Measures: SF-36 (scores from 0–100) Timing: baseline, 3 months, 1 year and 3 years (NR) Administration: telephone interview at baseline and at follow-up Analysis: multiple regression	Comparison between treatments Baseline: SF-36: PF 68, V 54, GH 61, RP 45, RE 63, MH 69, BP 62, SF 74 3 month: SF-36 PF 75, V 59, GH 64, RP 58, RE 70, MH 74, BP 69, SF 78 1 year: SF-36: PF 75, V 59, GH 64, RP 65, RE 75 MG 75, BP 70, SF 81 Significant predictors: variable (beta value) Baseline: SF: breathlessness (−5.53), angina (−3.53), exercise capacity (2.11), number of antianginal drugs (−1.62), female (−7.99), age per 10 years (1.57); V: breathlessness (−4.2), angina (−2.8), exercise capacity (0.58), number of antianginal drugs (−1.73), female (−5.72); GH: breathlessness (−3.65), angina (−3.15), exercise capacity (1.23), number of antianginal drugs (−1.54), female (3.32), age per 10 years (4.24) One year: SF: breathlessness (−3.87), angina (−3.05), exercise capacity (1.62), number of antianginal drugs (−3.4), baseline score (0.35); V: breathlessness (−2.8), angina (−3.14), exercise capacity (0.87), age per 10 years (2.13), baseline score (0.47); GH: breathlessness (−2.10), angina (−2.59), exercise capacity (0.97), number of antianginal drugs (−2.55), age per 10 years (1.38), baseline score (0.55)
Jamieson *et al.* (2002) USA	Descriptive Cohort Evaluation of effects of age, gender, type of procedure, risk stratification and comorbidity on HRQOL following cardiac rehabilitation for CABG and PTCA patients with angina and AMI (< 65 and ≥ 65 years)	*n* = 301 PCI: 37.9% (PTCA) Elective PCI Age: mean 63.3, SD 11 years Males: 72% Attrition: NR	Measures: SF-36 (compared with USA population norms) Timing: baseline and 3 months Administration: self-administered pre-and post-intervention Analysis: linear regression	Comparison for <65 vs >65 years Baseline: (pre-cardiac rehabilitation) SF-36: PF (50.7 vs 44.5, *P* < 0.001), RP (12.6 vs 13.0, *P* < 0.001), BP (53.4 vs 72.3, *P* < 0.001), GH (64.1 vs 62.5, *P* = NR), V (42.0 vs 37.0, *P* < 0.001), SF (58.5 vs 50.3), RE (46.8 vs 45.8, *P* < 0.05), MH (69.2 vs 69.6, *P* > 0.05) 3 months: (post-cardiac rehabilitation compared by age) SF-36: PF (74.3 vs 69.5, *P* = NR), RP (52.5 vs 47.7, *P* < 0.001), BP (70.2 vs 71.0, *P* = NR), GH (66.5 vs 64.1, *P* = NR), V (60.0 vs 54.5, *P* < 0.05), SF (82.1 vs 80.8, *P* = NR), RE (72.1 vs 73.3, *P* < 0.05), MH (76.4 vs 77.8, *P* = NR) Significant predictors: (beta value); SF age > 65 years (−0.4), RP age > 65 years (−0.5), baseline PF score (44.5) and RP (13.0). No age effect on other subscales.

Rumsfeld *et al.* (2003) USA	RCT (AWESOME Study) Comparison of HRQOL between PCI and CABG for stable angina in Veteran Affairs patients (< 70 vs > 70 years)	*n* = 389 PCI: 49.6% Elective PCI Age: PCI only, mean 67.6, SD 9.3 years Males: PCI only: 99% Attrition: 8% (at 6 months)	Measures: SF-36 (PCS and MCS: MCID > 4–7 points change) Timing: 6 months Administration: mail and telephone back-up Analysis: linear regression	Comparison between treatments Baseline: NR 6 months: SF-36: PCS 38.7, MCS 45.5. (mean) Significant predictors: Co-morbidity, COPD, diabetes, smoking, elevated creatinine and hypertension. Age not a predictor. Beta values NR
Spertus *et al.* (2004) USA	Descriptive Cohort Investigation of predictors of QOL benefit with PCI for symptomatic angina (age per 10 years)	*n* = 1518 PCI: 100% Elective PCI Age: mean (SD): 66 (11) years Males: 69% Attrition: 31% (at 1 year)	Measures: SAQ (MCID ≥ 10 points change) Timing: baseline, 1 year Administration: telephone interview Analysis: logistic regression	Comparisons for all ages Baseline: SAQ: PL 69, AF 68, QOL 56 1 year: (compared to baseline by ±SE points) SAQ: AF (monthly, weekly and daily angina) improved (20.0 ± 2.4, 28.3 ± 2.5 and 32.0 ± 3.2, $P < 0.001$); SF (mild, moderate and severe) improved with PCI (7.8 ± 2.0, 12.8 ± 2.2 and 4.7 ± 3.6, $P < 0.001$) Overall PL 18 ± 25, AF 24 ± 28, QOL 30 ± 26, $P < 0.001$ Significant predictors: age, physical function and baseline angina frequency. age a predictor by 10-year increments (2.0 ± 0.7, $P < 0.01$)
Zhang *et al.* (2006) UK, Europe, Canada	RCT (SoS Trial, substudy) Comparison of age-related differences in HRQOL between PCI and CABG for symptomatic angina (including ACS) (< 65 vs > 65 years)	*n* = 988 PCI: 49.3% Elective PCI Age: mean (SD) : 55.5 (6.6) to 70.4 (3.8) years Males: PCI only overall range 71.6–85.2% Attrition: 1.6% (at 1 year) Missing data (up to 11.3%) of sample	Measures: SAQ (MCID 5–8 points) Timing: baseline, 6 and 1 year Administration: NR Analysis: multivariable analysis	Comparisons for < 65 vs > 65 years Baseline: *SAQ: PL (48.8 vs 45.1, NR), AS (46.6 vs 46.1, NR), AF (50.6 vs 49.1, NR), TS (83.7 vs 83.8, NR), QOL (34.5 vs 39.1, $P = 0.001$) 6 months (compared to baseline by age groups) SAQ: PL (4.3 vs 6.8, $P < 0.001$), AS NR, AF (21.4 vs 26.8, $P < 0.001$), TS NR, QOL (19.9 vs 25.5, $P < 0.001$) 1 year (compared to baseline by age) SAQ: PL (4.5 vs 7.5, $P < 0.001$), AS NR, AF (24.1 vs 29.7, $P < 0.001$), TS NR, QOL (23.5 vs 30.7, $P < 0.001$) Significant predictors: age not a predictor.
Graham *et al.* (2006) Canada	Descriptive (APPROACH Registry) Comparison of QOL after PCI or CABG with medical therapy in stable and unstable angina and AMI (< 70 vs 70–79 *vs* ≥ 80 years)	*n* = 16, 525 PCI: 22.1% Elective and emergency PCI Age: PCI group < 70 years, 70–90 and ≥ 80 years, mean: 59.1, 73.9, 82.1 Males: PCI group overall range 56–78% Attrition: 32% (at 1 year)	Measures: SAQ Timing: 1 year, 3 and 5 years Administration: Mail and telephone follow-up Analysis: linear regression Note: 3 year and 5 year follow-up results not cited in this review	Comparisons for < 70 vs 70–79 vs ≥ 80 years Baseline: NR 1 year: SAQ: EC (74.9 vs 63.2 vs 51.9), AS (76.7 vs 78.2 vs 74.7, $P < 0.001$), AF (85.4 vs 84.0 vs 79.3), QOL (72.5 vs 75.8 vs 72.9), TS (85.5 vs 87.1 vs 88.0) Significant predictors: age not a predictor.
Moore *et al.* (2006) UK	Descriptive Cohort Comparison of effect of age on HRQOL after PCI for stable coronary artery disease (<60 *vs* 60–70 *vs* > 70 years)	*n* = 105 PCI: 100% Elective PCI Age: mean 76, SD 5 years Males: 73% Attrition: 5% (at 1 year)	Measures: SF-12 and SAQ (SF-12 PCS and MCS: score of 50 represents UK population norm; 10-point change = 1 SD) Timing: 1 year Administration: NR Analysis: multiple regression	Comparisons for ages < 60 vs 60–70 vs > 70 years Baseline: NR 1 year: SF-12: PCS (7.8 p0.023 vs 4.0, p0.0435 vs 4.9,, p0.047), MCS (6.2 p0.002 vs 3.9 p0.026 vs 4.1, p0.001); SAQ: PL (19.7 p0.001 vs 12.0, p0.003 vs 10.0, p0.004), AS (29.8 p0.001 vs 12.5, NS vs 16.1, p0.001), AF (22.3 p0.001 vs 10.5 *P* 0.049, vs 16.3 $P < 0.001$), TS (10.9 vs 4.3 vs 4.1 NR), QOL (35.8 $P < 0.001$ vs 5.7p < 0.001 vs 24.4, $P < 0.001$) Significant predictors: age not a predictor.
Gunal *et al.* (2008) Netherlands	Descriptive Cohort Investigation of QOL after PCI for octogenarians with coronary artery disease and AMI (≥ 80 years)	*n* = 98 PCI: 100% 36% acute PCI, 64% elective PCI Age: mean 82.7, SD 2.9 years Males: 40% Attrition: 9% (at 1 year)	Measures: RAND-36 (SF-36) Dutch version Timing: 1 year Administration: questionnaire survey plus additional questions (process NR) Analysis: descriptive methods	Comparison with Dutch population norm for ≥ 80 years Baseline: NR 1 year: (compared to population norm) RAND-36: PF 41, (28) vs 43 (29) NR, RP 32, (37) vs 39 (41) NR, BP 69, (28) vs 60 (29) NR, GH 50, (18) vs 53 (22) NR, V (55, (20) vs 53 (27) NR, SF (67 (26) vs 66 (32) NR, RE (66 (42) vs 63 (44) NR, MH (70 (21) vs 67 (24) NR Significant predictors: NR

Table 2. Continued

Reference and country of study	Design and aim	Sample characteristics	Survey characteristics	Results†
Ho *et al.* (2008) USA	Descriptive Cohort (PREMIER Study) Comparison of the effect of age on HRQOL after AMI for the groups < 50, 50–< 65, 65 < 75, ≥ 75 years	n = 2498 PCI: 56–66.4% Acute PCI Age: mean 43.2 to 80.5, SD 2.8–5.2 years Males: range 53–76% Attrition: 1.8% for ≥ 75 years to 22.9% for < 50 years (at 1 year)	Measures: SAQ (MCID > 5 points score change) Timing: baseline, 1, 6 and 12 months Administration: telephone Analysis: multivariable/repeated measures Note: scores derived from graph illustration	Comparisons for ages < 50 vs 50–<60 vs 65–< 75 vs ≥ 75 years Baseline: SAQ: QOL 58.8 vs 60.5 vs 64.3 vs 67 (P < 0.0001, when adjusted for baseline differences) 1 year: SAQ: QOL 80 vs 82.5 vs 88.1 vs 89.1 (P < .001 when adjusted for baseline differences). Change in QOL between baseline and 1 year significantly different for age group Significant predictors: increasing age associated with better HRQOL at 1 year. Beta values NR
Weintraub *et al.* (2008) USA, Canada	RCT (COURAGE Trial) substudy Comparison of effect of PCI (with optimal medical therapy) to optimal medical therapy on QOL in stable angina (< 65 vs ≥ 65 years)	n = 2, 287 PCI (plus optimal medical group): 50% Elective PCI Age: NR Males: NR Attrition: NR	Measures: SAQ (MCID > 8 points) and RAND-36 (MCID > 10 points) Timing: baseline, 1, 3, 6 and 1 year, 2 and 3 years Administration: self-administered Analysis: linear regression/repeated measures ANOVA Scores: derived from graph illustration	Comparison for ages < 65 vs ≥ 65 year Baseline: SAQ: PL 66, (25), AS 54, (33), AF 68, (26), TS 88, (15), QOL 51, (25), RAND-36: PF (58), PL (38), EL (58), V (48), E (70), SF (70), BP (62), GH (58) 1 month: (compared to baseline by treatment groups) SAQ: PL 73 (24), P 0.003, AS 81 (26), P< 0.001, AF 82 (23), P< 0.001, TS 92 (12), P 0.001, QOL 68 (24), p0.00, RAND-36: PF 66, PL 62, EL 62, V 52, E 72, SF 75, BP 68, GH 62, P < 0.01. For all subscales; P < 0.001 3 months: (compared to baseline by treatment groups) SAQ: PL 76 (24), P 0.004, AS 77 (28), P< 0.002, AF 85 (22), TS 92 (12), P0.001, QOL 73 (22), RAND-36: PF 76, P PL 62, E 62, V 52, E 72, SF 75, BP 72,, GH 63. For all subscales; P< 0.001 6 months: (compared with baseline by treatment groups) SAQ: PL 77 (23), P< 0.001, AS 76, (28), p0.02, AF 87 (27) (26), p0.001, TS 92 (13), P 0.007, QOL 5 (22), P 0.001, RAND-36: PF 70, PL 63, E 62, V 5, E 71, SF 75, BP 71, GH 62, P< 0.001 For all subscales P< 0.001 1 year: (compared baseline by treatment groups) SAQ: PL 75 (24), P < 0.21, AS 74 (27), P 0.02, AF 87 (20) P < 0.003, TS 92 (12), p0.002), QOL 76 (21), P 0.008, RAND-36: PF 70, PL 64, EL 72, V 50, E 71, SF 75, BP 72, GH 62, P < 0.001. For all subscales, P< 0.001 Significant predictors: age not a predictor. Other predictors are physical limitation and anginal frequency
Agarwal *et al.* (2009) UK	Descriptive Cohort Assessment of functional status and QOL after PCI in octogenarians with ACS (≥ 80 years)	n = 74 PCI: 100% Emergency and elective PCI Age: mean 82.5, SD 2.1 years Males: 68% Attrition: NR	Measures: SF-36 and SAQ (SF-36 compared with USA population norms; subscales with UK normative data) Timing: baseline, 6 months and 1 year Administration: NR Analysis: NR	Comparison with USA population norm for ≥ 80 years Baseline: SF-36: PCS 31, MCS 44.6, PF 32.3, RP 7.9, BP 40.1, GH 49.2, V 34, SF 53.1, RE 35.8, MH 67.1; SAQ: PL 24.4, AS 50.0, AF 45.8, TS 74.3, DP/QOL 38.8 6 months: (compared to baseline) SF-36: PCS (47.0 P< 0.05), MCS (58.0 P< 0.05); SF 44.5, RP 33.8, BP 61.6, GH 50.1, V42.7, SF 72.0 RE 57.3, MH 71.0; SAQ: PL 42.3, AS 72.4, AF 76.5, TS 83.7, DP/QOL 66.7 1 year: (compared to baseline) SF-36: PCS 46.2, P< 0.05, MCS 57.6, P< 0.05; SF 42.3, RP 38.7, BP 58.4, GH 47.7, V 40.1, SF 68.0, RE 62.3, MH 70.1; SAQ: PL 41.4, AS 66.3, AF 73.5, TS 83.7, DB 62.3 Significant predictors: age not a predictor
Shah *et al.* (2009) USA	Descriptive cohort Evaluation of QOL and health outcomes of primary PCI for STEMI's ≥ 85 years (≥ 85 years)	n = 73 PCI: 70% Emergency and elective PCI Age: median 88 years (85–94) Males: 38% Attrition: 43.8% (at 1.1 years)	Measures: EQ-5D EQ-VAS (compared with US population-based survey of elderly ≥ 85 years) Timing: median 429 days (1.1 years) Administration: telephone and mail Analysis: logistic regression	Comparison with US population-based survey of elderly Baseline: NR 1 year: EQ-5D: 0.78 (0.04) vs 0.72 (0.01); EQ-VAS: 70.5 (4.5) vs 64.6 (1.4) Significant predictors: age not a predictor.

Melberg *et al.* (2010) Norway	RCT Comparison of HRQOL after PCI at a hospital with and without on-site surgical back-up for stable coronary artery disease and ACS (age per 10 years)	$n = 609$ PCI: 98.2% Elective PCI Age: median 58.4 years (51.6–67) Males: 79.7% Attrition: 38–24% (at 6 months)	Measures: SF-36 (Norwegian version) Timing: baseline and 6 months Administration: self-administered Analyses: linear regression	Comparison between treatment sites Baseline: SF-36: PCS 37.0 (9.0), MCS 45.1 (10.9); SF 62.8, RP 68.8, RE 40.9, BP 59.0, SF 72.7, MH 73, V 47.7, GH 64.3 6 months: (compared to baseline by treatment groups) SF-36: PCS 44.5 vs 43.5 NR, MCS 48.5 vs 48.0 NR; SF 79.7 vs 77.4 NR, RP 76.6 vs 81.8 NR, RE 63.3 vs 64.7 NR, BP 74.6 vs 71.4 NR, SF 72.7 vs 81.1 NR, MH 75.5 vs 76.3 NR, V 57.1 vs 57.1 NS, GH 66.6 vs 63.1 NR Significant predictors: age not a predictor Baseline: (beta values) PF: angina grade (−3.7), anginal drugs (−3.1), prior AMI (5.8), BMI (−0.8), RP, none, BP, anginal drugs (−3.4), prior AMI (9.5) 6 month: (beta values) PF: gender (−6.8), angina grade (−3.8), BMI (1.0), exercise capacity (2.5), baseline score (0.3), RP, angina grade (−7.7), BP, gender (−7.2), BMI (−4.0), exercise capacity (2.1), baseline score (0.2)
Li *et al.* (2012) China	Descriptive Cohort Comparison of HRQOL outcomes for PCI and medical therapy in ACS (< 60 vs 60–79 vs ≥ 80 years)	$n = 624$ PCI: 45.9% Elective PCI Age: mean 64, SD 11 years Males: 73.8% Attrition: 20% (at 6 months)	Measures: SF-36 (Chinese version) Timing: baseline and 6 months Administration: questionnaire and telephone interviews Analysis: logistic regression	Comparisons for ages <60 years, 60–70 and ≥ 80 years Baseline: SF-36: PCS 39 (13) vs 29 (15) NS 80 vs 22 (9) P = all NR, MCS 50 (12) NS vs 52 (12) NS vs 51 (12) P = all NR, PF 78 vs 64 vs 51 NR, BP 51 vs 45 vs 37, $P < 0.06$, RP 58 vs 44 vs 43 NR, GH 47 vs 48 vs 46 NR 6 months: (compared to baseline and between age groups) SF-36 PCS 46 (11) vs 41 (14) vs 40, p0.01 (11), $P < 0.02$ vs, 17 (9), $P < 0.01$ unadjusted, MCS 51 (10) vs 54 (10) vs 55 (13) P = NR, PF 86 vs 73 vs 65, $P < 0.01$, BP 75 vs 76 vs 84, P = NR, RP 72 vs 72 vs 66, P = NR, GH 52 vs 65 vs 63, P = NR, RE 75 vs 80 vs 85, P = NR, SF 83 vs 81 vs 79, P = NR, MH 75 vs 73 vs 78, P = NR, vitality 66 vs 66 vs 60, P = NR, PCI (OR = 1.79, 95% CI: 1.01–4.15), age per 10 years increase (OR = 1.27, 95% CI: 1.02–1.57) Significant predictors: Age a predictor (per 10 years increase). Other predictor is PCI
Gharacholou *et al.* (2012) USA	Descriptive Cohort Comparison of health status outcomes for frail and nonfrail patients > 65 years after PCI (age per 10 years)	$n = 629$ PCI: 100% Elective PCI: 35 %; emergency PCI: 18%; urgent PCI: 47% Age: frail (mean 77 years); intermediate frail (mean 75 years); not frail (mean 73 years) Males: 69% Attrition: 13% (at 30 days)	Measures: SF-36 and SAQ (SF-36 scores compared with USA population norms; SAQ MCID> 5 points) Timing: baseline and 30 days Administration: NR Analysis: linear regression	Comparison between frail and non-frail stratification Baseline: SF-36: PCS 29.0 vs 37.0 vs 42.9, $P < 0.001$, MCS 48.8 vs 52.3 vs 55.6, $P < 0.001$; SAQ: PL 59.5 vs 70.2 vs 77.6, $P < 0.001$ QOL 55.1 vs 59.7 vs 63.0, $P < 0.001$ 3 months SF-36: PCS-11.9, 95% CI −14.4, vs −9.6, $P < 0.001$, MCS −8.2, 95% CI −10.6 vs 5.8, $P < 0.001$; SAQ: PL −18.0 95% CI 23.1 vs −12.9, $P < 0.001$ QOL −9.0, 95% CI vs −15.5 vs −2.6, $P < 0.001$ Significant predictors: age not a predictor

†Mean (SD) for all scores unless otherwise stated. NA, not assessed; NR, not reported; PF, physical function; V, vitality; GH, general health; RP, role physical; RE, role emotional; MH, mental health; BP, bodily pain; SF, social function.

Table 3. Summary table of HRQOL score changes for PCI studies at 6 months and 1 year using SAQ and SF36/SF-12

Study (first author)	HRQOL follow-up 6 months	1 years	SF-36/SF12 PCS	MCS	Physical function (%)	SAQ Angina frequency (%)	Angina stability (%)	Disease burden/QOL (%)	↑ = better ↓ = worse	Age a predictor	Compared to baseline (↑ = better/↓ = Worse)
Nash	✓		↑6.4	↑1.5	–	–	–	–	–	No	↑
Kahler	✓		↑32	–	–	–	–	–	–	No	↑
Seto	✓		↑7	↑1	↑4	↑1	–	↑6	–	No	↑
		✓	↑9	↑4	↑21	↑40	–	↑42	–		
Pocock		✓	–	–	–	–	–	–	–	Yes	↑
Jamieson	✓3		↑25	↑8	–	–	–	–	–	Yes	↑
Rumsfeld	✓		–	–	–	–	–	–	–	No	↑
Spertus		✓	–	–	NS	↑18	↑24	–	↑30	Yes	↑
Zhang	✓	✓	–	–	↑58	↑25	–	↑28	–	No	↑
					↑67	↑23	–	↑31	–		
Shah†		✓	–	–	–	–	–	–	–	No	↑
Graham		✓	–	–	–	↓12	↓1	↑3	↑2	No	↑
Moore		✓	†↑4	†↑4	†↑12	†↑12	†↑10	†↑26	†↑4	No	↑
Gunal		✓	†↑9	†↑3	–	–	–	–	–	No	↑
Ho		✓	–	–	–	–	–	↑13	–	No	↑
Weintraub	✓		–	–	↑11	↑19	↑22	↑24	↑4	No	↑
		✓			↑9	↑19	↑20	↑41	↑4		
Agarwal	✓		↑16	↑13	↑18	↑31	↑20	↑28	↑9	No	↑
		✓	↑11	↑13	↑17	↑28	↑16	↑24	↑9		
Melberg	✓		↑7	↑3	–	–	–	–	–	No	↑
Li	✓	✓	↑4	↓1	–	–	–	–	–	Yes	↑
Gharacholou	✓3 months		↓2	↓2	↓5	–	–	↓7	–	No	↓

†Mean difference in scores at 1 year for > 60 years; –, HRQOL domains not assessed or not stated; EQ-5D and EQ-VAS used.

1999; Gunal *et al.*, 2008; Agarwal *et al.*, 2009; Shah *et al.*, 2009). The proportion of males in the studies varied from 38 to 99% and the mean proportion was 66.7% (SD 14.6) for 15 studies. Three studies did not describe gender composition (Seto *et al.*, 2000; Ho *et al.*, 2008; Weintraub *et al.*, 2008).

Risk of bias assessment

Half of the RCT's and substudies contained adequate sequence allocation (Table 1). Five descriptive cohort studies (28%) adopted measures such as repeated measures analysis, propensity scoring for selection bias, and sensitivity analysis for comparison of HRQOL scores in order to minimize bias (Spertus *et al.*, 2004; Graham *et al.*, 2006; Ho *et al.*, 2008; Gharacholou *et al.*, 2012; Li *et al.*, 2012). Eight studies (44%) addressed incomplete outcome data with an equivalent number free of selective outcome reporting.

Sampling bias is a common problem associated with RCTs and substudies. One-third (33%) of studies (Pocock *et al.*, 2000; Seto *et al.*, 2000; Rumsfeld *et al.*, 2003; Zhang *et al.*, 2006; Weintraub *et al.*, 2008; Melberg *et al.*, 2010) were in this category. Generally, participants in clinical trials tend to have less comorbidities and are therefore not representative of the cohort of interest. Elderly populations are often excluded from invasive treatment based on age, risk factors, and potential complications (Alexander *et al.*, 2006). Other studies showed potential gender bias, with more males comprising the majority of samples (Rumsfeld *et al.*, 2003; Spertus *et al.*, 2004; Graham *et al.*, 2006; Moore *et al.*, 2006; Agarwal *et al.*, 2009; Li *et al.*, 2012). Only two studies (Gunal *et al.*, 2008; Shah *et al.*, 2009) had 60 and 62% females. Four studies (Kahler *et al.*, 1999; Gunal *et al.*, 2008; Agarwal *et al.*, 2009; Shah *et al.*, 2009) on octogenarians comprised the smallest samples (68–98 participants). One possible explanation may be age inclusion criteria resulting in fewer participants being available for recruitment. Higher sample losses of 23–44% were reported by four studies (Spertus *et al.*, 2004; Graham *et al.*, 2006; Shah *et al.*, 2009; Melberg *et al.*, 2010), while others (Kahler *et al.*, 1999; Nash *et al.*, 1999; Jamieson *et al.*, 2002; Weintraub *et al.*, 2008; Agarwal *et al.*, 2009) did not describe participant drop-out rates.

Study designs and comparison of HRQOL with PCI by age

All studies used quantitative designs, of which most were prospective observational studies with two RCTs (Rumsfeld *et al.*, 2003; Melberg *et al.*, 2010) and four RCT substudies (Pocock *et al.*, 2000; Seto *et al.*, 2000; Zhang *et al.*, 2006; Weintraub *et al.*, 2008). The PCI was conducted as an elective procedure for stable and unstable angina and emergency or acute primary PCI for acute myocardial infarction (AMI). The timing of data collection included baseline in 72% of studies, with HRQOL assessed in hospital before or at the time of PCI (Table 3). Only one study (Li *et al.*, 2012) included PCI as baseline within 30 days. Five studies (28%) did not include baseline HRQOL assessment. Follow-up occurred at one year for 61% and six months for 56% (Kahler *et al.*, 1999; Nash *et al.*, 1999; Seto *et al.*, 2000; Rumsfeld *et al.*, 2003; Zhang *et al.*, 2006; Ho *et al.*, 2008; Weintraub *et al.*, 2008; Agarwal *et al.*, 2009; Melberg *et al.*, 2010; Li *et al.*, 2012). Five studies did not compare follow-up to baseline (Rumsfeld *et al.*, 2003; Graham *et al.*, 2006; Moore *et al.*, 2006; Gunal *et al.*, 2008; Shah *et al.*, 2009), and another five used population norms for comparison (Jamieson *et al.*, 2002; Moore *et al.*, 2006; Gunal *et al.*, 2008; Agarwal *et al.*, 2009; Melberg *et al.*, 2010). Attrition over time was reported by the majority of studies, 13 studies that varied from 8 to 38% at 6 months, and at one year, 2–44%. Five studies did not report attrition rates (Kahler *et al.*, 1999; Nash *et al.*, 1999; Jamieson *et al.*, 2002; Weintraub *et al.*, 2008; Agarwal *et al.*, 2009).

All studies used repeated measures for comparing changes in HRQOL over time with the exception of three (Rumsfeld *et al.*, 2003; Gunal *et al.*, 2008; Shah *et al.*, 2009), when HRQOL was measured only once. Regression analyses were used by 83% of studies to determine the independent predictors of HRQOL.

The HRQOL measures

The Short-Form 36 and 12 (SF-36 including RAND-36, SF-12) (Ware & Kosinski, 2001) and the Seattle Angina Questionnaire (SAQ) (Spertus *et al.*, 1995) were the most common HRQOL instruments used (eight and four respectively), with five studies (28%) using both. The EuroQol (EQ-5D) and EuroQol Visual Analog Scale (EQ-VAS) were used in one study (Shah *et al.*, 2009). These instruments were self-administered ($n = 6$) or combined with telephone interviews ($n = 5$). Two studies used only telephone interviews (Pocock *et al.*, 2000; Ho *et al.*, 2008); one one study conducted face-to-face interview (Kahler *et al.*, 1999), while four studies did not report the administration method (Moore *et al.*, 2006; Zhang *et al.*, 2006; Agarwal *et al.*, 2009; Gharacholou *et al.*, 2012).

The SF-12 measures eight general health domains reflecting physical functioning, physical role limitations, emotional role limitations, vitality, social functioning, bodily pain, general health, and mental health (Ware & Kosinski, 2001). The SF-12 is a shorter version of the SF-36, comprising 12 items and the same domains. The SF instrument scores range from 0 (lowest and worst score) to 100 (highest). While domain scores were collected, most studies reported only the two summary measures: physical component summary (PCS) and mental component summary (MCS), with population-standardized transformations (mean of 50; 10 SD).

Studies using the SF-36 presented scores as points of difference between age groups. The minimal clinically important difference (MCID) was cited by four studies (Seto *et al.*, 2000; Rumsfeld *et al.*, 2003; Weintraub *et al.*, 2008) within the range of 4–7 points for PCS and > 10 points for MCS, for detecting meaningful changes in HRQOL (Ware & Kosinski, 2001). Five studies (28%) compared scores with national population norms for different age groups (Jamieson *et al.*, 2002; Moore *et al.*, 2006; Gunal *et al.*, 2008; Agarwal *et al.*, 2009; Melberg *et al.*, 2010). Median scores cited by these studies varied from 29 to 51 for the PCS, and 46 to 54 for the

MCS. Lower values were reported by one study (Moore *et al.*, 2006) that used the SF-12 version, with mean differences ranging from 4.0 to 7.8 (PCS) and 3.9 to 6.2 (MCS). Another study (Shah *et al.*, 2009) reported higher mean EQ-5D scores of 0.78 and an EQ-VAS score of 70.5 obtained on a rating scale from 0 (poor) to 100 (best health state); comparable with a similar US population-based survey of the elderly ≥ 80 years.

The SAQ measures five dimensions of health status specific to coronary artery disease in the domains of physical limitations, angina stability, angina frequency, treatment satisfaction and the impact on quality of life (Spertus *et al.*, 1995). Angina stability is measured by the prevalence of chest pain with strenuous activity, while angina frequency reflects the number of times the person experiences chest pain and treats symptoms with nitroglycerine. The SAQ scores range from 0 (representing the worst QOL score) to 100. For comparisons of SAQ scores across time, the MCID indicating change in HRQOL status was 5–10 points (six studies). Scores ranged from 4 to 100% change for all SAQ domains across the reviewed studies. Results indicating differences from baseline for HRQOL comparisons across time are presented in Table 2.

The HRQOL results

Summary results indicated that HRQOL improves over time to six months and one year in 17 studies after the PCI. The HRQOL improvements ranged from 1 to 67% increase, with the largest gains in physical functioning of 4–67% (SAQ). This was followed closely by anginal frequency and QOL (disease burden) gains of 1–40% and 6–42% respectively. For studies using the SF-36, improvements in physical and mental health component scores ranged from 7 to 25 points and 1 to 13 points respectively, achieving the acceptable MCID ranges. Only one study (Moore *et al.*, 2006) demonstrated no significant differences between most HRQOL domains for ages < 60, 60–70, and > 70 years; the mean differences for physical limitation reflected better recovery in younger people (7.8 vs 4.0 vs 4.9, $P = 0.047$) 1 year after PCI.

Influence of age on HRQOL

For studies showing multiple age groups, score differences for ages > 60 years across time were used for comparison (Graham *et al.*, 2006; Moore *et al.*, 2006; Ho *et al.*, 2008; Li *et al.*, 2012). Summarized results including age as a predictor of HRQOL changes are displayed in Table 3. The majority of studies (72%) showed that there were no changes in overall HRQOL as age increased (Nash *et al.*, 1999; Pocock *et al.*, 2000; Jamieson *et al.*, 2002; Spertus *et al.*, 2004; Li *et al.*, 2012). The study by Seto *et al.* (2000), for example, showed that the probability of MCID gains following PCI was not significantly associated with age (Table 2). Two studies (Spertus *et al.*, 2004; Li *et al.*, 2012) showed that advancing age by 10-year increments was associated with better HRQOL in physical health at 6 months follow-up. Li *et al.* (2012) identified age and PCI as independent predictors of improved HRQOL, with significant improvements from baseline physical component scores of the SF-36. The earlier study using the SAQ revealed similar findings with age, physical function, and baseline angina as important predictors of quality of life benefits from PCI (Spertus *et al.*, 2004). However, in specific domains, older people had fewer physical limitations, higher vitality and better anginal relief (Pocock *et al.*, 2000; Jamieson *et al.*, 2002; Spertus *et al.*, 2004; Ho *et al.*, 2008; Melberg *et al.*, 2010; Li *et al.*, 2012), and better function with less symptom burden (Graham *et al.*, 2006; Zhang *et al.*, 2006; Gunal *et al.*, 2008; Agarwal *et al.*, 2009). As time passed, HRQOL improved with all ages, but patients aged ≥ 80 years by comparison experienced more benefits from better physical functioning.

Baseline HRQOL was an important predictor regardless of age. Anginal frequency prior to PCI was a strong predictor of HRQOL improvements (Pocock *et al.*, 2000; Spertus *et al.*, 2004), with those with more anginal severity at baseline demonstrating the most benefit. Even for patients experiencing monthly, weekly, and daily angina episodes, significant HRQOL corresponding improvements were achieved with PCI (21.4, 30.7, and 34.6, $P < 0.001$) from baseline (Spertus *et al.*, 2004). Most improvements in symptomatic angina occurred within one month of hospital discharge and continued until 12 months, after which no differences were evident between age groups. One study examined frailty in adults > 65 years with evidence that progressive frailty alongside increasing age was also associated with poorer physical HRQOL despite similar SAQ scores for angina frequency and treatment satisfaction (Gharacholou *et al.*, 2012). Factors which may be associated with older age were assessed in one study (Rumsfeld *et al.*, 2003), which identified that chronic comorbidities such as chronic obstructive airways disease, diabetes, elevated creatinine, smoking, and hypertension were predictive of HRQOL on their own. However, the sample of 389 patients comprised select Veterans Affairs patients, with 99% majority males.

DISCUSSION

Limitations

We note limitations for this review. Despite stringent search and selection criteria culminating in detailed data extraction and summation of findings, some potentially relevant publications may have been omitted. Baseline HRQOL was not measured in 33% of studies, limiting capacity for effective pre- and post-PCI comparisons. In addition, there was little focus on pre-PCI angina, an important predictor of HRQOL outcomes. Some studies (Seto *et al.*, 2000; Zhang *et al.*, 2006; Ho *et al.*, 2008) did not provide scores for angina stability, focusing instead on anginal frequency to measure HRQOL. This did not enable a complete interpretation of the total HRQOL benefits associated with relief from angina, and underscores the importance of symptomatic angina both at baseline and after PCI. Past studies demonstrated that the accurate assessment of angina is critical, as residual angina and symptom burden after PCI are major determinants of lower health status over time (Permanyer-Miralda *et al.*, 1999; Spertus *et al.*, 2005; Spertus, 2008).

Our results involved health-status assessments for both stable angina and acute coronary syndromes. Six of the studies reviewed (Graham *et al*., 2006; Gunal *et al*., 2008; Ho *et al*., 2008; Agarwal *et al*., 2009; Shah *et al*., 2009; Gharacholou *et al*., 2012) included these patients but did not show elective or emergency PCI comparisons, making it difficult to assess HRQOL results by age comparison for each specific treatment group. There was a mix of PCI and other treatment groups such as medical or coronary artery bypass graft (CABG) for comparisons, which may affect results due solely to PCI. Mental health domains were measured by 50% of studies in this review, with mean differences of scores ranging from 1 to 13 by comparison to physical component scores of 2–25, and results may not be generalizable to all older PCI cohorts.

Only a narrative summary was possible due to the heterogeneity between studies. Despite applying the Cochrane guide for comprehensive risk assessment, only six RCTs and substudies could be fully assessed; the majority being descriptive cohort designs and accurate cross-comparison was difficult. This was partially attributed to the different approaches adopted by various studies in using HRQOL instruments; each instrument with different emphasis on its main psychometric properties and not all components of HRQOL measurements were fully reported.

Major findings

This systematic review presents an integrated report of age on HRQOL changes following PCI over time at one year. The HRQOL improved across all age-groups following PCI, with important improvements in angina and physical function for all recipients. Although there were fewer gains for anginal stability (10–24%) in comparison to anginal frequency, this synthesis of 18 studies complements previous findings from other published literature showing the benefits of overall anginal relief and better HRQOL for PCI patients regardless of age (Kahler *et al*., 1999; Pfisterer, 2004; Kamiya *et al*., 2007). The PCI as a treatment is associated with improved HRQOL, attributed to anginal relief and better physical and mental functioning, and age is not an important predictor of better HRQOL gains. In fact, only a limited proportion (22%) of studies reviewed identified age to have an independent predictive effect on HRQOL following PCI. Furthermore, the oldest group studied, octogenarians, showed similar improvements to younger people in physical and mental scores across time. This is supported by a recent systematic review on quality of life for octogenarians, which showed improved physical functioning and angina status comparable to that of younger people, particularly in the first 6 months after PCI (Johnman *et al*., 2013).

The evidence so far suggests that higher HRQOL is achievable by older people after PCI, but other explanations may also need to be considered. It could be that older people may have lower expectations of recovery from PCI, which influence their perceptions of health as far better than expected (Zhang *et al*., 2006). This systematic review identified predictors of HRQOL improvement in 18 studies on PCI in older people and most studies focused on physical gain and angina relief as the two most common domains for assessment of improved health status. However, the greatest deficits in HRQOL assessment were the domains where older did not perform so well in. These relate to mental health and recovery strategies, such as cardiac rehabilitation and risk modification. Only one study (Jamieson *et al*., 2002) included cardiac rehabilitation in HRQOL assessment, and another included frailty (Gharacholou *et al*., 2012); both studies also identified higher baseline comorbidities and risks in older PCI patients to influence their HRQOL outcomes. With increased PCI for an aging population and higher quality of life expectancy, investigating HRQOL along with monitoring clinical outcomes for older people from a starting retirement age of 60 years forms an integral part of health status assessment. This justifies our systematic review, which enriches the limited information on PCI and HRQOL in the published literature where age 60 years plus is selected for older PCI cohorts.

The review did not discriminate between the results for elective and primary PCI because the majority of studies did not report results separately, although differences in HRQOL might be expected. The trajectory of symptoms preceding and/or accompanying PCI in an emergency situation, such as acute coronary syndromes, would likely differ to those of an elective procedure (Wijeysundera & Ko, 2009; Gharacholou *et al*., 2012), so it would be important that future reviews address these differences where possible.

Implications for practice

Our results have important relevance for nursing practice. The HRQOL measurement reflects a holistic approach to physiological and psychological aspects of recovery, and current care of PCI patients often does not address all of these aspects. The focus of nursing care often rests on PCI-procedural complications and institution-standardized, protocol-driven practices, irrespective of age and treatment pathways. The HRQOL is rarely assessed or addressed, which may impact on older people who are disadvantaged by inequitable PCI access (Alexander *et al*., 2006) and higher comorbidity risks (Moore *et al*., 2006). Therefore, to adequately evaluate PCI-related outcomes, there is a need to extend beyond the conventional assessment of MACE and age-related risks. Other than costing and symptom management, nursing-sensitive PCI care should include HRQOL assessment (Leeper, 2004) and monitoring, regulating, and improving standards of PCI nursing practice (Rolley *et al*., 2009). Recent research has identified other factors that also influence HRQOL, such as frailty, poor health status, and gender, but are these not routinely investigated with PCI (Schenkeveld *et al*., 2010; Singh *et al*., 2011; Gharacholou *et al*., 2012). There are limited data on cardiac rehabilitation attendance patterns post-emergency PCI for older people despite the potential impact on mortality, morbidity, HRQOL outcomes, and major cardiac events such as restenosis after PCI (Jamieson *et al*., 2002; Dendale *et al*., 2005; Goel *et al*., 2011), and these wider aspects of care delivery remain underresearched. In addition, future research should also differentiate results of primary and elective PCI.

CONCLUSION

This review demonstrated that age is not an influencing factor for HRQOL benefits following PCI. Everyone showed benefits after PCI, related to improved physical function, angina frequency, disease burden, and treatment satisfaction. Further research is needed, however, to evaluate the broader physical and emotional needs of older patients during the PCI recovery process, particularly the impact on HRQOL with aging and frailty in the setting of fast-paced PCI pathways such as pre-hospital diagnosis for STEMI and early field-triage to PCI. Integrating HRQOL assessment with good clinical practice would help identify patient-specific care for older people, who comprise an expanding proportion of the global population requiring primary PCI for coronary artery disease.

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CONTRIBUTIONS

Study Design: SH, RG, DG.
Data Collection and Analysis: SH.
Manuscript Writing: SH, RG, DG.

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Appendix 21: Publication - Chapter 5

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Field triage to primary percutaneous coronary intervention: Factors influencing health-related quality of life for patients aged ≥70 and <70 years with non-complicated ST-elevation myocardial infarction

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ABSTRACT

Objective: To examine clinical and health-related quality of life (HRQOL) outcomes and predictors of HRQOL for uncomplicated field triage ST-elevation myocardial infarction (STEMI) patients aged ≥70 years and <70 years after primary percutaneous coronary intervention (PPCI).
Background: Pre-hospital field triage for PPCI is associated with lower mortality but the impact of age and other factors on HRQOL remains unknown.
Methods: 77 field triage STEMI patients were assessed for HRQOL using the Short Form-12 (SF-12) and the Seattle Angina Questionnaire (SAQ) at 4 weeks and 6 months after PPCI.
Results: Regression analysis showed improvements in SF-12 domains and angina stability for older people. Age predicted lower physical function ($p = 0.001$) and better SAQ QOL at 6 months ($p = 0.003$).
Conclusion: Age, length of hospitalization, recurrent angina and hypertension were important predictors of HRQOL with PPCI. Assessment of HRQOL combined with increased support for physical and emotional recovery is needed to improve clinical care for field triage PPCI patients.

Introduction

Field (pre-hospital) triage of patients with ST-elevation myocardial infarction (STEMI) represents a fast-track pathway to percutaneous coronary intervention (PCI). With STEMI, primary PCI (PPCI) is the urgent intervention for coronary reperfusion by comparison to routine or elective PCI. A pre-hospital ECG is performed by ambulance paramedics at the scene, and transmitted to the Emergency Department (ED) of a regional major heart center. When an STEMI is confirmed, the patient is transported directly to the heart center for urgent PPCI. Unlike patients triaged through ED, who experience delays with routine assessment and admission processes, field triage directly to PPCI reduces myocardial ischemic time, resulting in better left ventricular function[1] and lower mortality.[2–7] For example, pre-hospital ECG STEMI diagnosis and field triage PPCI was associated with a 45-min reduction in revascularization delay ($p = 0.001$), and a two-thirds reduction for in-hospital mortality ($p = 0.019$)[3] including lower one month (5.4% vs 13.3%, $p = 0.006$) and one year mortality (6.6% vs 17.5%, $p = 0.019$).[8] While these effects on mortality are clear, influences on HRQOL for this patient cohort has not been investigated.

Rates of PCI in people over 70 years with STEMI have increased substantially in the United States with a 33.5% increase in PCI rates for those aged 65–79 years and 22% for ≥80 years between 2001 and 2010.[9] In Australia, PCI procedures increased with age until 75–84 years, but declined after 85 years.[10] Historically, older patients were excluded from PCI clinical trials[11] due to frailty, poor coronary vasculature and multiple comorbidities which predisposed them to increased major adverse cardiovascular events (MACE) such as strokes or death.

Despite these limitations, older individuals appear to benefit from PCI.[12,13] The Senior PAMI trial for example, demonstrated that STEMI patients aged ≥70 years treated with PCI had significantly

Abbreviations: ACS, acute coronary syndrome; ED, emergency department; HRQOL, Health-related quality of life; MACE, major adverse cardiovascular events; PCI, percutaneous coronary intervention; PPCI, primary percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

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reduced incidences of death, strokes and AMI.[14] Later studies comparing PCI with thrombolysis confirmed similar findings[15,16] for patients with cardiogenic shock[9] and other forms of acute coronary syndromes (ACS).[17] However, a recent large cohort study on STEMI patients aged ≥75 years reported higher co-morbidities of hypertension, chronic airway disease, previous angina including prior revascularization but patients had more PPCI-related MACE and that age was the strongest predictor of 90 day mortality after PPCI.[18]

Few studies have however examined health-related quality of life (HRQOL) in older people after PCI. HRQOL assessment is included in the American Heart Association's guidelines for PCI[19] to ensure all physical, mental, and social aspects of recovery are considered. However, with new technological advancements and increased emphasis on early coronary revascularization, research is still lacking on HRQOL for field triage cohorts particularly for older people despite age being a strong predictor of mortality and MACE after STEMI.[20,21] Results of a systematic review on octogenarians showed better physical functioning, angina status and quality of life improvements comparable to younger people and these outcomes were not age-dependent with PCI.[22] A more recent systematic review on HRQOL in PCI patients aged over 60 years also reported improved HRQOL, mainly from angina relief and better physical and mental function, with increasing age not demonstrating a predictive effect on HRQOL.[23] It is apparent therefore, that the most prevalent factors influencing HRQOL after PCI are likely to be age and angina symptoms, but it remains unclear if older people who have fast field triage PPCI experience similar HRQOL changes. Past studies have primarily reported improved mortality and better clinical outcomes associated with early reperfusion rather than evaluating the biopsychosocial aspects that HRQOL assessment confers in the setting of field triage PPCI. With projections for a global aging population[24] and increased risk of cardiovascular diseases, HRQOL assessment is crucial for strategic cardiac health care planning and improving clinical care for older people with acute coronary occlusion.

To date, there are no published studies examining HRQOL in field triage patients nor the independent effect of age in this population for potential comparison with other PCI cohorts during recovery. Similarly, the impact of socio-demographic and other potential covariates on health status and clinical outcomes of field triage PPCI patients aged ≥70 years after an STEMI event also remain relatively unknown.

The objectives for conducting this study were to:

1. Compare socio-demographic and clinical characteristics between field triage STEMI patients aged ≥70 and <70 years.
2. Differentiate HRQOL outcomes at 4 weeks and 6 months after PPCI.
3. Determine any independent predictors of HRQOL after PPCI such as age and clinical factors including hypertension, recurrent angina, smoking status and length of hospital stay which impact on HRQOL outcomes.

Methods

Design, setting and sample

This study is a component of a larger study which examined multiple outcomes following PPCI including HRQOL, qualitative and clinical data. The current study included only the field triage cohort, which comprised 31.3% of all patients recruited and examined a contemporary issue that had not been previously reported. A prospective repeated measures cohort study design was developed to address the study objectives. All consecutive STEMI patients admitted by field triage and treated exclusively with PPCI between April 2010 and November 2011 were recruited from the PCI registry of a large university-affiliated public teaching hospital and a private hospital in Sydney, Australia. These hospitals provide 24-h cardiac catheterization services in collaboration with a state-wide ambulance program for pre-hospital field triage of STEMI patients.

Sample inclusion/exclusion criteria

The inclusion criteria for the field triage cohort were: 1) STEMI diagnosis characterized by dynamic ST-segment elevation on field triage ECG or new left bundle branch block 2) persistent chest pain and symptoms of myocardial ischemia 3) no initial thrombolysis 4) Serum Troponin T > 14 ng/L or Troponin I > 0.14 ng/mL 5) able to provide informed consent in English and 6) has telephone for contact for follow-up. Exclusion criteria included a diagnosis of 1) dementia, 2) deafness, or 3) intensive care admission >5 days. The study was approved by the Human Research Ethics Committees of the two hospitals and all participants provided informed consent prior to data collection.

HRQOL measurement

Health-related quality of life was measured using the Medical Outcomes Short Form (SF-12) for general health and the Seattle Angina Questionnaire (SAQ) for cardiac-specific health. The SF-12 measures eight health domains: physical function, physical role limitations, emotional role limitations, vitality, social function bodily pain, general health and mental health.[25] Patients rated their responses on a Likert scale from 3 to 6 and scores were transformed from the lowest 0 (worst health state) to the highest 100 (best health state). The SF-12 has two summary components; the physical component summary (PCS) and mental component summary (MCS) and all domains and summary scores can be compared with population-standardized norms.[26] The instrument has been validated internationally for cardiovascular populations,[27,28] epidemiological studies[29] and for Australian population health surveys,[30,31] and also in smaller studies on HRQOL in cardiac patients, often combined with the SAQ[32] and is highly correlated and comparable with other HRQOL instruments.[33] In this study, all domains showed high internal consistency (Cronbach's alpha 0.79–0.95) for the SF-12 at both measurement points.

The SAQ is a 19-item questionnaire for patients with coronary artery disease and measures domains of physical limitations, angina stability, angina frequency, treatment satisfaction, and quality of life.[34] Responses are measured on a 5 or 6 point Likert scale, with scores summed and transformed from 0 (worst health) to 100 (best health). SAQ scores for each domain are calculated creating a percentage of the total possible score – an adjusted score. Higher scores represent better function, fewer symptoms and higher HRQOL. As a disease-specific tool, the SAQ is sensitive and detects small changes in cardiac status not adequately captured by a general instrument[35] hence its addition in this study. The SAQ has been demonstrated as valid in determining the impact of angina relief after PCI.[36–41] A difference in scores of 5–10 points is considered a minimal clinically important difference (MCID) representing a significant change in HRQOL status.[36,42,43] In the current study internal consistency reliability for the SAQ was moderate (Cronbach alpha coefficients were 0.58 and 0.79 at 4 weeks and 6 months). Both instruments are brief and suitable for telephone interviews[44] with feasibility for our study initially confirmed by a pilot test.

Procedure

Consecutive field triage patients were identified from the hospital PCI registry and screened for eligibility. Post-PPCI, participants were visited by a research nurse who provided printed information and explanation of the study. A consent form for study participation was signed and follow-up telephone interview times arranged before hospital discharge. Socio-demographic, baseline clinical and cardiovascular risk factors, PPCI data and MACE were recorded during hospitalization. Telephone interviews were conducted at 4 weeks and 6 months by a trained research nurse using an interview guide for uniformity of the interview process and HRQOL was assessed using the SF-12 and the SAQ. Each interview lasted approximately 15 min. These two interview times were selected as previous studies had reported improved physical and mental health up to 6 months post-PPCI, after which no significant differences occurred.[42,45] For age comparison, 70 years was chosen as it was more representative of older, retired people in Australia based on the national health statistics for 2014 which indicated a 3.6% population growth for people aged over 65 years.[17]

Statistical analyses

Data analyses were conducted using the Statistical Package for the Social Sciences (SPSS version 22, IBM Corp., Armonk, New York). Data were reported as frequencies and percentages or means and standard deviations. Differences between patients ≥70 and <70 years were compared using chi-squared analysis for categorical data and *t*-test for continuous data (baseline socio-demographic, clinical and PPCI characteristics including MACE), with possible correlations examined using Spearman's; a $p < 0.05$ was set as the level of significance. Due to uneven sample numbers, Levene's test for homogeneity was applied, accepting $p > 0.05$.

Scores for HRQOL measures (SF-12 and SAQ) at 4 weeks and 6 months were compared between age groups using repeated measures ANOVA with testing of interaction effects for age and time. A Bonferroni correction of $p = 0.01$ was used to control for Type I error. All SF-12 data were complete. Missing SAQ responses ($n = 4$) were adjusted and replaced by the average score for that scale of activity according to the SAQ scoring algorithms.[34] This was calculated by subtracting the lowest crude score, dividing the range and multiplying by 100. As each SAQ scale had its own computation formula, adjusted SAQ scores were used for analysis. Multivariable linear regression analyses were then conducted on three HRQOL scores; SF PCS and physical functioning and SAQ QOL at 4 weeks and 6 months using 5 potential predictors (age, recurrent angina, current smoking, hypertension and length of hospital stay). These variables were selected based on findings from previous literature,[22,38,40,41,46,47] and from statistically significant associations in the preliminary univariate analyses. Regression analysis was conducted on the physical and QOL domains, as the aims of PPCI are to relieve angina and improve QOL and physical function. Power calculation (A-priori) for two group comparisons of all STEMI patients receiving PPCI indicated that 45 participants were required for each group, with alpha level 0.05, medium effect size (Cohen's *d* 0.6), power level 0.8 using two-tailed *t*-test for 4 week analysis and an estimated 15% drop-out rate.

All predictor variables were entered into one block for analysis with separate regression models constructed, using a *p*-value of <0.05 as significant. Six models were created; one for each of the three HRQOL domains (SF-12 PCS, physical functioning and SAQ QOL) and for each time analysis (4 weeks and 6 months). Pearson's correlation was used to assess multicollinearity between the five independent covariates; results of collinearity statistics (VIF) did not exceed 10 for all models (range 1.016–1.190). Assumptions of linearity, collinearity and homoscedasticity in analyses were met and the predictive strength of all models were evaluated using an adjusted $R^2 \geq 0.10$ with 95% confidence intervals.[48]

Results

Demographic and clinical characteristics

Patients who received PPCI by field triage ($n = 77$) comprised 31.3% of all patients recruited in the larger cohort study ($n = 246$) which included STEMI patients from ED (24%) and inter-hospital transfers (44.7%). Participants were mainly male (82%) with a mean age of 77.7 years (SD 5.8) and Caucasian (93%). At 6 months 71 patients had completed both interviews; 8% were lost to follow-up and one patient had deceased. Most participants were married/partnered (65%), employed (56%) and had completed year 12 education (70%). Participants aged ≥70 years ($n = 24$) were less likely to have year 12 education (54% vs 79%, $p = 0.039$) compared to younger patients <70 years ($n = 53$) (Table 1). Risk factors for cardiovascular disease included hypertension (48%), hyperlipidemia (48%), diabetes (10%), prior AMI (11%), prior PCI (10%), BMI ≥25 kg/m^2 (65%) and current smoking (28%) (Table 1). Participants ≥70 years had more risk factors than those <70 years, including hypertension (63% vs 25%, $p = 0.001$) and prior strokes (13% vs 0%, $p = 0.031$), but were less likely to smoke (21% vs 42%, $p = 0.042$), had longer hospitalization days (5.7 vs 3.4, $F = 14.50$, df = 1, $p = 0.008$) and experienced less recurrent angina at 4 weeks (0% vs 23%, $p = 0.033$). There were no significant differences for other risk factors. Over half (56%) of the cohort had single vessel disease, 39% had double vessel disease and 5% had triple vessel disease.

At 4 weeks, the highest scores and (therefore the best HRQOL) were for role emotional (91.8 ± SD 15.3), bodily pain (92.6 ± SD 15.2) and mental health (83.3 ± SD 27.6) while the lowest scores

Table 1
Characteristics of field triage patients – comparison across age categories.

Characteristics	≥70 yrs n = 24 (%)	<70 yrs n = 53 (%)	p
Sociodemographics			
Male	18 (75)	46 (87)	0.231
Partnered	18 (75)	33 (62)	0.587
Employed	5 (21)	11 (21)	0.762
Year 12 (completed high school)	13 (54)	42 (79)	**0.039**
Lives alone	5 (21)	11 (21)	0.762
Clinical characteristics			
Hypertension	15 (63)	13 (25)	**0.001**
Hyperlipidemia	7 (29)	26 (49)	0.095
Diabetes	2 (8)	3 (6)	0.335
Prior stroke	3 (13)	0 (0)	**0.031**
Prior AMI	4 (16)	6 (12)	0.605
Prior PCI	2 (8)	5 (9)	0.898
Angina	4 (16)	2 (4)	0.170
Renal impairment	1 (4)	0 (0)	0.227
Body Mass Index ≥25 kg/m^2	13 (54)	37 (70)	0.299
Current smoker	5 (21)	22 (42)	**0.042**
Family history	14 (58)	32 (60)	0.879
Clinical outcomes			
Single vessel disease	16 (64)	27 (51)	0.287
Ejection fraction mean ± SD	48.0 ± 9.5	50.3 ± 7.3	0.251
LOS (mean days) ± SD	5.73 ± 7.1	3.48 ± 3.2	**0.008**
Re-admission at 4 weeks	0 (0)	2 (4)	0.527
Re-admission at 6 months	3 (13)	5 (9)	0.809
Recurrent angina at 4 weeks	0 (0)	12 (23)	**0.033**
Recurrent angina at 6 months	0 (0)	6 (12)	0.232

AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; LOS: length of stay.
χ^2 for categorical data comparison, continuous variables expressed as mean ± standard deviation, $p < 0.05$.
Significant *p*-values are in highlighted in bold.

(the worst HRQOL) were for PCS (40.2 ± SD 10.7), role physical (50.7 ± SD 29.5) and vitality (56.8 ± SD 22.9) (Table 2). For cardiac specific HRQOL, higher scores at 4 weeks were for treatment satisfaction (95.3 ± SD 6.6), QOL (78.7 ± SD 16.9) and physical limitation (76.4 ± SD 21.8) while angina stability had the lowest score (50.0 ± SD 0.0).

At 6 months, scores were consistently high for bodily pain (100 ± SD 0.0) and role emotional (99.3 ± SD 2.7), while physical function had improved statistically (93.1 ± SD 15.8) and the PCS remained low (52.9 ± SD 5.6) (Table 2). For cardiac specific HRQOL, the higher scores were again for treatment satisfaction (98.7 ± SD 4.3), physical limitation (96.6 ± SD 7.4) and QOL (92.1 ± SD 10.2), with angina stability remaining low and with no improvement (48.4 ± SD 7.9).

Effects of time and age

The main effect on HRQOL outcomes was time; almost all SF-12 domains (except for MCS) improved significantly over time (Table 2). An independent effect of age was also noted for physical functioning ($F = 3.554$, df = 2, $p < 0.030$) and role emotional ($F = 3.68$, df = 2, $p < 0.036$), but no interaction effect of age and time. By 6 months, physical functioning scores had improved for both age categories (52.5 and 83.7 vs 64.7 and 93.1, $F = 74.88$, df = 2, $p < 0.001$, respectively), with the older age category achieving greater improvements (12.2 and 9.4). Conversely, role emotional scores were better in older patients at 4 weeks (91.8 vs 81.6, $F = 3.368$, df = 2, $p < 0.036$) but worsened with time ($p < 0.001$), with 10.2 and 5.9 mean score differences, respectively. For the SAQ, time also had the greatest effect; with the exception of angina frequency, all domains improved significantly over time; QOL and physical limitation showing 13.4 and 18.7 score differences. One interaction effect (0.035) was observed between age and time ($F = 4.112$, df = 2, $p < 0.018$) for angina stability; people over 70 years had no change in angina stability, while people aged <70 years had worse angina stability over time (Table 3).

Statistically significant differences were observed in age for two domains; participants aged ≥70 years had lower SF physical function scores (52.5 vs 64.7, $F = 3.554$, df = 2, $p < 0.030$) but higher role emotional scores (91.8 vs 81.6, $F = 3.368$, df = 2, $p < 0.036$) at 4 weeks (Table 2). No differences were noted for cardiac-specific (SAQ) HRQOL (Table 3). At 6 months, older people continued to have lower SF physical functioning (83.7 vs 93.1, $F = 74.88$, df = 2, $p < 0.001$), vitality (61.2 vs 65.6, $F = 11.85$, df = 2, $p < 0.001$) but maintained higher role emotional scores (99.3 vs 93.8, $F = 15.81$, df = 2, $p < 0.001$) reflecting 9.4, 4.4 and 5.5 score differences respectively. No effect for age was demonstrated for the SAQ.

The influence of age and covariates on HRQOL

At 4 weeks, the PCS showed negative associations with age ($r = -0.211$, $p = 0.001$), hypertension ($r = -0.223$, $p = 0.001$), length of stay ($r = -0.372$, $p = 0.001$) and recurrent angina ($r = -0.134$, $p = 0.036$). By 6 months, only age ($r = -0.234$, $p = 0.001$), length of stay ($r = -0.352$, $p = 0.001$) and recurrent angina ($r = -0.236$, $p = 0.001$) were significantly associated with SF PCS. The SAQ QOL domain at 4 weeks was positively associated with age ($r = 0.126$, $p = 0.048$) and had a negative association with recurrent angina ($r = -0.216$, $p = 0.001$). By 6 months, only age ($r = 0.210$, $p = 0.001$) and smoking ($r = -0.186$, $p = 0.004$) showed positive associations with SAQ QOL. Age was therefore correlated with HRQOL changes for both SF-PCS and SAQ QOL at both time periods.

Independent predictors

Five predictors (age, hypertension, smoking, LOS and recurrent angina) independently predicted different aspects of HRQOL (Tables 4 and 5). All models were statistically significant; however the variance explained was generally small and varied from 5% to 20% at 4 weeks and from 12% to 15% at 6 months. Four SF-12 model statistics including SF PCS were statistically significant at 4 weeks ($R^2 = 0.20$, $F = 13.2$, df = 5, $p < 0.001$) and 6 months ($R^2 = 0.15$, $F = 13.9$, df = 5, $p = 0.001$). The PCS models were strongest, reflecting 20% and 15% respectively of the shared variance explained by the predictors (Table 4).

Age was a significant independent predictor at both time points for all physical HRQOL outcomes, except overall cardiac HRQOL at 4 weeks, when other factors were controlled for in the models (Table 4). Older participants reported significantly worse HRQOL for SF physical functioning at both 4 weeks (β = −0.294, 95% CI: −0.938 to −0.316, $p = 0.001$) and for PCS at 6 months (β = −0.241, 95% CI: −0.804 to −0.250, $p = 0.001$) (Table 4). For each year increase in age, physical functioning decreased by 0.29 points at 4 weeks and 0.24 points at 6 months, while the PCS decreased by 0.13 points and 0.21 points, respectively. In contrast, age was a significant predictor at 6 months for improved SAQ QOL (β = 0.19, 95% CI: 0.07–0.34, $p = 0.003$) (Table 5).

Similar to age, length of hospital stay (LOS) was a significant independent predictor at both time points for all HRQOL outcomes, explaining the highest variances for the SF-Physical Functioning (25%) and the PCS (32%) at 6 months. Participants with a longer

Table 2
HRQOL (SF-12) in field triage patients compared for over and under 70 years age groups.

HRQOL measurement	≥70 years Mean scores (SD)		<70 years Mean scores (SD)		Within subjects Time		Between subjects age		Interaction Age × time	
	4 Week	6 Month	4 Week	6 Month	F[a]	p	F[a]	p	F[a]	p
PCS	40.2 (10.7)	49.3 (8.8)	43.8 (7.4)	52.9 (5.6)	99.20	**0.001**	2.567	0.079	0.018	0.982
MCS	57.0 (7.2)	57.7 (3.0)	52.8 (10.2)	55.3 (7.9)	2.693	0.102	2.729	0.067	0.264	0.768
Physical function	52.5 (34.3)	83.7 (28.4)	64.7 (24.5)	93.1 (15.8)	74.88	**0.001**	3.554	**0.030**	0.073	0.929
Role physical	50.7 (29.5)	83.7 (27.2)	67.0 (24.8)	86.2 (26.1)	105.0	**0.001**	0.759	0.469	0.663	0.516
General health	65.5 (25.1)	76.0 (18.0)	64.6 (23.1)	75.4 (21.5)	26.51	**0.001**	1.128	0.880	0.017	0.983
Bodily pain	88.7 (24.9)	100.0 (0.00)	92.6 (15.2)	96.5 (11.2)	19.74	**0.001**	0.106	0.899	1.358	0.259
Vitality	58.7 (26.0)	61.2 (17.1)	56.8 (22.9)	65.6 (19.2)	11.85	**0.001**	1.480	0.230	1.043	0.354
Social function	82.5 (29.3)	96.2 (16.7)	83.3 (27.6)	92.5 (15.8)	17.98	**0.001**	1.107	0.332	0.008	0.992
Role emotional	91.8 (15.3)	99.3 (2.7)	81.6 (24.7)	93.8 (18.2)	15.81	**0.001**	3.368	**0.036**	0.238	0.789
Mental health	81.2 (11.8)	88.1 (9.4)	77.2 (16.9)	88.3 (16.8)	11.37	**0.001**	0.492	0.227	0.544	0.581

MCS: mental component summary; PCS: physical component summary.
Significant p-values are in highlighted in bold.
[a] Repeated measures ANOVA, df = 2.

Table 3
Cardiac-specific HRQOL (SAQ) in field triage patients compared for over and under 70 years age groups.

HRQOL measurement	≥70 years Mean scores (SD)		<70 years Mean scores (SD)		Within subjects Time		Between subjects Age		Interaction effect Age × time	
	4 Week	6 Month	4 Week	6 Month	F[a]	p	F[a]	p	F[a]	p
Physical limitation	76.4 (21.8)	95.1 (11.7)	75.1 (15.3)	96.6 (7.4)	120.1	**0.001**	1.207	0.301	0.206	0.814
Angina stability	50.0 (0.0)	50.0 (0.0)	61.7 (21.1)	48.4 (7.9)	8.565	**0.004**	1.475	0.231	4.112	**0.018**
Angina frequency	100.0 (0.0)	100.0 (0.0)	94.31 (12.3)	95.49 (16.1)	1.417	0.235	1.666	0.191	0.880	0.416
Treatment satisfaction	95.3 (6.6)	98.7 (4.3)	94.9 (7.7)	96.4 (9.4)	7.223	**0.008**	0.746	0.475	0.606	0.547
Quality of life	78.7 (16.9)	92.1 (10.2)	74.5 (19.7)	89.1 (15.6)	67.30	**0.001**	0.778	0.461	0.034	0.966

Significant p-values are in highlighted in bold.
[a] Repeated measures ANOVA, df = 2. All SAQ scores are adjusted values.

length of stay had worse HRQOL for physical functioning and PCS (both $p = 0.001$) (Table 4), and for SAQ QOL at both measurement points ($p = 0.049$ and $p = 0.012$) respectively (Table 5). For each additional day of hospitalization, physical functioning and PCS decreased by 0.28 and 0.34 points at 4 weeks and by 0.25 and 0.32 points at 6 months. In addition, QOL also decreased by 0.12 points at 4 weeks and a further 0.15 points at 6 months. Hypertension had a negative impact on one domain, the SF-PCS at 4 weeks ($p = 0.010$) (Table 4). Participants with hypertension had poorer SF PCS scores (0.15 points less) at 4 weeks while smoking was not a significant predictor of better or worse HRQOL.

Recurrent angina emerged as a predictor of lower SF physical functioning ($p = 0.003$) and SF-PCS ($p = 0.001$) at 4 weeks and 6 months ($p = 0.002$ and $p = 0.001$ respectively). Recurrent angina explained the highest variances for the SAQ QOL at both 4 weeks (20%) and 6 months (28%) but predicted lower SAQ QOL at both times ($p = 0.001$) (Table 5). For people who had recurrent angina, their SAQ QOL score decreased by 0.20 points at 4 weeks and even more, by 0.28 points at 6 months of recovery.

Discussion

We examined the patterns of HRQOL during recovery from early triage PPCI and found that HRQOL was moderate to high. We also examined the effect of age, socio-demographic and clinical variables on HRQOL for field triage STEMI patients at 4 weeks and 6 months of recovery. Our results confirmed that patients aged ≥70 years can achieve significant improvements for physical functioning, angina stability, treatment satisfaction and quality of life domains over time. The high QOL and physical limitation scores for our sample showed differences of 13.4 and 18.7 which exceeded the MCID of 5–10 point differences as recommended for the SAQ. After accounting for hospital length of stay and recurrent angina, age had an important independent and negative effect on SF-12 physical and role emotional domains, which was not surprising, given the comorbidities older people commonly have.[37] Age-related conditions such as frailty affecting physical activity may combine with angina symptoms to impact on HRQOL.[38] Despite poorer physical function, older people improved in cardiac QOL by 6 months, most likely from improved angina stability. Our results were comparable with an earlier study conducted in the UK using both the SF-12 and SAQ[32] which identified similar poorer physical function for people >60 years after PCI but with improvements in other health domains.

The effect of age on HRQOL is an important consideration in facilitating PPCI recovery from fast field triage; our results however, could not be compared unequivocally with any existing study. A previous study[18] reported age to be a strong predictor of mortality and adverse health outcomes after PPCI for STEMI but results were not exclusive to field triage cohorts. From this perspective, our results provide beginning information for clinical research on older adults with early presentation of STEMI for PPCI, particularly for post-procedure and community approaches for managing people over 70 years recovering from fast-track pathways to PPCI, as their physical recovery patterns differ from general PCI cohorts.

We identified recurrent angina as a predictor of worse physical and cardiac health status after PPCI, supporting previous research on the prevalence of angina symptoms particularly during the first month of recovery.[22,40,41] Our results also indicated recurrent angina to be a predictor of worse physical function and QOL with a significant interaction effect between age and time. Therefore angina is an important symptom to detect and treat.[49] This finding differed from previous systematic reviews where octogenarians reported better physical functioning and angina status after PCI[22] and patients of all ages reported improved HRQOL after PCI, with age not a predictor of HRQOL outcomes.[23] An earlier study reported residual recurrent angina following PCI as a major determinant of poorer 3-year quality of life.[50] In view of such differences, it is possible that recurrent angina had more impact on field triage patients who rated their physical recovery and QOL as poorer despite early PPCI. Further research into this phenomenon is indicated especially with field triage and PPCI as the recognized first-line treatment for STEMI without any age delineation.

Interestingly, the domains with least improvements were SF-12 vitality and mental health for both age groups. A recent study on HRQOL in ACS patients reported high anxiety and depression impacting on long-term HRQOL improvements at 36 months but

Table 4
Predictors of HRQOL in patients for SF-physical functioning, SF-PCS and SAQ-QOL at 4 weeks.

Predictor variables	SF-physical functioning			SF-PCS			SAQ-QOL		
	Beta	95% CI	p	Beta	95% CI	p	Beta	95% CI	p
Constant	105.6	85.4–125.9	0.001	52.0	46.7–57.4	0.001	65.3	52.1–78.6	0.001
Age	−0.29	−0.93 to −0.31	**0.001**	−0.13	−0.17 to −0.01	**0.035**	0.12	−0.01 to 0.40	0.057
Hypertension	0.03	−9.87 to 5.86	0.616	−0.15	−4.81 to −0.66	**0.010**	−0.03	−6.44 to 3.86	0.622
Smoking status	−0.07	−1.53 to 7.42	0.197	−0.05	−0.61 to 1.75	0.342	0.07	−1.08 to 4.78	0.216
Length of stay (days)	−0.28	−2.65 to −1.09	**0.001**	−0.34	−0.80 to −0.39	**0.001**	−0.12	−1.02 to −0.01	**0.049**
Recurrent angina	−0.17	−27.1 to −5.64	**0.003**	−0.20	−7.76 to −2.09	**0.001**	−0.20	−18.8 to −4.75	**0.001**
Model statistics	($R^2 = 0.17$, $F = 11.2$, df = 5, $p = 0.001$)			($R^2 = 0.20$, $F = 13.2$, df = 5, $p = 0.001$)			($R^2 = 0.05$, $F = 3.88$, df = 5, $p = 0.002$)		

p-value <0.05 significant. All SAQ scores are adjusted scores.
Significant p-values are in highlighted in bold.

Table 3
Cardiac-specific HRQOL (SAQ) in field triage patients compared for over and under 70 years age groups.

HRQOL measurement	≥70 years Mean scores (SD)		<70 years Mean scores (SD)		Within subjects Time		Between subjects Age		Interaction effect Age × time	
	4 Week	6 Month	4 Week	6 Month	F[a]	p	F[a]	p	F[a]	p
Physical limitation	76.4 (21.8)	95.1 (11.7)	75.1 (15.3)	96.6 (7.4)	120.1	**0.001**	1.207	0.301	0.206	0.814
Angina stability	50.0 (0.0)	50.0 (0.0)	61.7 (21.1)	48.4 (7.9)	8.565	**0.004**	1.475	0.231	4.112	**0.018**
Angina frequency	100.0 (0.0)	100.0 (0.0)	94.31 (12.3)	95.49 (16.1)	1.417	0.235	1.666	0.191	0.880	0.416
Treatment satisfaction	95.3 (6.6)	98.7 (4.3)	94.9 (7.7)	96.4 (9.4)	7.223	**0.008**	0.746	0.475	0.606	0.547
Quality of life	78.7 (16.9)	92.1 (10.2)	74.5 (19.7)	89.1 (15.6)	67.30	**0.001**	0.778	0.461	0.034	0.966

Significant p-values are in highlighted in bold.
[a] Repeated measures ANOVA, df = 2. All SAQ scores are adjusted values.

length of stay had worse HRQOL for physical functioning and PCS (both $p = 0.001$) (Table 4), and for SAQ QOL at both measurement points ($p = 0.049$ and $p = 0.012$) respectively (Table 5). For each additional day of hospitalization, physical functioning and PCS decreased by 0.28 and 0.34 points at 4 weeks and by 0.25 and 0.32 points at 6 months. In addition, QOL also decreased by 0.12 points at 4 weeks and a further 0.15 points at 6 months. Hypertension had a negative impact on one domain, the SF-PCS at 4 weeks ($p = 0.010$) (Table 4). Participants with hypertension had poorer SF PCS scores (0.15 points less) at 4 weeks while smoking was not a significant predictor of better or worse HRQOL.

Recurrent angina emerged as a predictor of lower SF physical functioning ($p = 0.003$) and SF-PCS ($p = 0.001$) at 4 weeks and 6 months ($p = 0.002$ and $p = 0.001$ respectively). Recurrent angina explained the highest variances for the SAQ QOL at both 4 weeks (20%) and 6 months (28%) but predicted lower SAQ QOL at both times ($p = 0.001$) (Table 5). For people who had recurrent angina, their SAQ QOL score decreased by 0.20 points at 4 weeks and even more, by 0.28 points at 6 months of recovery.

Discussion

We examined the patterns of HRQOL during recovery from early triage PPCI and found that HRQOL was moderate to high. We also examined the effect of age, socio-demographic and clinical variables on HRQOL for field triage STEMI patients at 4 weeks and 6 months of recovery. Our results confirmed that patients aged ≥70 years can achieve significant improvements for physical functioning, angina stability, treatment satisfaction and quality of life domains over time. The high QOL and physical limitation scores for our sample showed differences of 13.4 and 18.7 which exceeded the MCID of 5–10 point differences as recommended for the SAQ. After accounting for hospital length of stay and recurrent angina, age had an important independent and negative effect on SF-12 physical and role emotional domains, which was not surprising, given the comorbidities older people commonly have.[37] Age-related conditions such as frailty affecting physical activity may combine with angina symptoms to impact on HRQOL.[38] Despite poorer physical function, older people improved in cardiac QOL by 6 months, most likely from improved angina stability. Our results were comparable with an earlier study conducted in the UK using both the SF-12 and SAQ[32] which identified similar poorer physical function for people >60 years after PCI but with improvements in other health domains.

The effect of age on HRQOL is an important consideration in facilitating PPCI recovery from fast field triage; our results however, could not be compared unequivocally with any existing study. A previous study[18] reported age to be a strong predictor of mortality and adverse health outcomes after PPCI for STEMI but results were not exclusive to field triage cohorts. From this perspective, our results provide beginning information for clinical research on older adults with early presentation of STEMI for PPCI, particularly for post-procedure and community approaches for managing people over 70 years recovering from fast-track pathways to PPCI, as their physical recovery patterns differ from general PCI cohorts.

We identified recurrent angina as a predictor of worse physical and cardiac health status after PPCI, supporting previous research on the prevalence of angina symptoms particularly during the first month of recovery.[22,40,41] Our results also indicated recurrent angina to be a predictor of worse physical function and QOL with a significant interaction effect between age and time. Therefore angina is an important symptom to detect and treat.[49] This finding differed from previous systematic reviews where octogenarians reported better physical functioning and angina status after PCI[22] and patients of all ages reported improved HRQOL after PCI, with age not a predictor of HRQOL outcomes.[23] An earlier study reported residual recurrent angina following PCI as a major determinant of poorer 3-year quality of life.[50] In view of such differences, it is possible that recurrent angina had more impact on field triage patients who rated their physical recovery and QOL as poorer despite early PPCI. Further research into this phenomenon is indicated especially with field triage and PPCI as the recognized first-line treatment for STEMI without any age delineation.

Interestingly, the domains with least improvements were SF-12 vitality and mental health for both age groups. A recent study on HRQOL in ACS patients reported high anxiety and depression impacting on long-term HRQOL improvements at 36 months but

Table 4
Predictors of HRQOL in patients for SF-physical functioning, SF-PCS and SAQ-QOL at 4 weeks.

Predictor variables	SF-physical functioning			SF-PCS			SAQ-QOL		
	Beta	95% CI	p	Beta	95% CI	p	Beta	95% CI	p
Constant	105.6	85.4–125.9	0.001	52.0	46.7–57.4	0.001	65.3	52.1–78.6	0.001
Age	−0.29	−0.93 to −0.31	**0.001**	−0.13	−0.17 to −0.01	**0.035**	0.12	−0.01 to 0.40	0.057
Hypertension	0.03	−9.87 to 5.86	0.616	−0.15	−4.81 to −0.66	**0.010**	−0.03	−6.44 to 3.86	0.622
Smoking status	−0.07	−1.53 to 7.42	0.197	−0.05	−0.61 to 1.75	0.342	0.07	−1.08 to 4.78	0.216
Length of stay (days)	−0.28	−2.65 to −1.09	**0.001**	−0.34	−0.80 to −0.39	**0.001**	−0.12	−1.02 to −0.01	**0.049**
Recurrent angina	−0.17	−27.1 to −5.64	**0.003**	−0.20	−7.76 to −2.09	**0.001**	−0.20	−18.8 to −4.75	**0.001**
Model statistics	($R^2 = 0.17$, $F = 11.2$, df = 5, $p = 0.001$)			($R^2 = 0.20$, $F = 13.2$, df = 5, $p = 0.001$)			($R^2 = 0.05$, $F = 3.88$, df = 5, $p = 0.002$)		

p-value <0.05 significant. All SAQ scores are adjusted scores.
Significant p-values are in highlighted in bold.

Table 5
Prediction models for SF-Physical Functioning, SF-PCS and SAQ-QOL at 6 months.

Predictor variables	SF-physical functioning			SF-PCS			SAQ-QOL		
	Beta	95% CI	p	Beta	95% CI	p	Beta	95% CI	p
Constant	125.5	107.4–143.6	0.001	63.0	58.2–67.8	0.001	77.9	69.1–86.8	0.001
Age	−0.24	−0.80 to −0.25	**0.001**	−0.21	−0.20 to −0.05	**0.001**	0.19	0.07–0.34	**0.003**
Hypertension	0.01	−6.29 to 7.51	0.862	−0.01	−1.91 to 1.73	0.923	0.03	−2.40 to 4.33	0.573
Smoking status	−0.06	−1.76 to 6.08	0.278	−0.06	−1.61 to 0.46	0.274	0.02	−1.56 to 2.26	0.716
Length of stay (days)	−0.25	−2.26 to −0.80	**0.001**	−0.32	−0.73 to −0.34	**0.001**	−0.15	−0.81 to −0.10	**0.012**
Recurrent angina	−0.18	−27.7 to −6.04	**0.002**	−0.28	−9.90 to −4.17	**0.001**	−0.28	−17.6 to −7.02	**0.001**
Model statistics	(R^2 = 0.15, F = 9.35, df = 5, p = 0.001)			(R^2 = 0.15, F = 13.9, df = 5, p = 0.001)			(R^2 = 0.12, F = 7.74, df = 5, p = 0.001)		

p-value <0.05 significant. All SAQ scores are adjusted scores.
Significant p-values are in highlighted in bold.

not initially in the first week to 6 months, with age and gender as influencing factors.[51] This indicates that physical and mental aspects of support for patients after a cardiac event and PPCI may need to extend beyond the early phase of recovery.

An important finding from this study is that length of hospitalization was a negative predictor of multiple aspects of HRQOL and consistent with past findings[46] which showed age and post-procedural complications as predictive of longer hospitalization for STEMI patients after PPCI. HRQOL was not however assessed in those studies. Another randomized trial on low-risk PPCI STEMI patients indicated that early hospital discharge within 72 h was safe and feasible.[52] Our study showed low-risk STEMI patients had longer hospitalizations with lower HRQOL and poorer physical function recovery. As there was no protocol governing discharge of low-risk STEMI patients at the study hospitals, our results has implications for early discharge planning with field triage PPCI.

Past studies demonstrated improved SAQ physical function for older patients after PCI[32,42] but not specifically for non-complicated STEMI patients treated by fast-track PPCI. Our study appears to be the first to identify the impact of age and other predictors on HRQOL within the context of rapid coronary revascularization for a unique cohort of STEMI patients whose recovery outcomes differ from those treated by routine ED pathways. Field triage of STEMI is recognized as the superior pathway to PPCI but it is not universally implemented. Our research from an Australian context may not translate to other countries with different health systems such as Korea[53] where STEMI patients are routinely assessed in ED first. By contrast, field triage is well-established in countries such as Denmark,[4,5] the United States[54,55] and Canada[8] with where PPCI can be performed expeditiously for STEMI patients. However, HRQOL is internationally recognized as a measure for health status outcomes. This study has provided insights into HRQOL as perceived by a select cohort of older STEMI patients and constituted first-time patient-reported recovery experiences following rapid coronary reperfusion.

Assessment of HRQOL is not routine practice for older patients receiving PCI despite higher comorbidity risks and frailty[2,13,24,49]; and often lacking equity in treatment access.[11] In practice, older STEMI patients remain vulnerable to protocol-driven nursing care that is not age-sensitive. Our results confirmed that older people have HRQOL benefits with PPCI. A concise and age-inclusive approach to post-PPCI care is therefore needed, including nursing-sensitive care[56] and better monitoring standards[57] particularly for patients who lacked routine pre-procedural information and preparation for urgent revascularization. With field triage, the prognosis for patient survival from an STEMI is enhanced but to date, this is the only identified study that has examined all HRQOL aspects during PPCI recovery in this unique cohort. Future research should focus on evaluating additional patient support, education and counseling for older STEMI patients in order to provide an optimal hospitalization period and to promote physical and emotional recovery after fast-track PPCI (Table 6). Larger scale studies including systematic assessments of HRQOL and factors which impact on health status outcomes for older patients treated by rapid pathways to PPCI is needed.

Table 6
Recommendations for nursing practice and research.

- HRQOL measurement is important and needs to be integrated into the routine clinical care of patients after urgent PPCI.
- Follow-up health status assessment post-hospital discharge is vital for monitoring patient recovery after STEMI and for targeting specific health care needs.
- Future research should focus on evaluating the potential for additional patient support and education for an aging population in order to optimize physical and emotional recovery after fast-track PPCI.
- Nursing research is lacking for field triage PPCI cohorts and systematic assessments of factors which impact on health status outcomes of older patients are warranted.

Methodological strengths and limitations

The strength of this study was its focus on field triage STEMI patients and our findings support the need for assessing HRQOL after fast-track PPCI. We also used validated tools, the generic SF-12 and the SAQ to comprehensively measure all aspects of general and cardiac-specific HRQOL. Our study participants met international guidelines for STEMI and PPCI management[58,59] but generalizability of our findings may however, be limited by the relatively small sample number of "non-complicated" STEMI participants. Power estimation for study size was conducted for entire cohort of STEMI patients rather than for the smaller study group. We also lacked baseline HRQOL measurements for comparison, although the urgency of field triage to PPCI makes it impractical to assess HRQOL prior to rapid coronary reperfusion. Finally, the regression models had limited explanatory power (5–20%), therefore it is likely that other important variables not included in the current study may be essential to include in a study which has a larger sample size.

Conclusion

HRQOL is an important measure of health status and recovery from PPCI by field triage. Age, length of hospitalization, recurrent angina and baseline hypertension are key predictors of HRQOL outcomes. This study is the first to report the impact of socio-demographic and clinical factors which influence and predict HRQOL in field triage STEMI patients, and expands the limited research evidence for this important cardiac subset. Further studies are required to determine the relationship between improved effectiveness of PPCI for STEMI by field triage, and other factors such as emotional, social and rehabilitative support that could potentially enhance health status outcomes for an aging global population.

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Appendix 22: Abstract: Heart Lung and Circulation, 2012

Health Related Quality of Life of Older People After Primary Percutaneous Coronary Intervention:AComparison of Health Status Outcomes by Age

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Background: Older people aged ≥60 years form a high proportion of patients undergoing primary percutaneous coronary intervention (PPCI) for ST-elevation myocardial infarction (STEMI). Health-related quality of life (HRQOL) evaluation following PPCI holds important predictive value for assessing clinical health status and guiding follow-up during recovery. While clinical outcomes such as major adverse coronary events (MACE) are commonly reported, few studies report HRQOL despite the importance of function for older people.We evaluated the effects of PPCI on the health status of older people≥60 years.

Methods: We recruited 92 consecutive patients undergoing PPCI for STEMI between April and October 2010 from a major tertiary teaching hospital. HRQOLwas measured four-weeks post PPCI using the Seattle Angina Questionnaire (SAQ) and the SF-12 by telephone interview and outcomes were compared by age group (<60 years versus ≥60 years).

Results: Mean age of the sample was 64 years (SD 13.16) and patients aged≥60 years comprised the majority (62%). Older patients were less likely to be male (65% vs 95% $p = 0.001$) butwere similar forMACEfollowing PPCI. Older and younger patients reported similar HRQOL, except for two areas. Older people experienced less impact on HRQOL due to anginal frequency (adjusted SAQ 95.26 vs 87.43, $p = 0.026$) but had worse overall physical function (SF-12 physical component subscale 40.14 vs 43.7, $p = 0.050$).

Conclusion: Patients ≥60 years have similar HRQOL benefits from PPCI for STEMI compared to patients < 60 years. The effects of gender on these outcomes should also be evaluated.

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Appendix 23: Abstract: Journal of The Hong Kong College of Cardiology, 2014

Cardiac Rehabilitation Participation and Health-Related Quality of Life Following Primary Percutaneous Coronary Intervention for ST-Elevation myocardial infarction: An Age Comparison

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Objectives: We compared participation in a cardiac rehabilitation program and health-related quality of life (HRQOL) following primary percutaneous coronary intervention (PPCI) for ST-elevation myocardial infarction (STEMI) by age ≥60 years and <60 years.

Methods: A descriptive comparative design was used to evaluate cardiac rehabilitation (CR) and HRQOL for people ≥60 vs <60 years with measures taken at 1 and 6 months after PPCI (n=246). Consecutive STEMI patients from a large metropolitan hospital were interviewed by telephone using selfreport CR participation and response and the Seattle Angina Questionnaire (SAQ) and the SF-12 for HRQOL.

Results: Mean age of the overall sample was 64 years • } SD13.16, the majority were male (78.9%). CR participation was 32.5% for ≥60 years and 42.7% for <60 years at 1 month (p=0.13) and at 6 months, 56.6% for ≥60 years vs 56.8% for <60 years (p=1.00); most attended up to 5 sessions. People <60 years were more likely to rate CR as helpful at each time point (13.5% vs 7.6%, p=0.18) and (22.2% vs 16.4%, p=0.29). People ≥60 years experienced less impact on HRQOL from angina frequency (SAQ 95.2 vs 87.4, p=0.02) but worse overall physical function (SF-12 PCS subscale 40.1 vs 43.7, p=0.05) at 1 month and at 6 months had significantly better overall HRQOL (SAQ 90.5 vs 85.5, p=0.01) and mental health (SF-12 MCS 55.7 vs 52.6, p=0.01) but worse physical function (SAQ 93.2 vs 96.2, p=0.01).

Conclusion: Older and younger people had similar participation in CR which increased over time during PPCI recovery. However, differences occurred for HRQOL aspects of angina frequency, physical function and mental health identifying areas for further research. Strategies for evaluating health status, monitoring CR participation and planning of appropriate CR programs for older PPCI patients are needed for an ageing population.

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